



BEST PRACTICE: INTERNAL AND EXTERNAL STATUS VALUES

1 Revision History

When Ennov releases a new version of Ennov InSight, they issue Release Notes which explain the new features and updates. The Ennov Business Consulting Team reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Ennov recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/Revision Date	Summary of Change(s) (Refer to Release Notes for Full Description)
v7.3.1	28-Jun-2024	Update Best Practice for Ennov rebranding & for v7.3.1 – No Impact
v7.3	01-Mar-2024	Update Best Practice for v7.3 – No Impact
v7.2	04-Apr-2023	Update Best Practice for v7.2 – Impact
v7.1	18-Jan-2022	Update Best Practice for v7.1 – No Impact
v7.0	14-Jul-2021	Update Best Practice for v7.0 – Impact
N/A	02-Apr-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF6	21-Oct-2020	Update Best Practice for v6.2 CHF6 – Impact
v6.2 CHF5	03-Aug-2020	Update Best Practice for v6.2 CHF5 – Impact
v6.2 CHF4	28-Feb-2020	Update Best Practice for v6.2 CHF4 – No Impact
v6.2 CHF3	27-Jun-2019	Update Best Practice for v6.2 CHF3 – No Impact
v6.2 CHF2	15-Feb-2019	Update Best Practice for v6.2 CHF2 – No Impact

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3 Document Purpose and Scope

The purpose of this document is to provide a Best Practice for

- Understanding the interaction between INTERNAL and External Status Values
- Defining Status Values
- Identifying the impact of the INTERNAL Status Values when using the associated Wizards

The management of INTERNAL and External Statuses is the responsibility of those users with Data Administration access within Ennov InSight, all mappings are maintained in Data Administration. These mappings have an impact on required Entity status and Wizard functionality. Users responsible for the mappings need to understand these key relationships in Ennov InSight.

Note: Users responsible for Data Administration are referred to as "Business Administrators" in this document.

To provide context for Ennov InSight Status best practice, this document will address:

- Locating Status Values in Data Administration
- INTERNAL and External Status Definitions
- Status Rules
- Status Value Mapping
- INTERNAL and External Status Values by Entity
- Wizard Status Actions
- Closing An Event and its Associations without a Wizard

3.1 Locating Status Values in Data Administration

Status Values are located in Data Administration under each applicable section.

Data Administration Section	Status Values
Application Maintenance	Application Status Values
Change Maintenance	Event-Change Detail Status Values
Event Maintenance	Event Status Values
Product Detail Set Maintenance	Product Detail Set Status Values
Product Family Maintenance	Product Family Status Values
Product Maintenance	Product Status Values
Project Maintenance	Project Status Values
Reference Maintenance	Reference Status Values
Registration Maintenance	Registration Status Values
Sequence Maintenance	Sequence Status Values
Task Maintenance	Task Status Values

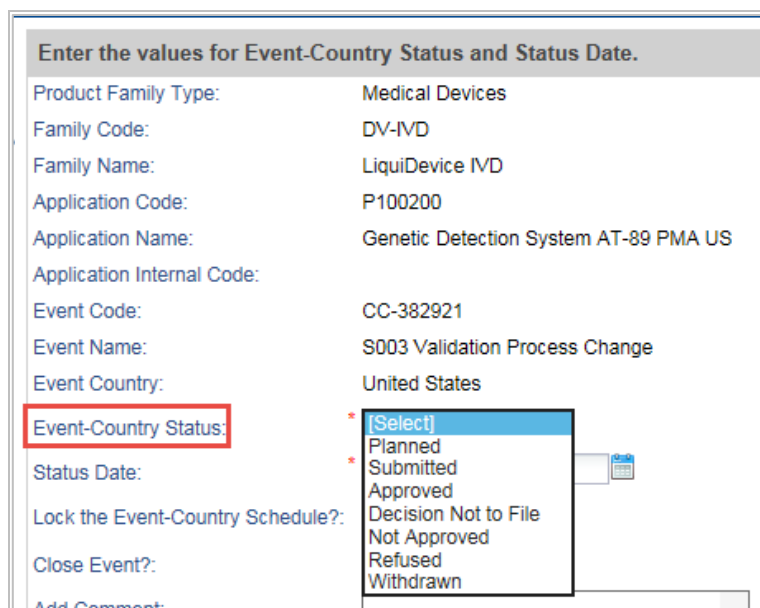
3.2 INTERNAL and External Status Definitions

Within Ennov InSight, two types of Statuses are defined and managed in Data Administration: External and INTERNAL.

3.2.1 External Statuses

These are the <Entity> status values that users see on most screens, e.g. Application Status, Event-Country Status. The values that are provided out-of-the-box (OTB) are always represented with the first letter of each word as upper case. Users can apply these status values to these Entities manually or via Status Wizards.

In the following example, a range of External Event-Country Status values are available for selection on the Event:



Enter the values for Event-Country Status and Status Date.	
Product Family Type:	Medical Devices
Family Code:	DV-IVD
Family Name:	LiquiDevice IVD
Application Code:	P100200
Application Name:	Genetic Detection System AT-89 PMA US
Application Internal Code:	
Event Code:	CC-382921
Event Name:	S003 Validation Process Change
Event Country:	United States
Event-Country Status:	[Select] Planned Submitted Approved Decision Not to File Not Approved Refused Withdrawn
Status Date:	
Lock the Event-Country Schedule?:	
Close Event?:	
Add Comment:	

Each OTB External Status is defined in the INTERNAL and External Status Values by Entity section of this document.

3.2.2 INTERNAL Statuses

These are programmed values that manage specific Ennov InSight behavior. INTERNAL Statuses are always represented in upper case letters, e.g. APPROVED, and are mapped to External Statuses in Data Administration. These status values are programmed to:

1. Trigger the External Status value display after a Status Wizard is invoked, e.g.:
 - a. Sequence Status updates from Planned to Submitted
 - b. Application Status updates from Submitted to Active
2. Perform additional status actions, including changing the status dates, in the system, e.g.:
 - a. Project Pivot Status
 - b. Event Closure
 - c. PDS Node Status Updates

- d. Change Detail Status Updates (Date not included)
- 3. INTERNAL Statuses are also used to determine the Active Navigation Tree View
 - a. Applications where the External Status is mapped to an INTERNAL Status of NOT APPROVED or WITHDRAWN are not presented in the navigation tree
 - b. Events that are closed at an INTERNAL Status of APPROVED, NOT APPROVED or WITHDRAWN are not displayed in the tree view

INTERNAL Statuses can also be applied without using System Wizards, e.g.:

- Manually updating the status of a PDS Node to a status of WITHDRAWN or NOT APPROVED will trigger internal status values to suppress the Withdrawn / Not Approved detail from future PDS views.
- Manually closing an Event and its Associations will trigger the closing status to be applied to the Event Associations e.g. PDS, Change Detail.

Because they have programmatic impact, INTERNAL System Status values cannot be modified or deactivated by clients, nor can new INTERNAL Status values be created.

Currently, there are eight INTERNAL Status values. It is important to note that not all INTERNAL Status values are used in all Entities.

INTERNAL Status	Definition
PLANNED	Regulatory Activity is planned.
DATA AVAILABLE	Data are available to support the specific regulatory objective.
DESPATCHED	Client has released the submission to an affiliate or a third party distributor.
SUBMITTED	The submission has been officially submitted to the Regulatory Authority, either by the sponsor directly, or by a distributor or affiliate. This status will also be used for internal reviews where there is no requirement to submit to a Regulatory Agency.
DAY 0	The Regulatory Authority commences the review of the Regulatory Submission (typically used for European Applications).
APPROVED	The Regulatory Activity has been accepted, either by an external Regulatory Body or by an internal review (as appropriate). This is a final disposition status.
NOT APPROVED	The Regulatory Activity has not been accepted, either by an external Regulatory Body or by an internal review (as appropriate). This is a final disposition status.
WITHDRAWN	The Regulatory Activity is withdrawn from review by the Marketing Authorisation Holder or the Sponsor. This may be before or after DESPATCH or SUBMISSION and is usually prior to a final decision. This is a final disposition status.
INACTIVE	This status only applies to Products. It is used in v7.0 to add at least one Product to each Application to fulfill v7.0 Application requirements. Products with the INACTIVE status do not display on widgets, wizards, multi-selects and drop-down lists.

Refer to the section entitled Status Wizards in this document for additional information on the application of INTERNAL System Statuses.

3.3 Interaction of INTERNAL and External Status Values

An INTERNAL Status cannot perform its programmed function unless it is mapped to an External Status value in Data Administration. The Application Status graphic, below, shows a representative mapping relationship between an External Status (Name) and an INTERNAL Status value:

The form titled "Application Status Values" contains three fields. The first field, "Name:", has a dropdown menu with "Active" selected. A red arrow points from this field to the text "External Status / Display Name". The second field, "Default Flag:", has a dropdown menu with "No" selected. The third field, "Internal System Status:", has a dropdown menu with "APPROVED" selected. A red arrow points from this field to the text "INTERNAL STATUS value".

It is the Business Administrator's responsibility to understand and manage these mapping relationships.

Ennov supports Business Administrators by providing many OTB External-to-INTERNAL Status mapping relationships. Although Business Administrators may rename External Status Values to align with their business processes, because of the programmatic impact of INTERNAL Status Values on Wizards, they should check with their Ennov Regulatory Consultant before changing External-to-INTERNAL Status value mappings.

It is important to note that many External Status Values have no corresponding INTERNAL Status Value. These values – such as *In Review* or *Refused* – inform users of an Entity's Status, but they have no programmatic impact.

As a general rule, only Business Administrators see INTERNAL Status values. However, in some instances, INTERNAL Status values display to users. The following graphic depicts a screen from the Update Event Status wizard. Note that the display informs users of the External Status (Event-Country) that users will see, as well as the INTERNAL Status (Associations Closed As) that will trigger programmatic status updates in the system.

The form titled "Update Event Country Status" contains several fields. The "Event Code:" field has the value "CC425205". The "Event Name:" field has the value "Change in Shelf Life for Prefilled Syringe". The "Event Country:" field has the value "United States". The "Event-Country Status:" field has a dropdown menu with "Submitted" selected, highlighted with a red box and labeled "External Status". The "Status Date:" field has the value "03-Jul-2018". The "Lock the Event-Country Schedule?:" field has a dropdown menu with "Yes" selected. The "Close Event?:" field has a dropdown menu with "Yes" selected. The "Closed Date:" field has the value "03-Jul-2018". The "Associations Closed As:" field has a dropdown menu with "APPROVED" selected, highlighted with a red box and labeled "Internal Status".

3.4 Status Rules

If status mappings are improperly managed, wizards may not function properly. Guidelines for status maintenance include:

- An INTERNAL Status value must be mapped to an External Status Value. If no External Status is mapped to an INTERNAL Status value, the Wizard cannot operate as designed OTB.
- Multiple external (display) status values can be mapped to the same Internal System Status value and the wizard logic can be retained by selecting a 'System Process Default Flag' value. The Entity statuses in scope are
 - Application Status
 - Product Status
 - Event Status
 - Event Change Detail
 - Sequence Status
 - Registration Status

The following screenshots demonstrate this functionality. In the example below, both the Transferred and Withdrawn status values are mapped to the Internal System Status of WITHDRAWN.



The screenshot shows a form titled "Application Status Values". The "Name:" field contains the text "Transferred" and is highlighted with a red box. The "Default Flag:" dropdown is set to "No". The "System Process Default Flag:" dropdown is also set to "No". The "Internal System Status:" dropdown is set to "WITHDRAWN".

The System Process Default Flag is selected to automate a single [Display] name value when using the status Wizards. In the graphic below, the Business Administrator has set the System Process Default Flag to Yes for the display Name of Withdrawn, so Withdrawn is the status that will display when users apply a status wizard to update the WITHDRAWN status.



The screenshot shows a form titled "Application Status Values". The "Name:" field contains the text "Withdrawn" and is highlighted with a red box. The "Default Flag:" dropdown is set to "No". The "System Process Default Flag:" dropdown is set to "Yes". The "Internal System Status:" dropdown is set to "WITHDRAWN".

For Entity Status values not noted above, only one External Status value should be mapped to an INTERNAL Status Value.

OTB External Statuses can be renamed and new ones created as required by business process. Consideration should be given before creating new status values to ensure that there is a balance between business benefit and a proliferation of statuses that will not be used or will be used inconsistently. Renaming an External Status will overwrite the status of existing records where the previous value has been used in the User Interface.

All External Statuses must be defined and referenced as appropriate in user guidance to ensure clarity of use.

Note: Changing the External to INTERNAL Status mapping is not recommended. Please contact your Ennov Consultant to discuss.

3.5 Status Value Mapping

Ennov InSight offers several Wizards to manage the status of certain Entities including the *Update Status Wizard*, *Change Submittal Wizard* and *Event-Country Status Wizard*. The list of all Wizards and impacted Statuses are described in the *Status Wizards in* section of this document

These Wizards are capable of operating on the following Entities:

- Application
- Event
- Event Change Details
- Sequence
- Product Detail Set
- Registration
- Project

For each Entity, the tables in the next section list the OTB External Status values and provide a definition for each Status, whether the value is set as the default for that Entity, and details of mappings to an INTERNAL Status. The section also includes INTERNAL Status definitions for Events and Projects. Where applicable, best practice comments are included.

4 INTERNAL and External Status Values by Entity

4.1 Product Family

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Active	Regulatory Activity is ongoing for the Product Family.	Yes	N/A	Retain Active Status as the default.
Planned	Regulatory Activity is planned.	No	N/A	NB: Consider deactivating the Planned Status if this will not be used.
Withdrawn	The Product Family is no longer maintained i.e. there are no active Products associated with the Product Family.	No	N/A	All associated Registrations and Applications are withdrawn, cancelled or divested to a third party.

Note: Product Family Status and Product Family Status Date fields are hidden OTB from Ennov InSight 7.1. This section of the document is being retained for those Clients who opted to unhide these fields.

4.2 Product

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Active	Regulatory Activity is ongoing for a Product.	Yes		
Approved	The Product is approved in at least one Country.	No	APPROVED	
Inactive	The Product was created as a requirement for v7.0 migration.	No	INACTIVE	

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Not Approved	The Product is not approved in all Countries.	No	NOT APPROVED	
Planned	Regulatory Activity is Planned.	No	PLANNED	
Submitted	The Product has been submitted in at least one country. This status will also be used for internal reviews where there is no requirement to submit to a Regulatory Agency.	No	SUBMITTED	
Withdrawn	The Product is withdrawn in all Countries.	No	WITHDRAWN	Populate the Reason for Termination / Withdrawal field.

4.3 Application

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

Mapping more than one Application External Status to a single INTERNAL Status is supported in RIM. To ensure that the Status is updated to the preferred Status when system logic is applied the System Process Default Flag can be set to Yes or No as required

An Application Status cannot be updated to the preferred status value mapped to the Internal Status of WITHDRAWN unless all associated Registrations are assigned to the External System Status mapped to the Registration Internal Status of WITHDRAWN.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Active	Regulatory Activity for the Application is ongoing and there is at least one approved Event.	No	APPROVED	APPROVED Applications display on the Navigation Tree.
Not Approved	The Initial Application has not been accepted, either by an external Regulatory Body or by an internal review (as	No	NOT APPROVED	NOT APPROVED Applications do not display in the Navigation Tree.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
	appropriate).and there is no other Regulatory Activity planned.			
Planned	Regulatory Activity is planned.	Yes	PLANNED	This is the default status when an Application is created. PLANNED Applications display on the Navigation Tree.
Submitted	The first Regulatory Objective has been officially submitted to the Regulatory Authority, either by the sponsor directly, or by a distributor or affiliate. This status will also be used for internal reviews where there is no requirement to submit to a Regulatory Agency.	No	SUBMITTED	SUBMITTED Applications display on the Navigation Tree.
Withdrawn	The Initial Application has been withdrawn by the Sponsor / MAH and no additional Regulatory Activity is planned.	No	WITHDRAWN	Populate the Reason for Termination / Withdrawal field. WITHDRAWN Applications do not display in the Navigation Tree.

4.4Associations Closed As Status (previously Event Closed As)

There are only three possible options to select, these are the INTERNAL Statuses of APPROVED, NOT APPROVED, and WITHDRAWN. Closing the details associated with an Event to any one of these statuses will result in the status being applied to any pending change on the associated Product Detail Set and to associated Change Details. For more information refer to the Best Practice:

Associations Closed As Status	Definition
APPROVED	The detail (PDS detail, Change detail) associated with the Regulatory Objective has been closed as APPROVED. This is a final disposition status.
NOT APPROVED	The detail (PDS detail, Change detail) associated with the Regulatory Objective has been closed as NOT APPROVED. This is a final disposition status.

WITHDRAWN	The detail (PDS detail, Change detail) associated with the Regulatory Objective has been closed as WITHDRAWN. This is a final disposition status.
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4.5 Event-Country Status

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

Mapping more than one Event External Status to a single INTERNAL Status is supported in RIM. To ensure that the Status is updated to the preferred Status when system logic is applied, the System Process Default Flag can be set to Yes or No as required

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Approved	The Regulatory Objective has been accepted, either by an external Regulatory Body or by an internal review (as appropriate) i.e. where there is no requirement for Regulatory Authority review e.g. Class I Non-sterile I Non-measuring Medical Devices, Cosmetic Products.	No	APPROVED	
Data Available	Data are available to support the specific regulatory objective.	No	DATA AVAILABLE	
Day 0	The Regulatory Authority commences the review of the Regulatory Submission (typically used for European Applications).	No	DAY 0	
Despatched	Client has released the submission to an affiliate or a third party distributor.	No	DESPATCHED	External Status can be renamed to Despatched as Client prefers.
In Discussion	Status provided OTB to describe an internal business process step.	No		May be deactivated if not required or renamed as appropriate.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
In Effect	Status provided OTB to describe an internal business process step.	No		May be deactivated if not required or renamed as appropriate.
In Review	Status provided OTB to describe an internal business process step.	No		May be deactivated if not required or renamed as appropriate.
Not Approved	The Regulatory objective has not been accepted, either by an external Regulatory Body or by an internal review (as appropriate).	No	NOT APPROVED	
Planned	Regulatory objective is planned.	Yes		
Refused	Status provided OTB to describe an internal business process step.	No		May be deactivated if not required or renamed as appropriate.
Submitted	The Regulatory Objective has been officially submitted to the Regulatory Authority, either by the sponsor directly, or by a distributor or affiliate. This status will also be used for internal reviews where there is no requirement to submit to a Regulatory Agency.	No	SUBMITTED	
Withdrawn	The Regulatory Objective is withdrawn by the Sponsor / Marketing Authorisation Holder. This status will also be used in scenarios where the Regulatory Objective cannot be progressed and a	No	WITHDRAWN	Populate the Reason for Termination / Withdrawal field

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
	decision not to file is made.			

4.6 Product Registration Event-Product

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Active	Regulatory Activity is ongoing for a Product.	Yes	N/A	
Approved	The Regulatory Objective with which the Product is associated has been accepted, either by an external Regulatory Body or by an internal review (as appropriate).	No	APPROVED	
Not Approved	The Regulatory objective with which the Product is associated has not been accepted, either by an external Regulatory Body or by an internal review (as appropriate).	No	NOT APPROVED	
Planned	Regulatory Activity is Planned	No	PLANNED	
Submitted	The Regulatory objective with which the Product is associated has been officially submitted to the Regulatory Authority, either by the sponsor directly, or by a distributor or affiliate. This status will also be used for internal reviews where there is no requirement to	No	SUBMITTED	

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
	submit to a Regulatory Agency			
Withdrawn	<p>The Regulatory Objective with which the Product is associated is withdrawn by the Sponsor / Marketing Authorisation Holder</p> <p>This status will also be used in scenarios where the Regulatory Objective cannot be progressed and a decision not to file is made</p>	No	WITHDRAWN	

4.7 Event Change Details

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

Refer to the Calyx RIM for Registrations Best Practice: Management of Change and Calyx RIM for Registrations Best Practice: Using the Associations Closed As Functionality.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Approved	The Change Detail has been accepted, either by an external Regulatory Body or by an internal review (as appropriate).	No	APPROVED	
Not Approved	The Change Detail has not been accepted, either by an external Regulatory Body or by an internal review (as appropriate).	No	NOT APPROVED	
Planned	Regulatory Activity is planned.	Yes	PLANNED	
Submitted	The Regulatory Objective with which the Change Detail is associated has been officially submitted to the Regulatory Authority, either by the sponsor directly, or by a distributor or affiliate. This status will also be used for internal reviews where there is no requirement to submit to a Regulatory Agency.	No	SUBMITTED	
Withdrawn	The Change Detail is withdrawn from review by the Marketing Authorisation Holder or the Sponsor. This status will also be used in scenarios	No	WITHDRAWN	

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
	where the Change Detail cannot be progressed and a decision not to file is made.			

4.8 Sequence

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

Mapping more than one Sequence External Status to a single INTERNAL Status is supported in RIM. To ensure that the Status is updated to the preferred Status when system logic is applied, the System Process Default Flag can be set to Yes or No as required.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Approvable	Status provided OTB to describe an internal business process step	No		May be deactivated if not required or renamed as appropriate
Approved	The Regulatory Objective with which the Sequence is associated has been accepted, either by an external Regulatory Body or by an internal review (as appropriate).	No	APPROVED	
In Discussion	Status provided OTB to describe an internal business process step.	No		May be deactivated if not required or renamed as appropriate.
In Effect	Status provided OTB to describe an internal business process step.	No		May be deactivated if not required or renamed as appropriate.
Not Approved	The Regulatory Objective with which the Sequence is associated has not been accepted, either by an external Regulatory Body or by	No	NOT APPROVED	

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
	an internal review (as appropriate).			
Planned	Regulatory Activity is planned.	Yes	PLANNED	
Refused	Status provided OTB to describe an internal business process step.	No		May be deactivated if not required or renamed as appropriate.
Submitted	<p>The Sequence (Regulatory Dossier) has been officially submitted to the Regulatory Authority either by the sponsor directly, or by a distributor or affiliate.</p> <p>This status will also be used for internal submissions where there is no requirement to submit to a Regulatory Agency.</p>	No	SUBMITTED	
Withdrawn	<p>The Regulatory Objective associated with the Sequence is withdrawn from review by the Marketing Authorisation Holder or the Sponsor.</p> <p>This status will also be used in scenarios where the Regulatory Objective associated with the Sequence cannot be progressed and a decision not to file is made.</p>	No	WITHDRAWN	Populate the Reason for Termination / Withdrawal field.

4.9 Registration

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Active	The initial Regulatory Objective to Market the Product(s) has been accepted, either by an external Regulatory Body or by an internal review (as appropriate). The Registration is Active and available to Market.	Yes	APPROVED	Registration Status should be reviewed in conjunction with the status of the Regulatory Objective(s) and approved Product Details.
Expired	The Registration Expiration date is past and the Registration has lapsed.	No	N/A	Populate the Reason for Termination / Withdrawal field.
Pending	The initial Regulatory Activity has been submitted and is pending the completion of Regulatory review.	No	N/A	Deactivate these values to prevent the creation of Registrations with a Pending or Planned status. It is best practice to create the Registration when the Product is approved in the market.
Planned	The Registration is planned.	No	N/A	
Withdrawn	The Registration is no longer active e.g. the Registration has been officially cancelled or all responsibility has been divested to a third party.	No	WITHDRAWN	Populate the Reason for Termination / Withdrawal field.

4.10 Project

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

A Project can be deleted if all Events are in the Planned status.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Completed	All Events associated with the Project are closed.	No	N/A	Update the Project Status to Complete when all Events are closed.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
In Progress	One or more Events associated with the Project are subject to ongoing Regulatory Activity.	Yes	N/A	
Planned	All Event(s) associated with the project are planned.	No	N/A	Consider deactivating the Planned status if this will not be used. Where the Planned status is used it should be the default value.

4.11 Project Pivot Status

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

The Project Pivot Status functionality will calculate projected dates for the selected Timeline/Event Plan based on the selected Pivot Status and Date. The Project Pivot Status is not an Entity Status.

INTERNAL STATUS	Action	OTB Ennov InSight Default Flag	Best Practice
APPROVED	The APPROVED Status and the desired Projected Approval Date will be used to calculate all projected milestone status dates.	N/A	The INTERNAL Status is selected in the Project Pivot Status Field. The External Status mapped to the INTERNAL Status needs to be included in the Timeline\Event Plan that will be assigned.
DATA AVAILABLE	The DATA AVAILABLE Status and the desired Projected Data Available Date will be used to calculate all projected milestone status dates.	N/A	
DAY 0	The DAY 0 Status and the desired Projected Day 0 Date will be used to calculate all projected milestone status dates.	N/A	
DESPATCHED	The DESPATCHED Status and the desired Projected Despatched Date will be used to calculate all projected milestone status dates.	N/A	

INTERNAL STATUS	Action	OTB Ennov InSight Default Flag	Best Practice
PLANNED	The PLANNED Status and the desired Projected Planned Date will be used to calculate all projected milestone status dates.	N/A	
SUBMITTED	The SUBMITTED Status and the desired Projected Submitted Date will be used to calculate all projected milestone status dates.	N/A	
WITHDRAWN	The WITHDRAWN Status and the desired Projected Withdrawn Date will be used to calculate all projected milestone status.	N/A	

4.12 Product Detail Set (PDS) Attributes

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

The Product Detail Set Attribute Status always reflects the status of the Product within the Country.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Active	The Product within the Application is Approved.	No	APPROVED	
Not Approved	The Product within the Application is Not Approved.	No	NOT APPROVED	
Planned	Introduction of the Product in an Application is planned.	Yes	PLANNED	
Submitted	The Product within the Application has been submitted to Regulatory Authority. This status will also be used for internal reviews where there is no requirement to submit to a Regulatory Agency.	No	SUBMITTED	The Status of the PDS Attributes can be updated manually to Submitted but it will not be updated by the Status Wizards.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Withdrawn	The Product within the Application has been Withdrawn.	No	WITHDRAWN	

4.13 Product Detail Set (PDS) Details

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

PDS Details are updated to a final disposition via the Associations Closed As functionality, individual PDS details can be updated manually to a final disposition status to override this functionality.

Note: Ensure that any manual updates are completed prior to updating to a final disposition status using the Associations Closed As functionality.

Product Detail Status	Definition
APPROVED	The PDS Detail has been accepted, either by an external Regulatory Body or by an internal review (as appropriate). This is a final disposition status
NOT APPROVED	The PDS Detail has not been accepted, either by an external Regulatory Body or by an internal review (as appropriate). This is a final disposition status
PENDING ADD	A new PDS detail has been added and the final disposition status has not been applied
PENDING MODIFY	An existing approved PDS detail has been modified and the final disposition status has not been applied
PENDING WITHDRAWAL	An existing approved PDS detail has been withdrawn and the final disposition status has not been applied
WITHDRAWN	The PDS Detail has been withdrawn from the approved Product. This is a final disposition status.

4.14 Reference

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Active	Status provided OTB to describe an internal business process step.	N/A	N/A	May be deactivated if not required or renamed as appropriate.
Closed	Status provided OTB to describe an internal business process step.	N/A	N/A	

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Completed	Status provided OTB to describe an internal business process step.	N/A	N/A	At least one Status has to be assigned for each Reference Type in use.
Not Active	Status provided OTB to describe an internal business process step.	N/A	N/A	
Open	Status provided OTB to describe an internal business process step.	N/A	N/A	
Planned	Status provided OTB to describe an internal business process step.	N/A	N/A	
Received	Status provided OTB to describe an internal business process step.	N/A	N/A	
Sent	Status provided OTB to describe an internal business process step.	N/A	N/A	

4.15 Task

Note: In the following table, values are presented alphabetically and do not reflect typical business process progression.

Name of OTB External Status	External Status Definition	OTB Ennov InSight Default Flag	OTB Ennov InSight Mapping to INTERNAL Status	Best Practice
Archived	Status provided OTB to describe an internal business process step.	No	N/A	May be deactivated if not required or renamed as appropriate. At least one Status has to be assigned for each Task Type in use.
Closed	Status provided OTB to describe an internal business process.	No	N/A	
Open	Status provided OTB to describe an internal business process.	Yes	N/A	

5 Status Wizards in Ennov InSight

5.1 How the Status Wizards Work in Ennov InSight

5.1.1 Change Submittal Status Wizard

Summary of Action	Status mapped to the INTERNAL Status	Status Updated?					When to use this Wizard
		Application	Event-Country	Sequence	Change Details	PDS Details	
<p>Initiate from an Application, Event or Sequence window.</p> <p>Where there are multiple Events associated with a Sequence always invoke the Wizard from the Sequence.</p> <p>Requires a Sequence to be associated with the Event.</p> <p>Applies the Submitted status to the Sequence.</p> <p>For the First Sequence Submitted for the Event.</p> <p>Applies the Submitted status to one or more Event-Countries.</p> <p>Applies the Submitted status to the Change Details associated with the Event.</p> <p>Applies the Submitted status to the Application.</p>	SUBMITTED	Y (if 1st Initiation of Wizard)	Y (if 1st Initiation of Wizard)	Y	Y (if 1st Initiation of Wizard)	N/A	Updating the Sequence and Event Status to Submitted.

5.1.2 Update Status Wizard

Summary of Action	Associations Closed As INTERNAL Status	Status Updated?				When to use this Wizard
		Application/ PDS Status	Sequence	Change Details	PDS Details	
	APPROVED	Y*^	Y	Y	Y	

Summary of Action	Associations		Status Updated?			When to use this Wizard
	Closed As INTERNAL Status	Application/ PDS Status	Sequence	Change Details	PDS Details	
<p>Initiate from any location in the system, (must know Product Family, Country and Application Name).</p> <p>Capable of updating PSUR fields on Application and Product Family entities.</p> <p>If no Timeline/Event Plan applied, displays all available Event status values.</p> <p>If Timeline/Event Plan applied, but progression is not enforced, displays all status values available in the assigned Timeline/Event Plan.</p> <p>If Timeline/Event Plan applied and the progression is enforced, displays next available status.</p> <p>Note: Where there are divergent statuses applied across different Timeline/Event plans the ability to update via the Wizard will be constrained.</p> <p>Events can be closed without locking the Event-Country Status Schedule.</p> <p>Events can be closed regardless of selected Event-Country Status.</p> <p>*If this is the first Event to be closed under the Application, applies the status of the Application & PDS Attributes to</p>	<p>NOT APPROVED</p> <p>WITHDRAWN</p>	<p>Y*^</p>	<p>Y</p>	<p>Y</p>	<p>Y</p>	<p>To update the Event-Country. Status for multiple Events within an Application.</p>

Summary of Action	Associations Closed As INTERNAL Status	Status Updated?			PDS Details	When to use this Wizard
		Application/ PDS Status	Sequence	Change Details		
<p>Active/Not Approved/Withdrawn (as appropriate).</p> <p>The Event Product Status is updated for Products associated with Events under a Product Registration Application.</p> <p>Sequence status is updated to the mapped INTERNAL Status when the Event is closed.</p> <p>The Sequence is closed when the Event is closed.</p>						

5.1.3 Update Event-Country Status Wizard

Summary of Action	Associations Closed As INTERNAL Status	Status Updated?			PDS Details	When to use this Wizard
		Event Product Application/ PDS Status	Sequence	Change Details		
<p>Initiate from the Event-Countries tab of the Event.</p> <p>If no Timeline/Event Plan applied, displays all available Event status values.</p> <p>If Timeline/Event Plan applied, but progression is not enforced, displays all status values available in the assigned Timeline/Event Plan.</p> <p>If Timeline/Event Plan applied and the progression is enforced, displays next available status.</p>	APPROVED	Y*^	Y	Y	Y	To update the Event-Country Status for a single Event.
	NOT APPROVED	Y*^	Y	Y	Y	
	WITHDRAWN	Y*^	Y	Y	Y	

Summary of Action	Associations Closed As INTERNAL Status	Event Product Application/ PDS Status	Status Updated?			When to use this Wizard
			Sequence	Change Details	PDS Details	
<p>Events can be closed without locking the Event-Country Status Schedule.</p> <p>Events can be closed regardless of selected Event-Country Status.</p> <p>*If this is the first Event to be closed under the Application, updates the status of the Application & PDS Attributes to Active/Not Approved/Withdrawn.</p> <p>^The Event Product Status is updated for Products associated with Events under a Product Registration Application.</p> <p>Sequence status is updated to the corresponding INTERNAL Status when the Event is closed but the Sequence is not closed.</p> <p>Note the Sequence is not closed.</p>						

5.1.4 Update Project Event-Country Status Wizard

Summary of Action	Associations Closed As INTERNAL Status	Event Product Application/ PDS Status	Status Updated?			When to use this Wizard
			Sequence	Change Details	PDS Details	
Initiate from the Event-Country Dates tab within a Project.	APPROVED	Y* ^	Y	Y	Y	To update multiple Events within
	NOT APPROVED	Y* ^	Y	Y	Y	

Summary of Action	Associations Closed As INTERNAL Status	Event Product Application/ PDS Status	Status Updated?			When to use this Wizard
			Sequence	Change Details	PDS Details	
<p>If no Timeline/Event Plan applied, displays all available Event status values.</p> <p>If Timeline/Event Plan(s) are applied, but progression is not enforced, displays all common status values available in the assigned Timeline/Event Plan(s).</p> <p>If Timeline/Event Plan(s) are applied and the progression is enforced, only where the next available status is common across all selected Timeline/Event Plans will the status be available for selection.</p> <p>Note: Where there are divergent statuses applied across different Timeline/Event plans the ability to update via the Wizard will be constrained.</p> <p>Events can be closed without locking the Event-Country Status Schedule.</p> <p>Events can be closed regardless of selected Event-Country Status.</p> <p>*If this is the first Event to be closed under the Application, updates the status of the Application & PDS Attributes to Active/Not Approved/Withdrawn.</p>	WITHDRAWN	Y* ^	Y	Y	Y	a Project with the same status value.

5.2 Closing An Event and its Associations without a Wizard

Summary of Action	Associations Closed As INTERNAL Status	Status Updated?			PDS Details	When to use this
		Application/ PDS Status	Sequence	Change Details		
Initiate from an Event. Events can be closed without locking the Event-Country Status Schedule. Event can be closed regardless of selected Event-Country Status. *If this is the first Event to be closed under the Application, updates the status of the Application & PDS Attributes to Active/Not Approved/Withdrawn. ^The Event Product Status is only available for Products associated with an Event under a Product Registration Application. Sequence status is updated to the corresponding INTERNAL Status when the Event is closed. Note the Sequence is not closed.	APPROVED	Y* ^	Y	Y	Y	Closing an Event when the Event can be closed at the current status.
	NOT APPROVED	Y* ^	Y	Y	Y	
	WITHDRAWN	Y* ^	Y	Y	Y	

5.3 Managing Product and Package Set Withdrawals

When the Withdraw Product Package Set Global Project Plan (GPP) is used to manage License Cancellations and Withdrawals, Ennov InSight action on associated Applications, Registrations, and PDSs are described in the following table.

Condition	Action	Result
Withdrawing an Application Note: Ennov InSight withdraws the Application	Apply GPP Withdraw Product [from] Package Set Registration Wizard	All Product Detail Sets associated with the Application must be selected and the details associated with the withdrawal Event are closed as APPROVED, Ennov InSight will: Update the Application Status to INTERNAL WITHDRAWN Status.

<p>by withdrawing all Registrations associated with the Application.</p>		<p>Update the Application Status Date to the Date the Event and the Associations are closed as APPROVED.</p> <p>Update the Product Detail Set Status to Withdrawn.</p> <p>Update the Product Detail Set Status Date to the Date the Event and the Associations are closed as APPROVED.</p> <p>Update the License Status to INTERNAL WITHDRAWN Status.</p> <p>Update the License Status Date to the date that the to the Date the Event and the Associations are closed as APPROVED.</p> <p>Update the Registration-Package Set Attributes to Withdrawn.</p>
<p>Withdrawing a Product under a multi-Product Application</p>	<p>Apply GPP Withdraw Product [from] Package Set Registration Wizard</p>	<p>If at least one but not all Product Detail Sets associated with the Application must be selected and the details associated with the withdrawal Event are closed as APPROVED, Ennov InSight will:</p> <p>Update the affected Product Detail Set Status to Withdrawn.</p> <p>Update the affected Product Detail Set Status Date to the Date the Event and the Associations are closed as APPROVED.</p> <p>Update the License Status to INTERNAL WITHDRAWN Status if all PDS associated with the Registration are withdrawn.</p> <p>Update the License Status Date to the Date the Event and the Associations are closed as APPROVED if all PDS associated with the Registration are withdrawn.</p> <p>Update the affected Registration-Package Set Attributes to Withdrawn.</p> <p>When the Event and Associations are closed as APPROVED Ennov InSight will not:</p> <p>Update the Application Status if at least one Registration is not linked to the WITHDRAWN INTERNAL Status.</p> <p>Update the License Status and Status Date if more than one PDS is associated with the Registration and that PDS is not withdrawn.</p>