Ennov InSight Registrations

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Chapter 1. Ennov InSight Registrations

Ennov InSight Registrations enables you to enhance the efficiency of your company by effectively managing the entire product submission process from conception to retirement.

Ennov InSight Registrations enables you to perform the following registration planning and tracking functions.

— Collect, manage, and analyze detailed product information to help you make better decisions faster.

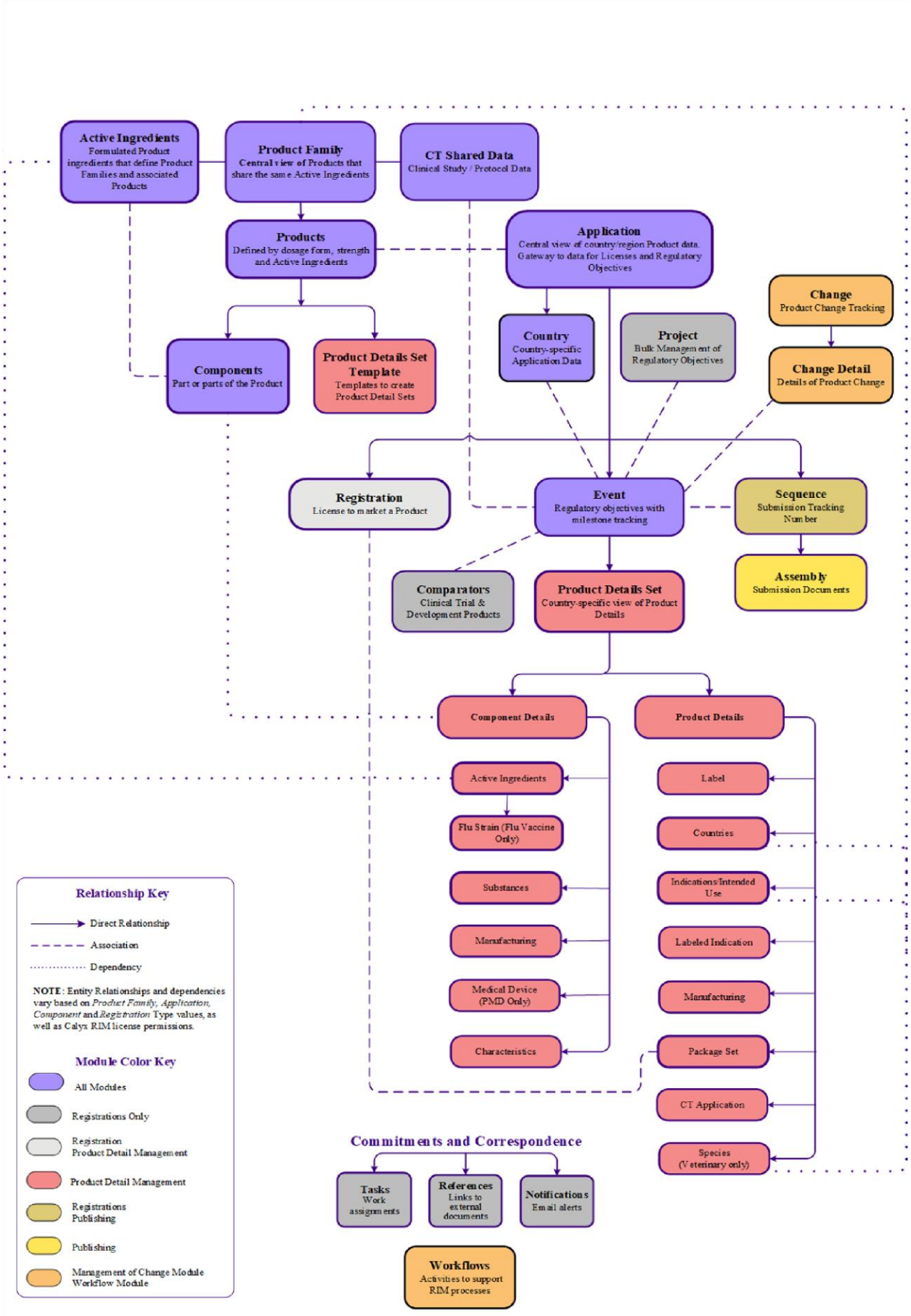
— Centrally collect, manage, and track worldwide product authorizations and registrations.

— Improve your time to market by using consistent, reliable processes for gathering document information, tracking submission status, and verifying official documents.

— Minimize compliance risk by allowing users to verify the external approval status of a submission or source document, while providing integrated support for 21 CFR part 11 regulations.

— Increase global coordination and collaboration between interdepartmental groups and affiliates by sharing a single, central resource with a unified Web interface. Ennov InSight Registrations Entity Diagram

Ennov InSight Registrations Entity Diagram



When you create an application, you choose how to manage your registrations. Typically, pharmaceutical registrations are associated with package sets created and approved in a PDS, and medical device registrations are associated with products from an event.

The process flow and procedure varies for each option.

Package Set Registrations

Create a product family, products and components, and a package set type registration application (with associated products) before beginning the registration creation process.

To create a package registration:

1. Create an event with associated products from the application.
2. Create a PDS for the products associated with the event. Each PDS should include package sets details for the product.
3. Before updating the approved/not approved status of the event in Ennov InSight, manually update the status of any pending PDS details that have a different status than the event.
4. Approve or not approve the event. This automatically approves/not approves the following:
   - The PDS associated with the event.
   - The pending PDS details are associated with the event.
5. Create a package set registration and associate the approved package sets with the registration.

Product Registrations

Create a product family, products and components, and a product set type registration application (with associated products) before beginning the registration creation process. **Note:** Creation of PDS entities is not included in this procedure since your registrations will be managed by product. However, depending on your security privileges, PDS and PDS details can be tracked for applications of the product registration type. To create a product registration

1. Create an event with associated products from the application.
2. After an approval/non-approval is received for the event, but before updating the approved/not approved status of the event in Ennov InSight, do the following:
   - Create a registration of the product registration type and associate the event and its products that have been approved. Associating products to a registration automatically updates the Event-Product

     Status and Status Date to "Approved" and the status date of the registration.
   - If any of the products associated with the event have a different status than the event, manually update the Event-Product Status and the Event-Product Status Date of each product.
3. Approve or not approve the event. This automatically approves/not approves the products associated with the event which are not already marked as “Approved”, “Not Approved” or “Withdrawn” in the Event-Product Status.

The Event-Product Status Date is also updated to the status date of the event.

In order to associate an event with a registration, the event must be open, that is, it cannot already be approved or not approved. This is why approval/non-approval of the event in Ennov InSight occurs after the creation of the registration.

Product Families

The product family is the highest level in the Ennov InSight registration hierarchy. Product families are the umbrella under which all other entities, such as products, components, applications, and registrations reside.

Product families are further differentiated by product family type. Product family types include pharmaceutical, medical device, a pharmaceutical-medical device combination, flu vaccines, and veterinary.

Pharmaceutical, pharmaceutical-medical device, and veterinary product families are further characterized by the active ingredients. Flu vaccine product families are characterized by active ingredient placeholders for which actual active ingredients can be assigned at the product detail set level. By nature, medical device product families are not characterized by an active ingredient, so no association is needed.

Note: *As a best practice, assign active ingredients when creating a pharmaceutical, pharmaceutical-medical device, or veterinary product family. When creating a flu vaccine product family, assign active ingredient place holders. If you created a product without the components, PDSs, or PDS templates related to this product before assigning an active ingredient, you can associate or disassociate the active ingredients in a product family. If there are multiple products associated to a product family and one of them has a component, PDS, or PDS template, you will not be able to associate or disassociate active ingredients on the Product Family Attributes page.*

You must have at least one of the following modules to perform product family activities:

— Registration Planning and Tracking (RPT)

— Product Detail Management (PDM)

You may also view product families if you have the following modules:

— Electronic Lifecycle Publishing (ELP)

— Registered Document Analysis (RDA) — Submission Planning and Tracking (SPT)

Creating Product Families

Only an administrator can create a product family. Product families are created in Liquent Data Administration. See: *Create a Product Family* in the Adminstrative Activites section of the Liquent InSight Administration guide.

After a product family is created, and if you have the appropriate security privileges, you can use the *Modify Product Family* page to define attributes for the product family, like active ingredients or PSUR attributes.

Modify a Product Family

You can modify a product family to change its attributes or its active ingredients.

The attributes you can modify for a product family depend on the product family type.

For example, PSUR attributes, which are available for a pharmaceutical product family, do not apply to a medical device product family, so they are not available on the *Modify Product Family* page.

To modify a product family:

1. Click a link for the product family you want to modify.
2. On the *Product Family Attributes* page, click Edit. The *Modify Product Family* page opens.
3. Choose or enter attributes.
4. Do one of the following:

Option	Action
To save the changes:	Save.
To save your changes and create a product associated with the product family:	Save and Add Product.

5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Modify the Active Ingredients Order

You can modify the order of active ingredients by modifying the product family.

To change the order of active ingredients for pharmaceuticals:

1. On the *Product Family Attributes* page, click the Reorder icon. The *Change Order* dialog box opens.
2. Click the active ingredient you want to move.
3. Click one of the following:

— Up to move the active ingredient up in the list — Down to move the active ingredient down in the list

4. Save, to save the new active ingredient order.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Product Family Attributes

The available attributes for a product family depend on the product family type. You see only the attributes available for the product family type.

Key for Product Family Type:

— FV = flu vaccine

— P = pharmaceutical

— MD = medical device

— PMD = pharmaceutical-medical device

— V = veterinary

— All = all product family types

Attribute	Product Family Type	Description
Active Ingredients	FV, P, PMD, V	Active ingredients to associate with the product family by Substance Selection list. If defined in data administration for the active ingredient entity, the compound number is the active ingredient name.
Approved Trade Names	FV, P, V, PMD	Trade names that are approved in a PDS for the product family. By default, the field is hidden.
Associated Trade Names	FV, P, V, PMD	Trade names that are associated but not approved for the product family.
ATC (Available/Selected)	FV, P, PMD, V	Anatomical therapeutic chemical class code in which the product family is categorized.
Development Sponsor	FV, P, PMD, V	Sponsor of the clinical trials. By default, the field is hidden.
Division	MD, PMD	Division of the Office of Device Evaluation (ODE) Review Divisions with which the product family is associated. By default, the field is hidden.

Attribute	Product Family Type	Description
EURD ID	FV, P, PMD, V	When the medicinal product is part of a PSUR single assessment procedure in accordance with the European Union reference date dates and frequency of submission of periodic safety reports list (EURD list), the EURD ID shall be provided. The EURD ID shall be derived from the procedure number of the PSUR single assessment, which is published in the EURD list Excel file available on the 'Period- ic safety update reports' webpage.
Family Code	All	Company-specific code for the product family.
Family Name	All	Standard name recognized internally and across countries.
International Birth Date	All	For a pharmaceutical product family, the date an approval was first given. For a medical device product family, the date the product family was first launched. By default, the field is hidden.
Product Family Add Comment	All	Comments you want to share with others in a discussion thread, stamped with the date and time you enter the information and your user ID.
Product Family Comments	All	Discussion thread that includes all comments entered by users, including the date and time the comments were entered and the user ID of the person who entered them.
Product Family Concerned Parties	All	Users who may be copied on notifications about this entity. Use se- mi-colons (;) to separate e-mail addresses; click the Search Person icon to choose from available users.
Product Family Comorbidi- ty(s)	FV, P, MD, PMD	Any comorbidity (concurrent condition) or co-infection described as part of the indication as it is referenced in the regulated product in- formation.
Product Family Description	All	Text that describes the product family.
Product Family Indication(s) (For	All	List of all possible indications/intended use for the product family.

		When modifying a product family, you cannot disassociate indications/intended use values from the product family if those values
Veterinary Product Family Type, this field is Product Family Indications/ Intended Use)		are associated with a CTA application. You must first disassociate the indications/intended use values from the CTA before you can disassociate them from the product family. Value is presented in concatenation of Indications/ Intended Use, MedDRA Level and MedDRA Version fields.
Product Family Keywords	All	Words you can use to search for the product family.
Product Family Status	All	Status of the product family. By default, the field is hidden.
Product Family Status Date	All	Date the product family status is effective. By default, the field is hidden.
Product Family Type	All	Type of products associated with this product family (for example, pharmaceutical, medical device).
PSUR Data Lock Date	FV, P, PMD, V	Date up to which information is to be compiled for the PSUR. By default, the field is hidden.
Generic Name	FV, P, PMD, V	Generic name given to a product family. By default, the field is hidden.
PSUR Due Date	FV, P, PMD, V	When the periodic safety update report is due. By default, the field is hidden.
Reason	All	Reason for creating, modifying or deleting a product family.
Reason for Comments	All	Comments related to reason entered by users.
Show in Tree	All	To show or hide product families in the tree on the home page.
Therapeutic Area	FV, P, PMD, V	Therapeutic area with which the product family is associated. By default, the field is hidden.
Therapeutic Classes (Available/Selected)	FV, P, PMD, V	Therapeutic classes in which the product family is categorized. By default, the field is hidden.
User ID		User name to validate user identity.
Password		User password to validate user identity.

View a Product Family

When you view a product family, you can see its attributes and take action on the product family.

You can modify and delete a product family and copy the URL to the Clipboard. You can also add entities to associate with the product family.

To view a product family:

1. Click a link for the product family you want to view.
2. On the *Product Family Attributes* page, do any of the following:

— To modify the product family attributes, click Edit.

— To delete the product family, click Delete.

— To copy the product family URL to the Clipboard, click Copy URL. A message confirms the URL has been copied.

— To create an Entity History query so you can review the product family history, click Report.

— To change the order of drug substances, click Reorder.

— To view an application, product, registration, task, reference, or notification associated with the product family, click the appropriate tab and then click the entity you want to view.

— To view the name of an active ingredient as it translates into other languages, click the Active Ingredient

Translations tab. Please note that only active ingredient translation values that are set to active in data administration will appear.

— To add an application, product, task, reference, or notification, click the appropriate tab and then click Create.

Delete a Product Family

A product family can be deleted based on permissions. Administrators can delete a product family.

Users with WRITE privileges cannot delete a product family if the product family has associations.

— Products

— Applications — Tasks

— References

— Notifications

— Clinical Trial (CT) Shared Data To delete a product family:

1. Click a link for the product family you want to delete.
2. Click Delete.
3. When you are prompted to confirm the deletion, click OK.
4. Select a reason and enter comments for the reason.

5. Click Next
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Clinical Trial Shared Data

The Clinical Trial Shared Data entity enables users to consolidate common details about Clinical Trial Authorization applications (CTAs).

The Clinical Trial Shared Data entity is created and maintained at the product family level, making the information available for association with CTA, CTR and IND application events. Upon associating the Clinical Trial Shared Data with a CTA, CTR or IND application event, the same information applies to all event-countries associated with the event without the need to continually re-enter the same information on the application for each event-country.

Clinical Trial Shared Data is identified by the protocol code number. You can associate the Clinical Trial Shared Data to more than one CTA, CTR or IND application event. However, you can only assign one Clinical Trial Shared Data entity to an event for CTA applications.

For an application with no products, created under a product family:

— You can associate one or more Clinical Trial Shared Data entities with an event that is associated with an IND or CTR application.

— You can associate only one Clinical Trial Shared Data entity with an event that is associated with a CTA application.

— You can associate the same Clinical Trial Shared Data with more than one event.

— You cannot associate Clinical Trial Shared Data with a closed event.

— You cannot disassociate Clinical Trial Shared Data from a closed event.

After all the products are disassociated from the application, on the CT Shared Data field is available on the Event page with the data from the product family application was created for.

If an orphan application is created via *Create Application* wizard, no CT Shared Data values will be displayed on the Event page until at least one product is assigned to the application.

If you have permissions to view the product family, you can also view information on the CT Shared Data tab. If

you have with at least Write for the event, you can associate or disassociate the CT Shared Data.

Create Clinical Trial Shared Data

You can create Clinical Trial Shared Data for a product family to associate common details to more than one CTA or IND.

To create Clinical Trial Shared Data:

1. Navigate to the product family for which you want to create Clinical Trial Shared Data.
2. On the **CT Shared Data** tab, click **Create**.The Create CT Shared Data page opens.
3. Select a protocol code number.
4. Enter or select values for the other attributes, as needed.
5. Do one of the following:

◦ Click **Create Another CT Shared Data** and repeat steps 1 through 5.
◦ Save

Upon completion, the Clinical Trial Shared Data is available to be applied to an event associated with a Clinical Trial Authorization application.

Clinical Trial Shared Data Attributes

You can create Clinical Trial Shared Data for a product family to associate common details to more than one CTA or IND.

Attribute	**Description**
Age Span Population	Indicates the age range of subjects included in the study, such as adult or adolescent
Condition Considered a Rare Disease	Indicates whether the condition studied is a rare disease
CT Shared Data Add Comment	Comments to share with other users in a discussion thread that are stamped with the date, time, and user ID for the entry
CT Shared Data Comment	Comments stamped with the date, time, and user who created them
CT Shared Data Description	Text that describes the content of the shared data
CT Shared Data Keywords	Terms used to search for the data within the system
Data Monitoring Committee	Indicates whether independent experts are monitoring a clinical trial
EudraCT Number	Unique number assigned by the European Commissions EudraCT database process
EU CT Number	European Clinical Trial Register number.

Family Code	Read-only field that displays the code identifying the product family
Family Name	Read-only field that displays the product family name
Gender	Use to specify the gender studied in single-sex clinical trials
Indications/Intended Use	The condition the drug is intended to treat
ISRCTN	The numbering scheme used to uniquely identify a clinical trial worldwide
Attribute	**Description**
Investigator Brochure Version	The version identifying the Investigator Brochure used in the clinical trial
Investigator Brochure Version Date	The date of the Investigator Brochure Version
LPLV Achieved	The date that the Last Patient Last Visit status was achieved for the clinical trial
Main Trial Objective	The reason for performing the clinical trial
Medical Condition Investigated	The medical condition that is the primary focus of the clinical trial
MedDRA term	The MedDRA term used to identify the the purpose of the trial
Planned # Subjects in EU Community	The number of subjects in the EU community that are intended to be included in the clinical trial
Product Family Type	Read-only field that displays the type of product family, such as Pharmaceutical
Protocol Code Number	The identification number for the protocol (study plan) used in the clinical trial
Protocol Title	The title for the protocol used in the clinical trial
Secondary Objective	The secondary reason for conducting the clinical trial
Studying for Rare Disease	Indicates whether the clinical trial involves study of a rare disease
Sub-Study Information	An ancillary study added to the clinical trial
Trial Design	The planned trials and experiments for a clinical trial, such as randomized or double blind
Trial Phase	The phase of the clinical trial, such as Phase I
Trial Scope	The focus of the clinical trial, such as safety or therapy
Trial Subject Groups	Identifies conditions defining the subject groups

Modify Clinical Trial Shared Data

You can modify attributes for the Clinical Trial Shared Data of a product family.

To modify Clinical Trial Shared Data:

1. Navigate to the product family.
2. On the **CT Shared Data** tab, click the hyperlink for the CT Shared Data that you want to edit.
3. **Edit**.The *Modify CT Shared Data* page opens.
4. Revise the CT Shared Data attributes, as needed.
5. **Save**.

Chapter 2. Products

A product is a marketed substance that includes a dosage, form, and strength. A product family can have many products.

A product is associated with a product family and is therefore represented under product family in the Ennov InSight registration hierarchy.

For a pharmaceutical product family, a product is the definition of the dosage form and strength, for example,

250 mg tablet, 80 mg/ml solution. For a medical device product family, a product might be a syringe or an inhaler. For example, a syringe would include the products that identify the various kinds of syringes, for example, blood collection syringes, safety syringes, and so on.

Note: *To view a product, you must have the appropriate security privileges for the product family. To view all entities associated with a product (applications, events, registrations, and so on), you must have security privileges to the countries associated with the lower-level entities.*

You must have one of the following modules to perform product activities:

— Product Detail Management

— Registration Planning and Tracking **Pharmaceutical Products**

Pharmaceutical products are tracked at the product level. The Pharmaceutical Product entity is required by the European Medicines Agency (EMA) for XEVMPD schema support.

Components

Products can be tracked at a component level of detail. Components are the parts that build the final product. A product may be made up of one or multiple components, and those components may or may not contain active ingredients. As best practice, it is recommended to always create one component for every product.

Active Ingredients

The active ingredients for a product are tracked at the component level, including the strength measure of the active ingredient in a component. When you define active ingredients for the components of a product, you are limited to the active ingredients that were defined at the product family level.

Reference Active Ingredients

The reference active ingredients for a component active ingredients are tracked at the components level, including the strength measure of the reference active ingredient in a component. You must have at least one active ingredient associated with a component to be able to associate a reference active ingredient.

Create a Product

Products are created under product families to be further associated with applications or events.

You associate products with a product family. Depending on the type of product, you specify information such as product dosage form, product route of administration, standards codes, safety codes, FDA information, and so on.

When you create a product, it is added to lists of products in Ennov InSight .

Note: *If you want to associate a product detail set (PDS) with the product you create, ensure to select one or more active ingredients by modifying the product family before you create a product.*

To create a product:

1. From the *Home* page on the Product Families tab, click a link for the product family for which you want to create a new product.
2. Do one of the following:

   — Click Edit on the *Product Family Attributes* page. Make any changes as needed (selecting active ingredients is recommended) and click Save and Add Product. — On the Products tab, click Create.

   The *Create Product* page appears.
3. Enter values for the product attributes.
4. Do one of the following:

   — Save, to save the product.

   — Create Another Product, to save this product and create another.

   — Save and Add Component, to save this product and associate a component with it.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Product Attributes

The attributes that are available for a product depend on the associated product family type.

Key for Product Family Type:

— FV - flu vaccine

— P - pharmaceutical

Create a Product

— MD - medical device

— PMD - pharmaceutical-medical device

— V - veterinary

— All - all product family types

Attribute	Product Family Type	Description
Alternate Product Description	MD, PMD	The product description for printing Certificates for Foreign Government (CFG).
Applicable Standards	MD, PMD	Standards (codes) to which the device adheres.
CE Date	MD, PMD	Date when the CE mark was granted.
CE Marked	MD, PMD	Conformité Européenne passport of free trade; signifies the device has been declared by an authorized company to conform to a uniform and high degree of safety as measured by technical standards and controlled by your quality management system.
Combined Pharmaceutical Dose Form	FV, P, PMD	The combined pharmaceutical dose form is a single term to describe two or more manufactured dose forms that are intended to be combined to create a single administrable dose form. — The field is displayed on the View/Modify Product Attributes page when more than one component is associated to the Product. — The values in the field are displayed if there are active *Dosage/Pharmaceutical Form* Data Administration values with RMS values assigned mapped to values from SPOR Master Lists > Combined Pharmaceutical Dose Form
Component Owner/ RA Responsible	All	RA person responsible for the component.
Conformity Assessment Path	MD, PMD	Path taken for conformity assessment.

Declaration of Conformity Completed	MD, PMD	Indicates whether there exists a signed statement of compliance to a recognized national or international standard provided in a product submission in lieu of providing data demonstrating conformance to the recognized standard.
Drug Safety Code	FV, P, V, PMD	Safety code for a drug.
EC Cert	MD, PMD	Design certs for class III products.
Equipment Type	MD, PMD	The type of equipment as stated in the Declarations of Conformity.
Attribute	Product Family Type	Description
EU Class	MD, PMD	Indicates the class of increasing risk to a patient as described by the MDD; classes are described as follows: — Class I - devices that pose a low risk to the patient and, except for sterile products or measuring devices, can be self-certified by the manufacturer — Class IIa - devices that pose a medium risk; may require assessed quality systems to the ISO 9000/EN46000 standards; invasive in their interaction with the human body, methods of invasion are limited to natur- al body orifices; may also include therapeutic devices used in diagnosis or in wound management — Class IIb - devices that pose a medium risk that may require assessed quality systems to the ISO 9000/ EN46000 standards; third-party certification is required; partially or totally implantable in the human body, and may modify the biological or chemical composition of body fluids — Class III - devices that pose a high risk and require design/ clinical trial reviews, product certification and an assessed quality system; all third-party product and system certification must be conducted by a European notified body (or designee through formal agreement); these devices affect the functioning of vital organs and/or lifesupport systems
EU Classification Rule	MD, PMD	EU Classification Rule: Rule 1 through Rule 18, and Rule 99.
EURD ID	FV, P, PMD	The EURD ID is a unique identification number that is used for the sub-mission process of all the entries and procedures in the EURD list.

Family Code	All	The code for the product family code you are associating the product with.
Family Name	All	The name of the product family you are associated the product with.
Attribute	Product Family Type	Description
FDA Device Class	MD, PMD	FDA classification based on risk: — Class I - least risk-laden for which general controls are sufficient to ensure safety and effectiveness — Class II - devices for which general controls are determined to be insufficient to provide reasonable assurance of safety and effectiveness, but for which exists sufficient information to establish a performance standard to provide assurance — Class III - devices for which there is insufficient information to determine the adequacy of general controls, performance standards or special controls providing reasonable assurance of safety and effectiveness (usually life-supporting or life-sustaining devices)
FDA Product Code	MD, PMD	Product codes with which the device is associated; identify the product in further detail; for example, Manual Surgical Instruments for General Use contains several product codes including GAB (disposable suturing needle), GDX (scalpel), HTD (forceps) and HRQ (hemostat).
FDA Regulation Number	MD, PMD	Generic category that is represented by a separate classification regulation found in Title 21 Code of Federal Regulations parts 862-89.
Global Harmonization Task Force Class (GHTF)	MD, PMD	Class as defined by the GHTF with values 1, 2, 3.
Global Medical Device Nomenclature (GMDN) Code	MD, PMD	Classification system that allows for the classification of all medical devices put onto the market as defined in the three European Directives.

Indications/Intended Use	FV, P, PMD, V	A display-only field on the *Product Attributes* page showing the indications from the product detail sets associated with the product.
Intended Use	MD, PMD	Intended use of a device (based on Annex 1, I.1; Annex X, 1.1; Annex X, 2.1).
Medical Device Link	MD, PMD	Number assigned to the device through MDL.
Attribute	Product Family Type	Description
Product Add Comment	All	Comments you want to share with others in a discussion thread. Will be displayed in the Product Comments box, stamped with the date and time you enter the information and your user ID. ***Note:*** *The Product Add Comment field is available on the Create/Modify Product Attributes pages only.*
Product Category	FV, P, PMD	Classification value for product category.
Product Code	All	The company-specific code for the product. On some pages, the product name is shown with the product code to identify a product. For example, Origine 390 could identify a product that has the name Origine and the code 390.
Product Comments	All	The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.
Product Concerned Parties	All	Users who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses.
Product Description	All	Text that describes the product.
Product Dose Form	FV, P, PMD, V	The physical form in which a drug is produced and dispensed. This may be defined at the product level, the component level, or both.
Product Family Type	All	The type of product family with which the product is associated.
Product Keywords	All	Words you can use to search for the product.
Product Manufacturing Location	MD, PMD	Locations of the device manufacturers (assuming there are no product detail sets).

Product Name	All	The standard product name recognized internally and across countries. On some pages, the product name is shown with the product code to identify a product. For example, Origine 390 could identify a product that has the name Origine and the code 390.
Product National Drug Code	FV, P, PMD, V	NDC; identifies the labeler, product and trade package size.
Attribute	Product Family Type	Description
Product Route of Administration	FV, P, PMD	How the product is to be administered. The values that appear for this attribute are based on the dosage form you selected. You may select multiple routes of administration. This may be defined at the product level, the component level, or both.
Product Shelf Life	MD, PMD	Standard shelf life of the device.
Product Status	All	The status of the product.
Product Status Date	All	The date the product status is effective.
Product Sterilization	MD, PMD	Defines the type of sterilization the device provides.
Product Strength Measure 1	FV, P, PMD, V	The minimum value used to define the product strength.
Product Strength Measure 2	FV, P, PMD, V	The maximum value used to define the product strength.
Product Strength Unit 1	FV, P, PMD, V	The measurement used to quantify the minimum strength.
Product Strength Unit 2	FV, P, PMD, V	The measurement used to quantify the maximum strength.
Reason	All	Reason for creating, modifying or deleting a product.
Reason for Comments		Comments related to reason entered by users.
Reason for Termination/ Withdrawal	All	The reason that the product was terminated or withdrawn.

Summary of Technical Documentation (STED)	MD, PMD	Your STED IDs that apply to the product.
Tech File Number	MD, PMD	Identifies the technical file that is submitted to the EU for the device.
UMDNS Code	MD, PMD	UMDNS computer code that is used in ECRI databases and publications, as well as in thousands of health care institutions world- wide for the device.
User ID		The user name to validate user identity.
Password		The user password to validate user identity.

Modify a Product

The attributes you can modify for a product depend on the associated product family type. Different attributes are available for pharmaceutical products, medical device products, pharmaceutical-medical device combination products, and veterinary products.

To modify a product:

1. Click a link for the product you want to modify.
2. On the *Product Attributes* page, click Edit.

   The *Modify Product Attributes* page opens.
3. Enter your changes to the product attributes.
4. Save, to save your changes.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Copy a Product

You can copy a product to add another product in the same product family or to a different product family. Ennov InSight copies the attributes, components and product detail set templates from the source product. The Concerned Parties attribute does not copy to the target product or component.

You should have at least Write permission for Products to be able to copy a product. Product Detail Set (PDS) templates will only be copied if you have at least Write permission for PDS Templates.

— If the Product Family type of the Source Product is Pharmaceutical, the target Product Family type must be Pharmaceutical or Pharmaceutical Medical Device.

— If the Product Family type of the Source Product is Medical Device, the target Product Family type must be Medical Device or Pharmaceutical Medical Device

— If the Product Family type of the Source Product is Pharmaceutical Medical Device, the target Product Family type must be Pharmaceutical Medical Device.

To copy a product:

1. Click the link for the product you want to copy.
2. On the *Product Attributes* page, click Copy.

   After the copy process is complete, you are returned to the *Product Attributes* page of the source product that you copied.
3. Click the Family Name link.

   Modify a Product

   The *Product Family Attributes* page appears.
4. On the Products tab, the new product is listed with Copy <#> of pretended to the name of the source product you copied, where <#> represents the number of times you have copied the source product.
5. To change the name of the new product as well as other product attributes, click the link of the new product to open the *Product Attributes* page, and then click Edit.

The *Modify Product Attributes* page appears.

View a Product

You can view a product to see its attributes and take action on the product. You can modify, copy, and delete a product, and copy the URL to the Clipboard. You can also view attributes for the entities associated with the product.

To view a product:

1. Click a link for the product you want to view.
2. On the *Product Attributes* page, do any of the following:

— To modify the product attributes, click Edit.

— To delete the product, click Delete. You can delete a product only if it has no associated product detail sets, applications, tasks, references, or notifications. — To copy the product, click Copy.

— To copy the product URL to the Clipboard, click Copy URL. A message confirms the URL has been copied.

— To create an Entity History query so you can review the product history, click Report.

— To view an application, product detail set (PDS), PDS template, registration, task, reference, or notification associated with the product, click the appropriate tab and then click the entity you want to view.

Delete a Product

You can delete a product only if you have the appropriate security privileges, and none of the following entities are associated with the product: applications, product detail sets (PDSs), PDS templates, registrations, tasks, references, or notifications.

To delete a product:

1. Navigate to the product you want to delete.
2. Click the link for the product you want to delete.
3. Delete.
4. Choose the applicable procedure to enter an electronic signature for entities:

View a Product

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Components

Components are the parts that build the final product. A product may have one or multiple components. Products can be tracked at a component level of detail.

For example, an ibuprofen tablet has one component, the tablet itself, or a product may have multiple components, like a powder and a diluent to be mixed. Furthermore, components may or may not contain active ingredients and reference active ingredients. For example, a tri-phasal birth control product may have an inert component with no active ingredients and reference active ingredients.

Note: *While Ennov InSight does not require you to define component detail for a product, it is considered best practice to define at least one component for a product.*

You must have one of the following modules to perform component activities: — Product Detail Management

— Registration Planning and Tracking **Active Ingredients for Components**

The active ingredients for a product are tracked at the component level, including the strength measure of the active ingredient in a component. When you define active ingredients for the components of a product, you are limited to the active ingredients that were defined at the product family level. **Reference Active Ingredients for Component Active Ingredients**

The reference active ingredients for a product are tracked at the component level, including the strength measure of the reference active ingredient in a component. When you define reference active ingredient for a component active ingredient, you are not limited to the active ingredients that were defined at the product family level. All Substances from Data Administration are available for selection. You must have at least one active ingredient associated with a component to have an ability to associate a reference active ingredient.

Create a Component

You create a component for a product and add it to the list of components for that product. Depending on the type of component, you specify information such as the component's physical form, the route of administration, the type of sterilization, and so on.

You must have the appropriate security privileges to create a component. If you have the right to add a product, you can add a component. Also, you cannot create a component for a product that already has a PDS template or application associated with it.

You can create components for an existing product or when you create a product.

To create a component:

1. Navigate to the product for which you want to associate a component.
2. While viewing the *Product Attributes* page, click the Components tab.
3. Click Create.

   The *Create Component* page appears.
4. Select a component type.

   The values available in the drop-down list were created by your Ennov InSight system administrator and are mapped to an entity type of pharmaceutical, medical device, pharma-med device combination, flu vaccine, or veterinary.
5. Enter a name for the component.

   You must enter a name, unless in the next step you select a component form when defining the component attributes. In that case, the component name defaults to the selected form, but you can change the name.
6. Enter the additional component attribute values, as needed.
7. Do one of the following:

— Save, to save the component.

— Create Another Component, to save this component and create another.

— Save and Add Active Ingredients, to save this component and add active ingredients. This option is available for all except Flu Vaccine and Medical Device component types.

If your component contains at least one active ingredient, you can create a reference active ingredient that is also tracked at the component level of your product.

Component Attributes

The attributes that are available for a component depend on the component type. Key for Component Type:

— FV for the flu vaccine component type

— P for the pharmaceutical component type

— MD for the medical device component type

— PMD for the pharmaceutical-medical device component type

— V for the veterinary component type

— All for all component types

Attribute	Component Type	Description
Active Ingredients	FV	Active ingredients available for selection that are associated with the product family.
Allergenicity Indicator	MD	Specifies whether the device contains allergens and/or materials of concern.
Component Add Comment	All	Comments you want to share with others in a discussion thread. Comments are stamped with the date and time you enter the information, and your user ID.
Component Code	All	The Code for the specific component.
Component Comments	All	The discussion thread that includes all comments entered by users, plus the date and time the comments were entered and the user ID of the person who entered them.
		Note: *Comments are available on the Modify Components page.*
Component Concerned Parties	All	Users who may be copied on notifications about this entity. Use semi-colons (;) to separate e-mail addresses.
Component	All	Text that describes the component.

Description		
Component Form	FV, P, PMD, V	The physical form in which this component is produced and dispensed. For example: tablet, capsule, powder, or liquid.
Component Keywords	All	Words you can use to search for the component.
Component	MD, PMD	Locations of the device manufacturers (assuming there are no product detail sets).

Manufacturing Location		
Component Name	All	Name given to identify the specific component. If this is a single component product, the name would most likely be the same as the product name.
Attribute	Component Type	Description
Component National Drug Code	FV, PMD, V	Universal product identifier for human drugs. There are three segments to the Component National Drug Code: — Labeler code - pertains to the manufacturer — Product code - pertains to the bulk product — Packaging code - pertains to the presentation (e.g: 5pack, 10pack, bottle, blister, etc.) For devices, NDC only applies to medical devices that have a drug component(s).
Component Owner/ RA Responsible	FV, MD, PMD, V	RA person responsible for the component.
Component Route of Administration	FV, P, PMD	How the component is to be administered. The values that appear for this attribute are based on the dosage form you selected. You may select multiple routes of administration. This field may be left blank because the component itself may not administered, rather it is the combination of components that define the administration.
Component	MD, PMD	Defines the type of sterilization the device provides.

Sterilization		
Component Type	All	Defines the type of component. The component type is based on the entity type to which it is associated: pharmaceutical entity type, medical devices entity type, or a pharmaceutical-medical devices combination.
Device Alternate Material	MD	The alternative material(s) of the device.
Device Material	MD	The material(s) of the device.
Device Nomenclature	MD	The term for the device from the specified nomenclature system.
Device Type	MD	The type of device.
Device Usage	MD	The number of times that the device may be used.
Family Code	All	The code of the product family to which this component is associated.
Family Name	All	The name of the product family to which this component is associated.
Model Number	MD	Specifies the device model or reference number, where applicable, in text.
Attribute	Component Type	Description
Product Name	All	The standard product name recognized internally and across countries.
Product Family Type	All	The product family type to which this component is associated.
Product Name	All	The name of the product to which the component is associated.
Sterility Indicator	MD	Specifies whether the device is supplied as sterile.
Sterilization Requirement Indicator	MD	Specifies whether the device shall be sterilized before use.

Modify a Component

The attributes you can modify for a component depend on the component type. Different attributes are available for pharmaceutical, medical device, pharmaceutical-medical device, and veterinary components.

To modify a component:

1. Click a link for the component you want to modify.
2. On the *Component Attributes* page, click Edit.

   The *Modify Component Attributes* page opens.
3. Enter your changes to the component attributes.
4. Save, to save your changes.

Copy a Component

You can copy a component to add additional components to a product. You must have at least Write permission for both Product Family and Products to copy a component.

To copy a component:

1. Click the link for the component you want to copy.
2. On the *Component Attributes* page, click Copy.

   After the copy process is complete, you are returned to the *Component Attributes* page of the source component that you copied.
3. Click the Product Name link. The *Product Attributes* page opens. On the Components tab, the new component is listed with Copy <#> of prepended to the name of the source component you copied, where <#> represents the number of times you have copied the source product.
4. To change the name of the new component as well as other component attributes, click the link of the new component to open the *Component Attributes* page, and then click the Edit icon.

Note: *If source Component had associations with Pharmaceutical Product this associations will not be copied.*

The *Modify Component Attributes* page opens.

View a Component

You can view a component to see all its attributes and take action on the component.

You can modify, delete, and copy a component. You can also maintain active ingredient information for pharmaceutical, pharmaceutical-medical device, and veterinary type components.

To view a component:

1. Click a link for the component you want to view. The *Component Attribute* page opens.
2. On the *Component Attributes* page, do any of the following:

— To modify the component attributes, click Edit.

— To delete the component, click Delete. With the appropriate security privileges, you can delete a component if there are no notifications associated with the component, and if there are no PDS templates or applications associated with the product to which the component is associated. — To copy the component, click Copy.

— To create an Entity History query so you can review the component history, click Report.

— To view an active ingredient associated with the component, on the Active Ingredients tab click the link for the active ingredient that you want to view.

— To view a notification associated with the component, on the Notifications tab click the link for the active ingredient that you want to view.

— To view the name of an active ingredient as it translates into other languages, click the Active Ingredient

Translations tab. Please note that only active ingredient translation values that are set to active in data administration will show on the tab.

— To view the alias of an active ingredient, click the Active Ingredient Aliases tab. Please note that only active ingredient alias values that are set to active in data administration will show on the tab.

— To view a reference active ingredient associated with the component active ingredient, on the Reference Active Ingredients click the link for reference active ingredient that you want to view.

Delete a Component

You can delete a component and associated active ingredients if you have the proper permissions. You can delete a component if:

— You have the appropriate security privileges to delete a component. If you have the rights to delete a product, you can delete a component.

— There are no notifications for the component, and no PDS templates or applications associated with the component's product.

To delete a component:

1. Navigate to the component that you want to delete.
2. Click a link for the component you want to delete.

   The *Component Attributes* page opens.
3. Delete.
4. When you are prompted to confirm the deletion, click OK.

Manufactured Items for Components

The administrable pharmaceutical form of the product, as contained in the packaged medicinal product, is referred to as a Manufactured Item.

The manufactured items for a product are tracked at the component level. It is not mandatory for a component to have a manufactured item. To associate a manufactured item with a component:

— You must have the same user privileges required for adding a product.

— The component type must be pharmaceutical, pharmaceutical-medical device, flu vaccine or veterinary.

— The product family type for the associated product family must be flu vaccine, pharmaceutical, pharmaceuticalmedical device, or veterinary.

— A PDS template or an application must not be associated with the product.

Create a Manufactured Item

Create a manufactured item for the pharmaceutical, pharmaceutical-medical device, veterinary, and flu vaccine component types.

To create a manufactured item for a component:

1. Click the link for the component for which you want to create a manufactured item.
2. Click the Manufactured Items tab.
3. Click Create.

   The *Create Manufactured Item* page opens.
4. Enter values for the manufactured item attributes. See *Manufactured Item Attributes.*
5. Save.

Manufactured Item Attributes

Description of the attributes used for manufactured items.

Use the following descriptions of manufactured items attributes to enter attribute values when creating or modifying a manufactured item. The attributes that are displayed depend on your security privileges.

Attribute	Description
Component Name	Name of a component.
Family Code	Code of the Product Family the component is associated to.
Family Name	Name of the Product Family the component is associated to.
Family Type	Type of the Product Family the component is associated to.
Attribute	Description
Manufactured Dose Form	The physical form in which a drug is produced and dispensed. This may be defined at the product level, component level, or both.
Manufactured Item Add Comment	Comments you want to share with others in a discussion thread. Comments are stamped with the date and time you enter the information, and your user ID.

Manufactured Item Characteristics/ Description	Text that describes the manufactured item or its characteristics.
Manufactured Item Comments	Existing comments.
Manufactured Item Concerned Parties	Users who may be copied on notifications about this entity; use semicolons (;) to separate e-mail addresses.
Manufactured Item Description	The description of manufactured item must be included whenever a medicinal product contains more than one pharmaceutical product.
Manufactured Item Keywords	Text you can use to search for the manufactured item.
Manufactured Item Name	The name of the manufactured item.
Manufactured Item Quantity	The quantity of the manufactured items in the medicinal product package, specified as a value and units (as per section 6.5 of the summary of product characteristics (SmPC)). For solid dose forms and other items measured by counting, discrete countable entities, the unit for quantity is “unit” and the “unit of presentation” is the item counted within the immediate container. For formulations contained in a vial, the unit for quantity is volume/quantity and the “unit of presentation” is the discrete countable entity, in which a pharmaceutical product or manufactured item is presented. You can enter both non-integer and integer values.
Manufactured Item Quanti- ty Operator	Names of quantity operator values: Equal, Not Less Than, Range, Up to.
Manufactured Item Quanti- ty Unit	Unit of quantity. This field displays values only from the Data Administration > Other > Unit of Measurement Values table.
Product Name	Name of the Product the component is associated to.
Unit of Presentation	Specifies the units the quantity of the manufactured item is presented in. Example: Bottle, Capsule, Tablet.

Modify a Manufactured Item

You can modify the values of the manufactured item attributes.

To modify the values of the manufactured item attributes:

1. Click a link for the manufactured item you want to modify.
2. On the *Manufactured Item Attributes* page, click Modify.
3. Enter your changes to the manufactured item attributes.
4. Save.

Delete a Manufactured Item

You can delete a manufactured item associated with a component.

Prerequisites

You cannot delete a Manufactured Item:

— If there is a PDS: Package Set: Packaging with the associated Manufactured Item Reference — If there is a PDS: Package Set: Component with the associated Manufactured Item Reference You can delete a Manufactured Item:

— If there is a PDS with Packaging Detail that does not have associated Manufactured Item Reference

— If there is a PDS: Package Set: Component with the associated Manufactured Item Reference with the WITHDRAWN status

— If there is a PDS: Package Set: Packaging with the associated Manufactured Item Reference with the

WITHDRAWN status

To delete a manufactured item:

1. Navigate to the manufactured item associated with a component.
2. Click the link for the manufactured item you want to delete.
3. On the *Manufactured Item Attributes* page, click Delete.
4. When you are prompted to confirm the deletion, click OK.

Note: *If there are any reference active ingredients associated to a manufactured item, they will be deleted with the parent active ingredient.*

Pharmaceutical Product

The Pharmaceutical Product entity is required by the European Medicines Agency (EMA) for XEVMPD schema support. Ennov InSight enables you to view, create, modify, and delete the Pharmaceutical Product.

You must have at least READ permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security to view Pharmaceutical Product.

You can also add notifications on the Notification tab. Notifications associated with the Pharmaceutical Product display only if you have at least WRITE privileges for the Notifications.

Note: *The Pharmaceutical Product reports that you see on the Querying tab refer to Product of Pharmaceutical type, and are not for a Pharmaceutical Product entity.*

Create a Pharmaceutical Product

Ennov InSight enables you to create a Pharmaceutical Product for a Product, which contains one or more components.

You must have at least Write privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security to create the Pharmaceutical Product entity.

To create a Pharmaceutical Product:

1. Create a Product and a one or more Components for it.
2. On the *Product Attributes* page select the Pharmaceutical Products tab.
3. Click Create Pharmaceutical Product.

   The Create Pharmaceutical Product page opens.
4. Enter the needed properties and click Save to save the data. To cancel the action, Cancel.

Note: *You can create a Pharmaceutical Product under all Product Family types except Medical Devices.*

If Pharmaceutical Product required properties are not populated with valid data, a message is displayed and the entity is not created. The required fields are the Pharmaceutical Product Name and Components. Other fields are optional.

Product Family Type, Family Code, Family Name, and Product Name are already populated by the system in display mode.

Pharmaceutical Product Attributes

The Pharmaceutical Product entity is required by the European Medicines Agency (EMA) for XEVMPD schema support.

The following attributes describe the specific Pharmaceutical Product under the Product.

Attribute	Description
Family Type	The type of products associated with this product family (for example: pharmaceutical, medical device).
Family Code	The company-specific code for the product family.
Family Name	The standard name recognized internally and across countries.
Attribute	Description

Product Name	The standard product name recognized internally and across countries. On some pages, the product name is shown with the product code to identify a product. For example, Origine 390 could identify a product that has the name Origine and the code 390.
Pharmaceutical Product Name	The standard pharmaceutical product name recognized internally and across countries. The product name must be unique.

Pharmaceutical Product Summary	The value in the field is displayed as a concatenation of the values: — First line: Administrable Dose Form + Route of Administration divided by space. — Second Line: List of Active Ingredient Name values (or Reference Active Ingredient if specified) + Unit of Presentation + Strength, divided by comma. • Active Ingredients are in the alphabetical order • If a reference active ingredient is defined, no corresponding active ingredients are in the list. • If there are no pharmaceutical active ingredients, the component active ingredients show. • The strength values Equal to and Range do not show in the Pharmaceutical Product Summary field. • The Strength is defined by IDMP presentation values, if not specified, IDMP concentration values are taken. Otherwise, XEVMPD strength values are present. Otherwise, an active ingredient name with empty strength value. — If the Pharmaceutical Product Description and Unit of Presentation values are empty, no third line is available. By default, the field is hidden.
Medical Device	Describes the code of a medical device where it forms an integral part of the medicinal product.
Components	The parts that build the final product. Selected list includes selected Components for the Pharmaceutical Product.
Administrable Dose Form	The physical form in which this product is administered.
Product Quantity Value	The quantity (or count number) of the pharmaceutical product. By default, the field is hidden.

Product Quantity Unit	The quantity (or count number) of the pharmaceutical product. By default, the field is hidden.
Attribute	Description
Unit of Presentation	The unit of presentation is a qualitative term describing the discrete unit in which a pharmaceutical product is presented to describe strength or quantity in cases where a quantitative unit of measurement is not appropriate.
Product Characteristics	The individual value from the code system that describes the actual characteristic. By default, the field is hidden.
Pharmaceutical Product Concerned Parties	Contains email addresses and User Ids for which Notifications can be sent. Concerned parties are anyone who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses
Pharmaceutical Product Keywords	Words you can use to search for the Pharmaceutical Product.
Pharmaceutical Product Description	Text that describes the Pharmaceutical Product.
Pharmaceutical Product Comments	The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.
Pharmaceutical Product Add Comment	Comments you want to share with others in a discussion thread. Will be displayed in the Pharmaceutical Product Comments box, stamped with the date and time you enter the information and your user ID. ***Note:*** *The Pharmaceutical Product Add Comment field is available on the Create/Modify Pharmaceutical Product Attributes pages only.*
Route of Administration	Defines how this product is introduced into the system, such as oral, and intravenous. Route of Administration is dependent on Dosage Form - this may be defined either at the product level or at the individual component level or both.

Modify a Pharmaceutical Product

You can modify a previously created Pharmaceutical Product to change the existing data.

You should have at least WRITE privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security to modify the Pharmaceutical Product entity.

To modify the Pharmaceutical Product:

1. On the Pharmaceutical Product tab, select the Pharmaceutical Product entity you want to modify.
2. Click Modify.
3. On the *Modify Pharmaceutical Product* page, modify the attributes and Save. To cancel your changes, click

Cancel.

If Pharmaceutical Product required properties are not populated with valid data, a message appears and the entity is not modified.

Note: *You can modify the Pharmaceutical Product until it is not associated to the Application.*

The *Pharmaceutical Product* View displays the updates.

Delete a Pharmaceutical Product

You can delete a previously created Pharmaceutical Product entity data from the system.

At least Write privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security are required to delete the Pharmaceutical Product entity.

To delete the Pharmaceutical Product:

1. On the Pharmaceutical Product tab, select the Full Pharmaceutical Product entity you want to delete.
2. Delete.
3. A warning message appears, click OK.
4. On the message confirming that the data has been deleted, click OK.

The *Product Attributes* page opens. The Pharmaceutical Product is deleted and no longer displays in any Pharmaceutical Product value lists.

PhPIDs

The Pharmaceutical Product Identifier (PhPID) enables you to uniquely associate medical products with the same or similar pharmaceutical composition based on data elements and structures for unique identification and exchange of regulated pharmaceutical product information.

The PhPID entity is required by the Identification of Medicinal Product (IDMP) data standards to maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data. Ennov InSight enables you to view, create, modify, and delete the PhPIDs.

You must have at least Read permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security to view Pharmaceutical Product and PhPID.

Create a PhPID

Use PhPID for unique identification and exchange of regulated pharmaceutical product information.

Prerequisites

You must have the appropriate security privileges to create a PhPID. If you have the rights to add a product, you can add a PhPID.

To create a PhPID:

1. Navigate to the pharmaceutical product for which you want to create a PhPID.
2. On the *Pharmaceutical Product Attributes* page, click the PhPIDs tab.
3. Click Create.

   The *Create PhPID* page appears.
4. Enter the PhPID attribute value.
5. Save.

PhPID Attributes

The following are the Pharmaceutical Product Identifier (PhPID) attributes.

Attribute	Description
Family Code	The company-specific code for the product family.
Family Name	The standard name recognized internally and across countries.
Family Type	The type of products associated with this product family (For example, pharmaceutical, veterinary).
Pharmaceutical Product Name	The standard pharmaceutical product name recognized internally and across countries. The value for the product name is unique.
PhPID	Pharmaceutical Product Identifier. Used for unique identification of regulated pharmaceutical product information.
Product Name	The standard product name recognized internally and across countries. In some sections of the application, the product name is shown with the product code to identify a product. For example, Origine 390 could identify a product that has the name Origine and the code 390.
Version	Indicates the version of the PhPID.
Version Date	Indicates the date the PhPID is versioned.

Modify a PhPID

You can modify a previously created Pharmaceutical Product Identifier (PhPID) to change the existing data.

Prerequisites

You should have at least WRITE privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security to modify the PhPID entity.

To modify a PhPID:

1. Click a link for the PhPID you want to modify.
2. On the *PhPID Attributes* page, click Modify. The *Modify PhPID Attributes* page opens.
3. Make necessary changes to the PhPID attributes.
4. Save.

Delete a PhPID

You can delete previously created Pharmaceutical Product Identifier entity data from the system.

Prerequisites

At least Write privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security are required to delete the Pharmaceutical Product Identifier entity.

To delete a PhPID:

1. On the PhPIDs tab, click the link to the PhPID you want to delete.
2. Delete.
3. On the warning message, click OK.
4. On the message confirming that the data has been deleted, click OK.

The *Pharmaceutical Product Attributes* page opens. The PhPID is deleted and no longer displays in the list of PhPIDs.

Country Specific Detail

The Country Specific Detail entity is required by the European Medicines Agency (EMA) for XEVMPD schema support.

You must have at least READ permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security to view Country Specific Detail. Ennov InSight enables you to view, create, modify, and delete the Country Specific Detail.

You can:

— View Country Specific Detail - View a previously created or modified entity.

— Create Country Specific Detail - Create the new Country Specific Detail entity.

— Modify Country Specific Detail - Change the previously created entity data.

— Delete Country Specific Detail - Remove the previously created data from the system.

The following actions can be performed from the *Country Specific Detail* attributes page:

Country Specific Details are applicable for a Product that belongs to a Family Type of Medical Devices and Pharmaceutical Medical Device.

— Modify

— Delete

Create a Country Specific Detail

Ennov InSight enables you to create a Country Specific Detail for a Medical Device Product, which contains one or more components.

You must have at least Write privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security to create the Country Specific Detail entity.

To create a Country Specific Detail:

1. Create a Product and a one or more Components for it.
2. On the *Product Attributes* page, select Country Specific Details.
3. Click Create Country Specific Detail.

   The *Create Country Specific Detail* page opens.
4. Enter the needed properties and Save.

To cancel the action, Cancel.

If the Country Specific Detail required property is not populated with valid data, a message is displayed and the entity is not created. The required field is the Country Specific Detail Type field. Other fields are optional.

Modify a Country Specific Detail

You can modify a previously created Country Specific Detail to change the existing data.

You should have at least WRITE privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security to modify the Pharmaceutical Product entity.

To modify the Country Specific Detail:

1. On the Country Specific Details tab, select the Country Specific Detail entity you want to modify.

   The *Country Specific Detail* Attributes page is displayed.

2. Click Modify.
3. On the *Modify Country Specific Detail Attributes* page, modify the attributes and Save. To cancel your changes, click Cancel.

If Country Specific Detail required properties are not populated with valid data, a message appears and the entity is not modified.

The *Country Specific Detail* view displays the updates.

Delete a Country Specific Detail

You can delete a previously created Country Specific Detail entity data from the system.

At least Write privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security are required to delete the Pharmaceutical Product entity.

To delete the Country Specific Detail:

1. On the Country Specific Details tab, select the Country Specific Detail entity you want to delete.
2. Delete.
3. A warning message appears, click OK.
4. On the message confirming that the data has been deleted, click OK.

The *Product Attributes* page opens. The Country Specific Detail is deleted and no longer displays in any Country Specific Details list.

Chapter 3. Active Ingredients and Reference Active Ingredients

Active Ingredients and Reference Active Ingredients are associated to entities to provide data points for the product structure.

Active ingredients are associated to entities. Reference active ingredients are associated to the active ingredients of an entity. It is not mandatory for an entity to have active ingredients and reference active ingredients. Active Ingredients are associated to the following entities:

— Component

— Pharmaceutical Product — Manufactured Item

The following guidelines apply when associating an active ingredient to an entity: — You must have the same user privileges required for adding a product.

— The entity type must be pharmaceutical, pharmaceutical-medical device, or veterinary, and the product family type for the associated product family must be flu vaccine, pharmaceutical, pharmaceuticalmedical device, or veterinary.

— Only active ingredients that are associated to the product family are available to be associated with component active ingredient.

— All active substances from Data Administration are available to be associated with reference active ingredients.

— Active ingredients cannot be associated with a component once a PDS template or application is associated with a product.

— When associating an active ingredient, you enter strength value only for an active ingredient selected from the Active Ingredient Name drop-down list.

— Not all values are required to be populated. However, you must enter the Concentration Measure Type, Low Amount Numerator Value and Low Amount Numerator Unit or any IDMP Strength field values. — Multiple Reference Active Ingredient can be added to:

- Manufactured Item Active Ingredients
- Pharmaceutical Product
- Component Active Ingredients

Associate an Active Ingredient

Associate active ingredients to entities to provide additional data points for a product.

To associate an active ingredient:

1. Click the link of the entity to which you want to associate an active ingredient.
2. Select the **Active Ingredients** tab.
3. Click **Create**.On the *Create Active Ingredient* page, select the active ingredient from the **Active Ingredient Name** drop-down list.
4. Enter values for **active ingredient concentration** and **measure** fields.
5. Do one of the following:

Option	Action
To create and associate the active ingredient to an entity	**Save**
To save your settings and create a new reference active ingredient	**Save and Create Reference Active Ingredient**
To save your settings and create a new active ingredient	**Create Another Active Ingredient**

Active Ingredient Attributes

The following table lists the attributes for the active ingredients. The attributes that are available to you depend on your security privileges.

Attribute	Component Type	Description
Active Ingredient Name	P, PMD, Vet,	The name of the active ingredient. Drop-down list. **Note:** If **Alternate IDMP Reference Active Ingredient** is configured via overrides and populated with a unique value, the **Active Ingredient** field on the *Create Active Ingredient* page allows to select same substance values multiple times.
	FV	
Alternate IDMP	P, PMD,	The name of the alternate IDMP active ingredient. This field is available for Pharmaceutical Product Active Ingredient attributes and Manufacturer Item Active Ingredients attributes only. You cannot modify the value selection after saving.
Active Ingredient	Vet, FV	• For Manufactured Item Active Ingredient: this field can be configured as a drop-down list with the values from the **Component Reference Active Ingredients**. • For Pharmaceutical Product Active Ingredient: this field can be configured as a drop-down list with the values from the **Component Reference Active Ingredients** of **Components** associated with a Pharmaceutical Product. To search for a Component Active Ingredient, you need to assign Components to Pharmaceutical Product.
		This field can also be configured as the substance selection widget with all the active values from **Data Administration** > **Substance Values**. You can select only one value. **Note:** For configuration assistance, please contact your Business Development Representative.

Attribute	**Component Type**	**Description**
Com ponent Name	P, PMD, Vet, FV	The component that contains the active ingredient. This filed is available for Active Ingredient Attributes for Component only.
Concen tration Mea sure Type	P, PMD, Vet	Used with other attributes to specify information about the concentration of the active ingredient. Values: Equal, Range, Up to, or Not Less Than. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
Exclude from IDMP Sub- mission	P, PMD, Vet, FV	Indicates the presence or absence in IDMP Submission. Yes or No values. This field is available for Active Ingredient Attributes for Pharmaceutical Product only.
Family Code	P, PMD, Vet,	The company-specific code for the product family with which the active ingredient is associated.

	FV	
Family Name	P, PMD, Vet, FV	The product family with which the active ingredient is associated.
Family Type	P, PMD, Vet, FV	The type of products in the product family with which the active ingredient is associated.
High Amount Denominator Prefix	P, PMD, Vet	The high limit amount denominator value. Must only be specified when a Range is described. Must be a Value from the published list. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
High Amount Denominator	P, PMD, Vet	The high limit amount denominator unit. Must only be specified when a Range is described. Must be a Value from the published list. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.

Attribute	**Component** **Type**	**Description**
Dinominator Unit		
High	P,	The high limit amount denominator value. Must only be specified when a Range is described. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.

Amount Denominator Value	PMD, Vet	
High Amount Numerator Prefix	P, PMD, Vet	The high limit amount numerator prefix must only be specified when a Range is described. Must be a Value from the published list. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
High Amount Numerator Unit	P, PMD, Vet	The high limit amount numerator unit must only be specified when a Range is described. Must be a Value from the published list. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
High Amount Numerator Value	P, PMD, Vet	The high limit amount numerator value. Must only be specified when a Range is described. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
Low Amount Denominator Prefix	P, PMD, Vet	The low limit amount denominator prefix or for non-range measurements the amount denominator prefix. Must be a Value from the published list. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
Low Amount Denominator Unit	P, PMD, Vet	The low limit denominator unit or for non-range measurements the amount numerator unit. Must be a Value from the published list. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
Low Amount	P, PMD,	The low limit amount denominator value or for non-range measurements the amount denominator value. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
Denominator	Vet	

Attribute	**Component Type**	**Description**
Dinominator Value		
Low Amount Numerator Prefix	P, PMD, Vet	The low limit amount numerator prefix or for non-range measurements the amount numerator prefix. Must be a Value from the published list. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
Low Amount Numerator Unit	P, PMD, Vet	The low limit amount numerator unit or for non-range measurements the amount numerator unit. Must be a Value from the published list. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
Low Amount Numerator Value	P, PMD, Vet	The low limit amount numerator value or for non-range measurements the amount numerator value. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.
Manu factured Item Name	P, PMD, Vet, FV	The name of manufactured item. This field is available for Active Ingredient Attributes for Manufactured Item only.
Measurement Point	P,	The physical or logical location at which a condition is described. This field is available for the Active Ingredients Attributes of Component and Pharmaceutical Product only.

	PMD, Vet	
Product Name	P, PMD, Vet, FV	The product that contains the active ingredient.
Pharmaceutical Product Name	P, PMD, Vet, FV	The standard pharmaceutical product name recognized internally and across countries. The product name must be unique. This field is available for Active Ingredient Attributes for Pharmaceutical Product only.
Attribute	**Component Type**	**Description**
Strength Same as Component?	P, PMD, Vet, FV	Indicates if the Strength is the same as the Component with a Yes or No value. This field is available for Active Ingredients Attributes for Pharmaceutical Product and for Manufactured Item only.

Table 1. Table 1. IDMP Presentation Strength

Table 1. Table 1. IDMP Presentation Strength

Attribute	**Component** **Type**	**Description**
Strength (Presentation) Quantity Operator	P, PMD, Vet, FV	Equates to Quantity Operator in IDMP. Refers to values per unit being defined. Example: Equal, Range, Up to, Not Less Than. **Note:** When Equal is selected, it is not displayed in the **XEVMPD Strength, IDMP Presentation Strength** , **IDMP Concentration Strength** columns on the related tabs.
Presentation Single/Low Limit - Numerator Value	P, PMD, Vet	The Presentation Single or Low Limit Numerator Value.
Presentation Single/Low Lim- it Numerator - Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
DP Presentation Single or Low Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.
Presentation Single/Low Limit Denominator Value	P, PMD, Vet	The value for Presentation Single/Low Limit Denominator.
Presentation Single/Low Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value from Unit of Presentation and Unit of Measurement.

Table 1. Table 1. IDMP Presentation Strength (continued)

Attribute	Component Type	Description
Presentation High Limit Numerator Value	P, PMD, Vet	The Presentation High Limit Numerator Value.
Presentation High Limit Numerator - Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
DP Presentation High Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.
Presentation High Limit Denominator Value	P, PMD, Vet	The value for Presentation High Limit Denominator.
Presentation High Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value is taken from Unit of Presentation and Unit of Measurement.

Table 2.Table 2. IDMP Concentration Strength

	FV	
Concentration	P,	The Concentration Single or Low Limit Denominator Value.
Single or Low Limit Denomina- tor Value	PMD, Vet	

Table 2. Table 2. IDMP Concentration Strength (continued)

Attribute	**Component Type**	**Description**
Concentration Single or Low Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration Single or High Limit Numerator Value	P, PMD, Vet	The Concentration High Limit Numerator Value.
Concentration High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration High Limit Denominator Value	P, PMD, Vet	The Concentration High Limit Denominator Value.
Concentration High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

The attributes shown in columns below are concatenations of some fields values defined above.

Attribute Name	**Description**
IDMP Presentation Strength	A concatenation of : • **IDMP Concentration Measure Type** • **Presentation Single or Low Limit Numerator Value**: ◦ **Presentation Single or Low Limit Unit of Measurement** ◦ **Presentation Single or Low Limit Unit of Presentation** • **Presentation High Limit Numerator Value** ◦ **Presentation High Limit Unit of Measurement** ◦ **Presentation High Limit Unit of Presentation**
Attribute Name	**Description**
IDMP Concentration Strength	A concatenation of : • **IDMP Concentration Measure Type** • **Concentration Single or Low Limit Numerator Value** : ◦ **Concentration Single or Low Limit Unit of Measurement** • **Concentration Single or Low Limit Denominator Value** ◦ **Concentration Single or Low Limit Unit of Measurement** • **Concentration High Limit Numerator Value** ◦ **Concentration High Limit Unit of Measurement** • **Concentration High Limit Denominator Value** ◦ **Concentration High Limit Unit of Measurement**

Modify an Active Ingredient

Modify the attributes of the active ingredients to include the necessary values.

To modify an active ingredient:

1. Click a link for the active ingredient you want to modify.
2. On the *Active Ingredient Attributes* page, click **Edit**.
3. Enter your changes to the active ingredient attributes.
4. **Save**.

Delete an Active Ingredient

Delete an active ingredient that is not required for an entity. Deleting an active ingredient deletes the reference active ingredient associated to it.

To delete an active ingredient:

1. Click the link for the active ingredient you want to delete.
2. On the *Active Ingredient Attributes* page, click **Delete**.
3. When you are prompted to confirm the deletion, click **OK**.

Associate a Reference Active Ingredient

Associate a reference active ingredient to an active ingredient that is associated to an entity.

When associating a reference active ingredient, you must enter the **Concentration Measure Type**, **Low Amount Numerator Value** and **Low Amount Numerator Unit** or any **IDMP Strength** field value.To associate a reference active ingredient:

1. Under *Active Ingredient Attributes*, select the **Reference Active Ingredients** tab.
2. Click **Create**.
3. On the *Create Reference Active Ingredient* page, select the active ingredient from the **Reference Active Ingredient Name** drop-down list.
4. Do one of the following:

Option	**Action**
To save the reference active ingredient settings	**Save**
To save your settings and create a new reference active ingredient	**Create Another Reference Active Ingredient**
To cancel the changes	**Cancel**

Reference Active Ingredient Attributes

Use the following descriptions of reference active ingredient attributes to enter attribute values when creating or modifying a reference active ingredient. The attributes that are displayed depend on your security privileges.

Attribute	**Component Type**	**Description**
Active Ingredient Name	P, PMD, Vet, FV	The name of the active ingredient. Drop-down list.
Alternate IDMP Reference Active Ingredient	P, PMD, Vet, FV	The name of the alternate IDMP active reference ingredient. This field is available via overrides for *Pharmaceutical Product Reference Active Ingredient* attributes and *Manufacturer Item Reference Active Ingredients* attributes only. You cannot modify the value selection after saving. For both *Pharmaceutical Product Reference Active Ingredient* and *Manufactured Item Reference Active Ingredient*, this field can be configured as a substance selection widget with all active values from **Data Administration** > **Substance Values**, or as drop-down list with the values from the **Component** > **Reference Active Ingredient**. **Note:** For configuration assistance, please contact your Business Development Representative.

Attribute	**Component Type**	**Description**
Component Name	P, PMD, Vet, FV	The component that contains the active ingredient with reference active ingredient. This filed is available for Active Ingredient Attributes for Component only.

Concentration Measure Type	P, PMD, Vet	Used with other attributes to specify information about the concentration of the reference active ingredient. Values: **Equal**, **Range**, **Up to**, or **Not Less Than**. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product on- ly.
Exclude from IDMP Sub- mission	P, PMD, Vet, FV	Indicates the presence or absence in IDMP Submission. Yes or No values. This field is available for Reference Active Ingredient Attributes for Pharmaceutical Product only.
Use for x EVMPD	P, PMD, Vet, FV	Indicates if Reference Active Ingredient is used for xEVMPD. Yes or No values. This field is available for Reference Active Ingredient Attributes for Pharmaceutical Product only and is added to the **XEVMPD Submission Wizard** logic to take into consideration only that Pharmaceutical Product Reference Active Ingredient which has a field value as a **Yes**.
Family Code	P, PMD, Vet, FV	The company-specific code for the product family that is associated with the reference active ingredient.
Family Name	P, PMD, Vet, FV	The product family that is associated with the active ingredient.
Family Type	P, PMD, Vet, FV	The type of products in the product family that are associated with the reference active ingredient. For example, pharmaceutical, medical, or device.

High Amount Denominator	P, PMD, Vet	The high limit amount denominator value. Must only be specified when a Range is described. Must be a Value from the published list. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.

Attribute	**Component Type**	**Description**
High Amount Denominator Unit	P, PMD, Vet	The high limit amount denominator unit. Must only be specified when a Range is described. Must be a Value from the published list. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.
High Amount De- nomi nator Value	P, PMD, Vet	The high limit amount denominator value. Must only be specified when a Range is described. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.
High Amount Numerator Prefix	P, PMD, Vet	The high limit amount numerator prefix must only be specified when a Range is described. Must be a Value from the published list. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.
High Amount Numerator Unit	P, PMD, Vet	The high limit amount numerator unit must only be specified when a Range is described. Must be a Value from the published list. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.

High Amount Numerator Value	P, PMD, Vet	The high limit amount numerator value. Must only be specified when a Range is described. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.
Low Amount Denominator Prefix	P, PMD, Vet	The low limit amount denominator prefix or for non-range measurements the amount denominator prefix. Must be a Value from the published list. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.
Low Amount Denominator Unit	P, PMD, Vet	The low limit denominator unit or for non-range measurements the amount numerator unit. Must be a Value from the published list. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.
Low Amount Denominator	P, PMD, Vet	The low limit amount denominator value or for non-range measurements the amount denominator value. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.

Attribute	**Component Type**	**Description**
Dinominator Value		
Low Amount Numerator Prefix	P, PMD, Vet	The low limit amount numerator prefix or for non-range measurements the amount numerator prefix. Must be a Value from the published list. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.

Low Amount Numerator Unit	P, PMD, Vet	The low limit amount numerator unit or for non-range measurements the amount numerator unit. Must be a Value from the published list. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.
Low Amount Numerator Value	P, PMD, Vet	The low limit amount numerator value or for non-range measurements the amount numerator value. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.
Manufactured Item Name	P, PMD, Vet, FV	The name of manufactured item. This field is available for Reference Active Ingredient Attributes for Manufactured Item only.
Measurement Point	P, PMD, Vet	The physical or logical location at which a condition is described. This field is available for the Reference Active Ingredients Attributes of Component and Pharmaceutical Product only.
Product Name	P, PMD, Vet, FV	The product with a component and active ingredient that contains the reference active ingredient.
Pharma ceutical Product Name	P, PMD, Vet, FV	The standard pharmaceutical product name recognized internally and across countries. The product name must be unique. This field is available for Reference Active Ingredient Attributes for Pharmaceutical Product only.

Reference Active Ingredient Name	P, PMD, Vet, FV	The list with all active Substances in Data Administration.
Attribute	**Component Type**	**Description**
Strength Same as Component?	P, PMD, Vet, FV	Indicates the strength. Yes or No values. This field is available for Reference Active Ingredients Attributes for Pharmaceutical Product and for Manufactured Item only.

Table 3. Table 1. IDMP Presentation Strength

Attribute	**Component Type**	**Description**
Strength (Presentation) Quantity Operator	P, PMD, Vet, FV	Equates to Quantity Operator in IDMP. Refers to values per unit being defined. Example: Equal, Range, Up to, Not Less Than. **Note:** When Equal is selected, it is not displayed in the **XEVMPD Strength, IDMP Presentation Strength** , **IDMP Concentration Strength** columns on the related tabs.
Presentation Single/Low Limit - Numerator Value	P, PMD, Vet	The Presentation Single or Low Limit Numerator Value.

Presentation Single/Low Lim- it Numerator - Unit of Measure- ment	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
DP Presentation Single or Low Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.
Presentation Single/Low Limit Denominator Value	P, PMD, Vet	The value for Presentation Single/Low Limit Denominator.
Presentation Single/Low Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value from Unit of Presentation and Unit of Measurement.

Table 3. Table 1. IDMP Presentation Strength (continued)

Attribute	**Component Type**	**Description**
Presentation High Limit Numerator Value	P, PMD, Vet	The Presentation High Limit Numerator Value.
Presentation High Limit Numerator - Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

DP Presentation High Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.
Presentation High Limit Denominator Value	P, PMD, Vet	The value for Presentation High Limit Denominator.
Presentation High Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value is taken from Unit of Presentation and Unit of Measurement.

Table 4. Table 2. IDMP Concentration Strength

Attribute	**Component Type**	**Description**
Concentration Measure Type	P, PMD, Vet, FV	Used with other attributes to specify information about the quantity operator in IDMP. Values: Equal, Range, Up to, or Not Less Than.
Concentration Single or Low Limit Numerator Value	P, PMD, Vet	The Concentration Single or Low Limit Numerator Value.
Concentration Single or Low Limit Unit of Measurement	P, PMD, Vet	The Concentration Single or Low Limit Unit of Measurement.
Concentration Single or Low Limit Denominator Value	P, PMD, Vet	The Concentration Single or Low Limit Denominator Value.
Concentration Single or Low Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

Table 4. Table 2. IDMP Concentration Strength (continued)

Attribute	Component Type	Description
Concentration High Limit Numerator Value	P, PMD, Vet	The Concentration High Limit Numerator Value.
Concentration High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration High Limit Denominator Value	P, PMD, Vet	The Concentration High Limit Denominator Value.
Concentration High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

The attributes shown in columns below are concatenations of some fields values defined above.

Attribute Name	Description
IDMP Presentation Strength	A concatenation of: • **IDMP Concentration Measure Type** • **Presentation Single or Low Limit Numerator Value**: ◦ **Presentation Single or Low Limit Unit of Measurement** ◦ **Presentation Single or Low Limit Unit of Presentation** ◦ **Presentation Single or High Limit Numerator Value** ◦ **Presentation High Limit Unit of Measurement** ◦ **Presentation High Limit Unit of Presentation**
IDMP Concentration Strength	A concatenation of: • **Concentration Measure Type** • **Concentration Single or Low Limit Numerator Value**: ◦ **Concentration Single or Low Limit Unit of Measurement** • **Concentration Single or Low Limit Denominator Value** ◦ **Concentration Single or Low Limit Unit of Measurement** • **Concentration High Limit Numerator Value** ◦ **Concentration High Limit Unit of Measurement**
Attribute Name	**Description**
	• **Concentration High Limit Denominator Value** ◦ **Concentration High Limit Unit of Measurement**

Modify a Reference Active Ingredient

Modify the attributes of the reference active ingredients to include the necessary values. To

modify a reference active ingredient:

1. Click a link for the reference active ingredient you want to modify.
2. On the *Reference Active Ingredient Attributes* page, click **Edit**.
3. On the *Edit Reference Active Ingredients* page, enter your changes to the reference active ingredient attributes.
4. **Save**.

Delete a Reference Active Ingredient

Delete a reference active ingredient that is not required for an entity.

To delete a reference active ingredient:

1. Click the link for the reference active ingredient you want to delete.
2. On the *Reference Active Ingredient Attributes* page, click **Delete**.
3. When you are prompted to confirm the deletion, click **OK**.

Chapter 4. Substances and Reference Substances

Substances are associated to entities to provide additional data points for the product structure.

Substances are associated to entities. Reference substances are associated to the substances of an entity. It is not mandatory for an entity to have substances and reference substances. Substances are associated to the following entities:

— Pharmaceutical Product — Manufactured Item

The following guidelines apply when associating a substance to an entity:

— You must have the same user privileges required for adding a product.

— The entity type must be pharmaceutical, pharmaceutical-medical device, or veterinary, and the product family type for the associated product family must be flu vaccine, pharmaceutical, pharmaceuticalmedical device, or veterinary.

— Associating substances to an entity allows Identification of Medicinal Product (IDMP) data standards to maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data. Ennov InSight enables you to view, create, modify, and delete the substances entity.

— The component type must be pharmaceutical, pharmaceutical-medical device, or veterinary, and the product family type for the associated product family must also be pharmaceutical, pharmaceutical-medical device, or veterinary.

— Multiple substances can be added to the entity.

— A substance can have only one reference substance.

Associate a Substance

Associate substances to entities to provide additional data points for a product.

You must have appropriate security privileges to create a substance. If you have the privileges to add a product, you can associate a substance.

To create a substance:

1. Navigate to the entity for which you want to create and associate a substance.
2. On the entity attributes page, select the **Substances** tab.
3. Click **Create**.
4. Select and enter the respective attribute values.
5. **Save**.

Associate a Substance from a PDS Template

Associate a substance to an entity using a PDS template to provide additional data points for a product. At least one PDS template with a substance must be present in a product to associate it with an entity.

To associate a substance from a PDS template:

1. Navigate to the entity for which you want to create and associate a substance.
2. On the entity attributes page, select the **Substances** tab.
3. Click **Associate Substance from a PDS Template**.
4. Select the respective attribute values.
5. **Save**.A substance is created and associated with substance values copied from a PDS template.

Substance Attributes

The following attributes are used for a substance to associate it with an entity.

Attribute	**Component Type**	**Description**
Component Name	P, PMD, Vet, FV	Name of the component associated.
Family Code	P, PMD, Vet, FV	The company-specific code for the product family.
Family Name	P, PMD, Vet, FV	The standard name is recognized internally and across countries.
Family Type	P, PMD, Vet, FV	The type of products associated with this product family (For example, pharmaceutical, medical device).

Manufactured Item Name	P, PMD, Vet, FV	The name of manufactured item. This field is available for Substance Attributes for Manufactured Item only.
Pharmaceutical Product Name	P, PMD, Vet, FV	The standard pharmaceutical product name recognized internally and across countries. The value for the product name is unique. This filed is available for Substance Attributes for Pharmaceutical Product only.
Attribute	**Component Type**	**Description**
Product Name	P, PMD, Vet, FV	The standard product name recognized internally and across countries. In some sections of the application, the product name is shown with the product code to identify a product. For example, Origine 390 could identify a product that has the name Origine and the code 390.
Strength Same as PDS Substance?	P, PMD, Vet, FV	Indicates if the strength is same as the PDS substance. Yes or No values.
Substance Name	P, PMD, Vet, FV	The name of substance.
Substance Type	P, PMD, Vet, FV	The type of substance.

Table 5. Table 1. IDMP Presentation Strength

Attribute	Component Type	Description
Strength (Presentation) Quantity Operator	P, PMD, Vet, FV	Equates to Quantity Operator in IDMP. Refers to values per unit being defined. Example: Equal, Range, Up to, Not Less Than.**Note:** When Equal is selected, it is not displayed in the **XEVMPD Strength** , **IDMP Presentation Strength, IDMP Concentration Strength** columns on the related tabs.
Presentation Single/Low Limit - Numerator Value	P, PMD, Vet	The Presentation Single or Low Limit Numerator Value.
Presentation Single/Low Limit Numerator - Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

1. **Table 1. IDMP Presentation Strength (continued)**

Attribute	**Component Type**	**Description**
DP Presentation Single or Low Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.
Presentation Single/Low Limit Denominator Value	P, PMD, Vet	The value for Presentation Single/Low Limit Denominator.
Presentation Single/Low Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value from Unit of Presentation and Unit of Measurement.
Present ation High Limit Numera tor Value	P, PMD, Vet	The Presentation High Limit Numerator Value.
Presentation High Limit Numerator Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
DP Presentation High Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.

Presentation High Limit Denominator Value	P, PMD, Vet	The value for Presentation High Limit Denominator.
Presentation High Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value is taken from Unit of Presentation and Unit of Measurement.

2. **Table 2. IDMP Concentration Strength**

Attribute	**Component Type**	**Description**
Concentration Measure Type	P, PMD, Vet, FV	Equates to Quantity Operator in IDMP. Refers to values per unit being defined. Example: Equal, Range, Up to, Not Less Than. **Note:** When Equal is selected, it is not displayed in the **XEVMPD Strength** , **IDMP Presentation Strength** , **IDMP Concentration Strength** columns on the related tabs.
Concentration Single or Low Limit Numerator Value	P, PMD, Vet	The Concentration Single or Low Limit Numerator Value.
Concentration Single or Low Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

Concentration Single or Low Limit Denomina-tor Value	P, PMD, Vet	The Concentration Single or Low Limit Denominator Value.
Concentration Single or Low Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration High Limit Numerator Value	P, PMD, Vet	The Concentration High Limit Numerator Value.
Concentration High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration High Limit Denominator Value	P, PMD, Vet	The Concentration High Limit Denominator Value.

6 Table 2. IDMP Concentration Strength (continued)

Attribute	**Component Type**	**Description**
Concentration High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

The attributes shown in columns below are concatenations of some fields values defined above.

Attribute Name	Description
Presentation Strength	a concatenation of : • **IDMP Concentration Measure Type** • **Presentation Single or Low Limit Numerator Value**: ◦ **Presentation Single or Low Limit Unit of Measurement** ◦ **Presentation Single or Low Limit Unit of Presentation** • **Presentation High Limit Numerator Value** ◦ **Presentation High Limit Unit of Measurement** ◦ **Presentation High Limit Unit of Presentation**
Concentration Strength	a concatenation of : • **IDMP Concentration Measure Type** • **Concentration Single or Low Limit Numerator Value**: ◦ **Concentration Single or Low Limit Unit of Measurement** • **Concentration Single or Low Limit Denominator Value** ◦ **Concentration Single or Low Limit Unit of Measurement** • **Concentration High Limit Numerator Value** ◦ **Concentration High Limit Unit of Measurement** • **Concentration High Limit Denominator Value** ◦ **Concentration High Limit Unit of Measurement**

Modify a Substance

You can modify a previously created Substance to change the existing data.

You should have at least WRITE privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security to modify the substance attributes.

To modify the substance attributes:

1. Click a link for the substance you want to modify.
2. On the *Substance Attributes* page, click **Modify**.
3. Make necessary changes to the substance attributes.
4. **Save**.

Associate a Reference Substance

Associate a reference substance to a substance that is associated to an entity.

To associate a reference substance:

1. On the **Substances** tab, click a link for the substance to which you want to associate a reference substance.
2. Click the **Reference Substances** tab.
3. Click **Create**.
4. Enter values for the reference substance attributes.
5. **Save**.

Associate a Reference Substance

Associate a reference substance to a substance that is associated to an entity.

To associate a reference substance:

1. On the Substances tab, click a link for the substance to which you want to associate a reference substance.
2. Click the Reference Substances tab.
3. Click Create.
4. Enter values for the reference substance attributes.
5. Save.

Reference Substance Attributes

The following table lists the attributes for the reference substance. The attributes that are available to you depend on your security privileges.

Attribute	Component Type	Description
Component Name	P, PMD, Vet, FV	Name of the component associated.
Family Code	P, PMD, Vet, FV	The company-specific code for the product family.

Family Name	P, PMD, Vet, FV	The standard name recognized internally and across countries.
Family Type	P, PMD, Vet, FV	The type of products associated with this product family (for example: pharmaceutical, medical device).
Manufactured Item Name	P, PMD, Vet, FV	The name of manufactured item. This field is available for Reference Substance Attributes for Manu- factured Item only.
Pharmaceutical Product Name	P, PMD, Vet, FV	The standard pharmaceutical product name recognized internally and across countries. The value for the product name is unique. This filed is available for Reference Substance Attributes for Pharmaceutical Product only.
Attribute	Component Type	Description
Product Name	P, PMD, Vet, FV	The standard product name recognized internally and across countries. In some sections of the application, the product name is shown with the product code to identify a product. For example, Origine 390 could iden- tify a product that has the name Orig- ine and the code 390.
Reference Substance Name	P, PMD, Vet, FV	The name of the reference sub- stance.
Substance Name	P, PMD, Vet, FV	The name of substance.
Substance Type	P, PMD, Vet, FV	The substance type.

Table 7: IDMP Presentation Strength

Attribute	Component Type	Description
Concentration Measure Type	P, PMD, Vet, FV	Equates to Quantity Operator in IDMP. Refers to values per unit being defined. Example: Equal, Range, Up to, Not Less Than.
Presentation Single or Low Limit Numerator Value	P, PMD, Vet	The Presentation Single or Low Limit Numerator Value.
Presentation Single or Low Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Presentation Single or Low Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.
Presentation High Limit Numerator Value	P, PMD, Vet	The Presentation High Limit Numerator Value.
Presentation High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Attribute	Component Type	Description
Presentation High Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.

Table 8: IDMP Concentration Strength

Attribute	Component Type	Description
Concentration Measure Type	P, PMD, Vet, FV	Used with other attributes to specify information about the quantity operator in IDMP. Values: Equal, Range, Up to, or Not Less Than.
Concentration Single or Low Limit Numerator Value	P, PMD, Vet	The Concentration Single or Low Limit Numerator Value.

Concentration Single or Low Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration Single or Low Limit Denominator Value	P, PMD, Vet	The Concentration Single or Low Limit Denominator Value.
Concentration Single or Low Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration High Limit Numerator Value	P, PMD, Vet	The Concentration High Limit Numerator Value.
Concentration High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration High Limit Denominator Value	P, PMD, Vet	The Concentration High Limit Denominator Value.
Concentration High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

The attributes shown in columns below are concatenations of some fields values defined above.

Attribute Name	Description
Presentation Strength	a concatenation of : — IDMP Concentration Measure Type — Presentation Single or Low Limit Numerator Value: • Presentation Single or Low Limit Unit of Measurement • Presentation Single or Low Limit Unit of Presentation — Presentation High Limit Numerator Value — Presentation High Limit Unit of Measurement — Presentation High Limit Unit of Presentation

Concentration Strength	a concatenation of : — IDMP Concentration Measure Type — Concentration Single or Low Limit Numerator Value:
	• Concentration Single or Low Limit Unit of Measurement — Concentration Single or Low Limit Denominator Value • Concentration Single or Low Limit Unit of Measurement — Concentration High Limit Numerator Value • Concentration High Limit Unit of Measurement — Concentration High Limit Denominator Value • Concentration High Limit Unit of Measurement

Modify a Reference Substance

Modify the attributes of the reference substance to include the necessary values. To

modify a reference substance:

1. On the *Reference Substances* tab, click the link for the reference substance that you want to modify.
2. On the *Reference Substance Attributes* page, click Modify.
3. Make the necessary changes.
4. Save.

Delete a Reference Substance

You can delete a reference substance that is not required for an entity.

To delete a Reference Substance:

1. On the *Reference Substances* tab, click the link of the reference substance that you want to delete.
2. On the *Reference Substance Attributes* page, click Delete.
3. On the confirmation message, click OK.

Reference Substance Attributes

The following table lists the attributes for the reference substance. The attributes that are available to you depend on your security privileges.

Attribute	**Component Type**	**Description**
Component Name	P, PMD, Vet, FV	Name of the component associated.
Family Code	P, PMD, Vet, FV	The company-specific code for the product family.
Family Name	P, PMD, Vet, FV	The standard name recognized internally and across countries.
Family Type	P, PMD, Vet, FV	The type of products associated with this product family (for example: pharmaceutical, medical device).
Manufactured Item Name	P, PMD, Vet, FV	The name of manufactured item. This field is available for Reference Substance Attributes for Manufactured Item only.

Pharmaceutical Product Name	P, PMD, Vet, FV	The standard pharmaceutical product name recognized internally and across countries. The value for the product name is unique. This filed is available for Reference Substance Attributes for Pharmaceutical Product only.	
Product Name	P, PMD, Vet, FV	The standard product name recognized internally and across countries. In some sections of the application, the product name is shown with the product code to identify a product. For example, Origine 390 could identify a product that has the name Origine and the code 390.	
Reference Substance Name	P, PMD, Vet, FV	The name of the reference substance.	
Attribute	**Component Type**		**Description**
Substance Name	P, PMD, Vet, FV	The name of substance.	
Substance Type	P, PMD, Vet, FV	The substance type.	

Table 7. Table 1. IDMP Presentation Strength

Attribute	**Component Type**	**Description**
Strength (Presentation) Quantity Operator	P, PMD, Vet, FV	Equates to Quantity Operator in IDMP. Refers to values per unit being defined. Example: Equal, Range, Up to, Not Less Than.**Note:** When Equal is selected, it is not displayed in the **XEVMPD Strength, IDMP Presentation Strength** , **IDMP Concen- tration Strength** columns on the related tabs.
Presentation Single/Low Limit - Numerator Value	P, PMD, Vet	The Presentation Single or Low Limit Numerator Value.
Presentation Single/Low Limit Numerator Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
DP Presentation Sin- gle or Low Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.
Presentation Single/Low Limit Denom- inator Value	P, PMD, Vet	The value for Presentation Single/Low Limit Denominator.

Table 7. Table 1. IDMP Presentation Strength (continued)

Attribute	Component Type	Description
Presentation Single/Low Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value from Unit of Presentation and Unit of Measurement.
Presentation High Limit Numerator Value	P, PMD, Vet	The Presentation High Limit Numerator Value.
Presentation High Limit Numerator Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
DP Presentation High Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.
Presentation High Limit Denominator Value	P, PMD, Vet	The value for Presentation High Limit Denominator.
Presentation High Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value is taken from Unit of Presentation and Unit of Measurement.

Table 8. Table 2. IDMP Concentration Strength

Attribute	Component Type	Description
Concentration Measure Type	P, PMD, Vet, FV	Used with other attributes to specify information about the quantity operator in IDMP. Values: Equal, Range, Up to, or Not Less Than.
Concentration Single or Low Limit Numerator Value	P, PMD, Vet	The Concentration Single or Low Limit Numerator Value.
Concentration Single or Low Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

Table 8. Table 2. IDMP Concentration Strength (continued)

Attribute	Component Type	Description
Concentration Single or Low Limit Denominator Value	P, PMD, Vet	The Concentration Single or Low Limit Denominator Value.
Concentration Single or Low Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration High Limit Numerator Value	P, PMD, Vet	The Concentration High Limit Numerator Value.

Concentration High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration High Limit Denominator Value	P, PMD, Vet	The Concentration High Limit Denominator Value.
Concentration High Limit Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

The attributes shown in columns below are concatenations of some fields values defined above.

Attribute Name	**Description**
Presentation Strength	a concatenation of : • **IDMP Concentration Measure Type** • **Presentation Single or Low Limit Numerator Value**: ◦ **Presentation Single or Low Limit Unit of Measurement** ◦ **Presentation Single or Low Limit Unit of Presentation** • **Presentation High Limit Numerator Value** ◦ **Presentation High Limit Unit of Measurement** ◦ **Presentation High Limit Unit of Presentation**
Concentration Strength	a concatenation of : • **IDMP Concentration Measure Type** • **Concentration Single or Low Limit Numerator Value**: ◦ **Concentration Single or Low Limit Unit of Measurement** • **Concentration Single or Low Limit Denominator Value**
Attribute Name	**Description**
	• **Concentration Single or Low Limit Unit of Measurement** • **Concentration High Limit Numerator Value** ◦ **Concentration High Limit Unit of Measurement** • **Concentration High Limit Denominator Value** ◦ **Concentration High Limit Unit of Measurement**

Modify a Reference Substance

Modify the attributes of the reference substance to include the necessary values. To

modify a reference substance:

1. On the *Reference Substances* tab, click the link for the reference substance that you want to modify.
2. On the *Reference Substance Attributes* page, click **Modify**.
3. Make the necessary changes.
4. **Save**.

Delete a Reference Substance

You can delete a reference substance that is not required for an entity.

To delete a Reference Substance:

1. On the *Reference Substances* tab, click the link of the reference substance that you want to delete.
2. On the *Reference Substance Attributes* page, click **Delete**.
3. On the confirmation message, click **OK**.

Associate a Substance or Reference Substance from Substance Search

Ennov InSight *Substance Search* selection widget enables you to associate a substance or reference substance to an entity.

To associate a substance or reference substance:

1. Open the attributes page of an entity to which you want to associate a substance or reference substance.
2. Look for the appropriate entity field and click **Select**. This field is labeled differently for entities. For example, the **Active Ingredients** field on the *Product Family Attributes* page. See: *Get Started* > *Substance Search* for the details. The *Substance Search* window appears.
3. Use the search options in the **Search By** section. The search results are displayed.
4. Select a substance and click **Associate Substance**. The associated substance name appears for the substance field.
5. Click **Save** on the entity attributes page.

Chapter 5. Applications

An application is an entity that represents all submissions created for the purpose of obtaining regulatory agency approval for products associated with the application.

Applications define country-specific product registration information. In case of the European Union (EU), product registration information is for one or more countries. The application entity in Ennov InSight tracks data about the country, application type, procedure type, and the products associated with an application.

Application categories:

Category	**Description**
National	Used to obtain approval for the associated products in one country only.
Centralized Procedure (CP)	Used to obtain simultaneous approval for the associated products in the entire EU region or WA-HO region.
Decentralized Procedure (DCP)	Used for products that have not yet received authorization in an EU country. It is similar to the Mutual Recognition Procedure (MRP), without requiring that a national marketing authorization be granted in one EU country.
Mutual Recognition Procedure (MRP)	Used to obtain approval of the associated products in one EU country (an RMS - Reference Member State). The intent is to obtain approval in subsequent EU countries (CMS - Concerned Member States) by having those countries recognize the assessment of the first EU country. EU Clinical Trial Regulation Procedure (EU CTR) is mapped to MRP.

Applications are specific to the following Ennov InSight licensed modules:

- Electronic Lifecycle Publishing (ELP)
- Paper Review Publishing (PRP)
- Product Detail Management (PDM)
- Registered Document Analysis (RDA)
- Registration Planing and Tracking (RPT)
- Submission Planning and Tracking (SPT)

Create Applications

It is best practice to use the *Create Application* wizard to create an application. Alternatively, you can also use the **Create Application** option available on the **Applications** tab of the *Product Family Attributes* page.

When creating an application, the application types and procedure types you assign to the application can vary by country, based on the values configured by your Data Administrator.

Applicable rules:

- You can associate any Product to an Application, regardless of the Product Family, except for products with the status of **Not Approved** or **Withdrawn**. This allows the submission of products from different product families as part of the same submission for an application.
- You cannot complete an Application without associating a Product.
- **The Product Selection** field displays only those Product values of the Product Families that are assigned to the appropriate Reviewing Country in Security Administration.
- More than one Product Family can be associated with an Application through the associated products.
- The Application Name and Application Code must be unique. Uniqueness rule combinations:

◦ For CTA and CTR Application type: Application Code + Study Number

◦ For Non-CTA Application type: Application Code + Application Name

Applications and Registration Types in Ennov InSight , when a registration is created it is associated with an application. To support the association and tracking of registrations with package sets or with products, you need to specify the registration type. This registration type is mapped to a Ennov InSight internal type of either Package Set or Product.**Note:** Ennov InSight can be configured such that the registration type defaults to either the product or package set for applications, and registration type selection is disabled. **Tracking Clinical Trial Applications (CTAs)**

Ennov InSight allows you to track data for European Clinical Trial Applications, including Comparators, Placebo, and Investigational Medicinal Product (IMP) used in the study.

To track CTA data in an application, that is to have the data attributes related to CTA appear on the *Create Application* page, the application type selected must be mapped to the **Liquent_Cta** XML in data administration. **Note:** By default, the application type Clinical Trial Authorization is already mapped to this XML, however your data administrator can define custom application types that are mapped to the **Liquent_Cta** XML.**Tracking Clinical Trial Regulation Applications (CTRs)**

Ennov InSight allows you to track data for European Clinical Trial Regulation Applications, including Comparators, Placebo, and Investigational Medicinal Product (IMP) used in the study.

To track CTR data in an application that is, to have the data attributes related to CTR appear on the *Create Application* page, the application type selected must be mapped to the **Liquent_Ctr** XML in data administration.**Note:** By default, the application type Clinical Trial Regulation is already mapped to this XML, however your data administrator can define custom application types that are mapped to the **Liquent_Ctr** XML.**CT Shared Data**

For ease of use, the CT Shared Data entity is created to enable users to consolidate common details about CTA and CTR. The CT Shared Data entity is created and maintained at the product family level, making the information available for association with CTA, CTR, and IND application events. Upon associating the CT Shared Data to a CTA,

CTR, or IND application event, the same information applies to all event-countries associated with the event without the need to re-enter the same information on the application for each event-country.

CT Shared Data is identified by the protocol code number. You can associate the CT Shared Data to more than one CTA, CTR or IND application event. However, you can only assign one CT Shared Data entity to an event. The product you select determines the values for the **CT Shared Data** field.

Deleting Applications

- Only an administrator can delete an application regardless of whether other entities are associated with it.
- A non-administrator user can delete an application only with the appropriate security privileges and if no other entities are associated with the application.

Create Application Wizard

To use *Create Application* wizard, you must have WRITE permissions for events. You must have WRITE permissions to create events, sequences, and PDSs.

With *Create Application* wizard, you can:

- Create an application with an associated product family or product and event.
- Create an application and an associated event.
- Calculate projected dates for the countries associated with the event, if a timeline/event plan is used to create the event.
- Optionally, create sequences associated with the event.
- Optionally, create a PDS using a PDS template, if one or more PDS templates are saved in Ennov InSight.
- Optionally, create an application that does not have a product or product family associated to it to update in future.

Note: To use all functions in the *Create Application* wizard, you must have timeline/event plans and PDS templates saved in the Ennov InSight before using the wizard. You can select the timeline/event plan types below for the timeline/event plans:

- If you select an event type timeline/event plan, the *GPP* wizard creates an event that has sequence statuses relevant to the event type that you select.
- If you select a procedure type timeline/event plan, the GPP wizard creates an event that has sequence statuses relevant to the procedure type that you select.
- If you do not use a timeline/event plan, the GPP wizard creates an event that has sequence statuses that are active.

Use the Create Application Wizard

You can use the *Create Application* wizard to create new applications including events, sequences, and PDS.

You can view all the associations and entities created in the *summary* page. To create a new application:

1. Click **Wizards** > **Create Application**.
2. On the *Create Application* page, select or enter values for the application attributes. If you select **CTR, MRP, CP, DCP** or **National** Procedure Type for any Application type, except CTA and IND, the following fields will appear:
   - **Procedure Start Date**
   - **Procedure End Date**
   - **Procedure Identifier**
3. Click **Next.**A confirmation page states that an application will be created.
4. Select a reason and enter comments for the reason.
5. Click **Next**.
6. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next**.The *Create Event* page appears.
2. Enter values for the event attributes.
3. Click **Next**.A confirmation page shows that an event will be created.
4. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next**.The *Create additional entities* page appears.
2. You can select any of the following options to complete the application creation process:

Scenario	Steps
If you created an event based on a time-line/event plan and need to calculate projected dates, select **Calculate Projected Dates**.	a. Click **Next**. The *Update Event Country Status Projected Dates* page appears. b. Make selections for the event country status options presented. c. Click **Next**. A confirmation page states that the actions selected will be taken.
Scenario	**Steps**
	a. Select a reason and enter comments for the reason. b. Click **Next**
To create a sequence, select **Create Sequence**.	Click **Next**. A confirmation page states that the sequence will be created.
To create a PDS, select **Create a PDS using a PDS Template**.	a. Click **Next**. The *Select PDS Templates* page appears. b. Select the product and one or more templates. c. Click **Next**. One of the following occurs: ◦ If more than one product is associated with the event, you will have the option to select another product to create a PDS for that product. Repeat the steps for creating a PDS using a PDS template. ◦ When no additional products are selected, a confirmation page states that the PDS will be created. ◦ Select a reason and enter comments for the reason. ◦ Click **Next**
Make no selection on this page and simply view the entities and the associations created:	a. Click **Next.** All the entities and associations created are listed in the summary page. b. Do one of the following: ◦ Click one of the available links to view the entity created. ◦ Click **Finish** to return to the view from where you invoked the wizard.

3. To view the application or event after closing the wizard, click **Home** > **Applications** tab or **Home** > **Events** tab.
4. Click the link for the application or event that you want to view listed on the respective tabbed pages.

CTA, CTR and IND Application

CTA, CTR, and IND application types are used to obtain authorization to conduct a clinical trial in a specific country.

Using the *Create Application* wizard, you can create applications for different regions:

Application Type	**Countries**
Clinical Trial Authorization (CTA)	• European Union Countries • Western African Health Organization (WAHO) • Canada • Other countries except United States, Japan, Gulf Cooperation Council (GCC) region countries, and South Africa

Application Type		**Countries**
Investigational New Drug applications (INDs)	United States and Canada	
EU Clinical Trial Regulation (CTR)	• Austria • Belgium • Bulgaria • Croatia • Republic of Cyrus • Czech Republic • Denmark • Estonia • Finland • France • Germany • Greece • Hungary • Iceland • Ireland • Italy • Latvia • Liechtenstein • Lithuania • Luxembourg • Malta • Netherlands • Norway • Poland • Portugal • Romania • Slovakia • Slovenia • Spain • Sweden	

The CTA, CTR, and IND applications are used for tracking specific data required by the regulatory authorities:

- To track CTA data on the application, the application type selected must be mapped to the **Clinical Trial**

Application Entity XML Type XML in Data Administration. By default, the application type **Clinical Trial Authorization** is already mapped to this XML type.

- To track CTR data on the application, the application type selected must be mapped to the **Clinical Trial**

Regulation Entity XML Type XML in Data Administration. By default, the application type **Clinical Trial Regulation** is already mapped to this XML type.

- To track IND data on the application, the application type selected must be mapped to the **Investigational New Drug Entity XML Type** in Data Administration. By default, the application type **Investigational New Drug** is already mapped to this XML type.
- You can create a CTA, CTR or an IND application using the *Create Application* wizard or the *GPP* wizard.

Create a CTA, CTR or an IND Application

Different applications can be created depending on the region using the *Create Application* wizard. To

create a CTA, CTR or an IND application using the *Create Application* wizard:

1. Click **Wizards** > **Create Application**.
2. On the *Create Application* page, select the reviewing country:

Option	**Description**
CTA application	Select the **European Union**, **Canada**, **WAHO**, and any other country except the United States, Japan, a GCC region country, or South Africa.
CTR application	Select Austria, Belgium, Bulgaria, Croatia, Republic of Cyrus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden.
IND application	Select the **United States** or **Canada**.

Note: The **Procedure Start Date**, **Procedure End Date**, **Procedure Identifier** fields will appear when you select a **MRP, CP, DCP** or **National** Procedure Type for any Application type, except CTA, CTR and IND.

3. Enter or select values for the application attributes. The attributes will vary, based on the registration type (CTA, CTR or IND) selected. Upon selecting **Clinical Trial Authorization** as the registration type, the **Application Name** field changes to **Study Number.**
4. **Next**.
5. On the *Create Event* page, enter or select values for the event attributes.
6. Select the values for the **Comparator**.
7. **Next**.
8. **Save**.
9. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Create an Application from the Product Family Attributes Page

An application for a submission can be created from the *Product Family Attributes* page.

In addition to the method described in this topic for creating an application, you can also use the *Create Application* wizard.

To create an application from the *Product Family Attributes* page:

1. Click a link for the product family with which you want to associate an application.
2. On the *Product Family Attributes* page, on the **Application** tab, click **Create**.
3. On the *Create Application* page, enter values for the application attributes. The attributes may change after you select the application type.
4. **Save**.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Application Attributes

The attributes values that appear on the page depend on:

- How you create the application.
- If you are creating a National, Centralised Procedure (CP), Decentralised Procedure (DCP), or Mutual Recognition (MRP) application.
- If you are creating a Clinical Trial Authorization (CTA), Clinical Trial Regulation (CTR) or Investigational New Drug (IND) application or another type of application.

Use the following descriptions to help you choose and modify attribute values.

Attribute	**Description**
Actual Approval Date	When the application is first approved.
Actual Launch Date	Actual date of the product launch.
Actual Submission Date	When the application is submitted.
Annual Report Date	The date when the next annual report is due. This attribute is only for a CTA and CTR application.
Applicant ID	Identity of the entity that submits the application to regulatory authorities.
Application Add Comment	Comments you want to share with others in a discussion thread. Stamped with the date and time that you enter the information and your user ID.

Application Code	Agency-identified application number (or identifier). Possibly unknown until submittal time. For this reason, it can be the same as the internal code.
Application Comments	The discussion thread that includes all comments entered by users. Includes the date and time the comments were entered and the user IDs of those who entered them. Comments appear on the *Modify Application Attributes* page.
Application Concerned Parties	Users who may be copied on notifications about this entity. Use semi-colons (;) to separate e-mail addresses.

Attribute	**Description**
Application Description	Text that describes the application.
Application Keywords	Words that you can use to search for the application.
Application Name	The name of the application.
Application Owner	The person responsible for creating the application.
Application Prefix	The prefix of the application.
Application Status	The status of the application. **Note:** The **Application Status** can be set to Withdrawn only when all Registrations associated to this Application have a status mapped to internal WITHDRAWN status.
Application Status Date	The date when the current status was set.
Application Type	The type of application that you are creating. The application types you can choose from are dependent on the reviewing country. The attributes displayed vary by the application type selected: • CTA, CTR, and IND application types have different attributes than all other application types. You cannot modify the application type in Ennov InSight after creating the application.

Arbitration	For CP, DCP, and MRP procedure type applications, indicates if the application has been in arbitration.
Associated Products	The products to associate with the application. Available for RPT-licensed users only.

Attribute	**Description**
Clinical Trials #	The number used to identify the clinical trials assigned to the application.
Co-Rapporteur	For a CP application, the co-rapporteur associated with an application.
Countries	MRP/CP/Herbal/Homeopathic countries. When creating a new application, if the application procedure type is MRP, CP, Herbal or Homeopathic, you can add countries to the application as Concerned Member States (CMS). For CP procedure type applications, in addition to the individual countries that you add as CMS, you must also add the European Union to the application as a CMS.
Dossier Language	The language in which supporting documentation is written.
IMPID	Investigational Medicinal Product Identifier for CTA, CTR, and IND applications.
Last Role Change Date	When the country's role for the application date last changed.
Legal Basis	The legal basis for the authorization of the product.

Legal Status of Supply	How the product is approved to be sold. Might be unavailable for ELP users.
Local PSUR Date	The date that the periodic safety report is due for this application.
Local PSUR Data Lock Date	The date up to which information must be compiled for the periodic safety report for this application.
Next Renewal Date	Date of the next renewal.

Attribute	**Description**
Orphan Drug	Indicates whether the drug treats a rare disease affecting less than 200,000 people in the reviewing country.
Orphan Drug Last Up-dated	The date on which the Orphan Drug attribute was last updated. This attribute is only for an IND application.
Planned Approval Date	When the application is to be approved for the first time.
Planned Launch Date	Expected date for the launch of the product.

Planned Submission Date	When the application is to be submitted for the first time.
Procedure Date End	The date when the procedure was completed. For National, MRP, DCP and CP applications.
Procedure Date Start	The date when the procedure commenced. For National, MRP, DCP and CP applications.
Procedure Identifier	The unique identifier for the specific instance of a procedure undertaken. For National, MRP, DCP and CP applications.
Procedure Type	Defines the strategy used when applying for market approval: National, CP, DCP or MRP.**Note:** Procedure Start Date, Procedure End Date, Procedure Identifier will appear if you select MRP, CP, DCP or National Procedure Type for any Application type, except CTA, CTR and IND.
Product Family Type	The type of products associated with this product family, for example, pharmaceutical, medical device.
Reason	Reason for creating, modifying, or deleting an application.

Attribute	**Description**
Reason for Comments	Comments related to reason entered by users.
Reason for Not Approving	The reason that the application was not approved. This attribute is only for CTA and CTR applications.
Reason for Premature Ending	The reason that the application ended prematurely. This attribute is only for CTA and CTR applications.
Reason for Termination/Withdrawal	The reason that the application was terminated or withdrawn.

Region(s)	The region of the world that is associated with the reviewing country. Provided automatically. The value displayed is a comma-separated list that includes Region Type-Region pairs for the selected Reviewing Country. The list is alphabetical by region type.
Registration Type	When you create a registration, you associate it with an application. This attribute specifies whether the registrations you associate with the application will be of a registration type that is mapped to an internal value of either package set or product. **Note:** This attribute can be configured to default to one registration type and be non-editable.
Related Applications	Any applications to which the new application is related.
Reviewing Country	Primary country reviewing the application. For a CP application, this is the rapporteur. For an MRP or DCP application, this is the reference member state (RMS). For all other applications, it is the national country. The page refreshes to display the appropriate attributes for the country you choose.
Reporting Member State	Primary country reviewing the application. For a CP application, this is the rapporteur. For an MRP or DCP application, this is the reference member state (RMS). For all other applications, it is the national country.The page refreshes to display the appropriate attributes for the country you choose.This attribute is only for CTR applications.
Sender-defined	The unique automatically generated set of symbols that defines the code system of the sender-defined keywords.
Attribute	**Description**
Keywords Codesystem	
Sponsor	The individual, company, institution, or organization that takes responsibility for the Clinical Trial's initiation, management, and/or financing. Values for this come from the MAH/Sponsor/Legal Representative list. This is an attribute only for CTA and CTR applications. The value is presented in concatenation of MAH/Development Sponsor/Organization Name, Address, City and Country Code.
Starting Sequence Number	The number of the first sequence in the application, used if special permission by the agency allows starting on a sequence number other than 0000.
Study Number	Identifier for the study for which the CTA or CTR is created. This attribute is only for CTA or CTR applications.

Termination/Withdraw Date	The date when the application is terminated or withdrawn. Cannot be greater than today's date plus one day.
UUID	UUID (version 4 of UUID types) is a universal unique identifier that is automatically generated by the system. This field is visible and available for modification and view pages only. • The value can be modified only by users with Administrator permissions to the application, based on Application/Country rights. • Through the eCTD wizard, users with appropriate permissions are able to modify the UUID to support Sequences that may require a different UUID than the remainder of the Application. In most cases, the UUID value should not change. **Note:** The UUID should contain 32 digits separated by 4 hyphens (xxxxxxxx-xxxx-xxxx-xxxxxxxxxxxxxxxx).

Application Code Guidelines

As the application codes differ for various countries, the guidelines will help you while entering application code or number values in Ennov InSight.

When publishing with Ennov InSight , the following should be considered:

- For US applications, the application code is always a 6-digit number.
- For Canadian applications, the application is generally an 'e' followed by a 6-digit number (for example, e123456).
- For Japan the application code is generally 'ectd-' followed by a 6-digit number (for example, ectd-123456). This is the default value that appears in the Submission Number property when you use the Create eCTD wizard. The value must be numeric.
- For the EU, applications numbers are generally not available until you have filed and numbers may vary by country. It is best to enter with an application number that is unique and meaningful according to the specification. Samples may include a country abbreviation or an internal drug code abbreviation or number, for example: uk-h-323-001.
- The Application Code value must be populated with valid characters for it to be automatically and correctly formatted in the top level directory of an eCTD. You can update the Application number in the Regional XML within the assembly structure on the regional information folder.

Modify an Application

You modify an application to make edits in the application attributes, which were entered while creating the application.

To modify an application:

1. Click a link for the application you want to modify. The *Application Attributes* page appears.
2. Click **Edit**. The *Modify Application* page appears. **Note:** The **Application Status** can be set to Withdrawn only when all Registrations associated to this Application have a status mapped to internal WITHDRAWN status.
3. Enter your changes to the application attributes.
4. **Save**.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Use the Update Application Wizard

With the proper permissions, you can use the *Update Application* wizard to update the attributes of one or more applications. This is useful, for example, when regulatory changes require updates to several applications.

To update applications by using the *Update Application* wizard:

1. Click **Wizards** > **Update Application**. The *Update Application* page opens.
2. Enter search criteria for the applications that you want to update:
   - Select the product family type of applications.
   - Optionally, select the product families.
   - Select the application type.
   - Optionally, select other criteria. To search for applications using the Region information, you need to specify the Region Type first. Regions available for selection in the Region box depend on this selection. The regions list is filtered automatically to show only regions associated to the selected region type.
   - Change the columns included in the displayed results or change their order of appearance.
   - Change the order in which the results will be presented.
3. Click **Next**.
4. On the *Select Applications* page, select the check box for each application that you want to update, and click **Next**.
5. On the *Select Attributes* page:
   - Select the check box next to the attribute you want to change and enter values.

◦ If you select a check box and leave the associated field blank, the application attribute is updated with a blank value.

◦ Only the selected attributes will be updated. The values for attributes that are not selected will remain unchanged in the application you are updating.

6. Click **Next**.The *Confirmation* page lists the actions that the wizard will perform if you proceed.
7. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. To complete the update wizard, click **Finish**.
2. To view the applications after closing the wizard:
    a. Click **Home** > **Applications**.
    b. Click the link for each application that you want to view.

Application Countries

You can add countries to applications for which the internal procedure type in Data Administration has been set to Centralised Procedure (CP) or Mutual Recognition (MRP). If you do not know what the internal procedure type is for the application, consult your system administrator.

For CP procedure type applications, in addition to the countries that you add as Concerned Member States (CMS), you must also add the European Union to the application as a CMS.

The following rules apply to the **Application Country** > **Withdraw Date** if this specific country is associated to the Country PDS Detail:

- If the Country Status field of the related Country PDS Detail is modified to Approved, the **Application Country** > **Withdraw Date** field is automatically updated to be equal to Today's Date.
- If the Event is closed as Approved, meaning it has the **Association Closed As** field set to APPROVED, the

Application Country > **Withdrawn Date** field is automatically updated to be equal to **Event Closed Date** value.

As an additional rule, the withdrawn **Country PDS Detail** > **Country Status** field is automatically updated to Approved. See *If the Event Is Closed with the Status Approved*.

Add a Country to an Application

You must add a country to an application to obtain approval for the associated products in that country.

Note: You must have the appropriate security privileges to add a country to an application. To add a country to an application:

1. Click a link for the application to which you want to add an application country.
2. Click **Countries**.
3. Click **Create**. The *Add Application Country* page appears.
4. Enter values for the application country attributes. **Note:** For CP procedure type applications, in addition to the individual countries that you add as Concerned Member States (CMS), you must also add the European Union to the application as a CMS.
5. **Save**.
6. Select a reason and enter comments for the reason.
7. Click **Next**.
8. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Application Country Attributes

The application country attribute descriptions will help you to select the appropriate values while adding a country to an application.

Use the following descriptions to choose and enter attribute values.

Attribute	Description
Application Code	Agency-identified application number (or identifier); may not be known until submittal time, therefore it may be the same as the internal code.
Application Country Add Comments	The information that will be stamped with the date/time/user ID of the person entering the information.
Application Country Comments	Additional information you want to save with the country.
Application Country Description	Text that describes the information associated with the country.
Application Country Keywords	Words you can use to search for the country in the application.

Application Name	The name of the application.
Actual Approval Date	When approval has been granted by the appropriate regulatory authority for that country.
Actual Launch Date	When the product associated with the application is available to consumers for the first time in the new country.
Actual Submission Date	When the application is submitted for the first time in the country you are adding.
Country	Country on the application for which the details are being displayed/modified.
Planned Approval Date	The date on which the application is to be approved for the first time in the country you are adding.
Planned Launch Date	The date on which the application is to be launched for the first time in the country you are adding.
Planned Submission Date	The date on which the application is to be submitted for the first time in the country you are adding.
Concerned Member States	When the Reviewing Country is a member of the European Union (EU), the Concerned Member States attribute is available and enables you to select multiple countries for the submission. This section does not appear if the Reviewing Country is not a member of the EU.
Last Role Change Date	The date when the country's role for the application changed.
Local Early Termination/Withdrawal/Suspension Date	The local early termination, withdrawal or suspension date of a clinical trial by a sponsor for reasons of subject safety in relation to a Member State through the EU portal. This field is available for CTR applications only.

Attribute	Description
Local Early Termination/Withdrawal/Suspension Reason	The local early termination, withdrawal or suspension reason of a clinical trial by a sponsor for subject safety in relation to a Member State through the EU portal. This field is available for CTR applications only.
Local End of Recruitment Date	The local end date for recruitment of subjects of a clinical trial in relation to a Member State through the EU portal. This field is available for CTR applications only.
Local End of Trial Date	The local end date of a clinical trial in relation to a Member State through the EU portal. This field is available for CTR applications only.
Local First Visit of First Subject Date	The local first visit date of the first subject of a clinical trial in relation to a Member State through the EU portal. This field is available for CTR applications only.
Local Restart of Temporarily Halted Trial Date	The local restart date of the temporary halted clinical trial in relation to a Member State through the EU portal. This field is available for CTR applications only.
Local Start of Trial Date	The local start date of a clinical trial in relation to a Member State through the EU portal. This field is available for CTR applications only.
Local Temporary Halt Date	The local temporary halt date of a clinical trial in relation to a Member State through the EU portal. This field is available for CTR applications only.
Member States Concerned	Countries added to the application from the Countries tab.
Role	The role this country plays with respect to this Application.
Sequences	The list of the Sequence Codes of the Sequences the Application Country is associated to.
Withdrawn Date	The date the application is withdrawn in the country.
Reason	Reason for creating, modifying or deleting an Application Country.
Reason for Comments	Comments related to reason entered by users.

User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Modify an Application Country

You need to modify an application country to make changes in the application country attribute values. This procedure is based on a typical user who has Registration Planning and Tracking module or Product Detail Management module privileges. The attributes you can modify depend on your security privileges.

To modify an application country:

1. On the *Application Attributes* page, click **Countries**.
2. Click a link for the application country you want to modify. The *Application Country Attributes* page appears.
3. Click **Edit**. The *Modify Country Attributes* page appears.
4. Change the attributes, then **save**.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	**Steps**
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Remove Application Countries

You need to remove a country from an application when approval is not required for the associated products in that country.

You can remove an application country under the following conditions:

- For an MRP application, the country is not the RMS
- For a CP application, the country is not the rapporteur or co-rapporteur
- For a CP application, the application country is not an EU or WAHO country
- The country is not associated with any of the application's sequences
- The country has not been used for the following details in any PDS associated with the application:

◦ Label Detail

◦ Country Detail

◦ Manufacturer Detail

◦ Indication/Intended Use Detail (for Non-Veterinary Product Detail Sets) Detail

◦ Species Indication Detail (for Veterinary Product Detail Sets) Detail

- The country is not associated with any registration associated with the application
- The application country is not associated with any event associated with the application

Note: You cannot remove a country for National Applications, because only one country is assigned.

You can remove a country from a CP, DCP, or MRP type application only if:

- you have the appropriate security privileges
- no sequences, PDS or registrations are associated with the country

Remove a Country from an Application

You must remove a country from an application when approval is not required for the associated products in that country. To remove a country from an application:

1. Navigate to the *Application Attributes* page for the application.
2. Click **Countries**.
3. Click the link for the country you want to remove from the application.
4. Click **Delete**.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	**Steps**
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Chapter 6. Copy Applications

Create an application by using an existing National type application as a template.

Note: You must have at least

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privileges for the product family and the countries for which the application is copied. The name and code of the application you are copying must be different to the existing application name and code.

The following attributes are copied from the source application to the copies:

- Legal Status
- Application Description
- Application Keywords
- Application Owner
- Orphan Drug
- Dossier Language
- Products
- Registration Type

The Reviewing Country and Region(s) for the copied applications is based on the countries selected when using the *Copy Application* wizard.

The following attributes are also populated in the copy based on the country selected and the default settings for the country set by your data administrator:

- Application Type
- Procedure Type
- Application Code
- Application Name
- Internal Code
- Current Status
- Current Status Date

An event is created for each new application with the event attributes you define. The following additional conditions apply to events and the event-country relationship:

- The newly created events are open, not closed.
- For countries that are mapped to National application types, the reviewing country on the copied application is automatically associated with the event.
- For countries mapped to MRP application types, the RMS on the new application is automatically associated with the event.
- For countries mapped to EU-CP application types, the EU country is automatically associated with the event.

- For countries mapped to WAHO-CP application types, the WAHO country is automatically associated with the event.
- The event-country status schedule created for the new application is unlocked and has a default entry with the status selected by the user and the user entered status date.

The new UUID is generated automatically. It is unique across all the applications.

If the application you are copying has any product detail sets, they are also copied to the new application with the exception of label details.

If you copy an application for the same country, the *Copy Application* wizard assigns the applicant ID from the first application to the new application.

When you copy an application for a different country:

- If a default applicant ID is defined for the region associated with the new application, the *Copy Application* wizard assigns the default applicant ID to the new application.
- If a default applicant ID is not defined for the region associated with the new application, the *Copy Application* wizard does not assign an applicant ID to the new application.
- To set the default, go to **Data Administration** > **Submission Maintenance** > **Applicant ID Values**. This default is not shown in the *Copy Application* wizard.

To differentiate the application copies, the original application name is appended by the country code. For example, if you copy RR-APP001-NATIONAL and choose St. Lucia for the country, the name of the new application is RR-APP001NATIONALLC.

After the application without a product is copied with the **Copy Application** wizard:

- The copy of that application is displayed on the **Applications** tab of the *Product Family Attributes* page the initial application was created for.
- The copy of that application is displayed under the **Product Family** node the initial Application was created for on the **Product Family** or **Countries** tree.

If the application without a product and product family was created and copied through the **Copy Application** wizard, the copy of that application is displayed under the **NOT DEFINED** on the **Product Family** or **Countries** tree.

Event Attributes

When an application is copied, the product detail sets (PDS) associated with it are copied and associated with the each new application.

The following attributes have the same values as the PDS you are copying:

— Product

— Product Detail Set Name

— Product Characteristics

— Description

— Comments

— Keywords

— Product Detail Set Code

— Current Status is set to the default status identified for the product detail set status — Current Status Date is set to the current date

With the exception of labeling details, all details associated with the product detail set you are copying are copied to the appropriate product detail set as follows:

— Status is set to Pending

— Status Date is set to the current date

— In country details, Country is set to the country associated with the application you are copying.

When you copy the application, an event is created for and associated with the new application using the event attributes defined when completing the *Copy Application* page. The products associated with the PDSs are automatically associated to the newly created events.

Copy an Application

Use this procedure to copy a National procedure type application to one or more countries.

An application and an associated open event with an event status schedule for the country are created for each country you select.

To copy an application:

1. View the product family.
2. On the **Application** tab, click the link for the application that you want to copy.
3. On the *Application Attributes* page, click **Copy**.The *Copy Application* page appears.
4. Enter and select the attributes for the application copy.
5. Click **Copy Application**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Copy Application Attributes

The attribute descriptions will help you to enter appropriate application attribute values when creating an application in Ennov InSight.

Attribute	Description
Action Type	The type of approval required to consider the event active.
Application Code	Code for the application you are copying.
Application Name	Name of the application you are copying.
Available Countries/Selected Countries	Countries for which the new application is being created.
Comment	Free format text box where users can enter information that will be stamped with the date/time/userid of the person entering the information.
Description	Free format text box for entering descriptive information.
Event Code	Code for the event being created for the new application.
Event Concerned Parties	Users who may be copied on notifications about this entity. Use semi-colons (;) to separate e-mail addresses.
Event Name	Name for the event being created for the new application.
Event Type	Type of Regulatory action taking place.
Attribute	**Description**
Event-Country Status	The status of the event.
Keywords	Free format text box where users can enter text for searching purposes
PSUR Flag	Indicate whether the event is a safety event.
PSUR Reason/Comment	Enter a description for the PSUR.
PSUR Report Code	The code for the PSUR.
Reviewing Country	The country reviewing the application.

Secondary Event Type	Secondary Event Type Values based on selected Event Type Value.
Status Date	The effective date of the event status, cannot be greater than today's date plus one day.
Variation Number	The regulatory agency-assigned number that identifies the event as a variation of a submission.

Copied Application Attribute Results

When an application is copied, some attributes remain the same while some are updated.

The following application attributes remain the same when an application is copied:

- Legal Status
- Application Description
- Application Keywords
- Application Owner
- Orphan Drug
- Dossier Language
- Products
- Registration Type

The following application attributes are updated when an application is copied:

- Application Type is set to the default application type of the country for which you are copying the application.
- Procedure Type is set to the default procedure type for the country for which you are copying the application.
- Reviewing Country is set to the country you choose.
- Region(s) is set to the country you choose.
- New UUID value is generated.
- Application Code is set to the application code of the application you are copying. The country code is added to this value.
- Application Name is set to the application name of the application you are copying. The country code is added to this value.
- Internal Code is set to the internal code of the application you are copying. The country code is added to this value.
- Orphan Drug Last Updated is set to a current date.
- Application Status is set to the default status for the application you are copying.
- Application Status Date is set to the current date.
- All other application attributes are blank.

Copied PDS Attribute Results

Event Attributes

When an application is copied, the product detail sets (PDS) associated with it are copied and associated with the each new application.

The following attributes have the same values as the PDS you are copying:

- Product
- Product Detail Set Name
- Product Characteristics
- Description
- Comments
- Keywords
- Product Detail Set Code
- Current Status is set to the default status identified for the product detail set status
- Current Status Date is set to the current date

With the exception of labeling details, all details associated with the product detail set you are copying are copied to the appropriate product detail set as follows:

- Status is set to Pending
- Status Date is set to the current date
- In country details, Country is set to the country associated with the application you are copying.

When you copy the application, an event is created for and associated with the new application using the event attributes defined when completing the *Copy Application* page. The products associated with the PDSs are automatically associated to the newly created events.

Chapter 7. View an Application

You can view the application details and perform actions like add, modify, copy, delete, import, and generate history from the *Application Attributes* page.

To view and work with the application:

1. Click a link for the application you want to view. The *Application Attributes* page opens.
2. On the *Application Attributes* page, do any of the following:

◦ To modify the application attributes, click **Edit**.

◦ To copy an application, click **Copy**.

◦ To delete the application, click **Delete**.

◦ To copy the application URL to the Clipboard, click **Copy URL**. A message confirms the URL has been copied.

◦ To import an application from an eCTD, click **Import from eCTD**.

◦ To generate the Entity History query for the application, click **Report**.

◦ To add an event, sequence, registration, task, reference, or notification, select the appropriate tab and then click **Create**.

◦ To view products, countries, product detail sets (PDSs), and submitted and approved sequences (views) associated with the application, select the appropriate tab, then click a link for the entity.

Import an eCTD Application

You can import an existing eCTD into an application and give it a new sequence or assembly prefix. When performing an import of an existing eCTD, the import progress is reported in the **server.log** file. The **Job Request Details** also show messages about each sequence that is imported. The administrator can monitor the server log to follow the overall progress of the import and see more detailed messages, such as timestamps and Oracle information.

To import an eCTD application:

1. Click a link for the application into which you want to import an eCTD application. The *Application Attributes* page opens.
2. Click  to open the *Import eCTD to Application* window.
3. Click **Browse**, locate and select the eCTD application folder to import, then click **OK**.
4. In the *Sequence Name Prefix* box, enter a prefix to use for sequences.
5. In the *Assembly Name Prefix* box, enter a prefix to use for the assembly name.

◦ To import only XML leafs found in the eCTD XML, without importing references to the content files, select **Import Leaf Elements Only**. This prevents Ennov InSight from creating and assigning content document elements below each leaf during the import. It can also improve import speed significantly, as the content

files are not necessary for subsequent sequence publishing. This option captures all lifecycle operations correctly, and it prevents republishing of submissions already published. If extracts and renditions are needed for the imported documents, you can run create renditions and extractions from each assembly.

◦ To include orphan leaf elements in the import, select the **Import Orphan Leaf Elements** option. This informs the Ennov InSight system that some of the eCTD XML could be incorrect in that it might contain references to leaf IDs or files that do not exist in the current view of the application. This can occur, for example, if an identical leaf is replaced twice, or if a deleted leaf is replaced. During a normal import, Ennov InSight fails when it finds these instances. However, if the Import Orphan Leaf Elements checkbox is selected, Ennov InSight ignores orphan leaf instances and creates new leaf elements instead.

◦ Automatically, each imported leaf element is assigned with the **Published** leaf status, or any other leaf status that has the **Internal System Status** set to "PUBLISHED".

6. Click **Next**. The *Summary* page indicates the import has been scheduled.
7. Click **Finish**. For performance reasons, the status of the import is logged to the **server.log** file on the Application server (rather than to the job requests).

Chapter 8. Associate or Disassociate a Product to an Application

A product can be associated or disassociated from an application.

Applications can be created without products. Products can be associated later if required.

When associating or disassociating a product, the following rules apply:

- You must have appropriate security permissions to associate products from the **Products** tab of an application.
- From **Application Country Rights**, select the product families for the products you want to add to an application. **Countries** must be set to **All** or individual countries must be selected. The **Access Level** must be at least **Read**.

Note: You can search for any Product, regardless of the Product Family, except for products with the status of

Withdrawn or Not Approved.

To associate or disassociate a product:

1. Click a link for the application you want to associate/disassociate a product to. The *Application Attributes* page appears.
2. Click the **Products** tab.
3. Click the **Associate/Disassociate Products** icon. The *Associate/Disassociate Products* page appears.
4. For the **Associated Products** field, under the **Selected** box:
    - To associate products to an application, click **Select**, choose the desired products, and **Save**.
5. To disassociate products from an application, select products in the **Selected** box. To select more than one product, hold down the **CTRL** key and click each product. Then click **Deselect**.
6. Save.
7. Click **OK** to associate/disassociate a product.

Chapter 9. Delete an Application

You can delete an application from Ennov InSight. In the deletion process, all the associated entities with the application are also deleted. **Note:** Subject to your user and security privileges, you might be able to delete the application and its associated entities.

To delete an application:

1. Navigate to the application you want to delete.
2. Click a link for the application.
3. On the *Application Attributes* page, click **Delete**.
4. When you are prompted to confirm the deletion, click **OK**.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	**Steps**
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Chapter 10. Medicinal Product

Medicinal Products are associated to entities to provide data points for the product structure. They are available only for the Registration with Package Set Type.

The Medicinal Product entity is required by the Identification of Medicinal Product (IDMP) data standards to maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data.

You must have appropriate security privileges to create a medicinal product.

You should have at least **Write** privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses and Medicinal Product entity security to modify a medicinal product.

Create a Medicinal Product

Associate medicinal products to applications to provide additional data points for a product.

To create a Medicinal Product:

1. Navigate to the application with the package set registration type for which you want to create a medicinal product.
2. On the *Application Attributes* page, click the **Medicinal Products** tab.
3. Click **Create**.
4. Enter the Medicinal Products attribute values.
5. **Save**.

Medicinal Product Attributes

The following table includes the Medicinal Product attributes .

Attribute	**Description**
Application Code	The code of the associated application.
Application Name	The name of the associated application.
Authorised Pharmaceutical Form	The pharmaceutical form of the product that is authorised by the agencies.
Full Indication Text	The medical condition that a medicine is used for. This can include the treatment, prevention and diagnosis of a disease.
Full Indication Language	Language used for authorised full therapeutic indication(s).
Genetically Modified Organisms	Indicates if the genetics of an organism is modified using genetic engineering techniques.

License Code	The license code of the application.
License Root Number	Root Marketing Authorisation Number.
MAH/Organisation	The organization that holds the marketing authorization granted by the European Medicines Agency (EMA)
Medicinal Product Comments	Comments for the medicinal product. Any comments entered will have the stamp of the date/time/user id of the person entering the comments.
Medicinal Product Description	Description for the medicinal product.
Medicinal Product Keywords	The medicinal product keywords for searching.
Medicinal Product Name	Name of the medicinal product used in Ennov InSight .
Package Sets	Package Sets assigned to Registrations for the selected Product.
Pediatric Use Indicator	Indicates whether a medicinal product is authorised and explicitly intended for pediatric use.
Pharmaceutical Products	Displays the administrable pharmaceutical products related to the selected product.
Product	Name of the product in the Registration – Package Set.
Registrations	The Registration of associated Country and selected Product shown in concatenation License Code + MAH Name + License Status.

Modify a Medicinal Product

Modify a previously created medicinal product to include the necessary values.

To modify a medicinal product:

1. Click a link for the medicinal product you want to modify.
2. On the *Medicinal Product Attributes* page, click **Modify**.
3. Make necessary changes to the medicinal product attributes.
4. **Save**.

Delete a Medicinal Product

Delete a medicinal product that is not required for an entity.

To delete a medicinal product:

1. On the **Medicinal Products** tab, click the link to the medicinal product you want to delete.
2. **Delete**.
3. On the warning message, click **OK**.
4. On the message confirming that the data has been deleted, click **OK**.

Chapter 11. Medicinal Product Action

Medicinal Products Names are associated to a medicinal product to provide data points for the product structure.

The Medicinal Product Name is required by the Identification of Medicinal Product (IDMP) data standards to maintain a standardized and structured method of collecting, reporting, coding, and evaluating authorized medicinal product data.

You can create multiple medicinal product names for a medicinal product.

The **Medicinal Product Name** has specific conditions:

- You can create or modify a country for a medicinal product name for applications with Centralized Procedure (CP) only. By default, the value is populated in *Medicinal Product Name* **Country** with the countries associated to a Registration.
- For the applications with non-centralized procedure, you cannot create or modify a country for a Medicinal Product Name. The **Country** field is hidden on the *Medicinal Product Name* create/view and modify pages.

Create a Medicinal Product Name

Associate medicinal product names to medicinal products to provide additional data points.

To associate a Medicinal Product Name:

1. Navigate to the medicinal product for which you want to create a medicinal product name.
2. On the *Medicinal Product Attributes* page, click the **Medicinal Products Names** tab.
3. Click **Create**.
4. Enter the Medicinal Products Name attribute values.
5. **Save**.

Medicinal Product Name Attributes

The following table lists the attributes used for a Medicinal Product Name .

Attribute	**Description**
Application Code	The code of the associated application.
Application Name	The name of the associated application.
Container or Pack Part	The container or pack details. This information is taken from medicinal product name.

Country	The associated country. The selection list of Countries is associated to a Registration. A country can be created or modified for Medicinal Product Name for applications with Centralized Procedure (CP) only. The European Union is included for applications with Centralized Procedure (CP). This field is hidden on the *Medicinal Product Name Attributes* page for applications with non- centralized procedure.
Date of First Approval	The date on which the approval was provided to the medicinal product name to market. This field is available only for the applications with Centralized Procedure (CP), and for Iceland, Liechtenstein, and Norway countries. This field is hidden on the *Medicinal Product Name Attributes* page for applications with non- centralized procedure.
Delimiter Part	A delimiter separates one composite in a segment from another or separates one sub-composite from another.
Device Part	A device part number is used to identify specifics of a medicinal device such as design, material, etc. This information is taken from medicinal product name.
Flavour Part	A flavour part number is used to identify specifics of flavoring agents of a medicinal product. This information is taken from medicinal product name.

Attribute	**Description**
Formulation Part	A formulation part is used to identify specifics of the drug formulation of a medicinal product. This information is taken from medicinal product name.
Full Name	The full name of a medicinal product.
Full Indication Text	The full indication text of a medicinal product name.

Intended Use Part	An intended use part is used to identify the conditions or reasons for using the medicinal product. This information is taken from medicinal product name.
Invented Name Part	An invented name part is used to identify the trade name of a medicinal product.
Language	Language of the Member State where the product is placed on the market. Language is filtered based on the selected country mapped in Data Administration. If no languages are mapped, this field will be empty.
Medicinal Product License Code	The license code of a medicinal product.
Medicinal Product Name	The name of a medicinal product.
Medicinal Product Name Comments	Text field for medicinal product name comments. Any comments entered will have the stamp of the date/time/user id of the person entering the comments
Medicinal Product	Text field for including additional information about a medicinal product name.

Attribute	Description
Name Description	
Medicinal Product Name Keywords	Text field for including the medicinal product name keywords for searching.
Pharma ceutical Dosage Form Part	A pharmaceutical dosage form part is used to identify the form of a drug product that is used for marketing. This information is taken from the medicinal product name.
Scientific Name Part	A scientific name part identifies the chemical name of a drug that describes the atomic or molecular structure. This information is taken from the medicinal product name
Strength Part	A strength part is used to identify the strength of a medicinal product. This information is taken from the medicinal product name.
Target Population Use Part	A target population use part is used to identify the group of people that benefit from a particular experimental drug. This information is taken from the medicinal product name.
Trademark or Company Name Part	A trademark or company name part is used to identify the trademark or company name that manufactures the medicinal product. This information is taken from medicinal product name.
Time/ Period Part	A time/period part is used to identify the shelf life of a medicinal product. This information is taken from the medicinal product name.

Modify a Medicinal Product Name

Modify the attributes of a medicinal product name to include the necessary values. To

modify a medicinal product name:

1. Click a link for the Medicinal Product Name you want to modify.
2. On the *Medicinal Product Name Attributes* page, click **Modify**.
3. Make necessary changes to the medicinal product name attributes.
4. **Save**.

Delete a Medicinal Product Name

Delete a medicinal product name that is not required for an entity.

To delete a medicinal product name:

1. On the **Medicinal Products Names** tab, click the link to the Medicinal Product Name you want to delete.
2. **Delete**.
3. On the warning message, click **OK**.
4. On the message confirming the medicinal product name has been deleted, click **OK**.

Chapter 12. Product Cross-References

The Product Cross-References are required to display the additional information for the same product.

The *Product Cross-References* tab appears under *Medicinal Product Atrributes*. You can create, modify or delete the Product Cross-References values.

Product Cross-Reference Attributes

The following table includes the Product Cross-Reference attributes.

Attribute	**Description**
Application Code	The code of the associated application.
Application Name	The name of the associated application.
License Code	License code to which the combination of registration and package set is associated.
Medicinal Product Name	The name of the medicinal product.
Product Cross-Reference Type	The type of product cross-reference. The values for this attribute are assigned under *Data Administration* in **Product Maintenance** > **Product Cross-Reference Type Values**.
PMS ID	The Product Management Service Identifier for the SPOR master data in pharmaceutical regulato- ry processes.

PMSID Attributes

The identifier for the PMS that is used to identify a medicinal product based on pharmaceutical regulations.

The PMSIDs tab appears under *Medicinal Product Atrributes.* You can create, modify or delete the PMSIDs values.

Use the PMSID attributes in the following table.

Attribute	**Description**
Application Code	The code of the associated application.

Application Name	The name of the associated application.
Medicinal Product Name	Name of the medicinal product used in Ennov InSight .
PMSID	The identifier for the Product Management Service (PMS).
Country	This field with the values below is available if the application procedure type is CP. • European Union • Iceland • Liechtenstein • Norway
Date of First Approval	The date when the Marketing Authorisation (MA) procedure is first approved. The date when the first authorisation (either from an initial marketing authorisation application regulatory procedure or line extension application regulatory procedure) was granted by the competent authority.
Procedure Start Date	The date when procedure starts.
Procedure	The date when procedure ends.
Attribute	**Description**
End Date	

MPID Attributes

Medicinal Product Identifier (MPID) is required for describing the data elements and their structural relationships necessary for the unique identification of regulated medicinal products.

The MPIDs tab appears under *Medicinal Product Atrributes*. You can create, modify or delete the MPIDs values.

Use the MPID attributes in the following table.

Attribute	**Description**
Application Code	The code for the application with which the medicinal product is associated.
Application Name	The name of the application with which the medicinal product is associated.
Country	This field with the values below is available if the application procedure type is CP. • European Union • Iceland • Liechtenstein • Norway
Medicinal Product Name	The name of the medicinal product.
MPID	MPID defines and describes data elements and their structural relationships.
Version	Indicates the version of the MPID. This value is set up in the database.
Version Date	Indicates the date the MPID is versioned. This value is set up in the database.

Associate a Pharmaceutical Product to a Medicinal Product

Associate pharmaceutical products to medicinal products to provide additional data points.

To associate a pharmaceutical product:

1. On the *Medicinal Product Attributes*, click the **Pharmaceutical Products** tab.
2. Click **Associate/Dissassociate Pharmaceutical Product**.
3. Under **Selected Pharmaceutical Products**, click **Select**.
4. Select a pharmaceutical product and **Save**.
5. **Save**.

Disassociate a Pharmaceutical Product from a Medicinal Product

Disassociate the pharmaceutical products that are not required for medicinal products.

To disassociate a pharmaceutical product:

1. On the *Medicinal Product Attributes* page, click the **Pharmaceutical Products** tab.
2. Click **Associate/Dissassociate Pharmaceutical Product**.
3. Under **Selected Pharmaceutical Products,** select the pharmaceutical products. To select more than one product, hold down the **CTRL** key and click each pharmaceutical product.
4. Click **Deselect**.
5. **Save**.

Chapter 13. Medicinal Product Action

Medicinal Product Action entity can be associated to the application with the package set registration type to provide data points for the product structure.

You need at least **Write** permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses and Medicinal Product Action entity security to modify a medicinal product action. This entity is available only for the application with the **Package Set Registration** type. You can also edit Medicinal Product Actions via Data Exchange and API. You can associate the **Attached Document** entity to the **Medicinal Product Action**.

The **Event** field is displayed on the *Medicinal Product Action Attributes* page only when the following conditions are met:

- CP Applications:

◦ Event is either Open or Closed and the status is Approved.

◦ Event Closed Date should not be greater than 31 days.

◦ Event Country = Registration Country.

- Non-CP Applications:

◦ Event is Closed and the status is Approved (Open Events are not displayed).

◦ Event Closed Date should not be greater than 31 days.

◦ Event Country = Registration Country.

Create a Medicinal Product Action

Associate a medicinal product action to entities to provide additional data points for a product.

To create a medicinal product action:

1. Create an application using the **Package Set Registration** type and create a registration for it.
2. On the *Application Attributes* page, select **Medicinal Product Action**.
3. Click the **Create Medicinal Product Action** icon.
4. On the *Create Medicinal Product Action* page, enter values for the attributes.
5. **Save**.

Medicinal Product Action Attributes

The following table includes the Medicinal Product Action attributes.

Attribute	Description
Action Name	Name of the action.
Application Code	The code of the associated application.
Application Name	The name of the associated application.
Content of Change	The content of change provided for the IDMP attachment. Data Administration values assigned from **Registration Maintenance** > **Content of Change Values**.
Event	All the events from the related sequence.
Event EU Grouping/Work-sharing	Event EU Grouping/Worksharing from the related events.
Event Variation Number	Variation numbers from related events.
FHIR Protocol Type	Fast Healthcare Interoperability Resources Protocol Type. You can select **FHIR XML** for CP applications or **FHIR API** for other application types.
License Code	License code to which the combination of registration and package set is associated.
MAH/Organisation	The organization that holds the marketing authorization granted by the European Medicines Agency (EMA).
Medicinal Product Action Comments	Comments for the medicinal product action. Any comments entered will have the stamp of the date/time/user id of the person entering the comments.
Medicinal Product Action Description	Description for the medicinal product action.
Attribute	**Description**
Medicinal Product Action Keywords	Keywords for searching medicinal product action.
Medicinal Product	All the medicinal products used for the parent registration.

Provenance Reason	The reason of provenance to provide additional clarity on requirements for Postmarketing surveillance (PMS) submissions. Data Administration values assigned from **Registration Maintenance** > **Provenance Reason Values**.
Regulatory Application End Date	The end date for the regulatory application. This value is taken from the Event Status Date.
Regulatory Application Identifi er/Number	Variation Number or EU Grouping/Worksharing from the selected event.
Regulatory Application Submission Type	Default value with short name matching sequence filing type eCTD code. Data Administration values with Application Submission Type values assigned from **Other** > **Application Submission Types Values**.
Sequence	All the sequences from the application.
Status	Indicates the status.
Status Date	Indicates the date the status is changed.

Modify a Medicinal Product Action

Modify the attributes of a medicinal product action to include the necessary values.

To modify the medicinal product action:

1. Go to **Medicinal Product Action** tab, select the medicinal product action you want to modify.
2. On the *Medicinal Product Action Attributes* page, click **Modify**.
3. Modify the attributes as needed. **Save.**The *Medicinal Product Action* view displays the updates.

Delete a Medicinal Product Action

Delete a medicinal product action that is not required for an entity. To

delete the medicnal product action:

1. On the **Medicinal Product Action** tab, select the Medicinal Product Action entity you want to delete.
2. On the *Medicinal Product Action Attributes* page, click **Delete**.
3. When you are prompted to confirm the deletion, click **OK**.
4. On the message confirming that the medicinal product action has been deleted, click **OK**.

Attached Documents

Attached Document entity can be associated to Medicinal Product Action entity to provide data points for the product structure.

This entity is available only for the application with package set registration type. You can create Attached Documents entity for all the application procedure types.

Create Attached Documents

Attached documents are associated to medicinal product action entities to provide additional data points for a product.

To create an attached document:

1. Create an application with the **Package Set Registration** type.
2. On the *Medicinal Product Action Attributes* page, select **Attached Documents** tab.
3. Click the **Create Attached Documents** icon.
4. On the *Create Attached Document* page, enter values for the attributes.
5. **Save**.

Attached Document Attributes

The following table includes the Attached Document attributes.

Attribute	**Description**
Application Code	The code of the associated application.
Application Name	The name of the associated application.
Attached Document Name	The name of the attached document.
Attached Document Identifier (Master)	The ID assigned to the document once it is uploaded to the Property Management System (PMS), which refers to the medicinal product This identifier is specific to this version of the document. This unique identifier is used elsewhere to identify this version of the document.

Attribute	Description
Attached Document Status	The status of the document attached. Examples: Planned, Current.
Attached Document URL	The Document Management System (DMS) location link.
Alternate Identifier (EV Code)	The ID assigned to the document by another source system. The EV Code of the attachment referring to the authorised medicinal product may be specified if applicable.
Content Link	Link to document in DMS.
Attached Document Type	The type of the content. Data Administration values assigned from **Other** > **Attached Document Content Type**.
Attached Document Effective Date	The attached document effective date.
Attached Document Country	The name of the country for which the attached document is created.
Full Indication Text	The medical condition that a medicine is used for. This can include the treatment, prevention and diagnosis of a disease.
Attached Document Language	The language used for the information related to the regulatory submission. Data Administration values assigned from **Other** > **Language Values**.

License Code	The license code of the application.
Medicinal Product List	Medicinal Product Name to which Attached Document is associated.
Sequence	Sequence Code to which Medicinal Product Action is associated
Sequence Assembly Section	The section mapped to the type for the sequence.
Title	The name of title.

Modify Attached Documents

Modify the attributes of the attached documents to include the necessary values.

To modify the attached documents:

1. Go to **Attached Documents** tab, select the Attached Document you want to modify.
2. On the *Attached Document Attributes* page, click **Modify**.
3. Modify the attributes and click **Save.**The updated values are shown on the *Attached Documents* page.

Delete Attached Documents

You can delete an Attached Document entity that is no longer required.

To delete an attached document:

1. On the **Attached Documents** tab, select the Attached Document entity you want to delete.
2. On the *Attached Document Attributes* page, click **Delete**.
3. On the message that appears, click **OK**.
4. On the message that the data has been deleted, click **OK**.

IDMP

Use the IDMP feature to uniquely identify and describe the medicinal products for exchange of product information between global regulators, manufacturers, suppliers and distributors.

Identification of Medicinal Product (IDMP) is a standard used to maintain a standardized and structured method for collecting, reporting, coding, and evaluating authorized medicinal product data. The information on the IDMP tab is read-only. The IDMP tab appears under Application Attributes when the Medicinal Product is created.

You should have at least **Read** privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Medicinal Product Entity Security to view the *IDMP* tab.

The IDMP tab includes the following:

Column Name	Column Type	Description
License Root Number	Read-only text (populated automatically)	The root number of license.
Medicinal Product Action	Hyperlink	The actions taken for the medicinal product.
Medicinal Product Name	Hyperlink	The name of the medicinal product.
Column Name	**Column Type**	**Description**
MPID	Read-only text (populated automatically)	Indicates the Medicinal Product Identifier (MPID).
Product	Hyperlink	The name of the product.
PMSID	Hyperlink	The name of the Product Management Service Identifier (PMSID).
Registration Country	Read-only text (populated automatically)	Indicates the name of registration country.
Related MAH(s)	Read-only text (populated automatically)	Indicates the name of marketing authorisation holder.
Related Registration(s)	Read-only text (populated automatically)	Indicates the names of related registrations.
Related Sequence	Read-only text (populated automatically)	Indicates the sequence number,

Sender-defined Keywords

Keywords defined by the submitter using the keyword definitions in the eCTD v4.0 message.

Sender-defined keywords (SDK) are defined for each application but to enable the use of grouped submissions, manage the keyword definitions across applications. The Code and Type of the **Sender-defined Keyword** are read-only. The Name of the **Sender-defined Keyword** can be updated by user.

The user can create new, associate existing SDK from Data Administration with the current Application, edit name for existing SDK, delete existing (if it has not been associated with any field).

The Sender-defined Keywords can be associated with the specific assembly folders. See:

Publishing eCTD 4.0 > Folder Elements > Associate Sender-defined Keywords to an Assembly Folder.

You should have at least **Read** privileges for Electronic Lifecycle Publishing (ELP) and Submission Planning and Tracking (SPT) to view the *Sender-defined Keywords* tab.

The Sender-defined Keywords tab appears under Application Attributes if there is **at least one** Sequence with **Sequence Standard Type** set to the **eCTD 4.0** in the Application.

The Sender-defined Keywords tab includes the following columns:

Column Name	Column Type	Description
Code	Hyperlink	Sender-defined keyword code defined and referenced in eCTD 4.0 published output. Editable on Create screen and read-only on Edit screen. Unique per Application.
Display Name	Text	Sender-defined keyword name to be mapped to the Code value in eCTD 4.0 published output.
Keyword Type	Text	Sender-defined keyword type to be mapped to the corresponding field among the Context of Use code for the folder in eCTD 4.0 assembly.

Comparators

Comparators are used in clinical trials to compare the success of a medicine under study to another medicine or placebo. In Ennov InSight , comparators are treated as separate entities that are not part of any existing Ennov InSight hierarchy. As separate entities, comparators can be created and managed from the **Comparators** tab, accessible from the *Home* page.

Comparators can only be applied to Clinical Trial Authorization (CTA) and Investigational New Drug (IND) applications. For these applications, comparators are further defined by product type. You can designate the comparator entity as a placebo, Investigational Medicinal Product (IMP), or a comparator that is an existing product.

Additional comparator product types can be created in Data Administration, if needed.

The following table differentiates the default comparator product types.

Product Type	**Description**
Comparator	A marketed product that contains an active ingredient. A comparator can be a competitor's product or a internal product. In Ennov InSight, an internal product is considered a comparator if it is not included in the product family to which the product under study is associated.
IMP	A medicinal product under investigation that contains an active ingredient. In Ennov InSight , any product associated with the product family to which the product under study is associated is considered an IMP. You do not need to set IMP as the product type. Use the IMP product type to identify a product outside of the product family.
Placebo	A comparator that does not contain an active ingredient.

Note: Be sure to select best comparator for the trail in the early stages of the study to derive the full benefit of tracking the comparator. In Ennov InSight, the comparator cannot be changed later in the study.

When you create a comparator entity, you have the option to assign an active ingredient. Selecting an active ingredient is not required, even if you are creating a product type of comparator or IMP. The available active ingredients listed are those that your data administrator has added to the system.

You also have the option of assigning suppliers to comparators, which lists active manufacturers in Data Administration.

Create a Comparator

You must create a comparator to assign it to an event associated with a CTA or an IND applications in Ennov InSight.

To create a comparator:

1. From the *Comparators* tabbed page, click **New** > **Comparator**.The *Create Comparator* page appears.
2. Do the following:
    a. Enter a name.
    b. Select a product type.
3. Enter or select other comparator attributes, as needed.
4. Do one of the following:

◦ **Save**. The *Comparator Attributes* page appears.

◦ Click **Create Another Comparator** and repeat steps 1 through 4.

Upon completion, the comparator is listed on the **Comparators** tab under *Home* page.

Comparator Attributes

The attribute descriptions will help you to enter appropriate comparator attribute values while creating a comparator.

The table lists all the Comparator attributes that appear in the *Create Comparator* page while you create a comparator.

Attribute	**Description**
Active Ingredients	The active ingredient used to compare to the active ingredient under clinical trial
Comparator Add Comment	Comments you want to share with others in a discussion thread that are identified with your user ID and stamped with the date and time you enter the information
Comparator Comments	The discussion thread that includes all comments entered by users, including the date and time the comments were entered and the user ID of the person who entered them. Comments are displayed when you modify the comparator.
Comparator Description	Text that describes the comparator for easier identification by users
Attribute	**Description**
Comparator Keywords	Words that can be used to search for the comparator in the system
Name	The name given to identify the comparator in the system
Package Set Name	The name used to identify the package set for the comparator in the system
Product Description	Text that describes the product for easier identification by users

Product Type	The type of comparator, which includes **comparator**, **IMP**, or **placebo**. A placebo is considered a comparator that does not have an active ingredient
Suppliers	The name of the company that provides/sells the ingredient

Modify a Comparator

You must modify a comparator to make changes in the selection of comparator attributes and its values.

To modify a comparator:

1. Select the **Comparators** tab on the *Home* page.
2. Select the link for the comparator that you want to edit. The *Comparator Attributes* page opens.
3. Click **Edit**. The *Modify Comparator* page opens.
4. Change the attributes as needed.
5. **Save**.

Delete a Comparator

If it is no longer required in the clinical trials-medicine success study, you can delete a comparator from Ennov InSight .

Consider the following conditions before deleting a comparator:

- If a comparator (a placebo, IMP, or comparator) is associated with an event, you must disassociate it.
- You cannot delete a comparator if it is associated with a closed event.

To delete a comparator:

1. Click the **Comparators** tab on the *Home* page.
2. Click the comparator hyperlink.
3. Click **Delete**. A confirmation message appears.
4. Click **OK**. Another confirmation message appears.
5. Click **OK**. Upon completion, the comparator is removed and is no longer available.

Associate or Disassociate a Comparator

Comparators are associated to Clinical Trial Authorization (CTA) and Investigational New Drug (IND) applications for tracking the clinical trail data which are further defined by product type.

To associate or disassociate a comparator:

1. Navigate to an event associated with a CTA or and IND application.
2. Click the **Comparators** tab.

3. On the **Comparators** tab, click **Associate**.The *Associate/Disassociate Comparator to/from Event* page appears.
4. Use the multi-select list to add or remove comparators.
5. **Save**.The comparators selected for association are listed on the **Comparators** tab of the *Event Attributes* page.

Orphan Designation

A status used for Marketing authorisation applications for designated orphan medicines.

The Orphan Designation status in Ennov InSight allows you to indicate if a product authorised in a jurisdiction is qualified to be treated as an orphan drug.

The following guidelines apply when using Orphan Designation in Ennov InSight :

- The Application type must be **Marketing Authorization Application** (MAA).
- The Application country must belong to EMA.
- The **Orphan Drug** flag on the *Application Attributes* page is set to **Yes**.

Create an Orphan Designation

Create an orphan designation to assign a status for Marketing authorisation applications and submit if for designated orphan medicines approval.

To create an orphan designation:

1. Click a link for the application for which you want to create an orphan designation.
2. On the *Application Attributes* page, click the **Orphan Designations** tab.
3. Click **Create**.
4. Select and enter the orphan designation attributes.
5. **Save**.

Orphan Designation Attributes

Use the description for the orphan designation attributes in the following table.

Attribute	Description
Application Code	Agency-identified application number (or identifier). Can be the internal code until it is provided by the agency.
Application Name	The name of the application.

Community Registered Orphan Indication	The orphan designation indication that is registered in the community register.
Indications	The list of indications based on the product families selected. **Note:** When the Indications are selected in the *Orphan Designation* page, they are moved to the **Assigned Indications** section in Product Families. Their selection cannot be cancelled from a Product Family until cleared from an Orphan Designation.
Market Exclusivity Start Date	Defines the validity start date of the market exclusivity of the orphan medicinal product. Date of validity of the market exclusivity of the orphan medicinal product can be found in the individual product entry at the European Commission Register of medicinal product.
Number	Orphan designation number. Must be a unique value within an application.
Orphan Designation Comments	The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.
Orphan Designation Description	The description of the Orphan Designation.
Orphan Designation Keywords	Keywords you can use to search for the Orphan Designation.
Orphan Status	Indicates if the product authorised in a jurisdiction is qualified as an orphan drug.
Orphan Status Date	The date the orphan designation status of the medicinal product is assigned or modified.

Modify an Orphan Designation

Modify a previously created orphan designation to include or update the necessary values. To

modify an orphan designation:

1. Click a link to the orphan designation number you want to modify.
2. On the *Orphan Designation Attributes* page, click **Edit**.
3. Change and enter orphan designation attributes.
4. **Save**.

Delete an Orphan Designation

Delete an orphan designation that is not required for an entity.

To delete an orphan designation:

1. Navigate to the orphan designation you want to delete.
2. Click a link for the orphan designation number you want to delete.
3. On the *Orphan Designation Attributes* page, click **Delete**.
4. Click **OK**.

Chapter 14. Ennov InSight XEVMPD

Ennov InSight XEVMPD is designed to support a standardized and structured method of collecting, reporting, coding, and evaluating authorised medicinal product data. You can then use this data to submit medicinal product information to the European Medicines Agency (EMA).

The Ennov InSight XEVMPD module enables you to capture, maintain, and submit data about pharmaceutical products to comply with the Extended EudraVigilance Medicinal Product Database (XEVMPD) directive.

Your organization can use Ennov InSight XEVMPD to gather the data needed for submission in an XML file, which is referred to as the Extended EudraVigilance Product Report Message (XEVPRM). You can then create a **.zip** file that includes the XML content and electronic files of required attachments referenced in the XML file to transmit to the EudraVigilance system.

With the XEVMPD license, you can also access the **XEVMPD Submissions - QC Verification** and **XEVMPD Submissions and Acknowledgements** query reports. For more information, see *Submission Planning and Tracking Queries* in the Ennov InSight Registrations online help.

Chapter 15. XEVMPD Wizards

In Ennov InSight , XEVMPD Wizards help you to create or update XEVMPD data.

Wizards presents you with a sequence of dialog boxes that lead you through a series of well-defined steps.

There are two wizards that enable you to perform file creation and update functions:

— *XEVMPD Submission* Wizard

— *XEVMPD Acknowledgement* Wizard

XEVMPD Submission Wizard

The *XEVMPD Submission* Wizard enables you to collect data and files from the database to include in XEVMPD submissions, and to generate **.zip** files that include the collected data and attachment files to submit to the European Medicines Agency (EMA).

The XEVMPD Submission wizard can be invoked from the Ennov InSight *Home* Page menu bar or from the *Create a New - XEVMPD Submission* section in the *I Am Looking To* pane. The wizard is available only for users with

XEVMPD License, RPT (Registration Planning and Tracking), and Product Detail Management (PDM) with at least Write permissions, Data Administration rights set to Yes or NO (both options are acceptable since Ennov InSight 7.3.1 release), and at least Write permission for the XEVMPD Wizards.

The XEVMPD Submission wizard functionality of creating XEVMPD XML file can also be done via workflows. The Ennov Client Enablement team can assist in developing the necessary workflow configuration files to meet your process needs. Please contact your Business Development Representative for more information.

Create an XEVPRM ZIP File

You can use the *XEVMPD Submission* wizard to create the XEVPRM **.zip** file for submission to the EMA.

The *XEVMPD Submission* wizard is available only for users with xEVMPD license, and Write permissions for RPT

(Registration Planning and Tracking), Product Detail Management (PDM), and Data Administration rights set to **Yes** or **NO** (both options are acceptable since Ennov InSight 7.3.1 release) and Write permission for *XEVMPD Wizards*.You can access the *XEVMPD Submission* wizard from the **Wizards** menu or from **I Am Looking To** > **Create New** > **XEVMPD Submission**.To create your XEVPRM **.zip** file:

1. Select the **Wizards** > **XEVMPD Submission**.
2. On the *Select Sender/Receiver Information* page:
    a. Select a **Sender** (menu with active values from **Data Administration** > **Message Sender Values**).
    b. Select a **Receiver** (menu with two predefined by system values - EVTEST and EVHUMAN).
3. Click **Next**.
4. On the *Authrorized Product Selection* page, select or enter the search criteria and click **Next**. Click **Next** to show all the authorized products without the search criteria selection.

5. Make a selection on the *Authrorized Product Search Results* page.
6. Click **Next**.
7. On the *Authrorized Product Attachment Results* page, see the list of attachments if exist.
8. Click **Next**.
9. On the *Create XEVPRM Confirmation* page, select the location where your XML file is saved.

The system can save your file to the predefined location. If the **Location for XEVMPD Submission** field is set correctly during the server setup, then after selecting **Next** on the *Create XEVPRM Confirmation* page, the generated Submission XML file will be saved to that location. The predefined location is selected by default on the *Create XEVPRM Confirmation* page. The information about the predefined location must be included in **insight.var** file. If you need to save your file to a folder other than the default, you can change the location manually.

This option is applicable to the following DMS repositories:

◦ File System

◦ Documentum

Use **Browse** to chose the location. Use **Clear** to clear the location.

Note: If your predefined location is other than File System and you are logging on to the DMS, you will be required to enter your DMS credentials.

1. Click **Next**.
2. On the *Create XEVPRM Summary* page:
    a. A message to confirm the generation of XEVPRM **.zip** file is displayed.
    b. Click the hyperlink to save the XEVPRM **.zip** file to your desktop.
    c. After the XEVPRM **.zip** file is saved, click **Finish**.

You can now submit the XEVPRM **.zip** file to EMA.

Search Criteria Selection - Authorized Product Selection

Select the criteria for the search for future authorised product data generation.

For the authorized product, the **Country** and **Procedure Type** fields display only the European Union (EU) and European Economic Area (EEA) related values. When selecting **Product Family** values or selecting **Product Family** values in combination with **Product** values, only the relevant values of other entities are filtered and displayed in their respective fields.

Field	**Value**
Application Name	The name of the application.

Country	The European Union (EU) and European Economic Area (EEA) countries.
Date Submitted to EMA	Filter based on the date submitted to EMA.

Field	**Value**
Display Columns	Columns to select to display in the result.
EV Code	The EV code of the authorised product.
Family Name	The name of the product family.
Full Product Name	The full name of the product.
Last Updated Date	Filter based on the last updated date.
License Code	The code assigned by the regulatory agency.
MAH/Organization	The company to which a license is given to market the product.
Procedure Type	Procedure types - EU specific.
Product Name	The name of the product. **Note:** The Product Name field shows only the products that are associated with the corresponding Full Product Presentation through the Package Set. If no products are associated, the Product Name column will be blank.
Show Only New Authorised Products	Filter to display only the new authorised products or all authorised products.
Sort Order	The order to display in the result.

Search Results

The Search Results include details about the section properties you selected:

Section Property	Details
Organisation	Operation type, organisation type, address, city, region, post code, country, SME status, SME number, last updated date, date submitted to EMA, local code, EV code, and XEVMPD comments
Source	Operation type, source name, last updated date, date submitted to EMA, local code, EV code, and XEVMPD comments
Section Property	**Details**
Master File Location	Operation type, master file location company, department, building, street, city, state, post code, country, last updated date, date submitted to EMA, local code, EV code, and XEVMPD comments
ATC	Operation type, ATC code, ATC code description, term type, acknowledged, last updated date, date submitted to EMA, version date, and XEVMPD comments
Pharmaceutical Form	Operation type, Pharmaceutical name, term type, last updated date, date submitted to EMA, local code, EV code, previous EV code, version date, and XEVMPD comments
Route of Administration	Operation type, route of administration name, term type, last updated date, date submitted to EMA, local code, EV code, previous EV code, version date, and XEVMPD comments
Authorised Product	Operation Type, Family Name, Product Name, Application Name, Procedure Type, License Code, Country, Full Product Name, EV Code, Authorisation Status, Authorisation/Renewal Date, MAH/ Organisation, Information Date, Withdrawn/Invalidated Date, Package Description. Last Updated Date, Date Submitted to EMA.

Names of sections, License Code and Full Product Name, are hyperlinks. Clicking the hyperlinks displays section data in a pop-up window. You can modify the section data in this window.

XEVMPD Submission Wizard Data Collection Features

The *XEVMPD Submission Wizard* enables you to collect data and files from the database to include in XEVMPD submissions, and to generate **.zip** files that include the collected data and attachment files to submit to the European Medicines Agency (EMA).

The following sets of features are applicable for the *XEVMPD Submission Wizard* data collection.

Full Product PresentationImportant: If any Package Set is associated to the Registration, but is not associated to the Full Product Presentation under the Registration, then the Active Ingredient, Substance, Indication/Intended Use

(non-Veterinary), or Species Indication (Veterinary) Details of the parent Product Details Set are not included to the XEVMPD submission. The following is applicable for the Full Product Presentation entity:

- Active Ingredient information or strain (for a Flu Vaccine) is displayed from the selected entity. **Reference Active Ingredient** or **Reference Strain** must have an appropriate EV_CODE in Data Administration.
- If the **XEVMPD Marketing Authorisation Number** and **XEVMPD MAH/Organisation** in the Full Product Presentation entity are populated with values, then these values are included to the appropriate section in the XML file instead of the Package Set Registration values. This feature is applicable for the Invalidate MA operation type for Not Valid Authorisation Status only.
- For the Authorised Product XEVMPD section, when an Application has one of the EU CP (Centralised Procedure) types (e.g. EU CP Bio) selected, you can send the XEVMPD submission specific for EEA Countries, such as Norway, Iceland, or Liechtenstein. To be included to the **.xml** file, Norway, Iceland, or Liechtenstein should be selected in the **EEA Country** field on the Full Product Presentation. Otherwise, the Country from the PSet (Package Set) Registration is added to the XML file.

Product Detail SetImportant: The Active Ingredient, Substance, Indication/Intended Use (non-Veterinary), or Species Indication (Veterinary) PDS Details are included in an XEVMPD submission only if Package Sets from the parent PDS are associated to the Full Product Presentation.The following is applicable for the Product Detail Set entity:

- If you set the **Use as Active Ingredient for XEVMPD** field in the PDS Substance Detail to **Yes**, then the data from Substance Detail is added as an Active Ingredient (regardless of the selected Substance Type) to an appropriate section in the XML file. If you set this field to **No**, then Substance Detail is used as an Excipient or Adjuvant, depending on the selected Substance Type.
- If the **Strength**-related fields in the PDS Active Ingredient are populated with values, then these values are included in the appropriate section in XML file instead of Component Active Ingredient values.
- For the Authorised Product XEVMPD section: if the PDS Indication/Intended Use Detail (non-Veterinary) or

PDS Species Indication Detail (Veterinary) has the same Country assigned as the Country selected for the Authorised Product, then this data is added to the appropriate section in the XML file.

Note: For Insert and Update operation types, at least one indication should exist within an Authorised Product for all supported Product Family types. The indication data is added to the appropriate section in the XML file if: it is associated on the Product Family level, it is created in the Product Detail Set with an Approved status, and the indication country is a value from either Registration entity (Country field) or Full Product Presentation entity (EEA Country filed).The prior approved PDS Detail from the previous Event is taken into the XEVMPD Submission if the current PDS Detail has one of the following statuses:

- Pending Modify
- Pending Withdrawal

This rule is applicable to the following PDS Details:

- Indication/Indented Use
- Indication (under Veterinary Product Family)
- Strain
- Reference Strain
- Substance (Excipient, Adjuvant, and Substance entities used as Active Ingredient)

The PDS Details with status set to Withdrawn are not included into XEVMPD Submission.

For Package Set Detail with the Withdrawn status, the following rules apply:

- If there is a FPP with EMA Authorisation Status Code for 'Not Valid' value, the PSet is included into XEVMPD logic.
- If there is a FPP with EMA Authorisation Status Code for 'Valid' value, then PSet is not included into XEVMPD logic.

For the Indication/Intended Use (non-Veterinary Product Detail Sets), Indication (Veterinary Product Detail Sets),

Active Ingredient, and Substance PDS Details when there are several identical values under different Product Detail Sets, but under the same Full Product Presentation, they are represented with a common tag in the XEVMPD XML file as one value, instead of multiple values.

ApplicationsThe following is applicable for applications of CP (Centralised Procedure) Type:

- For the **Authorised Product XEVMPD** section, when the Application is of CP Type, the CP number is taken from **Application Code** field when the **Procedure Identifier** field contains no data. When the **Procedure Identifier** field is populated with data, the CP number is taken from **Procedure Identifier**.

The following is applicable for applications of **Mutual Recognition Procedure (MRP)** or **Decentralised Procedure (DCP)** Types:

- For the **Authorised Product XEVMPD** section, when the Application is of MRP or DCP Type, the MRP or DCP number is taken from **Application Code** field when the **Procedure Identifier** field contains no data, with the addition of the **Speciality Number** field information from the *Product Detail Set Attributes* page. For example:

[Application Code][Speciality Number1]. When the **Procedure Identifier** field is populated with data, the MRP or DCP number is taken from **Procedure Identifier** field, with the addition of the **Speciality Number** field information from the *Product Detail Set Attributes* page. For example: [Procedure Identifier][Speciality Number1] .

If there is more than one PDS with the **Speciality Number** field populated with data, the formula for concatenation is: [Procedure Identifier/Application Code][Speciality Number1]'-'DISTINCT [Speciality Number2]. Where DISTINCT means the value different from the [Speciality Number1]. If both Speciality Number1 and Speciality Number2 are the same values, than only Speciality Number1 is taken. **Note:** The **Speciality Number** field is also available in PDS for the **EU**

Herbal and **EU Homeopathic** types. However, this field is not connected with the XEVMPD XML file for those Application Types.**Registrations**The **Package Set Registration** > **Legal Basis** value is included in the XEVMPD Submission XML file instead of the **Application** > **Legal Basis** value, when:

- The field is populated with a value for both entities.
- The **Application** > **Legal Basis** field is not populated with a value.

Important: If the Legal Basis field in not populated for an Application or for a Registration, a warning message is displayed.**Product Detail Sets**If configured, a field named **Local Route of Administration** for tracking country Route of Administration on PDS level is presented on the PDS Attributes page. This field is hidden by default and can be enabled via the overrides. The Route of Administration value can be taken into an XEVMPD submission from the PDS level according to the following set of rules:

- If the **Local Route of Administration** value is populated on the *PDS Attributes* page and the Component associated to this PDS is also associated to the Pharmaceutical Product, then this value is taken to the XEVMPD Submission XML file.
- If the **Local Route of Administration** value is not populated on the *PDS Attributes* page, then the Route of Administration value is taken from the Product or Component (if more than one component exists) to the XEVMPD Submission XML file.
- If the **Route of Administration** value is not populated on the PDS, Product, or Component Attribute page, then a warning message stating that Route of Administration is required is displayed in the XEVMPD Submission wizard.
- If the **Route of Administration** value selected in the **Local Route of Administration** field does not have an EV Code assigned in the **Data Administration** > **Product Maintenance** > **Route of Administration Values** > **Route of Administration XEVMPD Information**, then a warning message stating that Route of Administration must be submitted in the XEVPRM message is displayed in the XEVMPD Submission wizard.

Authorised Product Attachments

Every Authorised Product section can have Attachment file data that will be submitted in the final **.zip** file. The

content of the attachment cannot be updated. Each attachment must be uniquely identified within the

Attachments element by the local number or EV code. The language must be specified using the two-letter language code in the published set.

The Result Set of attachments, ready for submission, include:

- Attachment Name
- Attachment Type - Printed Product Information (PPI)
- File name
- File Type
- Attachment Version
- Attachment Language

- 2nd Attachment Language
- Attachment Link
- Local Code
- Version Date
- EV Code

The results are presented in read-only format and are not available for selection.

If there are errors related to attachments, a list of validation errors is displayed and not the attachments Result Set.

The error message includes Attachment Name (hyperlink), Attachment Type, Attachment Version, and an Error Message indicating the reason for failure.

- Substances, Pharmaceutical Forms, and Route of Administrations assigned to the MA should have data for Code Term Type in **Data Administration XEVMPD Information** subtabs.
- **Language Code** and **Procedure Type Code** must be correctly specified.
- Make sure that the Package Set Registration contains the Package Set. If not, you will not be able to view the Active Ingredient, Excipient, Adjuvant, and Indication Intended Use information.

When the **Use Rendition** field is set to **Yes** for the Registration Attachment and the **Rendition Identifier** value is selected, the existed in DMS location .pdf rendition file will be used instead of the source file in the submission creation:

- If the source file has a rendition with the same type as selected in the Rendition Identifier drop-down list, then the rendition .pdf file is used during the submission creation.
- If the source value has a rendition with a different type from the one selected in the **Rendition Identifier** drop-down list, then during the *XEVMPD Submission* wizard execution a warning message informs you that Rendition file has not been found.

Attachment types:

- Registration Attachment for Authorised Product

Operation Types

The medicinal product information provided via the XEVPRM is owned by the Sender Organisation that submitted the information.

The Sendor Organisation can perform the following types of operations by sending an XEVPRM:

Operation	**Description**
Insert	Provide new medicinal product information via an XEVPRM.
Update	Update the content of medicinal product information previously submitted via an XEVPRM.

Nullify	Nullify medicinal product information previously submitted via an XEVPRM.
Invalidate MA	Inform about the withdrawal of an authorised medicinal product from the market via an XEVPRM. The Invalidate MA operation covers a number of scenarios including transfer of an authorised medicinal product to a third party and renewal of the MA by the same MAH.

Not all operations are available for all XEVMPD entity types. The following table presents the available XEVMPD entity types and Operation Types:

XEVMPD Entity Type/Operation Type	**Insert**	**Update**	**Nullify**	**Invalidate MA**
Authorised Product	✓	✓	✓	✓
Development Product	✓	✓	✓	N/A
Approved Substance	N/A	N/A	N/A	N/A
Attachment	✓	N/A	N/A	N/A
Master File Location	✓	✓	✓	N/A
Source	✓	✓	✓	N/A
MAH	✓	✓	✓	N/A
Sponsor	✓	✓	✓	N/A
Development Pharmaceutical Form	✓	✓	✓	N/A
Proposed Pharmaceutical Form	✓	N/A	N/A	N/A
Development Route of Administration	✓	✓	✓	N/A
Proposed Route of Administration	✓	N/A	N/A	N/A
Development ATC Code	✓	✓	✓	N/A
Proposed ATC Code	✓	✓	✓	N/A

XEVMPD Acknowledgement Wizard

The *XEVMPD Acknowledgement* wizard enables you to upload the Acknowledgement XML file, received from the EMA, to Ennov InSight . The file contains EudraVigilance (EV) codes for updating the XEVMPD values.

Note: The file can be uploaded automatically if all the settings required for this process were configured during installation of the application server.

The *XEVMPD Acknowledgement* wizard can be invoked from the Ennov InSight *Home* Page menu bar or from the **Update - XEVMPD Acknowledgement** section in the *I Am Looking To* pane. The wizard is available only for users with XEVMPD License, RPT (Registration Planning and Tracking) and Product Detail Management (PDM) with at least Write permissions, Data Administration rights set to Yes or No (both options are acceptable since Ennov InSight 7.3.1 release), and at least Write permission for the *XEVMPD Wizards*.

Note: For the Registration FPP Attachment, the **Validity Declaration** field is automatically updated once the *XEVMPD*

Acknowledgement wizard passes. If the Registration FPP Attachment is associated to the acknowledged Authorised Product, or the Registration FPP Attachment is created from a Registration Attachment that was previously acknowledged, the value assigned is

Previous Copy was sent (1)

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The *XEVMPD Acknowledgement* wizard enables you to upload XEVPRM files that were exported by an external system, using the **Force XEVPRM Acknowledgement Import** functionality.

Note: When a

Message Sender from the

XEVPRM

file that you are uploading using the **Force XEVPRM Acknowledgement Import** functionality does not exist in the Ennov InSight system, then it is automatically created during the wizard execution. The

Message Sender Name with a prefix

[Inserted] and the

Message Sender ID are added to the *Data Administration* section (*Message Sender Values* under *Other Maintenance*).

For 3rd Acknowledgement type files only, the system automatically checks EV codes that have been entered by the

EMA into the <operationresultdesc> tag of the XML Acknowledgement File and puts the corresponding Entity Name in braces near it in the **OPERATION_RESULT_DESCRIPTION** database column, if the entity with such EV code exists in the system. Otherwise, the EV code is followed by Not Defined in braces. For example:

- Added: Authorised Pharmaceutical Form [PHF00010MIG { Collodion}]
- Added: Authorised Pharmaceutical Form [PHF00001MIG { Not Defined }]

The *XEVMPD Acknowledgement* wizard enables you to automate the inactivation of registration attachments once the corresponding acknowledgment has been received.

Note: Verify that the following value exists in the **insight.var** file: xevmpd.message.import.inactivate.attachment=true

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Acknowledgement File

Use the acknowledgement file to summarize medicinal product entry information required for future processing and authorization.

The Acknowledgement file consists of a message header and an acknowledgement report. The message header displays information that identifies the acknowledgement message.

The acknowledgement presents two sections:

- Message Acknowledgement: Summarizes findings on the message sent to the EMA for processing the medicinal product submitted for authorisation.
- Report Acknowledgement: Summarizes the results of the operation type (such as Insert, Update, Nulify, or Invalidate MA) requested for each medicinal product entry in an XEVPRM. It contains the mapping between the Local Code and the EV Codes.

Validation

The *Search Results Wizard* page displays the results included in the acknowledgement file. The results are described and the proper codes are assigned to them. The codes can be assigned to the message header and to the entities listed in the acknowledgement report.

The codes assigned to the message header:

- transmissionacknowledgmentcode = 01: All reports included in the XEVPRM file were successfully processed.
- transmissionacknowledgmentcode = 02: XEVPRM error. Not all information was successfully loaded in the database. These errors are listed in the Report Acknowledgement of the XEVPRM_Ack file.
- transmissionacknowledgmentcode = 03: Serious errors prevent the data from being loaded into the database.

Errors can occur due to:

- XML structure
- Schema validation
- Non-compliance with the business rules specified by the EMA

When an error occurs, the acknowledgement contains no data, it only contains the error message. The proper EV codes, submission, or acknowledgement entries are not updated in the database.

Upload XEVPRM XML File

After you have received the acknowledgement file from the EMA, upload it to Ennov InSight . The acknowledgement file contains EV codes for updating the XEVMPD values.

The *XEVMPD Acknowledgement* wizard is available only for users with:

- xEVMPD license
- Write permissions for RPT (Registration Planning and Tracking) and *XEVMPD Wizards*.
- Product Details Management (PDM) and Data Administration rights set to **Yes** or No (both options are acceptable since Ennov InSight 7.3.1 release).

To upload an XEVPRM XML File:

1. From the **Wizards** menu or from **I Am Looking To** > **Create New**, open *XEVMPD Acknowledgement* wizard.
2. On the *Import XEVPRM Acknowledgement XML* page, select the output location.
3. Click **Browse** and select the XML file.
4. On the *Verify XEVPRM Acknowledgement XML* page, the wizard verifies the correspondence of the imported XML file and the system, in which it was generated.
5. Click **Next**
6. On the *Force XEVPRM Acknowledgement Import* page, the following messages are displayed:

System Message	Description
No input is required on this page	This message appears if the submission file for the selected acknowledgment file was created using the Ennov InSight system.
XEVPRM was not exported from this system. Would you like to run Force Acknowledgement Import?	This message appears if the submission file for the selected acknowledgment file was created using the external system. The values available for selection in the **Force Import** field are **Yes** and **No**.

   On the *Import XEVPRM Acknowledgement Results* page, the import results appear with file details (entities that are successfully uploaded and errors, if any, occurred) are displayed. If **Yes** was selected, in addition to import results, the **Imported by Force** information appears with the number of imported entities.
7. Save the XML file on your desktop. On the subsequent page, Success or Failure codes are included in the XML file.

XEVMPD Acknowledgement Report Codes

Numbered codes that appear in the Acknowledgement Report can be Success Codes or Failure Codes. Those success and failure codes are described in the following tables.

Only the first error encountered is reported in the Acknowledgement Report.

For all elements and operations except product operations, any failure code results in the entire message being rejected with the 03 transmission acknowledgement code. Failures generated by product operations generate the 02 transmission acknowledgement code. In this case, all operation results will be reported in the acknowledgement.

9. Table 1. Success Codes

Operation Result Code	Text in Acknowledgement
2	The entity was inserted successfully.
3	The entity was nullified successfully.
4	The entity was updated successfully.
29	The entity was withdrawn, or the MA was invalidated successfully.

Table 10. Table 2. Failure Codes

Operation Result Code	Text in Acknowledgement
1	The entity is already presented in the EVMPD. You need to use the EV Code specified in the acknowledgement.
5	Impossible to find the specified EV Code.
6	Impossible to find a referred entity. You need to check the specified foreign keys.
7	Impossible to find a referred entity. You need to check the specified foreign keys.
8	The requested operation does not exist.
9	The requested operation is not implemented.
10	Security Error. Insufficient Rights. You need to check the Ownership of the specified entity.
12	Missing Mandatory Information.
13	Unsuccessful Insert. You need to contact the EMA Help Desk.
14	Unsuccessful Update. You need to contact the EMA Help Desk.
15	Unsuccessful Nullify. You need to contact the EMA Help Desk.
16	Security Error. Impossible to update a private entry owned by another Organisation.
17	Impossible to add the substance, a specified name is already present in the EVMPD.
18	Referred entity(EV_CODE) could not be found.
19	You need to contact the EMA Help Desk.

20	General Error. You need to contact the EMA Help Desk.
21	Security Error. The sender Organisation is not registered with EV system.
23	Impossible to find a referred entity. You need to check the specified foreign keys.
24	The entity is referred to by others entities: Nullification not allowed.
25	Ambiguous EV Code. You need to contact the EMA Help Desk.
26	Version Date specified is not valid.
27	Standard Term Type Error. There is a more recent term (Proposed or Standard) in the EVMPD.
28	Only Authorised Products can be withdrawn.
30	Unsuccessful Withdrawn Generic Error. You need to contact the EMA Help Desk.
70	Error in the Product indication referred by the Product.
71	Sponsor data supplied matches <EV CODE> within the xEVMPD. Please use <EV CODE> or correct the submitted data.
73	Update of preferred name of substance <EVCODE> is forbidden. If the name is a synonym of <current preferred name>, you need to add the new name as an alias for <EVCODE>. If <new name> is a different substance to <original name>, you need to enter a new substance with your preferred name. If the original name contains an error, you need to contact the EMA.
76	Only the EMA may update products where the authorisation status is within the not valid authorisation status sub-list. If your product is in this status in error, you need to contact the EMA to request a correction.
77	If the value of authorisation status is Valid – Transferred Marketing Authorisation or Valid – Renewed Marketing Authorisation of MA then the Previous EV Codes section must be present.
78	If the value of authorisation status is Valid – Transferred Marketing Authorisation or Valid – Renewed Marketing Authorisation then at least one Previous EV Code section must reference the EV Code of a current authorised product.
79	If the operation type is withdrawal or Invalidate MA, the authorisation status must be one of the values in the published Not Valid Authorisation Status.

Operation sult Code	Text in Acknowledgement
80	If the operation type is Insert, Update or Variation then the authorisation status must be one of the values from the published valid authorisation status.
81	If the value of authorisation status does not signify a current valid MA then WithdrawnDate must be present.
82	If the value of authorisation status signifies a current valid MA then Withdrawn Date must be empty.
83	The EMA is not currently accepting updates to proposed Pharmaceutical Forms and Routes of Administration standard terms. You need to check that the term you have used does not exist and if necessary add a new proposed term.
85	The EMA is not currently accepting nullifications of proposed Pharmaceutical Forms and Routes of Administration standard terms.
99	The code idicates the Parsing error(s).
500	SME status field must be absent for Sponsor organisation.
501	SME status field must be present for current MAH organisation.
502	SME number field value prohibited with SME status field value provided.
503	MAH data supplied matches <EV CODE> within the XEVMPD. You need to use <EV CODE> or correct the submitted data.
504	At least 1 authorised pharmaceutical form is mandatory for this operation type.
505	Where multiple authorised pharmaceutical forms are specified each must be unique, code <duplicated code> is duplicated.
506	Referenced local pharmaceutical form (local ref:<localref>) not found or is a development term.
507	Referenced global pharmaceutical form (<EVCode>) not found or is a development term.
508	The legal basis is mandatory for this operation type.
509	The value of the legal basis field is not in the list of permitted values.
510	Authorisation country must be in EEA if an EU authorisation procedure is specified.
511	At least 1 medicinal product type is mandatory for this operation type.

Operation Result Code	Text in Acknowledgement
512	Where multiple medicinal product types are specified each must be unique, code <duplicated code> is duplicated.
513	The value <unmatched value> in the medicinal product type field is not in the list of permitted values.

Error Message	Description
Validity Declaration on Registration FPP Attachment entity is required to be with value for submission.	This error occurs when there is no value in the Validity Declaration field for the selected Registration FPP Attachment enti- ty.
At least one Registered ATC must be selected on Registration entity.	This error occurs when there is no ATC assigned to the Registration entity.
Qualified Person for Pharmacovigilance (QPPV) is required for this operation type.	This error occurs when there is no value in the QPPV field on Registration entity.
QPPV name should be valid (positive integer).	This error occurs when there is no value in the QPPV field on Registration entity.
Short Name must be specified.	This error occurs when there is no value in the Short Name field for the selected FPP entity.
Short Name must not exceed 250 characters.	This error occurs when there are more than 250 characters in the Short Name field for the selected FPP entity.
Withdrawn/Invalidated Date must be specified to Invalidate MA the authorised product.	This error occurs when there is no date specified in the Withdrawn/Invalidated Date field for the selected FPP entity.
XEVMPD Comments must be specified on FPP entity for Invalidate MA operation of Authorised Product.	This error occurs when there is no value in the XEVMPD Comment field for the selected FPP entity.

XEVMPD Error Message for Authorised Product

The following table lists the Authorised Product error messages and their description.

Error Message	Description
Procedure Type is required.	This error occurs when there is no procedure type for the selected Application entity. This error also occurs if an incorrect value is entered for the Procedure Type Code in DA.

At least one Indication is required for this operation type.	This error occurs when there is a no Indications/Intended Use PDS Detail created.
MedDRA Code is required to submit indication data.	This error occurs when there is no value in the MedDRA Code field in DA for the created Indications/Intended Use PDS Detail.
MedDRA Level in Data Administration is required to submit indication data.	This error occurs when there is no value in the MedDRA Level field in DA for the created Indications/Intended Use PDS Detail.
MedDRA Term version is required to submit indication data.	This error occurs when there is no value in the MedDRA Term Version field in DA for the created Indications/Intended Use PDS Detail.
Authorisation Status on FPP entity is required to be with value for this Operation Type.	This error occurs when there is no value in the Authorisation Status field for the selected FPP entity and Operation Type in the Wizard.
Authorisation Number cannot exceed 100 characters.	This error occurs when there are more than 100 characters in the License Code field for the Registration entity.
Authorisation/Renewal Date on FPP entity is required to be with value for this Operation Type.	This error occurs when there is no Authorisation/Renewal Date field for the selected FPP entity.
MRP Number is required for this procedure type.	This error occurs when there is no value for the condition Application Code or the Application Identifier and PDS->Speciali- ty Number (CP only).
Orphan Drug on Application entity is required to be with value for selected Operation Type.	This error occurs when there is no value in the Orphan Drug field for the Application entity.
Withdrawn/Invalidated Date is required for this operation type.	This error occurs when there is no value in the Withdrawn/Invalidated Date field for the selected FPP entity.
Withdrawn/Invalidated Date must be empty if Authorisation Status is valid MA.	This error occurs when there is no value in the Withdrawn/Invalidated Date field for the selected FPP entity.
Withdrawn/Invalidated Date is required to be with value for this status type.	This error occurs when there is no value in the Withdrawn/Invalidated Date field for the selected FPP entity.
The operation type must be Invalidate MA for this status type.	This error occurs when an invalid value is selected for the Authorisation Status field for the selected FPP.

Error Message	**Description**
The operation type cannot be Invalidate MA for this status type.	This error occurs when an invalid value is selected for the Authorisation Status field for the selected FPP.

If the Operation Type is Insert, Update or Invalidate MA then Legal Basis on Registration or Application entity must be specified.	This error occurs when the Operation Type is Insert, Update or Invalidate MA and there is no value for the Legal Basis field on Registration or Application entity.
If the Operation Type is not Nullify then at least one Medicinal Product Type must be specified.	This error occurs when the Operation Type is not Nullify and there is no value for the Medicinal Product Type on Registration entity.
If the Operation Type is not Nullify then at least one Authorised Pharmaceutical Form must be specified.	This error occurs when the Operation Type is not Nullify and there is no value for the Authorised Pharmaceutical Form on FPP entity.
This Authorised Pharmaceutical Form must be submitted in this message.	This error occurs when there is no value in the Authorised Pharmaceutical Form field on FPP entity.
This Authorised Pharmaceutical Form must not represent a Development Pharmaceutical Form.	This error occurs when the Authorised Pharmaceutical Form selected on FPP entity has a Development Term in Dosage/ Pharmaceutical Form Values in DA.
If the Operation Type is Insert or Update and Authorised Pharmaceutical Form has XEVMPD Code then Authorised Pharmaceutical Form must represent a Standard or Proposed Pharmaceutical Form.	This error occurs when the Authorised Pharmaceutical Form selected on FPP entity does not have a EV Code or Standard Term, or Proposed Term in Dosage/Pharmaceutical Form Values in DA.
Product INN/Common Name on FPP entity is required to be with value.	This error occurs when there is no value in the Product INN/ Common Name field for the selected FPP entity.
Product INN/Common Name cannot exceed 250 characters.	This error occurs when there are more than 250 characters in the Product INN/Common Name field for the selected FPP entity.
Company Name on FPP entity is required to be with value.	This error occurs when there is no value in the Company Name field for the selected FPP entity.
Company Name cannot exceed 250 characters.	This error occurs when there are more than 250 characters in the Company Name field for the selected FPP entity.
Product Strength cannot exceed 250 characters.	This error occurs when there are more than 250 characters in the Product Strength field for the selected FPP entity.
Product Form cannot exceed 250 characters.	This error occurs when there are more than 250 characters in the Product Form field for the selected FPP entity.

Error Message	Description
Package Description cannot exceed 2000 characters.	This error occurs when there are more than 2000 characters in the Package Description field for the selected FPP entity.
MFL on Registration entity is required to be with value for selected Operation Type.	This error occurs when there is no value for the MFL field on Registration entity.
The Master File Location must be submitted in this message.	This error occurs when there is no value in the MFL field on Registration entity.
Registration Attachment EV Code is required for submission.	This error occurs when there is no value in the EV Code field on Registration Attachment entity.
This substance can be used only once within Pharmaceutical Product.	This error occurs when a same substance is selected as AI and Excipient/Adjuvant.
The Marketing Authorization Holder must be submitted in this message.	This error occurs when MAH/Organization selected on Registration entity does not have a EV Code or MAH Code in MAH/ Development Sponsor/Organisation Values in DA.
No Marketing Authorisation Holder was specified.	This error occurs when there is no value for the MAH/Organization field on Registration entity.
Pharmacovigilance Enquiry Email is required for this operation type.	This error occurs when there is no value in the Enquiry Email field on Registration entity.
Pharmacovigilance Enquiry Phone Number is required for this operation type.	This error occurs when there is no value in the Enquiry Phone Number field on Registration entity.
No valid Pharmaceutical Products were found. At least one Pharmaceutical Product with Active Ingredient measure information must be specified.	This error occurs when there is no Pharmaceutical Product created.
No Active Ingredients were specified.	This error occurs when Substance selected as Active Ingredient (Reference AI/Reference Strain/PDS AI) entity does not have a EV Code or Approved in Substance Values in DA.
High Amount Numerator Value must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Numerator field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity for selected Non-Range Concentration Type.

High Amount Numerator Unit must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Numerator Unit field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity for the selected Non-Range Concentration Type.

Error Message	**Description**
High Amount Numerator Prefix must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Numerator Prefix field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity for the selected Non-Range Concentration Type.
High Amount Denominator Value must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Denominator field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity for selected Non-Range Concentration Type.
High Amount Denominator Unit must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Denominator Unit field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity for selected Non-Range Concentration Type.
High Amount Denominator Prefix must be empty for non-Range Concentration Type.	This error occurs when there is no value in the High Amount Denominator Prefix field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity for selected Non-Range Concentration Type.
High Amount Numerator Unit must match Low Amount Numerator Unit.	This error occurs when the value in the High Amount Numerator Unit field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity is different to the value of the Low Amount Numerator Unit field for the same entity.
High Amount Denominator Unit must match Low Amount Denominator Unit.	This error occurs when the value in the High Amount Denominator Unit field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity is different to the value of the Low Amount Denominator Unit field for the same entity.
High Amount Denominator Prefix must match Low Amount Denominator Prefix.	This error occurs when the value in the High Amount Denominator Prefix field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity is different to the value of the Low Amount Denominator Prefix field for the same entity.

High Amount Denominator Value must match Low Amount Denominator Value.	This error occurs when the value in the High Amount Denominator field on Component Product AI/Reference AI or on PDS AI (Reference Strain/Excipient/Adjuvant) entity is different to the value of the Low Amount Denominator field for the same entity.

Error Message	**Description**
Concentration Measure Type Code is required.	This error occurs when there is no value for the Concentration Measure Type Code field on PDS AI (Reference Strain/Excipient/Adjuvant) entity.
Low Amount Numerator Value is required.	This error occurs when there is no value for the Low Amount Numerator field on PDS AI (Reference Strain/Excipient/Adjuvant) entity.
Low Amount Numerator Prefix is required.	This error occurs when there is no value for the Low Amount Numerator Prefix field on PDS AI (Reference Strain/Excipient/Adjuvant) entity.
Low Amount Numerator Unit is required.	This error occurs when there is no value for the Low Amount Numerator Unit field on PDS AI (Reference Strain/Excipient/Adjuvant) entity.
Low Amount Denominator Value is required.	This error occurs when there is no value for the Low Amount Denominator field on PDS AI (Reference Strain/Excipient/Adjuvant) entity.
Low Amount Denominator Prefix is required.	This error occurs when there is no value for the Low Amount Denominator Prefix field on PDS AI (Reference Strain/Excipient/Adjuvant) entity.
Low Amount Denominator Unit is required.	This error occurs when there is no value for the Low Amount Denominator Unit field on PDS AI (Reference Strain/Excipient/Adjuvant) entity.

Chapter 16. Auto Upload and Process Acknowledgement Files

Ennov InSight provides you with the ability to select an acknowledgement file to execute using the wizard, or to upload the file automatically. However, these actions can be performed only if the required settings are configured during the application server installation.

Acknowledgement Wizard Make sure that:

1. **Location for XEVMPD Acknowledgement file** has correct path to the folder **<Folder Name >**, which contains an additional folder with the name **processed** for the files that are already uploaded by the system.
2. **Defined Interval** field has the number in minutes that corresponds to the time period for the system to check this folder for files.
3. **XEVMPD Acknowledgement Force Import** field, for acknowledgement files that have related submission files that were created outside of the Ennov InSight system, is set to **Yes**. The default value is set to **No**.

When the file is uploaded by the system automatically, you can receive an alert in Alert Center about the processed file. You also can receive the details via email notification or by using both email and Alert Center functions.

A message appears in the Notes section of the System Alert to indicate that files have been imported using the Force XEVPRM Acknowledgement Import functionality.

Import Result Information	
Import Result:	EMA Acknowledgement file Ack_Insert_Update_all.xml was processed
Acknowledgement Message Name:	Ack_Insert_Update_all.xml
Acknowledgement Message Date:	11-Nov-2015
Acknowledgement Message Type:	2
Entities Acknowledged:	
Organisations:	0
Sources:	1 AMIS
Attachments:	0
Master File Locations:	0
Pharmaceutical Forms:	0
Routes of Administration:	0
ATCs:	0
Authorised Products:	0
Notes:	Acknowledgement file has been uploaded using Force Import functionality; See Reports for more information.

Note: To receive notifications regarding auto uploaded XML acknowledgement files, you must create an XEVMPD Import Result notification first.

If the acknowledgement file that is imported by Force XEVPRM Acknowledgement Import functionality has an EV Code identical to any already existing in the Ennov InSight system, the number of imported entities is displayed in the result table in the *System Alert* and *XEVMPD Acknowledgement Wizard Import XEVPRM Acknowledgement Result* page.

If you have configured acknowledgement file upload automatically through the application server setup, you do not need to execute the wizard manually because all required actions will be performed by the system.

Submission Wizard The system can show the predefined location path on the *Create XEVPRM Confirmation* page if the settings were configured during application server installation:

• The **Location for XEVMPD Submission** field should have the correct path to the folder **<Folder Name >** , where the system will put the created ZIP file.

Chapter 17. XEVMPD Data Administration Sections Correspondence

As a data administrator, you are responsible for setting up and maintaining the data available in selection lists in Ennov InSight.

The following tables represent the different Data Administration section groupings in correspondence to XEVMPD (Extended EudraVigilance Medicinal Product Dictionary).

Table 11. Table 1. Application Maintenance

Data Administration Section Groupings/Functionalities	XEVMPD
Procedure Type Values	✓

Table 12. Table 2. Other

Data Administration Section Groupings/Functionalities	XEVMPD
Concentration Measure Type Values	✓
Denominator Unit Values	✓
Indications/Intended Use Values	✓
Language Values	✓
Legal Basis Values	✓
MAH/Development Sponsor/Organization Values	✓
Master File Location (MFL) Values	✓
Message Sender Values	✓
Numerator Unit Values	✓
Previous EV Code Values	✓
SME Status Values	✓
Unit of Measure Prefix Values	✓

Table 13. Table 3. Product Detail Set Maintenance

Data Administration Section Groupings/Functionalities	XEVMPD
Compendial Designation/Source Values	✓
Substance Role Values	✓

Table 13. Table 3. Product Detail Set Maintenance (continued)

Data Administration Section Groupings/Functionalities	XEVMPD
Manufacturer Values	✓
Substance Type Values	✓

Table 14. Table 4. Product Family Maintenance

Data Administration Section Groupings/Functionalities	XEVMPD
ATC Values	✓
Substance Attachment Values	✓
Substance Class Values	✓
Substance Values	✓

Table 15. Table 5. Product Maintenance

Data Administration Section Groupings/Functionalities	XEVMPD
Dosage/Pharmaceutical Form Values	✓
Medical Device Values	✓
Route of Administration Values	✓

Table 16. Table 6. Registration Maintenance

Data Administration Section Groupings/Functionalities	XEVMPD
EMA Authorization Status Values	✓
Medicinal Product Type Values	✓
Qualified Person Responsible for Pharmacovigilance (QPPV) Values	✓

Chapter 18. XEVMPD Entities

The XEVMPD Entities are Ennov InSight entities, which take part in XEVMPD processes.

The full list of entities:

- Product Families
- Products
- Components
- Pharmaceutical Product
- Component Active Ingredient
- Reference Active Ingredient for Component Active Ingredient
- Applications
- Events
- Product Detail Sets (PDS)
- Package Set Registration
- Full Product Presentation
- FPP Previous EV Code
- Registration FPP Attachment
- Registration Attachment

Chapter 19. Events

An event is a regulatory activity associated to an application. An event can be an original NDA/MAA filing or a major update such as a supplement or a variation.

An event represents a key business objective or regulatory action, such as an original filing, a resubmission, or an annual report. **Note:** Although events are associated with an application, Ennov InSight does not require you to create an event when you create an application.

When an event is created, a status schedule is also created. Status schedules are applied to every country included in the application that you chose to include in the event. The event-country status schedule consists of statuses

(milestones) and lead times for planning and tracking the progress of the steps needed to complete an application. You can define lead times in days for every status and then calculate the projected dates for each status based on those lead times.

A status schedule can be developed specifically for an event or can be based on a timeline/event plan, which is essentially a template of commonly used statuses and lead times. You can individually modify status schedules for each country included in the event. You can add or revise statuses and lead times by country, which will not affect the statuses and lead times for other countries included in the event.

An event can have one or more associated sequences, which are the individual filings and amendments submitted to support a business objective. You can also create tasks and sub-tasks, references, and notifications for specific events.

The tabs that are available when you view event attributes give you access to the countries, country schedules, and Ennov InSight entities (such as products, sequences, change details, product detail sets, tasks, activities, workflows, references, pending changes, and notifications) that can be associated with an event or created through an event.

Copy Events

Copying an event enables you to create multiple events for a regulatory action that is needed in more than one country. The *Copy Event* wizard copies an event to multiple applications within the same product family. You can associate existing product detail sets with the new events and copy the tasks and references from the originating event to the new events.

You can copy an event only if all of the following criteria are met:

- The event is open.
- You have at least WRITE security privileges for events.
- You can access the *Copy Event* wizard.

When you copy an event:

- You can only copy an event when viewing the *Event Attributes* page.
- New events are created for the applications you choose.

- All event attributes except **Comments** and **Concerned Parties** are copied to the new events. **Comments** and **Concerned Parties** remain blank.
- The status schedule is not copied to the new event.
- If you copy tasks, all tasks and their task status dates are copied and associated with the new events and other attributes.
- If you choose to associate existing product detail sets with the new event, any products associated with them are automatically associated with the new event and if it is a product registration type the status date on the event-product relationship is set to today's date.
- The Applications multi-select field displays only those applications that are associated with the selected Product.
- With the exception of the **Last Changed Date**, **Updated By**, **Comments**, and **Concerned Parties** attributes, which are left blank, all task attributes are copied.
- If you copy references, all reference attributes, except **Comments**, and **Concerned Parties** are associated with the new events.

Create an Event

You create an event for an application to show a key business objective or regulatory action.

When you create an event, you specify important event attributes, including event name, event code, event type, PSUR information, and status dates. You also choose which countries and which products included in the application can be included in the event and choose whether to use an event plan to create the status schedules.**Note:** Withdrawn application countries with the Withdraw Date value equal to today’s date or earlier, are not available for selection in the **Countries** multi-select field on the *Create Event* page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.

When you create an event, Ennov InSight automatically associates the event schedule to each country selected for inclusion in the event.

An event is automatically created and associated with the submission entities when you use the *Create Submission* wizard to create an initial application or a major update.**Note:** At this time, Ennov InSight will not prevent you from associating non-veterinary events to projects with veterinary product families. Under this scenario, you will not see the non-veterinary details, however, they will be stored in the database and appear in related queries.

To create an event:

1. Click a link for the application for which you want to create an event.The *Application Attributes* page opens.
2. Click **Events**.
3. Click **Create**.The *Create Event* page appears.
4. Select and enter the event attributes.
5. **Save**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Event Attributes

Events represent key business objectives or regulatory actions for an Application. The attributes describe the type of Event and the Event details.

Attribute	Description
Action Type	The type of approval required to consider the Event active.
Application Code	The agency-identified Application number (or identifier), which may not be known until submittal time. It may be the same as the internal code.
Application Internal Code	The internal code for the Application. This is by default hidden for CTA and IND Applications.
Application Name	The name of the Application that is associated with the Event.
Closed	Indicates whether the Event is closed.
Copy Default Lead Times from the following Country	When adding an Event-Country, select this option to specify the country whose default lead times you want to apply to the country you are adding.
Countries	Countries of the Event.**Note:** Withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the **Countries** multi-select field on the *Create Event* page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.
CT Shared Data	Clinical Trial shared data associated with an event based on the type of application. This field is available on the *Create Event* page if the application type is CTA, CTR or IND.
Description	Text that describes the Event.
EU Grouping/Worksharing	Used to identify if the Event is part of a Grouping or Worksharing activity for a European variation. Worksharing is used when there is one change to multiple Applications in multiple Procedures. Grouping is used when there are many of the same changes for one Application.

Attribute	Description
EU Grouping/Worksharing Number	Used to identify the high-level submission number, either a 'Worksharing' number or the high-level submission number to be used when grouping Type 1A variations for multiple Marketing Authorizations.
Event Add Comment	Comments you want to share with others in a discussion thread. Will be displayed in the **Event Comments** box, stamped with the date and time you enter the information and your user ID.**Note:** The **Event Add Comment** field is available on the Create/Modify *Event Attributes* pages only.
Event Closed As	The status to capture how the entities associated with the Event were closed.
Event Closed Date	The date the Event is closed.
Event Code	The code your organization uses to identify the Event.**Note:** The Event Code and Event Name as a combination for an Event must be unique within an Application.
Event Comments	The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.
Event Concerned Parties	Concerned Parties are anyone who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses.
Event-Country Status	The current status for the country associated with the Event.When the Event-Country schedule enforces a status progression, only the next status in the progression and optional statuses are available for selection.
Event Name	The name of the Event.**Note:** The Event Code and Event Name as a combination for an Event must be unique within an Application.
Timeline/Event Plan Type	The type of Timeline/Event Plan. The Timeline/Event Plan Type can be Procedure Type, Event Type, or None. When the Timeline/Event Plan Type is Procedure Type, the Timeline/Event Plans avail- able for selection are those associated with the Application Procedure Type. When the Timeline/Event Plan type is Event Type the Timeline/Event Plans available for selection are those associated with the selected Event Type. When the Timeline/Event Plan Type is None, no Timeline/Event Plans will be available for selection. The Timeline/Event Plan Type is only displayed when an Event is created.

Timeline/Event Plan Used	The Timeline/Event Plan used to create the Event.

Attribute	**Description**
Event Type	The type of the Event.
Keywords	Words you can use to search for the Event.
Procedure Closure Date	The date of the first approval when the RMS approves an application.
Products	The Products associated with the Event.
Project Name	The name of the Global Project Planning (GPP) project with which this Event is associated.
PSUR Flag	Indicates whether or not there is information associated with the Event to drive the PSUR worldwide report.
PSUR Reason/Comment	Identifies the reason for the PSUR filing. **Note:** If you enter more than 4,000 characters in this field, none of the text is saved when you save changes to the event attributes.
PSUR Report Code	The Code identified in the World Wide PSUR Report. When PSUR flag is set to '**Y**', this field is used for the PSUR Report Code.
Reason	Reason for creating, modifying or deleting an event.
Reason for Comments	Comments related to reason entered by users.
Reason for Termination/Withdrawal	The reason that event was terminated or withdrawn. Appears and is required only when the Event Closed As is set to WITHDRAWN.
Reportable in PSUR	Indicates whether an Event needs to be included in the PSUR.

Secondary Event Type	Used to further define the Event Type.
Status Date	The effective date for the current event-country status.
Timeline/Event Plan	A Timeline/Event Plan provides the ability to create an Event-Country Schedule with statuses in the order they are expected to be achieved for a country(s). • The option to apply a Timeline/Event Plan is only available during initial creation of the Event. • The Timeline/Event Plans that are available for selection depend on the Timeline/Event Plan type selected. • If the Event was created with a plan, only the statuses associated with the plan will be available for selection when updating the Event-Country Status.
Attribute	**Description**
	• If the Event was not created with a plan, all active statuses available in the system will be available for selection when updating the Event-Country Status. • If the Event-Country schedule enforces a status progression, only the next status in the progression and optional statuses are available for selection when updating the EventCountry Status. • After the Event is created, changes in the Timeline/Event Plan in Data Administration are not applied to existing Event-Country Schedules.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.
Variation Number	The regulatory agency-assigned number that identifies the Event as a variation of a submission.

Copy an Event

You can copy an event to multiple applications within the product family associated with a source event.

Depending on the application type, conditions apply to the copied events.

- For National applications, the reviewing country from the source event is automatically assigned to the copied event.
- For MRP applications, the reference member state is automatically assigned to the copied event.
- For CP applications, European Union is automatically assigned to the copied event and to the application if European Union was not associated before the event copy was created.

For all event copies, regardless of application type, the timeline/event plan from the source event will not carry forward to the event copy. Ennov InSight automatically populates the event-country status schedules with the default status schedules established by your data administrator

Note: You can copy an event only if at least one country associated with the original event is unlocked and if the event is open.

Use the Copy Event Wizard

Use the *Copy Event* wizard to copy an event to multiple applications within the product family associated with a source event.To copy an event using the wizard:

1. Navigate to the event you want to copy.
2. Select **Wizards** > **Copy Event**.The *Copy Event* wizard opens to the *Choose Products* page.
3. On the *Choose Products* page, do one of the following:

Option	**Action**
To narrow down the list of applications:	Choose applications on the next page by selecting one or more available products. Only products that belong to the product family associated with the event are listed.
To see the entire list of applications on the next page of the wizard:	Do not choose products from the available list.

4. Click **Next**.
5. On the *Choose Applications* page, select one or more available applications, and optionally do one or more of the following:

Option	**Action**
To copy all tasks associated with the source event to the event copy:	Select **Copy Task**. This option is available only if you have at least WRITE security privileges for tasks.
To copy all references associated with the source event to the event copy:	Select **Copy References**. This option is available only if you have at least WRITE security privileges for references.

To copy the PDS associated with the source event to the event copy:	Select **Associate Product Detail Sets with Events**. This option is available only if you have a PDM license and at least WRITE security privileges for PDSs.

6. Click **Next**.A confirmation page indicates the new event will be copied to the applications selected in step 5.
7. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Modifying an Event

You can modify event attributes (such as: code, name, type, and PSUR information) and you can update status schedules by country for open events. You can reopen or close an event when it is no longer active. When closing an event, you enter the event close date and set the closed status, which affects the status and status dates for associated entities. You can only close an event if all the countries associated with the event are locked.

You must have WRITE privileges to Events to modify an event.

To modify an event:

1. Click a link for the event you want to modify.The *Event Attributes* page appears.
2. On the *Event Attributes* page, click **Edit**.The *Modify Event* page appears.
3. Change and enter event attributes. You can also close or reopen the event.
4. **Save**.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Associate Additional Countries with an Event

You can associate additional countries with an event from the countries associated to an application. You can set default lead times if the event is associated with a timeline/event plan.

To perform this procedure, the event must be open and you will need WRITE privileges for the event.To associate additional countries with an event:

1. Open the *Event Attributes* page.
2. On the **Countries** tab, click **Create**.The *Add Event Country* page opens.
3. Select one or more available countries.
4. Do one of the following:

◦ For events associated with timeline/event plans: to set default lead times for the countries selected for planned events, enter the number of days you want to set as the default in one or more of the fields listed on the screen.**Note:** The statuses shown on the screen depend on the timeline/event plan that you use.

◦ For events not associated with timeline/event plans: **Save**.

The selected countries are added to the list on the **Countries** tab. Any default lead times that you set appear on the **Country Schedules** tab or the individual **Status Dates** tabs for the countries added. You can see the **Status Dates** tab by clicking the country link in the **Countries** tab.

View an Event

You can view an event to see its attributes and to take actions on an event. You can modify and delete an event, and to copy the URL to the Clipboard. You can also add projected status dates and entities to associate with the event.

For ease of use, Ennov InSight enables you to view status schedules grouped by country. You can expand or close individual status schedules as needed.

To view an event:

1. View the application associated with the event.
2. Select the **Events** tab.
3. Click a link for the event you want to view.The *Event Attributes* page opens.
4. On the *Event Attributes* page, do any of the following:

◦ To modify the event attributes, click **Edit**.

◦ To delete the event, click **Delete**.

◦ To copy the event URL to the Clipboard, click **Copy URL**. A message confirms the URL has been copied.

◦ To generate an Entity History query for the event, click **Report**.

◦ To associate a workflow to an event, click **Associate Workflow**.

◦ To add, lock, or unlock country status schedules associated with the event, click **Countries** . You can also update the event country status or calculate projected dates for one or more countries.

◦ To view the schedules for each country associated with the event, click **Country Schedules**.

◦ To associate or disassociate a product, click **Products**.

◦ To view sequences, click **Sequences**.

◦ To add, modify, associate, or disassociate a product detail set (available for PDM users only), click **Product Detail Sets**.

◦ To add, modify, or view tasks associated with the event, click **Tasks**.

◦ To view, or modify associated activities, click **Activities**.

◦ To view, pause, resume, or delete associated workflows, click **Workflows**.

◦ To add, modify, or view references associated with the event, click **References**.

◦ To add, modify, or delete notifications associated with the event, click **Notifications**.

View Countries Associated with an Event

On the *Event Attributes* page, the **Countries** tab contains a list of all countries associated with the event when the event was created.

While viewing the **Countries** tab on the *Event Attributes* page, you can:

- Click the **Create** icon to associate additional countries with an event.
- Select one or more countries and click **Lock** to lock countries and their event-country status schedules.
- Select one or more countries and click **Unlock** to unlock countries and their event-country status schedules.
- Click **Update Event-Country Status** to update the event-country status for one or more countries that are not locked using the *Update Event Country Status* wizard.
- Click **Calculate Projected Dates** to calculate projected dates for one or more countries that are not locked using the *Update Event country Status Projected Dates* wizard.
- Click a country name hyperlink to view the event-country status schedule for a country.

To perform these activities, you must have a minimum of WRITE privileges for the Events entity and the event must not be closed.

Note: If the event-country status on the **Countries** tab is different from the event-country status on the **Country Schedules** tab, the status on the **Country Schedules** tab is the current value. If the two values are different, the status was changed twice in the same day. Do not change the status twice in the same day.

View Event-Country Status Schedules

On the *Event Attributes* page, the **Country Schedules** tab lists status schedules for each country associated with an event.

Ennov InSight lists status schedules in alphabetic order by country. You can expand or collapse grouped listings for each country as needed to view schedule details such as status, lead time, and schedule dates. You can use the options in the column headings to resort the list or determine which columns display.

Note: If the event-country status on the **Country Schedules** tab differs from the event-country status on the **Countries** tab, the status on the **Country Schedules** tab is the current value. If the two values differ, the status may have been changed more than once in the same day.

View a Product Associated with an Event

The **Products** tab on the *Event Attributes* page lists the products associated with the event you are viewing. The information presented differs for Package Set Registrations and Product Registrations.

For Package Set Registrations, the Product Name and Product Code are displayed.

For Product Registrations, the **Event-Product Status**, **Event-Product Status Date**, and **License Code** are displayed.

Ennov InSight initially sets the event-product status date to event-country status date. The event-product status is initially set to the default product status value defined by your data administrator.

Rules Governing Event-Product Statuses

When an event is approved/not approved/withdrawn:

- If the event-product status was not set to a status that maps to **Approved**, **Not Approved**, or **Withdrawn**, Ennov

InSight sets the event-product status to the status that maps to Approved/Not Approved or Withdrawn.

- The event-product status date is the same status date as the event.

When a product is associated with a registration:

- The event-product status is set to Approved.
- The event-product status date is set to the registration's status date.
- The license code value is updated with the code assigned by the regulatory agency.

Product Tab Action Buttons

From the **Products** tab on the *Event Attributes* page, use the action buttons to do the following:

- Click **Associate** to associate or disassociate a product to or from the event.
- Click **Edit** to modify the status and status date of a product associated with the event.

Modify an Event-Product Status and Status Date

You can modify the event-product status and event-product status date for a product associated with an event that is associated with an application of the product registration type.To modify an event-product status and status date:

1. Click the link for an event for which you want to modify the event-product status and status date. The *Event Attributes* page appears.
2. Click **Products**.
3. Using the checkbox column, select the row of the product you want to modify.
4. Click **Edit**.The *Modify Event-Product Status and Status Date* page appears.
5. Change the **Event-Product Status** or **Event-Product Status Date** attribute values as needed.
6. **Save**.

Associate or Disassociate a Product and an Event

You can associate product in an application to an event. You can also disassociate a product from an event. When associating or disassociating a product, the following conditions apply:

- A product can be associated with one or more events for an application.
- A product cannot be associated with or disassociated from an event when the event is associated with a project, or the event is closed.
- A product cannot be disassociated from the event when the product is associated with a registration for the selected event, or the product has a PDS associated with the selected event.

To associate or disassociate a product and event:

1. Click a link for the event with which you want to associate a product. The *Event Attributes* page opens.
2. Click **Products**.
3. Click **Associate**.The *Associate/Disassociate Products* page opens.
4. For the **Products** attribute, under the **Selected** box:

◦ To associate products with the event, click **Select**, select the products, and **Save**.

◦ To disassociate products from the event, select products in the **Selected** box. To select more than one product, hold down the **CTRL** key and click each product. Then click **Deselect**.

A confirmation message appears.

1. **OK**.
2. **Save**.
3. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

About Associating or Disassociating Clinical Trial Shared Data

You can associate Clinical Trial shared data with an event based on the type of associated application and the status of the event.

Consider the following regarding Clinical Trial shared data:

- You can associate Clinical Trial shared data only with a new or existing event that is associated with a CTA, CTR or IND application.
- You can associate one or more Clinical Trial shared data entities with an event that is associated with an IND application.
- You can associate only one Clinical Trial shared data entity with an event that is associated with a CTA application.
- You can associate one or more Clinical Trial shared data entity with an event that is associated with a CTR application.
- You can associate the same Clinical Trial shared data with more than one event.
- You cannot associate Clinical Trial shared data with a closed event.
- You cannot disassociate Clinical Trial shared data from a closed event.
- You cannot associate Clinical Trial shared data with an event that is associated with a project.
- You cannot disassociate Clinical Trial shared data from an event that is associated with a project.

Associate Clinical Trial Shared Data when Create an Event

Associate CT Shared Data with an event to consolidate common details for Clinical Trial Authorization applications.

To associate Clinical Trial shared data when you create an event:

1. On the *Create Event* page, in the **CT Shared Data** list, in the **Available** box, select one or more protocol numbers.
2. Click the button with the two right angle brackets. The **Selected** box now contains the protocol numbers.
3. **Finish**.
4. To enter an electronic signature, select a reason and enter comments for the reason.
5. Select **Save**.
6. Validate your identity by entering your user credentials in the dialog box.

Disassociate Clinical Trial Shared Data when Create an Event

Disassociate CT Shared Data that is not required when you create an event. To

disassociate Clinical Trial shared data when you create an event:

1. On the *Create Event* page, in the **CT Shared Data** list, in the **Selected** box, select one or more protocol numbers.
2. Click the button with the two right angle bracketsThe **Available** box now contains the protocol numbers.
3. **Finish**.

4. To enter an electronic signature, select a reason and enter comments for the reason.
5. Select **Save**.
6. Validate your identity by entering your user credentials in the dialog box.

Associate Clinical Trial Shared Data for Modified Events

Associate CT Shared Data with a modified event to consolidate common details for Clinical Trial Authorization applications.

To associate Clinical Trial Shared Data when you modify an event:

1. Navigate to the event associated with a CTA, CTR or IND application.
2. Click the **CT Shared Data** tab.
3. Click **Associate/Disassociate CT Shared Data**.
4. On the *Associate/Disassociate CT Shared Data to/from Event* page, the **Available** box, select one or more protocol numbers.
5. Click the button with the two right angle brackets.The **Selected** box now contains the protocol numbers.
6. **Save**.
7. To enter an electronic signature, select a reason and enter comments for the reason.
8. Select **Save**.
9. Validate your identity by entering your user credentials in the dialog box.

Disassociate Clinical Trial Shared Data from Modified Events

Disassociate CT Shared Data that is not required for Clinical Trial Authorization applications. To

disassociate Clinical Trial Shared Data when you modify an event:

1. Navigate to the event associated with a CTA, CTR or IND application.
2. Click the **CT Shared Data** tab.
3. Click **Associate/Disassociate CT Shared Data**.
4. On the *Associate/Disassociate CT Shared Data to/from Event* page, in the **Selected** box, select one or more protocol numbers.
5. Click the button with the two right angle bracketsThe **Available** box now contains the protocol numbers.
6. **Save**.
7. To enter an electronic signature, select a reason and enter comments for the reason.
8. Select **Save**.
9. Validate your identity by entering your user credentials in the dialog box.

Remove Countries from an Event

You can remove countries from an event in specific circumstances.

You can remove a country from an event for a CP or MRP type application only if:

- You have at least WRITE privileges for the Events entity.
- The country is locked.
- The country is not associated with a sequence, PDS, or a registration for that application.

You cannot remove a country from an event if:

- You do not have the required permissions.
- The country is a reviewing country.
- If the event is closed.
- The country is the only country associated with the event.
- The country has an actual date for a status that maps to the internal event status of Submitted, Approved, or Not Approved.

Remove a Country from an Event

You can remove a country from an event in specific circumstances.

To remove a country from an event:

1. Open the *Event Attributes* page.
2. Click **Countries**.
3. Click the link for the country that you want to remove from the event.
4. Click **Delete** on the Event-Country Attributes frame at the top of the page. **Note:** The **Delete** icon for **Status Dates** tab is used for deleting a selected event country status from the event status schedule.
5. If eSignature is enabled, validate your identify by entering your user credentials and click **Sign in** (for Microsoft Azure).

Pending Changes

Track pending changes specific to attributes for the Application, Medicinal Product and Registration.

You can enable or disable the Pending Changes functionality through a configuration file located at **\InSightManager \server\all\conf\insight\PendingChanges.json**. Please contact our support representatives for configuration assistance.

You must have at least Write privileges for both RPT and PDM licenses to read, create, apply and remove Pending Changes.

Pending Changes tab is available on the *Event Attributes* page only for the following:

- Procedure types: all EU procedure types.**Note:** Pending Changes are not available for EU CTR Procedure type.
  • Application types: Marketing Authorisation Application and the Marketing Authorisation Application - Animal Health.
- Registration types: Package Set Registration.

You can delete or apply the pending changes from the **Pending Changes** tab before closing an event.

Once you close an event, **Create, Apply** and **Delete Pending Changes** options will be disabled.

If you choose **Withdrawn** or **Not Approved** status when closing an event, the changes will not apply and the associated attributes will no longer appear on the **Pending Changes** tab. The selected entity type will remain with the current values without any updates.

The following are the Pending Changes properties:

Entity	**Description**
Ap plication	To successfully apply all your selected changes in the *Pending Changes* wizard, you must close the Event with the **Approved** status. This will update the **Procedure Type** and **Legal Status of Supply** attributes for the Application and the Pending Change item list will disappear from the **Pending Changes** tab. The **Procedure** **Type** attribute is available only for **EU National** applications, allowing to change from **EU National** to **EU MRP**. For applications with other than **EU National** procedure type, the only pending change available is **Legal Status of Supply**.
Med icinal Product	To successfully apply all your selected changes in the *Pending Changes* wizard, you must close the Event with the **Approved** status. This will update the **Pediatric Use Indicator** and **Full Indication Text** attributes for the Medicinal Product and the Pending Change item list will no longer ap- pear on the **Pending Changes** tab.
Full Product Presentation	To successfully apply all your selected changes in the *Pending Changes* wizard, you must close the Event with the **Approved** status. This updates the **Full Product Presentation**, **Authorised Pharmaceutical Form**, **Authorization/ Renewal Date**, **Authorization Status**, **Full Product Name**, **Full Product Short Name**, **Information Date**, **Product Company Name**, **Product Form**, **Product INN/ Common Name**, **Product Strength**, **XEVMPD Comments**, **Withdrawn/ Invalidated Date** attributes and the Pending Change item list will no longer appear on the **Pending Changes** tab.**Note:** It is im- possible to apply FPP using the **Pending Changes** tab if the following fields are populated with the same values as the other FPPs applied to the same registration: **Concatenation of Full Product Name**, **EEA Country**, **Language**, **Package Description**, **Authorisation Status**, **Authorisation/Re- newal Date**, **EVCode**.
Entity	**Description**
Registrati on	To successfully apply all your selected changes in the *Pending Changes* wizard, you must close the Event with the **Approved** status. This will update the **MAH/Organisation**, **QPPV**, **MFL**, **Subject to Additional Monitoring**, **Next Renewal Date**, **Last Renewal Date**, **License Status**, **License Status Date**, **Enquiry Email**, **Enquiry Phone Number**, **License Issue Date**, **Expiration Date/Registration Valid Until**, **Registered RTC** attributes and the Pending Change item list will no longer appear on the **Pending Changes** tab.

Registration Package Set	To successfully apply all your selected changes in the *Pending Changes* wizard, you must close the Event with the **Approved** status. This will update the **MAH/Organisation**, **Authrorisation Status**, **Authrorisation Status Date** and **Withdrawn Date** attributes for the and the Registration Package Set and the Pending Change item list will no longer appear on the **Pending Changes** tab.
Reg istration Package Set Country	To successfully apply all your selected changes in the *Pending Changes* wizard, you must close the Event with the **Approved** status. This will update the **Legal Status of Supply** attributes for the selected entity type and the Pending Change item list will no longer appear on the **Pending Changes** tab. **Note:** This option is available for MRP or DCP applications only.

Create Pending Changes

Pending Changes helps in tracking IDMP changes for Application, Medicinal Product and Registration attributes.

To create Pending Changes:

1. Navigate to the event you want to create Pending Changes.
2. On the **Pending Changes** tab, click **Create**. **Note:** The **Pending Changes** tab is only displayed if specific **Procedure Type**, **Application Type** and **Registration Type** are selected for an application. For more, see *Ennov InSight Registrations > Events > Pending Changes*.
3. On the *Create Pending Changes* page, select the entity in **Change Scope**.
4. Select the required values in the fields.
5. **Next**.The *Enter Values for Pending Changes* page appears.
6. Define the values for the Pending Changes.
7. **Next**.
8. On the *Summary* page, click **Finish**.You are returned to the *Event Attributes* page. **Note:** To apply the pending changes to an entity, close the event with the **Approved** status or use **Apply Pending Changes** option on the **Pending Changes** tab.

Apply Pending Changes

The **Apply Pending Changes** option allows to apply pending changes to an entity without closing an event.

Note: Applied pending changes are not displayed on the **Pending Changes** tab.To apply Pending Changes:

1. Navigate to the event on which you want to use **Pending Changes**.
2. On the **Pending Changes** tab, select the pending changes.

3. Click **Apply Changes** on the right corner. The confirmation message appears.
4. Click **OK**. **Note:** It is not possible to apply FPP using **Pending Changes** tab if the following fields contain the same values as the other FPPs applied to the same registration: **Concatenation of Full Product Name**, **EEA Country**, **Language**, **Package Description**, **Authorisation Status**, **Authorisation/Renewal Date**, **EVCode**.

Delete Pending Changes

You can delete the Pending Changes that are not required for an event.

You can delete a Pending Change item only when the event is in an open state. **Note:** You cannot delete a Pending Change item if an event is closed with the status as **Approved**, **Withdrawn**, or **Not Approved**.To delete a Pending Change:

1. Navigate to the event that has the Pending Change you want to delete.
2. On the **Pending Changes** tab, select the Pending Change that you want to delete.
3. Click **Delete**.A confirmation message appears.
4. **OK**.

Pending Changes and Entity Attributes

Use the following descriptions when working with Pending Changes.

Table 17. Table 1. Pending Changes Attributes

Attribute	Description
Approval Status	Current approval status of the Pending Changes.
Approval Status Date	Displays the approval status date of the event.
Attribute Name	Name of the Attribute.

17 Table 1. Pending Changes Attributes (continued)

Attribute	Description
	• For Application: **Procedure Type value** or **Legal Status of Supply** value or both. • For Registration: **MAH/Organisation**, **QPPV**, **MFL**, **Subject to Additional Monitoring**, **Next Renewal Date**, **Last Renewal Date**, **License Status**, **License Status Date**, **Enquiry Email**, **Enquiry Phone Number**. • Registration Package Set: **MAH/Organization**, **Authorisation Status**, **Authorisation Status Date**, **Withdrawn Date**. • For Registration Package Set Country: **Legal Status of Supply** • For Medicinal Product: **Pediatric Use Indicator** or **Full Indication Text** or both.
Change Value	Targeted value for the entity which needs to be updated.
Country	Name of the country selected in the **Application reviewing** field on the *Create Pending Changes* page.
Entity Name	Name of the Entity. Examples: Hyperlinked Application or Medicinal Product name.
Sub Entity Name	Name of the sub-entity. Used for Package- Set- Country only.

Table 18. Table 2. Entity Attributes for Pending Changes

Attribute	Description
Actual Launch Date	Actual date of the product launch.
Actual Submission Date	When the application is submitted.
Annual Report Date	The date that the next annual report is due. This attribute is only for a CTA and CTR application.
Application code	Agency-identified application number (or identifier). May not be available until submittal time. Hence, an internal code can be used for an application code.
Application Name	The name of the application.

Attribute	Description
Application Reviewing Coun- try	The associated country.
Autho risation Status	Regulatory Entitlement Status. The pending change result for this field can be found on the *Registration - Package Set Attributes* page.
Autho risation Status Date	Authorisation Status Date. The pending change result for this fieldbe found on the *Registration - Package Set Attributes* page.
Change Scope	Targeted entity which needs to be updated. Options are: Application, Medicinal Product, Registration, Registration Package Set, Registration Package Set Country.
Country	The European Union countries available for selection. This attribute is available on the *Pending Changes* wizard for Registration Package Set Country.
Enquiry Email	The e-mail address of the person or the agency registering the product. The pending change result for this field can be found on the *Registration Attributes* page.
Enquiry Phone Number	The phone number of the person or the agency registering the product. The pending change result for this field can be found on the *Registration Attributes* page.
Entity Type	The type of an Entity.

Full Indication Text	The medical condition that a medicine is used for. This can include the treatment, prevention and diagnosis of a disease. The pending change result for this field can be found on the *Medicinal Product Attributes* page.
Last Renewal Date	Date when it was last renewedThe pending change result for this field can be found on the *Registration Attributes* page.
Legal Status of Supply	The legal status of the medicinal product that includes the conditions and restrictions under which it should be made available to patients. The pending change result for this field can be found on the *Application Attributes* and on the *Package- Set- Country Attributes* page for Registration- Package Set.
License Status	The current renewal status. The pending change result for this field can be found on the *Registration Attributes* page.

Attribute	**Description**
License Status Date	The effective date of the status. The pending change result for this field can be found on the *Registration Attributes* page.
Medicinal Product	List of the Medicinal Products. This attribute is available on the *Pending Changes* wizard for Medicinal Product, Registration Package Set and Registration Package Set Country.
MAH/Organization	The company to which a license is given to market the product. The *Data Administration* values assigned in **Other Maintenance** > **MAH/Development Sponsor/Organisation Values**. The pending change result for this field can be found on the *Registration Attributes* and on the *Registration-Package Set Attributes* pages.
MFL (Master File Location)	The name and address information for master file location company. The pending change result for this field can be found on the *Registration Attributes* page.
Next Renewal Date	Date of the next renewal. The pending change result for this field can be found on the *Registration Attributes* page.
Pediatric Use Indicator	Indicates whether a medicinal product is authorised and explicitly intended for pediatric use. The pending change result for this field can be found on the *Medicinal Product Attributes* page.

Procedure Type	Defines the strategy being used when applying for market approval. The pending change result for this field can be found on the *Application Attributes* page.
QPPV	List of the Qualified Person for Pharmacovigilance (QPPV). The pending change result for this field can be found on the *Registration Attributes* page.
Registrations	List of the Registrations. This attribute is available on the *Pending Changes* wizard for Medicinal Product, Registration, Registration Package Set and Registration Package Set Coun- try.
Subject to Additional Monitoring	Indicates whether the product requires close monitoring. The pending change result for this field can be found on the *Registration Attributes* page.
Attribute	**Description**
Withdrawn Date	The date that a registration package set was withdrawn. The pending change result for this field can be found on the *Registration - Package Set Attributes* page.

Close an Event

Warning: Closing an event can affect several entities. The application, products, product detail sets, pending product detail set details, sequences, and change details associated to this event will be updated appropriately. Prior to closing an event, please ensure that you want all associations to be updated. **Note:** In *Data Administration*, if **Yes** is selected in the **System Process Default Flag** field, each display status shows the value specified in its **Name** field.To close an event:

1. Navigate to the event you want to close and click the link for the event.
2. On the *Event Attributes* page, click **Edit**.
3. On the *Modify Event* page, click **Closed**. **Note:** When you close the event, the status schedules associated with the event can be locked or unlocked. The closed date cannot be greater than today's date.
4. Select the **Closed Date**.
5. Select the **Associations Closed As** status.
6. **Save**.
7. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	**Steps**
When electronic signature is en- abled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

When an Event is closed as Approved, meaning the **Associations Closed As** field is set to APPROVED, and the PDS associated to this Event has a withdrawn Country Detail displayed as **Country (Pending Withdrawal)**:

- The **Country Status** field of this country is automatically set to Approved and this country is displayed as **Country (Withdrawn)** in the PDS Tree on the left.
- As an additional rule, the parent **Application Country** > **Withdrawn Date** field is automatically updated to be equal to **Event** > **Closed Date** value. The same rule applies to the parent Application Country when the **Country (Pending Withdrawal)** PDS Detail is modified and the **Country Status** field is set to Approved. See *If the Event Is Closed with the Status Approved*.

Lock One or More Event-Country Status Schedules

You can lock an event-country status schedule to prevent changes. You must have the necessary WRITE privileges. You can perform this action when the event is open or closed.To lock one or more event-country status schedules:

1. View the event you want to modify.
2. On the **Countries** tab, select the countries you want to lock.
3. Click **Lock**.**Yes** is displayed under **Status Schedule Locked**, indicating that the status schedules for each of the countries selected in step 2 are locked.

If the Event Is Closed with the Status Approved

When you close an event, you set a closing date and select a status for the closed event. The status can be **Approved**, **Not Approved**, or **Withdrawn**.

The status of the event affects associated entities. If you use the *GPP* wizard to close an event associated with a Withdraw Product Package Set Registrations project, results are different than those described here.**Note:** In *Data Administration*, if **Yes** is selected in the **System Process Default Flag** field, each display status shows the value specified in its **Name** field.

Entity	**Entity Status Before Event Is Closed**	**Entity Status After Event Is Closed**	**Entity Status Date After Event Is Closed**
Application	Any	The Termination/Withdrawal reason on the application is auto-populated with the Termination/Withdrawal reason selected on the Event.	**Event** > **Closed Date**

EventChange Detail	Not mapped to the internal event-change detail status Not Approved, or Withdrawn	Status mapped to the internal event-change detail status Approved	N/A
EventProduct	Not mapped to the internal event-product status Approved, Not Approved, or Withdrawn	Status mapped to the internal event-product status Approved	**Event > Closed Date**
Product Detail Set	Not mapped to the internal PDS status Approved, Not Approved, or Withdrawn	Status mapped to the internal PDS status Ap- proved	**Event > Closed Date**
Country PDS Detail	Pending (**Country (Pending Withdrawal)**)	Approved (**Country (Withdrawn)**)	**Event > Closed Date**
Entity	**Entity Status Before Event Is Closed**	**Entity Status After Event Is Closed**	**Entity Status Date After Event Is Closed**
Product Detail	Pending Add, Pending Modify, or Pending Withdraw	Approved	**Event > Closed Date**
Sequence	Any	Status mapped to the internal Sequence status.	**Event > Closed Date**

Other Results

For an application, if the original approval date was not entered it is set to the event closed date.

When an Event is closed as Approved and the PDS associated to this Event has a withdrawn Country Detail, displayed as **Country (Pending Withdrawal)**, the parent **Application Country** > **Withdrawn Date** field is automatically updated to be equal to the **Event** > **Closed Date** field value. The following explains specific conditions that govern the **Application Country** > **Withdrawn Date** field change:

- If Application Country does not have the Withdraw Date value and the Event is closed with today's date, -1 day (or more) before today's date, or +1 after today's date, then the **Application Country** > **Withdraw Date** inherits the **Event** > **Event Closed Date** value.
- If Application Country has the **Withdraw Date** field set to today's date and the Event is closed with -1 day (or more) before today's date, or +1 day after today's date, then the **Application Country** > **Withdraw Date** inherits the **Event** > **Event Closed Date** value.
- If Application Country has the **Withdraw Date** field set to a date greater then +2 days (or more) after today's date and the Event is closed with today's date, -1 day (or more) before today's date, or +1 day after today's date, then the **Application Country** > **Withdraw Date** inherits the **Event** > **Event Closed Date** value.

The **Application Country** > **Withdraw Date** is not updated, if:

- The **Application Country** > **Withdraw Date** value precedes the **Event** > **Event Closed Date** value and both dates are in the past.
- The **Application Country** > **Withdraw Date** value is equal to the **Event** > **Event Closed Date** value.
- The **Application Country** > **Withdraw Date** is set to today's date -1 day and the **Event** > **Event Closed Date** is set to today's date.

If the Event Is Closed with the Status Not Approved

When you close an event, you set a closing date and select a status for the closed event. The status can be **Approved**, **Not Approved**, or **Withdrawn**.

The status of the event affects associated entities. If you use the *GPP* wizard to close an event associated with a

Withdraw Product Package Set Registrations project, results are different than those described here. **Note:** In *Data Administration*, if **Yes** is selected in the **System Process Default Flag** field, each display status shows the value specified in its **Name** field.

Entity	Entity Status Before Event Is Closed	Entity Status After Event Is Closed	Entity Status Date After Event Is Closed
Application	Any	The Termination/Withdrawal reason on the application is auto-populated with the Termination/Withdrawal reason selected on the Event.	**Event** > **Closed Date**

EventChange Detail	Any	Status mapped to the internal event-change detail status Not Approved	N/A
EventProduct	Not mapped to the internal event-product status **Approved**, **Not Approved**, or **Withdrawn**	Status mapped to the internal event-product status Not Approved	**Event** > **Closed Date**
Product Detail Set	Not mapped to the internal PDS status **Approved**, **Not Approved**, or **Withdrawn**	Status mapped to the internal PDS status Not Approved	**Event** > **Closed Date**
Product De tail	**Pending Add**, **Pending Modify**, or **Pending Withdraw**	The status Not Approved	**Event** > **Closed Date**
Sequence	Any status that is not **Planned**	Status mapped to the internal Sequence status.	**Event** > **Closed Date**, except for sequences mapped to an internal status of **Planned**.

Other Results

For an application, the termination/withdraw date and termination/withdraw reason are not set.

If the Event Is Closed with the Status Withdrawn

When you close an event, you set a closing date and select a status for the closed event. The status can be **Approved**, **Not Approved**, or **Withdrawn**.

The status of the event affects associated entities. If you use the *GPP* wizard to close an event associated with a

Withdraw Product Package Set Registrations project, results are different than those described here. **Note:** In *Data Administration*, if **Yes** is selected in the **System Process Default Flag** field, each display status shows the value specified in its **Name** field.

Entity	Entity Status Before Event Is Closed	Entity Status After Event Is Closed	Entity Status Date After Event Is Closed
Application	Any status that is not mapped to the internal status of **Approved**, **Not Approved**, or **Withdrawn**	The Termination/Withdrawal reason on the application is auto-populated with the Termination/Withdrawal reason selected on the Event.	**Event** > **Closed Date**
EventChange Detail	Any	Status mapped to the internal event-change detail status Withdrawn	N/A
EventProduct	Not mapped to the internal event-product status **Approved**, **Not Approved**, or **Withdrawn**	Status mapped to the internal event-product status Withdrawn	**Event** > **Closed Date**
Product Detail Set	Not mapped to the internal PDS status **Approved**, **Not Approved**, or **Withdrawn**	Status mapped to the internal PDS status Withdrawn	**Event** > **Closed Date**
Product De tail	**Pending Add**, **Pending Modify**, or **Pending**, or **Withdraw**	The status Not Approved	**Event** > **Closed Date**
Sequence	Any status that is not **Planned**	Status mapped to the internal Sequence status.	**Event** > **Closed Date**, except for sequences mapped to an internal status of **Planned**

Unlock One or More Event-Country Status Schedules

You can unlock an event-country status schedule to make changes. You can perform this action when the event is open or closed.

You must have the necessary WRITE privileges. To unlock one or more event-country status schedules:

1. View the event you want to modify.
2. On the **Countries** tab, select one or more countries that you want to unlock.
3. Click **Unlock**. No is displayed under **Status Schedule Locked**, indicating that the countries selected in step 2 are unlocked.

Delete an Event

You can delete an event in specific circumstances, and if you have the appropriate security privileges.

You cannot delete an event if the event is associated with one or more of the following:

- Registration (product type only)
- Project
- Sequence
- Assembly
- Product detail set
- Task
- Reference
- Notification

After deleting an event, disassociated products are not deleted from Ennov InSight , since a product can be associated to more than one event.

To delete an event:

1. Navigate to the event you want to delete.
2. Click a link for the event you want to delete.The *Event Attributes* page opens.
3. Click **Delete**.
4. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	**Steps**
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Event-Country Statuses, Actual Dates, Projected Dates, and Lead Times

Users with WRITE privileges for an event can set or change the event-country status, projected dates, and the actual status date for countries associated with an event.

Event-country statuses, such as Submitted, Approved, Not Approved, or Withdrawn indicate the current state of an application for an event country.

The default set of statuses available in Ennov InSight can be changed by your system administrator to tailor them to your company workflow. Event-Country statuses are tracked individually for each country associated with an event.

Projected dates with their specified lead times are used for planning. When you add a projected date, you establish a milestone for a particular status that is expected to occur on a specific date. Lead times are used as a planning tool for calculating projected dates. Lead times enable you to set expectations for completion using the number of days, so the system can calculate the dates for you.

Actual dates are a record of when an event-country status change actually occurs. While you can set projected status dates to any time in the future for planning, you can only set the actual status date to a prior date, the current date, or to the day after the current date for countries located in time zones a day ahead of your location.

If you modify the status schedule for one country associated with an event, the changes for that country do not affect the timeline/event plan (if one was used to create the event) or the status schedules for any other country associated with the event, unless you explicitly choose to do so.

You can set or change event-country statuses, projected dates, and actual status dates individually by country on the country's **Status Dates** tab, or set them using one of the available update wizards. When you use the *Update Event Country Status* wizard or the Update Event Country Status Projected Dates wizard, you can make your status or date changes for several countries, rather than just one at a time using the options available on the **Status Dates** tab.

Status Dates Tab

The **Status Dates** tab is accessible by selecting a country listed on the **Countries** tab on the *Event Attributes* page for an event. This tab contains the event-country status schedule that lists the statuses defined for an event for the country selected. The lead time (expressed in days) determines when an event-country status is expected to occur based on the previous status in the status schedule.

If you used a timeline/event plan to create the event:

- All the statuses (except optional statuses) defined for the selected timeline/event plan are displayed.
- If the application associated with the event is a National or MRP procedure type application, the lead times displayed are those defined in the selected timeline/event plan for the reviewing country on the application. If lead times were not defined for the reviewing country in the selected timeline/event plan, lead times are not displayed
- If the application associated with the event is a CP procedure type application, the lead times displayed are those defined in the selected timeline/event plan for an EU or WAHO country. If lead times were not defined for an EU or WAHO country in the selected timeline/event plan, lead times are not displayed.

When the projected status date for one status is defined, the projected dates for the other statuses can be automatically calculated based on the lead times by using the **Calculate Projected Dates** icon.

Update Wizards

The *Update Event Country Status Projected Dates* wizard and the Update Event Country Status wizard enable you to update the status or projected dates for one or more countries associated with an event. You can invoke these wizards from the **Countries** tab of the *Event Attributes* page, rather than the **Status Dates** tab. These wizards minimize the number of steps you need to take to change statuses and their associated actual or projected dates.

Updating Event-Country Status for Projects

In addition to updating the event-country status and dates for an application event, you can also change them for a project event. This process is performed from the *View Project* page. You can update event-country status for specific countries, just as you can in the *Update Status* wizard.

Update Wizards

The *Update Event Country Status Projected Dates* wizard and the Update Event Country Status wizard enable you to update the status or projected dates for one or more countries associated with an event. You can invoke these wizards from the Countries tab of the *Event Attributes* page, rather than the Status Dates tab. These wizards minimize the number of steps you need to take to change statuses and their associated actual or projected dates.

Updating Event-Country Status for Projects

In addition to updating the event-country status and dates for an application event, you can also change them for a project event. This process is performed from the *View Project* page. You can update event-country status for specific countries, just as you can in the *Update Status* wizard.

Add an Event-Country Status

If you have WRITE privileges for events, you can add an event-country status for an application event. When adding an event-country status you can also add the lead time, projected date, and actual date of occurrence.

Changes made to the event-country status schedule for one country do not affect the event-country status schedules for other countries associated with the event, or the timeline/event plan if one was used to create the event.

If you want to change the event-country status, actual dates, or projected dates for several countries at one time, use the *Update Event Country Status* wizard or the *Update Event Country Status Projected Dates* wizard.

To add an event-country status:

1. View the event you want to modify.
2. On the Countries tab, click the link for the country that has the status schedule that you want to modify.

   The *Event-Country Attributes page* opens to the Status Dates tab.
3. Click Create.

   The *Add Event Country Status* page opens.
4. Select the Event-Country Status that you want to add.

   The list of available values is limited to those applicable to the event that have not already been added to the current schedule. Event-country status values are established by your data administrator.

   Note: *If the event was created from a timeline/event plan, you can only add optional statuses to the schedule.*

   You cannot track projected dates and lead times for an optional status.

5. Optionally, you can do any of the following: — Enter a lead time for the selected status.

   — Select an actual date for the event status.

   Note: *As the preceding step notes, a timeline/event plan that enforces status progression can restrict the event-country status. Such a timeline/event plan also restricts the dates from which you select the status date for a primary status after the first primary status. The dates from which you select are the date for the preceding primary status and later dates.*

   — Select a projected date for the event status.

6. Select a reason and enter comments for the reason.
7. Save.
8. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Event-Country Status Attributes

Use the following descriptions to enter and modify attribute values.

Attribute	Description
Actual Date	The date the status became effective.
Application Code	Agency-identified application number (or identifier), which may not be known until submission, so it may be the same as the internal code.
Attribute	Description
Application Internal Code	Application with which the event is associated.
Application Name	The name of the application.
Event Code	The event identification code established when the event was created.
Event Name	The name of the event established when the event was created.

Event Country Status	If the event was created by using a timeline/event plan, only the statuses defined for the timeline/event plan can appear in the drop-down list. You can add or modify an event-country status for a planned event that enforces status progression. When you add or modify a status for such an event, the statuses are limited to the next status as defined in the progression and optional statuses. If the event is not associated with a timeline/event plan, all the statuses defined in the system that are not already associated with the event country appear in the drop-down list.
	The current status has the most recent actual date. When more than one status in the schedule has the same most recent actual date the last modified date will be used to distinguish the current status. When more than one status exists with the same most recent actual date and the same most recent last modified date, the sequence order will be used to distinguish the current status.
Event-Country Status Comments	Comments entered when you add or modify the Event-Country Status.
Family Code	The code for the product family associated with the application.
Family Name	The name of the product family associated with the application.
Lead Time	The interval of days expected to occur between a status and the preceding status in the event-country status schedule.
Projected Date	The date the status is expected to become effective.
Reason	Reason for creating, modifying or deleting an Event-Country Status.
Reason for Comments	Comments related to reason entered by users.
Status Date	The date that the status becomes effective. You can update an event-country status for a planned event that enforces status progression. A planned event that enforces status progression restricts the date selection to the date for the preceding status in the progression and later dates.

Modify an Event-Country Status

You can modify the event-country status, including lead time, projected date, or actual date for an event-country status.

To modify an event-country status, at least one status must have an actual status date.

Note: *Do not change the event-country status more than once in the same day. If you do this, the Country Schedules tab on the Event Attributes page shows the current status, but the Countries tab on this page does not.*

To modify an event-country status:

1. View the event you want to modify.
2. On the Countries tab, click the link for the country you want to modify.

3. On the Status Dates tab, select the event-country status that you want to modify.
4. Click Edit.

   The *Modify Event Country Status* page opens.

5. Change the lead time, projected date, and actual date values as needed.
6. Add comments about the reason the status was changed.
7. Save.
8. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Use the Update Event-Country Status Wizard

You can use the *Update Event Country Status* wizard to update the event country status individually by country or to update several countries at the same time.

When you use the wizard, you can select event countries associated with an event that you have permissions to change, set the new status, and the status date.

Note: *You can change the event country status for unlocked countries associated with an open or closed event. At least one country associated with the event must be unlocked to run the wizard.*

To use the *Update Event-Country Status* wizard:

1. Navigate to the event you want to update.

   The *Event Attributes* page appears with the Countries tab active.

2. Click Update Event-Country Status to open the *Update Event Country Status* wizard.
3. Select one or more countries on the *Select Event Countries* page.
4. Click Next.

   The *Enter Event Country Status Values* page appears.

5. Do the following:

a. Select the event-country status.

Note: *You can update an event-country status for a planned event that enforces status progression. For such an event, the only statuses available for selection are optional statuses and the next primary status in the sequence of primary statuses defined in the timeline/event plan.* b. Select a status date.

Note: *As the preceding item notes, planned events that enforce status progression can restrict the event-country status. Such an event also restricts the status date selection. You can select the date for the preceding primary status and later dates.*

- 1. If you want to lock the event-country schedule for the selected countries after the event-country status is updated, select Yes for Lock the Event-Country Schedule?.
  2. If you want to close the event after the event-country status is updated, select Yes for Close Event?. If the event is closed, the status of related entities (application, event, sequence, and PDS) are updated.

     Note: *If you set Associations Closed As to WITHDRAWN, the Application Status will be set to*

     Withdrawn only when all Registrations associated to this Application have a status mapped to internal WITHDRAWN status. Otherwise, the following warning message appears: ! Associated Registration(s) must be Withdrawn prior to the Application.

     If the Event is closed as Approved, meaning it has the Association Closed As field set to APPROVED, the

     Application Country > Withdrawn Date field is automatically updated to be equal to Event Closed Date value. This rule is applicable to an event that has an associated PDS with this country assigned to a Country PDS Detail, and this country has a Withdrawn status, meaning it is displayed as Country (Pending Withdrawal) in the PDS tree. See *If the Event Is Closed with the Status Approved*.
  3. Optionally, add a comment that will appear on the event and sequence entities affected by this update.

1. Click Next.

A confirmation page lists the changes that will occur if you proceed.

1. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	1. In the confirmation page, select a reason and enter comments for the reason. 2. Click Next. 3. Validate your identity by entering your user credentials in the dialog box.

1. Click Finish.

After the wizard finishes, the event-country status is changed for the selected countries and the selected status date is applied. If you close the event, the status of related entities (application, event, sequence, and PDS) are updated. If you lock all countries associated with an event, the status and status date selected while using the wizard become the status and status date for the event. Additional changes occur for other entities.

Delete an Event-Country Status

You can delete an event-country status in certain circumstances. You cannot delete an event-country status if the country is locked, the status is the current status for the event, if only one event-country status is listed.

To delete an event-country status:

1. View the event you want to modify.
2. On the Countries tab, click the link for the country.
3. On the Status Dates tab, select the event-country status that you want to delete.
4. Click Delete.

   A confirmation message appears.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Calculate Projected Dates

Ennov InSight can calculate the projected dates for the statuses in the event-country status schedule based on the lead times and the projected date defined for the status that you designate as the pivot status.

The projected date for the pivot status is the date used to calculate the projected dates of the other statuses in the event-country status schedule.

Note: *If the event was created from a timeline/event plan, you cannot calculate projected dates based on a status that was defined as an optional status in the timeline/event plan.*

You can calculate projected dates individually by country as described in the instructions below, or set them for one or more countries using the *Update Event Country Status Projected Dates* wizard.

To calculate projected dates:

1. View the *Event Attributes* page for the event you want to modify.
2. On the Countries tab, click the link for country that you want to modify.
3. On the Status Dates tab, select the status you want to use as the pivot status. The status must have a projected date.
4. Click Calculate Projected Dates.

   The *Calculate Projected Dates* page opens.
5. For Pivot Operation, select one of the following:

— Select Backward to calculate the projected dates based on the lead times for the statuses before the selected pivot status in the event-country status schedule.

— Select Forward to calculate the projected dates based on the lead times for the statuses after the selected pivot status in the event-country status schedule.

— Select Both to calculate the projected dates based on the lead times for the statuses before and after the selected pivot status in the event-country status schedule.

6. Save.
7. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Use the Update Event Country Status Projected Dates Wizard

You can create or update projected dates for one or more event countries using the *Update Event Country Status Projected Dates* wizard.

Projected date planning is based on lead times set for each status. You select a pivot status, such as Submitted or Approved and enter a date for that status to enable the system to work forward, backward (or both) to calculate planned dates for other statuses.

Note: *If the event was created from a timeline/event plan, you cannot calculate projected dates based on a status that was defined as an optional status in the timeline/event plan.*

Only the event countries for which you have at least WRITE permissions are present for selection in the wizard. The wizard is only available if there is at least one unlocked event country schedule associated with the event. This wizard can only be used for events created from a timeline/event plan.

To use the *Update Event Country Status Projected Dates* wizard:

1. Navigate to the event you want to update.

   The *Event Attributes* page opens with the Countries tab active.

2. Click Calculate Projected Dates.

   The *Update Event Country Status Projected Dates* wizard opens.

3. Select one or more countries on the *Select Event Countries* page.
4. Click Next.

The *Enter Event-Country Status Values* page opens.

5. Do the following:
    a. Select the event-country pivot status.
    b. Change the projected date, if needed. The default is the current date.
    c. Select a pivot operation.
6. Click Next.
7. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	1. In the confirmation page, select a reason and enter comments for the reason. 2. Click Next. 3. Validate your identity by entering your user credentials in the dialog box.

Event-Country Status Rules

When the event-country status is associated with an event, several conditions apply when the event-country status is changed using the *Update Event Country Status* wizard.

Rules for Planned Events

For events created by using a timeline/event plan, if an optional status was selected, the event country schedule is updated with the optional status and the status date you selected when using the wizard.

You can update an event-country status for a planned event that enforces status progression. For such an event:

— Only one primary status is available for you to select. This status is next in the sequence of primary statuses defined in the timeline/event plan. Optional statuses are also available for selection.

— The planned event also restricts the status date for an event country schedule. The date cannot be earlier than the preceding status in the progression. **Rules for Events and Associated Entities**

If you selected a status of Approved, Not Approved, or Withdrawn (or statuses that map to those internal statuses) and the event is not closed:

If you selected Approved, Not Approved, or Withdrawn (or a status that maps to those internal statuses) and the event is closed:

— Only the event country status and status dates for the selected countries will be updated.

— The status and status date do not change for the associated applications, PDSs, PDS details, and sequences.

— The associations closed status becomes the last status selected in the wizard for the event countries.

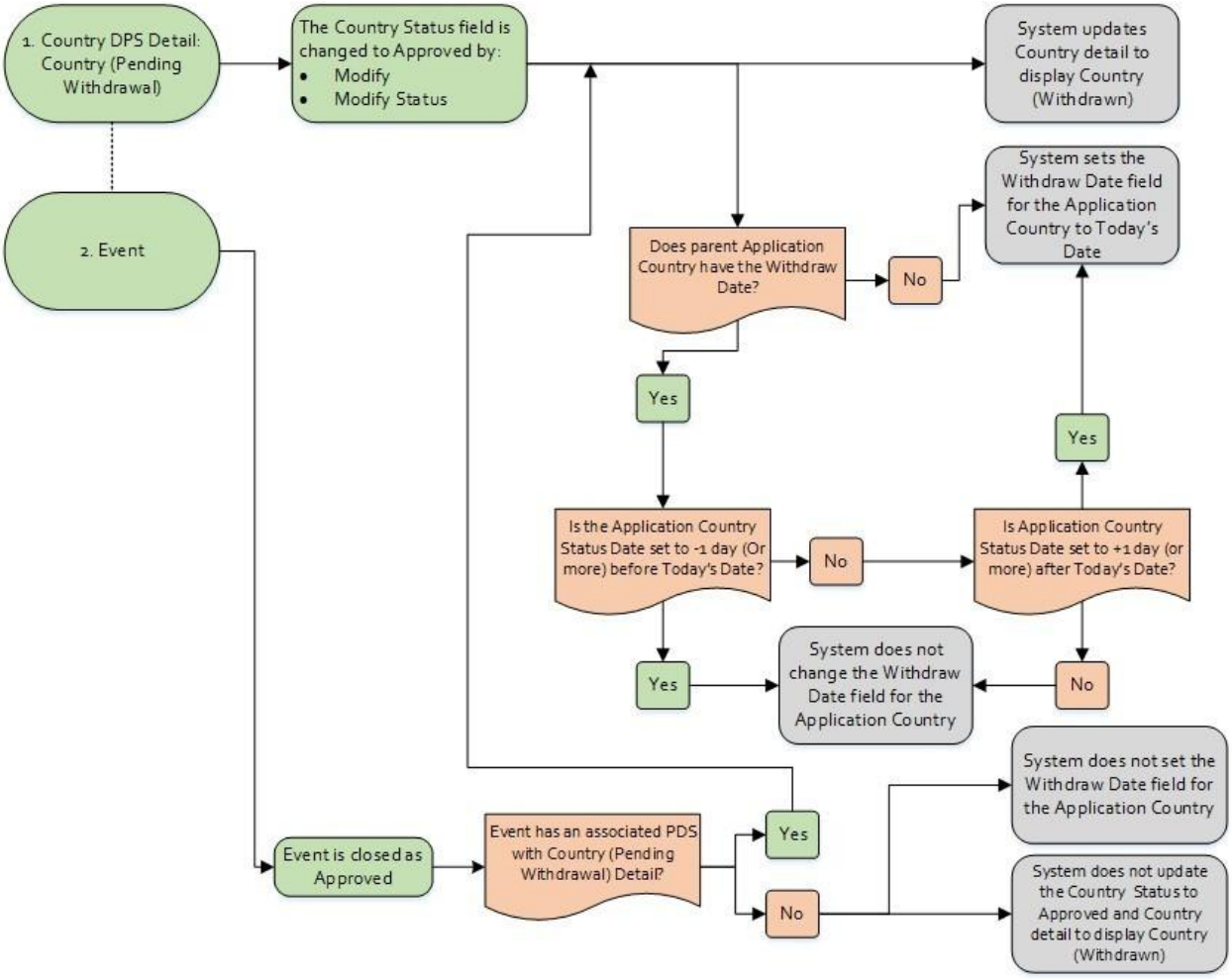
— The closed date becomes the status date selected in the wizard.

— Upon closing the event, associated entities are also affected, including the application, product detail set, and sequences.

— When an Event is closed as Approved, meaning the Associations Closed As field is set to APPROVED, and the PDS associated to this Event has a withdrawn Country Detail, displayed as Country (Pending

Withdrawal), the Country Status field of this country is automatically set to Approved and this country is displayed as

Country (Withdrawn) in the PDS Tree on the left. As an additional rule, the parent Application Country > Withdrawn Date field is automatically updated to be equal to Today's Date. The same rule applies to the Application Country when the Country (Pending Withdrawal) Detail is modified and the Country Status field is set to Approved. See the following flowchart diagram.



Note: *The Application Country > Withdrawn Date field is updated only if there is no withdraw date populated, or the withdraw date is set to +1 day (or more) after Today's Date.*

Reorder Statuses in the Event-Country Status Schedule

For a planned event that does not enforce status progression, you can change the order of the statuses for the country. The status order affects the calculation of projected dates. The projected dates are based on the lead time of the previous status in the status schedule.

To reorder event statuses:

1. View the event you want to modify.
2. On the Countries tab, click the name of the country that has the event-country status schedule that you want to reorder.
3. Click Reorder.

   The *Reorder Statuses* page opens.
4. In the Statuses field, select the status you want to move and then click up or down to change its place in the order.
5. Save.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Add an Event-Country Status

If you have WRITE privileges for events, you can add an event-country status for an application event. When adding an event-country status you can also add the lead time, projected date, and actual date of occurrence.

Changes made to the event-country status schedule for one country do not affect the event-country status schedules for other countries associated with the event, or the timeline/event plan if one was used to create the event.

If you want to change the event-country status, actual dates, or projected dates for several countries at one time, use the *Update Event Country Status* wizard or the *Update Event Country Status Projected Dates* wizard.

To add an event-country status:

1. View the event you want to modify.
2. On the **Countries** tab, click the link for the country that has the status schedule that you want to modify.The *Event-Country Attributes page* opens to the **Status Dates** tab.
3. Click **Create**.The *Add Event Country Status* page opens.
4. Select the **Event-Country Status** that you want to add. The list of available values is limited to those applicable to the event that have not already been added to the current schedule. Event-country status values are established by your data administrator. **Note:** If the event was created from a timeline/event plan, you can

only add optional statuses to the schedule. You cannot track projected dates and lead times for an optional status.

5. Optionally, you can do any of the following:

   ◦ Enter a lead time for the selected status.

   ◦ Select an actual date for the event status. **Note:** As the preceding step notes, a timeline/event plan that enforces status progression can restrict the event-country status. Such a timeline/event plan also restricts the dates from which you select the status date for a primary status after the first primary status. The dates from which you select are the date for the preceding primary status and later dates.

   ◦ Select a projected date for the event status.

6. Select a reason and enter comments for the reason.
7. **Save**.
8. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Event-Country Status Attributes

Use the following descriptions to enter and modify attribute values.

Attribute	Description
Actual Date	The date the status became effective.
Application Code	Agency-identified application number (or identifier), which may not be known until submission, so it may be the same as the internal code.
Application Internal Code	Application with which the event is associated.
Application Name	The name of the application.

Event Code	The event identification code established when the event was created.
Event Name	The name of the event established when the event was created.

Attribute	**Description**
Event Country Status	If the event was created by using a timeline/event plan, only the statuses defined for the timeline/event plan can appear in the drop-down list. You can add or modify an event-country status for a planned event that enforces status progression. When you add or modify a status for such an event, the statuses are limited to the next status as defined in the progression and optional statuses. If the event is not associated with a timeline/event plan, all the statuses defined in the system that are not already associated with the event country appear in the drop-down list.The current status has the most recent actual date. When more than one status in the schedule has the same most recent actual date the last modified date will be used to distinguish the current status. When more than one status exists with the same most recent actual date and the same most recent last modified date, the sequence order will be used to distinguish the current status.
EventCountry Status Comments	Comments entered when you add or modify the Event-Country Status.
Family Code	The code for the product family associated with the application.
Family Name	The name of the product family associated with the application.
Lead Time	The interval of days expected to occur between a status and the preceding status in the event-country status schedule.

Projected Date	The date the status is expected to become effective.
Reason	Reason for creating, modifying or deleting an Event-Country Status.
Reason for Comments	Comments related to reason entered by users.
Status Date	The date that the status becomes effective. You can update an event-country status for a planned event that enforces status progression. A planned event that enforces status progression restricts the date selection to the date for the preceding status in the progression and later dates.

Modify an Event-Country Status

You can modify the event-country status, including lead time, projected date, or actual date for an event-country status.

To modify an event-country status, at least one status must have an actual status date.**Note:** Do not change the event-country status more than once in the same day. If you do this, the **Country Schedules** tab on the *Event Attributes* page shows the current status, but the **Countries** tab on this page does not.To modify an event-country status:

1. View the event you want to modify.
2. On the **Countries** tab, click the link for the country you want to modify.
3. On the **Status Dates** tab, select the event-country status that you want to modify.
4. Click **Edit**.The *Modify Event Country Status* page opens.
5. Change the **lead time**, **projected date**, and **actual date** values as needed.
6. Add comments about the reason the status was changed.
7. **Save**.
8. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	**Steps**
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Use the Update Event-Country Status Wizard

You can use the *Update Event Country Status* wizard to update the event country status individually by country or to update several countries at the same time.

When you use the wizard, you can select event countries associated with an event that you have permissions to change, set the new status, and the status date. **Note:** You can change the event country status for unlocked countries associated with an open or closed event. At least one country associated with the event must be unlocked to run the wizard.To use the *Update Event-Country Status* wizard:

1. Navigate to the event you want to update.The *Event Attributes* page appears with the **Countries** tab active.
2. Click **Update Event-Country Status** to open the *Update Event Country Status* wizard.
3. Select one or more countries on the *Select Event Countries* page.
4. Click **Next**.The *Enter Event Country Status Values* page appears.
5. Do the following:
    a. Select the event-country status. **Note:** You can update an event-country status for a planned event that enforces status progression. For such an event, the only statuses available for selection are optional statuses and the next primary status in the sequence of primary statuses defined in the timeline/event plan.
    b. Select a status date. **Note:** As the preceding item notes, planned events that enforce status progression can restrict the event-country status. Such an event also restricts the status date selection. You can select the date for the preceding primary status and later dates.
    c. If you want to lock the event-country schedule for the selected countries after the event-country status is updated, select **Yes** for **Lock the Event-Country Schedule?**.
    d. If you want to close the event after the event-country status is updated, select **Yes** for **Close Event?**. If the event is closed, the status of related entities (application, event, sequence, and PDS) are updated. **Note:** If you set **Associations Closed As** to WITHDRAWN, the Application Status will be set to Withdrawn only when all Registrations associated to this Application have a status mapped to internal WITHDRAWN status. Otherwise, the following warning message appears: ! Associated Registration(s) must be Withdrawn prior to the Application.

        If the Event is closed as Approved, meaning it has the **Association Closed As** field set to APPROVED, the **Application Country** > **Withdrawn Date** field is automatically updated to be equal to **Event Closed Date** value. This rule is applicable to an event that has an associated PDS with this country assigned to a Country PDS Detail, and this country has a Withdrawn status, meaning it is displayed as **Country (Pending Withdrawal)** in the PDS tree. See *If the Event Is Closed with the Status Approved*.

    e. Optionally, add a comment that will appear on the event and sequence entities affected by this update.
6. Click **Next**.A confirmation page lists the changes that will occur if you proceed.
7. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Finish**.After the wizard finishes, the event-country status is changed for the selected countries and the selected status date is applied. If you close the event, the status of related entities (application, event, sequence, and PDS) are updated. If you lock all countries associated with an event, the status and status date selected while using the wizard become the status and status date for the event. Additional changes occur for other entities.

Delete an Event-Country Status

You can delete an event-country status in certain circumstances. You cannot delete an event-country status if the country is locked, the status is the current status for the event, if only one event-country status is listed.

To delete an event-country status:

1. View the event you want to modify.
2. On the **Countries** tab, click the link for the country.
3. On the **Status Dates** tab, select the event-country status that you want to delete.
4. Click **Delete**.A confirmation message appears.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Calculate Projected Dates

Ennov InSight can calculate the projected dates for the statuses in the event-country status schedule based on the lead times and the projected date defined for the status that you designate as the pivot status.

The projected date for the pivot status is the date used to calculate the projected dates of the other statuses in the event-country status schedule.**Note:** If the event was created from a timeline/event plan, you cannot calculate projected dates based on a status that was defined as an optional status in the timeline/event plan.

You can calculate projected dates individually by country as described in the instructions below, or set them for one or more countries using the *Update Event Country Status Projected Dates* wizard.

To calculate projected dates:

1. View the *Event Attributes* page for the event you want to modify.
2. On the **Countries** tab, click the link for country that you want to modify.
3. On the **Status Dates** tab, select the status you want to use as the pivot status. The status must have a projected date.
4. Click **Calculate Projected Dates**.The *Calculate Projected Dates* page opens.
5. For **Pivot Operation**, select one of the following:

   ◦ Select **Backward** to calculate the projected dates based on the lead times for the statuses before the selected pivot status in the event-country status schedule.

   ◦ Select **Forward** to calculate the projected dates based on the lead times for the statuses after the selected pivot status in the event-country status schedule.

   ◦ Select **Both** to calculate the projected dates based on the lead times for the statuses before and after the selected pivot status in the event-country status schedule.

6. **Save**.
7. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Use the Update Event Country Status Projected Dates Wizard

You can create or update projected dates for one or more event countries using the *Update Event Country Status Projected Dates* wizard.

Projected date planning is based on lead times set for each status. You select a pivot status, such as **Submitted** or **Approved** and enter a date for that status to enable the system to work forward, backward (or both) to calculate planned dates for other statuses.**Note:** If the event was created from a timeline/event plan, you cannot calculate projected dates based on a status that was defined as an optional status in the timeline/event plan.

Only the event countries for which you have at least WRITE permissions are present for selection in the wizard. The wizard is only available if there is at least one unlocked event country schedule associated with the event. This wizard can only be used for events created from a timeline/event plan.

To use the *Update Event Country Status Projected Dates* wizard:

1. Navigate to the event you want to update.The *Event Attributes* page opens with the **Countries** tab active.
2. Click **Calculate Projected Dates**.The *Update Event Country Status Projected Dates* wizard opens.
3. Select one or more countries on the *Select Event Countries* page.
4. Click **Next**.The *Enter Event-Country Status Values* page opens.
5. Do the following:
    a. Select the event-country pivot status.
    b. Change the projected date, if needed. The default is the current date.
    c. Select a pivot operation.
6. Click **Next**.
7. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	1. In the confirmation page, select a reason and enter comments for the reason. 2. Click **Next**. 3. Validate your identity by entering your user credentials in the dialog box.

Event-Country Status Rules

When the event-country status is associated with an event, several conditions apply when the event-country status is changed using the *Update Event Country Status* wizard.

Rules for Planned Events

For events created by using a timeline/event plan, if an optional status was selected, the event country schedule is updated with the optional status and the status date you selected when using the wizard.

You can update an event-country status for a planned event that enforces status progression. For such an event:

- Only one primary status is available for you to select. This status is next in the sequence of primary statuses defined in the timeline/event plan. Optional statuses are also available for selection.
- The planned event also restricts the status date for an event country schedule. The date cannot be earlier than the preceding status in the progression.

Rules for Events and Associated Entities

If you selected a status of **Approved**, **Not Approved**, or **Withdrawn** (or statuses that map to those internal statuses) and the event is not closed:

If you selected **Approved**, **Not Approved**, or **Withdrawn** (or a status that maps to those internal statuses) and the event is closed:

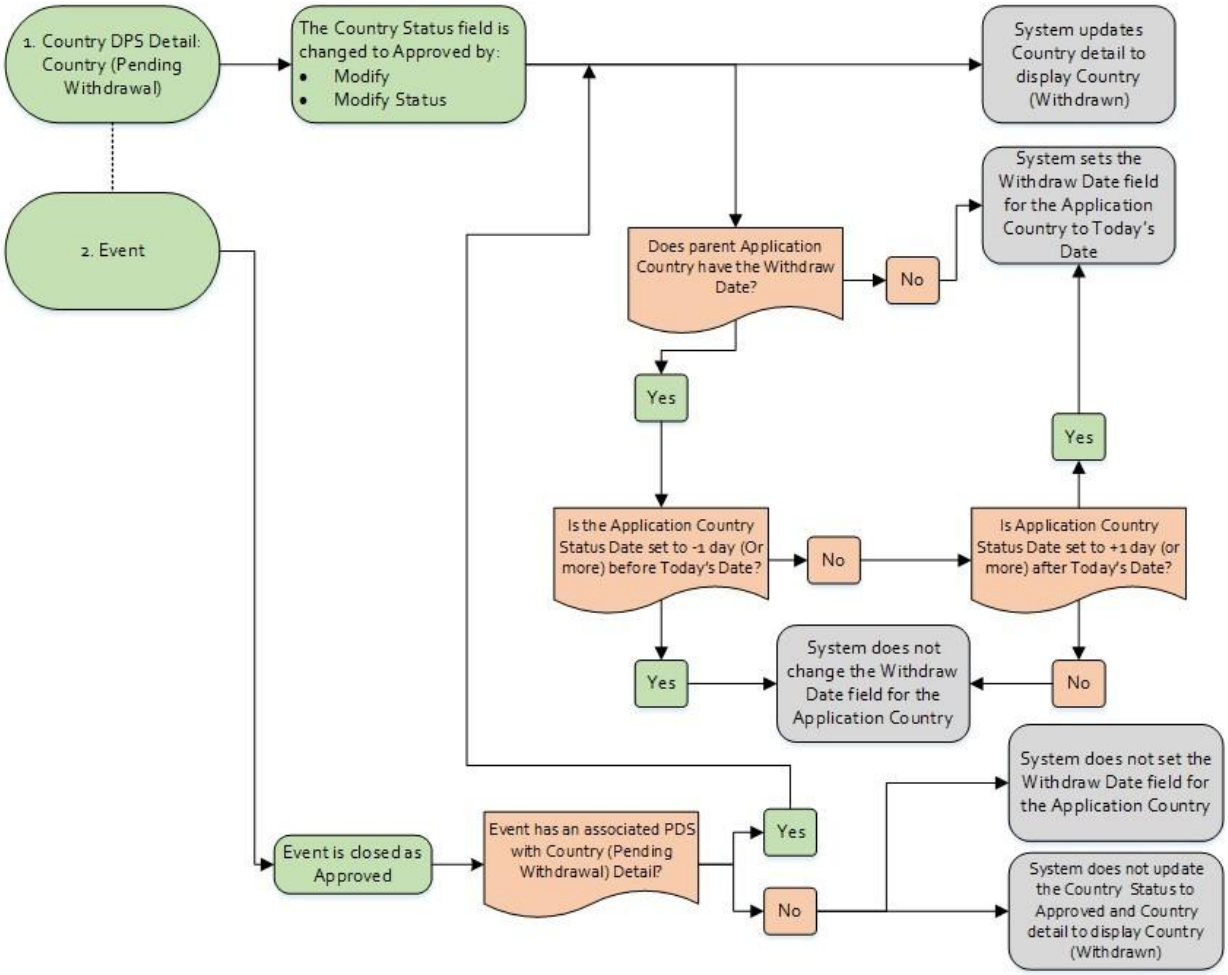
- Only the event country status and status dates for the selected countries will be updated.
- The status and status date do not change for the associated applications, PDSs, PDS details, and sequences.
- The associations closed status becomes the last status selected in the wizard for the event countries.
- The closed date becomes the status date selected in the wizard.
- Upon closing the event, associated entities are also affected, including the application, product detail set, and sequences.
- When an Event is closed as Approved, meaning the **Associations Closed As** field is set to APPROVED, and the

PDS associated to this Event has a withdrawn Country Detail, displayed as **Country (Pending Withdrawal)**, the

Country Status field of this country is automatically set to Approved and this country is displayed as **Country**

(Withdrawn) in the PDS Tree on the left. As an additional rule, the parent **Application Country** > **Withdrawn**

Date field is automatically updated to be equal to Today's Date. The same rule applies to the Application Country when the **Country (Pending Withdrawal)** Detail is modified and the **Country Status** field is set to Approved. See the following flowchart diagram.



Note: The **Application Country > Withdrawn Date** field is updated only if there is no withdraw date populated, or the withdraw date is set to +1 day (or more) after Today's Date.

Reorder Statuses in the Event-Country Status Schedule

For a planned event that does not enforce status progression, you can change the order of the statuses for the country. The status order affects the calculation of projected dates. The projected dates are based on the lead time of the previous status in the status schedule.To reorder event statuses:

1. View the event you want to modify.
2. On the **Countries** tab, click the name of the country that has the event-country status schedule that you want to reorder.
3. Click **Reorder**.The *Reorder Statuses* page opens.
4. In the **Statuses** field, select the status you want to move and then click **up** or **down** to change its place in the order.
5. **Save**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Approved Status Views

Sequences are added to a lifecycle and dispatched to a regulatory agency for approval based on your organization's and the agency's internal procedures.

Each sequence is associated with an event and each event may have multiple sequences associated with it. An event enables you to track the submission approval process.

In this capacity, an event is a grouping of sequences under one business objective, for example, an initial filing. As you submit sequences, they are added to the **Submitted Views** tab on the *Home* page and the *Application Attributes* page.

Sequences can be approved by the agency in a different order from which you submitted them. After the agency approves the submitted sequences, you can approve the associated event by adding it to the approved view. **Note:**

Approved status views are available to RDA module licensed users only.

The submission process can be illustrated as follows:

Application - Initial Filing

Event	Sequences	Submitted	Approved
EVENT-01	SQ-0001 SQ-0002 SQ-0003	01-01-2007	
EVENT-02	SQ-0004SQ-0005	02-01-2007	02-15-2007
EVENT-03	SQ-0006	03-01-2007	

In the table above:

- Events 01-03 are associated with an Application - Initial Filing.
- Event-01 comprises sequences 0001-0003 and was submitted to the regulatory agency for approval on January 1, 2007. It has not yet received approval.
- Event-02 comprises sequences 0004 and 0005 and was submitted to the regulatory agency February 2, 2007. It received approval from the agency February 15, 2007.
- Event-03 comprises sequence 0006 and was submitted to the regulatory agency March 1, 2007. It has not yet received approval.

When you add an event to the approved view, the following occur:

- The first application approval date is set.
- The event is closed.
- The event status is changed to Approved with the appropriate time stamp.
- The sequence statuses are changed to Approved with the appropriate time stamp.
- Any pending product details are approved.
- The event is added to the **Approved Views** tab. Application - Initial Filing

Event	Sequences	Submitted	Approved
EVENT-01	SQ-0001 SQ-0002 SQ-0003	01-01-2007	
EVENT-02	SQ-0004 SQ-0005	02-01-2007	02-15-2007
EVENT-03	SQ-0006	03-01-2007	

In the table above:

— Events 01-03 are associated with an Application - Initial Filing.

— Event-01 comprises sequences 0001-0003 and was submitted to the regulatory agency for approval on January 1, 2007. It has not yet received approval.

— Event-02 comprises sequences 0004 and 0005 and was submitted to the regulatory agency February 2, 2007. It received approval from the agency February 15, 2007.

— Event-03 comprises sequence 0006 and was submitted to the regulatory agency March 1, 2007. It has not yet received approval.

When you add an event to the approved view, the following occur:

— The first application approval date is set.

— The event is closed.

— The event status is changed to Approved with the appropriate time stamp.

— The sequence statuses are changed to Approved with the appropriate time stamp. — Any pending product details are approved.

— The event is added to the Approved Views tab.

Add Events to the Approved Status View

You can add an event to the Approved status view in one of the following ways.

— Using the *Update Status* wizard. For an event to be added to the *Approved* view successfully, at least one country associated with the event must be unlocked.

— Manually adding an event to the *Approved* view on the *Event Attributes* page. For an event to be added to the *Approved* view successfully, an event should be a closed as an approved event.

Manually Add an Event to the Approved Status View

You can add an event to the *Approved status* view if the event is closed as an 'approved' event. To

manually add an event to the *Approved status* view:

1. Click a link for the event you want to add to the *Approved status* view. The *Event Attributes* page opens.
2. Click Add Approved.
3. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

View an Event in the Approved Status View

You can view events with the approved status from several links in Ennov InSight .

To view an approved event status:

1. On the Ennov InSight *Home* page, click the Approved Views tab.
2. Click a link for the approved event you want to view.

   The *Approved Event Status View* page opens.
3. Right-click the root in the assembly tree and choose Expand Range to see the submission.

Remove an Event from the Approved Status View

You can remove an event from the approved status view for several reasons:

— It was added in anticipation of approval that was not received.

— An RTF (refusal to file) was received. — It was added accidentally.

To remove an event from the approved status view:

1. Click a link for the event you want to remove from the approved status view. The *Event Attributes* page opens.
2. Click Remove Approved.
3. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Add Events to the Approved Status View

You can add an event to the **Approved** status view in one of the following ways.

- Using the *Update Status* wizard. For an event to be added to the *Approved* view successfully, at least one country associated with the event must be unlocked.
- Manually adding an event to the *Approved* view on the *Event Attributes* page. For an event to be added to the *Approved* view successfully, an event should be a closed as an approved event.

Manually Add an Event to the Approved Status View

You can add an event to the *Approved status* view if the event is closed as an 'approved' event. To

manually add an event to the *Approved status* view:

1. Click a link for the event you want to add to the *Approved status* view.The *Event Attributes* page opens.
2. Click **Add Approved**.
3. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	**Steps**
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

View an Event in the Approved Status View

You can view events with the approved status from several links in Ennov InSight .To view an approved event status:

1. On the Ennov InSight *Home* page, click the **Approved Views** tab.
2. Click a link for the approved event you want to view.The *Approved Event Status View* page opens.
3. Right-click the root in the assembly tree and choose **Expand Range** to see the submission.

Remove an Event from the Approved Status View

You can remove an event from the approved status view for several reasons:

- It was added in anticipation of approval that was not received.
- An RTF (refusal to file) was received.
- It was added accidentally.

To remove an event from the approved status view:

1. Click a link for the event you want to remove from the approved status view.The *Event Attributes* page opens.
2. Click **Remove Approved**.
3. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Chapter 20. Global Project Planning

Ennov InSight Global Project Planning (GPP) facilitates planning and data entry for multiple countries or multiple applications. The *Project View* provides a centralized view of all applications, events, event countries, notifications, and references associated with a project.

GPP facilitates the process of planning and executing regulatory submissions where there are multiple countries or regions, or multiple applications within the same country, that are targeted at the same time for the same change. GPP is a valuable tool when variations, supplements, annual reporting, and other submissions need to occur simultaneously in more than one country or region, or for more than one application.

The *GPP* wizard enables you to create projects for:

- Creating applications for package set registrations
- Creating clinical trial authorization (CTA) applications
- Creating events for package set or product registrations
- Updating PDS details
- Withdrawing product package set registrations

Using the GPP, you can perform the following functions:

- Apply event plans to events
- Create sequences for applications
- Add, replace, or withdraw manufacturers in the PDS
- Add, modify, and withdraw package set component packaging
- Add species details to PDSs for veterinary product families
- Update the status and status date of event countries associated with a project
- Calculate projected dates for one or more event countries associated with a project
- Add event countries to project events
- Create sequences related to selected project events
- Create references for project events and sequences
- Associate workflows to events and sequences

Create a Project

The *Global Project Plan* (GPP) wizard enables you to create projects and perform actions on multiple Ennov InSight entities simultaneously.

Using the *GPP* wizard, you can create projects to:

- Create applications for package set registrations
- Create clinical trial authorization (CTA) applications
- Create events for package set or product registrations
- Update the extra fields in bulk on the Event Change Detail entity when Details are associated to an Event

- Update PDS details
- Withdraw product package set registrations

GPP Security Requirements

To use the *GPP* wizard, you must meet the following security requirements:

- A Registration Planning and Tracking module license or a Submission Planning and Tracking module license with at least WRITE privileges.
- To create a PDS with the *GPP* wizard, you must have a Product Detail Management module license with at least WRITE privileges, as well as WRITE privileges to the PDS entity.
- At least WRITE privileges to the projects, sequences, and events entities.
- *Home* page access security for the *GPP* wizard enabled.

If there are additional security requirements for a specific project type, they are documented with the instructions for performing the procedure.

Project Maintenance

Project values appear in drop-down lists on the *Project Attributes* page and are designated when a project is created or modified. Data Administration enables you to add and modify drop-down list values, and set the status of a value to **active** or **inactive**.

When you select a value under **Project Maintenance**, a page shows a table of all values that have been defined. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: The proper data administration access privileges are required to view and modify project maintenance values.

Project Maintenance: Project Values

You can create and maintain the following project values:

Value	Description
Project Status Name	Can be, for example, **completed**, **in progress**, or **planned**. Default Flag indicates whether the project status name is the default status in **Global Project Planning (GPP) project status** fields, and can be Yes or No.
Project Type	Describes the scope of the project, for example create new events, and so on.

Use the Global Project Plan Wizard

The *Global Project Plan* (GPP) wizard allows you to create and update multiple entities in bulk.

The following are considerations that should be taken into account when using the GPP functionality:

- Every project creates a new event and, for any PDS actions performed with a *GPP* wizard, the PDS and related products are associated with that event.
- For CP applications, the wizard automatically assigns the European Union country to the created events.
- For National and MRP applications, the wizard automatically assigns the reviewing country from the applications to the events.
- For MRP applications created, only the reviewing country is associated to the newly created applications and events. You must manually associate the concerned member states after the project is created. If you are using timeline/event plans you will have the ability to copy lead times from event-countries associated to the event when updating the event.
- For all application types, the event-country status is assigned to each country when the event is created.
- Projected status dates will not be calculated if the pivot status selected is not included in the chosen timeline/event plan.
- Confirmation pages appear during the execution of the wizard that indicate entities are being created, even though the wizard is still in progress. If the wizard is prematurely terminated after these confirmation screens, the entities created still exist in Ennov InSight .
- Excessive back-and-forth navigation through the *GPP* wizard using the **Back** and **Next** buttons can lead to unexpected results.
- When the **Finish** button appears on a page, the selections you made to that point in the wizard have resulted in the creation of, or modifications to, a project. At this point, you can exit the wizard with your settings saved, or progress through the subsequent sections of the wizard choosing additional settings. If you choose to progress through the wizard beyond the point where the **Finish** button appeared, the **Cancel** button will discard only pending changes made beyond that point.

New Applications Package Set Registration Project

Global Project Planning (GPP) enables you to create new package set registration applications for each country you specify based on the application category you select.

The procedure type used by the *GPP* wizard is determined by the default procedure type defined for the country in data administration. See **Data Administration** > **Application Maintenance** > **Country Values**.

With the wizard, you have the option to apply a timeline/event plan to the events that you create. You can select a timeline/event plan type for the timeline/event plan:

- If you select an event type timeline/event plan, the *GPP* wizard creates an event that will have a sequence of statuses relevant to the event type that you select.
- If you select a procedure type timeline/event plan, the *GPP* wizard creates an event that will have a sequence of statuses relevant to the procedure type that you select.
- If you do not use a timeline/event plan, the *GPP* wizard creates an event that can have any sequence of active statuses.

Note: Do not deactivate the default registration type value of Package Set Registration. There are Ennov InSight functions and procedures, such as the *"Create New Applications - Package Set Registration" Global Project Planning* wizard, that rely on this value remaining active.If possible, the *GPP* wizard assigns an applicant ID to an application that it creates:

- If a default applicant ID is defined for the region associated with the application, the *GPP* wizard assigns the default applicant ID to the application. To set the default, go to **Data Administration** > **Submission Maintenance** > **Applicant ID Values**. This default is not shown in the *GPP* wizard.
- If a default applicant ID is not defined for the region associated with the application, the *GPP* wizard does not assign an applicant ID to the application.

Create a New Applications Package Set Registration Project

You must create new package set registration applications for each country you specify based on the application category you select.

To create a new applications package set registratoin project:

1. Click **Wizards** > **Global Project Plan**.The *GPP* wizard opens to the *Project Details* page.
2. For the **Project Type** attribute, select **Create New Applications Package Set Registration** or a type that maps to the internal project type of Create New Applications Package Set Registration Project as defined in Data Administration.
3. Enter values for the project attributes. The wizard requires entry for the **project type**, **project name**, **project status**, and **project status date**.
4. Click **Next**.The *Select Application Category*, *Product Family*, *Products and Countries* page appears.
5. Define criteria for the applications that you want to create:
    a. Select an **Application Category** from the drop-down list. The application category determines the application type. Application type values are set in **Data Administration** > **Application Maintenance** > **Application Type Values**.
    b. Select a **Family Type**.
    c. Select a **Family Name**.
    d. Select one or more **Products** to associate with the applications you will create.
    e. For **Region Type**, select the region type that includes the regions with countries for which you want to create applications.

f. For **Region**, specify the regions that include the countries for which you want to create applications. The list of available regions is determined by the selected region type. For the European Union region and CP, or WAHO region and CP, or MRP applications, the country you choose will be set as the reviewing country.

g. For the **Country** attribute, the list of available countries is determined by the selected regions. The list of available countries is further limited to the countries for which you have at least WRITE privileges for the product family you selected, and to the countries with a default procedure type and application type defined for the application category you selected.

6. Click **Next**.The *Enter Application Details* page opens. Regarding this page:

◦ The application attributes listed on the page are determined by the XML to which the application type is mapped. Refer to **Data Administration** > **Application Maintenance** > **Application Type Values** for more information.

◦ Because you may be creating applications for multiple application types, such a clinical trial is an IND type in the US and a CTA type in the EU, separate screens show the attributes of each different XML to which the application types are mapped.

◦ When the applications are created by the wizard, the country code is appended to the value entered in the **Application Name** and **Application Code** boxes.

7. Click **Next** after completing each *Application Details* page presented.When all the *Application Details* pages are completed, the *Enter Event Details* page opens.
8. Enter values for the event attributes.An event will be created for each application created by the wizard and the following will occur:

◦ For EU-CP applications, the wizard automatically assigns the European Union to the created event.

◦ For WAHO-CP applications, the wizard automatically assigns the WAHO country to the created event.

◦ For National and MRP applications, the wizard automatically assigns the reviewing country for the event.

◦ For MRP applications, the selected countries will be assigned to the created event.

◦ For all application types, the event-country status is assigned to each country when the event is created.

◦ A *Select Timeline/Event Plan* page shows for each procedure type for which applications are being created.

9. From the **Timeline/Event Plan** drop-down list, do either of the following:

◦ Select the timeline/event plan to associate with the events being created by the wizard. If a timeline/ event plan chosen in the project does not have a country lead time for the reviewing country on the selected application, the lead times in the status schedule table are assumed to be zero. Projected dates are calculated using zero lead times and the project pivot status and status date. Click **Next** and continue at step 10.

◦ Leave it blank if you do not want to use a timeline/event plan and click **Next** as many times as is necessary to open the *Associate Selected Products with Events* page. Continue at step 12.

10. Click **Next** after completing each *Select Timeline/Event Plan* page presented.After all the *Select Timeline/ Event Plan* pages are completed, a confirmation page tells you what actions will be taken.
11. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next**.The *Associate Selected Products with Events* page opens.
2. Do one of the following:

◦ If you selected one or more products in step 5 to associate with the applications, select either **Yes** or **No** to associate these products with the events that will be created by this wizard.

◦ If you did not select products in step 5 to associate with the applications, you must select **No**.

3. Click **Next**.A confirmation page shows if the wizard will create your applications and the events for your applications.
4. Choose the applicable procedure in the table below to enter an electornic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. On the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next**.The *Create Sequence(s)* page opens.
2. On the *Create Sequence (s)* page:

◦ To create a sequence, select **Yes** and click **Next**. The *Sequence Attributes* page opens. Go to step 18.

◦ To proceed without creating a sequence, select **No** and click **Next**. A message states that no input is required for sequences. Click **Next** to proceed to the *Create Product Detail Sets* page. Go to step 19..

3. On the *Sequence Attributes* page, select or enter sequence attribute values.
4. Click **Next**.A confirmation page shows that sequences will be associated with the events. For each application you created in the *GPP* wizard:

◦ The system creates an initial sequence with the attribute values you specified

◦ Each sequence is associated with the event in the project

◦ The system generates a Lifecycle order

5. Click **Next**.The *Create Product Detail Sets* page opens. PDS templates must already exist in the system to create a PDS using the *GPP* wizard. One of the following occurs:

   ◦ If you have a PDM license with at least WRITE privileges to the PDS entity, you associated products with your applications in step 5, and you chose to associate products with events in step 12 , the wizard prompts you to create PDSs. Click **Yes** and proceed to step 20 or click **No** and proceed to step 27.

   ◦ If you do not have the PDM license with at least WRITE privileges to the PDS entity, or if you did not associate products with your applications in step 5, or if you chose not to associate products with events in step 12, proceed to step 27.

6. Click **Next**.
7. On the *Select PDS Templates* page, select a product from the **Product** drop-down list. The products listed are limited to those you selected for association with the applications earlier in the wizard.Any predefined PDS templates for the selected product are displayed in the **Available** list box.
8. Select one or more templates. **Note:** Ennov best practice is to create only one PDS per product per application, and define different package sets within a PDS for the various presentations that go into packaging a product.
9. Click **Next**.A confirmation page indicates whether the wizard will create a PDS for each template selected.
10. to create the PDSs.The *Select Another Product* page opens.
11. Do the following:

    ◦ If there were more products available for selection in step 22. , and you want to create PDSs from the PDS templates for another product, choose **Yes** and repeat step 20. through step 24. .

    ◦ If you have created all the PDS you want for the products available for selection in step 22. , choose **No** and proceed to step 27.

12. Click **Next**.The *Summary* page confirms that the *GPP* wizard is complete.
13. Do one of the following:

    ◦ Select the project link on the *Summary* page to review the new project you created.

    ◦ Click **Finish** to return to the view from which you invoked the *GPP* wizard.

14. To view the project after closing the *GPP* wizard, click **Home** > **Projects** tab.
15. Click the link for the project you just created to open the *Project Attributes* page. **Note:** If you created applications for the European Union of the Centralized Procedure (CP), WAHO (CP), Decentralized Procedure (DCP), or Mutual Recognition Procedure (MRP) procedure, you must manually modify the applications to include the **Co-Rapporteur**, **Concerned Member States**, and **Arbitration Flag**, when applicable.

New Events Package Set Registration Project

Global Project Planning (GPP) enables you to create new events for existing applications that you select in the wizard. This wizard is specifically for creating events for package set registration applications. With the wizard, you have the option to apply a timeline/event plan to the events that you create.

You can select a timeline/event plan type for the timeline/event plan:

- If you select an event type timeline/event plan, the *GPP* wizard creates an event that will have a sequence of statuses relevant to the event type that you select.
- If you select a procedure type timeline/event plan, the *GPP* wizard creates an event that will have a sequence of statuses relevant to the procedure type that you select.
- If you do not use a timeline/event plan, the *GPP* wizard creates an event that can have any sequence of active statuses.

You can also choose to create sequences to be associated to the events.

Create a New Events Package Set Registration Project

Using the Global Project Plan wizard, create a New Events Package Set Registration Project.

To create a new events project:

1. Click **Wizards** > **Global Project Plan**.The *GPP* wizard opens to the *Project Details* page.
2. For the **Project Type** attribute, select **Create New Events Package Set Registration** or a type that maps to the internal project type of Create New Events Package Set Registration Project as defined in Data Administration.
3. Enter values for the project attributes. The wizard requires entry for a project name, project status, and project status date.
4. .The *Search by Product, Country and Application Status* page opens.
5. Define search criteria for locating the applications for which you want to create events:
    a. Select the **Family Type** and **Family Name**.
    b. Optionally, select one or more products to include in the search.
    c. Select one or more application statuses to include in the search.
    d. Optionally, select one or more countries to include in the search.
    e. Optionally, select one or more application types to include in the search.
    f. Change the columns included in the displayed results, or change their order of appearance.
    g. Change the order in which the results will be presented.
6. Click **Next**.The *Select Applications* page opens. Only package set registration applications within the search parameters are listed.
7. Select one or more applications.
8. Click **Next**.The *Enter Event Details* page opens.
9. Enter values for the **event attribute** options presented.An event will be created for each application created by the wizard and the following will occur:

    ◦ For CP applications, the wizard automatically assigns the European Union to the created event. ◦ For National applications, the wizard automatically assigns the reviewing country for the event.

    ◦ For MRP applications, the selected countries will be assigned to the created event.

    ◦ For all application types, the event-country status is assigned to each country when the event is created.

10. Click **Next**.The *Select Timeline/Event Plan* page opens. The *Select Timeline/Event Plan* page is displayed for each procedure type associated with the applications that you selected. An event plan for a procedure type must exist in the system for you to select a timeline/event plan.
11. On the *Select Timeline/Event Plan* page, do one of the following:

    ◦ Select a timeline/event plan from the **Timeline/Event Plan** drop-down list to associate a timeline/event plan with the events created by the wizard. If a timeline/event plan chosen in the project does not have a country lead time for the reviewing country on the selected application, the lead times in the status schedule table are assumed to be zero. Projected dates are calculated using zero lead times and the project's $_{\text{pivot status}}$ and $_{\text{status date}}$. Click **Next**, and continue to the next step.

    ◦ Do not select a timeline/event plan. A timeline/event plan will not be associated if you do not make a selection. Click **Next** as many times as is necessary until the *Confirmation* page opens. Continue at step 16.
12. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. after completing each timeline/event plan page presented.When all the timeline/event plan pages are completed, the *Confirmation* page opens.
2. Click **Next**.The *Create Sequence(s)* page opens.
3. Do one of the following:

    ◦ To create a sequence, select **Yes** and click **Next**. The *Sequence Attributes* page opens. Go to step 18.

    ◦ To proceed without creating a sequence, select **No**. If you select **No**, the wizard displays a message that you do not need to enter sequence details. Go to step 19.
4. On the *Sequence Attributes* page, select or enter values for the **sequence attribute** fields presented.
5. Click **Next**.One of the following will occur:

    ◦ If you created one or more sequences, a message shows that sequences will be associated to the events. Click **Next**.

    ◦ If you did not choose to create a sequence, the *Summary* page opens.
6. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled.	a. In the confirmation page, select a reason and enter comments for the reason. b. Click Next. c. Validate your identiry by entering your user credentials in the dialog bos.

1. The *Summary* page confirms that the *GPP* wizard performed the selected actions. Do one of the following:
   - Select the project link on the *Summary* page to review the new project you created.
   - Click **Finish** to return to the view from which you invoked the *GPP* wizard.
2. To view the project after closing the *GPP* wizard, click **Home** > **Projects** tab.
3. Click the link for the project you just created to open the *Project Attributes* page. The **Events** tab shows the events created for each application you selected.

New Events Product Registration Project

Global Project Planning (GPP) enables you to create new events for existing applications that you select in the wizard. This wizard is specifically for creating events for applications of the product registration type. With the wizard, you have the option to apply a timeline/event plan to the events that you create.

You can select a timeline/event plan type for the timeline/event plan:

- If you select an event type timeline/event plan, the *GPP* wizard creates an event that will have a sequence of statuses relevant to the event type that you select.
- If you select a procedure type timeline/event plan, the *GPP* wizard creates an event that will have a sequence of statuses relevant to the procedure type that you select.
- If you do not use a timeline/event plan, the *GPP* wizard creates an event that can have any sequence of active statuses.

You can also choose to create sequences to associate with the events.

Create a New Events Product Registration Project

Use this procedure to create a New Events Product Registration Project in the *Global Project Plan* wizard.

To create a new events project:

1. Click **Wizards** > **Global Project Plan**.The *GPP* wizard opens to the *Project Details* page.
2. For the **Project Type** attribute, select **Create New Events Product Registration** or a type that maps to the internal project type of Create New Events Product Registration Project as defined in Data Administration.
3. Enter values for the project attributes. The wizard requires entry for a project name, a project status, and a project status date.
4. Click **Next**.The *Search Country and Application Status* page opens.

5. Define search criteria for locating the applications for which you want to create events with the *GPP* wizard: a. Select the **Family Type** and **Family Name**.
    a. Select one or more application statuses to include in the search.
    b. Optionally, select one or more countries to include in the search.
    c. Optionally, select one or more application types to include in the search.
    d. Change the columns included in the displayed results or change their order of appearance.
    e. Change the order in which the results will be presented.
6. Click **Next**.The *Select Applications* page opens. Only product set registration applications within the search parameters are listed.
7. Select one or more applications.
8. Click **Next**.The *Select Product* page opens.
9. Under the **Selected** box:

Action	Option
To associate products with the events that the project creates	Click **Select**, select the products, and click **Save**.
To disassociate products from the events	Select products in the **Selected** box.
To select more than one product	Hold down the CTRL key and click each product. Then click **Deselect**.

10. Click **Next**.The *Enter Event Details* page opens.
11. Enter values for the event attribute options presented.An event will be created for each application created by the wizard and the following will occur:

    ◦ For CP applications, the wizard automatically assigns the European Union to the created event. ◦ For National applications, the wizard automatically assigns the reviewing country for the event.

    ◦ For MRP applications, the selected countries will be assigned to the created event.

    ◦ For all application types, the event-country status is assigned to each country when the event is created.

12. Click **Next**.The *Select Timeline/Event Plan* page opens. The *Timeline/Event Plan* page shows for each procedure type associated with the applications that you selected.**Note:** A timeline/event plan must exist in the system for you to select a timeline/event plan.
13. On the *Timeline/Event Plan* page, do one of the following:

Description	Option
If a timeline/event plan chosen in the project does not have a country lead time for the reviewing country on the selected application, the lead times in the status schedule table are assumed to be zero. Projected dates are calculated using zero lead times, and the project pivot status and status date	Select a timeline/event plan from the **Timeline/Event Plan** drop- down list. Click **Next**, and continue at step 14.

Do not select a timeline/event plan. A timeline/event plan will not be associated if you do not make a selection.	Click **Next** as many as is necessary to open the *Confirmation* page. Continue at step 18.

14. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next** after completing each timeline/event plan page presented.When all the timeline/event plan pages are completed, the *Confirmation* page opens.
2. Click **Next**.The *Create Sequence(s)* page opens.
3. Do one of the following:

   ◦ To create a sequence, select **Yes** and click **Next**. The *Sequence Attributes* page opens. Go to the next step.

   ◦ To proceed without creating a sequence, select **No**. If you select **No**, a message shows that you do not need to enter sequence details. Go to step 21.

4. On the *Sequence Attributes* page, select or enter values for the sequence attributes fields presented.
5. Click **Next**.One of the following will occur:

   ◦ If you created one or more sequences, a message shows that sequences will be associated to the events. Click **Next**.

   ◦ If you did not choose to create a sequence, the *Summary* page opens.

   The *Summary* page confirms that the *GPP* wizard performed the selected actions.

6. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	1. In the confirmation page, select a reason and enter comments for the reason. 2. Click **Next**. 3. Validate your identity by entering your user credentials in the dialog box.

21.

1. Do one of the following:
   - Select the project link on the *Summary* page to review the new project you created.
   - Click **Finish** to return to the view from which you invoked the *GPP* wizard.
2. To view the project after closing the *GPP* wizard, click **Home** > **Projects** tab.
3. Click the link for the project you just created to open the *Project Attributes* page. After creating events with a

GPP project that maps to the internal project type of Create New Events Product Registration Project, you can create registrations for the events associated with the project using the *Create Product Registrations* wizard.

Product Maintenance

Product maintenance values appear in lists on the Product Attributes page and are designated when a product is created. Data Administration enables you to add and modify list values and set the status of a value to active or inactive.

When you select a value under **Product Maintenance**, a table of all values that have been defined appears. You can sort these values by column. The default view is sorted in ascending, alphanumeric order.

Note: The proper Data Administration access privileges are required to view and modify application maintenance values.

All **XEVMPD Data Administration** tables provide the ability to configure extra fields. The standard set consists of twenty extra **text** fields, five extra **date** fields, and five extra **number** fields.

Update a Product Detail Set Project

Global Project Planning (GPP) enables you to update approved product detail set (PDS) details for a PDS related to package set registration applications.

With GPP, you can perform the following update actions on approved PDS details:

- Add a substance
- Add indications and intended use details
- Add manufacturer details to certain approved PDS details
- Add a manufacturing process

- Add a manufacturing process step function
- Add a material
- Add package sets to a PDS
- Add component packaging details to a package set
- Add shelf life details to package sets
- Add species details for PDS under veterinary product families
- Add species indications for veterinary products
- Modify active ingredient details
- Modify a substance
- Modify a material
- Modify component characteristics, such as shape and color
- Modify manufacturing process step details
- Modify manufacturing process step function details
- Modify package set details (package set level only)
- Modify component packaging details for a package set
- Modify packaging details for a package set
- Modify shelf life details in the package sets
- Modify manufacturing process
- Withdraw component packaging for package set
- Withdraw a material
- Withdraw a manufacturer from a variety of approved PDF details
- Withdraw a manufacturing process
- Withdraw a substance
- Replace a flu strain active ingredient for a flu vaccine product
- Replace all instances of a manufacturer detail in selected PDS
- Replace every occurrence of an approved function with a new function
- Replace all instances of a material used in selected PDS

Using the *GPP* wizard, you create a project and define criteria to identify the PDS for which you want to update approved PDS details. When updating approved PDS details with the *GPP* wizard, a corresponding event is created and associated with the PDS and the product related to the PDS. One event is created for each application associated with the PDSs you select to update in the *GPP* wizard.

The *GPP* wizard offers two options to search for PDS to act upon. You can search by product and country or search by using an Assemblies Where Document Used query. The second method is available only to users that have the RDA module.

In the *GPP* wizard, to search for PDSs to update, you can select any of the following search criteria options:

- Active Ingredient
- Assemblies Used Query (You can select this option only if you have the RDA module.)
- PDS Code/PDS Name

- Product and Country
- Substance
- Trade Name

To update PDSs with the *GPP* wizard, you must have a PDM license with at least WRITE privileges, as well as WRITE privileges to the PDS entity.

GPP Selections to Update PDS Details

You have several options to update the different types of PDS details in the GPP.**Note:** These tables do not include labels, countries, and labeled indication because the GPP does not update these PDS details.**GPP Detail to Update:**

Active Ingredient (Component)

Update Task	**Select Action on the Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
Add a manufacturer to an active ingredient	Add Manufacturer	Add Active Ingredient Manufacturer	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturer/<manufacturer>**
Add a manufacturer to an active ingredient manufacturing process function	Add Manufacturer	Add Active Ingredient Manufacturing Process Function Manufacturer	**<PDS>/<component>/Active Ingredients/<active ingredient/Manufacturing Processes>/<manufacturing process>/<function>/<manufacturer>**
Add a manufacturing process	Add Manufacturing Process	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Processes/<manufacturing process>/step**
Add a manufacturing process step function	Add Manufacturing Process Step Function	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Processes/<manufacturing process>/step**

Add a material for an active ingredient manufacturing process step	Add Material	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Processes>/<manufactur- ing process>/<step>/<material>**
Modify a Material	Modify Material	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Process**
Update Task	**Select Action on the Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
			es>/<manufacturing process>/<step>/<material>
Modify an active ingredient	Modify Active Ingredient	(not applicable)	**<PDS>/<component>/Active Ingredients/<active in-gredient>**
Modify a Manufacturing process	Modify Manufacturing Process	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Processes/<manufactur- ing process>**
Modify a Manufacturing process step	Modify Manufacturing Process Step	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Processes/<manufactur- ing process>/<step>**
Modify a manufacturing process step function	Modify Manufacturing Process Step Function	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Processes/<manufactur- ing process>/<step>/<function>**
Withdraw a manufacturing process	Withdraw Manufacturing Process	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient/Manufacturing Processes>/<manufactur- ing process>**

Replace an approved flu strain with a new flu strain	Replace Flu Strain	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>Flu Strain<flu strain>**

PDS Detail to Update: Substance (Component)

Update Task	**Select Action on the Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
Add a substance	Add Substance	(not applicable)	**<PDS>/<component>/Substances/<substance>**
Add a substance manufacturer	Add Manufacturer	Add Substance Manufacturer	**<PDS>/<component>/Substances/<substance>/Manufacturer/<manufacturer>**
Add a manufacturer to a substance manufacturing process function	Add Manufacturer	Add Substance Manufacturing Process Function Manufacturer	**<PDS>/<component>/Substances/<substance/Manufacturing Processes/<manufacturing process>/<function>/<manufacturer>**
Update Task	**Select Action on the Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
Add a manufacturing process	Add Manufacturing Process	(not applicable)	**<PDS>/<component>/Substances/<substance>/Manufacturing Processes/<manufacturing process>**
Add a manufacturing process step function	Add Manufacturing Process Step Function	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Processes/<manufacturing process>/step**

Add a material for a substance manufacturing process step	Add Material	(not applicable)	**<PDS>/<component>/Substances/<substance>/Manufacturing Processes>/<manufacturing process>/<step>/<material>**
Modify a material	Modify Material	(not applicable)	**<PDS>/<component>/Substances/<substance>/Manufacturing Processes>/<manufacturing process>/<step>/<material>**
Modify a manufacturing process	Modify Manufacturing Process	(not applicable)	**<PDS>/<component>/Substances/<substance>/Manufacturing Processes/<manufacturing process>**
Modify a manufacturing process step	Modify Manufacturing Process Step	(not applicable)	**<PDS>/<component>/Substances/<substance>/Manufacturing Processes/<manufacturing process>/<step>**
Modify a manufacturing process step function	Modify Manufacturing Process Step Function	(not applicable)	**<PDS>/<component>/Substances/<substance>/Manufacturing Processes/<manufacturing process>/<step>/<function>**
Modify a substance	Modify Substance	(not applicable)	**<PDS>/<component>/Substances/<substance>**
Withdraw a manufacturing process	Withdraw Manufacturing Process	(not applicable)	**<PDS>/<component>/Substances/<substance/Manufacturing Processes>/<manufacturing process>**
Withdraw a substance	Withdraw Substance	(not applicable)	**<PDS>/<component>/Substances/<substance>**

PDS Detail to Update: Manufacturing (Component)

Update Task	**Select Action on the Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
Add a Manufacturer to a Component function	Add Manufacturer	Add Component Function Manufacturer	**<PDS>/<component>/ Manufacturing/Function/<function><manufacturer>**
Add a manufacturer to a component manufacturing process function	Add Manufacturer	Add Component Manufacturing Process Function Manufacturer	**<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>/<function><manufacturer>**
Add a Manufacturing process	Add Manufacturing Process	(not applicable)	**<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>**
Add a Manufacturing process step function	Add Manufacturing Process Step Function	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Processes/<manufacturing process>/step**
Add a material for a Component Manufacturing process step	Add Material	(not applicable)	**<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>/<step>/<material>**
Modify a material	Modify Material	(not applicable)	**<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>/<step>/<material>**
Modify a manufacturing process	Modify Manufacturing Process	(not applicable)	**<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>**
Modify a manufacturing process step	Modify Manufacturing Process Step	(not applicable)	**<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>/<step>**

Modify a manufacturing process step function	Modify Manufacturing Process Step Function	(not applicable)	**<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>/<step>/<function>**
Withdraw a manufacturing process	Withdraw Manufacturing Process	(not applicable)	**<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>**

PDS Detail to Update: Characteristics (Component)

Update Task	**Select Action on the** **Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
Modify Component characteristics	Modify Component Characteristics	(not applicable)	**<PDS>/<component>/Characteristics/Characteristics**

PDS Detail to Update: Indications Intended Use

Update Task	**Select Action on the** **Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
Add indications/intended use	Add Indications/Intended Use	(not applicable)	**<PDS>/Indications/Intended Use/** **<indication/intended use>**

PDS Detail to Update: Manufacturing

Update Task	**Select Action on the Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**

Add a manufacturer to a PDS Manufacturing function	Add Manufacturer	Add PDS Function Manufacturer	**<PDS>/Manufacturing/Function/<function><manufacturer>**
Add a manufacturer to a PDS Manufacturing process function	Add Manufacturer	Add a PDS Manufacturing Process Function Manufacturer	**<PDS>/Manufacturing/Manufacturing Processes/<manufacturing process>/<function>/<manufacturer>**
Add a manufacturing process	Add Manufacturing Process	(not applicable)	**<PDS>/Manufacturing/Manufacturing** **Processes/<manufacturing process>**
Add a manufacturing process step function	Add Manufacturing Process Step Function	(not applicable)	**<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Processes/<manufacturing process>/step**
Add a material for a Manufacturing process step	Add Material	(not applicable)	**<PDS>/Manufacturing/Manufacturing** **Processes/<manufacturing process>/<step>/** **<material>**
Modify a manufacturing process	Modify Manufacturing Process	(not applicable)	**<PDS>/Manufacturing/Manufacturing** **Processes/<manufacturing process>**
Modify a manufacturing process step	Modify Manufacturing Process Step	(not applicable)	**<PDS>/Manufacturing Processes/<manufacturing process>/<step>**
Update Task	**Select Action on the Select** **Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**

Modify a manufacturing process step function	Modify Manufacturing Process Step Function	(not applicable)	**<PDS>/Manufacturing Processes/<manufacturing process>/<step>/<function>**
Withdraw a manufacturing process	Withdraw Manufacturing Process	(not applicable)	**<PDS>/Manufacturing/Manufacturing Processes/<manufacturing process>**

PDS Detail to Update: Package Set

Update Task	**Select Action on the Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
Add a manufacturer for packaging in a package set	Add Manufacturer	Add Package Set Packaging Manufacturer	**<PDS>/Package Set/<package set>/Packaging/<package>/<manufacturer>**
Add a manufacturer for a function in a package set	Add Manufacturer	Add Package Set Function Manufacturer	**<PDS>/Package Set/<package set>/Function/<function>/<manufacturer>**
Add a manufacturer for component packaging in a package set	Add Manufacturer	Add Package Set Component Packaging Manufacturer	**<PDS>/Package Set/<package set><component>/Packaging/<package><manufacturer>**
Add packaging to a component in package set	Add Component Packaging to Package Set	(not applicable)	**<PDS>/Package Set/<package set><component>/Packaging/<package>**
Modify Packaging for a Component in a package set	Modify Component Packaging for Package Set	(not applicable)	**<PDS>/Package Set/<package set><component>/Packaging/<package>**

Withdraw packaging for a component in a package set	Withdraw Component Packaging for Package Set	(not applicable)	**<PDS>/Package Set/<package set><component>/Packaging/<package>**
Add a package set	Add package set	(not applicable)	**<PDS>/Package Set/<package set>**
Modify a package set	Modify package set	(not applicable)	**<PDS>/Package Set/<package set>**
Update Task	**Select Action on the Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
Modify Packaging for a pack- age set	Modify Packaging for Package Set	(not applicable)	**<PDS>/Package Set/<package set>/Packaging/<packaging>**
Add shelf life	Add Shelf Life	(not applicable)	One of these: • **<PDS>/Package Set/<package set>Shelf Life(s)/Storage Condition(s)/<shelf life>** • **<PDS>/Package Set/<package set>Shelf Life(s)/Storage Condition(s) After Opening<shelf life>** • **<PDS>/Package Set/<package set>Shelf Life(s)/Storage Condition(s) After Reconstitution<shelf life>**
Modify shelf life	Modify Shelf Life	(not applicable)	One of these: • **<PDS>/Package Set/<package set>Shelf Life(s)/Storage Condition(s)/<shelf life>** • **<PDS>/Package Set/<package set>Shelf Life(s)/Storage Condition(s) After Opening<shelf life>** • **<PDS>/Package Set/<package set>Shelf Life(s)/Storage Condition(s) After Reconstitution<shelf life>**

PDS Detail to Update: Species Veterinary Products

Update Task	Select Action on the Select Action Page	Select Type of Manufacturer on the Select Flow Page	Path to Updated Details
Add species	Add Species	(not applicable)	**<PDS>/Species<species>**
Add species indications	Add Species Indications	(not applicable)	**<PDS>/Species/<species>/Indications/<species indication>**

PDS Detail to Update: Manufacturer

Update Task	Select Action on the Select Action Page	Select Type of Manufacturer on the Select Flow Page	Path to Updated Details
Replace every occurrence of an approved Manufacturer with a new manufacturer	Replace Manufacturer	(not applicable)	Any path to a manufacturer. The paths to manufacturers are those shown in the other rows of this table plus the following: • **<PDS>/<component>/Active Ingredients/<active ingredient/Manufacturing Processes>/<manufacturing process>/<step>/<material>/<manufacturer>** • **<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>/<step><material>/<manufacturer>** • **<PDS>/Manufacturing/Manufacturing Processes/<manufacturing process>/<step>/<material>/<manufacturer>**

Withdraw an approved manufacturer from the selected ap- proved manufacturer parent type	Withdraw Manufacturer	(not applicable) **Important:** Options available in the Manufacturer Parent Type multi-select field: • Active Ingredient • Active Ingredient Manufacturing Process Function • Active Ingredient Manufacturing Process Step Function • Active Ingredient Manufacturing Process Step Material	Any path to a manufacturer. The paths to manufacturers are those shown in the other rows of this table.

Update Task	**Select Action on the Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**

		• Package Set Packaging • Product Detail Set Function • Product Detail Set Manufacturing Process Function • Product Detail Set Manufacturing Process Step Function • Product Detail Set Manufacturing Process Step Material • Substance • Substance Manufacturing Process Function	
Update Task	**Select Action on the** **Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
		• Substance Manufacturing Process Step Function • Substance Manufacturing Process step material	

PDS Detail to Update: Material

Update Task	**Select Action on the Select Action Page**	**Select Type of Manufacturer on the Select Flow Page**	**Path to Updated Details**
Withdraw every occurrence of a material	Withdraw Material	(not applicable)	Any path to a material added to a processing step: • **<PDS>/<component>/Active Ingredients/<active ingredient/Manufacturing Processes>/<manufacturing process>/ <step>/<material>** • **<PDS>/component/<Substances>/substance/Manufacturing/Manufacturing Processes/<manufacturing process>/ <step><material>** • **<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>/<step>/<material>** • **<PDS>/Manufacturing/Manufacturing Processes/<manufacturing process>/ <step>/<material>**
Replace every occurrence of an approved material with a new material	Replace Material	(not applicable)	Any path to a material added to a processing step: • **<PDS>/<component>/Active Ingredients/<active ingredient/Manufacturing Processes>/<manufacturing process>/ <step>/<material>**

Update Task	Select Action on the Select Action Page	Select Type of Manufacturer on the Select Flow Page	Path to Updated Details
			• **<PDS>/<component>/Substances/<substance>/Manufacturing Processes/<manufacturing process>/<step>/<function>** • **<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>/<step>/<material>** • **<PDS>/Manufacturing/Manufacturing Processes/<manufacturing process>/<step>/<material>**

PDS Detail to Update: Manufacturing Process Step Function

Update Task	Select Action on the Select Action Page	Select Type of Manufacturer on the Select Flow Page	Path to Updated Details
Replace every occurrence of an approved function with a new function	Replace Manufacturing Process Step Function	(not applicable)	Any path to a manufacturing process step function: • **<PDS>/<component>/Active Ingredients/<active ingredient>/Manufacturing Processes/<manufacturing process>/<step>/<function>** • **<PDS>/<component>/Substances/<substance>/Manufacturing Processes/<manufacturing process>/<step>/<function>** • **<PDS>/<component>/Manufacturing/Manufacturing Processes/<manufacturing process>/<step>/<function>** • **<PDS>/Manufacturing Processes/<manufacturing process>/<step>/<function>**

Create an Update Product Detail Set Project

Use this procedure to create an Update Detail Set Project in the *Global Project Plan* wizard. You can use the *GPP* wizard to manage and track bulk updates to PDS details.

To create an update PDS project:

1. Click **Wizards** > **Global Project Plan**.The *GPP* wizard opens to the *Project Details* page.
2. For the **Project Type** attribute, select **Update Product Detail Sets** or a type that maps to the internal project type of Product Detail Set Updates Project as defined in data administration.
3. Enter values for the project attributes. The wizard requires entries for project type, project name, project status, and project status date.
4. Click **Next**.
5. Select a family type.
6. Click **Next**.The *Select Search Option* or *Summary* page opens.
7. Do one of the following:

   ◦ Select **Active Ingredient**.

   ◦ Select **Assemblies Where Used Query**, if this option is available.

   ◦ Select **Substance**.

   ◦ Select **PDS Code/PDS Name**.

   ◦ Select **Product and Country**.

   ◦ Select **Trade Name**.

   ◦ Select **View Cumulative Summary of Selected PDSs**. This option is available only if you returned to this step from step 19, after selecting PDSs.
8. Click **Next**.

   ◦ If the *Input Query Filter Criteria* page opens, continue at step 12.

   ◦ If the *Cumulative Summary of Selected PDSs* page opens, showing the PDSs that you selected for the project, continue at step 9.

9. On the *Cumulative Summary of Selected PDSs* page, if you want to remove PDSs from the project, select these PDSs.
10. Click **Next**.A confirmation message tells you that the PDSs that you selected were removed from the project.
11. Click **Next** again. Go to step 18.
12. On the *Input Query Filter Criteria* page, define search criteria for locating the applications for which you want to update PDSs:

◦ If you selected **Active Ingredient** in step 7, define criteria to search for PDSs. Optionally, to limit the search, select the famil name. Select the active ingredient. Optionally, select one or more countries. Optionally, select one or more application types. Select one or more application statuses and one or more PDS statuses. Go to step 14 to choose display options.

◦ If you selected **Assemblies Where Used Query** in step 7, browse for the location of the document that you want to use as the basis for your query. Click **Next**, and go to step 13.

◦ If you selected **Substance** in step 7, define criteria to search for PDSs. Optionally, to limit the search, select the family name. Select the substance. Optionally, select one or more countries. Optionally, select one or more application types. Select one or more application statuses and one or more PDS statuses. Go to step 14 to choose display options.

◦ If you selected **PDS Code/PDS Name** in step 7, define criteria to search for PDSs. Optionally, to limit the search, enter the product detail code, the product detail set name, or both. Optionally, select one or more countries. Optionally, select one or more application types. Select one or more application statuses and one or more PDS statuses. Go to step 14 to choose display options.

◦ If you selected **Product and Country** in step 7, define criteria to search for PDSs. Optionally, limit the search results by selecting one or more products. Select one or more application statuses and one or more PDS statuses. Optionally, select one or more countries. Optionally, select one or more application types. Click **Next**, and go to step 14 to choose display options.

◦ If you selected **Trade Name** in step 7, define criteria to search for PDSs. Optionally, to limit the search, select the family name. Select the trade name. Optionally, select one or more countries. Optionally, select one or more application types. Select one or more application statuses and one or more PDS statuses. Go to step 14 to choose display options.

1. If you selected **Assemblies Where Used Query** in step 7, you can optionally do the following:

   ◦ By default, Working and Sequence assembly types are included in the Assemblies Where Used Query search. If you want to limit your search results, deselect one of those options. Working status means the assembly was changed, but not added to the submission lifecycle. Sequence status means that the assembly is added to the submission lifecycle.

   ◦ To search for only one version of the document, deselect **All Versions of Document**.

◦ Change the **Document Currency Status**. If you use the default setting of Current Status Only, the results include only PDSs that include the document currently relevant for a submission. If you select **All Statuses**, the results include every PDS in which the document version appeared, regardless of whether the document is current. In other words, the search will return PDSs that have the document which has been superseded for reasons of being appended, revised, replaced, or withdrawn.

2. On the *Input Query Filter Criteria* page, optionally do any of the following to change the displayed results:

   ◦ Change the columns included in the displayed results, or change their order of appearance.

   ◦ Change the order in which the results will be presented.

3. Click **Next**.The *Select Product Detail* Sets page opens, listing the PDSs and associated applications that meet the search criteria.
4. Select the PDSs that you want to update.
5. Click **Next**.The *How would like to continue?* page opens.
6. Choose either of these options:

   ◦ Search for additional PDSs or view a summary of selected PDSs

   ◦ Continue on to create an event

7. Click **Next**.

   ◦ If you chose to search for additional PDSs or view a summary of selected PDSs, the *Select Search Option or Summary* page opens. Return to step 7.

   ◦ If you chose to create an event, the *Enter Event Details* page opens. Continue at step 20.

8. Enter values for the event attribute options presented.An event will be created for each application included in the project and the following will occur:

   ◦ For CP applications, the wizard automatically assigns the European Union to the created event. ◦ For National applications, the wizard automatically assigns the reviewing country for the event. ◦ For MRP applications, the RMS country will be assigned to the created event.

   ◦ For all application types, the event-country status is assigned to each country when the event is created.

9. Click **Next**.The *Select Timeline/Event Plan* page opens.
10. On the *Select Timeline/Event Plan* page, do one of the following:

    ◦ Select a timeline/event plan from the **Timeline/Event Plan** drop-down list to associate an event plan with the events created by the wizard. An event plan must exist in the system for you to select a timeline/event plan. If a timeline/event plan chosen in the project does not have a country lead time for the reviewing country on the selected application, the lead times in the status schedule table are assumed to be zero. Projected dates are calculated using lead times and the project's pivot status and status date. Continue at step 23.

    ◦ Do not select a timeline/event plan. A timeline/event plan will not be associated with the project. Click **Next** as many times as is necessary to open the *Confirmation* page. Continue at step 30.

11. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next** after completing each timeline/event plan page.

   ◦ If you select a timeline/event plan the event-country status will be set to the first status in the timeline/ event plan and include an actual date for that status on the event-country status schedule.

   ◦ If you do not select a timeline/event plan the event-country status is set to the default event status set in Data Administration and include an actual date for this status on the event-country status schedule.

   ◦ When all the timeline/event plan pages are completed, the *Confirmation* page opens.

2. Click **Next**.Events are created for the selected applications, and the PDSs you selected are now associated with the events. The *Create Sequence(s)* page opens.
3. On the *Create Sequence(s)* page, do one of the following:

   ◦ To create a sequence, select **Yes** and click **Next**. The *Sequence Attributes* page opens. Go to step 29.

   ◦ To proceed without creating a sequence, select **No** and click **Next**. If you select **No**, the wizard displays a message indicating that you do not need to enter sequence details. Go to step 30.

4. On the *Sequence Attributes* page, select or enter values for the sequence attributes.
5. Click **Next**.A confirmation page listing the actions that will be taken opens.
6. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

30.

   a. Click **Next**.The *Select Action* page opens.
   b. Select one of the available options to perform a specific PDS update. After completing the PDS update pages related to the action you chose, the *Perform Another PDS Action* page appears.
   c. On the *Perform Another PDS Action* page, do one of the following:

- Click **Yes** to return to the *Select Action* page in step 34 and perform another update PDS action.
- Click **No** and the *Summary* page opens. Proceed to the next step.

d. On the *Summary* page, do one of the following:

- Select the project link on the *Summary* page to review the new project you created.
- Click **Finish** to return to the view from which you invoked the *GPP* wizard.

e. To view the project after closing the *GPP* wizard, click **Home** > **Projects** tab.
f. Click the link for the project you just created to open the *Project Attributes* page.

Add a Substance

Using the *Global Project Planning* (GPP) wizard, you can add a substance across multiple applications/events at the same time.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To add a substance from the *Select Action* page of the *GPP* wizard:

1. Select the **Add Substance** option and click **Next**.The *Select Component* page appears.
2. Select one or more **Components** that you would like to add a substance to, and click **Next**.The *Enter Substance Values* page appears.
3. Enter the values for the new substance, and click **Next**. Required fields are marked with a red asterisk (*).The *Perform Another PDS Action* page appears.
4. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to perform another update PDS action.
   - Click **No** to proceed to the *Summary* page of the *GPP* wizard.
5. Click **Next**.One of the following occurs:
   - If you selected **Yes** in the previous step, you return to the *Select Action* page of the *GPP* wizard.
   - If you selected **No** in the previous step, the *Summary* page appears. Proceed to the next step.
6. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**.

Add an Indications/Intended Use PDS Project

Using the *Global Project Planning* (GPP) wizard, you can add indications and intended use to the PDS for a product.

The following conditions apply to this function:

- The list of available indications/intended use options will include all indications/intended use options that are not currently included in the PDS with Pending or Approved status.
- You cannot use this function to assign indications or intended use to veterinary product families.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To add indications and intended use from the *Select Action* page of the *GPP* wizard:

1. Select **Add Indications/Intended Use** on the *Select Action* page.
2. Click **Next**.The *Select Indications/Intended Use* page opens.
3. Select one or more indications/intended uses. The only ones available to select are those associated with the product families selected for the project.
4. Click **Next**.The *Perform Another PDS Action* page opens.
5. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to return to the *Select Action* page to perform another update PDS action.
   - Click **No** and proceed to the *Summary* page of the *GPP* wizard. Go to step 6.
6. On the *Summary* page, do one of the following:
   - Select the project link on the *Summary* page to review the new project you created.
   - Click **Finish**.

   You are returned to the view from which you invoked the *GPP* wizard. Upon completion, the selected indications/intended uses are assigned a Pending Add status in the PDS tree and a Pending status on the *Indication/Intended Use Detail Attributes* pages. Also, the selected indications/intended uses are associated with the Product Family if they were not previously associated.
7. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
8. Click the link for the project you just created to open the *Project Attributes* page.
9. Navigate to the PDS to view the newly added detail.

Add a Manufacturer PDS Project

Using the *Global Project Planning* (GPP) wizard, you can add manufacturers to approved PDS details for active ingredients, substances, component functions, PDS functions, package set functions, package set packaging, and component packaging.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To add a manufacturer from the *Select Action* page of the *GPP* wizard:

1. Select **Add Manufacturer** on the *Select Action* page.
2. Click **Next**.The *Select Flow* page opens.
3. Select the action you want to perform from the list presented. You can only choose one.
4. Click **Next**.The page for specifying the PDS details you want to update opens.
5. Specify the PDS details you want to update. After specifying the PDS details you want to update, the *Perform Another PDS Action* page appears.
6. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to return to the *Select Action* page and perform another update PDS action.
   - Click **No** to proceed to the *Summary* page of the *GPP* wizard.
7. Click **Next**.One of the following occurs:
   - If you selected **Yes** in step 6, you return to the *Select Action* page of the *GPP* wizard.
   - If you selected **No** in step 6, the *Summary* page opens. Go to step 8.
8. On the *Summary* page, do one of the following:
   - Select the project link on the *Summary* page to review the new project you created.
   - Click **Finish** to return to the view from which you invoked the *GPP* wizard.

   Upon completion, the manufacturer you chose to add is assigned a Pending Add status in the PDS.
9. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
10. Click the link for the project you just created to open the *Project Attributes* page.
11. Navigate to the PDS to view the modified details.

Specify the PDS Detail for an Add Manufacturer PDS Project

Add manufacturers in an update PDS project to PDS details for active ingredients, substances, component functions, PDS functions, package set functions, package set packaging, and component packaging.

When adding a manufacturer in an update PDS project, you are presented with the *Select Flow* page. The *Select Flow* page lists several options for the PDS details to which a manufacturer can be added.

After selecting the type of PDS detail on the *Select Flow* page and clicking **Next**, the project wizard displays the pages for specifying the PDS detail to be updated. The following topics describe the pages and the rules determining the PDS details that are available for selection.

Add an Active Ingredient Manufacturer

You can add an active ingredient manufacturer to a PDS via the *Global Project Planning* (GPP) wizard.

Table 19. Table 1. Rules Determining the PDS Details Available for Selection

PDS detail	Rules for available selections
Active Ingredients	All the approved active ingredients associated with the selected PDSs
Manufacturers	• Manufacturers with an active association with each of the selected active ingredients in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Values**. • Manufacturers that do not already exist as a pending or approved manufacturer for any of the selected active ingredients.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add an active ingredient manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add Active Ingredient Manufacturer**.
2. Click **Next**.The *Select Parent Entities* page opens.
3. On the *Select Parent Entities* page, do the following:
    a. Select one or more active ingredients.
    b. Select a manufacturer.
4. Click **Next**.The *Perform Another PDS Action* page opens.
5. On the *Perform Another PDS Action* page, do one of the following:

    ◦ Click **Yes** to perform another PDS action.

    ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.
6. Click **Next**.One of the following occurs:

    ◦ If you selected **Yes** in step 5, you return to the *Select Action* page in the *GPP* wizard.

    ◦ If you selected **No** in step 5, the *Summary* page opens. Proceed to step 7.
7. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**.

You are returned to the view from which you invoked the *GPP* wizard. In the PDS tree, the added manufacturer appears as a child node of the active ingredient. The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer.

Add an Active Ingredient Manufacturing Process Function Manufacturer

Using the *Global Project Planning* (GPP) wizard, you can add an active ingredient manufacturing process function manufacturer to the PDS.

Table 20. Table 1. Rules Determining the PDS Details Available for Selection

PDS detail	Rules for available selections
Active Ingredients	All approved active ingredients common to the PDS previously selected in the project.
Functions	All manufacturing functions established by your data administrator in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Function Values**.
Manufacturer	• Manufacturers with an active association with each of the selected active ingredients in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Values**. • Manufacturers that do not already exist as a pending or approved manufacturer for any of the selected active ingredients.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add an active ingredient manufacturing process function manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add Active Ingredient Manufacturing Process Function Manufacturer**.
2. Click **Next**.The first *Add Active Ingredient Manufacturing Process Function Manufacturer* page opens.
3. Do the following:
    a. Select one or more active ingredients.
    b. Select one or more functions.
4. Click **Next**.The second *Add Active Ingredient Manufacturing Process Function Manufacturer* page opens, listing all PDSs with approved manufacturing process functions for approved active ingredient components that also meet the criteria you selected in step 3.
5. Select one or more PDS from the list.
6. Click **Next**.The third *Add Active Ingredient Manufacturing Process Function Manufacturer* page opens.
7. Select a manufacturer to apply to all of the PDS selected in step 5.
8. Click **Next**.The manufacturer is added to the PDS and the *Perform Another PDS Action* page opens.
9. On the *Perform Another PDS Action* page, do one of the following:

    ◦ Click **Yes** to perform another PDS action.

    ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

10. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in step 9, you return to the *Select Action* page in the *GPP* wizard.

◦ If you selected **No** in step 9, the *Summary* page opens. Proceed to step 11.

11. On the *Summary* page, do one of the following.

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish** to return to the view from which you invoked the *GPP* wizard

In the PDS tree, the added manufacturer appears as a child node of the manufacturing process function for the active ingredient. The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer.

Add a Substance Manufacturer

Using the *Global Project Planning* (GPP) wizard, you can add a substance manufacturer to selected PDSs.

Table 21. Table 1. Rules Determining the PDS Details Available for Selection

PDS detail	Rules for available selections
Substances	All the approved substances that are common among the PDSs previously selected in the project.
Manufacturers	• Manufacturers with an active association with each of the selected substances in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Values**. • Manufacturers that do not already exist as a pending or approved manufacturer for any of the selected substances.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add a substance manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add Substance Manufacturer**.
2. Click **Next**.The *Select Parent Entities* page appears.
3. On the *Select Parent Entities* page, do the following:
    a. Select one or more substances.
    b. Select a manufacturer.
4. Click **Next**.The *Perform Another PDS Action* page appears.
5. On the *Perform Another PDS Action* page, do one of the following:

◦ Click **Yes** to perform another PDS action.

◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

6. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in step 5, you return to the *Select Action* page in the *GPP* wizard.

◦ If you selected **No** in step 5, the *Summary* page appears. Proceed to step 7.

7. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

In the PDS tree, the added manufacturer appears as a child node of the substance. The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer.

Add a Substance Manufacturing Process Function Manufacturer

Using the *Global Project Planning* (GPP) wizard, you can add a substance manufacturing process function manufacturer to the selected PDSs.

Table 22. Table 1. Rules Determining the PDS Details Available for Selection

PDS detail	**Rules for available selections**
Substance	All approved substances with any type associated with the previously selected PDSs.
Functions	All manufacturing functions established by your data administrator in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Function Values**.
Manufacturer	• Manufacturers with an active association with each of the selected substances in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Values**. • Manufacturers that do not already exist as a pending or approved manufacturer for any of the selected substances.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add a substance manufacturing process function manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add Substance Manufacturing Process Function Manufacturer**.
2. Click **Next**.
3. On the *Add Substance Manufacturing Process Function Manufacturer 1* page, do the following:
    a. Select one or more substances (of any type).
    b. Select one or more functions.

4. Click **Next**.The *Add Substance Manufacturing Process Function Manufacturer 2* page appears, listing all PDSs with approved manufacturing process functions for approved substance components that also meet the criteria you selected in step 3.
5. Select one or more PDS from the list.
6. Click **Next**.
7. On the *Add Substance Manufacturing Process Function Manufacturer 3* page, select a manufacturer to apply to all of the PDS selected in step 5.
8. Click **Next**.The manufacturer is added to the PDS and the *Perform Another PDS Action* page appears.
9. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to perform another PDS action.
   - Click **No** to proceed to the *Summary* page of the *GPP* wizard.
10. Click **Next**.One of the following occurs:
    - If you selected **Yes** in step 9, you return to the *Select Action* page in the *GPP* wizard.
    - If you selected **No** in step 9, the *Summary* page appears. Proceed to step 11.
11. On the *Summary* page, do one of the following:

- Select the project link on the *Summary* page to review the new project you created.
- Click **Finish** to return to the view from which you invoked the *GPP* wizard.

In the PDS tree, the added manufacturer appears as a child node of the manufacturing process function for the substance. The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer. The Status Date of the added manufacturer is set to today's date.

Add a Component Function Manufacturer

Using the *Global Project Planning* (GPP) wizard, you can add a component function manufacturer to selected PDSs.

Table 23. Table 1. Rules Determining the PDS Details Available for Selection

PDS detail	Rules for available selections
Functions	The approved functions that are common among the components you selected.
Manufacturers	• Manufacturers with an active association with each of the selected functions in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Values**. • Manufacturers that do not already exist as a pending or approved manufacturer for any of the selected functions.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add a component function manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add Component Function Manufacturer**.
2. Click **Next**.The *Select Component Functions* page opens, listing approved components associated with the PDSs previously selected in the wizard.
3. Select one or more component functions.
4. Click **Next**.The *Select Manufacturer* page opens.
5. Select a manufacturer.
6. Click **Next**.The *Perform Another PDS Action* page opens.
7. On the *Perform Another PDS Action* page, do one of the following:

Option	Action
To perform another PDS action:	Click **Yes**.
To proceed to the *Summary* page of the *GPP* wizard:	Click **No**.

8. Click **Next** and one of the following occurs:

Option	Action
If you selected **Yes** in step 7:	You return to the *Select Action* page in the *GPP* wizard.
If you selected **No** in step 7:	The *Summary* page appears. Proceed to step 9:

9. On the *Summary* page, do one of the following:

Option	Action
To review the new project you created:	Select the project link on the *Summary* page.
You are returned to the view from which you invoked the *GPP* wiz- ard:	Click **Finish**.

The added manufacturer appears as a child node of the component function node. The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer.

Add a Component Manufacturing Process Function Manager

Using the *Global Project Planning* (GPP) wizard, you can add a component manufacturing process function manufacturer to the selected PDSs.

Table 24. Table 1. Rules Determining the PDS Details Available for Selection

PDS details	Rules for available selections
Functions	All manufacturing process functions set up in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Function Values**.
Manufacturers	• Manufacturers with an active association with each of the selected functions in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Values**. • Manufacturers that do not already exist as a pending or approved manufacturer for any of the selected components.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add a component manufacturing process function manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add Component Manufacturing Process Function Manufacturer**.
2. Click **Next**.The *Select Functions* page opens.
3. Select one or more functions.
4. Click **Next**.The *Select Manufacturing Process Function* page opens, listing all component manufacturing process functions associated with the PDSs previously selected in the wizard.
5. Select one or more component manufacturing process functions.
6. Click **Next**.The *Select Manufacturer* page opens.
7. Select a manufacturer to apply to all of the PDSs selected in step 5.
8. Click **Next**.The *Perform Another PDS Action* page opens.
9. On the *Perform Another PDS Action* page, do one of the following:

Action	Description
Yes	Perform another PDS action.
No	Proceed to the *Summary* page of the *GPP* wizard..

10. Click **Next**.One of the following occurs:

Action	Description
Select **Yes** in step 9	Returns to the *Select Action* page in the *GPP* wizard.
Select **No** in step 9	*Summary* page opens. Proceed to step 11.

11. On the *Summary* page, do one of the following:

Action	Description
Select the project link on the *Summary* page	You can review the newly created project.
Click **Finish**	You are returned to the view from which you invoked the *GPP* wiz- ard.

In the PDS tree, the added manufacturer appears as a child node of the component manufacturing process function. The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer.

Add a PDS Function Manufacturer

Using the *Global Project Planning* (GPP) wizard, you can add a manufacturer to selected PDS functions.

Table 25. Table 1. Rules Determining the PDS Details Available for Selection

PDS details	Rules for available selections
Functions	Approved functions that are common among the PDSs previously selected in the project.
Manufacturers	• Manufacturers with an active association with each of the selected functions in **Data Administration** | **Product Detail Set Maintenance** | **Manufacturer Values**. • Manufacturers that do not already exist as a pending or approved manufacturer for any of the selected functions.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add a PDS manufacturing manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add PDS Function Manufacturer**.
2. Click **Next**.The *Parent Entities* page opens.
3. On the *Parent Entities* page, do the following:
    a. Select one or more functions.
    b. Select a manufacturer to apply to the selected functions.
4. Click **Next**.The *Perform Another PDS Action* page opens.
5. On the *Perform Another PDS Action* page, do one of the following:

    ◦ Click **Yes** to perform another PDS action.

    ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

6. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in step 5, you return to the *Select Action* page in the *GPP* wizard.

◦ If you selected no in step 5, the *Summary* page opens. Proceed to step 7.

7. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

In the PDS tree, the added manufacturer appears as a child node of the PDS manufacturing function node.

The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer.

Add a PDS Manufacturing Process Function Manufacturer

You can add a PDS manufacturing process function manufacturer to selected PDSs via the *Global Project Planning* (GPP) wizard.

Table 26. Table 1. Rules for Determining the PDS Details Available for Selection

PDS details	**Rules for available selections**
Functions	All manufacturing process functions common to the PDSs previously selected in the wizard.
Manufacturers	• Manufacturers with an active association with each of the selected functions in **Data Administration** > **Product Details set Maintenance** > **Manufacturer Values**. • Manufacturers that do not exist as pending or approved manufacturers for any of the selected functions.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add a PDS manufacturing process function manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add PDS Manufacturing Process Function Manufacturer**.
2. Click **Next**.The first *Add PDS Manufacturing Process Function Manufacturer* page opens.
3. Select one or more functions.
4. Click **Next**.The second *Add PDS Manufacturing Process Function Manufacturer* page opens, listing all approved manufacturing process functions for the PDSs previously selected in the wizard.
5. Select one or more from the list.
6. Click **Next**.The third *Add PDS Manufacturing Process Function Manufacturer* page opens.

7. Select a manufacturer to apply to all of the PDSs selected in step 5.
8. Click **Next**.The *Perform Another PDS Action* page opens.
9. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to perform another PDS action.
   - Click **No** to proceed to the *Summary* page of the *GPP* wizard.
10. Click **Next**.One of the following occurs:
    - If you selected **Yes** in step 9, you return to the *Select Action* page of the *GPP* wizard.
    - If you selected **No** in step 9, the *Summary* page opens. Proceed to step 11.
11. On the *Summary* page, do one of the following:

- Select the project link on the *Summary* page to review the new project you created.
- Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

In the PDS tree, the added manufacturer appears as a child node of the PDS manufacturing process function.

The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer.

Add a Package Set Function Manufacturer

Using the *Global Project Planning* (GPP) wizard, you can add a package set function manufacturer to selected PDSs.

Table 27. Table 1. Rules Determining the PDS Details Available for Selection

PDS detail	Rules for available selections
Functions	All manufacturing process functions common the to the selected package sets.
Manufacturers	• Manufacturers with an active association with each of the selected functions in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Values**. • Manufacturers that do not already exist as a pending or approved manufacturer for any of the selected functions.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add a package set function manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add Package Set Function Manufacturer**.
2. Click **Next**.The first *Add Package Set Function Manufacturer* page opens, listing the approved package set functions for the PDSs previously selected in the wizard.

3. Select one or more package set functions.
4. Click **Next**.The second *Add Package Set Function Manufacturer* page opens.
5. On the *Add Package Set Function Manufacturer* page, do the following:
    a. Select one or more functions.
    b. Select a manufacturer to apply to the selected functions.
6. Click **Next**.The *Perform Another PDS Action* page opens.
7. On the *Perform Another PDS Action* page, do one of the following:

◦ Click **Yes** to perform another PDS action.

◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

8. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in step 7, you return to the *Select Action* page of the *GPP* wizard.

◦ If you selected **No** in step 7, the *Summary* page opens. Proceed to step 9.

9. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

In the PDS tree, the added manufacturer appears as a child node of the package set function node. The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer.

Add a Package Set Packaging Manufacturer

Using the *Global Project Planning* (GPP) wizard, you can add a package set packaging manufacturer to selected PDSs.

The following rules determine the PDS Details that are available for selection.

PDS detail	**Rules for available selections**
Packaging de tails	• All approved packaging details for each approved package set associated with PDSs previously selected in the project. • Approved packaging details available for selection are limited by packaging categories and packaging types criteria defined in **Data Administration** > **Product Detail Set Maintenance** > **Packaging Type Values** or **Packaging Category Values**.**Note:** You cannot create more than one **Packaging** with the same **Packaging Category** and **Packaging Type**.

Manufacturers	• Manufacturers with an active association with each of the selected functions in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Values**. • Manufacturers that do not already exist as a pending or approved manufacturer for any of the selected packaging details.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add a package set packaging manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add Package Set Packaging Manufacturer**.
2. Click **Next**.The first *Add Package Set Packaging Manufacturer* page opens.
3. On the *Add Package Set Packaging Manufacturer* page:
    a. Select one or more packaging categories.
    b. Select one or more packaging types.
4. Click **Next**.The second *Add Package Set Packaging Manufacturer* page opens, listing the approved package set packaging for the previously selected PDSs.
5. Select one or more from the list, then click **Next**.The third *Add Package Set Packaging Manufacturer* page opens.
6. Select a manufacturer, then click **Next**.The *Perform Another PDS Action* page opens.
7. On the *Perform Another PDS Action* page, do one of the following:

    ◦ Click **Yes** to perform another PDS action.

    ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

8. Click **Next**.One of the following occurs:

    ◦ If you selected **Yes** in step 7, you return to the *Select Action* page of the *GPP* wizard. If you perform another add package set packaging manufacturer action, the previously selected packaging category and packaging type remain selected.

    ◦ If you selected **No** in step 7, the *Summary* page opens. Proceed to the next step.

9. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

In the PDS tree, the added manufacturer appears as a child node of the packaging node, which is a child node of the package set. The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer.

Add a Package Set Component Packaging Manufacturer

Using the *Global Project Planning* (GPP) wizard, you can add a package set component packaging manufacturer to selected PDSs.

Table 28. Table 1. Rules Determining the PDS Details Available for Selection

PDS detail	Rules for available selections
Packaging details	• All the approved packaging details for each approved package set associated with PDSs previously selected in the project. • The approved packaging details available for selection are limited by packaging categories and packaging types criteria defined in **Data Administration** > **Product Detail Set Maintenance** > **Packaging Type Values** or **Packaging Category Values**.
Manufacturers	• Manufacturers with an active association with each of the selected functions in **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer Values**. • Manufacturers that do not already exist as a pending or approved manufacturer for any of the selected packaging details.

Note: This procedure is a continuation of the *Update Product Details Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first, followed by initiating *Adding a Manufacturer PDS Project*.To add a package set component packaging manufacturer:

1. On the *Select Flow* page of the *GPP* wizard, select **Add Package Set Component Packaging Manufacturer**.
2. Click **Next**.The first *Add Package Set Component Packaging Manufacturer* page opens.
3. On the *Add Package Set Component Packaging Manufacturer* page, do the following:
    a. Select one or more packaging categories.
    b. Select one or more packaging types.
4. Click **Next**.The second *Add Package Set Component Packaging Manufacturer* page opens, listing the approved packaging types for the package set component packaging in the previously selected PDSs.
5. Select one or more from the list.
6. Click **Next**.The third *Add Package Set Component Packaging Manufacturer* page opens.
7. Select a manufacturer.
8. Click **Next**.The *Perform Another PDS Action* page opens.
9. On the *Perform Another PDS Action* page, do one of the following:

    ◦ Click **Yes** to return to perform another update PDS action. ◦ Click **No** to proceed to *Summary* page of the *GPP* wizard.

10. Click **Next**.One of the following occurs:

- If you selected **Yes** in step 9, you return to the *Select Action* page of the *GPP* wizard.
- If you selected **No** in step 9, proceed to step 11.

11. On the *Summary* page, do one of the following:

- Select the project link on the *Summary* page to review the new project you created.
- Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

In the PDS tree, the added manufacturer appears as a child node of the packaging node, which is a child node of the component node in the package set. The status of the added manufacturer is Pending Add and is displayed in parentheses after the name of the manufacturer.

Add a Manufacturing Process

Using the *Global Project Planning* (GPP) wizard, you can add the manufacturing process for an active ingredient detail, component detail, substance detail, or PDS manufacturing detail in a PDS.

To add a manufacturing process on the *Select Action* page of the GPP wizard:

1. Select **Add Manufacturing Process**, and click **Next**.
2. On the *Select Manufacturing Process Parent* page, select the manufacturing process parent type: ◦ Active Ingredient
   - Component
   - Product Detail Set
   - Substance
3. Click **Next**.The *Enter Manufacturing Process Values* page appears.
4. On the *Enter Manufacturing Process Values* page, populate the needed attributes:
   - Manufacturing Process Name (required)
   - Manufacturing Process Specification
   - Manufacturing Process Keywords
   - Manufacturing Process Description
   - Manufacturing Process Comments
5. Click **Next**. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to perform another update PDS action.
   - Click **No** to proceed to the *Summary* page of the GPP wizard.
6. Click **Next**. Proceed as follows:

- If you selected **Yes** in the previous step, you return to the *Select Action* page of the GPP wizard.

  Proceed to Step 1, and execute the steps to perform another update PDS action.

- If you selected **No** in the previous step, the *Summary* page appears. Go to the next step.

7. On the *Summary* page, do one of the following:

- Select the project link on the *Summary* page to review the new project you created.
- Click **Finish**. You are returned to the view from which you invoked the GPP wizard.

To view the project after closing the GPP wizard, click **Home** > **Projects**. Click the link for the project you just created to open the *Project Attributes* page. Navigate to the PDS to view the modified details.

Add a Manufacturing Process Step Function

Using the *Global Project Planning* (GPP) wizard, you can add the manufacturing process step function for an active ingredient detail, component detail, substance detail, or PDS manufacturing detail in a PDS.

To add a manufacturing process on the *Select Action* page of the GPP wizard:

1. Select **Add Manufacturing Process Step Function**, and click **Next**.
2. On the *Select Manufacturing Process Step Function Parent* page, select the manufacturing process parent type:

   - Active Ingredient
   - Component
   - Product Detail Set
   - Substance

3. Click **Next**.The *Select Manufacturing Process Step* page appears.
4. On the *Select Manufacturing Process Step* page, select the value or values that you want to modify, and click **Next**.The *Enter Manufacturing Prcoess Step Function Values* page appears.
5. On the *Enter Manufacturing Prcoess Step Function Values* page, populate the needed attributes:

   - Function
   - Function Keywords
   - Function Description
   - Function Comments
   - (Any configured fields)

6. Click **Next**. On the *Perform Another PDS Action* page, do one of the following:

◦ Click **Yes** to perform another update PDS action.

◦ Click **No** to proceed to the *Summary* page of the GPP wizard.

7. Click **Next**. Proceed as follows:

◦ If you selected **Yes** in the previous step, you return to the *Select Action* page of the GPP wizard.

Proceed to Step 1, and execute the steps to perform another update PDS action.

◦ If you selected **No** in the previous step, the *Summary* page appears. Go to the next step.

8. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the GPP wizard.

To view the project after closing the GPP wizard, click **Home** > **Projects**. Click the link for the project you just created to open the *Project Attributes* page. Navigate to the PDS to view the modified details.

Add a Material

Using the *Global Project Planning* (GPP) wizard, you can add a material across multiple applications/events at the same time.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To add a material from the *Select Action* page of the *GPP* wizard:

1. Select the **Add Material** option and click **Next**.The *Select Manufacturing Process Step Material Parent* page appears.
2. In the **Material Parent Type** multi-select box, select one or more material parent types that you would like to add a material to and click **Next**.The *Select Manufacturing Process Step* page appears.
3. Select one or multiple values in the *Select Manufacturing Process Step* table by selecting the appropriate check boxes and click **Next**.The *Enter Manufacturing Process Step Material Values* page appears.
4. From the **Material Name** list, select the material that you want to add. Optionally, enter the following values:

◦ MCB ◦ WCB

◦ Biotechnology Origin

◦ Material Animal/Human Origin Certificate Filed?

◦ Material Animal/Human Origin

◦ Material Type

◦ Material Keywords

◦ Material Description

◦ Material Comments

Click **Next**. The *Perform Another PDS Action* page appears.

5. On the *Perform Another PDS Action* page, do one of the following:

◦ Click **Yes** to perform another update PDS action.

◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

6. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in the previous step, you return to the *Select Action* page of the *GPP* wizard.

◦ If you selected **No** in the previous step, the *Summary* page appears. Proceed to the next step.

7. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**.

Add a Package Sets PDS Project

You can add package sets to the PDS for a product via the *Global Project Planning* (GPP) wizard.

Consider the following before using this function:

- You must have PDS templates associated with the product
- The PDS templates must include package sets
- You cannot add a package set to a PDS if the PDS contain the selected package with a Pending or Approved package set status
- Package sets with a status of Pending or Approved will not be available for selection

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To add a package set from the *Select Action* page of the *GPP* wizard:

1. Select **Add Package Set**.
2. Click **Next**.The *Select Packaging Set*(s) page appears.
3. Do the following:
    a. Select a product.
    b. Select a PDS template.
    c. Select one or more package sets.

4. Click **Next**.The *Perform Another PDS Action* page opens.
5. On the *Perform Another PDS Action* page, do one of the following:

   ◦ Click **Yes** to return to the *Select Action* page to perform another update PDS action.

   ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

   ◦ Click **Finish**. The package set and all child nodes (Packaging, etc.), associated to the package set in the template are added to the PDS and you are returned to the view from which you invoked the *GPP* wizard. No further steps are necessary.
6. Click **Next**.One of the following occurs:

   ◦ If you selected **Yes** in step 5, the package sets are added to the PDS for the product selected in step 3 and you return to the *Select Action* page of the *GPP* wizard.

   ◦ If you selected **No** in step 5, proceed to step 7.
7. On the *Summary* page, do one of the following:

   ◦ Select the project link on the *Summary* page to review the new project you created.

   ◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.
8. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
9. Click the link for the project you just created to open the *Project Attributes* page.
10. Navigate to the PDS to view the newly added detail.

Add Component Packaging to a Package Set PDS Project

Using the *Global Project Planning* (GPP) wizard, you can add packaging to a component in a package set.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To add component packaging to a package set from the *Select Action* page of the *GPP* wizard:

1. Select **Add Component Packaging to a Package Set**.
2. Click **Next**.The *Select Packaging Set Components* page appears, listing PDSs that have approved package set components.
3. Select one or more package set components.
4. Click **Next**.The *Select Packaging* page appears.
5. Select a packaging category.
6. Select a packaging type.If a detail for that packaging type currently exists in the PDS, that type will not appear as an available option in the **Packaging Type** list.
7. Click **Next**.The *Perform Another PDS Action* page appears.
8. On the *Perform Another PDS Action* page, do one of the following:

   ◦ Click **Yes** to return to the *Select Action* page to perform another update PDS action.

◦ Click **No** and proceed to the *Summary* page of the *GPP* wizard.

9. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in step 8, the package set component packaging is added to the PDSs for each application that you selected in step 3 and you return to the *Select Action* page of the *GPP* wizard.

◦ If you selected **No** in step 8, proceed to step 10.

10. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

11. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
12. Click the link for the project you just created to open the *Project Attributes* page.
13. Navigate to the PDS to view the newly added detail.

Use the GPP Wizard to Add Shelf Life Details to Package Sets

You can track concurrent pending changes to product shelf life information by examining shelf life details. You can use the *Global Project Planning* (GPP) wizard to add shelf life details to package sets in PDSs.

Before you use the *GPP* wizard to do this, do the following:

- Make sure that you understand the constraints on shelf life details. See Shelf life/storage condition details.
- Create one or more PDS templates that define the shelf life details that you want to add.
- The package sets must exist in the destination PDS(s).

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To add shelf life details from the *Select Action* page of the *GPP* wizard:

On the *Select Action* page, select **Add Shelf Life**.

Click **Next**.

1. On the *Select Shelf Life from a PDS Template* page, in the **Product** box, click the product for which you are adding a shelf life.
2. In the **PDS Template** box, select the template that defines the shelf that you want to add.
3. In the **Package Set** box, select the template package set that contains the shelf life that you are adding.
4. In the **Shelf Life Grouping** box, select the group for the kind of shelf life that you are adding.
5. In the **Shelf Life** box, select the shelf life that you are adding.
6. To search for the package sets to which you want to add the shelf life, do the following:

a. In the **Display Columns** area, in the **Available** box, select the columns to display in the search results, and then click the right angle bracket button.
b. In the **Selected** area, click the **up** and **down** buttons to arrange the columns in the order in which you want them displayed.
c. In the **Sort Order** area, in the **Available** box, select the columns on which the package sets are sorted and the order in which they are sorted. **ASC** means ascending order, and **DESC** means descending order.

7. Click **Next**.
8. On the *Select Destination Package Set*(s) page, select the package sets to which you are adding the shelf life.

◦ Package Set(s) with Approved Shelf Life details for the selected category will be available for selection.

◦ Package Set(s) with no Shelf Life details for the selected category will be available for selection.

◦ Package Set(s) with a status of Not Approved, or Withdrawn will not be available for selection.

9. Click **Next**.
10. On the Perform Another PDS Action page, do one of the following:

◦ To return to the *Select Action* page to perform another update PDS action, click **Yes** and **Next**, and continue at the beginning of this procedure.

◦ To complete this procedure without performing another update PDS action, click **No** and **Next**, and continue at the next step.

11. On the *Summary* page, do one of the following:

◦ To review the new project that you created, select the project link on the *Summary* page.

◦ To return to the view from which you started the *GPP* wizard, click **Finish**.

12. To view the project after you close the *GPP* wizard:
    a. Click **Home**.
    b. Click **Projects**.
    c. Click the link for the project that you just created.
    d. To view the shelf life details that GPP added, navigate to the PDS.

Add a Species PDS Project

You can use the *Global Project Planning* (GPP) wizard to add one or more species to the PDS for veterinary product families.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To add one or more species to a product from the *Select Action* page of the *GPP* wizard:

1. Select **Add Species**.
2. Click **Next**.The *Select Species* page appears.

3. Select one or more species. If a species is currently included in any of the selected PDSs, it will not appear in the list of available species.
4. Click **Next**.The *Perform Another PDS Action* page appears.
5. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to return to the *Select Action* page to perform another update PDS action.
   - Click **No** to proceed do the *Summary* page of the *GPP* wizard.
6. Click **Next**.One of the following occurs:
   - If you selected **Yes** in step 5, you return to the *Select Action* page of the *GPP* wizard.
   - If you selected **No** in step 5, the *Summary* page opens. Go to step 7.
7. On the *Summary* page, do one of the following:
   - Select the project link on the *Summary* page to review the new project you created.
   - Click **Finish**. You are returned to the view from which you invoked the wizard.
8. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
9. Click the link for the project you just created to open the *Project Attributes* page.The new species product details will appear in the PDS tree on the *Product Details Attributes* page.**Warning:** At this time, you are not prevented from adding species details to non-veterinary PDSs using the *GPP* wizard. If you inadvertently add species details to non-veterinary products, you will not see species details added to the PDS tree for the product. However, the species details will be maintained in the database and they will appear in any related queries that you perform.

Add a Species Indication PDS Project

You can add species indications to the PDS for veterinary product families via the *Global Project Planning* (GPP) wizard.

The following conditions apply to this function:

- The list of available species indication options will include only indications that are not currently included in the selected PDSs with Pending or Approved status for the selected species.
- Only PDSs that have an Approved species associated with the PDS will be available for adding species indications.
- You cannot use this function to assign species indications to non-veterinary product families.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To add species indications and intended use from the *Select Action* page of the *GPP* wizard:

Select **Add Species Indications** on the *Select Action* page.

Click **Next**.The *Select Species* page appears.

1. Select one or more species in the multi-select box.
2. Click **Next**.The *Select the PDS*(s) page appears.
3. Select one or more of the listed PDSs.
4. Click **Next**.The *Select Indication and Sub-Indications* page appears.
5. On the *Select Indication and Sub-Indications* page, do the following:
    a. Select an indication.
    b. Optionally, select one or more sub-indications if any are available for selection based on the indication selected.
6. Click **Next**.The *Perform Another PDS Action* page appears.
7. On the *Perform Another PDS Action* page, do one of the following:

    ◦ Click **Yes** to return to the *Select Action* page to perform another update PDS action.

    ◦ Click **No** and proceed to the *Summary* page of the *GPP* wizard. Go to step 10.

8. On the *Summary* page, do one of the following:

    ◦ Select the project link on the *Summary* page to review the new project you created.

    ◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

    Upon completion, the selected species indications are added to the PDS and assigned a Pending Add status in the PDS tree and a Pending status on the *Species Indication Attributes pages*. If the selected species indications were not previously associated with the selected veterinary product families, then they will be associated after running the wizard.

9. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
10. Click the link for the project you just created to open the *Project Attributes* page.
11. Navigate to the PDS to view the newly added detail.

Modify an Active Ingredient

Using the *Global Project Planning* (GPP) wizard, you can modify an active ingredient across multiple applications/ events at the same time.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To modify an active ingredient from the *Select Action* page of the *GPP* wizard:

1. Select the **Modify Active Ingredient** option and click **Next**.The *Select Active Ingredient* page appears.
2. Select the ingredient(s) that you want to modify, and click **Next**.
3. In the *Enter Active Ingredient Values* page, select the check box next to the value(s) you want to modify.
4. Enter the new value(s), and click **Next**.The *Perform Another PDS Action* page appears.
5. On the *Perform Another PDS Action* page, do one of the following:

◦ Click **Yes** to perform another update PDS action.

◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

6. Click **Next**.One of the following occurs:

   If you selected **Yes** in the previous step, you return to the *Select Action* page of the *GPP* wizard. If

   you selected **No** in the previous step, the *Summary* page appears. Proceed to the next step.

7. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**.

Modify a Substance

Using the *Global Project Planning* (GPP) wizard, you can modify a substance across multiple applications/events at the same time.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To modify a substance from the *Select Action* page of the *GPP* wizard:

1. Select the **Modify Substance** option and click **Next**.The *Select Substance Type Detail* page appears.
2. Select one or more **Substance Type**(s) that you would like to modify, and click **Next**.The *Select Substance* page appears.
3. Select the check box next to the Product Family you want to modify the substance of, and click **Next**.The *Enter Substance Values* page appears.
4. Select the check box next to the field you want to modify the substance of, enter a new value, and click **Next**.The *Perform Another PDS Action* page appears.
5. On the *Perform Another PDS Action* page, do one of the following:

   ◦ Click **Yes** to perform another update PDS action.

   ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

6. Click **Next**.One of the following occurs:

   ◦ If you selected **Yes** in the previous step, you return to the *Select Action* page of the *GPP* wizard.

   ◦ If you selected **No** in the previous step, the *Summary* page opens. Proceed to the next step.

7. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**.

Modify a Material

Using the *Global Project Planning* (GPP) wizard, you can modify a material across multiple applications/events at the same time.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To modify a material from the *Select Action* page of the *GPP* wizard:

Select the **Modify Material** option and click **Next**.The *Select Material Parent* page appears.

Select one or more **Material Parent Types** that you would like to modify a material for and click **Next**.The *Select Material* page appears.

1. From the **Material** list, select the material that you want to modify and click **Next**.The *Enter Material Values* page appears.
2. Click the check box next to the material you want to modify, enter the new value, and click **Next**.The *Perform Another PDS Action* page appears.
3. On the *Perform Another PDS Action* page, do one of the following:

   ◦ Click **Yes** to perform another update PDS action.

   ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.
4. Click **Next**.One of the following occurs:

   ◦ If you selected **Yes** in the previous step, you return to the *Select Action* page of the *GPP* wizard.

   ◦ If you selected **No** in the previous step, the *Summary* page opens. Proceed to the next step.
5. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**.

Modify a Component Characteristics PDS Project

Using the *Global Project Planning* (GPP) wizard, you can modify approved characteristics for the product components associated with the PDSs selected in a project.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To modify component characteristics from the *Select Action* page of the *GPP* wizard:

1. Select **Modify Component Characteristics** on the *Select Action* page.
2. Click **Next**.The first *Modify Component Characteristics* page appears, listing PDSs that have approved component characteristic details.
3. Select one or more components.
4. Click **Next**.The second *Modify Component Characteristics* page appears, listing all the characteristic detail attributes that can be modified.
5. To modify an attribute, select the check box next to the attribute and then specify a value. If you select an attribute and leave the value blank, the component characteristic will be updated with a blank value.**Note:** Only the selected attributes will be updated. The values for unselected attributes will remain unchanged in the characteristic details you are updating.
6. Click **Next**.The *Perform Another PDS Action* page opens.
7. On the *Perform Another PDS Action* page, do one of the following:

   ◦ Click **Yes** to return to the *Select Action* page and perform another update PDS action.

   ◦ Click **No** and proceed to the *Summary* page of the *GPP* wizard.
8. Click **Next**.One of the following occurs:

   If you selected **Yes** in step 7, you return to the *Select Action* page of the *GPP* wizard.

   If you selected **No** in step 7, the *Summary* page appears. Go to step 9.
9. On the *Summary* page, do one of the following:

   ◦ Select the project link on the *Summary* page to review the new project you created.

   ◦ Click **Finish**. You are returned to the view from which you invoked the wizard.
10. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
11. Click the link for the project you just created to open the *Project Attributes* page.

Modify a Manufacturing Process

Using the *Global Project Planning* (GPP) wizard, you can modify the manufacturing process of an active ingredient detail, component detail, substance detail, or PDS manufacturing detail in a PDS.

To modify a manufacturing process on the *Select Action* page of the GPP wizard:

1. Select **Modify Manufacturing Process** on the *Select Action* page, and click **Next**.
2. On the *Modify Manufacturing Process 1* page, select the manufacturing process parent type: ◦ Active Ingredient

   ◦ Component

- Product detail Set
- Substance

3. Click **Next**.The *Modify Manufacturing Process 2* page appears, listing PDSs containing approved manufacturing processes for approved parent details that also meet the criteria selected in the previous step.
4. Select one or more PDSs, and click **Next**.The *Enter Manufacturing Process Values* page appears, presenting the options to change:
   - Manufacturing Process Name
   - Manufacturing Process Specification
   - Manufacturing Process Keywords
   - Manufacturing Process Description
   - Manufacturing Process Comments
5. Select the check box next to the attribute you want to change. Enter text in the available field.
   - If you select a check box and leave the associated field blank, the manufacturing process property is updated with a blank value.
   - Only the selected property attributes will be updated. The values for property attributes that are not selected will remain unchanged in the manufacturing process you are updating.
6. Click **Next**. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to perform another update PDS action.
   - Click **No** to proceed to the *Summary* page of the GPP wizard.
7. Click **Next**. Proceed as follows:
   - If you selected **Yes** in the previous step, you return to the *Select Action* page of the GPP wizard.

     Proceed to step 1, and execute the steps to perform another update PDS action.
   - If you selected **No** in the previous step, the *Summary* page appears. Go to the next step.
8. On the *Summary* page, do one of the following:

Select the project link on the *Summary* page to review the new project you created.

Click **Finish**. You are returned to the view from which you invoked the GPP wizard.

To view the project after closing the GPP wizard, click **Home** > **Projects**. Click the link for the project you just created to open the *Project Attributes* page. Navigate to the PDS to view the modified details.The Status of a selected Manufacturing Process is set to Pending Modify and the Status Date of the Detail is set to the current date.

Modify a Manufacturing Process Step

Using the *Global Project Planning* (GPP) wizard, you can modify Manufacturer Process Step value(s) across multiple applications/events at the same time.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To modify a Manufacturing Process Step from the *Select Action* page of the *GPP* wizard:

1. Select the **Modify Manufacturing Process Step** radio button and click **Next**.The *Select Manufacturing Process Step Parent* screen appears.
2. Select the **Manufacturing Process Parent Type** that you want to modify, and click **Next**.
3. On the *Select Manufacturing Process Step* page, select the value(s) you want to modify.
4. On the *Enter Manufacturing Process Step Values* page, select the checkbox next to the value(s) you want to modify.
5. Enter the new value(s), and click **Next**.The *Perform Another PDS Action* page appears.

Modify a Manufacturing Process Step Function

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To modify a manufacturing process step function on the *Select Action* page of the GPP wizard:

1. Select **Modify Manufacturing Process Step Function**, and click **Next**.
2. On the *Select Manufacturing Process Step Function Parent* page, select the manufacturing process parent type:
   - Active Ingredient
   - Component
   - Product Detail Set
   - Substance
3. Click **Next**.The *Select Manufacturing Process Step Function* page appears, listing PDSs containing approved manufacturing process step functions for approved parent details that also meet the criteria selected in the previous step.
4. Select one or more PDSs, and click **Next**.The *Enter Manufacturing Process Step Function Values* page appears, presenting the options to change:

   Function Keywords

   Function Description

   - Function Comments
5. Select the check box next to the attribute you want to change. Enter text in the available field.

◦ If you select a check box and leave the associated field blank, the manufacturing process property is updated with a blank value.

◦ Only the selected property attributes will be updated. The values for property attributes that are not selected will remain unchanged in the manufacturing process you are updating.

6. Click **Next**.The *Perform Another PDS Action* page opens.
7. On the *Perform Another PDS Action* page, do one of the following:

◦ Click **Yes** to perform another update PDS action.

◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

8. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in the previous step, you return to the *Select Action* page of the *GPP* wizard.

◦ If you selected **No** in the previous step, the *Summary* page opens. Proceed to the next step.

9. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**.

Use the GPP Wizard to Modify Package Set Details

Using the *Global Project Planning* (GPP) wizard, you can modify the properties of approved package sets at the package set level, such as shelf life and storage conditions, for the package sets associated with the PDSs selected in a project. The changes you make with the package set *PDS project* wizard are applied to all the approved package sets you select.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.

To modify package set details from the *Select Action* page of the *GPP* wizard:

1. Select **Modify Package Set** on the *Select Action* page.
2. Click **Next**.
3. On the first *Modify Package Set* page, select the product families containing products that have PDSs with the approved package sets that you want to update.
4. Click **Next**.
5. On the second *Modify Package Set* page, modify package set properties.

◦ To modify an attribute, click the check box next to the **attribute** field and then specify a value. If you select a check box and leave the associated field blank, the package set property is updated with a blank value.

◦ Only the property attributes you check will be updated. The values for unchecked property attributes will remain unchanged in the package set you are updating.

6. Click **Next**.The *Perform another PDS Action* page opens.
7. Do one of the following:

Option	Action
To return to the *Select Action* page to select another update PDS action:	Click **Yes**.
To proceed to the *Summary* page of the *GPP* wizard:	Click **No**.

8. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in step 7, the package set attributes are modified in the PDSs that you selected in step 3, and you return to the *Select Action* page of the *GPP* wizard.

◦ If you selected **No** in step 7, the *Summary* page opens. Go to step 9.

9. On the *Summary* page, do one of the following:

Option	Action
To review the new project you created:	Select the project link on the *Summary* page.
To return to the view from which you invoked the *GPP* wizard:	Click **Finish**.

10. To view the project after you close the GPP wizard:
    a. Click **Home**.
    b. Click **Projects**.
    c. Click the link for the project that you just created.
    d. To view the details that GPP modified, navigate to the PDS.

Modify Component Packaging for a Package Set PDS Project

Using the *Global Project Planning* (GPP) wizard, you can modify packaging for a component in a package set. The changes you make with the wizard are applied to all approved package set component packaging details that you select.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project type in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To modify component packaging for a package set on the *Select Action* page of the *GPP* wizard:

1. Select **Modify Component Packaging for Package Set** on the *Select Action* page.
2. Click **Next**.The *Select Packaging* page appears.
3. On the *Select Packaging* page, do the following:

a. Select one or more packaging categories.
b. Select one or more packaging types.

4. Click **Next**.The *Select Package Set Component Packaging* page appears, listing only PDSs that have approved package sets and approved packaging details that were selected in the previous screen.
5. Select one or more PDSs.
6. Click **Next**.The *Modify Package Set Component Packaging Details* page appears, presenting the options to change the **packaging comments**, **keywords**, and **description**. Making entries on this page is optional. If you want to make changes, go to step 7. If you do not want to make changes, go to step 8.
7. Select the check box next to the attribute you want to change.
   a. Enter text in the available field. If you select an attribute and leave the associated field blank, the package set component packaging will be updated with a blank value.

      Note: Only the property attributes that you select are updated. The values for unselected property attributes remain unchanged.
8. Click **Next**.The *Perform Another PDS Action* page appears.
9. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to perform another update PDS action.
   - Click **No** to proceed to the *Summary* page of the *GPP* wizard.
10. Click **Next**.One of the following occurs:
    - If you selected **Yes** in step 9, you return to the *Select Action* page of the *GPP* wizard.
    - If you selected **No** in step 9, the *Summary* page appears. Go to step 11.
11. On the *Summary* page, do one of the following:
    - Select the project link on the *Summary* page to review the new project you created.
    - Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.
12. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
13. Click the link for the project you just created to open the *Project Attributes* page.
14. Navigate to the PDS to view the modified details.

Modify Packaging for a Package Set

Using the *Global Project Planning* (GPP) wizard, you can modify the packaging for a package set across multiple applications/events at the same time.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To modify the packaging for a package set from the *Select Action* page of the *GPP* wizard:

1. Select the **Modify Packaging for Package Set** option and click **Next**.The *Select Packaging* page appears.
2. Select one or more **Packaging Categories** that you would like to modify.
3. Select one or more **Packaging Types** that you would like to modify, and click **Next**.The *Select Packaging for Package Set* page appears.
4. Click the check box next to the Product Family you want to modify the packaging of, and click **Next**.The *Enter Packaging Values* page appears.
5. Click the check box next to the field you want to modify the packaging of, enter a new value, and click **Next**.The *Perform Another PDS Action* page appears.
6. On the *Perform Another PDS Action* page, do one of the following:

   ◦ Click **Yes** to perform another update PDS action.

   ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.
7. Click **Next**.One of the following occurs:

   ◦ If you selected **Yes** in the previous step, you return to the *Select Action* page of the *GPP* wizard.

   ◦ If you selected **No** in the previous step, the *Summary* page opens. Proceed to the next step.
8. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**.

Modify a Shelf Life PDS Project

Using the *Global Project Planning (GPP)* wizard, you can modify approved shelf life(s) for the product components associated with the PDSs selected in a project.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project type in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To modify shelf life from the *Select Action* page of the *GPP* wizard:

1. Select **Modify Shelf Life** on the *Select Action* page.
2. Click **Next**.The first *Modify Shelf Life* page appears, listing PDSs that have approved component characteristic details.
3. Select one or more components.
4. Click **Next**.The second *Modify Component Characteristics* page appears, listing all the characteristic detail attributes that can be modified.
5. To modify an attribute, select the check box next to the attribute and then specify a value. If you select an attribute and leave the value blank, the component characteristic will be updated with a blank value.**Note:** Only the attributes you select will be updated. The values for unselected attributes will remain unchanged in the characteristic details you are updating.

6. Click **Next**.The *Perform Another PDS Action* page appears.
7. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to return to the *Select Action* page and perform another update PDS action.
   - Click **No** and proceed to the *Summary* page of the *GPP* wizard.
8. Click **Next**.One of the following occurs:
   - If you selected **Yes** in step 7, you return to the *Select Action* page of the *GPP* wizard.
   - If you selected **No** in step 7, the *Summary* page appears. Go to step 9.
9. On the *Summary* page, do one of the following:

- Select the project link on the *Summary* page to review the new project you created.
- Click **Finish**. You are returned to the view from which you invoked the wizard.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**. Click the link for the project you just created to open the *Project Attributes* page.

Withdraw Component Packaging for a Package Set PDS Project

Using the *Global Project Planning* (GPP) wizard, you can withdraw approved packaging for a component in a PDS package set.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project type in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To withdraw component packaging for a package set on the *Select Action* page of the *GPP* wizard:

1. Select **Withdraw Component Packaging for Package Set** on the *Select Action* page.
2. Click **Next**.The *Select Packaging* page appears.
3. On the *Select Packaging* page, do the following:
   - Select one or more packaging categories.
   - Select one or more packaging types.
4. Click **Next**.The *Select Package Set Component Packaging* page appears, listing PDSs containing approved packaging details and approved package sets that also meet the criteria selected in step 3.
5. Select the package set component packaging that you want to withdraw.
6. Click **Next**.The *Perform Another PDS Action* page opens.
7. Do one of the following:
   - Click **Yes** to perform another update PDS action.
   - Click **No** to proceed to the *Summary* page of the *GPP* wizard.
8. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in step 7, you return to the *Select Action* page of the *GPP* wizard.

◦ If you selected **No** in step 7, the *Summary* page appears. Go to step 9.

9. On the *Summary* page, do one of the following:

Action	Option
To review the new project you created	Select the project link on the **Summary** page.
To return to the view from which you invoked the GPP wizard	Click **Finish**.

10. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
11. Click the link for the project you just created to open the *Project Attributes* page.
12. Navigate to the PDS to view the modified details.

Withdraw a Material

Using the *Global Project Planning* (GPP) wizard, you can withdraw a material across multiple applications/events at the same time.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To withdraw a material from the *Select Action* page of the *GPP* wizard:

1. Select the **Withdraw Material** option and click **Next**.The *Select Material Parent* page appears.
2. Select a material from the **Material Name** list that you would like to withdraw, and click **Next**.The *Select Material* page appears.
3. Click the check box next to the Material you want to withdraw, and click **Next**.The *Perform Another PDS Action* page appears.
4. On the *Perform Another PDS Action* page, do one of the following:

◦ Click **Yes** to perform another update PDS action.

◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

5. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in the previous step, you return to the *Select Action* page of the *GPP* wizard.

◦ If you selected **No** in the previous step, the *Summary* page appears. Proceed to the next step.

6. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**.

Withdraw a Manufacturer

Using the *Global Project Planning* (GPP) wizard, you can withdraw an approved manufacturer from the selected approved manufacturer detail in a PDS.

The following procedure is a continuation of the *Update Product Detail Sets* project type in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To withdraw the manufacturer on the Select Action page of the GPP wizard:

1. Select **Withdraw Manufacturer** on the *Select Action* page.
2. Click **Next**.The *Withdraw Manufacturer 1* page appears.
3. On the *Withdraw Manufacturer 1* page, do the following:
   - Select the manufacturer you want to withdraw. The values available for selection are all Active manufacturers from data administration.
   - Select one or more manufacturer parent types.
4. Click **Next**.The *Withdraw Manufacturer 2* page appears, listing PDSs containing approved manufacturer details for approved manufacturer parent types that also meet the criteria selected in step 3.
5. Select one or more PDSs.
6. Click **Next**.The *Perform Another PDS Action* page appears.
7. On the *Perform Another PDS Action* page, do one of the following:
   - Click **Yes** to perform another update PDS action.
   - Click **No** to proceed to the *Summary* page of the GPP wizard.
8. Click **Next**. One of the following occurs:
   - If you selected **Yes** in step 7, you return to the *Select Action page of the GPP* wizard. Go to step 1.
   - If you selected **No** in step 7, the *Summary* page appears. Go to step 9.
9. On the *Summary* page, do one of the following:

- Select the project link on the *Summary* page to review the new project you created.
- Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

The Status of the selected Manufacturer is set to Pending Withdrawal and the Status Date of the Detail is set to Today's Date.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**|. Click the link for the project you just created to open the *Project Attributes* page. Navigate to the PDS to view the modified details.

Withdraw a Manufacturing Process

Using the Global Project Planning (GPP) wizard, you can withdraw manufacturing process from an active ingredient detail, component detail, substance detail, or PDS manufacturing detail in a PDS.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To withdraw manufacturing process on the *Select Action* page of the *GPP* wizard:

1. Select **Withdraw Manufacturing Process** on the *Select Action* page.
2. Click **Next**.
3. On the *Withdraw Manufacturing Process 1* page, select the manufacturing process parent type: ◦ Active Ingredient
   ◦ Component
   ◦ Product Detail Set
   ◦ Substance
4. Click **Next**.The *Withdraw Manufacturing Process 2* page appears, listing PDSs containing approved manufacturing processes for approved parent details that also meet the criteria selected in step 3.
5. Select one or more PDSs.
6. Click **Next**.
7. On the *Perform Another PDS Action* page, do one of the following:

Action	Description
Click **Yes**	Perform another update PDS action.
Click **No**	Proceed to the *Summary* page of the *GPP* wizard.

8. Click **Next**.One of the following occurs:

Action	Description
If you selected **Yes** in step 7	You return to the *Select Action* page of the *GPP* wizard.
If you selected **No** in step 7	The *Summary* page appears. Go to step 9.

9. On the *Summary* page, do one of the following:

Action	Description
Select the project link on the *Summary* page	You can review the newly created project.

Click **Finish**	You are returned to the view from which you invoked the *GPP* wizard.

The Status of the selected Manufacturing Process(es) is set to Pending Withdrawal and the Status Date of the Detail is set to the current date.

10. To view the project after closing the *GPP* wizard, click **Home** > **Projects**. Click the link for the project you just created to open the *Project Attributes* page. Navigate to the PDS to view the modified details.

Withdraw a Substance

Using the *Global Project Planning* (GPP) wizard, you can withdraw an approved substance for a Product Detail Set (PDS).

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.

To withdraw a substance from the *Select Action* page of the *GPP* wizard:

1. Select the **Withdraw Substance** option and click **Next**.The *Select Substance Type Detail* page appears.
2. Select one or more **Substance Type**(s) that you would like to withdraw, and click **Next**.The *Select Substance* page appears.
3. Click the check box next to the product family with a **PDS** > **Substance** detail that you want to withdraw, and click **Next**.The *Perform Another PDS Action* page appears.
4. On the *Perform Another PDS Action* page, do one of the following:

   ◦ Click **Yes** to perform another update PDS action.

   ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

5. Click **Next**.One of the following occurs:

   ◦ If you selected **Yes** in the previous step, you return to the *Select Action* page of the *GPP* wizard.

   ◦ If you selected **No** in the previous step, the *Summary* page appears. Proceed to the next step.

6. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

The Status of the selected Substance is set to Pending Withdrawal in the PDS tree and the Status Date of the Detail is set to Today's Date.

To view the project after closing the *GPP* wizard, click **Home** > **Projects**. Click the link for the project you just created to open the *Project Attributes* page. Navigate to the PDS to view the modified details.

Replace a Flu Strain PDS Project

Using the *Global Project Planning* (GPP) wizard, you can replace an approved flu strain in a PDS.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To replace a flu strain from the *Select Action* page of the *GPP* wizard:

1. Select **Replace Flu Strain** on the *Select Action* page.
2. Click **Next**.The *Select Flu Strain* page appears.
3. On the *Select Flu Strain* page, do the following:
    a. Select the approved flu strain that you want to replace.
    b. Select the new flu strain.
4. Click **Next**.The *Perform Another PDS Action* page appears.
5. Do one of the following:

    ◦ Click **Yes** to perform another update PDS action.

    ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.
6. Click **Next**.One of the following occurs:

    ◦ If you selected **Yes** in step 5, you return to the *Select Action* page of the *GPP* wizard.

    ◦ If you selected **No** in step 5, the *Summary* page appears. Go to step 7.
7. On the *Summary* page, do one of the following:

    ◦ Select the project link on the *Summary* page to review the new project you created.

    ◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

    Upon completion, the flu strain you chose to replace is assigned a Pending Withdrawal status in the PDS. The status for the new flu strain is **Pending Add**.
8. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
9. Click the link for the project you just created to open the *Project Attributes* page.
10. Navigate to the PDS to view the modified details.

Replace a Manufacturer PDS Project

You can use the *Global Project Planning* (GPP) wizard to replace an approved manufacturer in the PDSs with a new manufacturer. When you replace an approved manufacturer using the *GPP* wizard, the manufacturer is replaced in each instance that it appears as Approved in the PDSs you choose to modify.

The following conditions apply to the **Replace Manufacturer** function:

- You cannot replace an approved manufacturer unless the approved manufacturer is assigned in at least one location in every PDS associated with the project.
- The new manufacturers available for selection are all active and inactive manufacturers set up by the data administrator. Only manufacturers that have an active association to the component, manufacturing process, packaging, or function will be replaced in the PDS.
- The *GPP* wizard lists all manufacturers saved in the system as available replacements. However, manufacturers that have a Pending or Approved status at the selected component, manufacturing process, packaging, or function will not be replaced.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To replace a manufacturer from the *Select Action* page of the *GPP* wizard:

1. Select **Replace Manufacturer** on the *Select Action* page.
2. Click **Next**.The *Select Manufacturers* page appears.
3. On the *Select Manufacturers* page, do the following:
    a. Select the approved manufacturer that you want to replace.
    b. Select the new manufacturer.
4. Click **Next**.The *Perform Another PDS Action* page appears.
5. Do one of the following:

Action	Description
Yes	Perform another update PDS action.
No	Proceed to the *Summary* page of the *GPP* wizard.

6. Click **Next**.One of the following occurs:

Action	Description
Yes	Select Yes in step 5 and you return to the *Select Action* page of the *GPP* wizard.
No	Select No in step 5 and the *Summary* page appears. Go to step 7.

7. On the *Summary* page, do one of the following:

Action	Description
Select the project link on the *Summary* page	You can Review the newly created project.
Click **Finish**	You are returned to the view from which you invoked the *GPP* wizard.

Upon completion, the approved manufacturer you chose to replace is assigned a Pending Withdrawal status in the PDS. The new manufacturer status in the PDS is Pending Add.

8. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
9. Click the link for the project you just created to open the *Project Attributes* page.
10. Navigate to the PDS to view the modified details.

Replace a Material PDS Project

Using the *Global Project Planning* (GPP) wizard, you can replace an approved material in one or more PDSs with a new material. When you replace an approved material using the *GPP* wizard, the material is replaced in each instance that it appears as Approved in the PDSs you choose to modify.

The following conditions apply to the **Replace Material** function:

- The approved materials listed as available for replacement include all materials that exist in all the PDSs selected when using the *GPP* wizard.
- The new materials available for selection include only active materials set up by your data administrator.
- The approved material will be assigned a Pending Withdrawal status when it is replaced by a new material.
- A new material added to the PDS will be assigned a Pending Add status. However, the new material will not be replaced if the same material currently resides in the parent detail with a Pending or Approved status.
- Materials that have a Withdrawn status in the PDS can be added again to the PDS.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To replace materials from the *Select Action* page of the *GPP* wizard:

1. Select **Replace Material** on the *Selection Action* page.
2. Click **Next**.The *Select Materials* page appears.
3. Do the following:
    a. Select the approved material that you want to replace.
    b. Select the new material.
4. Click **Next**.The *Perform Another PDS Action* page appears.
5. Do one of the following:

    ◦ Click **Yes** to perform another update PDS action.

    ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

6. Click **Next**.One of the following occurs:

    ◦ If you selected **Yes** in step 5, you return to the *Select Action* page of the *GPP* wizard.

    ◦ If you selected **No** in step 5, the *Summary* page opens. Go to step 7.

7. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

Upon completion, the approved material you chose to replace is assigned a Pending Withdrawal status in the PDS. The new material status in the PDS is Pending Add.

8. To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
9. Click the link for the project you just created to open the *Project Attributes* page.
10. Navigate to the PDS to view the modified details.

Replace a Manufacturing Process Step Function PDS Project

Using the *Global Project Planning* (GPP) wizard, you can replace an approved manufacturing process step function in one or more PDSs with a new manufacturing process step function. When you replace an approved manufacturing process step function using the *GPP* wizard, the manufacturing process step function is replaced in each instance that it appears as Approved in the PDSs you choose to modify.

The following conditions apply to the **Replacing a Manufacturing Process Step Function** flow:

- The approved functions listed as available for replacement in the **Approved Function** drop-down list include all functions that exist in all the PDSs selected when using the *GPP* wizard.
- The new functions available for selection in the **New Function** drop-down list include all active Functions for the **Data Administration** > **Product Detail Set Maintenance** > **Manufacturer** set up by your data administrator.
- The approved function will be assigned a Pending Withdrawal status when it is replaced by a new function.
- A new function added to the PDS will be assigned a Pending Add status. However, the new function will not be replaced if the same function currently resides in the parent detail with a Pending or Approved status.

Note: The procedure below is a continuation of the *Update Product Detail Sets* project in the *GPP* wizard. The procedure presented in *Creating an Update Product Detail Set Project* must be initiated first.To replace a manufacturing process step function from the *Select Action* page of the *GPP* wizard:

1. Select **Replace Manufacturing Process Step Function** process flow.
2. Click **Next**.The *Select Manufacturing Process Step Function Parent* page appears.
3. Do the following:
    a. Select the approved function that you want to replace.
    b. Select the new function.
4. Click **Next**.The *Perform Another PDS Action* page appears.
5. Do one of the following:

    ◦ Click **Yes** to perform another update PDS action.

    ◦ Click **No** to proceed to the *Summary* page of the *GPP* wizard.

6. Click **Next**.One of the following occurs:

◦ If you selected **Yes** in step 5, you return to the *Select Action* page of the *GPP* wizard.

◦ If you selected **No** in step 5, the *Summary* page opens. Go to step 7.

7. On the *Summary* page, do one of the following:

◦ Select the project link on the *Summary* page to review the new project you created.

◦ Click **Finish**. You are returned to the view from which you invoked the *GPP* wizard.

Upon completion, the approved function you chose to replace is assigned a Pending Withdrawal status in the PDS. The new function status in the PDS is Pending Add.

- To view the project after closing the *GPP* wizard, click **Home** > **Projects**.
- Click the link for the project you just created to open the *Project Attributes* page.
- Navigate to the PDS to view the modified details.

Restart an Update PDS Project

Global Project Planning (GPP) enables you to restart an update PDS project without reentering the PDS and event information you originally specified when Creating an Updated Product Detail Set Project.

You can restart an update PDS project if:

- You have a PDM license with at least WRITE privileges, as well as WRITE privileges to the PDS entity.
- All the events associated with the project are open. This means if just one event associated with the project is closed, you cannot restart the project.

To restart an update PDS project:

1. From the *Home* page, click the **Projects** tab.
2. Using the Project Type column to identify the update PDS projects in your system, click the project name link for the update PDS project that you want to restart.The *Project Attributes* page appears.
3. Select **Wizards** > **Global Project Plan**.The *GPP* wizard opens to the *Select Action* page for the project you selected.
4. Select the action you want to perform.

Withdraw a Product Package Set Registration Project

Global Project Planning (GPP) enables you to withdraw a product package set registration from selected countries, without withdrawing the PDS details.

With the wizard, you have the option to apply a timeline/event plan to the events that you create. You can select a timeline/event plan type for the timeline/event plan:

- If you select an event type timeline/event plan, the *GPP* wizard creates an event that will have a sequence of statuses relevant to the event type that you select.
- If you select a procedure type timeline/event plan, the *GPP* wizard creates an event that will have a sequence of statuses relevant to the procedure type that you select.
- If you do not use a timeline/event plan, the *GPP* wizard creates an event that can have any sequence of active statuses.

To withdraw a product package set registration:

1. Click **Wizards** > **Global Project Plan**.The *GPP* wizard opens to the *Project Details* page.
2. For the **Project Type** attribute, select **Withdraw Product Package Set Registration** or a type that maps to the internal project type of Withdraw Product Package Set Registration as defined in Data Administration.
3. Enter values for the project attributes. The wizard requires entries for the **Project Type**, **Project Name**, **Project Status**, and **Project Status Date**.
4. Click **Next**.The *Search by Product, Country, and Application, and PDS Statuses* page appears.
5. Define search criteria for locating the applications for which you want to include events in the GPP project:

Action
Select the **Family Type** and **Family Name**.
Optionally, select one or more products to include in the search.
Select one or more application statuses to include in the search.
Enter the **Product Detail Set Code**, the **Product Detail Set Name**, or both.
Select one or more PDS statuses to include in the search.
Optionally, select one or more countries to include in the search.
Optionally, select one or more application types to include in the search.
Change the columns included in the displayed results, or change their order of appearance.
Change the order in which the results will be presented.

6. Click **Next**.The *Select Applications* page appears. Only package set registration applications within the search parameters are listed.
7. Select one or more applications.The *Enter Event Details* page appears.
8. Enter values for the event attribute options.An event will be created for each application created by the wizard and the following will occur:

Application Type	**Description**
For CP applications:	The wizard automatically assigns the European Union to the created event.
For National applications:	The wizard automatically assigns the reviewing country for the event.

For MRP applications:	The selected countries will be assigned to the created event.
For all application types:	The event-country status is assigned to each country when the event is created.

9. Click **Next**.The *Select Timeline/Event Plan* page appears.

   ◦ The *Timeline/Event Plan* page appears for each procedure type associated with the applications that you selected.

   ◦ A timeline/event plan must exist in the system for you to select a timeline/event plan.

10. On the *Timeline/Event Plan* page, do one of the following:

Option	**Action**
To associate a timeline/event plan with the events created by the wizard. If a timeline/event plan chosen in the project does not have a country lead time for the reviewing country on the selected application, the lead times in the status schedule table are assumed to be zero:	Select a timeline/event plan from the **Timeline/Event Plan** drop-down list.
Projected dates are calculated using zero lead times and the pivot status and status date of the project:	Click **Next**, and continue at step 11.
Do not select a timeline/event plan. A timeline/event plan will not be associated if you do not make a selection:	Click **Next** as many times as is necessary to open the *Confirmation* page, indicating that the wizard will perform the selected actions. Continue at step 12.

11. Select a reason and enter comments for the reason.
12. Click **Next**
13. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	**Steps**
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next** after completing each timeline/event plan page presented.When all the timeline/event plan pages are completed, the *Confirmation* page project, indicating that the wizard will perform the selected actions.
2. Click **Next**.The *Create Sequence(s)* page project.
3. Do one of the following:

Option	Action
To create a sequence:	Select **Yes** and click **Next**. The *Sequence Attributes* page project. Go to step 14.
To proceed without creating a sequence:	Select **No**. If you select **No**, the a message shows that you do not need to enter sequence details. Go to step 15.

4. On the Sequence *Attributes* page, select or enter values for the sequence attribute fields presented.
5. Click **Next**.One of the following will occur:

   ◦ If you created one or more sequences, a message shows that sequences will be associated with the events. Click **Next**.

   ◦ If you did not choose to create a sequence, the *Summary* page shows.

   The *Summary* page confirms that the *GPP* wizard performed the selected actions.
6. Select a reason and enter comments for the reason.
7. Click **Next**
8. If eSignature is enabled, validate your identify by entering your user credentials and click **Sign in**.
9. Do one of the following:

Option	Action
To review the new project you created:	Select the project link on the *Summary* page.
To return to the view from which you invoked the *GPP* wizard:	Click **Finish**.

10. To view the project after closing the *GPP* wizard, click **Home** > **Projects** tab. Click the link for the project you created to open the *Project Attributes* page for that project.

Withdraw Product Package Set Registrations Results

After creating a Withdraw Product Package Set Registrations project with the *GPP* wizard and approving the associated event, certain conditions occur in addition to what normally happens when you close an event.

In *Data Administration*, if **Yes** is selected in the **System Process Default Flag** field, each entity status shows the value specified in its **Name** field.

Initial Condition	Resulting Conditions
The event countries have a status that maps to the internal event status of Approved	If the PDS status was not previously set as Withdrawn or a status that maps to the internal status of Withdrawn, then: • The PDS status is set to a status mapped to the internal status of Withdrawn The PDS status date is set to the date selected in the wizard • The status for any pending PDS details is set to Approved • The status date for the PDS details is set to the date selected in the wizard. The registration package set status of Withdrawn is set to Yes and the date withdrawn is updated with the date selected in the wizard. If all the package sets associated with the registration (license) are withdrawn, then the license status will be set to a status that maps to the internal status of Withdrawn.
Initial Condition	**Resulting Conditions**
	If all the package sets associated with the registration are not withdrawn, then the license status and license status date are not changed. If all the PDSs and registrations associate with the application are withdrawn, then the application status is changed to the internal status of Withdrawn and the application status date is change to the date selected in the wizard. If all the PDS and registrations associated with the application have not been withdrawn, then the application status and status date are not updated.

See *Entities Affected by Closing an Event* for more information about the conditions that occur when you close the event.

GPP Wizard: New Clinical Trial Projects

You can create CTA and IND applications with the *Global Project Planning (GPP)* wizard.

The *Global Project Planning (GPP)* wizard enables you to create the following:

- Clinical trial authorization (CTA) and investigational new drug (IND) applications
- CTA applications and events for IND applications
- Events for CTA applications and IND applications

The applications and events that the *GPP* wizard creates for a clinical trial project are associated with the same clinical trial data.

If possible, the *GPP* wizard assigns an applicant ID to each application that it creates:

- If a default applicant ID is defined for the region associated with an application, the *GPP* wizard assigns the default applicant ID to the application. To set the default, go to **Data Administration** > **Submission Maintenance** > **Applicant ID Values**. This default is not shown in the *GPP* wizard.
- If a default applicant ID is not defined for the region associated with an application, the *GPP* wizard does not assign an applicant ID to the application.

You can use a timeline/event plan to create the events for the project, and you can select a timeline/event plan type for the timeline/event plan:

- If you select an event type timeline/event plan, the *GPP* wizard creates an event that will have a sequence of statuses relevant to the event type that you select.
- If you select a procedure type timeline/event plan, the *GPP* wizard creates an event that will have a sequence of statuses relevant to the procedure type that you select.
- If you do not use a timeline/event plan, the *GPP* wizard creates an event that can have any sequence of active statuses.

You can associate other entities with the project. These entities include comparators, sequences, and a new PDS based on a PDS template.

Create a New Clinical Trial Project

You can create a new clinical trial project with the *Global Project Plan (GPP)* Wizard.

To create a new clinical trial project:

1. Click **Wizards** > **Global Project Plan**.The *Project Details* page appears.
2. For the **Project Type** attribute, select **Clinical Trial** or a type that maps to the internal project type of Clinical Trial, defined in Data Administration.
3. Enter or select values for the project attributes.
4. Click **Next**.The *Define Project Flow* page appears.
5. Select the flow option for the project.

   ◦ If you select **Create New CTA and/or IND Application(s)** or **Create New CTA and Create New Event for Existing IND Application(s)**, the *Select Products and Countries* page appears.

   ◦ If you select **Create New Event for Existing CTA and/or IND Application(s)**, the *Select Filter Criteria* page appears.
6. Click **Next**.
7. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Create a new CTA and/or IND Application, a new CTA and New Event for an existing IND, or a new Event for an Existing CTA and/or IND Application.

Timeline/Event Plans and Country Lead Times

In Ennov InSight, a timeline/event plan is an ordered set of milestones that you define for an event. The ordered milestones in a timeline/event plan represent the progression of event statuses you expect to occur for an event. You have the option to apply a timeline/event plan when creating an event.

Note: The set of event statuses can vary depending on the regulatory action taking place or on the procedure type.

Country lead times is a feature that enables you to predefine a default interval of days on a per country basis for each event status in a timeline/event plan. The lead times are tracked in a table on the *Timeline/Event Plan* page that displays all of the event statuses per country in the order defined for the timeline/event plan.

You can create a timeline/event plan by using the *Timeline/Event Plan* Wizard.

New CTA and/or IND Applications

You can create new CTA applications or IND applications with the *Global Project Plan (GPP)* Wizard.

To create a new CTA and/or IND Application:

1. On the *Select Products and Countries* , define criteria for the applications that you want to create:

Option	**Action**
To select an Application category:	Select an **Application Category** from the drop-down list. The application category determines the application type.
To select a Family Type:	Select a **Family Type**.
To select a Family Name:	Select a **Family Name**.
Optionally, to associate Products with the applications that you want to create:	Select one or more **Products**.
For **Region Type**:	Select the region type that includes the regions with countries for which you want to create applications.

For **Region**:	Specify the regions that include countries for which you want to create applications. The list of available countries is determined by the selected region type.
For the **Country** attribute:	Select the countries for which you want to create applications. The list of available countries is determined by the selected regions. The list of available countries is further limited to the countries for which you have at least WRITE privileges for the product family that you selected, and to the countries with a default procedure type and application type defined for the application category that you selected.

2. Click **Next**.The *Select CT Shared Data* page opens.
3. Select the **Clinical Trial Shared Data**, which is identified by a protocol code number.
4. Click **Next**.The *Enter Application Details* page opens.
5. Enter or select values for the relevant application properties.
6. After you complete the properties for each application, click **Next**. After you complete the properties for the last application, the *Enter Event Details* page opens.
7. Enter or select values for the event attributes. The event-country status is assigned to each country when the event is created.
8. Click **Next**.The *Select Timeline/Event Plan* page opens.
9. On the *Select Timeline/Event Plan* page, do one of the following:

Option	Action
To associate a timeline/event plan with the events that the wizard creates:	Select a timeline/event plan from the **Timeline/Event Plan** drop-down list. If a timeline/event plan chosen in the project does not have a country lead time for the review- ing country on the selected application, the lead times in the status schedule table are assumed to be zero. Projected dates are calculated using zero lead times, and the project's pivot status and status date. Continue at step 10.
If you do not want to select a timeline/event plan:	Do not select a timeline/event plan. In this case, a timeline/event plan is not associated with the project. Click **Next** until the *Confirmation* page opens, indicating that applications and events will be created for the countries selected in step 1. Continue at step 11.

10. Click **Next**.
11. Continue selecting timeline/event plans and clicking **Next** on the *Select Timeline/Event Plan* page until the *Confirmation* page opens and shows that applications and events will be created for the countries selected in step 1.
12. Click **Next**.The *Associate or Create Additional Entities* page opens.
13. On the *Associate or Create Additional Entities* page, do one or more of the following:

Option	Action
To associate comparators with the clinical trial application:	Select **Associate Comparators** and go to step 14.

To create a sequence:	Select **Create Sequence** and go to step 16.
To create a PDS by using a PDS template:	Select **Create a PDS using a PDS Template** and go to step 19.
To close the wizard without associating additional entities to the CTA:	Click **Finish**. You return to the view from which you invoked the *GPP* wizard.

14. Click **Next**.The *Select Comparators* page opens.
15. On the *Select Comparators* page, do the following:

Option	**Action**
For comparators:	Select one or more comparators.
For next step:	Click **Next**.
If you selected **Create Sequence** in step 13:	Go to step 17.
Option	**Action**
If you selected **Create PDS using a PDS Template** in step 13:	Go to step 21.
If you did not select other options in step 13:	The *Summary* page opens. Click **Finish** to return to the view from which you invoked the *GPP* wizard.

16. Click **Next**.The *Sequence Attributes* page opens.
17. Select or enter values for the sequence attributes.
18. Click **Next**.A confirmation page shows that sequences will be created. Go to step 21.
19. Click **Next**. One of the following occurs:

Option	**Action**
If you selected **Create PDS using a PDS Template** in step 13:	the *Select PDS Templates* page opens. Go to step 22.
If you did not select other options in step 13, the *Summary* page opens:	Click **Finish** to return to the view from which you invoked the *GPP* wizard.

20. On the *Select PDS Templates* page, do the following:

Action	**Description**
Select a product.	The products available for you to select are limited to those that you selected in step 1.

Select one or more PDS templates.	Any predefined PDS templates for the selected product are displayed in the **Available** list box. Product details sets are created from each of the selected templates.

Note: A Ennov best practice is to create only one PDS per product per application, and to define different package sets in a PDS for the various presentations that go into packaging a product.

21. Click **Next**.A confirmation page shows that product detail sets will be created for the templates selected in step 20.
22. Click **Next**.The *Complete Additional Entities Creation* page opens.
23. On the *Complete Additional Entities Creation* page, do one of the following:

Option	**Action**
To select PDS Templates:	Click **Yes** and **Next**. The *Select PDS Templates* page opens. Repeat steps 20 to 22.
To view the *Summary* page:	Click **No** and **Next**. Then click **Finish** to return to the view from which you invoked the *GPP* wizard.

Option		**Action**
To return to the view from which you invoked the *GPP* wizard.	Click **Finish**.	

To view the project after closing the *GPP* wizard, click the **Home** > **Projects** tab. Click the link for the project that you just created to open the *Project Attributes* page.

New CTA Applications and Create New Event for IND Applications

You can create new CTA applications and new events for IND applications with the Global Project Plan (GPP) Wizard. To create new CTA Applications and Create New Event for Existing IND Applications:

1. On the *Select Products, Countries, and IND Application Statues* page, define criteria for the applications that you want to create or for which want to create events:
    - a. Select an **Application Category** from the drop-down list. The application category determines the application type.
    - b. Select a **Family Type**.
    - c. Select a **Family Name**.
    - d. Optionally, select one or more **Products** to associate with the applications that you want to create.
    - e. for **Region Type**, select the region type that includes the regions with countries for which you want to create applications.
    - f. For **IND Application Status**, select the application statuses of the IND applications for which you want to create new events.

g. For **Region**, specify the regions that include countries for which you want to create applications. The list of available countries is determined by the selected region type.
h. For the **Country** attribute, select the countries for which you want to create applications and events. The list of available countries is determined by the selected regions. The list of available countries is further limited to the countries for which you have at least WRITE privileges for the product family that you selected, and to the countries with a default procedure type and application type defined for the application category that you selected.

1. Click **Next**.The *Select CT Shared Data* page appears.
2. Select the **Clinical Trial Shared Data**, which is identified by a protocol code number.
3. Click **Next**.The *Enter Application Details* page appears.
4. Enter or select values for the relevant application properties.The *Associate IND Applications* page appears.
5. Select the IND applications for which you want to create an event.
6. Click **Next**.The *Enter Event Details* page appears.
7. Enter or select values for the event attributes.The event-country status is assigned to each country when the event is created.
8. Click **Next**.The *Select Timeline/Event Plan* page appears.
9. On the *Select Timeline/Event Plan* page, do one of the following:

Action	Option
Select a timeline/event plan from the **Timeline/Event Plan** drop-down list to associate a timeline/event plan with the events that the wizard creates. If a timeline/event plan chosen in the project does not have a country lead time for the reviewing country on the selected application, the lead times in the status schedule table are assumed to be zero. Projected dates are calculated using zero lead times, and the project's pivot status and status date.	Continue at step 11.
Do not select a timeline/event plan. In this case, a timeline/event plan is not associated with the project	Click **Next** as many as is necessary to open the *Confirma- tion* page, indicating that appli- cations and events will be cre- ated for the countries selected in step 1. Continue at step 12.

10. Click **Next** after completing each timeline/event plan page presented.After completing all timeline/event plan pages, the *Confirmation* page opens, indicating that applications and events will be created for the countries selected in step 1.
11. Click **Next**.The *Associate or Create Additional Entities* page appears.
12. On the *Associate or Create Additional Entities* page, do one or more of the following:

Action	Option

To associate comparators with the clinical trial application	Select **Associate Comparators**. Go to step 14
To create a sequence	Select **Create Sequence**. Go to step 16.
To create a PDS using a PDS template	Select **Create a PDS using a PDS Template**. Go to step 19.
To close the wizard without associating additional entities with the CTA	Click **Finish**. You return to the view from which you invoked the *GPP* wizard.

13. Click **Next**.The *Select Comparators* page appears.
14. On the *Select Comparators* page, do the following:
    a. Select one or more comparators.
    b. Click **Next**.
    c. If you selected **Create Sequence** in step 13, go to step 17.
    d. If you selected **Create PDS using a PDS Template** in step 13, go to step 20.
    e. If you did not select other options in step 13, the *Summary page* opens. Click **Finish** to return to the view from which you invoked the *GPP* wizard.
15. Click **Next**.The *Sequence Attributes* page appears.
16. Select or enter values for the sequence attributes.
17. Click **Next**.A confirmation page opens, indicating that sequences will be created. Go to step 19.
18. Click **Next**.One of the following occurs:

    ◦ If you selected **Create PDS using a PDS Template** in step 13, the *Select PDS Templates* page appears.

    Go to step 20.

    ◦ If you did not select other options in step 13, the *Summary* page opens. Click **Finish** to return to the view from which you invoked the *GPP* wizard.

19. On the *Select PDS Templates* page, do the following:
    ◦ a. Select a product. The products available for you to select are limited to those that you selected in step 1.
    b. Select one or more PDS templates. Any predefined PDS templates for the selected product are displayed in the **Available** list box. Product details sets are created from each of the selected templates.

Note: A Ennov best practices is to create only one PDS per product per application, and to define different package sets in a PDS for the various presentations that go into packaging a product.

1. Click **Next**.A confirmation page indicates that product detail sets will be created for the templates selected in step 20.
2. Click **Next**.The *Complete Additional Entities Creation* page appears.
3. On the *Complete Additional Entities Creation* page, do one of the following:

Action	Option
Click **Yes** and **Next**. The *Select PDS Templates* page appears.	Repeat step 20 to step 22.
To view the *Summary* page	Click **No** and **Next**, then click **Finish** to return to the view from which you invoked the *GPP* wizard.
To return to the view from which you invoked the *GPP* wizard	Click **Finish**.

To view the project after closing the *GPP* wizard, click **Home** > **Projects** tab. To open the *Project Attributes* page for the project that you just created, click the link.

New Event for CTA and/or IND Applications

You can create a new event for an existing CTA and/or IND application with the *Global Project Plan (GPP)* Wizard.

To create a New Event for Existing CTA and/or IND Application:

1. On the *Select Filter Criteria* page, define criteria for the applications for which want to create events: a. Select a **Family Type**.
    a. Select a **Family Name**.
    b. Optionally, select one or more **Products** to associate with the applications you want to create.
    c. For **Region Type**, select the region type that includes the regions with countries for which you want to create events.
    d. For **Region**, specify the regions that include countries for which you want to create events. The list of available regions is determined by the selected region type.
    e. For **Application Status**, select the application statuses of the applications for which you want to create new events.
    f. For the **Country** attribute, select the countries for which you want to create events. The list of available countries is determined by the selected regions. The list of available countries is further limited to the countries for which you have at least WRITE privileges for the product family that you selected, and to the countries with a default procedure type and application type defined for the application category that you selected.
    g. For **Application Type**, select the types of applications for which you want to create events.
    h. For **Application Status**, select the statuses of the applications for which you want to create events.

1. Click **Next**.The *Select CT Shared Data* page appears.
2. Select the **Clinical Trial Shared Data**, which is identified by a protocol code number.
3. Click **Next**.The *Select Applications* page appears.
4. Select the applications for which you want to create events.
5. Click **Next**.The *Enter Event Details* page appears.

6. Enter or select values for the event attributes. The event-country status is assigned to each country when an event is created.
7. Click **Next**.The *Select Timeline/Event Plan* page appears.
8. On the *Select Timeline/Event Plan* page, do one of the following:

Action	Option
Select an timeline/event plan from the **Timeline/Event Plan** drop-down list to associate a timeline/event plan with the events that the wizard creates. If a timeline/event plan chosen in the project does not have a country lead time for the reviewing country on the selected application, the lead times in the status schedule table are assumed to be zero. Projected dates are calculated using zero lead times, and the project pivot status and status date.	Continue at step 10.
Do not select an event plan. A timeline/event plan is not associated.	Click **Next** as many as is necessary to open the *Confirmation* page, indicating that the events will be created for the countries selected in step 1. Continue at step 11.

9. Click **Next**.After completing the last *Select Timeline/Event Plan* page and clicking **Next**, the *Confirmation* page opens, indicating that the events will be created for the countries selected in step 1.
10. Click **Next**.The *Associate or Create Additional Entities* page appears.
11. On the *Associate or Create Additional Entities* page, do one or more of the following:

Action	Option
To associate comparators with the clinical trial application	Select **Associate Comparators**. Go to step 13.
To create a sequence	Select **Create Sequence**. Go to step 15.
To create a PDS using a PDS template	Select **Create a PDS using a PDS Template**. Go to step 18.
To close the wizard without associating additional entities with the CTA	Click **Finish**. You return to the view from which you invoked the *GPP* wizard.

12. Click **Next**.The *Select Comparators* page appears.
13. On the *Select Comparators* page, do the following:
    a. Select one or more comparators.
    b. Click **Next**.
    c. If you selected **Create Sequence** in step 12, go to step 16.

d. If you selected **Create PDS using a PDS Template** in step 12, go to step 19.
e. If you did not select other options in step 12, the *Summary* page appears. Click **Finish** to return to the view from which you invoked the *GPP* wizard.

14. Click **Next**.The *Sequence Attributes* page appears.
15. Select or enter values for the sequence attributes.
16. Click **Next**.A confirmation page opens, indicating that sequences will be created. Go to step 21.
17. Click **Next**.One of the following occurs:

    ◦ If you selected **Create PDS using a PDS Template** in step 12, the *Select PDS Templates* page opens. Go to step 19.

    ◦ If you did not select other options in step 12, the *Summary* page appears. Click **Finish** to return to the view from which you invoked the *GPP* wizard.

18. On the *Select PDS Templates* page, do the following:
    a. Select a product. The products available for you to select are limited to those that you selected in step 1.
    b. Select one or more PDS templates. Any predefined PDS templates for the selected product are displayed in the **Available** list box. Product details sets are created from each of the selected templates.

       Note: A Ennov best practices is to create only one PDS per product per application, and to define different package sets in a PDS for the various presentations that go into packaging a product.

19. Click **Next**.A confirmation page opens, indicating that product details sets will be created for the templates selected in step 19.
20. Click **Next**.The *Complete Additional Entities Creation* page appears.
21. On the *Complete Additional Entities Creation* page, do one of the following:

Action	**Option**
Click **Yes** and **Next**. The *Select PDS Templates* page opens.	Repeat step 19 to step 21.
To view the *Summary* page	Click **No** and **Next**.
To return to the view from which you invoked the *GPP* wizard	Click **Finish**.

To view the project after closing the *GPP* wizard, click **Home** > **Projects** tab. To open the *Project Attributes* page for the project that you just created, click the link for the project.

Project Attributes

ou use the project attributes to set its status and projected dates. Your security privileges determine the attributes displayed.

Attribute	Description
Closed	Use this check box to indicate when a project has closed.**Note:** This information-only field serves as an indicator to users that changes to the project should not be made. Checking **Closed** does not restrict users from making changes.
Project Add Comment	Use this to add comments that you want to share with others in a discussion thread. Comments are stamped with the date and time you enter the information, and your user ID.
Project Code	The code your organization uses to identify the project.
Project Concerned Parties	Concerned parties are anyone who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses.
Project Description	Text that describes the project.
Project Keywords	Words you can use to search for the project.
Project Name	The name of the project.
Project Pivot Status	This lists all of the Ennov InSight internal event status types, with the exception of Not Approved, as this is not a valid pivot status. The event status you choose and the **Project Pivot Status Date** you define are used to calculate projected status dates based on lead times and event mile-stones.
Attribute	**Description**
Project Pivot Status Date	This is the projected date for the Project Pivot Status.
Project Projected Completion Date	This is the projected date for the completion of the project.
Project status	The status of the project. A default can be set in Data Administration.

Project Status Date	The date the project status is effective.
Project Type	The type of the project.
Reason	Reason for creating, modifying or deleting a project.
Reason for Comments	Comments related to reason entered by users.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Modify a Project

You can modify the project attributes to change the status or projected dates.

To modify a project:

1. On the *Home* page, click **Projects**.The list of projects appears.
2. Click the name of the project that you want to modify.The *Project Attributes* page appears.
3. Click **Edit**.The *Modify Project Attributes* page appears.
4. Change the project attributes as needed.
5. **Save**.

View a Project

You can view a project to see its attributes or take action on the project.

Your security permissions determines the actions available to you.

To view a project:

1. On the *Home* page, click **Projects**.The list of projects appears.
2. Click the name of the project that you want to view.The *Project Attributes* page appears.
3. On the *Project Attributes* page, do any of the following:

Option	Action
To modify the project attributes:	Click **Edit**.
To delete the proj ect:	Click **Delete**.**Note:** You cannot delete a project if you do not have Administrator rights for project or if changes were made to the entities related to the project.
To copy the project URL to the Clipboard:	Click the **Copy URL** icon. A message confirms the URL has been copied.
To create product registrations for project events:	Click **Create Product Registration**. (This icon is active only for projects that map to the internal type Create New Events Product Registration Project).
To create sequences related to the project events:	Click **Add Sequence**.
To create references for project events and sequences:	Click **Create Reference**.
To manage the PDS associated with the project:	Click **Associate**. (This icon is active only for projects that map to the internal type Create New Applications Package Set Registration Project.
To create leaf updates for assemblies:	Click **Leaf Update**.
To navigate to events associated with the project:	Click **Events**.
To update project event-country status or calculate projected dates for an event status:	Click **Event Country Dates**.
To navigate to products associated with events related to a project if it is mapped to the internal type Create New Events Product Registrations:	Click **Products**.
To view or create notifications for the project:	Click **Notifications**.
To create references for this project and to navigate to references associated with this project:	Click **References**.

Manage a PDS in GPP

You can use a wizard to create or replace a PDS.

When you manage a PDS in GPP, certain conditions apply:

- You must have the licenses and privileges to use the GPP features, a PDM license with at least WRITE privileges, and WRITE privileges for each affected PDS entity.
- The event must be open.
- The project must have been created in the *GPP* wizard as a Create New Applications - Package Set Registration project.
- A PDS template must be available for the product selected.
- None of the countries associated with the events tied to the project have an actual status date for a status of Approved, Not Approved, or Withdrawn (or the equivalent statuses mapped by your data manager for your application).
- If the product has an associated PDS, the *GPP* wizard replaces the entire PDS with an updated PDS until the event is submitted or approved.
- All the PDSs associated with the events for the project have only Pending details (or the equivalent status mapped by your data manager).

To manage the PDS associated with the project in GPP:

1. On the *Home* page, click **Projects**.Your projects are listed on the *Projects* page.
2. Click the name of the project that you want to manage.The *Project Attributes* page appears.
3. Click **Associate**.The *Manage PDS* wizard opens to the *Select Product* page.
4. Select a product.
5. Click **Next**.The *Select PDS Template* page appears.
6. Select the PDS template you want to use to create a PDS for the product selected. **Note:** If you entered a comment in the **Add Comment** field of the template, the comment is not carried forward to the PDS that you create.
7. Click **Next**.The wizard displays a confirmation message indicating that a PDS will be created and associated with the project events.
8. Click **Next**.The wizard opens the *Summary* page that summarizes the actions taken.
9. Click **Finish**.When you finish this procedure:

◦ Ennov InSight creates a PDS from the selected PDS template for each application associated with the project and automatically associates the new PDS with the event associated with the project.

◦ The product selected is automatically associated with the project applications and events, if the product was not associated with the application before the wizard was run.

◦ The product is automatically associated with the project events, if the product was associated with the application before the wizard was run, but not previously associated with the project events.

◦ Any existing PDSs for the selected product that were associated with project events before the wizard was run are disassociated from the project events.

◦ The previous PDSs are deleted from the system, if only one event was associated with the PDS before the wizard was run.

Leaf Updates for Assemblies

Use the *Leaf Update for Assemblies* wizard to update "list of document assemblies" for existing projects that have associated planned sequences.

Limited functionality around assemblies has been extended to Ennov InSight customers with an SPT license that enables you to centrally manage changes to documents for the purpose of notifying your regional publishing centers of the changes.

Using the Ennov InSight sequence and assembly functionality, you can create a list of leafs (documents) for each regional application. After the "assemblies" (the list of documents) are locked and lifecycled as sequence assemblies, you can use a GPP project to create new planned sequences for the regional center applications and then use the *Leaf Update for Assemblies* wizard to update the leafs for the applications using a predefined template of New, Replace, and Delete operations.

Assemblies should not contain any folder elements. They should contain leaf elements and documents only.

The updates appear in the new working "assembly" created under the planned sequence for each application included in the GPP project.

Note: To determine which applications need updated leaf assemblies, open a sequence assembly that contains one of the documents to be updated. Select the document and run the **View Where Used** query. Select the **Show for Sequence Assemblies** option to see all instances for which the document was used. Use this information to create associations between the project and sequences. See the topic *Global Project Planning* for more information.

After using GPP to create planned sequences, the wizard will create a new working assembly under the planned sequence using the structure of the predefined assembly template you select in the wizard. The predefined assembly template should include the documents to be updated and the leaf operations to be performed on the documents. The wizard performs the leaf operations on documents whose names match exactly in both the "list of documents assembly" and the assembly template.

When the wizard applies the template to a sequence assembly, the following rules are applied for adding leafs or updating the leaf operation status based on a comparison of the leafs contained in the target (existing) assembly and the template.

Leaf Operation Status	**No leaf (Existing)**	**New (Existing)**	**Replace (Existing)**	**Delete (Existing)**
New (Template)	New	Replace	Replace	New
Replace (Template)	New	Replace	Replace	New
Delete (Template)	No new leaf	Delete	Delete	No new leaf

Assembly Templates

An assembly template enables you to set up an assembly structure that you can use to create similar assemblies.

The template can include the elements and metadata that are common to the assemblies you create.

You must have any of the following modules to perform assembly template activities:

- Electronic Lifecycle Publishing (ELP)
- Registered Document Analysis (RDA)
- Submission Planning and Tracking (SPT)
- Paper Review Publishing (PRP)

Publishing Requests

This feature enables you to query tasks that are directly or indirectly associated with publishing. You can use Job requests to view the status of the operations such as publishing jobs and print or view an output log from a completed job list.

For all publishing jobs:

- Documents are rendered (for customers who have licenses for rendering and publishing services).
- Links are resolved.
- Rendered documents are concatenated.
- Variables are resolved.
- TOCs may be regenerated.
- Overlay preferences are calculated and applied.
- Special sheets are inserted as appropriate.
- Output files are created in the document repository with the appropriate names, locations, and metadata.
- Any errors and warnings are noted in the job requests.
- Ennov InSight Publisher will not re-render or re-extract documents that have been checked in as the same version in a DMS. However, you can manually re-render and re-extract documents by right-clicking on any document and creating renditions and extractions or using Force New Renditions and Extractions functionality. This will refresh all links, bookmarks, and page count data as well as rendering the document.
- When you publish **.pdf** document that has a rendition, source **.pdf** document, not the rendition is used for publishing.

Electronic/eCTD Publishing

- XML files are created and validated against their specified XML definition files.
- Checksums for all published files are calculated and are included in the values in their respective leaf elements.
- Files are concatenated for each standard leaf element.
- Cross-references are converted to hyperlinks. See the chart in the *Linking Tools* section.

Paper Publishing

- Volumes are refreshed.
- Files are concatenated as per defined volume ranges.
- Cross-references are converted to margin cross-references. See the chart in the *Linking Tools* section.

Create a Leaf Update for an Assembly

Use this procedure to create a list of leafs (documents) for regional applications.

To create leaf updates for assemblies:

1. Navigate to the *View Project* page for the project you want to update.
2. Click **Leaf Update**.The *Leaf Update for Assemblies* wizard opens to the *Select Assembly Template* page, which lists the assembly templates available for use.
3. Select a template.
4. Click **Next**.The *Select Sequences* page opens, listing sequences associated with the project.
5. Select one or more sequences.
6. Click **Next**.A confirmation page opens, describing the action that will be taken based on the previous selections.
7. Click **Next**.The *Summary* page opens, confirming the actions taken. Checking the job table for status is also recommended.
8. On the *Summary* page, click **Finish**.You are returned to the project you were viewing when you stated the wizard. The **Events** tab of the *Project Attributes* page for the project indicates that the application has an assembly.
9. As the *Summary* page recommends, you can check the job table by clicking **Go To** > **Job Requests** and entering search parameters, such as **User Name**, to locate the job.Assembly Leaf Update will appear in the Job Name column in the search results. See the topic *Viewing a publishing request* for more information about using this option. Click **Details** to view further information.

Prerequisites

When you manage a PDS in GPP, certain conditions apply:

— You must have the licenses and privileges to use the GPP features, a PDM license with at least WRITE privileges, and WRITE privileges for each affected PDS entity.

— The event must be open.

— The project must have been created in the *GPP* wizard as a Create New Applications - Package Set Registration project.

— A PDS template must be available for the product selected.

— None of the countries associated with the events tied to the project have an actual status date for a status of Approved, Not Approved, or Withdrawn (or the equivalent statuses mapped by your data manager for your application).

— If the product has an associated PDS, the *GPP* wizard replaces the entire PDS with an updated PDS until the event is submitted or approved.

— All the PDSs associated with the events for the project have only Pending details (or the equivalent status mapped by your data manager).

To manage the PDS associated with the project in GPP:

1. On the *Home* page, click Projects.

   Your projects are listed on the *Projects* page.
2. Click the name of the project that you want to manage.

   The *Project Attributes* page appears.
3. Click Associate.

   The *Manage PDS* wizard opens to the *Select Product* page.
4. Select a product.
5. Click Next.

   The *Select PDS Template* page appears.
6. Select the PDS template you want to use to create a PDS for the product selected.

   Note: *If you entered a comment in the Add Comment field of the template, the comment is not carried forward to the PDS that you create.*
7. Click Next.

   The wizard displays a confirmation message indicating that a PDS will be created and associated with the project events.
8. Click Next.

   The wizard opens the *Summary* page that summarizes the actions taken.
9. Click Finish.

When you finish this procedure:

— Ennov InSight creates a PDS from the selected PDS template for each application associated with the project and automatically associates the new PDS with the event associated with the project.

— The product selected is automatically associated with the project applications and events, if the product was not associated with the application before the wizard was run.

— The product is automatically associated with the project events, if the product was associated with the application before the wizard was run, but not previously associated with the project events.

— Any existing PDSs for the selected product that were associated with project events before the wizard was run are disassociated from the project events.

— The previous PDSs are deleted from the system, if only one event was associated with the PDS before the wizard was run.

Leaf Updates for Assemblies

Use the *Leaf Update for Assemblies* wizard to update "list of document assemblies" for existing projects that have associated planned sequences.

Limited functionality around assemblies has been extended to Ennov InSight customers with an SPT license that enables you to centrally manage changes to documents for the purpose of notifying your regional publishing centers of the changes.

Using the Ennov InSight sequence and assembly functionality, you can create a list of leafs (documents) for each regional application. After the "assemblies" (the list of documents) are locked and lifecycled as sequence assemblies, you can use a GPP project to create new planned sequences for the regional center applications, and then use the *Leaf Update for Assemblies* wizard to update the leafs for the applications using a predefined template of New, Replace, and Delete operations.

Assemblies should not contain any folder elements. They should contain leaf elements and documents only.

The updates appear in the new working "assembly" created under the planned sequence for each application included in the GPP project.

Note: *To determine which applications need updated leaf assemblies, open a sequence assembly that contains one of the documents to be updated. Select the document and run the View Where Used query. Select the Show for Sequence Assemblies option to see all instances for which the document was used. Use this information to create associations between the project and sequences. See the topic Global Project Planning for more information.*

After using GPP to create planned sequences, the wizard will create a new working assembly under the planned sequence using the structure of the predefined assembly template you select in the wizard. The predefined assembly template should include the documents to be updated and the leaf operations to be performed on the documents. The wizard performs the leaf operations on documents whose names match exactly in both the "list of documents assembly" and the assembly template.

When the wizard applies the template to a sequence assembly, the following rules are applied for adding leafs or updating the leaf operation status based on a comparison of the leafs contained in the target (existing) assembly and the template.

Leaf Operation Status	No leaf (Existing)	New (Existing)	Replace (Existing)	Delete (Existing)
New (Template)	New	Replace	Replace	New
Replace (Template)	New	Replace	Replace	New
Delete (Template)	No new leaf	Delete	Delete	No new leaf

Assembly Templates

An assembly template enables you to set up an assembly structure that you can use to create similar assemblies.

The template can include the elements and metadata that are common to the assemblies you create.

You must have any of the following modules to perform assembly template activities:

— Electronic Lifecycle Publishing (ELP)

— Registered Document Analysis (RDA)

— Submission Planning and Tracking (SPT)

— Paper Review Publishing (PRP)

Publishing Requests

This feature enables you to query tasks that are directly or indirectly associated with publishing. You can use Job requests to view the status of the operations such as publishing jobs and print or view an output log from a completed job list.

For all publishing jobs:

— Documents are rendered (for customers who have licenses for rendering and publishing services).

— Links are resolved.

— Rendered documents are concatenated.

— Variables are resolved.

— TOCs may be regenerated.

— Overlay preferences are calculated and applied.

— Special sheets are inserted as appropriate.

— Output files are created in the document repository with the appropriate names, locations, and metadata. — Any errors and warnings are noted in the job requests.

— Ennov InSight Publisher will not re-render or re-extract documents that have been checked in as the same version in a DMS. However, you can manually re-render and re-extract documents by right-clicking on any document and creating renditions and extractions or using Force New Renditions and Extractions functionality. This will refresh all links, bookmarks, and page count data as well as rendering the document.

— When you publish .pdf document that has a rendition, source .pdf document, not the rendition is used for publishing.

Electronic/eCTD Publishing

— XML files are created and validated against their specified XML definition files.

— Checksums for all published files are calculated and are included in the values in their respective leaf elements. — Files are concatenated for each standard leaf element.

— Cross-references are converted to hyperlinks. See the chart in the *Linking Tools* section.

Paper Publishing

— Volumes are refreshed.

— Files are concatenated as per defined volume ranges.

— Cross-references are converted to margin cross-references. See the chart in the *Linking Tools* section.

Create a Leaf Update for an Assembly

Use this procedure to create a list of leafs (documents) for regional applications.

To create leaf updates for assemblies:

1. Navigate to the *View Project* page for the project you want to update.
2. Click Leaf Update.

   The *Leaf Update for Assemblies* wizard opens to the *Select Assembly Template* page, which lists the assembly templates available for use.
3. Select a template.
4. Click Next.

   The *Select Sequences* page opens, listing sequences associated with the project.
5. Select one or more sequences.
6. Click Next.

A confirmation page opens, describing the action that will be taken based on the previous selections.

1. Click Next.

   The *Summary* page opens, confirming the actions taken. Checking the job table for status is also recommended.
2. On the *Summary* page, click Finish.

You are returned to the project you were viewing when you stated the wizard. The Events tab of the *Project Attributes* page for the project indicates that the application has an assembly.

3. As the *Summary* page recommends, you can check the job table by clicking Go To > Job Requests and entering search parameters, such as User Name, to locate the job.

Assembly Leaf Update will appear in the Job Name column in the search results. See the topic *Viewing a publishing request* for more information about using this option. Click Details to view further information.

Update Multiple Events from a Project

You can use the *Bulk Update Events* wizard to modify the attributes of multiple events associated with a project.

To update multiple project events, do the following:

1. Click a link to the project.
2. On the *Project Attributes* page, click **Bulk Update Events**.
3. Select search criteria for the events that you want to update, and click **Next**.
4. On the *Select Events* page, select the events that you want to update.
5. Click **Next**.
6. On the *Select Attribute* page, for each event that you want to update, click the box to the left of the attribute and type or click a value in the box.
7. Click **Next**.
8. On the *Confirmation* page, click **Next**.
9. On the *Summary* page, click **Finish**.

Update Multiple Sequences from a Project

You can use the *Bulk Update Sequences* wizard to modify the attributes of multiple sequences associated with a project.

To update multiple project sequences, do the following:

1. Click a link to the project.
2. On the *Project Attributes* page, click **Bulk Update Sequences**.The *Enter Sequences Search Criteria* page appears.
3. Select search criteria for the sequences that you want to update and click **Next**.The *Select Sequences to Update* page appears.
4. On the *Select Sequences to Update* page, select the sequences that you want to update, and click **Next**.The *Select Attributes to Update* page appears.
5. On the *Select Attributes to Update* page, for each sequence that you want to update, click the box to the left of the attribute and type or click a value in the box.
6. Click **Next**.

7. On the *Confirmation* page, click **Next**.
8. On the *Summary* page, click **Finish**.

Create Product Registrations for Project Events

If your GPP project maps to the internal project type of Create New Events Product Registration Project, you can create registrations for the events associated with the project using the *Create Product Registrations GPP* wizard.

The wizard also enables you to associate the products related to the events with the registrations you create.

To create registrations with this *GPP* wizard, you must have a Registration Planning and Tracking license with WRITE privileges, and at least WRITE privileges for the registration and project entities.

Rules Governing Registration Country Be aware of the following with regards to the country set on a registration by the *Create Product Registrations GPP* wizard:

- If the procedure type on the application is a National type application, the country on the registration is automatically set to the Reviewing Country on the application.
- If the procedure type on the application is an EU-CP type application, the country on the registration is automatically set to the EU Country.
- If the procedure type on the application is a WAHO-CP type application, the country on the registration is automatically set to the WAHO Country.
- If the procedure type on the application is a MRP type application, the country on the registration is automatically set to the RMS (Reviewing Country). If you want to create registrations for other CMS countries on a MRP application, you must navigate to the application and manually create the registrations for the CMS countries.

Create Product Registrations for Project Events

If your GPP project maps to the internal project type of Create New Events Product Registration Project, you can create registrations for the events associated with the project using the *Create Product Registrations GPP* wizard.

The wizard also enables you to associate the products related to the events with the registrations you create.

To create registrations with this *GPP* wizard, you must have a Registration Planning and Tracking license with WRITE privileges, and at least WRITE privileges for the registration and project entities.

Rules Governing Registration Country Be aware of the following with regards to the country set on a registration by the *Create Product Registrations GPP* wizard:

- If the procedure type on the application is a National type application, the country on the registration is automatically set to the Reviewing Country on the application.
- If the procedure type on the application is a CP type application, the country on the registration is automatically set to the EU Country.

- If the procedure type on the application is a MRP type application, the country on the registration is automatically set to the RMS (Reviewing Country). If you want to create registrations for other CMS countries on a MRP application, you must navigate to the application and manually create the registrations for the CMS countries.

Create Product Registrations for Events Associated with a Product Registration Project

To create product registrations for events associated with a product registration project:

1. On the **Home** > **Projects** tab, click the link for a project that maps to the internal project type of Create New Events Product Registration Project.The *Project Attributes* page appears.
2. Click the **Products** tab, and then click **Create Product Registration**.The *Create Product Registrations* wizard opens and the *Select Events* page is displayed.**Note:** Only one Event per Application can be selected when creating a Product Registration.
3. Using the check box column to the left, check the events with which you want to associate the registrations you create.
4. Click **Next**.The *Enter Registrations Detail* page appears.
5. Enter values for the registration attributes. Set the topic *Rules Governing a Registration Country* below for additional information.
6. Click **Next**.The *Select Products* page appears.
7. Under the **Selected** box:

   ◦ To associate products with the registrations, click **Select**, select the products, and **Save**. The products that can be selected include all products associated with the events selected in step 3 that do not have a Not Approved or Withdrawn event-product status for any of the selected events, and are not already associated to a registration for any of the selected events.

   ◦ To disassociate products from the registrations, select products in the **Selected** box. To select more than one product, hold down the CTRL key and click each product. Then click **Deselect**.
8. Click **Next**.A confirmation page is displayed indicating that the wizard will create registrations and associate the events and products you selected.
9. Click **Next**.The *Summary* page is displayed confirming that the *GPP* wizard is complete.
10. Click **Finish**.Upon completion, you are returned to the *Project Attributes* page of the project you selected in step 1. On the **Events** tab, you can navigate to the *Application Attributes* page for an application to view newly created registrations. On the **Products** tab, for any products you associated with the registration, the event-product status is set to Approved, the event-product status date is set to the license status date, and the registration license code is shown.

Delete GPP Projects

If you have the proper permissions, you can delete a Global Project Planning (GPP) project and all its associated entities.

You must have Administrative privileges to the project entity.

Note: Administrative privileges to the project entity supersede other security rights. This means when deleting a project, a user with administrative right to the project entity can delete other entities that he may not have rights to outside of GPP, such as applications, events, notifications and PDSs.

Rules Determining When a Project Cannot Be DeletedA project cannot be deleted when:

- An approved PDS detail is associated with an event that is associated with the project.
- For projects mapped to the internal type Create New Applications Package Set Registration, if any single application associated with the project has another event associated with it, that is, another event in addition to the Create New Application event.
- For projects mapped to the internal type Create New Events Product Registration the project cannot be deleted if any event associated with the project is associated with a registration.
- For projects mapped to the internal type Withdraw Product Package Set Registrations the project cannot be deleted if any events associated with the project were previously closed.

Deleting a Project

Use this procedure to delete a project.

To delete a project:

1. On the *Home* page, click **Projects**.The list of projects appears.
2. Click the name of the project that you want to delete.The *Project Attributes* page appears.
3. Click **Delete**.
4. Click **OK** when you are prompted to delete the project.
5. Click **OK** to close the confirmation that the project has been deleted.For projects mapped to the internal types

Create New Events Package Set Registration, Create New Events Product Registration or Update Product Detail Set the system deleted:

◦ The events associated with the project. Please note that products associated with the events are not deleted, but they are disassociated from the events.

◦ If there were PDS associated with the events, then all pending PDS detail changes associated with the events were also deleted.

◦ The PDSs associated with the deleted events were also deleted if the deleted events were the only events associated with the PDSs.

◦ Any notifications associated with the project.

For projects mapped to the internal type Create New Applications Package Set Registration the system deleted:

◦ The applications associated with the project.

◦ Any notifications associated with the project.

Update Project Event-Country Statuses and Dates

Global Project Planning enables you to update the status and status date for one or more event countries that are associated with a project.

To update statuses and status dates, you must have at least WRITE privileges for events and projects, and either a Submission Planning and Tracking or a Registration Planning and Tracking module license with WRITE privileges.

To update the status and status date for events associated with a project:

1. On the *Home* page, click **Projects**.
2. On the **Projects** tab, click the project name link.The *Project Attributes* page appears.
3. Click **Event Country Dates**.
4. Click **Update Project Event Country Status**.The *Update Project Event Status* wizard starts and opens the *Select Event Countries* page.
5. Click the check-box on the row that contains the country for which you want to change the status or status date.
6. Click **Next**.The *Enter Event-Country Status Values* page opens.
7. In the **Event-Country Status** drop-down list, select a status. The drop-down lists the statuses that the selected events have in common.**Note:** You can update an event-country status for a planned event that enforces status progression. For such an event, the only statuses available for selection are optional statuses and the next primary status in the sequence of primary statuses defined in the timeline/event plan.
8. In the **Status Date** box, type or use the **Calendar** icon  to select the date that this event status is effective. An event that enforces status progression can restrict the event-country status selection. Such an event also restricts the date selection. The dates from which you select are the date for the preceding primary status and later dates.
9. If you want to lock the event-country schedule for the selected countries after the event-country status is updated, select **Yes** for **Lock the Event-Country Schedule?**.
10. If you want to close the event, select **Yes** for **Close Event?**.

Option	Action
To select the closed date:	In the **Closed Date**, type or use the **Calendar** icon.
To select the status:	In the **Associations Closed As**, select the status that will be assigned to the related entities.

If the event is closed, the status of related entities (application, event, sequence, and PDS) will be updated to Approved, or Not Approved, or Withdrawn depending on the selected **Associations Closed As** Status (or a company custom status that maps to one of these internal statuses).

If the Event is closed as Approved, meaning it has the **Association Closed As** field set to APPROVED, the

Application Country > **Withdrawn Date** field is automatically updated to be equal to **Event Closed Date** value.

This rule is applicable to an event that has an associated PDS with this country assigned to a Country PDS Detail, and this country has a Withdrawn status, meaning it is displayed as **Country (Pending Withdrawal)** in the PDS tree. See *If the Event Is Closed with the Status Approved*.

11. Make a selection in the **Reason for Termination/Withdrawal** drop-down list, if needed. All active values from **Data Administration** > **Other** > **Reason for Termination/Withdrawal Values** table are available for selection.
12. In the **Add Comment** box, type a comment that appears on the events that this update affects.
13. Click **Next**.The *Confirmation* page lists the actions that will be taken.
14. Click **Next**.The *Summary* page lists the events that were updated.
15. Click **Finish**.The *Project Attributes* page, from which you started the wizard, appears again.
16. Click **Event Country Dates** to view your changes.

Calculate Projected Event-Country Status Dates for a Project

You can calculate the projected dates in the event-country status schedule based on the project pivot status and project pivot status date for one or more events.

To calculate projected dates, you must have either a Submission Planning and Tracking or a Registration Planning and Tracking module license with at least WRITE privileges, WRITE privileges for the event entity, and WRITE privileges for projects. Also, the events you select must have a status that maps to the project pivot status you select when completing the wizard.

To calculate projected dates for a project:

1. From the *Home* page, click **Projects**.
2. On the **Projects** tab, click the project link.The *Project Attributes* page appears.
3. Click **Event Country Dates** to view a list of events associated with the project.
4. Click **Calculate Projected Dates**.The *Update Project Event Status Projected Dates* wizard opens to the *Select Events* page.
5. Select one or more events.
6. Click **Next**.The *Enter Project Pivot Dates* page appears.
7. Specify a **Project Pivot Status** and a **Project Pivot Status Date**.
8. Select a **Pivot Operation**. See the topic *Calculating Projected Dates* for an explanation of this attribute.
9. Click **Next**.A confirmation page opens, indicating the actions that will be taken.

10. Click **Next**.The *Summary* page appears, confirming that the projected dates for the selected dates were updated.
11. Click **Finish**.Upon completion, the *Project Attributes* page appears for the project you just updated. The **Project Pivot Status** and **Project Pivot Status Date** project attributes show the updated information you entered. On the **Events** tab, click an event name link to navigate to the *Events Attributes* page.

You can also open the *Event Attributes* page by clicking the event code link on the **Event Country Dates** tab. On the **Countries** tab, click the country name link to view the event-country status schedule. The calculated projected dates appear in the event-country status schedule presented on the **Status Dates** tab.

Associate or Disassociate an Event with or from a Project

When you create or modify an event, you can associate or disassociate an event to an existing project with the **Project Name** attribute.

Specific rules determine when and how you can use the **Project Name** attribute when creating or modifying events.

- When creating a new event, the attribute is enabled for you to associate a project.
- When modifying an existing event, the attribute is enabled for you to associate or disassociate a project, unless the event is associated with a project that is closed. You cannot disassociate an event from a closed project.
- When the attribute is enabled for associating or disassociating a project, the projects in the selection list include:

◦ Projects with an $_{\text{Open}}$ status.

◦ A project can be associated with one, or multiple, events per application.

◦ Projects based on the registration type set on the parent application related to the event. The following table explains the application registration type-project type relationship.

- You can associate more than one event with the same project.

Application registration type	**Project mapped to internal project type**
Product registration type	"Create New Events Product Registration Project"
Package set registration type	◦ "Create New Events Package Set Registration Project" ◦ "Create New Applications Package Set Registration Project" ◦ "Product Detail Set Updates Project"

- When you associate or disassociate an event, all the product detail sets associated with the event are included in the associated project or excluded from the disassociated project. Ennov InSight displays a confirmation message regarding this when you change the attribute value.

Create a Reference for Project Events or Sequences

You can create references using the *Create References for Project Events or Sequences* wizard.

You can access the wizard from the *Project Attributes* page.**Note:** You must have the Registration Planning and

Tracking (RPT) or Submission Planning and Tracking (SPT) license to invoke the *Create References or Project Events or Sequences* wizard. Additionally, you must have WRITE privileges for References, the Product Family, and the associated application Country.

To create a reference for project events or sequences:

1. View the project for which you want to create references for the associated events or sequences.
2. Click **Create Reference**.The *Create References for Project Events or Sequences* wizard opens to the *Select Events or Sequences* page.
3. On the *Select Events or Sequences* page, do one of the following:

Action	**Description**
To create references for events associated with the project	click **Create References for Events**.
Action	**Description**
To select one or more of the events listed on the **Select Events** page	Click **Next**.
To create references for sequences associated with the project	Click **Create References for Sequences**. Click **Next** and select one or more of the sequences listed on the **Select Sequences** page.

4. Click **Next**.The *Enter Reference Details* page appears.
5. Enter or select the reference attributes presented. At minimum, you need to enter a reference name and select the **type**, **status**, and **status date** for the reference.
6. Click **Next**.A confirmation page indicates that the reference will be created for the events or sequences selected in step 3.
7. Click **Next**.The wizard presents an option to create additional references.
8. Do one of the following:

Action	**Description**
Select **Yes**	To create additional references, the *Enter Reference Details* page appears. Repeat steps 5 through 7.

Select **No**	For no additional references, the *Summary* page indicates that references were created. Go to step 9.

9. On the *Summary* page, click **Finish**.You are returned to the *Project Attributes* page from which you invoked the wizard. Upon completion, references are associated with the project event or sequence.
10. To view the references you created, do the following:

Action	Description
Click **References**	View one or more references for a project event on the *Event Attributes* page.
Click **References**	View one or more references for an project sequence on the **Sequence Attributes** tab.

Associate Workflows to Events or Sequences

You can associate workflows from a project to all related events or sequences from the *Project Attributes* page.

You must have WRITE privileges on **Activities** within the entity security to associate workflows to events or sequences. In addition you must have WRITE privileges for the **Product Family**, and the associated **Application Country** to be able to select specific **Events** or **Sequences**.

To associate workflows to events or sequences:

1. On the *Homepage*, click **Projects**.The *Project Attributes* page appears.
2. Click a link for the project for which you want to associate workflows to events or sequences.
3. Click **Associate Workflow to Events or Sequences**.
4. Do one of the following:

Option	Action
To associate workflows to events:	Select **Associate Workflow to Events**.
To associate workflows to sequences:	Select **Associate Workflow to Sequences**.

5. Click **Next**.
6. Select the Events or Sequences and click **Next**.
7. Select the workflows from the list to associate and click **Next**.
8. On the *Confirmation* page, click **Next**.
9. On the *Summary* page, click **Finish**.

Associate Change Details

Ennov InSight enables you to associate existing change details with events under a project.

When associating change details to an event under a project, the following conditions apply:

- You must have at least WRITE permission on changes within the entity security.
- You must have at least WRITE permission on events within the entity security.
- The event must not be closed.
- A closed change detail cannot be associated.
- Change detail of a closed change cannot be associated.
- Change detail cannot be associated with more than one open event of the same application.
- Change detail cannot be associated with the event of the application if another closed event of the same application has the same change detail associated, and is closed as Approved.

Note: If there are multiple **Change Details** associated with one **Event** and one of the **Change Details** has a status of **Not Approved** or **Withdrawn**, it will be available for selection even if the overall **Event** is closed as **Approved**.

Associate Change Details to Events from a Project

Associating change details to an event list out the values under the **Event Change Details** tab on the *Project Attributes* page.

To associate change details to an event:

1. On the *Homepage*, click **Projects**.The *Project Attributes* page appears.
2. Click a link for the project for which you want to associate change details to events.
3. Click **Associate Change Detail(s) to Event**.
4. On the *Select Events* page, select an event and click **Next**.
5. On the *Select Change Detail(s) to Associate* page, click **Select**.
6. Select the **Change Detail(s)** and click **Save**.
7. In the **Change Detail Status** list, select a status for the selected **Change Detail(s)**.
8. Click **Next**.
9. On the *Confirmation* page, click **Next**.
10. On the *Summary* page, click **Finish**.The change detail(s) is associated with the event. The change detail associated with the event is listed under the **Event Change Details** tab on the *Project Attributes* page.

Chapter 21. Product Detail Sets (PDS)

A product detail set (PDS) is a set of specific product information that a sponsor is seeking (or has received) regulatory approval to market a product in a specific country.

Although PDSs are associated with an application, you create a PDS specifically for an event to maintain the history of regulatory changes to the component and product details.

The details tracked within a PDS are categorized as component details and product details. The component details are related to the components defined at the product level, such as active ingredients in the case of a pharmaceutical product or the details about a medical device. The product details, such as labeling or packaging details, basically define the PDS itself.

For more information about the details tracked within the two types of PDS, see the topics *Component Details in a PDS* and *Product Details in a PDS*.

PDSs are specific to the Product Detail Management (PDM) module in Ennov InSight.

Create a PDS

You create a product detail set (PDS) specifically for an event to maintain the history of regulatory changes to the component and product details.

To create a PDS, you must have a Product Detail Management (PDM) license with at least WRITE privileges and WRITE privileges for the PDS entity.You can create a PDS:

- By using the Manage PDS wizard.
- Directly, by accessing an event. See the following procedure.

To create a product detail set directly:

1. Click a link for the event for which you want to create the PDS.The *Event Attributes* page appears.
2. Click **Product Detail Set**, then click **Create**.
3. Enter values for the PDS attributes.
4. **Save**.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

PDS Attributes

You create a PDS for an event to maintain the history of regulatory changes to the component and product details.

The attributes describe the specific PDS for an event.

Attribute	Description
Actual Launch Dates	The dates when the product was actually launched in each of the countries associated with the application. Dates are stored in the application countries associated with the application. This attribute appears on the *Product Detail Set Attributes* page.
Application Code	Agency-identified application number (or identifier). The application code may not be known until submittal time, therefore it may be the same as the internal code.
Application Internal Code	Your organization's internal tracking identifier for the application.
Application Name	The name of the application.
Event Name	The event to which the PDS is associated.
Exemption Date	The date an exemption from the application of the Sunset Clause was granted.
Family Code	Code assigned to the product family with which the application is associated.
Family Name	Name of the product family with which the application is associated.

Local Route of Administration	The configured Local Route of Administration field is used for XEVMPD (Extended Eudra-Vigilance medicinal product dictionary) and is hidden by default. Can be configured to be available for the PDS via overrides.When configured, it is used for tracking country Route of Administration on the PDS level. The **Local Route of Administration** field is a multi-select list. The values available for selection are displayed as a concatenation of Product Route of Administration and Component Route of Administration values. The values are sorted in ascending alphanumeric order.

Attribute	**Description**
Local Trade Names	The local brand or trade names associated with the PDS. This attribute appears on the *Product Detail Set Attributes* page.
PDS Add Comment	Comments you want to share with others in a discussion thread. Comments are stamped with the date and time you enter the information, and your user ID. This attribute appears on the *Modify Product Detail Set* page.
PDS Comments	The discussion thread that includes all comments entered by users. This includes the date and time the comments were entered and the user ID of the person who entered them.Comments are displayed when you modify the entity.
PDS Concerned Parties	Users who may be copied on notifications about this entity. Use semi-colons (;) to separate e-mail addresses.
PDS Descrip-tion	Text that describes the PDS.
PDS Keywords	Words you can use to search for the PDS.
PDS Status	The status of the PDS.
PDS Status Date	The date the status is effective.
Planned Launch dates	The dates when the product is expected to be launched in each of the countries associated with the application. Dates are stored in the countries associated with the application. This attribute appears on the *Product Detail Set Attributes* page.

Product Detail Set Code	Your organization's code for the PDS. On some PDS pages, the product detail set name is shown with the product detail set code to identify a PDS. For example, AXL PDS 390 could identify a PDS that has the name AXL PDS and the code 390.
Attribute	**Description**
Product Detail Set Name	The name of the PDS. On some PDS pages, the product detail set name is shown with the product detail set code to identify a PDS. For example, AXL PDS 390 could identify a PDS that has the name AXL PDS and the code 390. The name of the PDS must be unique within an application.
Product Name	The product for which you are creating a detail set. The list of products from which you can choose is limited to the products associated with the event.
Reason	Reason for creating, modifying or deleting a PDS.
Reason for Comments	Comments related to reason entered by users.
Speciality Number	A part of mrpnumber for XEVMPD. The value is taken as a concatenation of the Procedure Identifier/Application Code and Speciality Number for MRP (Mutual Recognition Procedure) and DCP (Decentralised Procedure) Types. The concatenation formula is: [Procedure Identifier/Application Code][Speciality Number1]'-'[Speciality Number2], if there are two PDSs under the Full Product Presentation and the Speciality Number2 value is different from Speciality Number1 value.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Create a PDS from a PDS Template

You can use a PDS template to create a similar PDS.

The following limitations apply:

- If you enter a comment in the **Add Comment** field in the PDS template and then create a PDS from the template, the comment is not carried forward to the newly created PDS.
- The PDS details are given the QC Status of the details in the template.
- If the default QC Status is changed in Data Administration, the QC Status of PDS details in a PDS template that already exists is not automatically updated to the new default.

To create a PDS from a PDS template:

1. Click a link for the event for which you want to associate the new PDS.The *Event Attributes* page appears.
2. Click **Product Detail Sets**, then click **Create Product Detail Sets from Template**.The *Create Product Detail Sets from Template* page appears.
3. Select the product for which you are creating the PDS. The list of products from which you can choose is limited to the products associated with the event selected in step 1.The available PDS templates are displayed.
4. Select the template.
5. Click one of the following:

Option	**Action**
To create the PDS and return to the *Event Attributes* page:	**Save**.
To save the PDS and create another PDS from templates associated with the product:	**Save and Create Another PDS**.

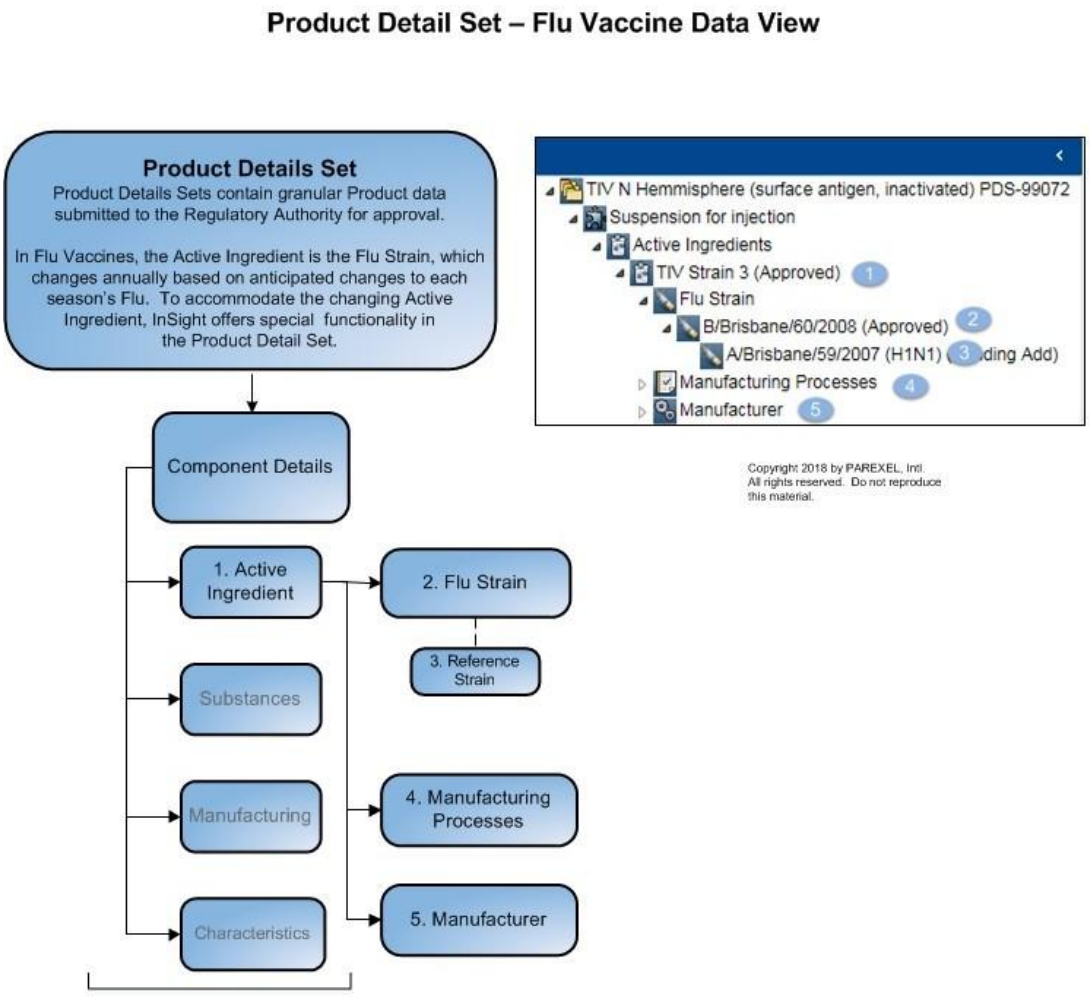
Upon completion the status of the new PDS is Planned. All countries associated with an event will be added to PDS when creating a PDS from a PDS template, not from the application.

Flu Vaccine PDS

Because the active ingredient (flu strain) for a flu vaccine changes annually, the process of creating a PDS for a flu vaccine differs slightly from the typical PDS creation process.

Active ingredient placeholders at the product family level and component level are used to enable active ingredient tracking at the PDS level. You can also add a reference active ingredient (reference strain) to your flu stain detail.

The following diagram illustrates the PDS hierarchy for a flu strain active ingredient and a reference flu strain active ingredient:



Create a PDS for a Flu Vaccine

The active ingredient (flu strain) for a flu vaccine changes annually, and a new PDS for each flu vaccine must be created.

Your Data Administrator needs to do the following before you can create a PDS for a flu vaccine:

- Create a product family for the flu vaccine, selecting **Flu Vaccine** as the **Product Family Type.**
- Create active ingredient values (under **Product Family Maintenance**) for one or more placeholder flu strains and actual flu strains or reference strains. The placeholder flu strains will be used as a grouping device in the PDS hierarchy, so using generic terms such as Strain 1 and Strain 2 is recommended.

To create a PDS for a flu vaccine:

1. Modify the flu vaccine product family created by your Data Administrator by selecting the placeholder flu strains (i.e., Strain 1, Strain 2, etc.) for the active ingredient.
2. Create a flu vaccine product associated with flu vaccine product family.
3. Create a component for the flu vaccine product, using Flu Vaccine as the **Component Type** and by selecting the placeholder strains as active ingredients.

Option	Action
To choose a Component name:	Click a component name that reflects the nature of the component, such as Seasonal Flu Vaccine.
To create a component:	Select **Save and Create a Component** from the *Product Attributes* page, or follow the instructions provided in the topic *Creatie a Component*.

4. Create an application and event for the flu vaccine product.

Option	Action
To associate the flu vaccine product with the application:	Select Flu Vaccine as the **Product Type** for the application and associate the flu vaccine product with the application.

5. Create a product detail set for the event.Upon creating the PDS, the *Product Detail Set Attributes* page opens and the PDS hierarchy contains a grouping node for the flu vaccine component.
6. Expand the component node.
7. Do the following:

Option	Action
To add an active ingredient:	Right-click the **Active Ingredients** node and select **Add Active Ingredient**. Select one of the placeholder strains as the active ingredient.
To save the changes:	Click **Save**.The selected Strain is listed in the PDS hierarchy tree with a **Pending Add** status, unless you changed the status while working in the *Product Detail Set Attributes* page.

8. Repeat the previous step to add additional flu strain placeholders, if needed.
9. Expand the placeholder active ingredient node to view the **Flu Strain** node beneath it.
10. Right-click the **Flu Strain** node and select **Add Flu Strain**. The *Add Flu Strain* page appears.
11. Select **Flu Strain Name**. Only the actual active ingredients for the vaccine are available for selection. Placeholder active ingredients will not be presented for selection. **Note:** You can only assign one flu strain for each active ingredient placeholder.
12. Make additional changes to the Add Flu Strain page, as needed.
13. Perform step 9 through step 12, as needed, for additional strains selected in step 7.
14. Right-click the Strain created on the step 10 under a Flu Strain and select **Add Reference Strain**.

15. Select **Reference Strain Name**. **Note:** You can assign only one reference strain for each flu strain. Only active **Flu Strain Substance** values are available for selection.
16. Make additional changes to the *Add Reference Strain* page, as needed.Upon completion, the actual flu strain active ingredient will appear under the **Flu Strain** node in a **Pending Add** status, unless you changed the status while working in the *Add Flu Strain* page. From this point, you will use the same methods used to manage the PDS as you do for other products. The reference flu strain active ingredient will appear under the flu strain active ingredient under the **Flu Strain** node.

Flu Strain Attributes

The following table represents the flu strain attributes and their descriptions.

Attribute	**Description**
Application Code	Code identifying the application associated with the PDS.
Application Name	Name of the application associated with the PDS.
Component Name	Component to which this detail is associated.
Concentration Measure Type	Used with other attributes to specify information about the concentration of the flu strain. Values: Equal, Range, Up to, or Not Less Than.
Date QC'd	The date the QC Status was set.
Family Code	Product family with which the PDS is associated.
Family Name	Product family with which the PDS is associated.
Flu Strain Comments	Free format text box where users can enter comments.
Flu Strain Description	Free format text box for entering descriptive information.
Flu Strain Keywords	Free format text box where users can enter text for searching purposes.
Flu Strain Name	Name of the flu strain, such as H1N1, Swine, etc.
Flu Strain Status	Status of detail.
Flu Strain Status Date	Date on which the status of the detail was set.
High Amount Denominator Prefix	The high limit amount denominator value. Must only be specified when a Range is described. Must be a Value from the published list.

High Amount Denominator Unit	The high limit amount denominator unit. Must only be specified when a Range is described. Must be a Value from the published list.

Attribute	**Description**
High Amount Denominator Value	The high limit amount denominator value. Must only be specified when a Range is described.
High Amount Numerator Prefix	The high limit amount numerator prefix must only be specified when a Range is described. Must be a Value from the published list.
High Amount Numerator Unit	The high limit amount numerator unit must only be specified when a Range is described. Must be a Value from the published list.
High Amount Numerator Value	The high limit amount numerator value. Must only be specified when a Range is described.
Like or Derived Strain Name	Name of similar or derived flu strain.
Low Amount Denominator Prefix	The low limit amount denominator prefix or for non-range measurements the amount denominator prefix. Must be a Value from the published list.
Low Amount Denominator Unit	The low limit denominator unit or for non-range measurements the amount numerator unit. Must be a Value from the published list.
Low Amount Denominator Value	The low limit amount denominator value or for non-range measurements the amount denominator value.
Low Amount Numerator Prefix	The low limit amount numerator prefix or for non-range measurements the amount numerator prefix. Must be a Value from the published list.
Low Amount Numerator Unit	The low limit amount numerator unit or for non-range measurements the amount numerator unit. Must be a Value from the published list.
Low Amount Numerator Value	The low limit amount numerator value or for non-range measurements the amount numerator value.
Measurement Point	The physical or logical location at which a condition is described.

Product Detail Set Name	PDS with which this detail is associated.
Product Name	Full concatenated product name to which the PDS/Template is associated.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.

Table 29. Table 1. IDMP Presentation Strength

Attribute	**Component Type**	**Description**
Strength (Presentation) Quantity Operator	P, PMD, Vet, FV	Equates to Quantity Operator in IDMP. Refers to values per unit being defined. Example: Equal, Range, Up to, Not Less Than.**Note:** When Equal is selected, it is not displayed in the **XEVMPD Strength** , **IDMP Presentation Strength** , **IDMP Concentration Strength** columns on the related tabs.
Presentation Single/Low Limit Numerator Value	P, PMD, Vet	The Presentation Single or Low Limit Numerator Value.
Presentation Single/Low Lim- it Numerator - Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
DP Presentation Single or Low Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.

Presentation Single/Low Limit Denominator Value	P, PMD, Vet	The value for Presentation Single/Low Limit Denominator.
Presentation Single/Low Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value from Unit of Presentation and Unit of Measurement.
Presentation High Limit Numerator Value	P, PMD, Vet	The Presentation High Limit Numerator Value.
Presentation High Limit Numerator - Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
DP Presentation High Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.

Table 29. Table 1. IDMP Presentation Strength (continued)

Attribute	**Component Type**	**Description**
Presentation High Limit Denominator Value	P, PMD, Vet	The value for Presentation High Limit Denominator.

Presentation High Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value is taken from Unit of Presentation and Unit of Measurement.

Table 30. Table 2. IDMP Concentration Strength

Attribute	Description
Concentration Measure Type	Equates to Quantity Operator in IDMP. Refers to values per unit being defined. Example: Equal, Range, Up to, Not Less Than.
Concentration Single or Low Limit Denominator Value	The Concentration Single or Low Limit Denominator Value.
Concentration Single or Low Limit Unit of Measurement	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration Single or Low Limit Numerator Value	The Concentration Low Limit Numerator Value.
Concentration High Limit Unit of Measurement	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration High Limit Denominator Value	The Concentration High Limit Denominator Value.
Concentration High Limit Unit of Measurement	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

Reference Strain Attributes

The following table represents the reference strain attributes and their descriptions.

Attribute	Description
Application Code	Code identifying the application associated with the PDS.

Attribute	Description
Application Name	Name of the application associated with the PDS.
Component Name	Component to which this detail is associated.
Concentration Measure Type	Used with other attributes to specify information about the concentration of the reference strain. Values: Equal, Range, Up to, or Not Less Than.
Date QC'd	The date the QC Status was set.
Family Code	Product family with which the PDS is associated.
Family Name	Product family with which the PDS is associated.
Flu Strain Name	Name of the flu strain, which this reference strain is associated, such as H1N1, Swine, etc.
High Amount Denominator Prefix	The high limit amount denominator value. Must only be specified when a Range is described. Must be a Value from the published list.
High Amount Denominator Unit	The high limit amount denominator unit. Must only be specified when a Range is described. Must be a Value from the published list.
High Amount Denominator Value	The high limit amount denominator value. Must only be specified when a Range is de- scribed.
High Amount Numerator Prefix	The high limit amount numerator prefix must only be specified when a Range is described. Must be a Value from the published list.
High Amount Numerator Unit	The high limit amount numerator unit must only be specified when a Range is described. Must be a Value from the published list.
High Amount Numerator Value	The high limit amount numerator value. Must only be specified when a Range is described.
Like or Derived Reference Strain Name	Name of similar or derived reference strain.
Low Amount Denominator Prefix	The low limit amount denominator prefix or for non-range measurements the amount denominator prefix. Must be a Value from the published list.

Low Amount Denominator Unit	The low limit denominator unit or for non-range measurements the amount numerator unit. Must be a Value from the published list.
Low Amount Denominator Value	The low limit amount denominator value or for non-range measurements the amount denominator value.
Low Amount Numerator Prefix	The low limit amount numerator prefix or for non-range measurements the amount numerator prefix. Must be a Value from the published list.
Low Amount Numerator Unit	The low limit amount numerator unit or for non-range measurements the amount numerator unit. Must be a Value from the published list.
Attribute	**Description**
Low Amount Numerator Value	The low limit amount numerator value or for non-range measurements the amount numerator value.
Measurement Point	The physical or logical location at which a condition is described.
Product Detail Set Name	PDS with which this detail is associated.
Product Name	Full concatenated product name to which the PDS/Template is associated.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.
Reference Strain Name	The name of reference strain for the flu strain, such as H1N1, Swine, etc..
Reference Comments	Free format text box where users can enter comments.
Reference Description	Free format text box for entering descriptive information.
Reference Keywords	Free format text box where users can enter text for searching purposes.
Reference Status Date	Date on which the status of detail was set.
Reference Strain Status	Status of detail.

Modify a PDS

You can modify a PDS for an open event.

You must have a PDM license with at least WRITE privileges and WRITE privileges for the PDS entity.You can modify a PDS:

- By using the *Manage PDS* wizard.
- Directly, by accessing an event.

To modify PDS attributes directly:

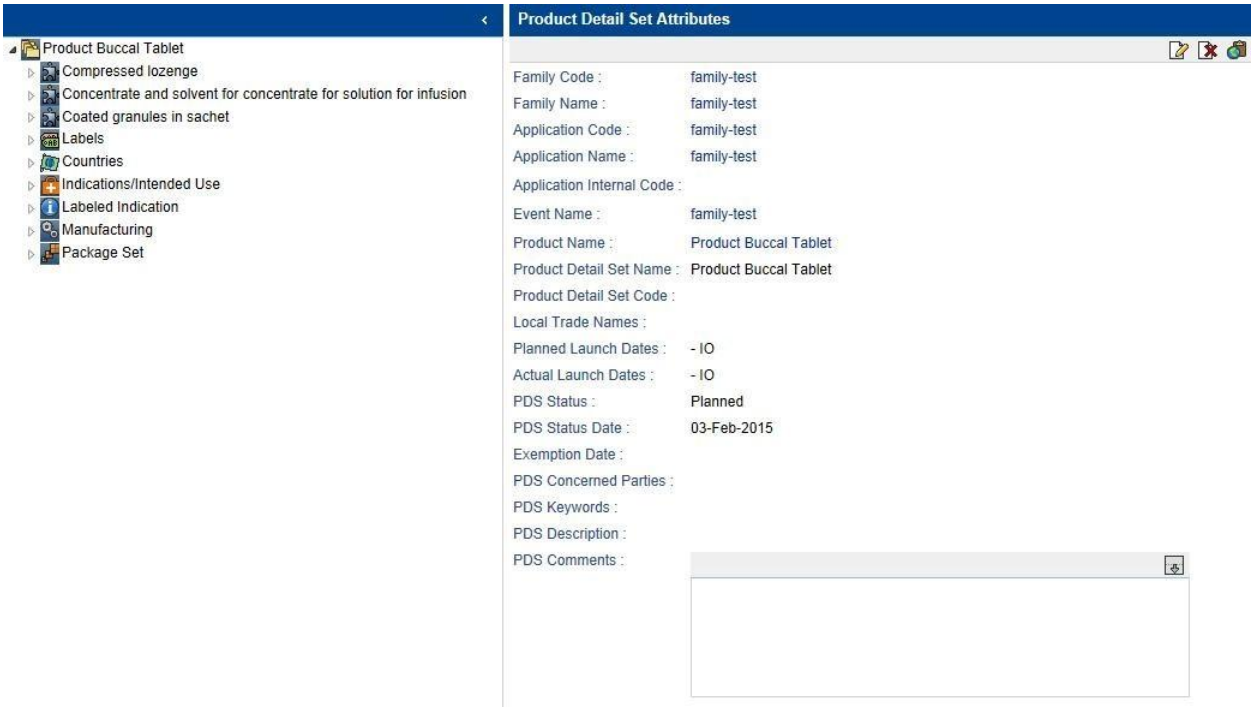
1. Click a link for the event whose PDS you want to modify.
2. On the **Product Detail Sets** tab, click the PDS to modify.
3. On the *Product Detail Set* page, click **Edit**.The *Modify Product Detail Set* page appears.
4. Enter or select changes to the PDS attributes.
5. Click **Save**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

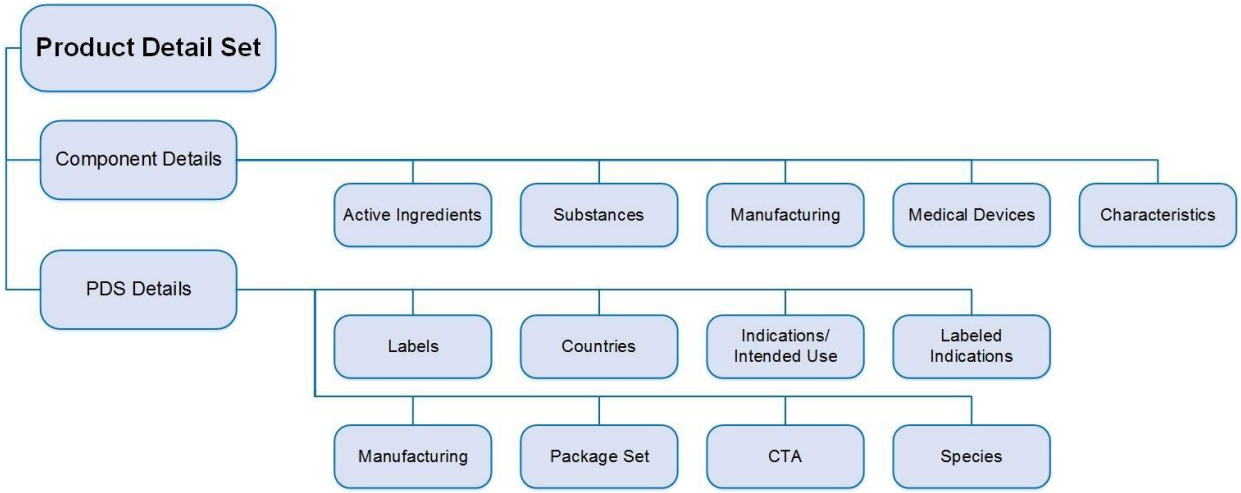
PDS Page

You can view PDS details on the *Product Detail Set* page.

You must have READ privileges for PDS entity security.



The right pane provides links to the product family, product, application, and the event with which this PDS is associated, as well as the attributes for the PDS. The left pane presents the details you can define for a PDS in the form of a navigation tree. The chart below is a representation of the PDS tree.



The PDS tree can be broken down into two groups of detail component details and details specific to the product detail set. The component details are related to the components that were defined at the product level. The remaining details in the tree are specific to defining the PDS itself.

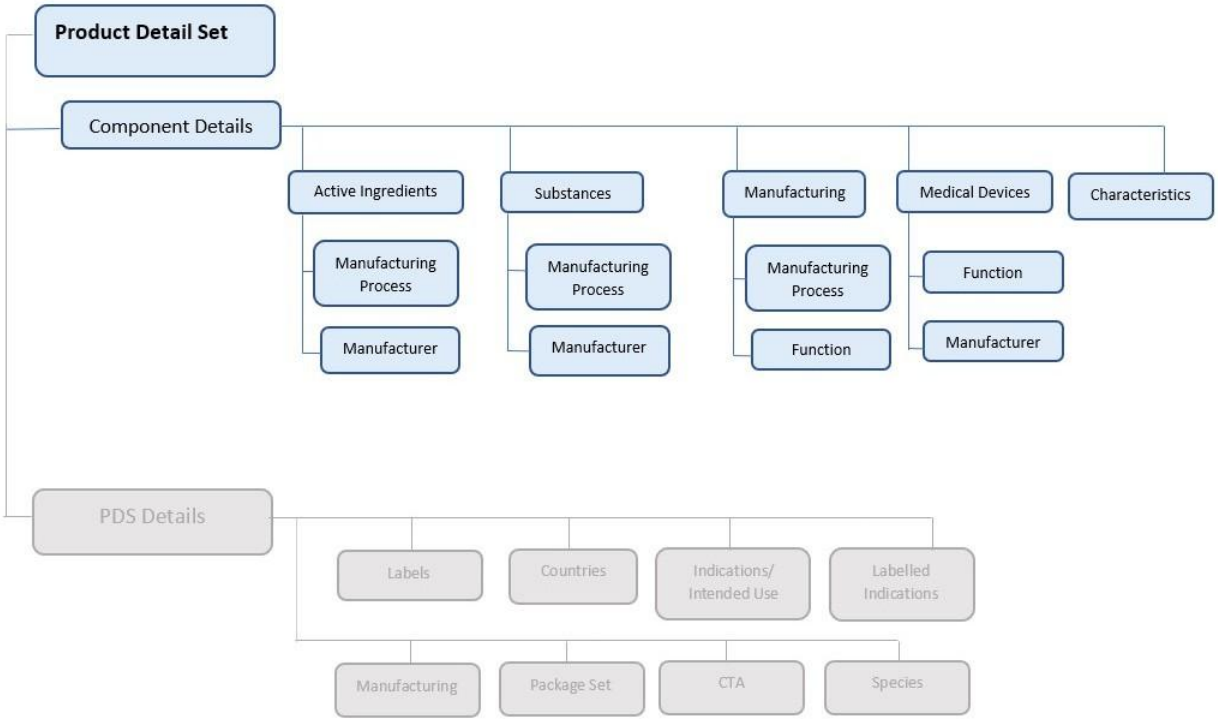
PDS Tree Right-Click Menu Options

Maintaining the details tracked in a PDS is accomplished by right-clicking the nodes in a PDS navigation tree to reveal the popup menu. The options that are available in the popup menu vary depending upon what Ennov InSight allows for the PDS detail. This is usually regulated by the status of the event from which you are viewing the PDS or the status of the PDS detail itself. For more information, see the topic PDS detail statuses. This table below describes the options that may appear in the right-click menu for a PDS tree node.

Popup Menu Option	**Icon**	**Description**
Refresh Tree		Updates the PDS navigation tree to show any changes that you have made.
Expand Range		Display the child nodes that are nested under the parent node on which you use this menu option. This is available for each node within the PDS navigation tree except for the root node.
Add <PDSdetail>		On nodes where you can track PDS-related details, the **Add <PDSdetail>** option is available, where <PDS detail> specifies the type of PDS detail you can associate.
Modify		Modify existing PDS detail, including the Product Detail's Status. This option is available only for users with WRITE privileges for PDS entity security.
Delete		Delete pending PDS detail (Pending Add, Pending Modify, and Pending Withdrawal). This option is available only for users with ADMIN privileges for PDS entity security.
Popup Menu Option	**Icon**	**Description**
Withdraw		Withdraw a previously approved PDS detail
Reorder		Specify the order in which child nodes appear under a parent node.
Copy		• This option is available for every occurrence of the following detail nodes in the PDS tree: Manufacturing Processes • Processing Step • Package Set Under these parent nodes, this option enables you to copy a child node and all associated details. This option is available only for users with WRITE privileges for PDS entity security.

Component Details in a PDS

You can track the details of a *Product Detail Set* for each component that was defined at the product level.



Note: You can also use the PDS to track flu strains as an Active Ingredient. You can assign only one flu strain for each active ingredient.The entities in the chart under **Component Details** represent the cosmplete set of grouping nodes that may appear under a component parent node in a PDS tree. The component's entity type determines if any nodes are excluded:

- Flu Vaccine, Pharmaceutical, or Veterinary entity type - **Medical Devices** node is excluded.
- Medical device entity type - **Active Ingredients** and **Substances** nodes are excluded.
- Pharmaceutical-medical device combination entity type - No nodes are excluded.

When you click a grouping node, the right pane provides links to 7.3 registration entities associated with the PDS, like product family, product, application, event, and any PDS details already associated with the grouping node.

Active Ingredients

For each component defined at the product level that is of the flu vaccine, pharmaceutical, veterinary, or pharmaceutical-medical device combination entity type, the PDS enables you to associate active ingredients with those components. You may associate none or several active ingredient entities with each component in a PDS.

However, the active ingredients you can associate is limited to those associated at the product component level. After you associate an active ingredient with a component, you can associate information regarding the manufacturer or manufacturing process for the active ingredient.

Substances

There are two types of Substances - Excipients and Adjuvants. Excipients and Adjuvants are tracked at the PDS level for product components of the pharmaceutical, veterinary, or pharmaceutical-medical device combination entity type. You may associate zero or more excipient entities with each component in the PDS. The substances that you may choose from when associating an excipient and an adjuvant are pre-defined by your 7.3 system administrator. When associating an excipient to a component, you define the role that the substance serves in the delivery of the component. Since an excipient may serve multiple roles, the same excipient substance may be associated multiple times with a component in different roles.

Component Manufacturing Details

Manufacturing details related to product components are tracked at the PDS level. Manufacturing details are categorized in the tree as the manufacturing processes and functions performed to produce a component. You may associate zero or more processes and functions to a component, and you can "drill down" to specify more granular details about the steps, materials and manufacturers related to the processes and functions.

Medical Devices

For each component defined at the product level that is of the medical device or pharmaceutical-medical device combination entity type, the PDS allows you to associate medical device details with those components. You may associate zero or more medical device detail entities with each component in a PDS.

Characteristics

The characteristic PDS detail allows you to capture information that describes a component. Using predefined attributes and a free-form text, you can track features of a component, such as color and shape, in the characteristic PDS detail. You may associate only one characteristic detail entity per component in a PDS.

Associate an Active Ingredient with a PDS

For each component defined at the product level that is of the flu vaccine, pharmaceutical, veterinary, or pharmaceutical-medical device combination entity type, the PDS enables you to associate active ingredients with those components.

Note: Active Ingredients that exist under the component are auto-populated in the PDS. You

may associate one or several active ingredient entities with each component in a PDS. To

associate an active ingredient with a PDS:

1. In the PDS tree on the *Product Detail Set* page, expand the tree node for a component, and then right-click the **Active Ingredients** node and choose **Add Active Ingredient**.The *Add Active Ingredient* page opens in the right pane.**Note:** You can add only those active ingredients that exist under the component and are deleted from the PDS. You cannot add a new active ingredient directly from the PDS.
2. Enter values for the active ingredient PDS attributes.
3. Click **Save**.The active ingredient appears in the PDS tree under the **Active Ingredient** node and the *Active Ingredient Detail Attributes* page opens in the right pane.
4. After associating an active ingredient with a PDS, you can:

◦ Associate a manufacturer with the active ingredient.

◦ Associate a manufacturing process with the active ingredient.

Active Ingredient PDS Attributes

You can use the PDS attributes to describe the active ingredients.

Attribute	**Description**
Active Ingredient	Active ingredient for which this detail is created.
Active Ingredient Comments	Free format text box where users can enter comments.
Active Ingredient Description	Free format text box for entering descriptive information.
Active Ingredient Keywords	Free format text box where users can enter text for searching purposes.
Active Ingredient Scale	Free format text box for describing the volume at which a manufacturer is producing an active ingredient. For example: lab-scale, development scale or production scale.
Active Ingredient Status	Status of the detail - non configurable - values are Pending, Approved, Not Approved.

Active Ingredient Status Date	Date on which the status of the detail was set.

Attribute	Description
AI Animal/Human Origin	Indicates if a substance is of animal or human origin.
AI animal/human origin certificate filed?	Indicates if a certificate was filed.
Application Code	Code identifying the application associated with the PDS.
Application Name	Name of the application associated with the PDS.
Compendial Designation/Source	Compendial designation/Source is related to Pharmacopoeia - and should contain all values for which approval is requested/given. For example: USP, PhEUR, JP
Component Name	Component to which this detail is associated.
Composition Grouping Description	Description of composition grouping for the active ingredient. You cannot modify the description after saving.
Concentration Measure Type	Used with other attributes to specify information about the concentration of the active ingredient. Values: Equal, Range, Up to, or Not Less Than.
Date QC'd	The date the QC Status was set.
Drug Safety Alerts	Information related to drug safety for this active ingredient.
Family Code	Product family with which the PDS is associated.
Family Name	Product family with which the PDS is associated.
High Amount Denominator Prefix	The high limit amount denominator value. Must only be specified when a Range is described. Must be a Value from the published list.
High Amount Denominator Unit	The high limit amount denominator unit. Must only be specified when a Range is described. Must be a Value from the published list.
High Amount Denominator Value	The high limit amount denominator value. Must only be specified when a Range is de- scribed.
High Amount Numerator Prefix	The high limit amount numerator prefix must only be specified when a Range is described. Must be a Value from the published list.

High Amount Numerator Unit	The high limit amount numerator unit must only be specified when a Range is described. Must be a Value from the published list.
High Amount Numerator Value	The high limit amount numerator value. Must only be specified when a Range is described.
Low Amount Denominator Prefix	The low limit amount denominator prefix or, for non-range measurements, the amount denominator prefix. Must be a Value from the published list.
Attribute	**Description**
Low Amount Denominator Unit	The low limit denominator unit or, for non-range measurements, the amount numerator unit. Must be a Value from the published list.
Low Amount Denominator Value	The low limit amount denominator value or, for non-range measurements, the amount denominator value.
Low Amount Numerator Prefix	The low limit amount numerator prefix or, for non-range measurements, the amount numerator prefix. Must be a Value from the published list.
Low Amount Numerator Unit	The low limit amount numerator unit or, for non-range measurements, the amount numera- tor unit. Must be a Value from the published list.
Low Amount Numerator Value	The low limit amount numerator value or, for non-range measurements, the amount numera- tor value.
Measurement Point	The physical or logical location at which a condition is described.
Origin of Substance	Name of the substance source for the active ingredient. You cannot modify the value after saving.
Product Detail Set Name	PDS with which this detail is associated.
Product Name	Full concatenated product name to which the PDS/Template is associated.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.

Retest Interval	Retest interval requirements for this active ingredient.
Storage Conditions	Storage conditions requirements for this active ingredient.
Storage Container	Storage container requirements for this active ingredient.

Associating a Substance with a PDS

You can associate a Substance with the PDS by choosing among the available types. Two substance types are available for you to choose by default - **Excipient** and **Adjuvant**. You can create and use your own types.

To associate substance with a PDS:

1. In the PDS tree on the *Product Detail Set* page, expand the tree node for a component, and then right-click the **Substance** node and choose **Add Substance**.The *Add Substance* page opens in the right pane.
2. On the *Add Substance* page select the substance type you want to add **Excipient** or **Adjuvant** from the dropdown
3. Select the **Substance** name by clicking the **Select** button.

   a. Enter the values for the excipient or adjuvant PDS attributes.

   Note: If you set the Use as Active Ingredient for XEVMPD field to **Yes** and there is no PDS Active Ingredient value, then the data from Substance Detail is added as an Active Ingredient (regardless of the selected Substance Type) in the XEVMPD XML creation via the *XEVMPD Submission Wizard*. If you set this field to **No**, then Substance Detail is used as an Excipient or Adjuvant, depending on the selected Substance Type.
4. Click **Save**.
5. After associating substance with a PDS, you can associate a manufacturer with the excipient or adjuvant. See the topic Associating a Manufacturer for more information.



When associating a substance to a component, you define the role that the substance serves in the delivery of the component.

For PDS and PDS Template you can add, delete or modify:

◦ Manufacturing Process under substance detail

◦ Step under manufacturing process

◦ Function under step

◦ Manufacturer under function

◦ Material under step

◦ Manufacturer under the material

◦ Function under manufacturing process

◦ Manufacturer under function

Substance PDS Attributes

You can use the following attributes to describe substances in a PDS. The substance type attribute should be used to categorize substances as excipients, adjuvants, allergens, and so on.

Attribute	**Description**
Application Code	Application Code for the Application associated with the PDS.

Attribute	**Description**
Application Name	Application Name for the Application associated with the PDS.
Biotechnology Origin	The biological source such as bovine, feline, etc..
Compendial Designation/Source	Designation related to Pharmacopoeia. For example: USP, PhEUR, JP.
Component Name	Component Name associated with the PDS.
Composition Grouping Description	Description of composition grouping for the substance. You cannot modify the description after saving.
Date QC'd	The date the QC Status was set.
Drug Safety Alerts	Items related to drug safety information.
Family Code	Product Family Code associated with the PDS.
Family Name	Product Family Name associated with the PDS.
High Amount Denominator Prefix	The high limit denominator prefix for range measurements.

High Amount Denominator Unit	The high limit denominator unit for range measurements.
High Amount Denominator Value	The high limit denominator value for range measurements.
High Amount Numerator Prefix	The high limit numerator prefix for range measurements.
High Amount Numerator Unit	The high limit numerator unit for range measurements.
High Amount Numerator Value	The high limit numerator value for range measurements.
Include Concentrations to XEVMPD?	Used to include or exclude concentration data in XEVMPD submission XML file.
Low Amount Denominator Prefix	The low limit denominator prefix or for non-range measurements the denominator prefix.
Low Amount Denominator Unit	The low limit denominator unit or for non-range measurements the denominator unit.
Low Amount Denominator Value	The low limit denominator value or for non-range measurements the denominator value.
Low Amount Numerator Prefix	The low limit numerator prefix or for non-range measurements the numerator prefix.
Low Amount Numerator Unit	The low limit numerator unit or for non-range measurements the numerator unit.

Attribute	**Description**
Low Amount Numerator Value	The low limit numerator value or for non-range measurements the numerator value.
Measurement Point	The physical or logical location at which a condition is described.
Concentration Measure Type	Used with other attributes to specify information about the concentration of the substance. Values: **Equal**, **Range**, **Up to**, or **Not Less Than**.
Presentation Single or Low Limit Numerator Value	The Presentation Single or Low Limit Numerator Value for the Substance.
Presentation Single or Low Limit Unit of Measurement	The unit of measurement for the Presentation Single or Low Limit Numerator Value.
Presentation Single or Low Limit Unit of Presentation	The unit of presentation for the Presentation Single or Low Limit Numerator Value.

Presentation High Limit Numerator Value	The Presentation High Limit Numerator Value for the Substance.
Presentation High Limit Unit of Measurement	The unit of measurement for the Presentation High Limit Numerator Value for the Substance.
Presentation High Limit Unit of Presentation	The unit of presentation for the Presentation High Limit Numerator Value for the Substance.
Concentration Single or Low Limit Numerator Value	The Concentration Single or Low Limit Numerator Value for the Substance.
Concentration Single or Low Limit Unit of Measurement	The unit of measurement for the Concentration Single or Low Limit Numerator Value.
Concentration Single or Low Limit Denominator Value	The Concentration Single or Low Limit Denominator Value for the Substance.
Concentration Single or Low Limit Unit of Measurement	The unit of measurement for the Concentration Single or Low Limit Denominator Value.
Concentration High Limit Numerator Value	The Concentration High Limit Numerator Value for the Substance.
Concentration High Limit Unit of Measurement	The unit of measurement for the Concentration High Limit Numerator Value.
Concentration High Limit Denominator Value	The Concentration High Limit Denominator Value for the Substance.
Attribute	**Description**
Concentration High Limit Unit of Measurement	The unit of measurement for the Concentration High Limit Denominator Value.
Product Detail Set Name	The name of the PDS associated with this detail. Displayed as (PDS Name + PDS Code).

Product Name	The name of the product associated with this detail. Displayed as (Product Name + Product Strength + Product Dosage Form +Product Code).
Origin of Substance	Name of the substance source. You cannot modify the value after saving.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to **QC Passed** or **QC Failed**.
Sort Substance	The ability to select the menu option and re-order the Substances.
Substance Comments	Additional text about the entity.
Substance Description	Free format text box for entering descriptive information.
Substance Keywords	Free format text box where users can enter text for searching purposes.
Substance Name	The name of the substance.
Substance Role	The purpose of the substance.
Substance Status	Status of the detail - non configurable - values are **Pending**, **Approved**, **Not Approved**.
Substance Status Date	Current date for substance status.
Substance Type	Classifies the type of substance such as excipient, adjuvant, allergen, etc.
Use as Active Ingredient for XEVMPD	Identifies if the current Substance Detail will be used as an Active Ingredient in the XEVMPD XML creation via the *XEVMPD Submission Wizard*.

Table 31. Table 1. IDMP Presentation Strength

Attribute	**Component Type**	**Description**
Strength (Presentation) Quantity Operator	P, PMD, Vet, FV	Equates to Quantity Operator in IDMP. Refers to values per unit being defined. Example: Equal, Range, Up to, Not Less Than.**Note:** When Equal is selected, it is not displayed in the **XEVMPD Strength** , **IDMP Presentation Strength** , **IDMP Concentration Strength** columns on the related tabs.

Table 31. Table 1. IDMP Presentation Strength (continued)

Attribute	Component Type	Description
Presentation Single/Low Limit - Numerator Value	P, PMD, Vet	The Presentation Single or Low Limit Numerator Value.
Presentation Single/Low Limit Numerator - Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
DP Presentation Single or Low Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.
Presentation Single/Low Limit Denominator Value	P, PMD, Vet	The value for Presentation Single/Low Limit Denominator.
Presentation Single/Low Limit Denominator - Unit of Presentation/Measurement	P, PMD, Vet	The value from Unit of Presentation and Unit of Measurement.
Presentation High Limit Numerator Value	P, PMD, Vet	The Presentation High Limit Numerator Value.

Presentation High Limit Numerator - Unit of Measurement	P, PMD, Vet	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
DP Presentation High Limit Unit of Presentation	P, PMD, Vet	The Unit of Presentation is available for some of the attributes. Some of the values are: Bottle, Tablet, Capsule.
Presentation High Limit Denominator Value	P, PMD, Vet	The value for Presentation High Limit Denominator.
Presentation High Limit Denominator -	P, PMD, Vet	The value is taken from Unit of Presentation and Unit of Measurement.

Table 31. Table 1. IDMP Presentation Strength (continued)

Attribute	**Component Type**	**Description**
Unit of Presentation/Measurement		

Table 32. Table 2. IDMP Concentration Strength

Attribute	**Description**
Concentration Measure Type	Equates to Quantity Operator in IDMP. Refers to values per unit being defined. Example: Equal, Range, Up to, Not Less Than.

Concentration Single or Low Limit Denominator Value	The Concentration Single or Low Limit Denominator Value.
Concentration Single or Low Limit Unit of Measurement	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration Single or Low Limit Numerator Value	The Concentration Low Limit Numerator Value.
Concentration High Limit Unit of Measurement	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.
Concentration High Limit Denominator Value	The Concentration High Limit Denominator Value.
Concentration High Limit Unit of Measurement	The Unit of Measurement is available for some of the attributes. Some of the values are: ml, mg.

Associating Component Manufacturing with a PDS

Manufacturing details related to product components are tracked at the PDS level.

To associate component manufacturing details with a PDS:

1. In the PDS tree on the *Product Detail Set* page, expand the tree node for a component.
2. Under the component node, expand the **Manufacturing** node. Be sure to expand the node nested under a product component. Do not expand the node nested under the top-most node for the PDS.
3. Under the Manufacturing node, you can do the following:

◦ To associate a manufacturing process, right-click **Manufacturing Processes** and choose **Add Manufacturing Process**. See the topic Associating a manufacturing process for instructions.

◦ To associate a manufacturing function, right-click **Function** and choose **Add Function**.

Associating Medical Device Details with a PDS

You can associate medical device details with components defined at the product level, if the product is a medical device or pharmaceutical-medical device combination entity type.

To associate a medical device with a PDS:

1. In the PDS tree on the *Product Detail Set* page, expand the tree node for a component, and then right-click the **Medical Devices** node and choose **Add Medical Device**.The *Add Medical Device* page opens in the right pane.
2. Enter values for the medical device PDS attributes.
3. Click **Save**.

Medical Device PDS Attributes

You can use the attributes to associate medical device details with components defined at the product level, if the product is a medical device or pharmaceutical-medical device combination entity type.

Attribute	**Description**
Application Code	The code of the application which this PDS is associated.
Application Name	The name of the application which this PDS is associated.
Component Name	The name of the component which this PDS is associated.
Date QC'd	The date the QC Status was set.
Device Classification	The classification of the type of medical device. The availability of the device classification values in PDS depends on the countries selected in **Data Administration** for the **Device Classification Values** and the **Reviewing Country** selected in application where the PDS is created.
Device Description	The high-level description of the applicable medical device.
Device Description Language	The formal language of the medical device description.

Device Description of Intended Purpose	The description of the intended purpose of the medical device type.
Device Identifier	The identifier of a Device.

Attribute	**Description**
Device Trade Name	The Trade Name of the Device.
Device Type	The value is mapped to the Device – Type values in Data Administration.
Device - Type of Combination	The value is mapped to the Device – Type of Combination values in Data Administration.
Family Code	The code of the product family which this PDS is associated.
Family Name	The name of the product family which this PDS is associated.
Medical Device Comments	Text about the entity.
Medical Device Description	Text that describes the PDS detail.
Medical Device Keywords	Words you can use to search for the entity.
Medical Device Name	The name of the medical device.
Medical Device Part Code	The part code number connected to the medical device.
Medical Device Status	The status of the entity.
Medical Device Status Date	The date the entity status is effective.

Product Detail Set Name	The name for the PDS which this detail is associated.
Product Name	The name for the product which this detail is associated.
QC Status	QC Status of the detail.
Attribute	**Description**
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.

Associating Component Characteristics with a PDS

You can describe a component in the characteristic PDS detail. You can track features of a component, such as color and shape, in the characteristic PDS detail.

To associate component characteristics with a PDS:

1. In the PDS tree on the *Product Detail Set* page, expand the tree node for a component, and then right-click the **Characteristics** node and choose **Add Characteristics**.The *Add Characteristics* page opens in the right pane.
2. Enter values for the component characteristic PDS attributes.
3. Click **Save**.

Component Characteristic PDS Attributes

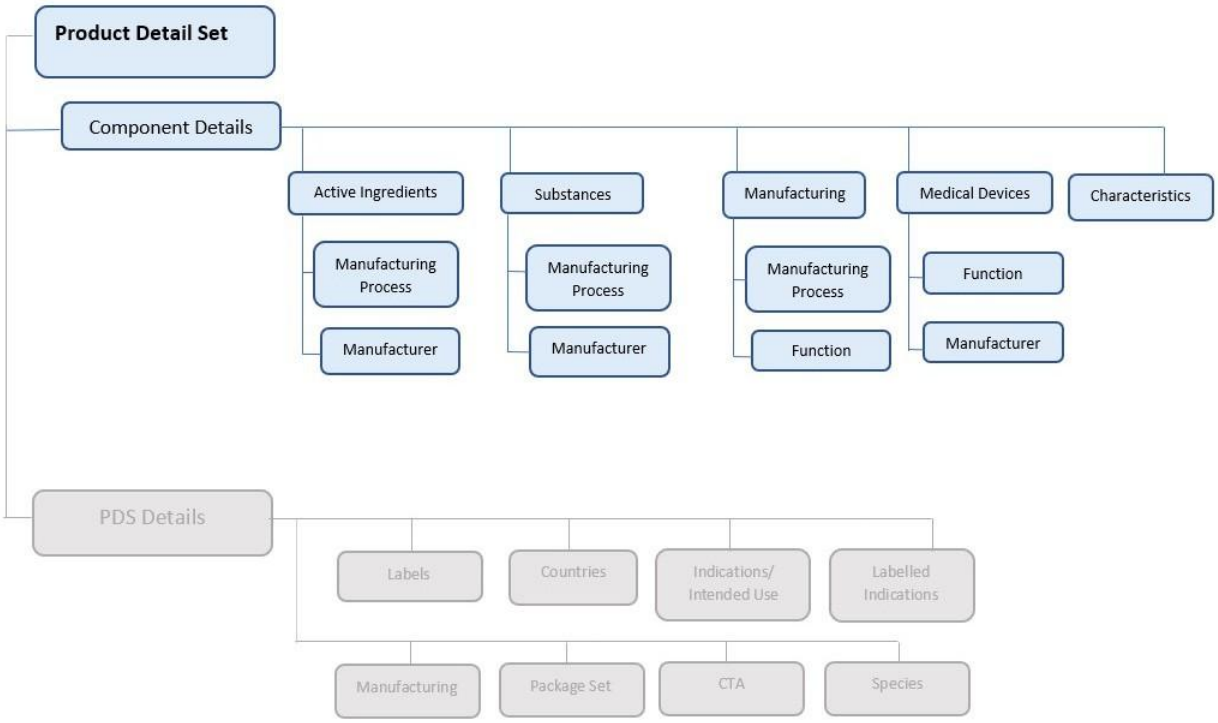
You can describe a component in the characteristic PDS detail. You can track features of a component, such as color and shape, in the characteristic PDS detail.

Attribute	**Description**
Application Code	The code of the application with which this PDS is associated.
Application Name	The name of the application with which this PDS is associated.
Characteristics Comments	Text about the entity.
Characteristics Description	Text that describes the PDS detail.
Characteristics Keywords	Words you can use to search for the entity.
Characteristics Status	The status of the entity.

Characteristics Status Date	The date the entity status is effective.
Color	The color of the component.
Component Characteristics	Additional characteristics beyond color and shape.
Component Name	The name of the component.
Date QC'd	The date the QC Status was set.
Attribute	**Description**
Depth	The depth can be specified using a numerical value and its unit of measurement.
Depth Unit	Unit of depth.
External Diameter	The external diameter is specified using a numerical value and its unit of measurement.
External Diameter Unit	Unit of external diameter.
Height	The height is specified using a numerical value and its unit of measurement.
Height Unit	Unit of height.
Family Code	The code of the product family which this PDS is associated.
Family Name	The name of the product family which this PDS is associated.
Nominal Volume	The nominal volume is specified using a numerical value and its unit of measurement.
Nominal Volume Unit	Unit of nominal volume.
Product Detail Set Name	The name for the PDS which this detail is associated.
Product Name	The name for the product which this detail is associated.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.
Shape	The shape of the component.
Weight	The weight is specified using a numerical value and its unit of measurement.
Weight Unit	Unit of weight.
Width	The width is specified using a numerical value and its unit of measurement.
Width Unit	Unit of width.

Component Characteristic PDS Attributes

You can track details for a product detail set, based on the type of product.



Associating Labeling with a PDS

You can associate and track product labels at the PDS level.

To associate labeling with a PDS:

1. In the PDS tree on the *Product Detail Set* page, right-click the **Labels** node and choose **Add Labels Detail**.The *Add Label* page appears in the right pane.
2. Enter values for the label PDS attributes and **Save**.

Label PDS Attributes

You can use the attributes to describe the label associated with a PDS.

Attribute	Description
Application Code	The code of the application with which this PDS is associated.

Attribute	Description
Application Name	The name of the application with which this PDS is associated.
Date Label Last Updated	When the label content was last modified.
Date QC'd	The date the QC Status was set.
Family Code	The code of the product family with which this PDS is associated.
Family Name	The name of the product family with which this PDS is associated.
Label Code	Any code specific to the label.
Label Comments	Text about the entity.
Label Country	The country with which the label is associated. **Note:** Withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the **Label Country** drop-down field on the *Add Label* page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.
Label Description	Text that describes the PDS detail.
Label Keywords	Words you can use to search for the entity.

Label Language	The language in which the label is published. Multiple languages can be selected for bi-lingual and tri-lingual countries.
Attribute	**Description**
Label Reference	The file path location of a document, usually containing label-related verbiage. • Do not target a folder for the Label Reference as this results in a error. • When viewing the Label Detail Attributes page, the file path is presented as a link. • You must log in to Documentum before hyperlinks to Documentum content from the Label Detail Attributes page will work.
Label Status	The status of the entity.
Label Status Date	The date the entity status is effective.
Label Type	The type of label you are associating with the PDS.
Product Detail Set Name	The name for the PDS with which this detail is associated.
Product Name	The name of the product with which this PDS is associated.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.

Associate a Country with a PDS

You track details for countries associated with an application at the PDS level.

To associate a country with a PDS:

1. In the PDS tree on the *Product Detail Set Attributes* page, right-click the **Countries** node and select **Add Country**.The *Add Country* page appears in the right pane.
2. Enter values for the country PDS attributes. Please note that the withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the **Countries** multi-select field. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.
3. **Save**.

Country PDS Attributes

You can use the attributes to define the countries associated with an application.

Attribute	**Description**
Application Code	The code of the associated application.
Application Name	The name of the associated application.
Country	The associated country.**Note:** Withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the **Countries** multi-select field on the *Add Countries* page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.
Country Comments	Additional text about the entity.
Country Description	Text that describes the PDS detail.
Country First Approval of PDS	First time this PDS was approved for this country.
Country Keywords	Words you can use to search for the entity.

Country Status	The status of the country detail.
Country Status Date	The date the entity status is effective.

Attribute	**Description**
Country Trade Name	Trade name approved in this country.
Date QC'd	The date the QC Status was set.
Family Code	The code for the product family with which the PDS is associated.
Family Name	The name for the product family with which the PDS is associated.
Import Company	The name of the company contracted to import the product into the country.
Marketing Company	The name of the company contracted to market the product in the country.
Product De tail Set Name	The name for the PDS with which this detail is associated.

Product Name	The name of the product with which this PDS is associated.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.
Short Name	Is the value used to populate Short Name when submitting to the EVMPD.
Short Name Last Updated	The most recent date that the Short Name was changed.
SMPC Name	Is the SMPC Name that will be used when submitting to the EVMPD.
Attribute	**Description**
SmPC Name Last Updated	The most recent date that the SmPC name was changed.

Associate an Indication/Intended Use with a PDS

You can associate indications or intended uses that were approved or have been submitted for approval at the PDS level.

To associate an indication/intended use with a PDS:

1. In the PDS tree on the *Product Detail Set* page, right-click the **Indications/Intended Use** node and choose **Add Indication/Intended Use**.The *Add Indication/Intended Use* page appears in the right pane.
2. Enter values for the indication/intended use PDS attributes.
3. **Save**.

Indication/Intended Use PDS Attributes

You can use the attributes to describe the indication/intended use associated to a product.

Attribute	Description
Application Code	The code of the application with which the indication is associated.
Application Name	The name of the application with which the indication is associated.
Countries	Country (countries) for which the detail is created. The countries available for selection are all countries associated with the Application. The exceptions are application countries with the Withdraw Date value equal to today's date or earlier. Such countries are not available for selection in the **Countries** multi-select field on the *Add/Modify Indication/Intended Use* page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types. If several countries are selected, they are displayed as comma-separated on the View detail page. Defines the value that is included to the XML file during the XEVMPD Submission Wizard execution. **Note:** By default, all countries associated to the Application appear in the **Selected** box of the **Countries** field on the *Add Indication/Intended Use* page.

Attribute	Description
Date QC'd	The date the QC Status was set.
Family Code	The code of the product family with which the indication is associated.
Family Name	The name of the product family with which the indication is associated.
Indications	Selected indications for this detail, for example a migraine or stroke.

Indication/Intended Use Comments	Text area where you can enter comments about the indication.
Indication/Intended Use Description	Text area where you can enter a description about the indication.
Indication/Intended Use Keywords	Area where you can enter text for searching purposes.
Indication/Intended Use Last Updated	The date the indication/intended use was last changed.
Attribute	**Description**
Indication/Intended Use Status	The status of the entity.
Indication/Intended Use Status Date	The date on which the status of the detail was set.
Product De tail Set Name	The name of the PDS with which the indication is associated.
Product Name	The name of the product with which the indication is associated.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the **QC Status** for the detail to **QC Passed** or **QC Failed**.

Associate an Intended Effect/Comorbidity

Associate an Intended Effect/Comorbidity to conform to the regulatory guidelines.

Note: Add Effect/Comorbidity option is only available when values are already populated for Indication and Countries fields on the *Indications/Intended Use Detail* window.To associate an Intended Effect/Comorbidity sub-node:

1. On a Product Detail Set, right-click the **Indications/Intended Use** node and choose **Add Indication/Intended Use**.The *Add Indication/Intended Use* page appears on the right pane.
2. Select values for the **Indication** field and add countries.
3. Click **Save**.A new sub-node is added under the **Indications/Intended Use** node.
4. Right-click on the newly added sub-node and choose **Add an Intended Effect/Comorbidity**.
5. Select the **Countries** and the **Intended Effects/Comorbidity** values from the list.
6. Click **Save**.A new sub-node appears under the Indications/Intended Use node.

Intended Effect/Comorbidity Attributes

You can use the attributes to describe the intended effect/comorbidity associated to a product.

Attribute	**Description**
Application Code	The code of the application with which the PDS is associated.
Application Name	The name of the application with which the PDS is associated.
Countries	The name of the country (countries) for which the intended effect/comorbidity is created. The countries available for selection are all countries associated with the Application. This attribute defines the values included in the XML output during XEVMPD Submission wizard execution.
Family Code	The code of the product family with which the PDS is associated.
Family Name	The name of the product family with which the PDS is associated.
Comorbidity	Any comorbidity (concurrent condition) or co-infection described as part of the indication as is referenced in the regulated product information.
Intended Effect	The intended effect as part of the indication describes the result/type of outcome intended for the target condition.
Indication/Intended Effect/Comorbidity Last Update Date	The date the Indication was set from Pending Add to Approved. This attribute is updated automatically by the system.
Product Detail Set Name	The name of the PDS with which the intended effect/comorbidity is associated. The Product Details Set name is the concatenation of PDS Name + PDS Code.
Product Name	The name of the product with which the PDS/template is associated including Product Name, Product Strength, Product Dosage Form, Product Code.

Associate a Labeled Indication with a PDS

The labeled indication represents text that you and the regulatory body have agreed upon for briefly explaining what ailments the product treats.

Only one labeled indication may be associated with a PDS.

To associate a labeled indication with a PDS:

1. In the PDS tree on the *Product Detail Set* page, right-click the **Labeled Indication** node and choose **Add Labeled Indication**.The *Add Labeled Indication* page appears in the right pane.
2. Enter text for the labeled indication.
3. Enter any other values for the labeled indication PDS attributes.
4. **Save**.

Labeled Indication PDS Attributes

You can use the attributes to record and track the details of the labeled indication at the PDS level.

Attribute	**Description**
Application Code	The code of the application with which the labeled indication is associated
Application Name	The name of the application with which the labeled indication is associated
Date QC'd	The date the QC Status was set
Family Code	The code of the product family with which the labeled indication is associated
Family Name	The name of the product family with which the labeled indication is associated
Labeled Indication	Text that has been negotiated for licensing
Labeled Indication Comments	Text about the entity
Labeled Indication Description	Text area where you can enter a description about the labeled indication
Labeled Indication Keywords	Area where you can enter text for searching purposes
Labeled Indication Status	The status of the entity
Labeled Indication Status Date	The date the entity status is effective
Product Detail Set Name	The name of the PDS with which the labeled indication is associated

Product Name	The name of the product with which the labeled indication is associated
QC Status	QC Status of the detail
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.

Associate PDS Manufacturing with a PDS

You can track manufacturing details specifically for package sets and active ingredients in components, or for the product detail set as a whole.

To associate PDS manufacturing details with a PDS:

1. In the PDS tree on the *Product Detail Set* page, expand the **Manufacturing** node. **Note:** Be sure to expand the node nested under the top-most node for the PDS. Do not expand the node nested under a product component.
2. Under the Manufacturing node, you can do the following:

Option	**Action**
To associate a manufacturing process:	Right-click **Manufacturing Processes** and choose **Add Manufacturing Process**.
To associate a manufacturing function:	Right-click **Function** and choose **Add Function**.

Associate a Package Set with a PDS

Package set detail entities represent the various configurations and presentations that go into packaging a product. To associate a package set with a PDS:

1. In the PDS tree on the *Product Detail Set* page, right-click the **Package Set** node and select **Add Package Set**.The *Add Package Set* page appears.
2. Enter values for the package set PDS attributes.
3. Click **Save**.The package set you added appears in the PDS tree under the **Package Set** node.
4. After associating a package set, you can do the following:

Option	**Action**
Associate packaging details with the package set:	Add package Details.
Associate a function with the package set:	Right-clicking the **Function** node under the package set node you added and click **Add Function**.

Package Set PDS Attributes

You can use the attributes to describe the package sets associated with a PDS.

Attribute	Description
Application Code	The code of the application with which this PDS is associated.
Application Name	The name of the application with which this PDS is associated.
Date QC'd	The date the QC Status was set.
Family Code	The code for the product family with which the PDS is associated.
Family Name	The name for the product family with which the PDS is associated.
Attribute	**Description**
NDC Packaging Code	The packaging portion of the NDC code.
Package Set Comments	Text about the package set.
Package Set Keywords	Words you can use to search for the package set.
Package Set Last Updated	The date that the package set was most recently changed.
Package Set Name	The name of the package set.
Package Set Name Last Updated	The date that the package set name was most recently changed.
Package Set Status	The status of the package set.
Package Set Status Date	The date the package set status is effective.
Package Set Description	Text that describes the package set.
Package Size	A number that identifies the size of the package.
Product Detail Set Name	The name of the PDS with which this detail is associated.
Product Name	The name of the product with which this detail is associated.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.

Associate Pack Size with a PDS

You can associate the Pack Size details for product packaging with a PDS package set.

To associate pack size detail with a PDS:

1. In the PDS tree, expand a package set detail node that you created. The nodes for the components associated with the PDS are nested under the package set detail node. A **Pack Size** node also appears under the package set detail node.
2. Do one of the following:

Option	Action
To choose **Add Pack Size** from the component node	Expand a component node and right-click the **Packaging** node nested un- der the component node, and then choose **Add Pack Size**.
To choose **Add Pack Size** from the Packaging node	Right-click the **Packaging** node nested under the package set detail node, and then choose **Add Pack Size**.

   The *Add Pack Size* page appears.

3. Enter values for the pack size PDS attributes.
4. **Save**.

Pack Size PDS Attributes

You can use the attributes to describe the pack size associated with a PDS.

Attribute	Description
Application Code	The code of the application with which this PDS is associated.
Application Name	The name of the application with which this PDS is associated.
Date QC'd	The date the QC Status was set.
Family Code	The code for the product family with which the PDS is associated.
Family Name	The name for the product family with which the PDS is associated.
Pack Size Comments	Additional notes for pack size.
Pack Size Description	Text about the package set.
Pack Size Keywords	Words you can use to search for the pack size.
Pack Size Quantity Opera- tor	Names of quantity operator values: **Equal**, **Not Less Than**, **Range**, **Up to**.
Pack Size Status	The status of the pack size.
Pack Size Status Date	The date the pack size status is effective.
Pack Size Value	A unique pack size numeric value.
Product Name	The name of the product with which this detail is associated.
Product Detail Set Name	The name of the PDS with which this detail is associated.

QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.
QC Status	QC Status of the detail.
Unit of Presentation	The Unit of Presentation.

Shelf Life/Storage Condition Details

You can track concurrent pending changes to product shelf life information by examining shelf life details.

For a PDS package set, you can add and modify shelf life details under the Shelf life(s)/storage condition(s) grouping node. Each detail specifies the complete shelf life of the product. Shelf Life(s)/Storage Condition(s) detail must be

a unique concatenation of required PDS Node fields - (Shelf Life + Shelf Life Unit + Shelf Life Category + Shelf Life Type).

Shelf Life Conditions

The different conditions that impact the quality of a drug substance or drug product over a period of time.

- Shelf life categories are defined in Data Administration.
- A category can be registered for an actual product shelf life that is registered with the registration authority, or labeled for a shelf life that is on the product package label. Examples that identify details: **4 Year(s) Registered**, **2 Year(s) Labeled**.
- Under each shelf life grouping node, for each category, only one shelf life detail can be approved.
- Under each shelf life grouping node, for each category, only one shelf life detail can be pending for one event.

Multiple shelf life details can be pending, but each must be for a different event.

- If a shelf life detail has a Pending Modify status, you cannot add a pending shelf detail with the same type and category for any event associated with the application. This prevents you from creating multiple approved shelf life details for the same PDS.
- Shelf life types can include After first opening, After transformation, In original pack, Unopened.
- You can edit shelf life type, shelf life, shelf life unit or shelf life category if shelf life/storage conditions detail attributes are in **Pending Add** status only.

Modify a Shelf Life Detail

You can modify a shelf life detail in a package set only when viewing the shelf life from the event from which you added the detail.

To view the event from which a detail was added:

1. In the left pane, click the shelf life detail grouping node.
2. In the bottom right area of the right pane, under **Updated in Event**, click the event.

Superseded Detail

When a shelf life detail is approved and the PDS contains a previously approved shelf life detail in the same grouping and category, the status of the previously approved shelf life detail is automatically updated to Superseded.

A superseded shelf life detail is not shown in the PDS, when viewing the PDS for subsequent events. The detail is shown in the PDS as:

- Superseded, when viewing the PDS from the event for which the approved detail was superseded.
- Approved, when viewing the PDS from the event for which the pending detail was approved.

Shelf Life/Storage Condition Attributes

The following are the attributes for the package set details that are associated at the PDS level.

Attribute	**Description**
Family Code	Code of the Product Family to which the PDS is associated.
Family Name	Name of the Product Family to which the PDS is associated.
Application Code	Code of the Application to which the PDS is associated.
Application Name	Name of the Application to which the PDS is associated.
Product Name	Name of the Product to which the PDS/Template is associated.
Product Detail Set Name	Name of the PDS to which this detail is associated.
Shelf Life Type	Shelf life type such as shelf life of the packaged Medicinal Product, shelf life after transformation, and shelf life after the first opening of a bottle.
Shelf Life	Shelf life number.
Shelf Life Unit	Shelf life time unit values. (For example: week, month, year).
Shelf Life Category	Shelf Life Categories available for selection are all the active categories in the Shelf Life Category Values in Data Administration.
Storage Conditions	The conditions under which the package can be stored.

Status	The status of the detail at the time of the associated event.
Status Date	The date on which the status is selected.
Keywords	Keywords that you can use in a search for the detail.
Description	Description of the Shelf Life/Storage Conditions detail.
Comments	Any additional information that you want to save with the Shelf Life/Storage Conditions detail.
Date QC'd	The date the QC Status was set.
QC Status	QC Status of the detail.
QC'd by	User who sets the QC Status for the detail to QC Passed or QC Failed.

Associate Package Detail with a PDS Package Set

You can associate the details for product packaging with a PDS package set.

To associate packaging detail with a PDS package set:

1. In the PDS tree, expand a package set detail node that you created. The nodes for the components associated with the PDS are nested under the package set detail node. A **Packaging** node also appears under the package set detail node.
2. Do one of the following:

Option	**Action**
To add a Package Detail:	Expand a component node and right-click the **Packaging** node nested under the component node, and then choose **Add Packaging**.
To add a Package Detail:	Right-click the **Packaging** node nested under the package set detail node, and then choose **Add Packaging**.

   The *Add Package* page appears.

3. Enter values for the packaging PDS attributes and **Save**.After associating packaging detail with a package set, you can associate a manufacturer with the packaging detail.
4. Right-click the node for the packaging detail you added and choose **Add Manufacturer**.

PDS Package Detail Attributes

You can use the attributes to describe product packaging associated with a PDS.

Attribute	Description
Application Code	The code of the application which this PDS is associated.
Application Name	The name of the application which this PDS is associated.
Component Name	Component name of the component to which this packaging detail is associated.
Component Quantity	The quantity of the component. This attribute is specified as a value and a unit. The unit is specified as a symbol and a symbol identifier, as defined in ISO 11240 and the resulting controlled vo- cabulary.
Component Quantity Unit	The unit used to specify the component quantity.

Attribute	Description
Data Carrier Identifier	The individual value from the identification system that applies to the packaged Medicinal Product.
Date QC'd	The date the QC Status was set.
Device Quantity	The number of devices for packaging details. This field is displayed after the Medical Device Reference when Product has Med Device or PharmaMed Components.

Device Quantity Operator	Names of quantity operator values: **Equal**, **Not Less Than**, **Range**, **Up to**.
Device Quantity Unit of Presentation	Represents a qualitative concept that describes a countable entity. Example: capsule, pack, aerosol.
Device Quantity Unit of Measurement	Represents a standard for measurement of the device. Example: milliliter, milligram, gram.
Family Code	The code of the product family which this PDS is associated.
Family Name	The name of the product family which this PDS is associated.
Manufactured Item Reference	Reference to the manufactured item. The values available for selection is a concatenation of the following from the Manufactured Item entities associated with the PDS Product:<Manufactured Item Name> <Unit of Presentation> <Manufactured Item Quantity> <Manufactured Item Quantity Unit of Measure> <Manufactured Item Dose Form> <Manufactured Item Characteristics>
Medical Device Reference	Reference to the medical device in the PDS. This field is only available for Med Dev and Pharma Med Dev components.
Package Item Al	The alternate material(s) of the package item.

Attribute	Description
ternate Material	
Package Item Compo nent(s)	Package Components available for selection. It is a concatenation of Component Type and Component Material. (For example: Stopper – Rubber)
Package Item Ma terial	The material(s) of the package item.
Package Item Quantity	The quantity of the containers containing the packaged item.
Package Item - MI Quantity	The unit used to define the Packaging Manufacturer Item quantity. You can enter both integer and non-integer values.
Packagi ng MI Quantity Operator	Names of quantity operator values: **Equal**, **Not Less Than**, **Range**, **Up to**.
Package Item - MI Quantity Unit	Units of Measurement Values or Units of Presentation Values in the Data Administration.

Package Item Quantity Operator	Names of quantity operator values: **Equal**, **Not Less Than**, **Range**, **Up to**.
Package Item Type	The kinds of packaging associated with the selected packaging category.
Package Set Name	Name of the Package Set.

Attribute	**Description**
Packaging Comments	Text about the entity.
Packaging Category	Category which this packaging belongs to.**Note:** You cannot create more than one **Packaging** with the same **Packaging Category** and **Packaging Type**.
Packaging Description	Text that describes the PDS detail.
Packaging Keywords	Words you can use to search for the entity.
Packaging Status	The status of the entity.
Packaging Status Date	The date the entity status is effective.
Parent Package	Displays values previously added to the *Packaging Type Values* Data Administration list.
Product Name	Full concatenated product name to which the PDS/Template is associated.

Product Detail Set Name	The name for the PDS which this detail is associated.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.
QC Status	QC Status of the detail.
Unit of Presentation	The unit of presentation is a qualitative term describing the discrete unit in which a component is presented to describe strength or quantity in cases where a quantitative unit of measurement is not appropriate. It is a term and a term identifier as defined in ISO 11239 and the resulting terminology.

Associate a Species with a PDS

For veterinary entity type products, you can associate a species with a PDS either manually or through the GPP wizard.

To associate a species with a PDS:

1. In the PDS tree on the *Product Detail Set* page, right-click the **Species** node and choose **Add Species**.The *Add Species* page appears.
2. Enter values for the species PDS attributes.
3. Click **Save**.The species you added appears in the PDS tree under the **Species** node.
4. After associating a species, you can do the following:

Option	**Action**
To associate indication detail with the species:	Right-click the **Indications** node under the species node you added and choose **Add Indication**.
To associate route of administration detail with the species:	Right-click the **Route of Administration** node under the species node you added and choose **Add Route of Administration**.

Species PDS Attributes

For veterinary entity type products, you can use the attributes to describe the details of a species associated with a PDS.

Attribute	**Description**
Application Code	The code of the application with which this PDS is associated.
Application Name	The name of the application with which this PDS is associated.

Date QC'd	The date the QC Status was set.
Family Code	The code of the product family with which this PDS is associated.
Family Name	The name of the product family with which this PDS is associated.
Product Detail Set Name	The name for the PDS with which this detail is associated.
Product Name	The name of the product with which this PDS is associated.
Species	The animal for which the PDS detail is created.
Species Comments	Comments about the PDS detail.
Species Description	A description about the PDS detail.
Species Keywords	Terms that can be used when performing a keyword search in .
Attribute	**Description**
Species Status	The approval status of the PDS detail.
Species Status Date	The date on which the status is effective.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.

Associate an Indication with a PDS Species

For veterinary entity type products, you can associate an indication details with a PDS species. To

associate indication detail with a PDS species:

1. In the PDS tree on the *Product Detail Set* page, right-click the **Indications** node under the animal species node with which you want to associate the indication and choose **Add Indication**.The *Add Indication* page appears in the right pane.
2. Enter values for the species indication PDS attributes.
3. **Save**.The species indication you added appears in the PDS tree under the **Indications** node. After associating indication detail, you can associate dose schedules with the species indication detail, right-click the **Dose Schedules** node under the indication node you added and choose **Add Dose Schedule**.

Species Indication PDS Attributes

You can use the attributes to describe details for the species indication associated to a PDS.

Attribute	Description
Application Code	Code of the Application to which the PDS is associated.
Application Name	Name of the Application to which the PDS is associated.
Coun tries	Country (countries) for which this detail is created. The countries available for selection are all countries associated with the Application. The exceptions are application countries with the Withdraw Date value equal to today's date or earlier. Such countries are not available for selection in the **Countries** multi-select field on the *Add/Modify Indication* page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.If several countries are selected, they are displayed as comma-separated on the *View detail* page. Defines the value that is included to the XML file during the *XEVM-*

Attribute	Description
	PD Submission Wizard execution.**Note:** By default, all countries associated to the Application appear in the **Selected** box of the **Countries** field on the *Add Indication* page.
Date QC'd	The date the QC Status was set.
Family Code	Code of the Product Family to which the PDS is associated.
Family Name	Name of the Product Family to which the PDS is associated.
Indication	Indication or Indication group. The value is shown as a concatenation of Indication/Intended Use + Med DRA Level + MedDRA Version. Values available for selection are indications that are associated with a Product Family and that do not already exist as a Pending or Approved detail for the related Species detail.
Indication Comments	Any additional information that you want to save with the Indication detail.

Indication Description	Description of the detail.
Indication Keywords	Keywords that you can use in a search for the detail.
Indication Status	Status of the detail. Values available for selection are Pending, Approved, and Not Approved.
Indication Status Date	The date the status of the detail was set.
Product Detail	PDS to which this detail is associated in the following concatenation delimited by space PDS Name + PDS Code.
Attribute	**Description**
Set Name	
Product Name	Full concatenated product name to which the PDS/Template is associated (Product Name + Product Strength + Product Dosage Form +Product Code).
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.
Sub-Indication	Sub-indication for the indication. On the *Create* page, the values available for selection are all sub-indications associated to the selected indication in Data Administration. On the *Modify* page, the values available for selection are all sub-indications associated to the selected indication in Data Administration, except for those already associated in the PDS.

Associate a Dose Schedule with a PDS Species Indication

For veterinary entity type products, you can associate a dose schedule with a species indication.

To associate a dose schedule with a PDS species indication:

1. In the PDS tree on the *Product Detail Set* page, right-click the **Dose Schedules** node under the species indication node with which you want to associate the dose schedule and choose **Add Dose Schedule**.The *Add Dose Schedule* page appears in the right pane.
2. Enter values for the dose schedule PDS attributes. **Note:** As a best practice, the route of administration you define for a dose schedule should also be defined under the Routes of Administration node for the species PDS detail.
3. **Save**. The new dose schedule node includes the route of administration, concentration unit and measure, and dose frequency. You will be unable to edit the selected parameters, because they are used to identify the dose schedule. If you make an error, delete the dose schedule and enter the parameters again using these instructions.The dose schedule you added appears in the PDS tree under the *Dose Schedules* node.

Dose Schedule PDS Attributes

You can use the attributes to describe the details of a dose schedule associated to a PDS.

Attribute	Description
Application Code	The code of the application with which this PDS is associated.

Attribute	Description
Application Name	The name of the application with which this PDS is associated.
Concentration Measure 1	Numeric value of the concentration based on the **Concentration Unit** selected.
Concentration Measure 2	Numeric value of the concentration based on the **Concentration Unit** selected.
Concentration Unit	Unit of measure for the active ingredient concentration.
Date QC'd	The date the QC Status was set.
Dose Frequen-cy	This is how often a dose is administered in a dosing schedule.
Dose Schedule Comments	Comments about the PDS detail.
Dose Schedule Description	A description about the PDS detail.

Dose Schedule Keywords	Terms that can be used when performing a keyword search in Ennov InSight .
Dose Schedule Status	The approval status of the PDS detail.
Dose Schedule Status Date	The date on which the status is effective.
Family Code	The code of the product family with which this PDS is associated.
Attribute	**Description**
Family Name	The name of the product family with which this PDS is associated.
Measure Type	How the measure per unit is quantified.
Product Detail Set Name	The name for the PDS with which this detail is associated.
Product Name	The name of the product with which this PDS is associated.

Production Type	The varieties of a species for which a drug is targeted. The production type values listed is based on the values associated with the species in data administration.
Route of Administration	The route of administration for which the dosing is being created. As a best practice, the route of administration you define for a dose schedule should also be defined under the Routes of Administration node for the species PDS detail.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.

Associate Route of Administration Detail with a PDS Species

For veterinary entity type products, you can add details for the route of administration for a species associated to a PDS.

To associate route of administration (ROA) detail with a PDS species:

1. In the PDS tree on the *Product Detail Set* page, right-click the **Route of Administration** node under the animal species node with which you want to associate the ROA and choose **Add Route of Administration**.The *Add Route of Administration* page appears in the right pane.
2. Enter values for the ROA PDS attributes.
3. **Save**.The ROA you added appears in the PDS tree under the **Route of Administration** node.
4. After associating ROA detail, you can do the following:

◦ To associate withdrawal times with the ROA detail, right-click the **Withdrawal Times** node under the ROA node you added and choose **Add Withdrawal Time**.

Route of Administration PDS Attributes

You can use the attributes to describe the details of the route of administration for a species associated to a PDS.

Attribute	**Description**
Application Code	The code of the application with which this PDS is associated.
Application Name	The name of the application with which this PDS is associated.
Date QC'd	The date the QC Status was set.
Family Code	The code of the product family with which this PDS is associated.
Family Name	The name of the product family with which this PDS is associated.
Product Detail Set Name	The name for the PDS with which this detail is associated.

Product Name	The name of the product with which this PDS is associated.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.
Route of Administration	The path by which the drug product is introduced into the body of the animal species.
Route of Administration Comments	Comments about the PDS detail.
Route of Administration Description	A description about the PDS detail.
Route of Administration Keywords	Terms that can be used when performing a keyword search in Ennov InSight .
Route of Administration Status	The approval status of the PDS detail.
Route of Administration Status Date	The date on which the status is effective.

Associate Withdrawal Time with ROA PDS Details

For veterinary entity type products, you can associate a withdrawal time with a route of administration for a species in a PDS.

To associate a withdrawal time with ROA PDS detail:

1. In the PDS tree on the *Product Detail Set* page, right-click the **Withdrawal Times** node under the route of administration node with which you want to associate the withdrawal time and choose **Add Withdrawal Time**.The *Add Withdrawal Time* page appears in the right pane.
2. Enter values for the withdrawal time PDS attributes.
3. **Save**.The withdrawal time you added appears in the PDS tree under the **Withdrawal Times** node.

Withdrawal Time PDS Attributes

ou can use the attributes to describe details about the withdrawal time for a route of administration.

Attribute	**Description**
Application Code	The code of the application with which this PDS is associated.

Application Name	The name of the application with which this PDS is associated.
Date QC'd	The date the QC Status was set.
Do Not Use	This flag indicates if the human consumption product produced by the animal species cannot be used after the drug is administered. When selected, the **Withdrawal Time** and **Withdrawal Time Unit** attributes are not applicable, and are hidden from view.
Family Code	The code of the product family with which this PDS is associated.
Family Name	The name of the product family with which this PDS is associated.
Human Consumption Product	A human use product produced by the animal species that either should not be used after the drug is administered or is considered safe for use after a specified withdrawal time.
Product De tail Set Name	The name for the PDS with which this detail is associated.
Product Name	The name of the product with which this PDS is associated.
QC Status	QC Status of the detail.
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.
Attribute	**Description**

Withdrawal Time	This is the amount of time that must pass after administering the drug before the human consumption product produced by the animal species is considered safe for use. Enter a numeric val- ue in conjunction with the **Withdrawal Time Unit** attribute. If **Do Not Use** is checked, this attribute is not applicable and is hidden from view.
Withdrawal Time Comments	Comments about the PDS detail.
Withdrawal Time Descrip- tion	A description about the PDS detail.
Withdrawal Time Keywords	Terms that can be used when performing a keyword search in Ennov InSight .
Withdrawal Time Status	The approval status of the PDS detail.
Withdrawal Time Status Date	The date on which the status is effective.
Withdrawal Time Unit	The time unit for the numeric value specified for the **Withdrawal Time** attribute. If **Do Not Use** is checked, this attribute is not applicable and is hidden from view.

Associate Clinical Trial Details with a PDS

If the PDS is associated with a Clinical Trial Application or Investigational New Drug Application, you can track the details in the PDS.

To associate clinical trial details with a PDS:

1. In the PDS tree on the *Product Detail Set* page, right-click the **Clinical Trial** node and then click **Add Clinical Trial**.The *Add Clinical Trial* page appears.
2. Enter values for the clinical trial attributes and **Save**.The clinical trail details are added to the PDS.

Clinical Trial PDS Attributes

You can use the attributes to describe the details of a clinical trial application for the European Union.

Attribute	Description
Application Code	Code of the Application to which the PDS is associated.
Application Name	Name of the Application to which the PDS is associated.
Comments	Any additional information that you want to save with the Shelf Life/Storage Conditions detail.
Date QC'd	The date the QC Status was set.
Description	Description of the Shelf Life/Storage Conditions detail.
Family Code	Product Family to which the PDS is associated.
Family Name	Product Family to which the PDS is associated.
Keywords	Keywords that you can use in a search for the detail.
Product Detail Set Name	PDS to which this detail is associated in the following concatenation delimited by space PDS Name + PDS Code.
Product Name	Full concatenated product name to which the PDS/Template is associated (Product Name + Product Strength + Product Dosage Form +Product Code).
Product of Human or Animal Origin	Origin of product: Animal or Human
QC Status	QC Status of the detail
QC'd by	Person logged on to the system who set the QC Status for the detail to QC Passed or QC Failed.
Status	The status of the detail at the time of the associated event.
Status Date	The date that the detail had the status.

Common PDS Details Associations

As you navigate the PDS tree to define PDS details, several of the nodes in the tree are "common" in that they can be defined at different levels in the tree for various parent nodes. The procedures for defining these detail entities are the same regardless of where in the PDS tree they appear.

Associate a Manufacturer

You can associate a manufacturer to the PDS for a product event.

To associate a manufacturer:

1. In the PDS tree on the *Product Detail Set* page, right-click the grouping node or PDS detail with which you want to associate a manufacturer and choose **Add Manufacturer**.The *Add Manufacturer* page appears in the right pane.
2. Enter values for the manufacturer PDS attributes.
3. **Save**.

Manufacturer PDS Attributes

You can use the attributes to describe a manufacturer associated with a PDS.

Attribute	**Description**
Application Code	Application code associated with the PDS.
Application Name	Application name associated with the PDS.
Component Name	Component name associated with the PDS.
Countries	Application countries associated with the manufacturer.**Note:** Withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the **Countries** drop-down field on the *Add/Modify Manufacturer* page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.
Date QC'd	The date the QC status was set.
Family Code	Product Family Code associated with the PDS.

Attribue	Description
Family Name	Product Family Name associated with the PDS.
Manufacturer	Name of the manufacturer displayed as a concatenation of Manufacturer Name + Address Line 1 + Country Code.
Manufacturer Comments	Any additional information that you want to save with the manufacturer detail.
Manufacturer Description	Description of the manufacturer.
Manufacturer Keywords	Keywords that you can use in a search for the detail.
Manufacturer Status	The manufacturing status that includes Pending, Approved, and Not Approved.
Manufacturer Status Date	The date the manufacturer status was set.
Manufacturing Operation Start Date	The date on which the manufacturing starts .
Manufacturing Operation End Date	The date on which the manufacturing stops.
Product De	The name of the PDS. The name is displayed as PDS Name + PDS Code.

Attribute	Description
tail Set Name	
Product Name	The name of the product associated with the PDS. The name is displayed concatenated as Product Name + Product Strength + Product Dosage Form + Product Code.
QC Status	QC status of the detail.
QC'd by	The name of the person who has performed the quality check for the detail.
Qualified Person	The person qualified for the manufacturing site.

Modify PDS Details

Use this procedure to modify PDS Details.

To modify PDS details:

1. Click a link for the event whose PDS detail you want to modify. **Note:** The event for which you want to modify the PDS detail must be open.
2. On the **Product Detail Sets** tab, click the PDS that contains the detail to be modified.The *PDS* page appears.
3. In the left pane of the *PDS* page, locate the PDS detail you want to modify.
4. Determine whether QC statuses are being used with PDS details. If the PDS detail attributes in the right pane include the **QC Status** attribute and the value of that attribute is not **Not Applicable**, QC statuses are being used with PDS details.
5. Right-click the PDS detail, and choose **Modify** or **Modify Status**:

Option	Action
If QC statuses are not being used with PDS details:	You can use the **Modify** option to modify any attribute of the PDS detail. You can also use the **Modify Status** option to modify the **Status** attribute of the PDS detail.
If QC statuses are being used with PDS details:	You can use the **Modify** option to modify the PDS detail attributes, except to assign the final value **Approved** or **Not Approved** to the **Status** attribute. In that case make sure that you use the **Modify Status** option because that option never changes the **QC Status** attribute.

Using the **Modify** option always changes the **QC Status** attribute back to the default, set in Data

Administration. The default is a value, such as **Not QC'd**, that might be different from the value that the **QC Status** attribute has before you assign a final value to the **Status** attribute.

If QC statuses are being used with PDS details, you can always use the **Modify Status**option to assign a value to the **Status** attribute.

After you choose **Modify** or **Modify Status**, the *PDS Detail Attributes* page appears in the right pane.

6. Enter your changes to the attribute values. **Note:** On the *PDS Detail Attribute* page, the value for **Status** defaults to **Pending**. Before saving your changes, confirm that the status for the PDS detail is properly set.
7. **Save**. **Note:** If QC statuses are being used with PDS details and you modified the detail by using the **Modify** option, the **QC status** attribute changes back to the default.

PDS Detail Statuses

As regulatory actions related to an application occur, the status of events pertaining to those regulatory actions and the status of product detail set (PDS) details associated with those events must be maintained.

When maintaining PDS detail statuses, enforces rules regarding how a detail's status transitions through the course of events. The status of events and how a PDS detail status has changed over the course of those events impact what PDS detail status changes that will allow.

PDS Detail Status Types

The following table describes each of the statuses that may be assigned to a PDS detail.

Status	**Description**
Pending Add	The details are to be added when approval by the regulatory agency is granted.
Pending Modify	The details are to be changed when approval by the regulatory agency is granted.
Pending Withdraw	The details are to be withdrawn when approval by the regulatory agency is granted.
Approved	The detail has been approved by the regulatory agency.
Not Approved	The detail has not been approved by the regulatory agency.
Withdrawn	Your organization has submitted a request to withdraw a detail and the regulatory agency has approved the withdrawal.
Superseded	The regulatory agency approved the detail, but later approved another detail that replaced the earlier one. This status is limited to shelf life details.

View a Product Detail Set (PDS) through an Event

Best practices for Ennov InSight recommend that you navigate to view a PDS via an event. That is, you should first navigate to an event and then select the PDS from the Event page. By doing so, Ennov InSight can present the status of PDS details in the context of the event.

For example, if a PDS detail was approved in Event 1, and then a change for the detail was submitted to the regulatory authority in Event 2, the status for that PDS detail in Event 1 is **Approved**, and **Pending Modify** in Event 2. By navigating via an event, Ennov InSight can provide this status information. The following images shows how Ennov InSight presents PDS detail statuses on the PDS page.



In this example screen, the PDS is being viewed through Event 3. For the **Characteristic** PDS detail, the closest prior status of **Pending Modify** was defined in Event 2, which is shown in parentheses next to the detail in the PDS tree in the left pane. In the right pane, information about the pending status and the most current approved status are shown side-by-side. Since the PDS detail has a pending status in a prior event (Event 2), it is not editable in this event (Event 3). Therefore, Ennov InSight provides a link to the prior event in which this detail may be modifed.

Rules that Govern PDS Detail Statuses

The following summarizes rules used by Ennov InSight for presenting the statuses of PDS details on the PDS page.

When an event is set to a status that maps to the internal event status of **Approved** or **Not Approved**:

- If the PDS status is not already mapped to Approved, Not Approved, or Withdrawn, the PDS status is set to the status that maps to **Approved/Not Approved** and the PDS status date is set to the event status date.
- The statuses for all PDS details pending through the event are automatically set to Approved/Not Approved.
- The status dates for all PDS details pending through the event are automatically set to the event status date.
- The event is closed.

When an Event is closed as Approved, meaning the **Associations Closed As** field is set APPROVED, and the PDS associated to this Event has a withdrawn Country Detail displayed as **Country (Pending Withdrawal)**:

- The **Country Status** field of this country is automatically set to Approved and this country is displayed as **Country (Withdrawn)** in the PDS Tree on the left.
- As an additional rule, the parent **Application Country** > **Withdrawn Date** field is automatically updated to be equal to **Event** > **Closed Date** value. The same rule applies to the parent Application Country when the **Country (Pending Withdrawal)** PDS Detail is modified and the **Country Status** field is set to Approved. See *If the Event Is Closed with the Status Approved*.

No changes can be made to a PDS or its details through a closed event.

When viewing a PDS within the context of an event whose status is either Approved or Not-Approved:

- If the PDS detail is approved, only that occurrence of the detail is shown.
- If the PDS detail is not-approved, side-by-side comparison of the non-approved detail and the closest prior approved version of that detail is shown.
- For PDS details not associated with the event, the closest prior approved detail is shown.

When viewing a PDS within the context of an event whose status is neither Approved nor Not-Approved:

- If a PDS detail status is pending modify, side-by-side comparison with the closest prior approved version of that detail is shown.
- For all details not associated with the event, all currently approved and currently pending details are shown, that is, not approved details are not shown. For a pending detail, side-by-side comparison with the closest prior approved version of that detail is shown. A hyperlink is provided to the event through which the pending detail is modifiable.

When viewing a PDS outside the context of an event:

- All currently approved and currently pending details are shown. For a pending detail, side-by-side comparison with the closest prior approved version of that detail is shown. A hyperlink is provided to the event through which the pending detail is modifiable.

Transition Rules for the Status of a PDS Detail

The following summarized how Ennov InSight regulates the status changes you may make to a PDS detail with regards to event statuses and how the status of the PDS detail has changed through the events with which the PDS is associated.**Note:** No action, including Modify, Delete and Withdraw, can be performed on a detail through an open event if it has a pending detail in another event.

From status	**Action**	**To status**
n/a	Add a new de tail	**Pending Add**. The option to add children to a parent detail is not available if the parent detail is in a pending state through another event.
Approved	Modify	• **"Pending State"** (If Status is set to **Pending**) • **Not Approved** (If Status is set to **Not Approved**). Not approved version of detail is only displayed in the event through which it was **Not Approved** • **Approved** (No change if status is set to **Approved**)
Approved	Withdraw	**Pending Withdrawal** (This is automatically set)
Pending Add	Modify	• **Pending Add** (No change if status is set to **Pending**) • **Approved** (If status is set to **Approved**) • **Not Approved** (If status is set to **Not Approved)**. Not approved version of detail is only displayed in the event through which it was **Not Approved**
Pending Add	Delete	n/a (Detail is removed from PDS)
Pending Modify	Modify	• **Pending Modify** (No change if status is set to **Pending**) • **Approved** (If status is set to **Approved**) • **Not Approved** (If status is set to **Not Approved**). Not approved version of detail is only displayed in the event through which it was **Not Approved**
Pending Modify	Delete	n/a (Detail is removed from PDS)

From status	Action	To status
Pending Withdrawal	Modify	• **Pending Withdrawal** (No change if status is set to **Pending**) • **Withdrawn** (If status is set to **Approved**) • **Not Approved** (If status is set to **Not Approved**). Not approved version of detail is only displayed in the event through which it was **Not Approved**
Pending Withdrawal	Delete	n/a (Detail is removed from PDS)
Not Approved	Modify	• **"Pending State"** (If status is set to **Pending**) • **Approved** (If status is set to **Approved**) • **Not Approved** (No change if status is set to **Not Approved**).Not approved version of detail is only displayed in the event through which it was **Not Approved**
With-drawn	Modify	• **Pending Withdrawal** (If status is set to **Pending**) • **Withdrawn** (No change if status is set to **Approved**). Withdrawn version of detail is only displayed in the event through which it was **Withdrawn** • **Not Approved** (If Status is set to "Not Approved"). Not approved version of detail is only displayed in the event through which it was **Not Approved**

View PDS Details

You can view attributes and take actions on a PDS.

To view details for a PDS:

1. Click a link for the product detail set you want to view.
2. Do any of the following:

Option	Action
To create a PDS template from the PDS:	Click **Create**.
To modify the PDS attributes:	Click **Edit**.

To view a PDS detail:	Navigate the PDS tree in the left pane and click the detail you wish to view.
Option	**Action**
To modify a PDS detail:	Navigate the PDS tree in the left pane, right-click the detail you wish to edit, and click **Modify**.
To delete a PDS detail:	Navigate the PDS tree in the left pane, right-click the detail you wish to delete, and click **Delete**.

Delete PDS Details

You can delete a PDS from an open event, unless the event has a pending detail in another event.

Note: For information regarding conditional requirements related to deleting a PDS detail, see *PDS Detail Statuses*.To delete PDS details:

1. Click a link for the event whose PDS detail you want to delete. **Note:** The event for which you want to delete the PDS detail must be open.
2. On the **Product Detail Sets** tab, click the PDS that contains the detail to be deleted.The *PDS* page appears.
3. In the left pane of the *PDS* page, locate the PDS detail you want to delete.
4. Right-click the PDS detail, and click **Delete**.
5. When you are prompted to confirm the deletion, click **OK**.
6. Click **OK** to close the confirmation that the PDS detail has been deleted. The detail no longer appears in the PDS tree. **Note:** When you delete a PDS detail that has any children, they will be deleted as well. For example, if there is a reference strain associated to a flu strain detail, it will be deleted along with the parent flu strain.

Withdraw PDS Details

You can withdraw PDS details for an approved application, if necessary.

Note: See *PDS Detail Statuses* for information regarding conditional requirements related to withdrawing an approved detail.To withdraw PDS details:

1. Click a link for the event whose approved PDS detail you want to withdraw. **Note:** The event for which you want to delete the PDS detail must be open.
2. On the **Product Detail Sets** tab, click the PDS that contains the detail to be withdrawn.The *PDS* page appears.
3. In the left pane of the **PDS** page, locate the approved PDS detail you want to withdraw.
4. Right-click the PDS detail, and click **Withdraw**.The PDS detail is updated in the left pane with the status **Pending Withdrawal**.

Associate or Disassociate PDSs and Events

When creating a PDS, you are required to associate the newly created PDS with an event. However, after you create a PDS, allows you to associate an existing PDS with other events. Furthermore, you can disassociate an existing set of

product details from an event for an application if the PDS was inadvertently associated with the event and you need to undo the association.

Keep in mind the following when you select an event for associating or disassociating a PDS:

- You can associate a PDS with more than one event.
- You cannot associate or disassociate a PDS if the event is associated with a project.
- The only PDSs available for association are those PDSs: 1) already created for other events under the same application as the selected event, and 2) where the related products are associated with the selected event.
- You can disassociate a PDS from an event only if: 1) the event is not the only event with which the PDS is associated, and 2) no changes were made to any of the PDS details for the selected event. If the event is the only event associated with the PDS, you cannot disassociate the PDS from the event. Instead, you must delete the PDS.

Associate or Disassociate a PDS

You can associate a PDS to an open event, or disassociate a PDS from an open event.

To associate or disassociate a PDS:

1. Click a link for the event you want to associate or disassociate the PDS with.The *Event Attributes* page appears.
2. Click **Product Detail Sets**.
3. Click **Associate**.The *Associate/Disassociate Product Detail Sets* page appears.
4. Do one of the following:

Option	**Action**
To associate PDSs with the event:	Click PDSs in the *Available* box and move them to the *Selected* box.
To disassociate PDSs from the event:	Click PDSs in the *Selected* box and move them to the *Available* box.

5. **Save**.

Updating MedDRA Version

You can update a MedDRA version for multiple indications/intended entities simultaneously.

To mass update a MedDRA version:

1. On the home page, click **Go To** > **Data Administration**.
2. Under the *Other* category, click **Indications/Intended Use Values**.
3. Do one of the following:

Option	Action
To update the version for all indications/intended entities:	Select the check box next to the **Indications/Intended Use** column header.
Option	**Action**
To update the version for individual **Indications/Intended Use** entities:	Select the check boxes applicable to the entities.

4. Click **Mass Update** at the top of the page.A text box appears
5. Select the check box next to **MedDRA Term Version** and enter the new version to update.
6. Do one of the following:

Option	Action
To update the new version for all the selected indications/intended entities:	Click **Update and Overwrite**.
To update the new version for only those selected indications/intended entities which have no values:	Click **Update and Preserve**.

QC Status for a PDS Detail

You can use the QC Status feature to track whether the PDS detail has had, or requires, a QC (quality control) evaluation.

When a detail has been QC evaluated, the system enables you to update the QC Status for the detail to QC Passed or QC Failed. QC Failed can indicate that some action needs to be taken before the detail is approved.

The system tracks the person who was logged into and updated the QC Status and tracks the date and time the QC Status is updated.

You can also view the history of QC status changes for an application using the **Application QC Status History** query.

This query is useful, for example, to identify PDS details that failed a QC check.

Prepare to Assign QC Statuses

To set up to enable you to assign QC statuses, go into Data Administration and set the default QC status.

This value is displayed on a PDS detail when it is created or modified to a pending status. The QC Status **Not Applicable** is the initial default status and indicates that the QC Status feature is not being used.

Assign the QC Passed Status to Details to Be Hidden by an Overrides File

If you want to use QC verification and use an overrides file to hide a PDS node, first assign the QC status **QC Passed** to every detail associated with the node, and then apply the overrides. After you apply the overrides, you cannot

change the QC status of a hidden detail. If the QC status of every PDS detail associated with the node is not QC Passed, you cannot close an event associated with the PDS.

Assign a QC Status to a PDS Detail

You can assign a pass or fail QC status to a Product Detail Set.

1. On the *Product Detail Set* page, navigate to a pending detail. **Note:** You can assign a QC status only to a pending PDS detail.
2. Select the detail.
3. In the upper right corner of the **Detail Attributes** pane, click one of the following buttons to indicate whether the detail passed or failed the QC check.

Option	**Action**
To indicate that the detail passed the QC check:	Click **QC Passed -**.
To indicate that the detail passed the QC check:	Click **QC Failed -**.

Finalize a PDS Detail Status without a QC Status Change

You can use the **Modify Status** option to assign the final value Approved or Not Approved to the Status attribute of a PDS detail because that option never changes the QC Status attribute.

Modifying a PDS detail by using the **Modify** option always changes the QC Status attribute back to the default, set in Data Administration. The default indicates that a QC check is necessary. The default value for the default QC status is Not QC'd.

Close an Event when the QC Status Feature is Used

When the QC Status feature is used, you can close an event only if all PDS details associated with the event have a QC Status of approved.

If a PDS detail has a QC status of not approved or not QC'd , you cannot close the event. If you try to close the event, the following message is displayed: "The event cannot be closed. The QC Status for all PDS details associated

with the event must be approved prior to closing the event."

QC Status of all PDS Details

When the QC Status feature is used, the **QC Passed** column is on the PDS tab on the *Event Attributes* page, and the **QC Passed** column or field is on several wizard pages. The **QC Passed** column or field indicates whether all the PDS details associated with an event passed the QC check.

The value **Yes** for QC Passed indicates that all PDS details associated with the event have passed the QC check.

The value **No** for QC Passed indicates that some PDS details failed the QC check or have not been QC evaluated. In this case, you cannot close the event.

Delete a PDS

Use this procedure to delete a PDS.

You can delete a PDS, if necessary, only if:

- You have the required security privileges to delete the PDS.
- You access the PDS through an event associated with the PDS.
- No detail associated with the PDS has a status of Approved or Not Approved.

To delete a PDS:

1. Click the link for the PDS you want to delete.The *PDS page* appears.
2. Click **Delete**.
3. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

PDS Templates

You can create a product detail set (PDS) template for creating other PDSs for products in the same product family.

The process of creating a PDS template is similar to creating a PDS. The attributes of the details in a PDS template are identical to the PDS detail attributes with the following exceptions:

- No application is associated with the PDS template.
- No event is associated with the PDS template.
- **Status** and **Status Date** fields are not included in PDS template details. This exception is applicable for all PDS Details.
- No countries are associated with the PDS template. The country detail entity that appears in the PDS template is named **Country**.
- For any occurrence of a **Manufacturer** detail entity in a PDS hierarchy tree, the **Countries** attribute is not applicable.
- For **Label** details, the **Label Country** attribute is not applicable. The name of a label detail entity is derived by concatenating the word “Country” to the **Label Type** and **Label Code** attribute values.
- For **Indication/Intended Use** and **Species Indication** details, the **Countries** attribute is not applicable.

You can create a PDS template from a product listed on the *Product Attributes* page, from an existing PDS, or from another PDS template.

When creating a PDS template form an existing PDS or another PDS template:

- The product associated with the source PDS or PDS template cannot have more than one component.
- The target product for the PDS template you are creating cannot have more than one component.
- The target product for the PDS template you are creating must be associated with the same product family as the source PDS or PDS template.

Create a PDS Template from the Product Attributes Page

You can create a PDS template to quickly add additional PDS to the product family.

To create a PDS template:

1. Click a link for the product for which you want to create a PDS template.The *Product Attributes* page opens.
2. Click the **Product Detail Set Templates** tab, then click **Create**.The *Product Detail Set Template* page appears.
3. Enter values for the PDS template attributes.
4. **Save**.The *Product Detail Set* page for the PDS tempate you created appears.

PDS Template Attributes

You can use the attributes to define the details of the PDS template.

Attribute	**Description**
Family Code	Code assigned to the product family with which the application is associated.
Family Name	Name of the product family with which the application is associated.
PDS Template Add Comment	Free format text box where users can enter information that will be stamped with the date/time/ userid of the person entering the information.
PDS Template Comments	The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them. Comments are displayed when you modify the entity.
PDS Template Description	Text that describes the PDS.
PDS Template Keywords	Words you can use to search for the PDS.

Product Name	The product for which you are creating a detail set.
Product Detail Set Template Code	Your organization's code for the template. This attribute appears on the create and modify screens.
Attribute	**Description**
Product Detail Set Template Name	The name of the template. This attribute appears on the create and modify screens.The name of the PDS template must be unique within a product.

Create a PDS Template from a PDS

You can create a Product Detail Set (PDS) template from an existing PDS.

If you enter a comment in the **Add Comment** field and then create a PDS template from a PDS (or from another PDF template), the comment is not carried forward to the newly created PDS.To create a PDS template from a PDS:

1. Click a link for the PDS from which you want to create the template.
2. On the *Product Detail Set* page, click **Create**.
3. On the *Product Detail Set Template* page, enter the PDS template attribute values.
4. **Save**.The *Product Detail Set* page for the PDS from which you created the template appears.

Create a PDS Template from Another PDS Template

You can create a product detail set (PDS) template from another PDS template and use it to create similar PDS for a product.

If you enter a comment in the **Add Comment** field and then create a PDS template from a PDS template (or from a PDS), the comment is not carried forward to the newly created PDS.To create a PDS template from a PDS template:

1. Click a link for the PDS template from which you want to create another PDS template.The *Product Detail Set* page appears.
2. Click **Create**.The *Product Detail Set Template* page appears.
3. Enter values for the PDS template attributes.
4. **Save**.The *Product Detail Set* page for the PDS template from which you created the template appears.

Chapter 22. Sequences

A sequence is a set of documents to be submitted together to a regulatory authority (for example, an initial filing or amendment). These documents are submitted to support a business objective.

When you create a sequence, you associate it with an event. Events determine how the sequence is to be approved in the *Update Status* wizard. This helps to determine which documents are added to the approved views, as well as which sequences get marked with the approved status.

Sequences are applicable to the following Ennov InSight modules:

- Electronic Lifecycle Publishing
- Registered Document Analysis
- Registration Planning and Tracking
- Submission Planning and Tracking
- Paper Review Publishing

Create a Sequence from the Application Attributes Page

You can create sequences from the *Application Attributes* page.

Alternately, you can also create sequences from the *Project Attributes* page, from the *GPP* wizard and from the *Create Application* wizard.**Note:** You must have the appropriate security privileges to create a sequence.

To create a sequence:

1. Click **Home**.
2. Select **Product Families**.
3. Click the product family which includes the application for which you want to create a sequence.The *Product Family Attributes* page appears.
4. Click a link for the application for which you want to create a sequence.The *Application Attributes* page appears.
5. Click **Sequences**.
6. Click **Create**.The *Create Sequence* page appears.
7. Enter values for the sequence attributes. Please note that the withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the **Concerned Member States** or **Member States Concerned** (for EU CTR applications) multi-select field. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.
8. **Save**.
9. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Create a Sequence from the Event Attributes Page

You can create sequences from the *Event Attributes* page. You can also create sequences from the *Application Attributes* page, the *Project Attributes* page, or the *GPP* wizard.

Note: You must have the appropriate security privileges to create a sequence.

To create a sequence from an event, the event from which you create a sequence must be open.

1. Navigate to an open **Event**.
2. On the *Event Attributes* page, click **Sequences**.
3. Click **Create**.
4. On the *Create Sequence* page, enter values for the sequence attributes. Please note that the withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the **Concerned Member States** or **Member States Concerned** (for EU CTR applications) multiselect field. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.
5. **Save**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Create a Sequence from the Project Attributes Page

You can create sequences from the *Project Attributes* page using the *Create Sequences* wizard.

You can also create sequences from the *Application Attributes* page, or by using the *GPP* wizard.**Note:** You must have WRITE privileges to create a sequence.

To create a sequence:

1. Click **Home**.
2. Select **Projects**.

3. Click a link for the project for which you want to create a sequence.The *Project Attributes* page appears.
4. Click **Create Sequence**.The *Create Sequence* wizard opens to the *Select Events* page.
5. Select one, or multiple, events for which you want to create sequences.
6. Click **Next**.The *Enter Sequence Details* page appears.
7. Enter values for the sequence attributes.
8. Click **Next**.The *Enter Filing Type* page appears.
9. Select the filing type.
10. Click **Next**.
11. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next**.The *Summary* page appears, confirming the sequences are created.
2. Click **Finish**.You return to the *Project Attributes* page from which you invoked the *Create Sequence* wizard.

Sequence Attributes

The attribute descriptions will help you to enter appropriate sequence attribute values while creating a sequence. The following table lists all the attributes that are available to you in the *Enter Sequence Details* page while creating a sequence.

Attribute	Description
Application Code	Agency-identified application number (or identifier); may not be known until submittal time, therefore it may be the same as the internal code.
Application Name	The name of the application.
Assign Workflow	Defines the workflow that will be associated with the sequence automatically when the sequence is created.
Closed	Indicates whether the sequence is completed.
Concerned	For a DCP (Decentralised Procedure) or MRP (Mutual Recognition Procedure) application, the countries that may review the application; cannot be changed.**Note:** Withdrawn application countries with the With

Attribute	Description
Member States (Available/Seleed)	draw Date value equals to today's date or earlier are not available for selection in the **Concerned Member States** multi-select field on the *Create Sequence* page. ct
Member States Concerned	This field is available for a EU CTR (EU Clinical Trial Regulation Procedure) only.
Concerned Parties	Users who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses.
Co-Rapporteur	For a CP application, the corapporteur associated with the sequence; cannot be changed.
Electronic Output Location	The path name where the published output exists.
Events	Events associated with the sequence.
Filing Type	The sequence filing type.
Included in Grouped Submission	The hyperlinked name of the submission plan that the sequence is associated with.
Lifecycle Order	The order of this sequence in the lifecycle; cannot be changed.
Owner	The person responsible for the sequence.
Origination	Text about the item associated with the sequence.

Attribute	Description
Paper Reference	Any text about paper documents associated with the sequence.
Procedure Type	Identifies the strategy used in a regulatory approval process for a particular set of regulatory requirements.
Rapporteur	For a CP application, the country associated with the sequence; cannot be changed.
Reason for Termination/Withdrawal	The reason that sequence was terminated or withdrawn.
Reason	Reason for creating, modifying or deleting a sequence.
Reason for Comments	Comments related to reason entered by users.
Reference Member State	For an MRP application, the member state to perform the initial assessment of a sub- mission for the purposes of attaining a marketing authorization; cannot be changed.
Reviewing Country	The country that will review the application. When European Union (EU) is selected, multiple country selections are possible.
Sequence Add Comment	Comments you want to share with others in a discussion thread. Will be displayed in the **Sequence Comments** box, stamped with the date and time you enter the informa- tion and your user ID.**Note:** The **Sequence Add Comment** field is available on the Cre- ate/Modify *Sequence Attributes* pages only.
Sequence Category	The category for the sequence.

Attribute	Description
Sequence Code	A default value for the sequence to be associated with the application. For the very first sequence in an application, the recommended default is taken from the Application's Starting Sequence Number, however, this number can be changed. For subsequent sequences, all the sequences in the application are considered, though a default of P, followed by four digits is presented and is recommended for eCTD filings. When the highest existing sequence number has been determined, the default sequence number for the new sequence is the highest plus one. For example, if there are four sequences with the codes P0000, 0001, 0005, and R0006-512, the next sequence number by default is P0006.
Sequence Comments	The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.

Sequence Description	Text that describes the sequence.
Sequence Key-words	Words you can use to search for the sequence.
Sequence Name	The name of the sequence.
Sequence Status	The status of the entity.
Sequence Status Date	The date the entity status is effective.
Sequence Stan	The following standard types are available for selection: • **NeeS** • **Paper**
Attribute	**Description**
dard Type	• **eCTD 3.2** • **eCTD 4.0** If there is no **eCTD 4.0** type, **eCTD 3.2** is selected by default. If there is at least one **eCTD 4.0** Sequence under the Application,**eCTD 4.0** is selected by default.
UUID	UUID (version 4 of UUID types) is a universal unique identifier that is automatically generated by the system on sequence creation. This field is visible and available for modification and view pages only. • The value can be modified only by users with Administrator permissions to the sequence. • Through the eCTD wizard, users with appropriate permissions are able to modify the UUID to support sequences that may require a different UUID. In most cases, the UUID value should not change. The **UUID** field is not available in case of sequences bulk update. **Note:** The values should be unique (case-insensitive). The entered values should pass the val- idation to match the format: a hexadecimal number in the form of xxxxxxxx-xxxx-xxxx-xxxx- xxxxxxxxxxxx, having 32 digits and 4 hyphens. If format does not match, the The UUID must be in the form of xxxxxxxx-xxxx- Mxxx-Nxxx-xxxxxxxxxxxx, where x is a hexadecimal number, M is 1-5, and N is 8, 9, a or b. mes- sage is displayed. If uniqueness is violated, the The UUID must be unique. message appears.

User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Modify a Sequence

You must modify a sequence to make changes or revise the attribute values for a sequence.

You must have at least WRITE security privileges to modify a sequence. You will be unable to modify a sequence associated with an application if you do not have at least WRITE privileges for the application county as well. Having WRITE privileges for sequences is not sufficient under these circumstances.

To modify a sequence:

1. Go to the application or event that has the associated sequence that you want to modify.
2. Click **Sequences**.
3. Click the link for the sequence you want to modify.
4. On the *View Sequence* page, click **Edit**.
5. On the *Modify Sequence* page, revise the sequence attributes, as needed.
6. **Save**.
7. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	**Steps**
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

View a Sequence

You can view the sequence details and perform actions like add, modify, copy, delete, import, and change status on the *View Sequence* page.

To view and work with sequence:

1. Navigate to the application or event that has the sequence that you want to view.
2. Click **Sequences**.
3. Click a link for the sequence you want to view.
4. On the *View Sequence* page, do any of the following:

Option	**Action**
To modify the sequence attributes:	Click **Edit**.
To delete the sequence:	Click **Delete**. You can delete a sequence only if it has no associated tasks, references, or notifications.
To copy the sequence URL to the Clipboard:	Click **Copy URL**. A message confirms the URL has been copied.
To associate a workflow to a sequence:	Click **Associate Workflow**.
To view tasks, references, or notifications associated with the sequence:	Click the appropriate tab, then click an entity.
To view or modify associated activities:	Click **Activities**.
To view, pause, resume, or delete associated workflows:	Click **Workflows**.
To create an assembly:	Click **Assembly**.
Option	**Action**
To add a task, reference, or notification:	Click the appropriate tab and then and click **Create**.
To add or modify sequence status or status dates associated with the sequence:	Click the date under the **Status Dates** tab, then click the appropriate button. Only an administrator can delete a status date associated with a sequence.

Associate a Workflow

Workflows can be associated to entities within Ennov InSight , or can be started as a standalone workflow.

When associating a workflow, the following conditions apply:

- Only workflows active within Data Administration can be associated to an entity.
- The entity must be first enabled on a workflow for it to be available for associating.
- You must have at least WRITE permission on activities within the entity security to be able to associate a workflow.

To associate a workflow with an entity:

1. Navigate to the entity for which you want to associate.The attributes page for the entity opens.
2. Click **Associate Workflow**.
3. On the *Associate Workflow* page, select the workflow (use Ctrl key to select multiple workflows) and click **>>**.
4. **Save**.The workflows are associated to the entity and they are listed under **Workflows** on the entity attributes page.

Delete a Workflow

You can delete a workflow associated with an entity.

When deleting a workflow, the following conditions apply:

- You must have ADMIN permission on Activities within the entity security to be able to delete a workflow.
- Deleting a workflow deletes all its related activities. Any current time tracking will be lost.

To delete a workflow associated with an entity:

1. Navigate to the entity for which you want to delete a workflow.The attributes page for the entity opens.
2. Click **Workflows**.
3. Select the workflows you want to delete. To find specific workflows, use the Set Filter option.
4. At the top of the **Workflow** tab, click **Delete**.
5. Click **OK** when you are prompted to confirm the deletion.The workflows are deleted.

Work with an Activity

In Ennov InSight, activities are user tasks within a workflow, used to direct users through a defined process. For example, assigning and approving documents within a submission.

The following functions can be performed for an activity:

- Claim/Unclaim an activity
- Transfer an activity
- Track the time of an activity
- Mark activity as complete
- Add to Favorites
- Remove from Favorites
- Modify Favorites
- Enter data for an activity
- Viewing the workflow diagram
- Setting Due Date and Priority for an Activity

Delete a Sequence

You can delete a sequence if there are no assembly, task, or reference entities associated with it. If entities are associated with the sequence, you must delete them first.

Note: You must have the appropriate security privileges to delete a sequence.

To delete a sequence:

1. View the sequence that you want to delete.
2. Click the link for the sequence you want to delete.
3. On the *View Sequence* page, click **Delete**.
4. Select a reason and enter comments for the reason.
5. Click **OK**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Projected Status Dates for Sequences

The Registration Planning and Tracking and the Submission Planning and Tracking license modules for Ennov InSight enable you to add and modify projected status dates for sequences.

When you add a projected status date, you set up an action that is scheduled to occur on a specific date. For example, you might want to add a date that you expect a sequence to be approved.

Change Submittal Status Wizard

You can use this wizard for planned events that enforce status progression. For such an event, the wizard works only if the current status precedes the Submitted status in the event country schedule.

You can use the *Change Submittal Status* wizard under specific conditions only.

The conditions for working with *Change Submittal Status* wizard are:

- You can invoke the *Change Submittal Status* wizard only from an application, event, or a sequence.
- To use the *Change Submittal Status* wizard from an event, at least one country associated with the event schedule must be unlocked.
- To use the *Change Submittal Status* wizard from an application, at least one sequence must be associated with an event and at least one country associated with the event schedule must be unlocked.

- When executing the *Change Submittal Status* wizard, only the current version of the assembly is used, regardless of whether there are multiple versions of the assembly.
- The confirmed sequence code is determined based on the number of sequences that have been submitted to this application lifecycle. All previously submitted sequences are considered, even if the current **Sequence Status** is set to Approved.

Use the Change Submittal Status Wizard

You can change the submission status of sequences using the *Change Submittal Status* wizard. To

modify the submission status of a sequence:

1. Choose **Wizard** > **Change Submittal Status**.The *Change Submittal Status* wizard opens to the *Choose Submission Status Type* page.
2. Click **Submitted**. **Note:** You can use this wizard for a planned event that enforces status progression. For such an event, the wizard works only if the current status precedes the Submitted status in the event country schedule.
3. Click **Next**.The *Select Change Submission Status Properties* page appears.
4. Do the following:
    a. Select the **Current Sequence** code.
    b. In the **Confirmed Sequence Code** field, verify the number for the new sequence to be created by the wizard.
    c. The confirmed sequence code is determined based on the number of sequences that have been submitted to this application lifecycle, not the planned number that was used when creating the sequence. All previously submitted sequences are considered, even if the current **Sequence Status** is set to Approved. This ensures that the final sequence number remains consistent with what you are submitting. You can change the **Starting Sequence Number** attribute in the application attributes. That number becomes the confirmed sequence code. The wizard issues a message if you deviate from the default four-digit value. Respond to the message to continue.
    d. For the **Submittal Date**, choose when the submission status is to become effective.
    e. Use the **Comment** box to enter a comment that appears on the event and sequence entities affected by this update.
    f. If the submission is being submitted as a lifecycle eCTD, select the **Lifecycle** check box. Checking **Lifecycle** creates a submitted dossier view for the application and requires that all subsequent application updates are controlled lifecycle assemblies.
5. Click **Next**.If a multi-country submission is possible, the *Select Event Countries* page appears with the option to select event countries. If a multi-country submission is not possible, you will see a message indicating that no input is necessary. Go to step 7.
6. Select one or more **Countries** for the submission. Only unlocked countries associated with the event are available for selection.
7. Click **Next**.The *Change Submission Status Confirmation* page appears.

8. Click **Next** to confirm the submission status.The *Change Submission Status Summary* page displays a list of the actions performed by the wizard.
9. Click **Finish** to close the wizard.

Chapter 23. Registrations

A registration (license) is the agreement between a regulatory agency and a sponsor of a drug, drug product, or medical device for the purpose of marketing or free distribution of the product.

Registration is required after the drug or medical device has been evaluated for safety, efficacy and quality. A registration may also be referred to as a marketing authorization. Tracking registrations in Ennov InSight allows you to maintain information regarding a registration's status and any actions that need to be performed, such as renewals and periodic reporting.

You must have the following modules to perform registrations activities:

- Product Detail Management
- Registration Planning and Tracking

When you create a registration, you associate it with an application. You specify information such as the country for which the registration is being created, its license code, and the marketing authorization holder (MAH).

Registration Types

When you associate a registration to an application, the registration type of an application dictates how the registration is managed in Ennov InSight .

Registrations are managed by associating them either with package sets created and approved in a product detail set (PDS), or with products from an event associated with the registration.

Package Set Registration Types

Used typically for managing drug registrations, package sets created and approved in a PDS can be associated with registrations. The PDSs must belong to the same application as the registration. Package sets consist of the various configurations and presentations that go into packaging a product. Furthermore, for EU registrations, you can track Sunset Clause marketing status information on a per country, per package set basis.

Product Registration Types

Primarily used for managing medical device registrations, an event can be associated with a registration, and then one or more of the products associated with the event can be associated with the registration. This enables you to identify which products have been approved for an event and granted a license/registration.

Create a Package Set Registration

Typically used for managing drug registrations, package sets created and approved in a PDS can be associated with registrations.

To create a package set registration:

1. Click a link for the application for which you are creating the registration. The application must be of the package set registration type.
2. On the *Application Attributes* page, click **Registrations**.
3. On the **Registrations** tab, click **Create**.The *Create Registration* page appears.
4. Enter values for the registration attributes. While doing so, be aware of the following:

   ◦ When creating registrations for CP type applications, the country available for selection is the European Union country. The European Union country should be a country on the related CP application.

   ◦ When creating registration for DCP or MRP type applications, withdrawn application countries with the Withdraw Date value equal to the current date or earlier are not available for selection.

   ◦ Use the **Available Package Set** list box to select package sets created and approved in the product detail sets (PDSs) of the products related to the application that is associated with the registration.

5. Do one of the following:

Option	**Action**
To save the registration:	**Save** .
To save this registration and add another for the application:	**Save** and **Add Another Registration**.

Package Set Registration Attributes

The following attributes are used for associating a registration to a Package Set Registration type application.

Attribute	**Description**
Annual Report Date	The date that the next annual report for this registration is due.
Application Code	Agency-identified application number (or identifier). Can be the same as the internal code.
Application Name	The name of the application.
ATC Code Flag	The Anatomical Therapeutic Chemical (ATC) Code flag is used to indicate the status of the ATC code. • **Not Applicable** - This value is selected by default and is used when the ATC code is not applicable for the registration. • **Applied/Not Assigned** - Use this when an Applicant or Marketing Authorisation holder has applied for an ATC code but has been not assigned yet. **Not Applied/Not Assigned** - Use this when an Applicant or Marketing Authorisation holder has not applied for ATC code.
Country	The country with which the registration is associated.

Attribute	Description
	For registrations of the Centralised Procedure (CP) procedure type, European Union is the only country available for selection. **Note:** Withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the **Country** drop-down field on the *Create Registration* page. This is applicable only to applications of Mutual Recognition (MRP) or Decen- tralised Procedure (DCP) types.
Enquiry Email	For package set registrations only, the e-mail address of the person or the agency registering the product.
Enquiry Phone Number	For package set registrations only, the phone number of the person or the agency registering the product.
Expiration Date/Registration Valid Until	The date the registration is due to expire.
In-Licensing	Text that indicates whether the license is considered an in-license.
Last Renewal Date	The date when the license was last renewed.
Legal Basis	The legal basis for an authorisation of the product.
License Add Comments	Comments you want to share with others in a discussion thread. Will be displayed in the **License Comments** box, stamped with the date and time you enter the information and your user ID.**Note:** The **License Add Comment** field is available on the Create/Modify *Registration At- tributes* pages only.

License Code	The code assigned by the regulatory agency.
License Comments	The discussion thread that includes all comments entered by users. Includes the date and time the comments were entered, and the user ID of the person who entered them.
License Concerned Parties	Users who may be copied on notifications about this entity. Use semi-colons (;) to separate e-mail addresses.
License Description	Text that describes the registration.
License Issue Date	The date when the license is to be issued.

Attribute	**Description**
License Keywords	Words you can use to search for the registration.
License Status	The current renewal status.
License Status Date	The effective date of the status.
MAH/Organisation	The company to which a license is issued to market the product.
MAH/Organisation Last Updated	The date that the MAH was most recently updated.

Medicinal Product Type	For package set registrations only, this includes all the medicinal product types.
Medicines Regulatory Agency	Health Authority Name for a selected country where License was issued.
MFL (Mas ter File Location)	For package set registrations only, the name and address information for master file location company with EudraVigilance code and comments.
Next Renewal Date	The date when the license must be renewed again.
Out-Licensing	Text that indicates whether the license is considered an in-license.
Package Sets	For Package Set Registrations Type only. This is the name of the package set associated with a registration. Sunset Clause dates are tracked per country for the package set.
Perpetual License	Indicates whether a perpetual license has been granted in the European Union.
Pricing Approved	Indicates whether pricing approval has been given. This is by default hidden for package set registrations and product registrations.
QPPV	For package set registrations only, the EV registration system QPPV (Qualified Person Responsible for Pharmacovigilance) code assigned to the QPPV defined in the pharmacovigilance system master file for the product.
Attribute	**Description**
Reason for Termina- tion/Withdrawal	The reason that the package set registration was terminated or withdrawn.
Registered ATC	Registered anatomical therapeutic chemicals. For package set registrations only.If an application is associated to a product family, the values from the product family are available for selection. Otherwise, the values are taken from the associated application product.
Registered ATC Last Updated	Date on which the Registered ATC was added.

Reimbursement Approval	For product type registrations only, this indicates whether reimbursement approval has been given.
Sender Local Code	For package set registrations only, the local code of the person registering the product.
Subject to additional monitoring	For package set registrations only, this indicates whether the product requires close monitoring.

Create a Product Registration

Primarily used for managing medical device registrations, an event can be associated with a registration, and then one or more of the products associated with the event can be associated with the registration.

To create a product registration:

1. Navigate to the application for which you are creating the registration. The application must be a product registration, not a package set registration.
2. On the *Application Attributes* page, click **Registrations**.
3. On the **Registrations** tab, click **Create**.The *Create Registration* page appears.
4. Enter values for the registration attributes. While doing so, be aware of the following:

   ◦ When creating registrations for CP type applications, the country available for selection is the European Union country. The European Union country should be a country on the related CP application.

   ◦ When creating registration for DCP or MRP type applications, withdrawn application countries with the Withdraw Date value equal to the current date or earlier are not available for selection.

   ◦ Use the **Event** list box to select an event related to the application that is associated with the registration. Then for the **Products** attribute, under the **Selected** box click **Select** and select the products associated with the event.

   Note: Only one Event per Application can be selected when creating a Product Registration.

5. Do one of the following:

Option	**Action**
To save the registration:	**Save** .
To save this registration and add another for the application:	**Save** and **Add Another Registration**.

6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Product Registration Attributes

The attributes associate a registration to an application (of product registration type), and provide details of the registration.

Attribute	Description
Annual Report Date	The date that the next annual report for this registration is due.
Application Code	Agency-identified application number (or identifier). Can be the same as the internal code.
Application Name	The name of the application.
Associated Products	Products available for selection are those currently associated with the Event.
Country	The country that is associated with the registration.

Attribute	Description
	For registrations of the Centralised Procedure (CP) procedure type, **European Union** is the only country available for selection. **Note:** Withdrawn application countries with the Withdraw Date value equal to today's date or earlier are not available for selection in the **Country** drop-down field on the *Create Registration* page. This is applicable only to applications of Mutual Recognition (MRP) or Decentralised Procedure (DCP) types.
Currently Marketed	Indicates whether the product is actually being sold.

Event	The Event Name and Event Code are concatenated and displayed for selection.If you disassociate the Event/Product(s), the system displays the message: "You are about to dissociate the Event/ Product(s) by doing this, respective ATC value will be deleted from the Registered ATC field automatically. Select Ok to continue."
Expiration Date/Reg istration Valid Until	The date the registration is due to expire.
In-Licensing	Text that indicates whether the license is considered an in-license.
Last Renewal Date	The date when the license was last renewed.
License Add Comments	Comments you want to share with others in a discussion thread. Will be displayed in the **License Comments** box, stamped with the date and time you enter the information and your user ID.**Note:** The **License Add Comment** field is available on the Create/Modify *Registration Attributes* pages only.
License Code	The code assigned by the regulatory agency.
License Concerned Parties	Users who may be copied on notifications about this entity. Use semi-colons (;) to separate e-mail addresses.
License Comments	The discussion thread that includes all comments. Includes the date and time the comments were entered and the user ID of the person who entered them.
License Description	Text that describes the registration.
License Issue Date	The date when the license is to be issued.

Attribute	Description
License Keywords	Words you can use to search for the registration.
License Status	The current renewal status.
License Status Date	The effective date of the status.
MAH/Organisation	The company to which a license is issued to market the product.
MAH/Organisation Last Updated	The date that the MAH was most recently updated.
Medicines Regulatory Agency	Health Authority Name for a selected country where License was issued.
Next Renewal Date	The date when the license must be renewed again
Out-Licensing	Text that indicates whether the license is considered an in-license.
Perpetual License	Indicates whether a perpetual license has been granted in the European Union.
Product Family Type	The type of product family that is associated with the registration.
Reason	Reason for creating, modifying or deleting a registration.

Reason for Comments	Comments related to reason entered by users.
Reason for Termination/Withdrawal	The reason that the product registration was terminated or withdrawn.
Registered ATC	Registered anatomical therapeutic chemicals.
Attribute	**Description**
	If an application is associated to a product family, the values from the product family are available for selection. Otherwise, the values are taken from the associated application product. **Note:** Appears for all product family types except medical devices.
Registered ATC Last Updated	Date on which the Registered ATC was added.
Subject to Additional Monitoring	This indicates whether the product requires close monitoring.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Associate a Dosage Form to an Entity

Ennov InSight *Dose Form Search* selection widget enables you to associate a dosage form to an entity.

To associate a Dosage Form:

1. Open the attributes page of an entity to which you want to associate a dosage form.
2. Look for the entity dosage field and click **Select**. This field is labeled differently for entities:

Entity Name	Field Name	Description
Product	**Product Dosage Form**	A single dose form can be added.
Component	**Component Form**	A single dose form can be added.
Pharmaceutical Product	**Administrable Dose Form**	A single dose form can be added.
Manufactured Item	**Manufactured Dose Form**	A single dose form can be added.
Full Product Presentation	**Authorised Pharmaceutical Form**	Multiple dose forms can be added.
Medicinal Product	**Authorised Pharmaceutical Form**	Multiple dose forms can be added.

The *Dose Form Search* window appears.

3. Use the search options in the **Search By** section.The search results are displayed.
4. Select a dose form and click **Associate Dose Form**.The associated dose form appears for the dosage field.
5. Click **Save** on the entity attributes page.

Modify Registrations

You can modify attributes, including the approval date, countries associated with the registration, the license code, and the MAH/sponsor.

The attributes you can modify depend on your security privileges.

When modifying a registration, be aware of the following:

- For product registrations, you can associate only one event with a registration.
- For product registrations, you cannot disassociate the event with the registration. You must delete the registration to disassociate the event.

The products, package sets, and countries associated with a registration can be modified from their respective tabs or pages, which are nested under the *Registration Attributes* page.

Modify a Registration

You can modify a registration, including the approval date, countries associated with the registration, the license code, and the MAH/sponsor.

To modify a registration:

1. Click a link for the registration you want to modify.
2. On the *Registration Attributes* page, click **Edit**.The *Modify Registration* page appears. The attributes on this page depend on whether the registration is for a package set or a product.
3. Enter your changes to the registration attributes.
4. **Save**.
5. Select a reason and enter comments for the reason.
6. Click **Next**.
7. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

About the Copy Package Set Registrations Wizard

In the *Copy Package Set Registration* wizard, you can select one of the available flows and copy a Package Set

Registration. The new Package Set Registration appears under the same Application as the source Registration.

Important: The *Copy Package Set Registration* wizard can be invoked for a Registration under an Application with a

Package Set Registration type.**Security Information**You must have at least WRITE permissions for Registrations and Full Product Presentation (FPP) in the **Security Administration** > **Entity Security** section to copy Registrations and assigned Full Product Presentations (applicable for the *New Package Set specific Registration(s)* flow).**Note:** WRITE permissions for Registrations is enough to copy the Package Set Registration without copying the associated Full Product Presentations.**Wizard Navigation**

The *Copy Package Set Registration* wizard consists of multiple pages described in the tables below. The wizard navigates you through those pages depending on the selected flow.

When the *Copy Package Set Registration* wizard is invoked on the *Registration Attributes* page, the *Select Wizard Flow* page appears listing the copy flows available for selection:

- New Package Set specific Registration(s)
- New Product specific Registration(s)

Wizard Navigation: New Package Set specific Registration(s) flow

The following table describes the **Copy Package Set Registration** > **New Package Set specific Registration(s)** wizard flow.

Wizard Page Name		Values Available for Selection	Description
Selec Product De tail Set	t	• **Country** drop-down field, required • **Product Detail Set** drop- down field, required • **Copy License Code** check box	The following are specific rules applicable to the **Product Detail Set** required multi-select field: • Nothing is available for selection if there are no Package Sets associated to a Registration you select to copy. • At least one Package Set must be associated to the Registration you select to copy, and at least one approved but not associated (to any Registration) Package Set must exist.**Note:** If this rule is met, the parent Product Detail Set is selected by default in the **Product Detail Set** field. • The Package Sets associated to a Registration you select to copy can have different parent Product Detail Sets. The parent Product Detail Set that has more Package Set details with Approved status (and at the same time those details are not associated to the Registration you select to copy) is selected by default in the **Product Detail Set** field. The other Product Detail Sets are also available for selection.**Note:** If the quantity of Package Sets that have the Approved status and are not associated to the Registration is equal among all

Wizard Page Name	Values Available for Selection	Description
		Product Detail Sets, then the Product Detail Sets are alphabetically sorted and the one that is the first in the list is set by default. • For the **Country** field, the Package Sets will be available only if the selected country already has the assigned Registration. The **Copy License Code** check box is selected by default. You can clear it, so the License Code field appears blank on the Select Package Set(s) page.

Select Package Set(s)	t The list of all Package Sets available for selection.	• Multiple Package Sets can be selected. • License Code value for the selected Package Set must be added or updated.
Enter esignature information	When the e-signature option is configured, the following fields appear: • Reason • Reason for Comments • User ID • Password	When the e-signature option is not configured, the following message appears: No input required on this page .
Copy Full Product Presentation	When at least Write permissions for the Full Product Presentation (FPP) are set in the *Entity Securi ty* section, the **Copy Full Product Presen-tation** drop-down field appears with Yes and No values available for selection. Yes is selected by default.	When permissions for the Full Product Presentation (FPP) the in *Entity Security* section are set to None, or Read, the *Summary* page appears instead of the *Copy Full Product Presentation* page.
Selec Full Product Pre	t If you selected **Yes** on the *Copy Full Product Presenta-tion* page, the list of all available Full Product Presenta	The following message appears: No input is required on this page , if you selected No on the **Copy Full Product Presentation** page.

Wizard Page Name	**Values Available for Selection**	**Description**
sentation(s	tions displays the following columns:) • Full Product Name • EEA Country • Language • Authorisation/Renewal Date • Attachment Name **Note:** If there are more than one Registration FPP Attachment associated to a Full Product Presen- tation, then all Registration FPP Attachments are displayed as comma-separated values. You can select one, or more Full Product Presentations to copy with the Registration, by checking the appropriate check boxes.**Note:** You can proceed without making any selection.	
Summa ry Page	The messages presented on this page differ based on the previous selections.**Note:** If there are no Full Product Presentations associated to the Registration you select to copy, the *Summary Page* appears after you click **Next** on	The following messages can appear: • Registration [License Code] has been created. One line per each created registration is displayed. License Code is a hyperlink to the created entity. • Full Product Presentation has been copied. Full Product Presentation is a hyperlink to copied entity. This message is not displayed if
Wizard Page Name	**Values Available for Selection**	**Description**

Wizard Page Name	Values Available for Selection	Description
	the *Enter e-signature information* page.	• The Product must be associated to the same Application as the source Registration and must have an assigned PDS. • The PDS assigned to a specific Product must have at least one Approved Package Set that is not yet associated to any Registration. you did not select an option to copy Full Product Presentations, or if you do not have appropriate permissions to copy them. • Registration FPP Attachment(s) has been copied. The message is displayed if there is an attachment under the source Full Product Presentation. If not, the message is not shown.

Wizard Navigation: New Product specific Registration(s) flow

The following table describes the **Copy Package Set Registration** > **New Product specific Registration(s)** wizard flow.

Wizard Page Name	Values Available for Selection	Description
Copy License Code	• **Country** drop-down field, required • **Copy License Code** check box.	**Copy License Code** is selected by default and displays the License Code value on the *Select Product Name* page. If you clear this check box, the **License Code** field on the *Select Product Name* page will be blank. For the **Country** field, the Package Sets will be available only if the selected country already has the assigned Registration.

Select Product Name	The list of all Package Sets available for selection.	Multiple Product Names can be selected. The following columns are displayed: • Product Name • PDS Name • License Code The License Code value for the selected Product Names must be added or updated. To display the Product Name on the *Select Product Name page*, the following specific conditions must be met:
Enter esignature information	When the e-signature option is configured, the following fields appear: • Reason • Reason for Comments • User ID Password	When the e-signature option is not configured, the following message appears: No input required on this page .
Summa ry Page	The following confirmation message appears: Registration License Code has been created.	• If multiple Product Names have been selected on the Select Product Name, one line per each newly created registration is displayed on the Summary page. License Code value is a hyperlink to the created registration.

Copied Package Set Registration Attributes

When a registration is copied, some attributes remain the same while some are updated.

The following table describes the attributes of the copied Registration.

Attribute	**Package Set specific Registration(s)**	**Product specific Registration(s)**
Annual Report Date	The value is taken from the source Registration.	The value is taken from the source Registration.

Application Code	The value is taken from the source Registration.**Note:** The copied Registration appears under the same Application.	The value is taken from the source Registration.**Note:** The copied Registration appears under the same Application.
Application Name	The value is taken from the source Registration.**Note:** The copied Registration appears under the same Application.	The value is taken from the source Registration.**Note:** The copied Registration appears under the same Application.

Attribute	**Package Set specific Registration(s)**	**Product specific Registration(s)**
Country	The value is taken from the source Registration.**Note:** The copied Registration appears under the same Application.	The value is taken from the source Registration.**Note:** The copied Registration appears under the same Application.
Enquiry Email	The value is taken from the source Registration.	The value is taken from the source Registration.
Enquiry Phone Number	The value is taken from the source Registration.	The value is taken from the source Registration.
Expiration Date/Registration Valid Until	The value is taken from the source Registration.	The value is taken from the source Registration.
Family Code	The value is taken from the source Registration.	The value is taken from the source Registration.
Family Name	The value is taken from the source Registration.	The value is taken from the source Registration.
In-Licensing	The value is taken from the source Registration.	The value is taken from the source Registration.

Last Renewal Date	The value is taken from the source Registration.	The value is taken from the source Registration.
Legal Basis	The value is taken from the source Registration.	The value is taken from the source Registration.
License Code	The value you have entered on the *Select Package Set(s)* page.	The value you have entered on the *Select Product Name* page.
License Comments	Appears blank.	Appears blank.
License Concerned Parties	Appears blank.	Appears blank.

Attribute	**Package Set specific Registration(s)**	**Product specific Registration(s)**
License Description	Appears blank.	Appears blank.
License Issue Date	The value is taken from the source Registration.	The value is taken from the source Registration.
License Keywords	Appears blank.	Appears blank.
License Status	The value is taken from the source Registration.	The value is taken from the source Registration.
License Status Date	The value is taken from the source Registration.	The value is taken from the source Registration.
MAH/Organisation	The value is taken from the source Registration.	The value is taken from the source Registration.

MAH/Organisation Last Updated	• If the **MAH/Organisation Last Updated** attribute of the source Registration is populated, this value is updated to be equal to the current date. • If the **MAH/Organisation Last Updated** attribute of the source Registration is not populated, this attribute appears blank.	• If the **MAH/Organisation Last Updated** attribute of the source Registration is populat- ed, this value is updated to be equal to the current date. • If the **MAH/Organisation Last Updated** attribute of the source Registration is not populated, this attribute appears blank.
Medicinal Product Type	The value is taken from the source Registration.	The value is taken from the source Registration.
Medicines Regulatory Agency	The value is taken from the source Registration.	The value is taken from the source Registration.
MFL (Master	The value is taken from the source Registration.	The value is taken from the source Registration.

Attribute	**Package Set specific Registration(s)**	**Product specific Registration(s)**
File Location)		
Next Renewal Date	The value is taken from the source Registration.	The value is taken from the source Registration.
Out-Licensing	The value is taken from the source Registration.	The value is taken from the source Registration.
Package Sets	The field is populated with the Package Set Name of Package Set you have selected on the *Select Package Set(s)* page.	The field is populated with the Package Set Names of all available Package Sets assigned to the selected **Product** > **PDS**.**Note:** The Package Set must be Approved and must not be associated to any Registration.
Perpetual License	The value is taken from the source Registration.	The value is taken from the source Registration.

Product Family Type	The value is taken from the source Registration.	The value is taken from the source Registration.
QPPV	The value is taken from the source Registration.	The value is taken from the source Registration.
Reason for Termination/Withdrawal	The value is taken from the source Registration.	The value is taken from the source Registration.
Registered ATC	The value is taken from the source Registration.	The value is taken from the source Registration.
Registered ATC Last Updated	• If the **Registered ATC Last Updated** attribute of the source Registration is populated, this value is updated to be equal to the current date. • If the **Registered ATC Last Updated** attribute of the source Registration is not populated, this attribute appears blank.	• If the **Registered ATC Last Updated** attribute of the source Registration is populated, this value is updated to be equal to the current date. • If the **Registered ATC Last Updated** attribute of the source Registration is not populated, this attribute appears blank.
Attribute	**Package Set specific Registration(s)**	**Product specific Registration(s)**
Sender Local Code	The value is taken from the source Registration.	The value is taken from the source Registration.
Subject to Additional Monitoring	The value is taken from the source Registration.	The value is taken from the source Registration.

The following rules apply for the copied Package Set specific Registration(s):

- The Package Set entity for the copied Registration is created with the Package Set Name from the source Package Set selected on the Select Package Set(s) page.
- The Country entity for the created Package Set depends on the application type:

◦ For applications of any type except Centralised Procedure (CP) type, the Package Set Country is the same as for the source Package Set selected on the Select Package Set(s) page.

◦ For applications of CP type, the Country is taken from the Application level.

The following rules apply for the copied Product specific Registration(s):

- The Package Set entity for the copied Registration is created with only the Package Set Name field populated.
- The Country entity for the created Package Set is created with only the Country field populated:

◦ For applications of any type except Centralised Procedure (CP) type, the Package Set Country is the same as the source Registration Country.

◦ For applications of CP type, the Country is taken from the Application level.

Copied Full Product Presentations and Registration FPP Attachments

You can copy a Full Product Presentation assigned to the Registration being copied, if the security permissions are set correctly in the **Security Administration** > **Entity Security Section** and you select Yes for the **Copy Full Product Presentation** field in the wizard.

The following table describes the copied Full Product Presentation fields that are copied, populated with specific values, and not copied from the source Full Product Presentation:

Fields that are populated with values from the source Full Product Presentation	**Fields that appear blank**	**Fields that are populated with specific values**
• EEA Country • Full Product Name • Full Product Short Name • Product INN/Common Name • Product Company Name • Product Strength • Product Form • Formulation Part • Intended Use Part • Target Population Part • Container or Pack Part • Device Part • Time Period Part	• XEVMPD Marketing Authorisation Number • XEVMPD MAH/Organisation • Previous EV Code • Local Code • EV Code • Date Submitted to	• **Package Sets** field is set to the value selected in the **Select Package Set(s)** > **Package Set** field. • **Package Description** field is set to the value selected in the **Select Package Set(s)** > **Package Set** field. • **Last Updated Date** field is set to today's date

• Flavour Part • Language • Countries**Note:** For the applications of National, Mutual Recognition (MRP), or Decentralised (DCP) Procedure types. • Authorisation Status • Authorised Pharmaceutical Form • Authorisation/Renewal Date • Withdrawn/Invalidated Date • Information Date • XEVMPD Comments • Special Measures	EMA • Message Sender • Full Product Presentation Concerned Parties • Full Product Presentation Key- words • Full Product Presentation Description • Full Product Presentation Comments	

If there is at least one Registration FPP Attachment under Full Product Presentation assigned to the Registration being copied, and you selected Yes for the **Copy Full Product Presentation** field, it is copied as well:

- **Attachment Name** and **Validity Declaration** fields appear with the value from the source Registration FPP Attachment
- **Registration FPP Attachment Concerned Parties** and **Registration FPP Attachment Comments** fields appear blank

Copy a Package Set Specific Registration

Use this procedure to copy a Package Set specific Registration.

To copy a package set registration:

1. Navigate to a Package Set Registration you want to copy.
2. On the *Registration Attributes* page, click **Copy Registration**.The *Copy Package Set Registration* wizard appears.
3. On the *Select Wizard Flow* page, select the **New Package Set specific Registration(s)** flow.
4. Click **Next**.The *Select Product Detail Set* page appears.
5. On the *Select Product Detail Set* page:

Action
For the **MRP/DCP Application Types** only: Select the country to copy the Package Set Registration in the **Country** drop-down list.
Select a Product Detail Set (PDS) with an approved Package Set detail.**Note:** The Product Detail Set can already be selected by default. You can change the selected PDS, if applicable.

To specify if you need the License Code value of the source Registration to be copied, select the **Copy License Code** check box.**Note:** The **Copy License Code** check box is selected by default. You can clear it, if needed.

6. On the *Select Package Set(s)* page:

Option	**Action**
To select one or multiple Package Sets to be associated to a copied Registration:	Select the appropriate check boxes.
To add or update the License Code value:	Double-click the **License Code** field next to each selected Package Set.**Note:** The License Code value must be unique within a country.

7. Click **Next**.
8. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	**Steps**
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. On the Copy Full Product Presentation page, select Yes or No value in the **Copy Full Product Presentation** dropdown list. Yes is selected by default. To finish the wizard on this page, click **Finish**. This allows you to skip several steps related to copy Full Product Presentations. The *Summary* page appears.
2. Click **Next**.The *Select Full Product Presentation(s)* page appears.
3. On the *Select Full Product Presentation(s)* page, select one or more Full Product Presentations to copy with the Registration by selecting the appropriate check boxes on the left of each Full Product Presentation. You can proceed without making any selection.
4. Click **Next**.The *Summary* page appears.
5. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	1. In the confirmation page, select a reason and enter comments for the reason. 2. Click **Next**. 3. Validate your identity by entering your user credentials in the dialog box.

Copy a Product Specific Registration

Use this procedure to copy a Product specific Registration.

To copy a package set registration:

1. Navigate to a Package Set Registration you want to copy.
2. On the *Registration Attributes* page, click **Copy**.The *Copy Package Set Registration* wizard appears.
3. On the *Select Wizard Flow* page, select the **New Product specific Registration(s)** flow.
4. Click **Next**.The *Copy License Code* page appears.
5. On the *Copy License Code* page:

Action
For the **MRP/DCP Application Types** only: Select the country to copy the Package Set Registration in the **Country** drop-down list.
Action
The **Copy License Code** check box appears. The check box is selected by default. You can clear it, so the **License Code** field appears blank on the *Select Product Name* page.

6. Click **Next**.The *Select Product Name* page appears.
7. On the *Select Product Name* page:

Option	**Action**
To select one or multiple Product Names to be associated to a copied Registration:	Select the appropriate check boxes.
To add or update the License Code value:	Double-click the **License Code** field next to each selected Product Name.**Note:** The License Code value must be unique within a country.

8. Click **Next**.The *Enter e-signature information* page appears, even if the e-signature option is not configured.
9. On the *Enter e-signature information* page:

Option	**Action**
If the e-signature option is configured:	Enter the required information and click **Next**.
If the e-signature option is not configured:	Click **Next**.

10. The *Summary* page appears.If multiple Product Names have been selected on the *Select Product Name* page, one line per each newly created registration is displayed.

The Full Product Presentations and Registration FPP Attachments, if any are assigned to the Registration you selected to copy, are not copied.

Use the Update Status Wizard

You can use the *Update Status Wizard* to update event-country statuses and information about related entities.

In *Data Administration*, if **Yes** is selected in the **System Process Default Flag** field, each display status shows the value specified in its **Name** field.

To use the *Update Status* wizard:

1. Select **Wizards** > **Update Status**.The *Enter Event Search Criteria* page appears.
2. Select values for the attributes presented to locate the events you want to update.
3. Click **Next**.The *Select Event(s)* page appears.
4. Select an event or multiple events, and then click **Next**. For **National Enforced** events: the screens display order is based on which **Enforced** event checkbox was selected first, or by using ascending/descending sorting.
5. On the *Enter values to update entities* page, select values for one or more attributes.

   ◦ The options presented depend on the application procedure type. For example, a **Procedure Closure**

   Date is available for MRP applications but not for other application types. This field will be blank. If the **Event** has a value for **Procedure Closure Date**, upon completion of the wizard, the date will be updated only if the **Procedure Closure Date** is blank for the specific event.

   ◦ Event Name: Displays all selected Event names on the previous screen, listed alphanumerically (if all were selected), or based on the order of the selected checkbox(s).
6. Click **Next**.One of the following occurs:

   ◦ For National applications, the *Update Event Country Status* page appears. Go to step 7.

   ◦ For MRP, DCP, or CP applications, the *Select Event Countries* page appears. Go to step 8.
7. On the *Update Event Country Status* page, select an event-country status.

◦ If multiple events are being updated, this page may repeat based on the following rules:

All selected events where an **Event Plan** is not enforced will be displayed for updating.

For each selected event where an **Event Plan** is enforced, the screen will repeat after clicking **Next**.

The *Not-Enforced Events* screen will be displayed first (if at least one **Not-Enforced Event** is selected on the previous page) and *Enforced Event* screens will be displayed after.

◦ For **Not-Enforced Events** that are grouped on the same page, all **Event-Country** values will be displayed as comma separated values, with the order consistent across **Event Name**, **Event Code**, and **Event-Country**.

◦ You can use this wizard to update a planned event that enforces status progression. For such an event, the only statuses available for selection are optional statuses and the next primary status in the sequence of primary statuses defined in the timeline/event plan.

◦ In the *Status Date* box, type or use the **Calendar** icon  to select the date that this event country status is effective. For planned events that enforce progression, the status date can not be earlier than the status date for the previous status in the sequence of statuses defined in the timeline/event plan.

◦ If you want to lock the event-country schedule for the selected countries after the event-country status is updated, select **Yes** for **Lock the Event-Country Schedule?**.

◦ If you want to close the event after the event-country status is updated, select **Yes** for **Close Event?**. Select the **Closed Date** value and **Associations Closed As** status. If the event is closed, the status of related entities (application, event, event product, sequence, and PDS) are updated.**Application Status** and **Application Status Date** will be updated with the values from the last entered repeating screen.**Note:** If you set **Associations Closed As** to WITHDRAWN, the Application Status will be set to Withdrawn only when all Registrations associated to this Application have a status mapped to internal WITHDRAWN status. Otherwise, the following warning message appears: ! Associated

Registration(s) must be Withdrawn prior to the Application.

If the Event is closed as Approved, meaning it has the **Association Closed As** field set to APPROVED, the **Application Country** > **Withdrawn Date** field is automatically updated to be equal to **Event Closed Date** value. This rule is applicable to an event that has an associated PDS with this country assigned to a Country PDS Detail, and this country has a Withdrawn status, meaning it is displayed as **Country (Pending Withdrawal)** in the PDS tree. See *If the Event Is Closed with the Status Approved*.

If multiple events have been selected, the **Close Event** will only apply to the currently open events. Any closed events will not be updated.

Where there are multiple events tied to the same **Sequence**:

The actual **Sequence Status** and **Status Date** will be set based on the values for the event, which are based on the following priority order:

▪ Approved

▪ Not Approved

▪ Withdrawn

Example: If there are two events, one is Approved and one is Not Approved, the values from the Approved Event will be used to set the Sequence Status and Status Date.

Where multiple events meet the priority (i.e. two are Approved), the last entered values in the wizard will be used.

The **Next Renewal Date** and **Annual Report Date** will be updated with the values from the last entered repeating screen.

◦ Make other selections or entries, as needed.

◦ Click **Next**.

A confirmation page appears. Go to step 11.

1. On the *Select Event Countries* page, do the following:

   a. Select one or more event countries. The screens display order is based on which **Enforced EventCountry** checkbox was selected first, or by using ascending/descending sorting. b. Click **Next**.

   The *Enter Event Country Status Values* page appears.

2. On the *Enter Event Country Status Values* page: select an event-country status, and make other entries as needed.

◦ If multiple events are being updated, this page may be repeated based on the following rules:

All selected events where an Event Plan is not enforced will be displayed for updating.

For each selected event where an Event Plan is enforced, the screen will be repeated after clicking **Next**.

◦ For all not enforced events that are grouped on the same page, all **Event-Country** values will be displayed as comma separated values, with the order consistent across **Event Name**, **Event Code**, and **Event-Country**.

◦ You can use this wizard to update a planned event that enforces status progression. For such an event, only the next status as defined in the progression and optional statuses are available for selection.

◦ In the **Status Date** box, use the **Calendar** icon to select the date that this event country status is effective. For planned events that enforce progression, the status date can not be earlier than the status date for the previous status as defined in the progression.

◦ If you want to close the event after the event-country status is updated, select **Yes** for **Close Event?**. Select the **Closed Date** value and **Associations Closed As** status. If the event is closed, the status of related entities (application, event, event product, sequence, and PDS) are updated.

1. Click **Next**. One of the following occurs:

   ◦ An option to update additional event countries is presented. To update additional countries, select **Update Additional Event Countries** and click **Next**. Perform steps 7 through 10 again.

   ◦ An option to proceed to the Confirmation page is presented. To continue in the wizard, select **Continue to Confirmation Page** and click **Next**.

2. The *Confirmation* page lists the actions that the wizard will perform if you proceed. The *Confirmation* page is the last opportunity to go back to a different step in the wizard or to cancel the wizard actions. All confirmations must include the **Event Names** and **Sequence Codes** that are affected.Example: 'Event1,

   Event2: The following Event Countries will be locked: United States'

3. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. The *Summary* page offers only **Finish** or **Next** buttons (no **Back** or **Cancel** buttons), so when you reach the *Summary* page you can only proceed and complete the *Update Status* wizard actions. On the *Summary* page, do one of the following:

   ◦ All confirmations must include the **Event Names** and **Sequence Codes** that are affected.

   Example: 'Event1, Event2: The following Event Countries will be locked: United States'

   ◦ Select the application hyperlink to close the wizard and view the *Application Attributes* page.

   ◦ Select the event hyperlink to close the wizard and view the *Event Attributes* page.

   ◦ To create a registration, click **Create a new registration**. The wizard closes and the *Create Registration* page appears.

   ◦ Click **Next** to continue in the wizard to associate package sets with registrations. Go to step 14.

   ◦ Click **Finish** to close the wizard and return to the page viewed when you invoked the wizard.
2. Click **Next** on the summary page to update registrations.The *Select Package Sets* page appears.
3. Select one or more package sets.
4. Click **Next**.The *Select License Codes* page appears.
5. On the *Select License Codes* page, do the following:
   a. For National or CP applications, select one license
   b. For MRP or DCP applications, select one or more licenses.
6. Click **Next**.One of the following occurs:

   ◦ An option to associate additional package sets with licenses is displayed. If you want to associate additional licenses with package sets, select the option and click **Next.** The *Select Package Sets* page appears. Repeat steps 15 through 18.

   ◦ An option to proceed to the *Confirmation* page is presented. To continue in the wizard, select **Continue to Confirmation Page** and click **Next**.

   ◦ The *Confirmation* page appears.
7. The *Confirmation* page lists the actions that the wizard will perform if you proceed. The *Confirmation* page is the last opportunity to go back to a different step in the wizard or to cancel the wizard actions.

8. Click **Next**.The *Summary* page appears. The *Summary* page offers only **Finish** or **Next** buttons (no Back or Cancel buttons), so when you reach the *Summary* page you can only proceed and complete the *Update Status* wizard actions.
9. Click **Finish**.

View a Registration

Viewing a registration enables you to see all the attributes for the registration.

In addition, you can modify a registration, delete a registration, or copy the URL to the Clipboard. You can also add entities to associate with the registration.To view a registration:

1. Navigate to the registration you want to view.
2. Click the registration link.The *Registration Attributes* page appears.
3. On the *Registration Attributes* page, do any of the following:

Option	**Action**
To modify the registration attributes:	Click **Edit**.
To delete the registration:	Click **Delete**.
To copy the registration URL to the Clipboard:	Click **Copy URL**. A message confirms the URL has been copied.
For package set type registrations, to maintain package set associations:	Click **Package Sets**.
For product type registrations, to associate or disassociate a product:	Click **Products**.
Option	**Action**
To view a product, task, reference, or notification associated with the registration:	Click the appropriate tab and then click the entity you want to view.
To add a task, reference, or notification:	Click the appropriate tab and click **Create**.

Sunset Clause

Ennov InSight enables you to track and query on the information that the Marketing Authorization Holders (MAHs) must provide to the European Medicines Agency (EMEA) regarding the current marketing status of all the various presentations or pack sizes registered with each member state.

The Sunset Clause marketing status dates are tracked in Ennov InSight on a per country basis for every package set associated with a registration. This means if the registration is a CP procedure type, the marketing dates are tracked for each country associated with the application with regards to each package set associated with the registration.

Package Sets for Registrations

Package sets created and approved in Ennov InSight product detail sets (PDS) of the related product are associated with registrations. The PDS must belong to the same application as the registration.

A package set represents the set of details for which a registration is issued. Package sets consist of the various configurations and presentations that go into packaging a product. For example, a product with a specific dosage form and strength can be sold in different pack sizes, such as a 100 tablet bottle or a 500 tablet bottle. Each pack size translates to one package set in a PDS. You may associate one or more package sets with a PDS, or not associate a package set at all.

A registration for pharmaceuticals can have one or more associated package sets associated. However, you cannot associate the same package set with multiple registrations for the same country under one application.

Each package set associated with a registration is listed under the **Package Sets** tab. After a registration is created, package sets are associated, modified, and deleted under the **Package Sets** tab on the *Registration Attributes* page. Using the **Package Sets** tab, you can track the package set license code and the Sunset Clause marketing status information by country for each package set associated with the registration.

Associate a Package Set with a Registration

You can associate a package set when you create a registration, or later by modifying the *Registration Attributes* page. If you have the appropriate security privileges to modify a registration, you can associate a package set with an existing registration.

To associate a package set with a registration:

- The package set must already exist and be approved in the product detail set (PDS) of the related product
- The PDS must also belong to the same application as the registration.

To associate a package set with an existing registration:

1. Click a link for the application for which you are modifying a registration.
2. On the *Application Attributes* page, click **Registrations**.
3. On the **Registrations** tab, click the **License Code** link for the registration with which you want to associate package sets.The *Registration Attributes* page appears.
4. On the **Package Sets** tab, click **Create**.The *Associate Package Set* page appears.
5. Enter values for the registration package set attributes.
6. **Save.**

Registration Package Set Attributes

Package sets created and approved in the product detail set of the related product are associated with registrations.

The PDS must belong to the same application as the registration.

Attribute	Description
Application Code	The code of the application which the combination of registration and package set is associated
Application Name	The name of the application which the combination of registration and package set is associated
Authorization Status	Regulatory Entitlement Status.
Authorisation Status Date	Authorisation Status Date
Country	The country which the combination of registration and package set is associated.
Package Set License Code	The last three digits of the license number.
Legal Basis	The legal basis for an authorisation of the product.
License Code	The code of the license which the combination of registration and package set is associated
MAH/Organisation	The company to which a license is issued to market the product. The *Data Administration* values are assigned to **Other Maintenance** > **MAH/Development Sponsor/Organisation Values**.
Package Set Name	Package Sets for which this License was issued. The list is filtered to show only Approved and Pending Add package sets that are associated to the application and do not have a registration for the selected country.
Product Detail Set Name	The PDS which the package set is associated. The name is shown with the product detail set code. For example, AXL PDS 390 could identify a PDS that has the name AXL PDS and the code 390.
Attribute	**Description**
Registration-Package Set Comments	Information that will be stamped with the date/time/userid of the person

Registration-Package Set Description	Descriptive information about the association between the registration and package set
Registration-Package Set Keywords	Text that is inputted for searching.
Package PMS ID	Unique identifier for a specific packaged medicinal product.
PDS Package Set Status	Indicates the status taken from PDS Package Set Detail.
PDS Package Set Status Date	Indicates the status date taken from PDS Package Set Detail.
Withdrawn	Indicates whether a registration package set is withdrawn.
Withdrawn Date	The date that a registration package set was withdrawn.

Modify a Package Set for a Registration

You can modify a package set for a registration only if you have the security privileges to modify a registration.

To modify a package set for a registration:

1. Click a link for the application for which you are modifying a registration.
2. On the *Application Attributes* page, click **Registrations**.
3. On the **Registrations** tab, click the **License Code** link for the registration for which you want to modify package sets.The *Registration Attributes* page appears.
4. On the **Package Sets** tab, click the Package Set Name link for the package set you want to modify.The *Registration-Package Set Attributes* page appears.
5. Click **Edit**.The *Modify Registration-Package Set Association* page appears.
6. Enter your changes to the registration package set attributes.
7. **Save**.

Disassociate a Package Set from a Registration

You can disassociate a package set from a registration only if you have the security privileges to modify a registration.

To disassociate a package set from a registration:

1. Click a link for the application for which you are modifying a registration.The *Application Attributes* page appears.
2. Click the **Registrations** tab, and then click the License Code link for the registration for which you want to disassociate package sets.The *Registration Attributes* page appears.
3. Click the **Package Sets** tab, click the Package Set Name link for the package set you want to disassociate.The *Registration-Package Set Attributes* page appears.
4. Click **Delete**.
5. When you are prompted to confirm the disassociation, click **OK**.

Countries for Registration Package Sets

When you create a registration, countries are automatically associated with each package set associated with the registration.

For a National or Mutual Recognition Procedure (MRP) type applications, only the country on the registration is associated with each package set.

For a CP procedure type application, every country associated with the related application (except for the "European Union" country) is automatically associated with each package set. However, if a country is added to a CP procedure type application after the registration was created, you can manually associate the added country to a package set on the registration.

Sunset Clause marketing dates are tracked on a per country basis for every package set associated with the registration. You maintain these marketing dates using the **Modify action** button on the **Countries** tab on the *Registration-Package Set Attributes* page, with the exception of the **Exemption Date**, which is maintained at the Product Detail Set level.

Associate a Country with a Registration Package Set

If a country is added to a CP procedure type application after the related registration was created, you can manually associate the newly added country to a registration package set.

Note: You can associate a country with a registration package set only if you have the security privileges to modify a registration.To associate a country with a registration package set:

1. Click a link for the application for which you are modifying a registration.
2. On the *Application Attributes* page, click **Registrations**.
3. On the **Registrations** tab, click the **License Code** link for the registration with which you want to associate package set countries.
4. On the **Package Sets** tab, click the **Package Set Name** link for the package set with which you want to associate countries.The *Registration-Package Set Attributes* page appears.
5. On the **Countries** tab, click **Create**.The *Associate Country* page appears.

6. Enter values for the registration-package set-country attributes.
7. **Save**.

Registration-Package Set-Country Attributes

When you create a registration, countries are automatically associated with each package set associated with the registration.

Attribute	Description
Additional License Number	The license/registration number for the individual country
Application Code	The code for the application with which the combination of registration, package set, and country is associated
Application Name	The name of the application with which the combination of registration, package set, and country is associated
Country	The country with which the combination of registration, package set, and country is associated
Currently Marketed in this country?	A value from marketing status from Data Administration that indicates if a particular package set is currently marketed in this country. For example: **Marketed**, **Not Marketed**, **No Data Available**, **Temporarily Unavailable**.
Estimated Return to Market Date	The date the product is predicted to go to market
Family Code	The code for the product family with which the combination of registration, package set, and country is associated
Family Name	The name of the product family with which the combination of registration, package set and country is associated
Legal Status of Supply	How the product is approved to be sold. Might be unavailable for ELP users.
License Code	The code assigned by the regulatory agency
Marketed Date	The date when the package set is released into the distribution chain
Marketing Cessation Date	The date when the package set was last released into the distribution chain

Package Set Name	The package set associated with the registration for which the sunset clause dates are tracked by country
Product Detail Set Name	The PDS associated with the registration. The name is shown with the product detail set code. For example, AXL PDS 390 could identify a PDS that has the name AXL PDS and the code 390.
Attribute	**Description**
Reason for Temporary Cessation	The reason for temporary cessation
Registration-Package Set Country Comments	The information that will be stamped with the date/time/userid of the person entering the information
Registration-Package Set Country Description	Free format text box for entering descriptive information
Registration-Package Set Country Keywords	Free format text box where users can enter text for searching
Restart Marketed Date	The date when the package set was marketed again after a temporary cessation
Temporary Cessation Date	The date when the package set temporarily ceased to be marketed

Modify a Country for a Registration Package Set

You can modify a package set country only if you have the security privileges to modify a registration.

To modify a country for a registration package set:

1. Click a link for the application for which you are modifying a registration.The *Application Attributes* page appears.
2. Click the **Registrations** tab, and then click the License Code link for the registration for which you want to modify package set countries.The *Registration Attributes* page appears.
3. Click the **Package Sets** tab, and then click the Package Set Name link for the package set for which you want to modify countries.The *Registration-Package Set Attributes* page appears.
4. Click the **Countries** tab, and then click the Country link for the country you want to modify.The *Package SetCountry Attributes* page appears.
5. Click **Edit**.The *Modify Package Set Country Association* page appears.
6. Enter you changes to the registration-package set-country attributes.
7. **Save**.

Disassociate a Country from a Registration Package Set

You can disassociate a package set country only if you have the security privileges to modify a registration.

You cannot disassociate a country from a package set when it is the only country associated with the package set. Instead, you must disassociate the package set from the registration.To disassociate a country from a registration package set:

1. Click a link for the application for which you are modifying a registration.
2. On the *Application Attributes* page, click **Registrations**.
3. On the **Registrations** tab, click the License Code link for the registration for which you want to disassociate package set countries.
4. On the **Package Sets** tab, click the Package Set Name link for the package set for which you want to disassociate countries.The *Registration-Package Set Attributes* page appears.
5. On the **Countries** tab, click the Country link for the country you want to disassociate.The *Package Set-Country Attributes* page appears.
6. Click **Delete**.
7. When you are prompted to confirm the disassociation, click **OK**.

Data Carrier Identifiers Attributes

Use the following attributes to create Data Carrier Identifiers.

Attribute	**Description**
Application Code	The code for the application with which the combination of registration, package set, and country is associated
Application Name	The name of the application with which the combination of registration, package set, and country is associated

License Code	The code assigned by the regulatory agency	
Product Detail Set Name	The PDS associated with the registration. The name is shown with the product detail set code. For example, AXL PDS 390 could identify a PDS that has the name AXL PDS and the code 390.	
Package Set Name	The package set associated with the registration for which the sunset clause dates are tracked by country	
Country	The country with which the combination of registration, package set, and country is associated	
Currently Marketed in this country?	A value from marketing status from Data Administration that indicates if a particular package set is currently marketed in this country. For example: **Marketed**, **Not Marketed**, **No Data Available**, **Temporarily Unavailable**.	
Data Carrier Type	Data Carrier Type is GTIN or NTIN.	
Data Carrier Identifier	When you use different packaging levels of medicinal products (For Example, Secondary packaging or Primary packaging), specify the data carrier identifiers (For Example, barcodes).	
Attribute		**Description**
Data Carrier Description	Description for the Data Carrier Identifier.	
Data Carrier Language	Language Code.	
Status	Status of the Data Carrier.	
Status Date	Status Date for Data Carrier.	

PCID

Packaged Medicinal Product Identifier (PCID) determines a medicinal product based on its packaging.

You can generate multiple PCIDs based on the number of authorized packaged medicinal products. The PCID tab appears under *Registration- Package Sets Attributes*. You can create, modify or delete the PCID values.

The PCID tab includes the following:

Column Name	Column Type	Description
PCID	Hyperlink	Indicates the medicinal product based on its packaging.
Country	Read-only text (populated automatically)	Indicates the country. The column can be populated with the appropriate value if the Application procedure type is CP.
Version	Read-only text (populated automatically)	Indicates the version of the PCID. This value is set up in the database.
Version Date	Read-only text (populated automatically)	Indicates the date the PCID is versioned. This value is set up in the data- base.

Package Set-PCID Attributes

Use the PCID attributes in the following table.

Attribute	Description
Application Code	The code for the application to which the combination of registration, package set, and country is associated.
Application Name	The name of the application to which the combination of registration, package set, and country is associated.
Country	This field is available if the application procedure type is CP and has these values:
Attribute	**Description**
	• European Union • Iceland • Liechtenstein • Norway
License Code	The code assigned by the regulatory agency.

Product Detail Set Name	The PDS associated with the registration. The name is shown with the product detail set code. For example, AXL PDS 390 could identify a PDS that has the name AXL PDS and the code 390.
Package Set Name	The package set associated with the registration for which the sunset clause dates are tracked by country.
PCID	Indicates the PCID.
Version	Indicates the version of the PCID. This value is set up in the database.
Version Date	Indicates the date the PCID is versioned. This value is set up in the database.

Package Descriptions for Registration Package Set

Package Descriptions provide additional package information for Registration-Package Set type application.

The Package Description is available only for Package Set type application.

You must have appropriate security privileges to create a package description. If you have the rights to add a product and registration, you can add a package description.

You should have at least WRITE privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Product Entity Security to modify a package description.

Create a Package Description for a Registration Package Set

Package descriptions provide additional packaging information for the pharmaceutical product.

To create a package description:

1. On the *Registration Attributes* page, select the **Package Sets** tab.
2. Click the **Package Set Name** link for the package set you want to create a package description to.
3. On the **Package Descriptions** tab, click **Create**.
4. Enter details for the package description attributes.
5. **Save**.

Registration-Package Set Package Description Attributes

Use the package description attributes in the following table.

Attribute	Description
Application Code	Agency-identified application number (or identifier). Can be the same as the internal code.
Application Name	The name of the application. It is the combination of registration and package set names.
License Code	The code assigned by the regulatory agency.
Product Detail Set Name	The name of the product detail set the package set is associated to. It is the combination of the product details set name and product details set code - PDS Name + PDS Code.
Package Set Name	The name of package set the package description is associated to.
Short Package Description	The short description of the package.
PMP Package Description	The description of the packaged medicinal product.
PMP Package Description Language	Language of the package description.
Package Description Keywords	Keywords for package description.
PMP Package Description	Text to describe the package.
Package Description Comments	The discussion thread that includes all comments entered by users. Includes the date and time the comments were entered, and the user ID of the person who entered them.

Modify a Package Description for a Registration Package Set

Modify a previously created package description to include the necessary values.

To modify a package description:

1. Click a link for the package description you want to modify.
2. On the *Package Set - Package Description Attributes* page, click **Modify**.
3. Make necessary changes to the package description attributes.
4. **Save**.

Delete a Package Description from a Registration Package Set

Delete a package description that is not required for an entity.

To delete a package description:

1. On the **Package Descriptions** tab, click the link to the package description you want to delete.
2. On the *Package Set - Package Description Attributes* page, click **Delete**.
3. On the warning message, click **OK**.
4. On the message confirming that the data has been deleted, click **OK**.

Associate or Disassociate a Product and a Registration

When you create a registration, you can associate products to the registration, or you can associate products later by modifying the event attributes. You can also disassociate a product from a registration.

The products that can be associated with a registration include all the products related to the event associated with the registration that do not have a *Not Approved* or *Withdrawn* event-product status.To associate or disassociate a product with or from a registration:

1. Click a link for the registration with which you want to associate a product.The *Registration Attributes* page appears.
2. Click **Products**.
3. Click **Associate**.The *Associate/Disassociate Product* page appears.
4. For the **Products** attribute, under the **Selected** box click **Select** and select the products associated with the event.
5. **Save**.
6. Select a reason and enter comments for the reason.
7. Click **Next**.
8. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Delete a Registration

You must have the appropriate security privileges to delete a registration. In addition, no tasks, references, or notifications can be associated with the registration.

After deleting a registration, be aware of the following:When deleting a product type registration, the event and products associated with the registration are automatically disassociated from the registration. Please note that the event and products are not deleted from Ennov InSight.

- Deleting a registration does not automatically update the **Event-Product Status** or **Event-Product Status Date** on the **Products** tab of the *View Event* page for the disassociated products.
- The **License Code** value is removed from the **Products** tab of the *View Event* page for the disassociated products.

When deleting a package set type registration, the package sets associated with the registration are automatically disassociated from the registration. Please note that the package sets are not deleted from Ennov InSight .

To delete a registration:

1. Navigate to the registration that you want to delete.
2. Click a link for the registration you want to delete.
3. Click **Delete**.
4. Select a reason and enter comments for the reason.
5. Click **Next**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Full Product Presentation

The Full Product Presentation (FPP) entity is required by the European Medicines Agency (EMA) regulatory agency for XEVMPD schema support. Ennov InSight enables you to view, create, modify, or delete the Full Product Presentation.

You need at least Read permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security to view Full Product Presentation.

You can:

- View Full Product Presentation - View previously created or modified entity.
- Create Full Product Presentation - Create the new Full Product Presentation entity.
- Modify Full Product Presentation - Change the previously created entity data.
- Delete Full Product Presentation - Remove the previously created data from the system.
- Copy Full Product Presentation:

◦ Copy the existing Full Product Presentation data under the same registration.

◦ Copy the existing Full Product Presentation data under different registrations.

The Full Product Presentation provides detailed information about the product. There are multiple attributes for the FPP entity.

You can create the following entities for a Full Product Presentation:

- FPP Previous EV Code
- Registration FPP Attachment

The following actions can be performed from the *Full Product Presentation attributes* page:

- Modify
- Copy
- Delete
- Copy URL

Create a Full Product Presentation

Ennov InSight enables you to create a Full Product Presentation. The Full Product Presentation provides detailed information about the product.

You need at least Read permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security to create the Full Product Presentation entity.

To create the Full Product Presentation:

1. Create an application using the **Package Set Registration** type and create a registration for it.
2. On the *Registration Attributes* page, select **Full Product Presentation**.
3. Click the **Create Full Product Presentation** icon.
4. On the *Create Full Product Presentation* page, enter the needed properties and do one of the following:

Option	**Action**
To save the data:	**Save** .
To create another entity:	**Save** and **Add Another Full Product Presentation** .

Full Product Presentation Criteria

Ennov InSight presents detailed criteria about the Full Product Presentation.

- If Full Product Presentation required properties are not populated with valid data, the entity is not created.
- **Full Product Short Name**, **Product INN/Common Name**, **Product Company Name**, **Product Strength**, **Product Form** are case sensitive fields.

- The only required field is **Full Product Name**. Other fields are optional.
- **Application Code**, **Application Name**, and **License Code** are already populated by the system in display mode.
- The concatenation of **Full Product Name**, **EEA Country**, **Language**, **Package Description**, **Authorisation Status**, **Authorisation/Renewal Date**, and **EV Code** must be unique within a Registration.
- **EV Code** and **Date Submitted to EMA** remain blank during the Full Product Presentation creation process. These fields are populated automatically when the *XEVMPD Acknowledgement* Wizard is completed. The **Last Updated Date** appears when all changes are made.
- **Message Sender** field remains blank during the creation process. When the *XEVMPD Submission* Wizard passes, this field is updated automatically.
- For the *XEVMPD Submission* Wizard, in the Authorised Product XEVMPD section, when an Application has one of the EU CP (Centralised Procedure) Types (e.g. EU CP Bio) selected, you can send the XEVMPD submission specific for EEA Countries, such as Norway, Iceland, or Liechtenstein. To be included in the XML file, Norway, Iceland, or Liechtenstein should also be selected in the **EEA Country** field. Otherwise, the Country from the PSet (Package Set) Registration is added to the XML file.

Note: The **Package Sets** multi-select field will not display package sets with the status Withdrawn. It displays the full list of assigned to the Registration Product Sets for each Full Product Presentation creation. The **Package**

Description field is not displayed until the value for the **PSet** field is chosen. The value can be modified manually.

Modify a Full Product Presentation

You can modify a previously created **Full Product Presentation**.

At least WRITE privileges for Product Detail Management (PDM) and Registration Planning and Tracking (RPT) licenses, and Full Product Presentetion Entity Security are required to modify the Full Product Presentation entity.When modifying the Full Product Presentation information:

- If Full Product Presentation required properties are not populated with valid data, a message appears and the entity is not modified.
- The **Last Updated Date** will appear after all changes are made.
- **XEVMPD License Code** and **XEVMPD MAH/Organisation** values are populated only if the *XEVMPD*

Submission Wizard passes. The automatically assigned values are not available for further modifications or from the Create Full Product Presentation page.

- The **Message Sender** field is read-only and is automatically updated with data when the XEVMPD Submission Wizard passes. The automatically assigned values are not available for further modifications or from the Create Full Product Presentation page.

To modify the Full Product Presentation:

1. Go to **Full Product Presentation**, or in the *Navigation Pane* select **Full Product Presentations**.
2. Select the Full Product Presentation entity you want to modify.

3. Click **Modify** .
4. On the *Modify Full Product Presentation* page, modify the attributes. **Save.** To cancel your changes, click **Cancel**.The *Full Product Presentation* View displays the updates.

Delete a Full Product Presentation

You can delete a previously created Full Product Presentation entity.

At least Write privileges for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security are required to delete the Full Product Presentation entity.

To delete the Full Product Presentation:

1. On the **Full Product Presentation** tab, select the Full Product Presentation entity you want to delete.
2. Click **Delete**.
3. On the warning message that appears, click **OK**.
4. On the message confirming that the data has been deleted, click **OK**. If the Full Product Presentation entity has Registration Full Product Presentation Attachments, you must delete them first. The Full Product Presentation cannot be deleted if it has any dependencies.

When there is a URL in the system that points to the Full Product Presentation record that was deleted, a message appears when an attempt is made to launch that URL.

The *Registration Attributes* page appears.

Full Product Presentation Attributes

You create a Full Product Presentation for the Registration to provide the necessary information about the product in the XEVMPD submission for the European Medicines Agency (EMA).

The following attributes describe the specific Full Product Presentation for the Registration.

Attribute	**Description**
Application Code	The agency-identified application number (or identifier). May not be known until submittal time and so it can be the same as the internal code.
Application Name	The name of your application.
Application Procedure Type	Application Procedure Type associated to the combination of registration, package set, and country associated.

Authorisation Status	The status of the authorisation of a medicinal product.
Authorisation/Renewal Date	The date when the first authorisation was granted by the authorising body or the date when the renewal was granted.

Attribute	**Description**
Authorised Pharmaceutical Form	The pharmaceutical form of the product.
Container or Pack Part	The Container or Pack Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for The value. The database size of the field is VARCHAR2(500).For example: Drug LV,collapsible aluminium tube.
Countries	All Package Set Countries available for selection. The field appears after the package set is selected in the **Package Sets** field. For the application of National, Mutual Recognition (MRP) and Decentralised (DCP) Procedure types, the country of the parent Registration is selected by default.
Date Submitted to EMA	The date is assigned automatically when the *XEVMPD Acknowledgment* Wizard passes.
Device Part	The Device Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500).For example: DrugLV, solution for injection in pre-filled pen (device Tradename).
EEA Country	The EEA Country is available for selection only when the Application has one of EU CP Types (Centralised Procedure). Countries available for selection are: • Iceland • Norway • Liechtenstein If any of the listed countries is selected, then it is included to the XEVMPD XML file. Otherwise, the Country from Package Set Registration is added to the XML file.
EV Code	The EudraVigilance (EV) Code of the Master File Location.

Flavour Part	The Flavour Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500).For example: DrugLV for Children Strawber- ry
Formulation Part	The Formulation Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500).For example: DrugLV, sugar free.
Full Product Name	The full name of the product. For example: DrugLV Filmtabletten
Full Product Presen	Available on the Create/Modify *Full Product Presentation Attributes* pages. The free-format text box where users can add comments. The comments will be displayed in the **Full Product Presentation**

Attribute	**Description**
tation Add Comment	**Comments** box followed by the date and time the comments were entered, and the user ID of the person who entered them.
Full Product Presentation Comments	Available on the View/Modify *Full Product Presentation Attributes* pages. The display-only field that includes the previously added comments: • Includes all comments entered by users, including the date and time the comments were entered, and the user ID of the person who entered them. Can be updated or deleted from the *View Full Product Presentation Attributes* page.
Full Product Presentation Concerned Parties	Contains email addresses and User IDs for which Notifications can be sent. Concerned parties are anyone who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses.
Full Product Presentation Description	Text that describes the Full Product Presentation.
Full Product Presentation Keywords	Words you can use to search for the Full Product Presentation.

Full Product Short Name	The short name of the product. For example: DrugLV
Information Date	The date when the information is inserted.
Intended Use Part	The Intended Use Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500).For example: DrugLV 200 tablet Migraine
Language	Active language names from the languages values in Data Administration.
Last Updated Date	The date of the most recent update.
License Code	The code assigned by the regulatory agency. Current value from Package Set Registration.

Attribute	**Description**
MAH/Organisation	The license issued to a company to market the product. Current value from Package Set Registration in concatenation of MAH/Development Sponsor/Organisation Name + Address + City + Country Code.
MAH/Organisation Transferred To	Available for Authorisation Status when Not Valid - Superseded by Marketing Authorisation Transferis selected for FPP entity.
Message Sender	This field is read-only and is automatically updated with data when the *XEVMPD Submission* Wizard is used. Not available on the Create page.
Package Sets	Package Set associated to Registration. This attribute is related to Package Description.**Note:** Only package sets with Approved status are available for selection when you create FPP.

Package Description	Includes package set names from the Package Sets field. The field appears only if the Package Sets values are defined.
Product Company Name	Part of the medicinal product name without any other designations such as trade mark, strength, or pharmaceutical form.
Product Form	The physical form in which this product is produced and dispensed.
Product INN/Common Name	The international nonproprietary name recommended by the World Health Organization (WHO), or, if one does not exist, a nonproprietary name recommended by the ju- risdiction within which the name is used.
Pharmaceu tical Product	Pharmaceutical Products are available for selection that are assigned to the Product for the selected Package Sets in FPP.
Product Strength	The name of the strength and strength unit, if it is part of the Full Product Name (Sm-PC Name).For example: DrugLV 200 mg
Special Measures	A controlled term that is used to specify the Medicinal Product.
Target Population Part	The Target Population Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500).For example: DrugLV For Children.
Time Period Part	The Time Period Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500).For example: DrugLV 300 mg EXPRESS.
Attribute	**Description**
Withdrawn/Invalidated Date	The date of expiry of the marketing authorisation.

XEVMPD Comments	The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.
XEVMPD Marketing Authorisation Number	The code assigned by the regulatory agency. This field is populated automatically with a License Code value from a parent Package Set Registration via the *XEVMPD Submission* Wizard. This field is read-only. The value is used for the Invalidate MA operation for Not Valid statuses.
XEVMPD MAH/Organisation	The company to which the license is given to market the product. This field is populated automatically with a MAH/Organisation value from a parent Package Set Registration via the *XEVMPD Submission* Wizard, and is not available for further modifications. The value is used for the Invalidate MA operation for Not Valid statuses.
XEVMPD Submission Required?	The system auto-populates this field when XEVMPD related field on XEVMPD related entity is updated.

Copy Full Product Presentations

In the *Copy Full Product Presentation* wizard, you can copy a Full Product Presentation under the same Registration, or under different Registration(s).

Note: You must have at least Write permissions for the Full Product Presentation (FPP) in Entity Security section to copy Full Product Presentations.Some fields of the source Full Product Presentation (FPP) are not copied:

Full Product Presentation under the same Registration flow	**Full Product Presentation under different Registration(s) flow**
The **XEVMPD Marketing Authorisation Number**, **XEVMPD MAH/Organisatiom**, and **Date Submitted to EMA** val- ues are automatically assigned once the *XEVMPD Sub- mission* wizard is completed.	The **XEVMPD Marketing Authorisation Number**, **XEVMPD MAH/Organisatiom**, and **Date Submitted to EMA** values are automatically assigned once the *XEVMPD Submission* wizard is completed.
The **EV Code** value is not copied.	The **Previous EV Code** value from the *FPP Previous EV Codes* tab and **EV Code** values are not copied.
The **Local Code** value that is hidden on the Full Product Presentation Attributes page.	The **Local Code** value is not copied. This attribute is hidden on the Full Product Presentation Attributes page.
Full Product Presentation under the same Registration flow	**Full Product Presentation under different Registration(s) flow**

The **Message Sender** field is read only and is automatically updated with data when the *XEVMPD Submission* Wizard passed. Not available on the Create page.	The **Message Sender** field is read only and is automatically updated with data when the *XEVMPD Submission* Wizard passed. Not available on the Create page.

The following features apply to the copied full product presentation (FPP):

Full Product Presentation under the same Registration flow	**Full Product Presentation under different Registration(s) flow**
The **Last Updated Date** value is populated with the date of the copy action.	The **Last Updated Date** value is populated with the date of the copy action.
The **Previous EV Code** value is copied and appears on the *FPP Previous EV Codes* tab with the data from source Full Product Presentation.	The **Package Sets** and **Package Set Description** fields will have the **Package Set Name** values of the selected Registration.

The following features apply to the copied Registration FPP Attachment, if the Full Product Presentation you are copying has it assigned and you have selected Yes on the Copy Registration FPP Attachment page of the *Full Product Presentation under different Registration(s)* flow:

- The **Attachment** and **Validity Declaration** values are populated with the appropriate Registration FPP Attachment values of the source Full Product Presentation.
- The **Registration FPP Attachment Concerned Parties** and **Registration FPP Attachment Comments** values are not copied.

Wizard Navigation The *Copy Full Product Presentation* wizard consists of:

- **Select wizard flow** > **Select the flow for the Full Product Presentation copy you would like to perform**:

◦ Full Product Presentation under different Registration(s)

◦ Full Product Presentation under the same Registration

- Copy Full Product Presentation:

◦ Select Registration(s) under which you would like to copy Full Product Presentation**Note:** Available only for the *Full Product Presentation under different Registration(s)* flow.

◦ Copy Full Product Presentation Attributes

◦ Copy Registration FPP Attachment**Note:** Available only for the *Full Product Presentation under different Registration(s)* flow.

- Summary

Copy Full Product Presentation Attributes

The following attribute descriptions can help you to enter appropriate Full Product Presentation attribute values when copying a Full Product Presentation in Ennov InSight .

Copying Full Product Presentation under the Same Registrations

Use the following descriptions to choose and enter Full Product Presentation values when copying under the same Registration. Required information is indicated by an asterisk (*):

Attribute	Description
Authorisation Status	Appears blank. The status of the authorisation of a medicinal product. The statuses available for selection are all Active values from the **Data Administration** > **Authorisation Status Values** section.
Authorisation/Renewal Date	Appears blank. The date when the first authorisation was granted by the authorising body or the date when the renewal was granted.
Authorised Pharmaceutical Form	The value is taken from the source Full Product Presentation and can be changed, if needed. The pharmaceutical form of the product.
Container or Pack Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Container or Pack Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for The value. The database size of the field is VARCHAR2(500). For example: DrugLV, collapsible aluminium tube.
Countries	The value is taken from the source Full Product Presentation and can be changed, if needed. All Package Set Countries available for selection. The field appears after the package set is selected in the **Package Sets** field.
Device Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Device Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV, solution for injection in pre-filled pen (device Tradename)

EEA Country	The value is taken from the source Full Product Presentation and can be changed, if needed. The EEA Country is available for selection only when the Application has one of EU CP Types (Centralised Procedure). Countries available for selection are: • Iceland • Norway • Liechtenstein If any of the listed countries is selected, then it is included to the XEVMPD XML file. Otherwise, the Country from Package Set Registration is added to the XML file.

Attribute	**Description**
Flavour Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Flavour Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV for Children Strawberry
Formulation Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Formulation Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV, sugar free
Full Product Name *	The value is taken from the source Full Product Presentation and can be changed, if needed.The full name of the product. For example: DrugLV Filmtabletten
Full Product Presentation Add Comment	Appears blank. The discussion thread that includes all comments entered by users, including the date and time the comments were entered, and the user ID of the person who entered them.
Full Product Presentation Concerned Parties	Appears blank. Contains email addresses and User IDs for which Notifications can be sent. Concerned parties are anyone who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses

Full Product Presentation Description	Appears blank. Text that describes the Full Product Presentation.
Full Product Presentation Keywords	Appears blank. Words you can use to search for the Full Product Presentation.
Full Product Short Name	The value is taken from the source Full Product Presentation and can be changed, if needed.The short name of the product. For example: DrugLV
Information Date	Appears blank. The date when the information is inserted.
Intended Use Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Intended Use Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500).

Attribute	**Description**
	For example: DrugLV 200 tablet Migraine
Language	The value is taken from the source Full Product Presentation and can be changed, if needed.Active language names from the languages values in Data Administration.
Package Description	The value is taken from the source Full Product Presentation and can be changed, if needed.A brief package description of the pack size(s) corresponding to the referenced authorisation number.
Package Sets	The value is taken from the source Full Product Presentation and can be changed, if needed.Package Set names tied to Registration. This attribute is related to Package Description.**Note:** Only package sets with Approved status show on the *Full Product Presentation Attributes* page.
Product Company Name	The value is taken from the source Full Product Presentation and can be changed, if needed.Part of the medicinal product name without any other designations such as trade mark, strength, or pharmaceutical form.

Product Form	The value is taken from the source Full Product Presentation and can be changed, if needed.The physical form in which this product is produced and dispensed.
Product INN/ Common Name	The value is taken from the source Full Product Presentation and can be changed, if needed.The international nonproprietary name recommended by the World Health Organization (WHO), or, if one does not exist, a nonproprietary name recommended by the jurisdiction within which the name is used.
Product Strength	The value is taken from the source Full Product Presentation and can be changed, if needed. The name of the strength and strength unit, if it is part of the Full Product Name (Sm- PC Name). For example: DrugLV 200 mg
Special Measures	The value is taken from the source Full Product Presentation and can be changed, if needed.A controlled term which is used to specify the Medicinal Product.
Target Population Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Target Population Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV For Children.
Time Period Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Time Period Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV 300 mg EXPRESS
Attribute	**Description**
Pharmaceutical Product	Pharmaceutical Products are available for selection that are assigned to the Product for the selected Pack Sets in FPP.
Withdrawn/Invalidated Date	Appears blank. The date of expiry of the marketing authorisation.
XEVMPD Comments	The value is taken from the source Full Product Presentation and can be changed, if needed.The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.

Copying Full Product Presentation under Different Registrations

Use the following descriptions to choose and enter Full Product Presentation values when copying under different Registrations. Required information is indicated by an asterisk (*):

Attribute	Description
Authorisation Status	The value is taken from the source Full Product Presentation and can be changed, if needed. The status of the authorisation of a medicinal product. The statuses available for selection are all Active values from the **Data Administration** > **Authorisation Status Values** section.
Authorisation/Renewal Date	The value is taken from the source Full Product Presentation and can be changed, if needed. The date when the first authorisation was granted by the authorising body or the date when the renewal was granted.
Authorised Pharmaceutical Form	The value is taken from the source Full Product Presentation and can be changed, if needed. The pharmaceutical form of the product.
Container or Pack Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Container or Pack Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for The value. The database size of the field is VARCHAR2(500). For example: DrugLV, collapsible aluminium tube
Countries	The value is taken from the source Full Product Presentation and can be changed, if needed. All Package Set Countries available for selection. The field appears after the package set is selected in the **Package Sets** field.
Device Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Device Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500).

Attribute	Description
	For example: DrugLV, solution for injection in pre-filled pen (device Tradename)
EEA Country	The value is taken from the source Full Product Presentation and can be changed, if needed.The EEA Country is available for selection only when the Application has one of EU CP Types (Centralised Procedure). Countries available for selection are: • Iceland • Norway • Liechtenstein If any of the listed countries is selected, then it is included to the XEVMPD XML file. Otherwise, the Country from Package Set Registration is added to the XML file.
Flavour Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Flavour Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV for Children Strawberry
Formulation Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Formulation Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV, sugar free
Full Product Name *	The value is taken from the source Full Product Presentation and can be changed, if needed.The full name of the product. For example: DrugLV Filmtabletten
Full Product Presentation Add Comment	Appears blank. The discussion thread that includes all comments entered by users, including the date and time the comments were entered, and the user ID of the person who entered them.
Full Product Presentation Concerned Parties	Appears blank. Contains email addresses and User IDs for which Notifications can be sent. Concerned parties are anyone who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses

Full Product Presentation Description	Appears blank. Text that describes the Full Product Presentation.

Attribute	**Description**
Full Product Presentation Keywords	Appears blank. Words you can use to search for the Full Product Presentation.
Full Product Short Name	The value is taken from the source Full Product Presentation and can be changed, if needed.The short name of the product. For example: DrugLV
Information Date	The value is taken from the source Full Product Presentation and can be changed, if needed.The date when the information is inserted.
Intended Part Use	The value is taken from the source Full Product Presentation and can be changed, if needed. The Intended Use Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV 200 tablet Migraine
Language	The value is taken from the source Full Product Presentation and can be changed, if needed.Active language names from the languages values in Data Administration.By default, the field is hidden.
Product Company Name	The value is taken from the source Full Product Presentation and can be changed, if needed.Part of the medicinal product name without any other designations such as trade mark, strength, or pharmaceutical form.
Product Form	The value is taken from the source Full Product Presentation and can be changed, if needed.The physical form in which this product is produced and dispensed.
Product INN/ Common Name	The value is taken from the source Full Product Presentation and can be changed, if needed.The international nonproprietary name recommended by the World Health Organization (WHO), or, if one does not exist, a nonproprietary name recommended by the jurisdiction within which the name is used.

Product Strength	The value is taken from the source Full Product Presentation and can be changed, if needed. The name of the strength and strength unit, if it is part of the Full Product Name (Sm- PC Name). For example: DrugLV 200 mg
Special Measures	The value is taken from the source Full Product Presentation and can be changed, if needed.A controlled term which is used to specify the Medicinal Product.By default, the field is hidden.
Target Population Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Target Population Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV For Children.
Attribute	**Description**
	By default, the field is hidden.
Time Period Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Time Period Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV 300 mg EXPRESS By default, the field is hidden.
Withdrawn/Invalidated Date	The value is taken from the source Full Product Presentation and can be changed, if needed.The date of expiry of the marketing authorisation.
XEVMPD Comments	The value is taken from the source Full Product Presentation and can be changed, if needed.The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.

Wizard Navigation

The *Copy Full Product Presentation* wizard consists of:

— Select wizard flow > Select the flow for the Full Product Presentation copy you would like to perform:

- Full Product Presentation under different Registration(s)
- Full Product Presentation under the same Registration — Copy Full Product Presentation:
- Select Registration(s) under which you would like to copy Full Product Presentation

Note: *Available only for the Full Product Presentation under different Registration(s) flow.*

- Copy Full Product Presentation Attributes
- Copy Registration FPP Attachment

Note: *Available only for the Full Product Presentation under different Registration(s) flow.*

— Summary

Copy Full Product Presentation Attributes

The following attribute descriptions can help you to enter appropriate Full Product Presentation attribute values when copying a Full Product Presentation in Ennov InSight .

Copying Full Product Presentation under the Same Registrations

Use the following descriptions to choose and enter Full Product Presentation values when copying under the same Registration. Required information is indicated by an asterisk (*):

Attribute	Description
Authorisation Status	Appears blank. The status of the authorisation of a medicinal product. The statuses available for selection are all Active values from the Data Administration > Authorisation Status Values section.
Authorisation/ Re-newal Date	Appears blank. The date when the first authorisation was granted by the authorising body or the date when the renewal was granted.
Authorised Pharmaceutical Form	The value is taken from the source Full Product Presentation and can be changed, if needed. The pharmaceutical form of the product.

Container or Pack Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Container or Pack Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for The value. The database size of the field is VARCHAR2(500). For example: DrugLV, collapsible aluminium tube.
Countries	The value is taken from the source Full Product Presentation and can be changed, if needed. All Package Set Countries available for selection. The field appears after the package set is selected in the Package Sets field.
Device Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Device Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV, solution for injection in pre-filled pen (device Tradename)
EEA Country	The value is taken from the source Full Product Presentation and can be changed, if needed. The EEA Country is available for selection only when the Application has one of EU CP Types (Centralised Procedure). Countries available for selection are: — Iceland

	— Norway — Liechtenstein If any of the listed countries is selected, then it is included to the XEVMPD XML file. Otherwise, the Country from Package Set Registration is added to the XML file.
Attribute	Description
Flavour Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Flavour Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV for Children Strawberry

Formulation Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Formulation Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV, sugar free
Full Product Name *	The value is taken from the source Full Product Presentation and can be changed, if needed. The full name of the product. For example: DrugLV Filmtabletten
Full Product Presentation Add Comment	Appears blank. The discussion thread that includes all comments entered by users, including the date and time the comments were entered, and the user ID of the person who en- tered them.
Full Product Presentation Concerned Parties	Appears blank. Contains email addresses and User IDs for which Notifications can be sent. Concerned parties are anyone who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses
Full Product	Appears blank. Text that describes the Full Product Presentation.

Presentation Description	
Full Product Presentation Keywords	Appears blank. Words you can use to search for the Full Product Presentation.
Full Product Short Name	The value is taken from the source Full Product Presentation and can be changed, if needed. The short name of the product. For example: DrugLV
Information Date	Appears blank. The date when the information is inserted.

Attribute	Description
Intended Use Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Intended Use Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV 200 tablet Migraine
Language	The value is taken from the source Full Product Presentation and can be changed, if needed. Active language names from the languages values in Data Administration.
Package Description	The value is taken from the source Full Product Presentation and can be changed, if needed. A brief package description of the pack size(s) corresponding to the referenced authorisation number.
Package Sets	The value is taken from the source Full Product Presentation and can be changed, if needed. Package Set names tied to Registration. This attribute is related to Package Description.
	Note: *Only package sets with Approved status show on the Full Product Presentation Attributes page.*
Product Company Name	The value is taken from the source Full Product Presentation and can be changed, if needed. Part of the medicinal product name without any other designations such as trade mark, strength, or pharmaceutical form.
Product Form	The value is taken from the source Full Product Presentation and can be changed, if needed. The physical form in which this product is produced and dispensed.
Product INN/ Common Name	The value is taken from the source Full Product Presentation and can be changed, if needed. The international nonproprietary name recommended by the World Health Organization (WHO), or, if one does not exist, a nonproprietary name recommended by the jurisdiction within which the name is used.

Attribute	Description
Product Strength	The value is taken from the source Full Product Presentation and can be changed, if needed. The name of the strength and strength unit, if it is part of the Full Product Name (SmPC Name). For example: DrugLV 200 mg
Special Measures	The value is taken from the source Full Product Presentation and can be changed, if needed. A controlled term which is used to specify the Medicinal Product.
Target Population Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Target Population Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500).
	For example: DrugLV For Children.
Time Period Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Time Period Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV 300 mg EXPRESS
Pharmaceutical Product	Pharmaceutical Products are available for selection that are assigned to the Product for the selected Pack Sets in FPP.
Withdrawn/ Invalidated Date	Appears blank. The date of expiry of the marketing authorisation.
XEVMPD Comments	The value is taken from the source Full Product Presentation and can be changed, if needed. The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.

Copying Full Product Presentation under Different Registrations

Use the following descriptions to choose and enter Full Product Presentation values when copying under different Registrations. Required information is indicated by an asterisk (*):

Attribute	Description
Authorisation Status	The value is taken from the source Full Product Presentation and can be changed, if needed. The status of the authorisation of a medicinal product. The statuses available for selection are all Active values from the Data Administration > Authorisation Status Values section.
Authorisation/ Renewal Date	The value is taken from the source Full Product Presentation and can be changed, if needed. The date when the first authorisation was granted by the authorising body or the date when the renewal was granted.
Authorised Pharmaceutical	The value is taken from the source Full Product Presentation and can be changed, if needed. The pharmaceutical form of the product.

Form	
Container or Pack Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Container or Pack Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for The value. The database size of the field is VARCHAR2(500). For example: DrugLV, collapsible aluminium tube
Countries	The value is taken from the source Full Product Presentation and can be changed, if needed. All Package Set Countries available for selection. The field appears after the package set is selected in the Package Sets field.
Device Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Device Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV, solution for injection in pre-filled pen (device Tradename)

Attribute	Description
EEA Country	The value is taken from the source Full Product Presentation and can be changed, if needed. The EEA Country is available for selection only when the Application has one of EU CP Types (Centralised Procedure). Countries available for selection are: — Iceland — Norway — Liechtenstein If any of the listed countries is selected, then it is included to the XEVMPD XML file. Otherwise, the Country from Package Set Registration is added to the XML file.
Flavour Part	The value is taken from the source Full Product Presentation and can be changed, if need- ed.
	The Flavour Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV for Children Strawberry
Formulation Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Formulation Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV, sugar free
Full Product Name *	The value is taken from the source Full Product Presentation and can be changed, if needed. The full name of the product. For example: DrugLV Filmtabletten
Full Product Presentation Add Comment	Appears blank. The discussion thread that includes all comments entered by users, includ- ing the date and time the comments were entered, and the user ID of the person who en- tered them.

Full Product Presentation Concerned Parties	Appears blank. Contains email addresses and User IDs for which Notifications can be sent. Concerned parties are anyone who may be copied on notifications about this entity; use semi-colons (;) to separate e-mail addresses
Full Product Presentation Description	Appears blank. Text that describes the Full Product Presentation.
Attribute	Description
Full Product Presentation Keywords	Appears blank. Words you can use to search for the Full Product Presentation.

Full Product Short Name	The value is taken from the source Full Product Presentation and can be changed, if needed. The short name of the product. For example: DrugLV
Information Date	The value is taken from the source Full Product Presentation and can be changed, if needed. The date when the information is inserted.
Intended Part Use	The value is taken from the source Full Product Presentation and can be changed, if needed. The Intended Use Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV 200 tablet Migraine
Language	The value is taken from the source Full Product Presentation and can be changed, if needed. Active language names from the languages values in Data Administration. By default, the field is hidden.

Product Company Name	The value is taken from the source Full Product Presentation and can be changed, if needed. Part of the medicinal product name without any other designations such as trade mark, strength, or pharmaceutical form.
Product Form	The value is taken from the source Full Product Presentation and can be changed, if needed. The physical form in which this product is produced and dispensed.
Product INN/ Common Name	The value is taken from the source Full Product Presentation and can be changed, if needed. The international nonproprietary name recommended by the World Health Organization (WHO), or, if one does not exist, a nonproprietary name recommended by the jurisdiction within which the name is used.

Attribute	Description
Product Strength	The value is taken from the source Full Product Presentation and can be changed, if needed. The name of the strength and strength unit, if it is part of the Full Product Name (SmPC Name). For example: DrugLV 200 mg
Special Measures	The value is taken from the source Full Product Presentation and can be changed, if needed. A controlled term which is used to specify the Medicinal Product. By default, the field is hidden.
Target Population Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Target Population Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500).

	For example: DrugLV For Children. By default, the field is hidden.
Time Period Part	The value is taken from the source Full Product Presentation and can be changed, if needed. The Time Period Part of the Full Product Name (SmPC Name). You can enter up to 250 characters for the value. The database size of the field is VARCHAR2(500). For example: DrugLV 300 mg EXPRESS By default, the field is hidden.
Withdrawn/ Invalidated Date	The value is taken from the source Full Product Presentation and can be changed, if needed. The date of expiry of the marketing authorisation.
XEVMPD Comments	The value is taken from the source Full Product Presentation and can be changed, if needed.
	The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them.

Copy a Full Product Presentation under the Same Registration

Use this procedure to copy a Full Product Presentation (FPP) under the same registration.

To copy a full product presentation:

1. Go to the Full Product Presentation tab, or in the *navigation pane* select Full Product Presentations.
2. Select the Full Product Presentation entity you want to copy.
3. On the *Full Product Presentation Attributes* page, click Copy. 4. The *Copy Full Product Presentation* page appears. Under Select wizard flow > Select the flow for the Full Product Presentation copy you would like to perform, select *Full Product Presentation under same Registration*.

1. Click Next.
2. On the *Copy Full Product Presentation Attributes* page, enter or change the attributes for the Full Product Presentation Copy.

   When entering or modifying the Copy Full Product Presentation Attributes, remember that the concatenation of

   Full Product Name, EEA Country, Language, Package Description, Authorisation Status, Authorisation/Renewal Date, and EV Code must be unique for a Registration.

3. Click Next.

   The *Summary* page indicates that the Full Product Presentation has been copied.

4. Select a reason and enter comments for the reason.
5. Click Next.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Copy a Full Product Presentation under Different Registrations

Use this procedure to copy a Full Product Presentation (FPP) under different registrations.

To copy a full product presentation:

1. Go to the Full Product Presentation tab, or in the *Navigation Pane* select Full Product Presentations.
2. Select the Full Product Presentation entity you want to copy.
3. On the *Full Product Presentation Attributes* page, click Copy. 4. *Copy Full Product Presentation* page appears. Under the Select wizard flow > Select the flow for the Full Product Presentation copy you would like to perform page, select *Full Product Presentation under different Registration(s)*.

1. Click Next.
2. The *Select Registration(s) under which you would like to copy Full Product Presentation* page appears with the registrations to which you can copy the Full Product Presentation. The search is performed by the following values: — License Code

— License Status

— Package Sets. If there are several Package Sets, they are displayed as comma delimited.

— Product Detail Set. If there are several Product Detail Sets, they are displayed as comma delimited. — Country. The Country value from Package Set Registration.

— Application Code

— Application Name — Application Type

Only the Package Set Registration(s) that meet the following criteria are displayed on the *Select Registration(s) under which you would like to copy Full Product Presentation* page:

— The available Registrations have the same parent Application as the Registration of the source Full Product Presentation.

— The parent Registration > Country value of the available Registrations matches the parent Registration > Country value of the source Full Product Presentation.

Note: *The source Registration is not displayed.*

1. On the *Select Registration(s) under which you would like to copy Full Product Presentation* page, select one or more registrations and click Next.
2. On the *Copy Full Product Presentation Attributes* page, enter or change the attributes for the Full Product Presentation Copy.

   When entering or modifying the Copy Full Product Presentation Attributes, remember that the concatenation of

   Full Product Name, EEA Country, Language, Package Description, Authorisation Status, Authorisation/Renewal Date, and EV Code must be unique for a Registration.
3. Click Next.
4. On the *Copy Registration FPP Attachment* page:

Option	Action
If the Full Product Presentation you are copying has at least one Registration FPP Attachment assigned:	Select Yes to copy the Registration FPP Attachment data, or No to proceed without copying the Registration FPP Attachment data.
	Note: *The Yes value is selected by default.*
If the Full Product Presentation you are copying does not have any Registration FPP Attachments assigned:	The message No input is required on this page message appears.

5. Click Next.

   The *Summary* page indicates that the Full Product Presentation has been copied. If multiple registrations have been selected, the list is provided of all selected registrations displayed as License Code values, one line per each Registration.

   — The message Package Set and Package Description have been populated with the parent registration package set appears, if the values are available.

   — The messagePackage Set and Package Description have not been populated as values are absent on the parent registration package set appears, if the values are not available.

If there were any Registration FPP Attachments assigned and you selected Yes on the *Copy Registration FPP Attachment* page, the message Registration FPP Attachment(s) has been copied appears.

6. Select a reason and enter comments for the reason.
7. Click Next
8. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Registration Attachment

The Registration Attachment entity is a Printed Product Information (PPI) attachment type and should be created to later attach it to the Full Product Presentation (FPP) entity.

You can:

- **View Registration Attachment** - View previously created or modified Registration Attachment data.
- **Create Registration Attachment** - Create new Registration Attachment data.
- **Modify Registration Attachment** - Change previously created Registration Attachment data.
- **Delete Registration Attachment** - Remove previously created Registration Attachment data from the system.
- **Copy Registration Attachment** - Copy the existing Registration Attachment data.
- **Activate Registration Attachment** - Activate a previously deactivated Registration Attachment.
- **Deactivate Registration Attachment** - Deactivate an active Registration Attachment.
- Automate the inactivation of registration attachments once the corresponding acknowledgment has been received via the **XEVMPD Acknowledgement** wizard.**Note:** Verify that the following value exists in the insight.var file: xevmpd.message.import.inactivate.attachment=true

Registration Attachment Attributes

The following table shows the attributes of Registration Attachment.Using XML overrides, the system can be configured to disable the autopopulate function for one or more Registration Attachment fields, if the Attachment file is uploaded from a DMS Repository:

- Attachment Name
- File Name
- File Type
- Attachment Version

Attribute	Description
Active Flag	Identifies if the value is active or inactive. Available on *modify* and *view* pages only.
Attachment Language	Active Language Codes from the Languages values in Data Administration.
2nd Attach-ment Language	Additional Language Code to add to the attachment. Optional.
Attach	Link to the attached document.

Attribute	Description
ment Link	
Attachment Name	The name given to the document by the sender. When the valid attachment with the pdf, doc, docx, xls or xlsx extension is selected in the **Attachment Link** field, the **Attachment Name** field is automatically populated with a corresponding name. For example: Doc01. Can be updated if needed.
Attachment Version	The version of the attachment. When the valid attachment with the pdf, doc, docx, xls or xlsx extension is selected in the **Attachment Link** field, the **Attachment Version** field is automatically populated with the version of a selected document. Can be updated if needed.**Note:** The field will be auto-populated with value only if the attachment is selected from the Documentum DMS Repository.
Attachment Version Date	Version date of the attachment.
Date Submitted to EMA	The date that is automatically populated after the *Acknowledgement* Wizard passed.
EV Code	Official EV Code assigned by the EMA.

File Name	File Name of the attachment. When the valid attachment with the pdf, doc, docx, xls or xlsx extension is selected in the **Attachment Link** field, the **File Name** field is automatically populated with the corresponding name and extension. For example: Doc01.docx. Can be updated if needed. To pass the validation file extension should be present after the file name (for example **attachmen- t.pdf**), a warning message will be displayed if it is missing. The system verifies the presence of the special characters in the file name and displays a warning message if at least one of special character is entered: • \ / : * ? < > | • Non-ASCII characters
File Type	The available file types that can be selected:

Attribute	**Description**
	• **pdf** • **doc** • **docx** • **xls** • **xlsx** When the valid attachment with the pdf, doc, docx, xls or xlsx extension is selected in the **Attachment Link** field, the **File Type** field is automatically populated with the corresponding extension. For Example: docx. Can be updated if needed.
Internal Name	The Internal Company name for the Attachment. The field is a duplicate of the Attachment name value.
Last Updated Date	The date that the attachment was most recently changed. The last updated date is populated automatically.
Reason	Reason for creating, modifying or deleting a registration attachment.
Reason for Comments	Comments related to reason entered by users.

Registration Attachment Keywords	Free format text box for entering text for searching purposes. Enables you to search for the registration attachment using words from different attributes of the attachment.
Registration Attachment De	Free format text box for entering descriptive information about the registration attachment.
Attribute	**Description**
scription	
Registration Attachment Comments	The comments field for the attachment represents a box filled with the comments provided by this attachment.
Registration Attachment Add Comment	Text box for entering information or comments about the registration attachment. Comments will be stamped with the date/time/userid of the person entering the information.
Ren dition Identifier	The field appears only when the **Use Rendition** field is set to **Yes**. The values available for selection are all active rendition identifiers from **Data Administration** > **Rendition Identifier Values**. The **Standard Rendition** value is selected by default as a **Rendition Identifier**.
Use Rendition	You can use an existing rendition file from the DMS instead of the source file. The values available for selection are **Yes** and **No**, with **No** selected by default.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Create a Registration Attachment

Ennov InSight provides the ability to create a Registration Attachment that can be associated with a Full Product Presentation.

Note: All new Registration Attachments are displayed as **Active** by default.To create a Registration Attachment:

1. On the home page, go to **New** (go to step 2) or select **Create a New** from the *I Am Looking To pane* (go to step 3)
2. Select **Registration Attachment**.The *Create Registration Attachment* page appears.
3. Enter the attributes (**Attachment Name** and **Attachment Version** are required fields).**Note:** If you set the **Use Rendition** field to **Yes**, a message states that you are about to use the rendition file and you need to check if the extension type in the **File Name** and **File Type** fields is entered correctly. Click **OK** to continue.
4. Do one of the following:

Option	Action
To save the attachment:	**Save**.
To save this attachment and create another one:	**Create Another Registration Attachment**.

When the valid attachment with the pdf, doc, docx, xls or xlsx extension is selected in the Attachment Link field, the following fields are automatically updated with values:

◦ Attachment Name

◦ File Name and appropriate extension

◦ File Type

◦ Attachment Version**Note:** The Attachment Version field will be auto-populated with value only if the attachment is selected from the Documentum DMS repository.

If the selected file is not valid, then the **Attachment Name**, **File Name**, **File Type**, and **Attachment Version** are not auto-populated.

When the **File Name** field is auto-populated with a value that exceeds the limit of 200 characters, the appropriate warning message is displayed when you save the entity.

After the changes are saved with the auto-populated values and you modify the Registration Attachment, clicking **Clear** next to the **Attachment Link** field does not clear those values.

5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Modify a Registration Attachment

Ennov InSight enables you to modify the previously created Registration Attachment.

To modify a Registration Attachment:

1. On the navigation pane, select **Registration Attachments**.
2. Select from the list a Registration Attachment you want to modify and click its name.
3. On the *Registration Attachment Attributes* page, click **Modify**.
4. Modify the attributes of the registration attachment.

5. **Save**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Activate/Deactivate a Registration Attachment

You can activate a Registration Attachment to display, or deactivate a Registration Attachment to hide the value in the Attachment Name drop-down for the Registration FPP Attachment entity.

Ennov InSight does not delete a deactivated value from the database.**Note:** All newly created Registration Attachments are Active by default.To activate or deactivate a Registration Attachment:

1. On the navigation pane, select **Registration Attachments**.
2. From the list, select a Registration Attachment.
3. On the *Registration Attachment Attributes* page, click **Modify**.
4. In the **Active Flag** field, do one of the following:

Option	Action
To activate a value:	Select **Active**.
To deactivate a value:	Select **Inactive**.

5. **Save**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Delete a Registration Attachment

When a Registration Attachment entity is no longer needed, you can delete it from the system.

Note: The **Delete** icon is unavailable until Registration Attachment entity is associated to at least one Full Product Presentation.To delete the Registration Attachments:

1. On the navigation pane, select **Registration Attachments** and click the name of the attachment that you want to delete.
2. On the *Registration Attachment Attributes* page, click **Delete**.The warning message appears.
3. Select a reason and enter comments for the reason.
4. **Next**.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Copy Registration Attachments

In the *Copy Registration Attachment* wizard, you can create a registration attachment by using an existing registration attachment as a template.

Note: You must have at least Write permissions for the Registration Attachment and Full Product Presentation (FPP) in Entity Security section to copy Registration Attachments.

You can copy a registration attachments and immediately create a Registration FPP Attachment once the Full Product Presentation is selected on the appropriate page of the *Copy Registration Attachment* wizard. Or, you can copy a registration attachment and use the copied data to create a Registration FPP Attachment later.

Some fields of the source registration attachment, that are populated automatically when the *XEVMPD Submission* wizard is completed, are not copied. The following conditions apply to the copied registration attachments:

- The **Date Submitted to EMA** and **EV Code** values are automatically assigned once the *XEVMPD Submission* wizard is completed.
- The Last Updated Date value is automatically updated when you modify the copied registration attachment attributes.
- The **Attachment Language**, **2nd Attachment Language**, **File Name**, **File Type**, **Internal Name**, **Registration Attachment Keywords**, and **Registration Attachment Description** values are taken from the source attachment and can be updated manually.
- The **Attachment Link**, **Attachment Version Date**, and **Registration Attachment Add Comment** fields appear blank and can be updated with values manually.
- The **Attachment Name** and **Attachment Version** values must be added manually.
- The **Use Rendition** value is defaulted to **No**. Must be updated manually, if needed.
- The **Rendition Identifier** field appears only if the **Use Rendition** field is set to **Yes**.

Wizard Navigation The *Copy Registration Attachment* wizard consists of:

- Copy Registration Attachment Attributes
- Select Full Product Presentation(s)
- Summary

Note: In the *Copy Registration Attachment* wizard, the full product presentation entities selection is limited by full product presentations that the source registration attachment is assigned to.

Copy Registration Attachment Attributes

The following attribute descriptions can help you to enter appropriate registration attachment attribute values when copying a registration attachment in Ennov InSight .

Use the following descriptions to choose and enter registration attachment attribute values. Required information is indicated by an asterisk (*):

Attribute	Description
Attachment Language	Active Language Codes from the **Languages** values in Data Administration. The source registration attachment language value is assigned by default. The default language can be changed if required.
2nd Attach-ment Language	Additional Language Code from the **Languages** values in Data Administration. The source registration attachment language value is assigned by default. The default language can be changed if required.
Attachment Link	Link to the attached document.
Attachment Name *	The name of the source registration attachment is assigned by default. Must be updated with a new attachment name.**Note:** When the valid attachment with the pdf, doc, docx, xls or xlsx extension is selected in the **Attachment Link** field, the **Attachment Name** field is automatically populated with a corresponding name. For example: Doc01.
Attachment	The version of the attachment.**Note:** When the valid attachment with the pdf, doc, docx, xls or xlsx extension is selected in the **Attachment Link** field, the **Attachment Version** field is automatically populated

Attribute	Description
Version *	with the version of a selected document. The field will be auto-populated with value only if the attachment is selected from the Documentum DMS repository.
Attachment Version Date	Version date of the attachment.

File Name	The attachment file name from the source registration attachment. Can be updated with a new attachment file name. To pass the validation, a file extension should be added manually after the file name (for example **attachment.pdf**). With the exception of the file extension, the system also verifies the presence of the special characters in the file name and throws the warning message if at least one of them is entered: • \ / : * ? < > | • Non-ASCII characters **Note:** When the valid attachment with the pdf, doc, docx, xls or xlsx extension is selected in the **Attachment Link** field, the **File Name** field is automatically populated with the corresponding name and extension. For example: Doc01.docx.
File Type	The file type from the source registration attachment is assigned by default. Can be updated if needed. The available file types that can be selected: • **pdf** • **doc** • **docx** • **xls** • **xlsx** **Note:** When the valid attachment with the pdf, doc, docx, xls or xlsx extension is selected in the **Attachment Link** field, the **File Type** field is automatically populated with the corresponding extension. For Example: docx.
Internal Name	The Internal Company name for the Attachment from the source registration attachment. Can be updated if needed.
Registration Attachment	Free format text box for entering text for searching purposes. Enables you to search for the registration attachment using words from different attributes of the attachment. The source registration attachment keywords are assigned by default. Can be updated if needed.
Attribute	**Description**
Keywords	

Registration Attachment Description	Free format text box for entering descriptive information about the registration attachment. The source registration attachment description is assigned by default. Can be updated if needed.
Registration Attachment Add Comment	Text box for entering information or comments about the registration attachment. Comments will be stamped with the date/time/user id of the person entering the information.
Ren dition Identifier	The field appears only when the **Use Rendition** field is set to **Yes**. The values available for selection are all active rendition identifiers from **Data Administration** > **Rendition Identifier Values**. The **Standard Rendition** value is selected by default as a **Rendition Identifier**.
Use Rendition	You can use the existing rendition file instead of the source file. The values available for selection are **Yes** and **No**, with **No** selected by default.

Copy a Registration Attachment

Use this procedure to copy a registration attachment. Depending on your selections, you have the ability to immediately create a Registration FPP Attachment using the *Copy Registration Attachment* wizard.

To copy a registration attachment:

1. On the navigation pane, select **Registration Attachments**.
2. Select a Registration Attachment that you want to copy and click its name.
3. On the *Registration Attachment Attributes* page, click **Copy**.
4. On the *Copy Registration Attachment Attributes* page, enter, modify, or select the attributes for the registration attachment copy.If you set the **Use Rendition** field to **Yes**, the message appears stating that you are about to use the rendition file and you need to check if the extension type in the **File Name** and **File Type** fields is entered correctly. Click **OK** to continue.
5. Click **Next**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	a. Select a reason and enter comments for the reason. b. Select Save. c. Validate your identity by entering your user credentials in the dialog box.

1. On the *Select Full Product Presentation(s)* page, select a full product presentation to which you want to associate a registration FPP attachment. You can select none, one, or multiple Full Product Presentations.**Note:** The entities available for selection are limited by the full product presentations that the source registration attachment is assigned to.

2. Click **Next**.
3. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Registration FPP Attachment

The Registration Full Product Presentation Attachment entity is required by the European Medicines Agency (EMA) for XEVMPD schema support.

A least READ permission is required for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security, to view Full Product Presentation. Ennov InSight enables you to view, create, modify, and delete the Registration Full Product Presentation Attachment.

You can:

- **View Registration FPP Attachment** - View a previously created or modified entity.
- **Create Registration FPP Attachment** - Create a new Registration Full Product Presentation Attachment entity.
- **Modify Registration FPP Attachment** - Change previously created entity data.
- **Delete Registration FPP Attachment** - Remove previously created data from the system.

Actions that can be performed from the *Registration Full Product Presentation Attachment attributes* page:

- **Modify**
- **Delete**
- **Copy URL**

Note: The file extension is populated manually in Data Administration, and Administrators can modify the file name in Data Administration.

Create a Registration FPP Attachment

Ennov InSight provides the ability to create a Registration FPP Attachment for a Full Product Presentation Entity.

You must have at least at least Write privileges for Product Detail Management (PDM) and Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security to create the Registration FPP Attachments.

To create a Registration Full Product Presentation Attachment:

1. On the *Full Product Product Presentation attributes* page, click the **Create Registration FPP Attachment** icon.
2. On the *Create Registration FPP Attachment* page:

Option	Action
To find the Registration Attachment:	Launch the *Registration Attachment Selection* list by clicking **Select** next to the **Attachment Name** > **Selected** box.The search results page displays all Active Registration Attachments available in the system. You can search by **Internal Name**, **Attachment Language**, **2nd Attachment Name** (optional), **Attachment Name**, and **Attachment Version**.**Note:** The registra- tion attachments, already associated to the current *Full Product Presentation*, are not dis- played.
For the Full Product Presentation:	Select the Registration Attachment and **Save**.**Note:** Only one registration attachment can be selected.The selected Registration Attachment will be displayed in the **Attachment Name** > **Selected** box in the concatenation of four fields: ◦ **Internal Name** ◦ **Attachment Language** ◦ **2nd Attachment Language** (optional) ◦ **Attachment Name** ◦ **Attachment Version**
Optional:	Select **Validity Declaration**, **Attachment Concerned Parties** and enter the **Registration FPP Attachment Comments**.

3. **Click Save**. If Registration Attachment is not selected, a message appears and the Registration FPP Attachment is not created.The *Registration FPP Attachment* page appears.

Modify a Registration FPP Attachment

Ennov InSight enables you to modify the previously created Registration FPP Attachment. You need at least READ permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security to modify the Registration FPP Attachment entity.

To modify a Registration FPP Attachment:

1. On the *Full Product Presentation attributes* page, click the name of the Registration FPP Attachment that you want to modify.
2. On the *Registration FPP Attachment* page, click **Modify**.

3. On the *Modify Registration FPP Attachments attributes* page, select the **Validity Declaration** from the menu and add or modify Registration FPP Attachment Comments. The rest of the fields are populated automatically.
4. **Save**. **Note:** You can only modify the Validity Declaration and Registration FPP Attachment Comments attributes for the Registration FPP Attachment entity.The *Registration FPP Attachments* page appears.

Delete a Registration FPP Attachment

When a Registration FPP Attachment entity is no longer needed, you can delete it from the system.

You need at least Read permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security to delete the Registration FPP Attachment.To delete the Registration Full Product Presentation Attachments:

1. On the *FPP attributes* page, click on the name of the Registration FPP Attachments that you want to delete.
2. On the *Registration FPP Attachments* page, click **Delete**.
3. On the warning message that appears, click **OK**.
4. On the message confirming that the data has been deleted, click **OK**.The *Full Product Presentation Attributes* page appears. If there is a URL in the system that pointed to the Registration FPP Attachment record that was deleted, a message appears when an attempt is made to launch that URL.

Registration FPP Attachment Attributes

You create a Registration FPP Attachment for a Full Product Presentation (FPP) to include any attached data in the XEVMPD submission for the European Medicines Agency (EMA).

The following attributes describe the specific Registration FPP Attachment for a Full Product Presentation.

Attribute	Description
Application Code	Agency-identified application number (or identifier). May not be known until the time of submission. Therefore, this can be the same as the internal code.

Attribute	Description
Application Name	The name of the application.
Attachment Name	On the *Create Registration FPP Attachment* page, Attachment Name launches the *Registration Attachment Selection* list that displays all Active Registration Attachments that are available in the system and are not associated to the current Full Product Presentation. **Attachment Name** is a concatenation of five fields: **Internal Name** + **Attachment Language** + **2nd Attachment Language** + **Attachment Name** + **Attachment Version**.**Note:** On the *Modify Registration FPP Attachment* page, the Attachment Name field is display only.

Autho risation/Renewal Date	The date when the first authorisation was granted by the authorising body or the date when the renewal was granted.
Full Product Name	The full name of the product. For example: DrugLV Filmtabletten
Full Product Short Name	The short name of the product. For example: DrugLV
License Code	The code assigned by the regulatory agency. Current value from Package Set Registration.
MAH/ Organisation	The company to which a license is issued to market the product. Current value from Package Set Registration in concatenation of MAH/Development Sponsor/Organisation Name + Address + City + Country Code.
Package Description	A brief package description of the pack size(s) corresponding to the referenced authorisa- tion number.
Product Company Name	Part of the medicinal product name without any other designations such as trade mark, strength, or pharmaceutical form.
Attribute	**Description**
Product INN/ Common Name	International non-proprietary name. The part of the Full Presentation Name.

Registration FPP Attachment Comments	Comments for the Registration FPP Attachment. Available for modifications on the Create/Modify *Registration FPP Attachment Attributes* pages.
Registration FPP Attachment Concerned Parties	Contains email addresses and User IDs for which Notifications can be sent. Concerned parties are anyone who might be copied on notifications about this entity. Use semi-colons (;) to separate e-mail addresses.
Validity Declaration	Validity confirmation that the referenced attachment is the latest version of the documentation. The **Validity Declaration** field is automatically updated once the *XEVMPD Acknowl- edgement* Wizard passes. The automatically assigned value is Previous Copy was sent (1), if: • The Registration FPP Attachment is associated to the acknowledged Authorised Product. • The Registration FPP Attachment is created from a Registration Attachment that was previously acknowledged.
XEVM PD License Code	The current XEVMPD License Code from the Full Product Presentation entity.

FPP Pharmaceutical Products

As a part of the data model changes FPP has now updated with the Pharmaceutical Products. Pharmaceutical Products are associated to Full Product Presentation (FPP) to gather the ingredient data for XEVMPD at a Pharmaceutical Products level.

You should have at least READ permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Full Product Presentation permissions under Entity Security.

Only the Pharmaceutical Products that corresponds to the selected Package Sets are available for selection on the *Full Product Presentation* page.

Associate a Pharmaceutical Product

Associate pharmaceutical products to Full Product Presentation to gather the ingredient data for XEVMPD at a Pharmaceutical Products level.

You must have at least at least Write privileges for Product Detail Management (PDM) and Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security to associate pharmaceutical products.To associate a pharmaceutical product:

1. On the *Full Product Presentation Attributes* page, click **Pharmaceutical Products** tab.
2. Click the **Associate/Disassociate Pharmaceutical Product** icon.The *Associate/Disassociate Pharmaceutical Product* page appears.
3. On the *Associate/Disassociate Pharmaceutical Product* page, select the **Pharmaceutical Products** value.
4. **Save**.The newly associated pharmaceutical products are displayed under the **Pharmaceutical Product** tab on the *Full Product Presentation Attributes* page.

Disassociate a Pharmaceutical Product

You can disassociate pharmaceutical products that are not required for the Full Product Presentation.

You must have at least at least Write privileges for Product Detail Management (PDM) and Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security to disassociate pharmaceutical products.To disassociate a pharmaceutical product:

1. On the *Full Product Presentation Attributes* page, click **Pharmaceutical Products** tab.
2. Click the **Associate/Disassociate Pharmaceutical Product** icon.The *Associate/Disassociate Pharmaceutical Product* page appears.
3. On the *Associate/Disassociate Pharmaceutical Product* page, select the Pharmaceutical Products value you want to cancel the selection for, and click **Deselect**.
4. **Save**.

FPP Previous EV Code

The Previous EV Code value may be used to specify any EV Codes. If applicable, it can be used by the European Medicines Agency (EMA) for XEVMPD schema support.

You should have at least READ permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Full Product Presentation permissions under Entity Security.

Ennov InSight enables you to:

- **View FPP Previous EV Code** - View a previously created or modified entity.
- **Create FPP Previous EV Code** - Create a new FPP Previous EV Code entity.
- **Modify FPP Previous EV Code** - Change previously created entity data.
- **Delete FPP Previous EV Code** - Remove previously created data from the system.

Actions that can be performed from the *FPP Previous EV Code attributes* page:

- **Modify**
- **Delete**
- **Copy URL**

Create the FPP Previous EV Code

Ennov InSight provides the ability to create the FPP Previous EV Code for a Full Product Presentation Entity.

You must have at least at least Write privileges for Product Detail Management (PDM) and Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security to create the FPP Previous EV Code.

To create the FPP Previous EV Code:

1. On the *Full Product Presentation Attributes* page, navigate to the FPP Previous EV Codes tab and click the **Create Previous EV Code** icon.
2. On the *Create FPP Previous EV Code* page, enter the Previous EV Code value. You can enter up to 60 characters in the Previous EV Code field.
3. **Save**. The FPP Previous EV Code Attributes page appears.

Modify the FPP Previous EV Code

Ennov InSight enables you to modify the previously created FPP Previous EV Code value.

You need at least READ permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security to modify the FPP Previous EV Code value. To modify the FPP Previous EV Code:

1. On the *Full Product Presentation Attributes* page, navigate to the FPP Previous EV Codes tab and click the name of the FPP Previous EV Code that you want to modify.
2. On the *FPP Previous EV Code Attributes* page, click **Modify**.
3. On the *Modify FPP Previous EV Code Attributes* page, modify the Previous EV Code Value.
4. **Save**. The *FPP Previous EV Code Attributes* page appears.

Delete the FPP Previous EV Code

When the FPP Previous EV Code value is no longer needed, you can delete it from the system.

You need at least Read permissions for Product Detail Management (PDM), Registration Planning and Tracking (RPT) licenses, and Full Product Presentation Entity Security to delete the FPP Previous EV Code.To delete the FPP Previous EV Code:

1. On the *Full Product Presentation Attributes* page, navigate to the FPP Previous EV Codes tab.
2. Click the FPP Previous EV Code link of the entity that you want to delete.
3. On the *FPP Previous EV Code Attributes* page, click **Delete**.

4. On the warning message that appears, click **OK**.
5. On the message confirming that the data has been deleted, click **OK**.The *Full Product Presentation Attributes* page appears. If there is a URL in the system that pointed to the FPP Previous EV Code record that was deleted, a message appears when an attempt is made to launch that URL.

FPP Previous EV Code Attributes

You create a Previous EV Code for a Full Product Presentation (FPP) to include it in the XEVMPD submission for the European Medicines Agency (EMA).

The following attributes describe the FPP Previous EV Code for a Full Product Presentation.

Attribute	**Description**
Application Code	Application to which the combination of Registration, Package Set and Country is associated. Appears as a hyperlink to the parent Application.
Application Name	Application to which the combination of Registration, Package Set and Country is associated. Appears as a hyperlink to the parent Application.
Autho risation/Renewal Date	The date when the first authorisation was granted by the authorising body or the date when the renewal was granted. The value is populated by the system and appears as a display-only.
EEA Country	The EEA Country of the Full Product Presentation if the Application has one of EU CP Types (Centralised Procedure).The value is populated by the system and appears as a display-only.
Full Product Name	The full name of the product. Appears as a hyperlink to the parent Full Product Presentation.
Full Product Short Name	The short name of the product. The value is populated by the system and appears as a display-only.
License Code	The code assigned by the regulatory agency. License code to which the combination of Registration, Package Set and Country is associated Appears as a hyperlink to the parent Registration.

Attribute	Description
MAH/Organisation	The company to which a license is issued to market the product. Current value from Package Set Registration in concatenation of MAH/Development Sponsor/Organisation Name + Address + City + Country Code.The value is populated by the system and appears as a display-only.
Package Description	The list of Package Set descriptions tied to Registration.The value is populated by the system and appears as a display-only.
Package Sets	The list of Package Set names tied to Registration.The value is populated by the system and appears as a display-only.
Previous EV Code *	The previous EV code of the Authorised Product, if applicable. Appears as a text field. You can enter up to 60 characters for the previous EV code value.
Product Company Name	Name of the company, trademark, or manufacturer, if it is part of the Full Product Name (SmPC Name).The value is populated by the system and appears as a display-only.
Product INN/ Common Name	The generic name, if it is part of the Full Product Name (SmPC Name).The value is populated by the system and appears as a display-only.

Chapter 24. Notifications

This section describes how to create, modify and view notifications.

Note that notifications are specific to the following Ennov InSight modules:

- Registration planning and tracking (RPT)
- Submission planning and tracking (SPT)

Notifications trigger e-mails or alerts in the Alert center, based on changes that occur in Ennov InSight . You can create global notifications for all instances of the entity matching the criteria, or you can create notifications for specific instances of entities.

Notifications can be associated with the following entities:

- Product Family
- Product
- Product Component
- Manufactured Item
- Pharmaceutical Product
- Application
- Event
- Event-Country
- Sequence
- Registration
- Medicinal Product
- Medicinal Product Action
- Full Product Presentation
- Registration FPP Attachment
- Reference
- Task
- Project

Note: When creating a notification for an event country, you can create notifications for the event country or the eventcountry status schedule.

You can also create a notification for the **XEVMPD Acknowledgement Import.** This notification can be created using **Home Page** > **Wizards** > **Create Notification**functionality only. For more information about XEVMPD Acknowledgement Import notification see *Creating a Notification* topic.

Notification Specifications

Creating a notification will produce a notification specification in the system.

This is a set of predefined criteria used to create notifications automatically when the criteria in the specification is met. Notification specifications apply to all instances of the associated entity that satisfy the criteria mentioned in the specification. For example, if the specification is for product families, it applies to all product families that meet the specification criteria. Alternatively, a notification, whether created automatically by Ennov InSight or with the *Create Notification* wizard, applies only to the instance of the entity with which it is associated.

Notification Types

Different notification types are used to notify users of various events that occur when working with applications. A

notification can be triggered when the following occur:

- A value changes - A notification is sent to specified users when the value for the attribute you choose in the wizard is modified.
- A status changes to a specific value - A notification is sent to specified users when a status value is changed to the status you choose in the wizard. If you want to create a notification for an event-country status change, you must select the event-country status schedule as the descendant in the wizard. It is the event-country status schedule that tracks status changes for events.**Note:** When a notification for **When a value changes** is created for the EudraCT number on a CTA application, the field label on the notification is the **Application Code** rather than the **EudraCT Number**.
- A date approaches or passes - A notification is sent when a date you choose in the wizard is approaching or has passed. You can also have the notification sent repeatedly for the specified number of days.
- A new record is created - This is a global notification by default. This option is not available for specific instances of entities.

Notes Concerning Notification Types

For date-based notification types, Ennov InSight uses GMT (Greenwich Mean Time) and sends an e-mail only if GMT matches the criteria set in the notification. This happens for both the automated check that occurs every day (which is the same time the server was started) and when you click **Check for Date Based Notifications** on the *Notification Specifications* page under data administration.

Concerned Parties

Concerned parties (on the *Mail Settings* page) comprise e-mail addresses, user IDs, and groups to which an e-mail should be sent when a notification is triggered.

You can include concerned parties associated with any entity that falls in the hierarchy of the entity for which you are creating the notification. The e-mail addresses/user IDs/groups are not displayed in the selection list.

For example, if the notification is associated with a task and the parent/associated entity you select in the wizard is product family, the list of concerned parties includes the following: task concerned parties and product family concerned parties.

If the notification is associated with an event entity, the list of concerned parties includes the following: event concerned parties, application concerned parties, and product family concerned parties.

Chapter 25. Tasks and Sub-tasks

You can use tasks for many different reasons in Ennov InSight . You can track requests, help users follow processes for getting things done, and set up reminders when performing planning and tracking activities.

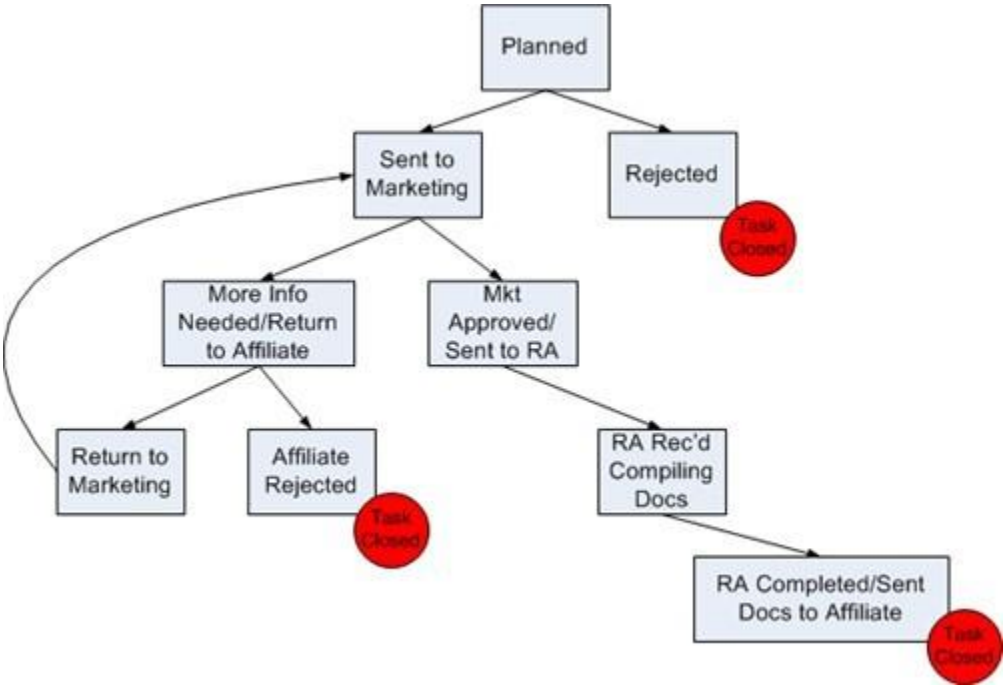
Tasks can identify correspondence response needs, periodic reporting requirements, data review, or maintenance requirements and other system needs.

You can associate tasks with any of the following entities:

- Product Families
- Products
- Pharmaceutical Products
- Manufactured Items
- Applications
- Registrations
- Medicinal Products
- Medicinal Product Action
- Events
- Sequences
- References
- Projects
- Workflows
- Change
- Change Details

Sub-tasks are associated with tasks or sub-tasks. These allow major tasks to be divided into smaller, more manageable tasks.

Your data administrator may set up task statuses in such a way that they help users understand the progression that specific types of tasks may take. We refer to this as task status progression. When a task status progression has been set up, Ennov InSight lets you choose from the statuses that have been defined as appropriate when moving from the current status. The following illustrates an example of a task status progression named Marketing Approval Required.



As this example illustrates, Ennov InSight displays only the statuses to which you can progress. For example, a task with a Planned status can progress only to the Send to Marketing status or to the Rejected status. These are the only statuses available when you modify the task status.

If your administrator has not set up a task status progression, you can choose from any of the available statuses when you modify the task.

Tasks are specific to the following Ennov InSight modules:

- Registration planning and tracking (RPT)
- Submission planning and tracking (SPT)

For Tasks Statuses, the order of the statuses is determined by the actual date. In cases where more than one status has the same actual date, the statuses will be ordered based on the creation date of the status row. For example, if the task status 'Open' exists and then the statuses 'Archived' and 'Closed' are added in that order, they appear in that same order in the Status Date tab.

Create a Task

You can set up tasks to track your work, including requests, help users follow processes for getting things done, and set up reminders when performing planning and tracking activities.

You must have the appropriate security privileges to create a task.

To create a task:

1. Click a link for the entity to which you want to add a task.
2. On the **Tasks** tab, click **Create**.The *Create Task* page appears.
3. Enter the attributes.
4. **Save**.

Create a Sub-task

You can create sub-tasks to break major tasks into smaller, more manageable tasks. Sub-tasks can be associated with tasks or other sub-tasks.

You must have the appropriate security privileges to create a task.

To create a sub-task:

1. Click a link for the task to which you want to add a sub-task.The *View Task* page opens.
2. On the **Sub-Tasks** tab, click **Create**.The *Create Task* page appears.
3. Enter attributes.
4. **Save**.

View Tasks and Sub-tasks

You can view a task to see the attributes, and take action on the task. The information displayed on the *View Task* page depends on the entity associated with the task or sub-task.

To view a task or sub-task:

1. Open the *View Task* page by doing one of the following:
   - On the *home* page, click **My Tasks** and click a link for a task for which you are the primary assignee or the assigner.
   - Navigate to the attributes page of any entity associated with a task, click **Tasks** or **Sub-Tasks** and click any link for a task or sub-task.
2. Do any of the following:

Option	Action
To modify the task attributes:	Click **Create**.
To delete the task or sub-task:	Click **Delete**.
To copy the task URL to the Clipboard:	Click **Copy URL**. A message confirms the URL has been copied.
To copy a task and associated sub-tasks:	Click **Copy**.
To move a task and associated sub-tasks:	Click **Move Task**.

To update tasks using the *Update Task* wizard:	Click **Edit**.	
Option		**Action**
To add, modify, view, or delete sub-tasks associated with the task:	Click **Sub-Tasks**.	
To add, modify, view, or delete references associated with the task:	Click **References**.	
To add, modify, view, or delete notifications associated with the task:	Click **Notifications.**	

Update Tasks and Sub-tasks

You can update the attributes for tasks and sub-tasks at one time.

You can perform this procedure if you have WRITE privileges for the task entity and you are the assignee or assigner of the task, or if you have Administrator privileges.

To modify tasks and sub-tasks:

1. Navigate to the entity that has the associated task that you want to modify.
2. On the entity's attribute page, click **Tasks**.
3. Click the task name link for the task you want to modify.The *View Task* page appears.
4. Click **Edit**.The *Update Task* wizard opens to the *Select Tasks and Sub-Tasks* page, listing the task from which the wizard was launched with its associated sub-tasks.
5. Select one or more tasks and sub-tasks.
6. Click **Next**.The *Update Task Attributes* page appears.
7. Modify one or more task attributes by clicking the check box next to the attribute field and then specifying a value. With regard to the task attribute fields:

Option	**Description**
If you select a check box and leave the associated field blank:	The attribute will be updated with a blank value.
If you select a check box for a field marked by an asterisk:	the wizard will require a selection in the associated field:

8. Click **Next**.A confirmation page describes the actions that will be taken.
9. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	**Steps**
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next**.The *Summary* page confirms the actions taken.
2. Click **Finish**.Upon completion, you are returned to the *View Task* page for the task that you just updated.

Move Tasks and Sub-tasks

You can move a task or sub-task from any entity to an event. Ennov InSight moves the selected source task or source sub-task and all associated sub-tasks with any associated references and notifications to the selected event.

Note: You must have at least READ permission for the application country to perform this procedure. You cannot move a task or sub-task to a closed event. To move a task or sub-task:

1. Navigate to the task or sub-task that you want to move.The *Task Attributes* page appears.
2. On the *Task Attributes* page, click **Move Task**.The *Move Task* wizard opens to the *Task Destination* page.
3. Select a destination for the task or sub-task.
4. Click **Next**.The *Enter Event Search Criteria* page appears.
5. Select a product family type.
6. Select the product.
7. Select the application.
8. Click **Next**.The *Select Event* page opens, listing all applications with open events that meet the criteria selected in step 5.
9. Select the destination event.
10. Click **Next**.A confirmation page opens, describing the action that will be taken.
11. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next**.The *Summary* page confirms the action.
2. On the *Summary* page, click **Finish**.You are returned to the view from which you invoked the *Move Task* wizard. Upon completion, the selected task or sub-task is moved to the selected destination event and removed from the source entity.

Copy a Task and Associated Sub-tasks

If you have WRITE privileges for tasks, you can copy a task and its sub-tasks.

Use this procedure to copy a task and all of its sub-tasks to:

- The same Ennov InSight entity
- Itself as a sub-task of the source task
- Other open events for which you have at least READ privileges to the related application country

To copy a task:

1. View the entity that has the associated task you want to copy.
2. On the entity attribute page, click **Tasks**.
3. Click the link for task you want to copy. The **View Task** page appears.
4. Click **Copy**.The *Copy Task* wizard opens to the *Task Destination* page.
5. In the **Destination** drop-down list, select one of the following:

Action	Description
Same As Source	Creates a sibling task for the same entity. After clicking **Next,** the wizard displays a mes- sage indicating that no further input is necessary. Proceed to step 10.
As Sub-Task of Source Task	Copies a task to itself as a sub-task. After clicking **Next,** the wizard displays a message in- dicating that no further input is necessary. Proceed to step 10.
Event	Copies the task to different event, and then proceed to step 6.

6. Click **Next**.The *Enter Event Search Criteria* page appears.
7. On the *Enter Event Search Criteria* page, select values to refine the search for a destination event.
8. Click **Next**.The *Select Event* page appears.
9. Select one event as the destination for the copied task.
10. Click **Next**.The first *Task Attributes* page appears.
11. Do the following:

Field/ Option	Description
Task Name	Specify the name you want for the copied task. This applies only to the parent task, not to any sub-tasks.
Task Status Date	You can change the date from the date set for the original task, if needed.

Task Attributes	Specify the optional attributes that you want to be copied with the task. By default, none of the optional attributes are copied.
Field/ Option	**Description**
Copy Task and Secondary Task Type	If you want to copy the task type and secondary task type to the destination task. On selecting this option, the **Copy Task Status Schedule** option appears.
Copy Task Status Schedule	Copies the task status schedule from the source task and sub-tasks to the destination task and sub-tasks. Only the statuses and projected dates are copied. Actual dates are not copied. This option is available only when **Copy Task and Secondary Task Type** is selected.
Copy All Sub-Tasks	Copies all sub-tasks associated with the original task to the destination task.
Copy All References	Copies the references from the source task and sub-task to the destination task
Number of Copies	Enter the number of times you want the task copied. The default is 001, but you can choose as many as 50 copies.
Task Name Starting Number	Determines the first number the wizard will use to assign identifiers for each of the copied tasks. For example, if you choose to make two copies of a task and use 005 as the starting number, the task name of the first copy will be appended with 005 and the second as 006.

12. Click **Next**.The second *Task Attributes* page appears. If you selected **Copy Task and Secondary Task Type** on the previous page, the wizard displays a message indicating that no input is needed on that page.
13. If you did not choose that **Copy Task and Secondary Task Type**, do the following:

Task	**Description**
Select a **Task Type**	To further identify the task. This setting is optional.
Select a **Secondary Task Type**.	This setting is optional.

14. Click **Next**.The *Select Primary Assignee* page is displayed.
15. Select one of the following:

Action	Description
Copy from the Source Task	The primary assignee for the destination task and sub-tasks is the same as the primary assignee for the source task and sub-tasks.
Set to Person Performing the Copy	The primary assignee for the destination task and sub-tasks is set to the user performing the copy.
Select from a List of Active InSight Users	After clicking **Next**, you are presented with a drop-list all active Ennov InSight users. Select a user as the primary assignee for the task and sub-tasks from that list.

16. Click **Next**.The wizard displays a confirmation message based on your selections. At this stage, you can still go back to previous screens to change your selections.
17. Choose the applicable procedure in the table below to enter an electronic signature in wizards:

Scenario	Steps
When electronic signature is enabled	a. In the confirmation page, select a reason and enter comments for the reason. b. Click **Next**. c. Validate your identity by entering your user credentials in the dialog box.

1. Click **Next**.The wizard displays a message summarizing the actions taken.
2. Click **Finish**.Upon completion, you are returned to the *View Task* page of the source task that you copied.

Delete a Task or Sub-task

Use this procedure to delete a task or a sub-task.

If necessary and you have the proper permissions, you can delete a task or sub-task.**Note:** Only an administrator can delete a task or sub-task that has no sub-tasks, references or notifications associated with it. The person who created the task cannot delete it.

To delete a task or sub-task:

1. Navigate to a task or sub-task you want to delete.
2. Click **Delete**.
3. Select a reason and enter comments for the reason.

4. Click **OK**.
5. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Projected Status Dates for Tasks

The Registration Planning and Tracking and the Submission Planning and Tracking license modules for Ennov InSight enable you to add and modify projected status dates for a task or sub-task.

When you add a projected status date, you set up an action that is scheduled to occur on a specific date. For example, you might want to add the date you plan to approve a task that has a current status of planned.

Task Attributes

You can use the attributes to help you track and complete your work.

Attribute	Description
% Com plete	The percentage that indicates how much of the task or sub-task has been completed.
Action/Resolution	The action required to perform the task or sub-task.
Actual Effort	The number of days it took to complete the task or sub-task.
Task Add Comment	Comments you want to share with others in a discussion thread. Stamped with the date and time you enter the information and your user ID.
Alternate Assignee	The name of the secondary person responsible for performing the task or sub-task.
Assigner	The person who assigned the task or sub-task. Only active users are available for selection. The inactive or disabled users are omitted from the lists of available values.
Comments	Comments that have been added for the task or sub-task. Available when you modify the task or subtask.

Com pleted	Identifies whether the task or sub-task has been completed.
Concerned Parties	Users who may receive notifications about this entity. Use semi-colons (;) to separate e-mail addresses.
Current Status	The current status of the task or sub-task.
Due Date	When the task or sub-task is due to be completed.
Entity Association	The type of entity to which the task or sub-task is associated.

Attribute	**Description**
Entry Date	The date the task or sub-task was created.
Estimated Effort	The number of days you estimate it will take to complete the task or subtask.
Last Changed Date	The date the task was last modified. Displayed when you view and modify the task or subtask.
Modify Current Status To	The next step to which the task status should progress.
New Status Date	If you choose a value for Modify Current Status to, this is the date the new status becomes effective.

Primary Assignee	The person responsible for performing the task or sub-task. Only active users are available for selection. The inactive or disabled users are omitted from the lists of available values.
Priority/Impact	The priority assigned to the task or sub-task.
Reason	Reason for creating, modifying or deleting a task.
Reason for Comments	Comments related to reason entered by users.
Related Task Name	Enables you to identify the association between the parent Task and its Sub-Task. When a Task has an associated Sub-Task entity, the **Related Task Name** field for the Sub-Task will be automatically populated with the parent Task Name value. The value is hyperlinked. When selected, navigates you to the appropriate Task Attributes page. The field appears as empty for the parent Task entity.
Secondary Task Type	Information that further identifies the task or sub-task type.

Attribute	**Description**
Task Association	The name of the entity to which the task or sub-task is associated.
Task ID Number	This is an auto-generated identification number that the system assigns to a task when the task is created, and the ID number is displayed as a read-only attribute on the *Modify Task* and *View Task* pages.
Task Name	The name for the task or sub-task. The task name must be unique within its parent entity.
Task Concerned Parties	The e-mail addresses, Insight Manager user IDs, or both for users to whom Ennov InSight can send notifications. Only active users are available for selection. The inactive or disabled users are omitted from the lists of available values.
Task Description	A description of the task or sub-task.

Task Keywords	Words you can use to search for the task or sub-task.
Task Status	The current status of the task.
Task Status Date	One of the following: • If you do not choose a value for **Modify Current Status To**, the date when the current status became effective. • If you choose a value for **Modify Current Status To**, the date the new status becomes effective.
Task Type	The type of task or sub-task.
Updated By	The user who updated the task or sub-task.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Chapter 26. References

References support affiliate and regulatory correspondence tracking activities by allowing DMS or file system content to be associated with system entities like product families, applications, events, sequences, and tasks.

References are pointers to external sources of information, such as documents or external URLs. They may also be used to associate internal URLs with major entities.

You can create references for any of the following entities:

- Product families
- Products
- Pharmaceutical Products
- Manufactured Items
- Projects
- Applications
- Events
- Sequences
- Registrations
- Medicinal Products
- Medicinal Product Action
- Tasks
- Submission Plans
- Change
- Change Details

References also support correspondence other than official regulatory content sent to the regulatory agency (for example, sequences). References can include telephone communication, dispatches of information to affiliates, or approval letters received from the authority.

References are specific to the following Ennov InSight modules:

- Registration Planning and Tracking
- Submission Planning and Tracking

Create a Reference

You can create references for the entities in Ennov InSight. The references are specific to the Registration Planning and Tracking (RPT) and Submission Planning and Tracking (SPT) modules.

Note: You must have the appropriate security privileges to create a reference. To

create a reference:

1. Navigate to the entity for which you want to create a reference.The attributes page for the entity appears.
2. Click **References**.
3. Click **Create**.
4. On the *Create Reference* page, enter or select the reference attributes. When selecting an assembly reference type and using the **Show** option, be sure to click the root of the assembly before clicking **OK**.
5. **Save**.
6. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Create an Assembly Reference Type

When creating an assembly reference type, follow the procedure to create a reference, be sure to follow the caution below about working with the assembly in the *Show* view.

- When creating a **Reference Link** of the **Assembly** reference type, the **Browse** option enables you to locate and select the target assembly for the reference.
- In the **Browse** dialog box, the **Show** button enables you to view all of the parts of the assembly. Do not select any parts within the assembly. Select only the assembly.
- When using the **Show** button functionality, click the root of the assembly before clicking **OK**.

Reference Attributes

The attributes and their descriptions enable you to choose and enter the appropriate attribute values while creating references.The following conditions apply while defining the links:

- When creating a URL link, the link must begin with the http://prefix.
- When creating a DMS link, you cannot target a folder. You must link to a file in a file system or DMS.
- You must be logged in to Documentum before hyperlinks to Documentum content will work.

Attribute	Description
Action	The name of the item created as a result of the correspondence.
Action Link	The link to the item; click Select to locate and choose the action.
Action Link Type	The type of entity associated with the link (assembly, DMS, or URL).
Content	The content for the reference.

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Attribute	Description
Entity Association	The type of entity the reference is associated with.
Entity Name	Name of the entity for which you are creating the reference.
Family Code	The code of the product family which this reference is associated.
Family Name	The name of the product family which this reference is associated.
Origination	The correspondence associated with the reference.
Origination Link	The link to the correspondence; click Select to locate and choose the correspondence.
Origination Link Type	The type of entity associated with the link (assembly, DMS, or URL).
Participant	The person who the reference is from or for.
Reason	Reason for creating, modifying or deleting a reference.
Reason for Comments	Comments related to reason entered by users.
Reference Add Comment	Comments you want to share with others in a discussion thread; stamped with the date and time you enter the information and your user ID.
Reference Comments	The discussion thread that includes all comments entered by users; includes the date and time the comments were entered and the user ID of the person who entered them. Comments are displayed when you modify the entity.

Reference Concerned Parties	Users who may be copied on notifications about this entity. Use semi-colons (;) to separate e-mail addresses.
Reference Description	The description of the reference.
Reference Keywords	Words you can use to search for the reference.
Reference Link	The link to the reference; click Select to locate and choose the reference.

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Attribute	**Description**
Reference Link Type	The type of entity associated with the link (assembly, DMS, or URL).
Reference Name	Name of the reference. The reference name must be unique within its parent entity.
Reference Status	The status of the reference.
Reference Status Date	The date the reference status is effective.
Type	The type of reference you are creating.
User ID	The user name to validate user identity.
Password	The user password to validate user identity.

Modify a Reference

You can modify a reference to make changes in the selection of attributes and the attribute values of that reference.

Note: The attributes you can modify depend on your security privileges.

To modify a reference:

1. Go to the entity associated with the reference you want to modify.The attributes page for the entity opens.
2. Click **References**.
3. Click the reference name link.
4. On the *View Reference* page, click **Edit** .
5. On the *Edit Reference* page, enter or select your changes.
6. **Save**.
7. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

View a Reference

On the *View Reference* page, you can view the created references and perform actions like add, delete, and copy the reference URL.

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To view a reference:

1. Go to the entity associated with the reference you want to view.
2. On the attributes page for the entity, click **References**.
3. Click the reference name link.
4. On the *View Reference* page, do any of the following:

Option	Action
To modify the reference:	Click **Edit**.
To delete the reference:	Click **Delete**.
To copy the reference URL to the Clipboard:	Click **Copy URL**. A message confirms the URL has been copied.

Delete a Reference

You cannot delete a reference if the reference has associated entities other than a task.

To delete a reference:

1. Navigate to the entity from which you want to delete a reference. The attributes page for that entity opens.
2. Click **References**.
3. Click the link for the reference you want to delete.
4. Click **Delete**.
5. Select a reason and enter comments for the reason.
6. Click **Next**.
7. Choose the applicable procedure to enter an electronic signature for entities:

Scenario	Steps
When electronic signature is enabled	1. Select a reason and enter comments for the reason. 2. Select Save. 3. Validate your identity by entering your user credentials in the dialog box.

Chapter 27. Projected Status Dates

When you add a projected status date, you set up an action that is scheduled to occur on a specific date.

The Registration Planning and Tracking and the Submission Planning and Tracking license modules for Ennov InSight enable you to add and modify projected status dates for sequences and tasks.

Add a Projected Status Date

You add a projected status date to set up an action that is scheduled to occur on a specific date.

To add a projected status date:

1. Click the link for the sequence or task for which you want to add a projected status date.
2. On the **Status Dates** tab, click **Add Status**.
3. On the *Add Status* page, choose a status and projected date.
4. In the **Add Comment** field, include the reason for the status change, if necessary.
5. **Save**.

Projected Status Date Attributes

The attributes and the descriptions enable you to choose and enter the appropriate attribute values for sequences or tasks while adding Projected Status Date.

Sequences

The table lists all attributes that are available for sequences while adding Projected Status Date.

Attribute	**Description**
Application Code	Agency-identified application number (or identifier); may not be known until submittal time, therefore it may be the same as the internal code.
Application Name	The name of the application.
Family Code	The code for the product family associated with the application.
Family Name	The product family associated with the application.
Sequence Code	Code for the sequence.
Sequence Name	Name of the sequence.
Sequence Status	The new status of the event.
Sequence Status Actual date	The date the status actually became effective.
Sequence Status Comments	Reason the Sequence Status was changed.

Attribute	Description
Sequence Status Projected Date	The date the event status is projected to become effective. This is the only attribute you can modify.

Tasks

The table lists all attributes that are available for Tasks while adding Projected Status Date.

Attribute	Description
Actual Date	The date the status actually became effective.
Entity Association	The type of entity associated with the task or sub-task.
Event Status	The status that becomes effective on the projected date.
Projected Date	The date the status is projected to become effective.
Related Task Type	Additional information to identify the related task type.
Secondary Task Type	Additional information that further identifies the type of task or subtask.
Task Association	The name of the entity associated with the task or sub-task.
Task Name	The name of the task or sub-task.
Task Status Comments	Reason the Task Status was changed.
Task Status	Status that becomes effective on the projected date.
Task Type	The type of task or sub-task.

Modify a Status Date

You need to modify the status date to make changes in the projected date.

Note: You must have the appropriate security privileges to modify a status date.

To modify a status date:

1. Click the link for the sequence or task whose status date you want to modify.
2. On the **Status Dates** tab, click the status date you want to modify.
3. Click **Modify**.

4. On the *Modify Status* page, change the date. Add comments if necessary.
5. **Save**.

Delete a Projected Status Date

You can delete the projected status date for the sequence or the task if the action is not required to be scheduled.

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Note: Only an administrator can delete a projected status date.

To delete a projected status date:

1. Click the link for the sequence or task of the projected status date you want to delete.
2. On the **Status Dates** tab, click the status date to delete.
3. Click **Delete**.A message prompts you to confirm the deletion.
4. Click **OK**.

Chapter 28. Change

Ennov InSight enables you to plan and track regulatory changes with Change numbers that refer to additional tools or software.

These tools provide further definition of the actual change being planned or requested and have specific metadata associated to them that include, but are not limited to, a complete description of the change.

Compliance tracking relies on the presence of Change numbers in Ennov InSight and on the ability to link independent regulatory events to the same global change project and/or different global change projects to the same regulatory event. This flexibility ensures alignment with the different submission requirements across regulatory authorities.

Note: When working with change, the Change Maintenance attributes must be active within Data Administration.

Create a Change

Ennov InSight enables you to create, plan and track regulatory revisions through change numbers that refer to additional tools or software.

To create a change:

1. On the **New** menu Ennov InSight , select **Change**.
2. On the *Create Change* page, enter or select change attributes, as needed. Required fields are indicated by an asterisk.
3. **Save**.Upon completion, the change is listed under the **Change** tab on the *Home* page.

Use the Change Management Wizard

The *Change Management* wizard guides you through the process to create a project and associate change details to the events of the project.

To use the *Change Management* Wizard, you must have at least

WRITE permissions on the following entities:

- Project
- Change
- Event

Using the *Change Management* wizard, you can:

- Create a project
- Associate existing change details to the project
- Create new change and change details and associate them to the project

Create Change and Change Details

Use the *Change Management* wizard to create change and change details.

To create change and change details:

1. On the *home* page, click **Wizard** > **Change Management**.The *Create or Associate Change/Change Details* page appears.
2. To create change/change details, select **Create**.
3. On the *Create Change* page, enter the change attributes.
4. Click **Next**.
5. On the confirmation page, click **Next** again.
6. On the *Summary* page, click **Next**.
7. On the *Create Change Detail* page, enter values for change details.
8. Click **Next**.
9. Do the one of the following:

Action	Description
Yes	Create additional change details and repeat steps 7 and 8.
No	Continue with the existing change details.

10. Click **Next**.
11. On the *confirmation* page, click **Next**.
12. On the *summary* page, click **Next**.
13. On the *Select Event-Change Detail Status* page, select the status for the Event-Change Details.
14. Click **Next**.The *Enter Project Details* page appears. The change/change details created and associated with the events of the project appear under **Event Change Details** on the *Project Attributes* page.

Associate Change Details

Use the *Change Management* wizard to associate change and change details.

To associate change details using the *Change Management* wizard:

1. On the *home* page, click **Wizard** > **Change Management**.
2. On the *Create or Associate Change/Change Details* page, to associate change/change details, select **Associate**.
3. Click **Next**.
4. To select **Change Detail(s)**, click **Select**.
5. Select the change details and click **Save**.
6. Click **Next**.

7. Select **Event-Change Details** status and click **Next**.
8. On the *Enter Project Details* page, enter details for a project.The change/change details associated appear on the *project attributes* page.

Delete a Change

If a change is no longer required, you can delete it from Ennov InSight.

A change cannot be deleted if at least one of its change details is associated with an event. All change details of this change must be disassociated prior to deletion of the change.

To delete a change:

1. On the *Home* page, click **Change**.
2. Click the change hyperlink.
3. Click **Delete**.A confirmation message appears.
4. Click **OK**.Another confirmation message appears.
5. Click **OK**.Upon completion, the change is removed and no longer available.

Create Change Details

You must create change details to associate it to Events.

To create change details:

1. On the **New** menu, select **Change**.
2. On the **Change Detail** tab, click **Create Change Detail**.
3. Enter or select change detail attributes, as needed.
4. **Save**.

Change Attributes

The attribute descriptions will help you to enter appropriate change attribute values when creating a change.

The following table lists all the Change attributes that appear in the *Create Change* page while you create a change.

Attribute	**Description**
Add Comment	Comments you want to share with others in a discussion thread. Stamped with the date and time that you enter the information and your user ID.
Change Initiation Date	Date on which the change request was initiated for submissions to start.

Change Long Description	Full description of the change.

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Attribute	Description
Change Short Description	Brief description for quick display.
Change Type	The type of change.
Closed	Indicates that a change is closed. That is, the change is no longer available for selection on the Events.
Concerned Parties	Users who may be copied on notifications about this entity. Use semi-colons (;) to separate email addresses.
External Change Number	Change number from external systems.
Ennov InSight Change Number	Internally assigned Ennov InSight code/number associated to the Change.
Responsible Person	The person responsible for the change.

Modify Change Attributes

You can modify a change to edit change attributes.

To modify change attributes:

1. On the *Home* page, select **Changes**.
2. Select the link for the change that you want to edit.The *Change Attributes* page appears.
3. Click **Edit**.The *Edit Change* page appears.
4. Edit the attributes as needed.
5. **Save**.

Associate or Disassociate Change Details and Events

Ennov InSight enables you to associate existing change details with other events. Furthermore, you can disassociate existing change details from an event for an application if the change details were inadvertently associated with the event and you need to undo the association.

When associating or dissociating change details to an event, the following conditions apply:

- You must have at least WRITE permission on changes within the entity security.
- You must have at least WRITE permission on events within the entity security.
- The event must not be closed.
- A closed change detail cannot be associated.
- Change detail of a closed change cannot be associated.

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- Change detail cannot be associated with more than one open event of the same application.
- Change detail cannot be associated with the event of the application if another closed event of the same application has the same change detail associated, and is closed as Approved.

To associate or disassociate a change:

1. Click a link for the event you want to associate or disassociate with the change.
2. On the *Event Attributes* page, click **Change Details**.
3. Do one of the following:

Option	**Action**
To associate a change:	Click **Associate/Disassociate Change Details** icon and move to step 4.
To dissociate a change:	Select the change details from the list and click the **Associate/Disassociate Change Details** icon. Click **OK** to confirm disassociation. The Change Details are disassociated.

4. To select change details to associate, click **Select** under **Select Change Detail(s)**.
5. Select the change details and click **Save**.
6. To change the status of a change detail, select an appropriate status from the **Change Detail Status** dropdown list.
7. **Save**. The change is associated with the event.

Chapter 29. Queries

A variety of queries are available for detailed lists of entities. For each entity that satisfies the query criteria, all attributes are presented in table format.

You can click links in the query results to view more details about the item you clicked. You can export this table to a Microsoft Excel™ spreadsheet for further analysis and archival purposes.

Querying is applicable to the following modules:

- Electronic Lifecycle Publishing
- Paper Review Publishing
- Product Detail Management
- Registered Document Analysis
- Registration Planing and Tracking
- Submission Planning and Tracking

Generate a Query

You can generate queries depending upon your security privileges. Queries for which you do not have security privileges are hidden from view To generate a query:

1. On the **Go To** menu, select **Querying**.Several tabs with query options appear.
2. Click the tab for the preferred query. You may need to use the arrows to the right and left of the listed tabs to view all of the available tabs.A list of query options appears.
3. Click the link for the query you want to generate.The *query criteria* page appears.
4. Select the criteria you want to use to generate the query.
5. Do either of the following:

Option	**Action**
To generate the query:	**Search**.
To clear the values you entered and start over:	**Reset**.

When the query criteria page is refreshed as a result of selecting filtering criteria, clicking **Reset** does not direct you back to the *Querying menu* page. Rather, you are returned to the *query criteria* page. To navigate back to the *menu* page, click **Cancel**.**Note:** If you inadvertently add species details to non-veterinary products, you will not see species details added to the PDS tree for the product. However, the species details will be maintained in the database and they will appear in any related queries that you perform.**Note:** If you run

a custom query created from a query, and then run the original query, when you click **Back** on the query output view you are returned to the filtering criteria page for custom query instead of the original query. As a workaround, navigate back to the query to return to the correct filtering criteria page for the original query.

Guidelines for Generating Queries

You can use the guidelines to enter the search values in the query pages and for query data you generate.

Pressing the Enter key in List Boxes For search attributes with list boxes, such as **Keywords**, **Description**, and **Comments**, pressing the Enter key in the list box causes new lines of text. Each line of text is returned as a new row when you export a query containing these values to Microsoft Excel™. **Selecting Values in Drop-down List Boxes**

In drop-down list boxes, you can choose only one value.

You can choose contiguous values by Shift+clicking them.

You can choose non-contiguous values by Ctrl+clicking them.

Double-clicking any value in an **Available Columns** list box moves it to the corresponding **Selected Columns** list box. Choose a column in the **Selected Columns** list and use **up** and **down** buttons to change the order the columns are displayed in the query results.

Dates

Enter formatted dates based on your Ennov InSight environment settings. For date ranges, enter date values in both the **From** and **To** boxes. To generate a query for only one day, enter the same value in the **From** and **To** boxes.

Sorting

You can use the **Sort Order** selection boxes to select how your query is sorted. You can move selected sort order entries up or down. Regardless of the number of item that you specify in **Selected Sort Orders** list box, only the first four are used to generate the query.

Resetting the Sort

If you click **Reset Sort** on the *query results* page, the sort order is cleared and you can specify up to four sort options only. When you generate some queries (such as List of Applications with Products) for a CP (Central Procedure) application, the Country column shows both the rapporteur and co-rapporteur of an EMEA (European Medicines Agency) country.

Viewing Queries

After you view a query, you can click **Back** on the *Search Results* page to return to the *query filtering criteria* page.

Then you must click **Reset** before you can change any filtering criteria.

Some queries might not display a vertical scroll bar if one or more rows have at least one cell that contains more than 25 characters and no spaces.

Registered Document Analysis Queries

The query links related to assemblies/templates, applications, events, sequences, and registered documents are defined on the Registered Document Analysis tab.

For easy reference, the query descriptions are arranged alphabetically by query name.

Assemblies Where Document Used

The Assemblies Where Document Used query enables you to view all assemblies in which a document or document version you specify is used. For lifecycle applications, it identifies whether a document is still the current, externally dispatched document. For example, you can query a sequence assembly to determine whether a document is used, and if the document is current or not current for a specified authority.

Enables you to query as follows:

- Document/Browse - enables you to choose a specific document and document version. Document version is applicable only in a DMS.
- Show assembly types - shows the template, standalone, working, or sequence assemblies in which a specified document is used. You can search for the document in one or more of these assembly types. If you select sequence assemblies for your search, the query returns the sequence assembly from each application in which the specified document most recently had an operation performed on it. If you select working assemblies, the query returns all working assemblies in which the specified document was newly assigned or had an operation performed on it. Selecting standalone or template assembly types returns all the assemblies of these types in which the specified document is used.
- Show for all document versions - includes all versions of the specified document in the query results. By not choosing this option, your query results include only the selected document version.
- Show for all assembly versions - shows both current and non-current assemblies in which the document is used. By not choosing this option, your query results include only the current assembly version.

You can select which columns to display and establish a sort order for the returned results.

List of Applications

The List of Applications query enables you to query applications using a combination of application attributes, for example, all applications in the top 20 countries for a product family. Returns all application attributes.

List of Assemblies/Templates

The List of Assemblies/Templates query enables you to query assemblies and templates using a combination of assembly/template attributes, for example, all approved assemblies and templates. Returns all assembly/template attributes. You may specify to include templates, sequences, standalone assemblies and sequence assemblies.

List of Events with Application Properties

The List of Events with Application Properties query enables you to query events using a combination of event and application attributes, for example, all initial approvals for the year or all non-notified events. Returns all events attributes and some application attributes.

List of Sequences with Application and Event Properties

The List of Sequences with Application and Event Properties query enables you to query sequences using a combination of sequence, application, and event attributes, for example, all planned submissions or amendments submitted in the past year that had to do with toxicity. Returns all sequence attributes and some application and event attributes.

Registered Document The Registered Document query enables you to generate a list of documents that meet status, date, country, product, application, and CTD location/section requirements. Used for determining the location, identity and version of a document to use for a new submission. Returns a set of document properties.**Note:** The Registered Document query is designed for optimal performance when filtering criteria are used. If you run this query without using filtering criteria, performance degradation may occur.

When you choose a value in the Status drop-down box, and you do not choose **Approved View** or **Submitted View**, no results are reported when you click **Search**. Please note that the Registered Documents query only shows certain columns in the query results. Also, using the **Back** button to return to the query filter after viewing the results screen removes the last entry for the **Approved View** filter.

Product Detail Management Queries

The query links related to product details are defined on the **Product Detail Management** tab.

For easy reference, the query descriptions are arranged alphabetically by query name.

Query Name	Description
Application History	The Application History Query enables you to list the history of events and types of product details affected for an application that you specify. Clicking the **Y** under any product detail displays details about the change that occurred.
Application QC Status History	The Application QC Status History Query enables you to view the history of QC status changes for an application that you specify. To use the QC status feature, go to Data Administration and set the default QC status to a value that enables you to use this feature. If you can use the QC status feature, the Application QC Status History Query enables you to list the following for an application that you specify: • The history of QC status changes • The PDS details that passed a QC check • The PDS details that failed a QC check • The PDS details that require a QC check

Query Name	Description
	In the results, a **Y** under a PDS detail indicates that the detail passed a QC check. Clicking a **Y** displays details about the QC check. An **N** under a PDS detail indicates that the detail failed a check or was not checked. When you are viewing the PDS details in the query, a QC Status of "Not Applicable" means the QC verification process is not being used.
Flu Strain with Registration and PDS De tails	The Flu Strain with Registration and PDS Details Query shows the following for flu vaccine products: • The flu strains in the products • The applications for the products • The countries where the products have been marketed and whether the products are currently marketed in these countries • The registrations for the products • The product detail sets (PDSs) that contain information about the products
Labeled Indications	The Labeled Indications Query enables you to determine the following for the labeled indication created for one or more products of a specific product family type: • The products developed to treat the labeled indication • The applications and registrations for the products • The PDSs that contain the labeled indication • The indications/intended uses for the products
List of Active Ingredient Manufacturers	The List of Active Ingredient Manufacturers query enables you to determine the manufacturers for one or more active ingredients. The query includes only approved and pending approval manufacturers.
List of Active Ingredient Function Manufacturers	The List of Active Ingredient Function Manufacturers enables you to determine the manufacturers that perform specific functions for an active ingredient (for example, quality testing). The query includes only approved and pending approval manufacturers.
List of Active Ingredient Material Manufacturers	The List of Active Ingredient Material Manufacturers query enables you to determine the manufacturers that provide materials for an active ingredient manufacturing process. The query includes only approved and pending approval manufacturers.

List of Application Countries with PDS	The List of Application Countries with PDS Country and Registration Details query enables you to query for the list of countries based on the following information:

Query Name	**Description**
Country and Registration Details	• Application Country • PDS Country • Registration • Registration Package Set • Registration Package Set Country The following filters are available on the Enter Search Criteria page: • Family Type, drop-down list • Family Name, drop-down list • Product, multi-select list • Application Name, multi-select list • Application Status, multi-select list • Application Country, multi-select list • Application With Withdrawn Country, drop-down list • Application Country Role, multi-select list • License Code, text field • MAH/Organisation, multi-select list • Annual Report Date, date field • License Issue Date, date field • Neat Renewal Date, date field • Last Renewal Date, date field • Expiration Date/Registration Valid Until, date field • License Status, multi-select list • License Status Date, date field • Reason for Termination/Withdrawal, multi-select list • In-Licensing, text field • Out-Licensing, text field The values displayed in the following columns on the query Search Result page are hyperlinks to the corresponding entity attributes page:

	• **Family Code** and **Family Name** lead to the related Product Family • **Product** leads to the related Product • **Application Name**, **Application Code** and **Application Internal Code** lead to the related Ap-application • **Application Country** leads to the related Application Country • **Country Trade Name** leads to the related PDS Country Detail • **License Code** leads to the related Registration

Query Name	**Description**
	The query Search Results page displays one row per Application Country, per PDS Country, per Registration.
List of Application Countries with Registration and Product De tails	The List of Application Countries with Registration and Product Details query enables you to list countries that are associated with applications, product, or registrations that include attributes that you choose. The query can be one of the following, based on your security privileges: • For SPT users, the query shows application, associated countries, and event information. Registered countries and PDSs are not available. • For RPT users, the query shows registration properties, application, application countries, event, and registration properties. PDS information is not included. • For PDM users, the query shows application, application countries, event, registration, and product detail set detail information.
List of Component Manufacturers	The List of Component Manufacturers query enables you to determine the approved and pending approval manufacturers for one or more product components. The query includes only Manufacturers associated with the following details in the PDS tree: • Component | Function • Component | Manufacturing Process | Function • Component | Manufacturing Process | Step | Function • Component | Manufacturing Process | Step | Material
List of CTA Applications with PDS De tails	The List of CTA Applications with PDS Details query enables you to determine the approved and pending approval investigational product details for a CTA (clinical trial authorization) application.

List of Dose Schedules	For veterinary product families, the List of Dose Schedules query enables you to determine dosing schedules for the criteria that you specify, such as the following: species, species indications, routes of administration, and dosing attributes.
List of Exceptent Manufacturers	The List of Excipient Manufacturers query enables you to determine the approved and pending approval manufacturers for one or more substances.
List of IND Applications with PDS Details	The List of IND Applications with PDS Details query enables you to view a list of IND applications and view the IND application attributes with associated CT shared data, comparators, and PDS details.

Query Name	**Description**
List of Package Set Manufacturers	The List of Package Set Manufacturers query enables you to determine the approved and pending approval manufacturers for one or more package sets. The query includes only manufacturers associated with the following details in the PDS tree: • PDS | Package Set | Function • PDS | Package Set | Packaging • PDS | Package Set | Component | Packaging
List of Package Set Registrations with Application and Product Detail Properties	The List of Package Set Registrations with Application and Product Detail Properties query enables you to list the registrations of package set type for applications and package set registrations that include attributes that you choose. For example, the query can list all package set registrations for Europe for a product family. The query shows all package set registration attributes and some application and product detail attributes.
List of PDS Manufacturers	The List of PDF Manufacturers query enables you to determine the approved or pending approval manufacturers for one or more products. The query includes only manufacturers associated with the following details in the PDS tree: • PDS | Function • PDS | Manufacturing Process | Function • PDS | Manufacturing Process | Step | Function • PDS | Manufacturing Process | Step | Material
List of Product Detail Set Templates	The List of Product Detail Set Templates query enables you to list all product detail set templates associated with the selected product family and product.

List of Product Detail Sets	The List of Product Detail Sets query enables you to list PDSs (product detail sets) that have the attributes that you specify. For example, you can list all PDSs associated with an active registration in a country you specify.
List of Products with Registration and Flu Strain Details	The List of Products with Registration and Flu Strain Details query enables you to identify products containing flu strains. The query returns the following information about the flu strains that you select: • Products, applications, registrations, and PDSs containing the flu strains • Countries in which the flu strains are marketed • PDSs containing approved package sets for the flu strains • Flu strain concentration measures

Query Name	**Description**
List of Product Registrations with Application and Product Detail Properties	The List of Product Registrations with Application and Product Detail Properties query enables you to list the registrations of product type for applications and product registrations that include attributes that you choose. For example, the query can list all product registrations for Europe for a product family. The query shows all product registration attributes and some application and product detail attributes.
List of Registration Package Sets Withdrawn	The List of Registration Package Sets Withdrawn query enables you to determine the registration package sets that have been withdrawn from the market or those that have not been withdrawn from the market. You can limit the returned registration package sets to those for applications that have a specific status or to those for registrations that have a specific license status. The query also shows information about the applications and registrations related to the registration package sets.
List of Registrations with Packaging	The List of Registrations with Packaging query enables you to list only registrations that contain the product details you specify, for example, all products or markets that use the packaging you specify. The query shows all associated PDSs with registration and related attributes.
List of Registrations with Active Ingredients	The List of Registrations with Active Ingredients query enables you to list the registrations that contain the product details that you specify, for example, all products or markets that use the active ingredient that you specify. The query shows all associated PDSs with registration and related attributes.
List of Registrations with Excipients	The List of Registrations with Excipients query enables you to list the registrations that contain the product details you specify, for example, all products or markets that use the substance that you specify. The query shows all associated PDSs with registration and related attributes.

List of Registrations with Indications/Intended Use	The List of Registrations with Indications/Intended Use query enables you to list the registrations that contain approved or pending approval indications/intended uses. The query shows approved PDS details associated with the indication/intended uses.
List of Registrations with Labeling	The List of Registrations with Labeling query enables you to list the registrations that contain the product details you specify, for example, all products or markets that use the labeling that you specify. The query shows all associated PDSs with registration and related attributes.
List of Registrations with Local Country Details	The List of Registrations with Local Country Details query enables you to list the registrations that contain the product details you specify, for example, all products or markets with the country detail you specify. The query shows all associated PDSs with registration and related attributes.
List of Registrations with Material	The List of Registrations with Material query enables you to list the registrations that contain the product details you specify, for example, all products or markets that use the material you specify. The query shows all associated PDSs with registration and related attributes.
Query Name	**Description**
List of Species and Indications	For veterinary product families, the List of Species and Indications query enables you to list the species and species indications that contain the criteria that you specify, such as the following: products, application countries, PDS statuses, species status- es, sub-indications, and indication statuses.
List of Withdrawal Times	For veterinary product families, the List of Withdrawal Times query enables you to list the withdrawal times that contain the criteria that you specify, such as the following: products, application countries, PDS statuses, species statuses, routes of administration, human consumption product, do not use flag, and withdrawal time attributes.
Shelf Life	You can track concurrent pending changes to product shelf life information by examining shelf life details. The Shelf Life query enables you to view approved, but not withdrawn, shelf life PDS details for products and where they are currently marketed.
Sunset Clause Marketing Status	The Sunset Clause Marketing Status query enables you to view the sunset clause date for each presentation in each country, for the product family that you specify. The query also shows the product family, application, and registration attributes.

Registration Planning and Tracking Queries

The Query links related to registration and planning are defined under **Registration Planning and Tracking** tab. One row per entity is returned.

For easy reference, the query descriptions are arranged alphabetically by query name.

List of Application Countries with Registration Details The List of Application Countries with Registration Details query enables you to view countries that are associated with applications or registrations that have specific attributes. The query can be one of the following, based on your security privileges:

- For Submission Planning and Tracking module users, the query contains application, associated countries and event information. Registered countries and PDS (Product Detail Sets) are not available.
- For Registration Planning and Tracking module users, the query contains registration attributes, application, application countries, event and registration attributes. PDS information is not included.
- For Product Detail Management module users, the query contains application, application countries, event, registration, and product detail set detail information.

List of Applications with Products

The List of Applications with Products query enables you to view all applications that have a combination of application attributes, for example, all applications in the top 20 countries for a product family. The query returns all application attributes and products associated with the application. One row of data is returned per application/product/component combination. This query applies for all the application types.

List of CTA Applications

The List of CTA Applications query enables you to view clinical trial authorization applications, the countries in which the related product is being tested, and the development sponsor for the clinical trial. You can limit the returned applications to those that are in a specific product family, have a specific status, and are associated with a clinical trial that has a specific development sponsor.

List of Events with Application Properties

The List of Events with Application Properties query enables you to view events that have specific attributes and are associated with applications that have specific attributes, for example, all initial approvals for the year or all non-notified events. The query returns all events attributes and some application attributes.

List of Events with Change Details

The List of Events with Change Details query enables you to view events that have specific attributes and are associated with change, change type, or change detail. You must have at least Read rights for Entity Security -> Change to view the report.

List of IND Applications

The List of IND Applications query enables you to view a list of all IND applications, the application attributes, the associated CT shared data, and the related comparators. You can limit the returned IND applications to those that have a specific status, Periodic Safety Update Report (PSUR) due date, or PSUR lock date.

List of Manufacturers from Data Administration

The List of Manufacturers from Data Administration query enables you to view manufacturers. The query returns one row per product detail associated with the manufacturer satisfying the criteria.

List of Medical Device Products The List of Medical Device Products query enables you to view medical device products associated with the product families you specify. You can choose only product families whose type is medical device. The query enables you to view the following:

- All products for a selected EU class
- All withdrawn products

List of Medical Device Products and Components The List of Medical Device Products and Components query enables you to query medical device products and their components that are associated with a product families you specify. You can choose only product families whose type is medical device. The query enables you to view the following:

- All medical device products in Ennov InSight
- All/specific products and components for a product family
- Components and product attributes for a selected product
- All the components for a specific component manufacturing location

List of Pharmaceutical and Medical Device Products The List of Pharmaceutical and Medical Device Products query enables you to view pharmaceutical-medical device combination products associated with the product families you specify. You can choose only product families whose type is pharma-med device. The query enables you to view the following:

- All products for a selected EU class
- All withdrawn products

List of Pharmaceutical Products The List of Pharmaceutical Products query enables you to view pharmaceutical products associated with the product families you specify. You can choose only product families whose type is pharmaceutical. The query enables you to view the following:

- All withdrawn products
- Products that have not been updated for a year
- All active products in a selected therapeutic class

List of Pharmaceutical Products and Components The List of Pharmaceutical Products and Components query enables you to view pharmaceutical products and their components that are associated with the product families

you specify. You can choose only product families whose type is pharmaceutical. The query enables you to view the following:

- All/specific products and components for a product family
- Components and product attributes for a selected product
- All the products and the components that contain a specific active ingredient
- All the components for a selected component manufacturing location

List of Pharmaceutical and Medical Device Products and Components The List of Pharmaceutical and Medical Device Products and Components query enables you to view pharmaceutical-medical device combination products associated with the product families you specify. You can choose only product families whose type is pharma-med device. The query enables you to view the following:

- All pharma-medical device products in Ennov InSight
- All/specific products and components for a selected product family
- Components and product attributes for a selected product
- All products and components that contain a specific active ingredient
- All components associated with a selected component manufacturing location

List of Product Families

The List of Product Families query enables you to view the product families that have a combination of product family attributes, such as all product families with the same therapeutic area or product families that contain an active ingredient you specify. The query returns all product family attributes.

List of Products with Event and Product Registration Details The List of Products with Event and Product Registration Details query enables you to view the product family type for the related products and their associated events that are being tracked on a registration. The query enables you to show the following:

- The associated application name and code
- Details about the associated event, including the event-product status, status date, and EU worksharing/ grouping status
- The license code, status, and status date for the associated registration

List of References

The List of References query enables you to view references that have a combination of reference attributes, for example, all non-regulatory correspondence with a specific agency. The query returns all reference attributes.

List of References - Rollup by Application The List of References - Rollup by Application query enables you to view all references that are directly or indirectly associated with an application that you specify. For example, all nonregulatory correspondence associated with an application. The query returns all reference attributes. **Note:** Product and product family references are not included.**List of References - Rollup by Product Family**

The List of References - Rollup by Product Family query enables you to view all references that are directly or indirectly associated with a product family that you specify. For example, all non-regulatory correspondence associated with a product family. The query returns all reference attributes.

List of References - Rollup by Project

The List of References - Rollup by Project query enables you to view references that are directly or indirectly associated with a project that you specify. The results are limited to references directly associated with the project or event, and references associated with applications and sequences that are indirectly associated with the project.

List of Registrations for a Product Family

The List of Registrations for a Product Family query enables you to view all registrations for products that are in a specific product family and have a specific registration status. This query returns registration attributes for the specified product family.

List of Registrations with Application Properties

The List of Registrations with Application Properties query enables you to view registrations for applications that have specific attributes, for example, all registrations for Europe for a product family and a specific application status.

This query returns all registration attributes and some application.

List of Sequences with Application and Event Properties

The List of Sequences with Application and Event Properties query enables you to view sequences that have specific attributes and are associated with applications and events that specific attributes, for example, all planned submissions or amendments submitted in the past year that had to do with toxicity. This query returns all sequence attributes and some application and event attributes.

List of Tasks

The List of Tasks query enables you to view tasks that have specific attributes, for example, all overdue tasks or all upcoming commitments. This query returns all task attributes.

List of Tasks - Rollup by Application The List of Tasks - Rollup by Application query enables you to view tasks that are directly or indirectly associated with an application you specify, for example, all tasks associated with an application.

This query returns all task attributes.**Note:** Product and product family tasks are not included.**List of Tasks - Rollup by Product Family**

The List of Tasks - Rollup by Product Family query enables you to view tasks that are directly or indirectly associated with a product family you specify, for example, all tasks associated with a product family. This query returns all task attributes.

List of Tasks - Rollup by Project

The List of Tasks - Rollup by Project query enables you to view a list of tasks that are directly or indirectly associated with a project that you specify. You can limit the returned tasks to those that have attributes that you specify. The query shows all attributes of the returned tasks.

List of Veterinary Products The List of Veterinary Products query enables you to view veterinary products associated with the product families you specify. You can choose only product families whose type is veterinary. This query shows the following:

- All withdrawn products
- Products that have not been updated for a year
- All active products in a selected therapeutic class or dosage form

List of Veterinary Products and Components The List of Veterinary Products and Components query shows veterinary products and their components that are associated with the product families you specify. You can choose only product families whose type is veterinary. This query shows the following:

- All/specific products and components for a product family
- Components and product attributes for a selected product
- All the products and the components that contain a specific active ingredient
- All the components for a selected component manufacturing location

PSUR World Wide Marketing Authorization Status The PSUR World Wide Marketing Authorization Status query shows events that have the PSUR flag set to yes and that satisfy the criteria you specify, for example, registration activity that has occurred for a product family. This query returns each country/event with PSUR reporting attributes. **Note:** You can export this query to RTF or Microsoft Excel™ to support PSUR reports. Also, users who do not have security privileges for an application country can see that country in the PSUR World Wide Marketing Authorization Status report. However, they will not be able to navigate to entities that are not permitted by their specified security privileges. **XEVMPD Submissions - QC Verification and Audit**The **XEVMPD Submissions - QC Verification and Audit** query shows all XEVMPD data associated with a particular Authorised Product for QC assessment. You can also see historical data for each of the XEVMPD fields associated with an Authorised Product, including:

- XEVMPD data mapped with a particular Full Product Presentation is correct
- Data mapped with a particular Full Product Presentation is ready to be submitted
- Last person to modify XEVMPD data
- Last time the XEVMPD data was updated

Note: You must have the Ennov InSight for XEVMPD license to access this query. **XEVMPD Submissions and Acknowledgements** The **XEVMPD Submissions and Acknowledgements** query shows the XEVMPD acknowledgement files information, including 3rd Acknowledgement Types with the description of the proposed changes from EMA. Use the **XEVMPD Submissions and Acknowledgements** to find:

- If there is an XEVMPD acknowledgement for a submitted XEVMPD XML file
- If there are any issues reported by EMA authority for the XEVMPD XML file sent

- If there are any errors and the changes required to provide to EMA authority for the XEVMPD XML file sent
- The acknowledgements received for a particular XEVMPD XML file
- The acknowledgements received in general from EMA authority for your XEVMPD files

Note: You must have the Ennov InSight for XEVMPD license to access this query.**List of RMS Fields**

The *List of RMS Fields* query shows the values from the SPOR Master Lists. You can use this query to identify the

SPOR values that have been created or updated. You can navigate to the associated entities from the Associated Data Administration List Name lists using the hyperlinks available in the Search Results section. The query enables you to access the full list of Associated DA List Name values.

List of OMS Fields

The *List of OMS Fields* query shows the values from the SPOR Master Lists. You can use this query to identify the

SPOR values that have been created or updated. You can navigate to the associated entities from the Associated Data Administration List Name lists using the hyperlinks available in the Search Results section. The query enables you to access the list of Associated DA List Name values.

Submission Planning and Tracking Queries

The query links related to submission and planning are defined on the **Submission Planning and Tracking** tab. For

easy reference, the query descriptions are arranged alphabetically by query name.

Assembly Comparison

The Assembly Comparison query enables you to compare two assembly structures, such as a template and an assembly or two current active views, for example, to determine whether document versions are different between sister submissions. The contents of the first assembly is compared with the second assembly. If the folder trees and document names match, version numbers are compared. This query cannot be sorted.

If the folder structure names and numbers in the assemblies are different, the Difference column identifies the sections that have been ADDED or REMOVED, SAME or DIFFERENT. If the folder structure names and numbers match, the documents in that folder structure are then compared.

If an assembly has been removed from the current active view, slip sheets that were added to the leaf and folder no longer appear in the assembly.

When documents are compared, the document names, binding, and file locations and binding IDs are all compared with precedence given to the binding IDs of the documents. If documents are different in any of these ways, the attributes for each document are reported in the columns on the right of the query. In this way, added or removed sections may be ascertained, and if anything about the base content is different it will show up in the query also.

Note: Export this query to Microsoft Excel™ for ease of viewing when you compare large assemblies. **Assembly Status**The Assembly Status query enables you to view the status of an assembly that contains documents with a

specific document assignment status and that has other attributes, for example, a specific percentage of documents that are in a submission and are locked, approved, or past due. This query returns the following:

- One row for the root plus one row per folder up to three folders in depth
- The number and percentage of documents in that folder (and any child folders) that satisfy the criteria
- Bound (approved), Missing Version, Missing (including Missing and Missing Content), and Unassigned based on their assignment status attribute (These are added to the total number of documents in the submission.)
- Locked documents based on the presence of locked folders in the assembly
- Past due documents that have a due date earlier than today's date and that are Bound

Note: Documents directly under the assembly root are not included in this query. **List of Application Countries**

The List of Application Countries query enables you to view all application countries that are associated with a specific product family and are associated with applications that have specific attributes, for example, all CP applications with a status of planned. This query returns all application attributes and some product family and event attributes.

List of Applications

The List of Applications query enables you to view applications that have specific attributes, for example, all applications in the top 20 countries for a product family. This query returns all application attributes.

List of Assemblies/Templates

The List of Assemblies/Templates query enables you to view assemblies and template that have specific attributes, for example, all approved assemblies and templates. This query returns all assembly and template attributes. You can define the query to return templates, sequences, standalone assemblies, and lifecycle assemblies.

List of Events with Application Properties

The List of Events with Application Properties query enables you to view events that have specific attributes and are associated with applications that have specific attributes, for example, all initial approvals for the year or all nonnotified events. This query returns all event attributes and some application attributes.

List of References

The List of References query enables you to view references that have specific attributes, for example, all nonregulatory correspondence with a specific agency. This query returns all reference attributes.

List of References - Rollup by Application The List of References - Rollup by Application query enables you to view all references that are directly or indirectly associated with an application you specify, for example, all non-regulatory correspondence associated with an application. This query returns all reference attributes. Product and product family references are not included.**Note:** The **Country Attribute** filter does not reset to **Select** after changing the

Product Family Type filter for this query. Restart the query process if this occurs.**List of References - Rollup by Product Family**

The List of References - Rollup by Product Family query enables you to view all references that are directly or indirectly associated with a product family that you specify, for example, all non-regulatory correspondence associated with a product family. This query returns all reference attributes.

List of Sequences with Application and Event Properties

The List of Sequences with Application and Event Properties query enables you to view sequences that have specific attributes and are associated with applications and events that have specific attributes, for example, all planned submissions or amendments submitted in the past year that were related to toxicity. This query returns all sequence attributes and some application and event attributes.

List of Tasks

The List of Tasks query enables you to view tasks have specific attributes, for example, all overdue tasks or all upcoming commitments. This query returns all task attributes.

List of Tasks - Rollup by Application

The List of Tasks - Rollup by Application query enables you to view tasks that are directly or indirectly associated with an application that you specify, for example, all tasks associated with an application. This query returns all task attributes. Product and product family tasks are not included.

List of Tasks - Rollup by Product Family

The List of Tasks - Rollup by Product Family query enables you to view tasks that are directly or indirectly associated with a product family that you specify, for example, all tasks associated with a product family. This query returns all task attributes.

List of Tasks - Rollup by Project

The List of Tasks - Rollup by Project query enables you to view a list of tasks that are directly or indirectly associated with a project that you specify. You can limit the returned tasks to those that have attributes that you specify.

The query shows all attributes of the returned tasks.

Administration Queries

All the query links related to actions with administrative privileges are defined on the **Administration query** tab.

For easy reference, the query descriptions are arranged alphabetically by query name. **Note:** You must have administrative privileges for Ennov InSight to access the **Administration query** tab.

Activity Audit Trail

The Activity Audit Trail query provides information regarding user activity. The query results show the date and time when users logged on and off of the system. The query also shows user executions of various Wizards, including *Change Submittal Status Wizard*, the *Update Status Wizard*, the *Create Submission Wizard*, and eSignature (if enabled in overrides).

Entity Audit Trail

The Entity Audit Trail query recounts the activities that have occurred for an Ennov InSight entity and product detail set details. The query results show when the entity was created, who created it, how and when it changed over time, and who performed each action included in the query results.

When you modify an IDMP related entity, the Version column in the Entity Audit Trial displays the value 1. Every time an entity is modified, the count of the **Version** field value increases by 1.

In the Entity Audit Trail query, there is no relation between the query's **Action** column and the PDS status or actions performed on PDS details. When you change a status in a detail's object, you always get a **U** row to signify a database record has been updated, including for a pending withdraw.

When selecting **Task** as the entity type in the Entity Audit Trail query, the **Task Association** column appears twice in the query with the first column showing as empty.

Job Requests

The Job Requests query provides information regarding tasks that are directly or indirectly associated with publishing. You can determine the status of each publishing job and print or view an output log from a completed job list.

Entity Audit Trail

List of indicators used on the query results page when actions are performed on an entity.

The table below lists the action indicators and their description.

Column **Value**	**Description**
I	Indicates an Insert action. For Insert, all fields associated with the entity are displayed.
D	Indicates a Delete action. For Delete action, all fields associated with the deleted record are displayed.
U	Indicates an Update action. For Update action, all fields before and after the updates made to the entity are displayed.

Modify a Custom Query

You can modify a query from the **Private Query** or **Public Query** tab.

To modify a custom query:

1. On the *Home* page, click **Go To** > **Querying**.
2. Click **Private Query** or **Public Query** to locate the query you want to modify.

3. Select the query.
4. Change the filter and sort information. To clear the information you have entered and start over, click **Reset**.
5. Click **Edit**.The *Save Query* page appears.
6. In the **Name** box, change the name of the query.
7. In the **Description** box, enter text to describe the query.
8. Select **Is Public** to make the custom query available on the **Public Query** tab for other users. If the *Is Public* box is blank, the custom query is available on the **Private Query** tab.
9. **Save**.

Entity History Query

The Entity History query recounts all the activities that have occurred for an entity. You can see when the entity was created, who created it, how and when it changed over time, and who performed each action included in the query results.

You can generate an Entity History query from the attributes pages for the following entities:

- Product Family
- Product
- Component
- Application
- Event
- Registration
- Registration-Package Set
- Registration-Package Set Country
- Registration-Package Set-Package Description
- Medicinal Product
- Medicinal Product Name
- Medicinal Product Action
- Task

These entities contain two kinds of properties:

- Contextual - References to other entities, used to set context for the entity
- Definition - Attributes of the entity itself

For example, some of the properties on an application are used to identify the relationship of the application to its parent product family. These contextual properties, including Family Code and Family Name, are references to the parent product family, and cannot be changed when the application is deemed to be a child of the parent product family. Most of the other properties on an application are used to define the application itself. These are properties such as Application Name, Application Code, and Procedure Type.

Due to the way Ennov InSight currently stores contextual properties, Entity History 'Action' queries (the query that displays when the user selects the **I/U/D** from the Action column of the query) show this data as an internal system ID, not as the name one sees through the user interface of the entity itself. These internal system IDs are typically a series of five or six digits, such as 12345.

For example, the Entity History 'Action' query for the application entity shows the internal system ID for the Family Name column. However, the Entity History 'Action' query for the product family shows the expected product family name in the Product Family Name column.

The Entity History query also enables you to view information for discussion threads and notifications, which have an associated entity value to specify the entity, such as product, application or event, to which the discussion thread or notification belongs. Due to the way Ennov InSight stores associated entity values, Entity History ‘Action’ queries do not show the associated entity if the associated entity has been deleted.

For example, the Entity History 'Action' query for an application’s discussion thread will show the application as the associated entity so long as the application exists. However the Entity History 'Action' query shows a blank value for the associated entity on the discussion thread’s Entity History ‘Action’ query if the application was deleted.

When you modify an IDMP related entity, the Version column in the Entity History Query displays the value 1. Every time an entity is modified, the count of the **Version** field value increases by 1.

On the entity attributes page, clicking the **Report** icon on the action toolbar opens the *Entity History Query* page where you can enter a date range during which changes occurred that you want to review. If you enter no dates, all change activity is included in the query results.

In addition, you can select the columns to display and the order in which to sort the results.

Results include all entity history records based on the selected date range. Additionally, the results include the current values for the selected entity.

Create an Entity History Query

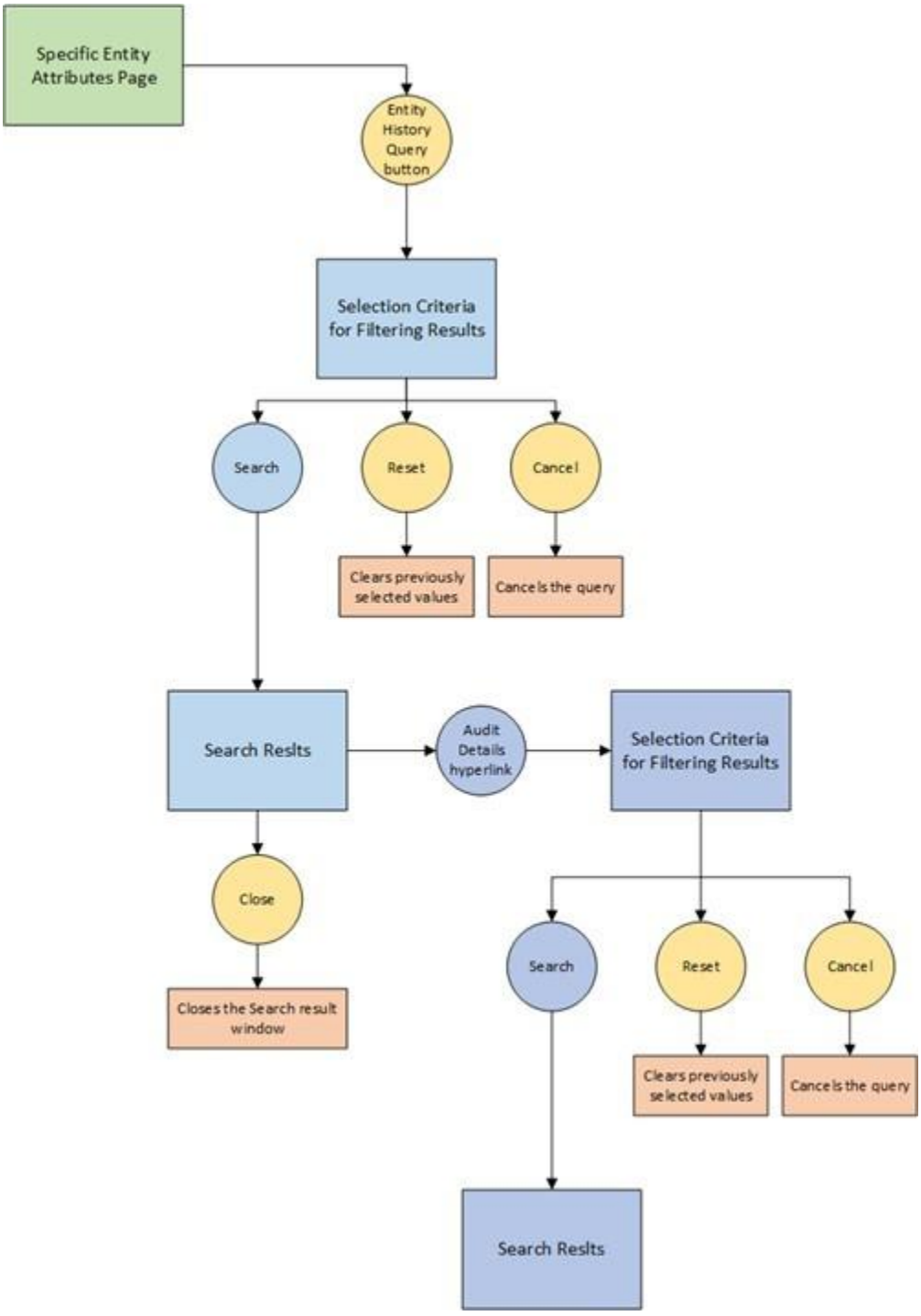
You can create an *Entity History* query on the *Entity History Query* page.

To create an *Entity History* query:

1. Click a link for the entity you want to view.
2. On the attributes page for the entity, click **Report**.
3. On the *Entity History Query* page, to view the history for a specific time period, type or use the **Calendar** icon  to select the beginning date in the first **Date** box and type or select the end date in the second **Date** box.
4. To select and order columns to be displayed, click values in the **Display Columns Selected** box, and use the **up** and **down** buttons to change the order of the values. All columns are selected by default.
5. To specify how to sort the displayed data, select and move columns between the **Sort Order Available** and **Selected** boxes and use the **up** and **down** buttons to specify the sequence in which columns are sorted. The default sort order is Last Date Changed ascending.

6. If you want to clear your selections, click **Reset**.
7. When you are ready to start the query, click **Search**.
8. Use the scroll bars to review the information.
9. To see additional information related to attributes associated with the entity, click **Audit Details**. When the *Entity Audit Trail Query* page appears, perform steps 3 through 8 to launch the query.**Note:** In the Entity History query, the **Action** column is not related to the PDS status or actions performed on PDS details. When you change a status in a detail object, you always get a **U** row to signify a database record has been updated, including for a pending withdraw.

Note: In the Entity History query, the **Action** column is not related to the PDS status or actions performed on PDS details. When you change a status in a detail object, you always get a **U** row to signify a database record has been updated, including for a pending withdraw.



Product Family Entity History Query Results

Entity History Query results vary depending on the values selected during the query creation. The following summaries describe the different results for all columns available for selection.**Note:** The results for the query appear in the order you have selected.Key for Product Family Type and Component Type:

- FV - flu vaccine
- P - pharmaceutical
- MD - medical device
- PMD - pharmaceutical-medical device
- V - veterinary
- All - all product family types

The entity history query for a product family describes all the activities that have occurred for a particular product family.

The columns for a product family entity history query may vary depending on the Product Family Type.

Product Family Type	**Display Column**	**Hyperlink for Audit Details**
All	Last Changed Date	
All	Last User Updated	
All	Product Family Code	
All	Product Family	
All	Product Family Status	
All	Product Family Status Date	
All	IBD (International Birth Date)	
P, FV, PMD, V	PSUR Due Date	
P, FV, PMD, V	PSUR Data Lock Date	
P, FV, PMD, V	Generic Name	
P, FV, PMD, V	ATC	✓
P, FV, PMD, V	Therapeutic Area	
P, FV, PMD, V	Therapeutic Classes	✓
P, FV, PMD, V	Active Ingredient Attributes	✓
All	Product Family Indications/Intended Use	✓
All	Associated Trade Names	✓

P, FV, PMD, V	Development Sponsor	
MD, PMD, V	Division	
Product Family Type	**Display Column**	**Hyperlink for Audit Details**
All	Product Family Keywords	
All	Product Family Description	
All	Product Family Comments	✓
All	Change Type	

Product Entity History Query Results

Entity History Query results vary depending on the values selected during the query creation. The following summaries describe the different results for all columns available for selection. **Note:** The results for the query appear in the order you have selected.Key for Product Family Type and Component Type:

- FV - flu vaccine
- P - pharmaceutical
- MD - medical device
- PMD - pharmaceutical-medical device
- V - veterinary
- All - all product family types

The entity history query for a product describes all the activities that have occurred for a particular product.

The columns for a product entity history query may vary depending on the Product Family Type.

Product Family Type	**Display Column**	**Hyperlink for Audit Details**
All	Last Changed Date	
All	Last User Updated	
All	Product Name	
All	Product Code	
FV, P, PMD, V	Product Family	
FV, P, PMD, V	Product Strength Measure 1	

FV, P, PMD, V	Product Strength Unit 1	
FV, P, PMD, V	Product Strength Measure 2	
FV, P, PMD, V	Product Strength Unit 2	
FV, P, PMD, V	Product Dosage Form	

Product Family Type	**Display Column**	**Hyperlink for Audit Details**
FV, P, PMD	Product Route of Administration	✓
FV, P, PMD	Combined Pharmaceutical Dose Form	
All	Product Status	
All	Product Status Date	
All	Product National Drug Code	
MP, PMD	FDA Regulation Number	
MP, PMD	FDA Product Code	
MP, PMD	FDA Device Class	
MP, PMD	Medical Device Link	
MP, PMD	EU Class	
MP, PMD	EU Classification Rule	
MP, PMD	Conformity Assessment Path	✓
MP, PMD	Declaration of Conformity Completed	
MP, PMD	Product Manufacturing Location	✓
MP, PMD	EU Cert	✓
MP, PMD	Applicable Standards	✓
MP, PMD	Equipment Type	
MP, PMD	Summary of Technical Documentation (STED)	✓
MP, PMD	Tech File Number	
MP, PMD	CE Marked	
MP, PMD	CE Date	

MP, PMD	Global Harmonization Task Force Class (GHTF)	
MP, PMD	Global Medical Device Nomenclature (GMDN) Code	
MP, PMD	UMDNS Code	
MP, PMD	Product Sterilization	✓
MP, PMD	Product Shelf Life	
Product Family Type	**Display Column**	**Hyperlink for** **Audit Details**
MP, PMD	Alternate Product Description	
MP, PMD	Intended Use	
All	Product Keywords	
All	Product Description	
All	Product Comments	✓
All	Change Type	

Component Entity History Query Results

Entity History Query results vary depending on the values selected during the query creation. The following summaries describe the different results for all columns available for selection.**Note:** The results for the query appear in the order you have selected.Key for Product Family Type and Component Type:

- FV - flu vaccine
- P - pharmaceutical
- MD - medical device
- PMD - pharmaceutical-medical device
- V - veterinary
- All - all product family types

The entity history query for a component describes all the activities that have occurred for a particular component.

The columns for a component entity history query may vary depending on the Component Type.

Product Family Type	Display Column	Hyperlink for Audit Details
All	Last Changed Date	
All	Last User Updated	
All	Product Family	
All	Component Name	
All	Component Form	
P, FV PMD	Component Route of Administration	✓
MD, PMD	Component Manufacturing Location	✓
MD, PMD	Component Sterilization	✓
Product Family Type	**Display Column**	**Hyperlink for Audit Details**
All	Component Keywords	
All	Component Description	
All	Component Comments	✓
All	Change Type	

Application Entity History Query Results

Entity History Query results vary depending on the values selected during the query creation. The following summaries describe the different results for all columns available for selection. **Note:** The results for the query appear in the order you have selected.Key for Product Family Type and Component Type:

- FV - flu vaccine
- P - pharmaceutical
- MD - medical device
- PMD - pharmaceutical-medical device
- V - veterinary
- All - all product family types

The entity history query for an application describes all the activities that have occurred for a particular application.

The columns for an application entity history query may vary depending on the Application Type and Procedure Type.

Application Types:

- CTA
- IND

Procedure Types:

- National
- CP
- DCP
- MRP

Application Type	**Display Column**	**Hyperlink for Audit Details**
All	Last Changed Date	
All	Last User Updated	

Application Type	**Display Column**	**Hyperlink for Audit Details**
All	Family Name	
All	UUID	
All	Application Code	
CP, DCP, IND, MRP, National	Application Name	
CTA	Study Number	
All	Procedure	
All	Status	
All	Status Date	
All	Local PSUR Date	
All	Local PSUR Data Lock Date	
All	Application Owner	
CTA	Sponsor	
CTA	Reason for Not Approving	
CTA	Reason for Premature Ending	

CP, DCP, MRP, National	Related Applications	
CP, DCP, MRP, National	Legal Status	
CP, DCP, MRP, CTA, National	Annual Report Date	
CP, DCP, MRP, National	Dossier Language	
All	Orphan Drug	
CP, DCP, MRP, National	Starting Sequence Number	
CP, DCP, MRP, IND, National	Arbitration	
CP, DCP, MRP, National	Clinical Trials #	
CP, DCP, MRP, National	Planned Submission Date	
CP, DCP, MRP, National	Actual Submission Date	
CP, DCP, MRP, National	Planned Approval Date	
CP, DCP, MRP, National	Actual Approval Date	
CP, DCP, MRP, National	Next Renewal Date	
Application Type	**Display Column**	**Hyperlink for** **Audit Details**
CP, DCP, MRP, National	Application Prefix	
All	Application Keywords	
All	Application Description	
CP, DCP, MRP, National	Creation Date	
CP, DCP, MRP, National	Creator ID	
All	Termination/Withdraw Date	
All	Termination/Withdraw Reason	
All	Application Comments	✓
All	Associated Products	✓
All	Countries	✓
All	Change Type	

Event Entity History Query Results

Entity History Query results vary depending on the values selected during the query creation. The following summaries describe the different results for all columns available for selection. **Note:** The results for the query appear in the order you have selected.Key for Product Family Type and Component Type:

- FV - flu vaccine
- P - pharmaceutical
- MD - medical device
- PMD - pharmaceutical-medical device
- V - veterinary
- All - all product family types

The entity history query for an event describes all the activities that have occurred for a particular event:

- Last Changed Date
- Last User Updated
- Closed
- Closed Date
- Associations Closed As
- Event Code
- Event Name
- Action Type
- Event Type
- Secondary Event Type
- Variation Number
- Procedure Closure Date
- PSUR Flag
- PSUR Reaon/Comment
- PSUR Report Code
- Reportable in PSUR
- EU Grouping/Worksharing
- EU Grouping/Worksharing Number
- Keywords
- Description
- Event Comments - hyperlink for audit details
- Associated Products - hyperlink for audit details
- Countries - hyperlink for audit details
- Change Type

Registration Entity History Query Results

Entity History Query results vary depending on the values selected during the query creation. The following summaries describe the different results for all columns available for selection. **Note:** The results for the query appear in the order you have selected.Key for Product Family Type and Component Type:

- FV - flu vaccine
- P - pharmaceutical
- MD - medical device
- PMD - pharmaceutical-medical device
- V - veterinary
- All - all product family types

The entity history query for a registration describes all the activities that have occurred for a particular registration.

The columns for a registration entity history query may vary depending on the Registration Type:

- Package Set Registration
- Product Registration

Registration Type	**Display Column**	**Hyperlink for Audit Details**
Both	Last Changed Date	
Both	Last User Updated	

Registration Type	**Display Column**	**Hyperlink for Audit Details**
Both	Creation Date	
Both	Creator ID	
Both	Family Name	
Both	Application Name	
Both	Country	
Package Set	Registration-Package Sets	✓
Both	License Code	
Product	Event	

Product	Products	✓
Both	MAH/Organisation	
Package Set	Medicines Regulatory Agency	
Package Set	QPPV	
Package Set	MFL	
Package Set	Subject to Additional Monitoring	
Package Set	Registered ATC	✓
Package Set	Medicinal Product Type	✓
Package Set	Sender Local Code	
Both	Annual Report Date	
Both	License Issue Date	
Both	Perpetual License	
Both	Next Renewal Date	
Both	Last Renewal Date	
Both	Expiration Date/Registration Valid Until	
Both	License Status	
Both	License Status Date	
Both	Currently Marketed	
Registration Type	**Display Column**	**Hyperlink for Audit Details**
Package Set	Enquiry Email	
Package Set	Enquiry Phone Number	
Both	In-Licensing	
Both	Out-Licensing	
Both	License Keywords	
Both	License Description	
Both	License Comments	✓
Both	Change Type	

Registration-Package Set Entity History Query Results

Entity History Query results vary depending on the values selected during the query creation. The following summaries describe the different results for all columns available for selection. **Note:** The results for the query appear in the order you have selected.Key for Product Family Type and Component Type:

- FV - flu vaccine
- P - pharmaceutical
- MD - medical device
- PMD - pharmaceutical-medical device
- V - veterinary
- All - all product family types

The entity history query for a registration-package set describes all the activities that have occurred for a particular registration-package set.

Display Column	**Hyperlink for** **Audit Details**
Last Changed Date	
Last User Updated	
Creation Date	
Creator ID	
Family Name	
Application Name	
Display Column	**Hyperlink for** **Audit Details**
Registration-Package Set Countries	✓
License Code	
Product Detail Set Name	
Package Set Name	
MAH/Organisation	
Package Set License Code	
Withdrawn	

Withdrawn Date	
Legal Basis	
Authorisation Status	
Authorisation Status Date	
Registration-Package Set Keywords	
Registration-Package Set Description	
Registration-Package Set Comments	✓
Change Type	

Registration-Package Set Country Entity History Query Results

Entity History Query results vary depending on the values selected during the query creation. The following summaries describe the different results for all columns available for selection. **Note:** The results for the query appear in the order you have selected.Key for Product Family Type and Component Type:

- FV - flu vaccine
- P - pharmaceutical
- MD - medical device
- PMD - pharmaceutical-medical device
- V - veterinary
- All - all product family types

The entity history query for a registration-package set country describes all the activities that have occurred for a particular registration-package set country.

Display Column	**Hyperlink for** **Audit Details**
Last Changed Date	
Last User Updated	
Creation Date	
Creator ID	
Family Name	
Application Name	
License Code	

Product Details Set Name	
Package Set Name	
Country	
Currently marketed in this country?	
Additional License Number	
Legal Status of Supply	
Marketed Date	
Marketing Cessation Date	
Temporary Cessation Date	
Reason for Temporary Cessation	
Estimated Return to Market Date	
Restart Marketed Date	
Registration-Package Set Country Keywords	
Registration-Package Set Country Description	
Registration-Package Set Country Comments	✓
Change Type	

Registration-Package Set - Package Description Entity History Query Results

Entity History Query results vary depending on the values selected during the query creation. The following summaries describe the different results for all columns available for selection. **Note:** The results for the query appear in the order you have selected.Key for Product Family Type and Component Type:

- FV - flu vaccine
- P - pharmaceutical
- MD - medical device
- PMD - pharmaceutical-medical device
- V - veterinary
- All - all product family types

List of the entity history query results and their description.

Display Column	Hyperlink for Audit Details
Last Changed Date	
Last User Updated	
Creation Date	
Creator ID	
Family Name	
Application Name	
License Code	
Product Detail Set Name	
Package Set Name	
Short Package Description	
Package Description	
Language	
Package Description Keywords	
Package Description	
Package Description Comments	✓
Change Type	

Medicinal Product Entity History Query Results

Entity History Query results vary depending on the values selected during the query creation. The following summaries describe the different results for all columns available for selection. **Note:** The results for the query appear in the order you have selected. Key for Product Family Type and Component Type:

- FV - flu vaccine
- P - pharmaceutical
- MD - medical device
- PMD - pharmaceutical-medical device
- V - veterinary
- All - all product family types

The entity history query for a medicinal product describes all the activities that have occurred for a particular medicinal product.

Display Column	Hyperlink for Audit Details
Last Changed Date	
Last User Updated	
Creation Date	
Creator ID	
Medicinal Product Name	
Product	
Pediatric Use Indicator	
Genetically Modified Organisms	
PMS ID	
Package Sets	✓
Authorised Pharmaceutical Form	
Full Indication Text	
Full Indication Language	
Medicinal Product Keywords	
Medicinal Product Description	
Medicinal Product Comments	✓

Display Column	Hyperlink for Audit Details
Change Type	

Chapter 30. Activities Associated with Ennov InSight Registrations Entities

You can view a list of activities that are associated with Ennov InSight Registrations entities such as an application, project, or a product family, as well as their related entities.

For a list of Ennov InSight Registrations entities and their related entities, see List of Ennov InSight Registrations Entities.

To view an activities list, you must have at least READ permissions to Activities in **Entity Security**, with **Find Activities in Home Page Access** set to Yes. The **Entity Security** and **Home Page Access** options are found under *Security Administration*.

View Activities Associated with Ennov InSight Registrations Entities

Use this procedure to view the activities list Associated with Ennov InSight Registrations Entities.

To view an activities list:

1. On the **Home page**, click **Find**.
2. Click **Activities**.
3. On the **Entity Type** drop-down list, select an entity.The options corresponding to the selected entity are displayed.
4. Select values for the various entity filters.
5. Click **Search**.A detailed list of entities and their associated activities are displayed in the Search Results window.
6. Do any of the following:

Option	**Action**
To find specific activities:	Use the **Set Filter** option.
To view the details of an activity:	Click on the activity name.
To perform other activity functions such as update, claim, unclaim, trans- fer, or complete:	Refer to the topic **Working with an Activity**.

View Activities List Filters

You can use the filter description to help choose the filter values for retrieving a specific activities list.

Common Filters

Filter Name	**Filter Description**
Entity Type	Select an entity to see its associated activities.

Filter Name	Filter Description
	• Application • Active Ingredient • Change • Event • Product Family • Product • Project • Registration • Sequence • XEVMPD
Assigned User (List box)	Only users with at least READ permissions to activities are listed.
Assigned User (Text box)	Use this option to enter a username as a search criterion.

Application Entity Filters

Filter Name	Filter Description
Application Type	The type of an application.
Application Country	Lists the countries associated with the selected application type(s). Use this option to search for an application by a reviewing country, a rapporteur, or a reference member state.
Application	Use this option to search for an application by an application code or an application name.

Active Ingredient Filters

Filter Name	Filter Description
Substance Name	Use these options to search for a substance in the **Alternate Active Ingredient** field on the *Pharmaceutical Product Active Ingredient Attributes* and *Manufactured Item Active Ingredient Attributes* pages. This field should be configured as a substance selection widget with all the active values Data Administration > Substance Values .**Note:** For configuration assistance, please contact your Business Develop- ment Representative.
Sub- stance Trans	

Filter Name	**Filter Description**
lations	
Substance Alliases	

Change Entity Filters

Filter Name	**Filter Description**
Change Type	The type of a change.
Change	Use this option to search for a change by using an InSight change number, an external change number, or by a short description of the change.

Event Entity Filters

Filter Name	**Filter Description**
Event Type	The type of an event.
Application Country	Use this option to search for an event by a reviewing country, a rapporteur, or a reference member state of the parent application.
Event	Use this option to search for an event by an event code or an event name.

Product Family Entity Filters

Filter Name	Filter Description
Family Type	The type of a product family.
Family Name	The name of a product family.
Product Family	Use this option to search for a product family by a product family code or a product family name.

Product Entity Filters

Filter Name	Filter Description
Product	Use this option to search for a product by a product code or a product name.

Project Entity Filters

Filter Name	Filter Description
Project Type	The type of a project.
Project	Use this option to search for a project by a project code or a project name.

Registration Entity Filters

Filter Name	Filter Description
Application Country	Use this option to search for a registration by a reviewing country, a rapporteur, or a reference member state of the parent application.
Registration	Use this option to search for a registration by a license code.

Sequence Entity Filters

Filter Name	Filter Description
Application Country	Use this option to search for a sequence by a reviewing country, a rapporteur, or a reference member state of the parent application.
Sequence	Use this option to search for a sequence by a sequence code or a sequence name.

XEVMPD Entity Filters

Filter Name Name	Filter Description
Family Type	The type of a product family.
Family Name	The name of a product family. You can select multiple Product Families.
PSet Registration	Use this option to search for the XEVMPD-related entities by the Package Set Registrations associated to the selected Product Families. Multiple values can be selected. Only registrations that match the following criteria are available for selection:

Filter Name	Filter Description
	• Only Registrations of Package Set type are available for selection. • The Package Set Registration must have at least one Full Product Presentation assigned.

List of Ennov InSight Registrations Entities

This topic provides a list of Ennov InSight Registrations entities and their related entities.

Application

- Application
- Event
- Change
- Change Detail
- Product Detail Set
- Sequence

Change

- Change
- Change Detail
- Event

- Product Detail Set
- Sequence

Event

- Event
- Change
- Change Detail
- Product Detail Set
- Sequence

Product Family

- Registration
- Registration-Package Set
- Registration-Package Set Country
- Application
- Event
- Change
- Change Detail
- Product Detail Set
- Sequence

Product

- Registration
- Registration-Package Set
- Registration-Package Set Country
- Application
- Event
- Change
- Change Detail
- Product Detail Set
- Sequence

Project

- Project
- Event
- Change
- Change Detail
- Product Detail Set
- Sequence

Registration

- Registration
- Registration-Package Set
- Registration-Package Set Country

Sequence

- Sequence

XEVMPD

- Application
- Event
- PDS
- PSet Registration
- Full Product Presentation

Chapter 31. Ennov InSight Registrations 7.3 Best Practices

The best practice topics provide recommendations to help you take advantage of built-in efficiencies in Ennov InSight .

The following topics are intended to be used in conjunction with the Ennov InSight user documentation. They provide best practice and process recommendations for using the Ennov InSight suite to create and manage eCTD submissions to regulatory authorities. These provide general best practice guidelines and module-specific tips and tricks to best leverage the lifecycle management aspects and assembly features of the Ennov InSight suite. It is not intended to replace the user documentation. Specific details on how to perform individual functions are included in the online help, not in these Best Practice guides. For Publishing Best Practice guides, See Publishing Best Practices.

Name
Associating SPOR Values in Data Admin
CE Mark Applications
Consumer Product Applications
Creating EU PSUR Events
Creating Flu Vaccines
EAEU Procedures
GCC Procedure
Guide to Managing BREXIT Related Regulatory Activities
Internal and External Status Values
Linked Systems
Management of Change
Managing Active Ingredients for XEVMPD Submissions
Managing Users Best Practice
MRP and DCP Variations Approvals
Named Patient Program and Import License
Orphan Drug Designation
Pediatric Plans
Plasma Master File
PMS Data Enrichment
Risk Management Plan

Submitting products pending approval to XEVMPD
Substance Registration (DMF, CEP, ASMF)
Sunset Clause Reporting
User Activity Report
Using the Association Closed As Functionality
Withdrawing Products