BEST PRACTICE: DATA MANAGEMENT

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2 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)
v7.3.4	22-May-2025	Update Best Practice for Ennov rebranding & for v7.3.4 – No Impact
v7.2	20-Jun-2023	Update Best Practice for v7.2 – No Impact
v7.1	13-Jan-2022	Update Best Practice for v7.1 – No Impact
v7.0	25-May-2021	Update Best Practice for v7.0 – 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

3 Document Purpose

The purpose of this document is to provide best practice guidance for tracking data in Ennov InSight Publisher. It is the responsibility of each organization to decide what and how data are tracked. This document reflects Ennov best practices based on why and how the system was designed and implemented, taking into consideration industry standards and experiences.

This best practice document focuses on Electronic Lifecycle Publishing (ELP), Paper Review Publishing (PRP) modules of Ennov InSight Publisher and the Submission Planning and Tracking (SPT) module. If utilizing the full Ennov InSight suite within your organization, the Ennov InSight for Registrations Data Management Best Practice document should be used in conjunction with this document. Additional Publishing best practice documents should also be used when implementing Ennov InSight Publisher.

Any entry followed by "(SPT)" indicates that the information relates to functionality available with the Ennov InSight Submission Planning and Tracking module.

4 Scope

This document covers tracking data in Ennov InSight Publisher and Ennov InSight Submission Planning and Tracking.

5 General Considerations

This section describes basic rules and expectations.

- Company Style Guides and Operation Guides should be in place (including naming conventions and abbreviations) and should be used consistently throughout the organization. Standard, agreed upon naming conventions are highly recommended. They are critical for consistency, searching, reporting and migration. Company Style Guides and Operation Guides will help enforce the use of the conventions.
- The System Configuration Specification will identify the fields that are included in each client's configuration of Ennov InSight Publisher or Ennov InSight Submission Planning and Tracking and company user guides will define any specific fields as required. Not every field in the system is described in this document.
- Fields should not be repurposed. Using fields for reasons other than what was intended could lead to future migration and upgrade problems.
- Special characters should be avoided. Different characters are often "reserved" in most software, meaning they are used in performing specific functions. One example is that the "/" and "\" often implies a change in folder structure, which is the case for Application Name & Application Code when clients are using the entire Ennov InSight Suite. It is considered best practice to not use any special characters.
- The use of Descriptions, Comments, and Keywords fields should be clearly stated in the Company Style Guide or Operation guide. If it is determined that these fields do not add extra value on a particular entity, they should be hidden. This will ensure that erroneous information is not being entered.
- Best practice is for each client to have a Business Process Workshop (BPW) and System Set-up Workshop (SSW). At the BPW essential data and processes are determined. The SSW will streamline the client's specific needs and identify fields to be hidden (attributes that are not needed), renamed or added into the client-specific configuration. This will minimize user errors and maximize data and process efficiency. This will also help identify and limit any potential conflicts with future migrations and upgrades.
- Best practice is to use the required fields for XEVMPD and those proposed for IDMP that are identified within the System Configuration Specification documentation. This will ensure alignment with harmonized regulatory requirements.

6 Design Overview

The Ennov InSight Publisher data model is designed with both a hierarchy and relationships. The relationship of the entities is as follows:

Project (SPT) can be for –

- 1 or more Product Families
- 1 or more Events within each Product Family
- 1 or more Events within an Application
- 0 or more Sequences within an Application

Application can –

- be for 1 or more Countries (e.g. GCC, EU DCP, MRP and CP Procedure Types)
- have 0 or more Events
- have 0 or more Sequence
- either have Package Set Registrations OR Product Registrations, but NOT both. (Once the Application entity is saved the Registration Type cannot be modified.)

Event can –

- have 0 or more Sequences

Sequence can –

- have 0 or 1 Assemblies

7 Product Family (PF)

Product Family (PF) is the highest level for logically grouping products, and the information tied to products. Defining the Product Family (PF) will depend upon the Product Family Type being created. Best practice is to have a company Style Guide / Operation Guide with these agreed upon terms to be used throughout the organization.

- When considering the naming convention for Product Family Names keep in mind that the system will be used globally, Product Family Name should be a name that is common to all areas (avoid names specific to one region or a handful of countries).
- Even when Product details are not being used within Ennov InSight it is important to follow the best practices below to support any future updates or roll outs to include new functionality.
- Note that the number of fields tracked within the Product Family level of the Ennov InSight Publisher or the Ennov InSight Submission Planning and Tracking module differs from the Ennov InSight for Registrations module.

7.1 Product Family Types

Product Family Types are used to control the type of data that is tracked at the various Product levels (PF, Product, PDS) regardless of how an application for the Product may be made in various countries. There are Products that are considered as Pharmaceutical (Medicinal) products in some countries and Medical Device in other countries. It is important to select the correct Product Family Type based on the data that needs to be tracked. The Application level in the system will identify how the product is classified in a country.

The following Product Family Types are included out-of-the-box:

- Pharmaceutical
- Medical Device
- Pharma-Med Device
- Veterinary
- Flu Vaccine

7.2 Pharmaceutical Product Families

In the case where the PF has only 1 or 2 active ingredients it is considered best practice to use a concatenation of the active ingredient names as the PF Name. If there are more than 2 active ingredients, the name can get quite long. Therefore, it is appropriate to discuss alternate naming conventions to ensure that the Name will be easily recognized globally.

Scenarios to consider when defining a Product Family:

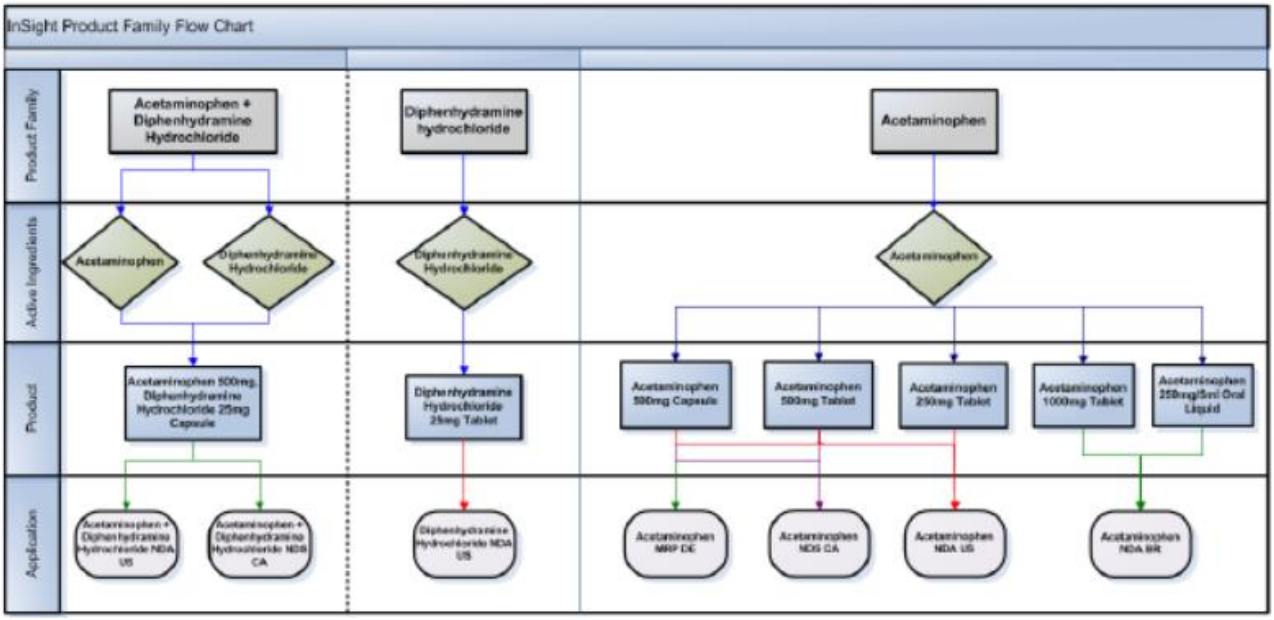
- A Pharmaceutical Product Family is a grouping based on the sum of its active ingredients, even if Ennov InSight is not used to capture Active Ingredients or other Product data.
- New active ingredients cannot be added to an established Product Family (one where a Product has already been created).

- A Pharmaceutical Product Family should not include active ingredients that are not used in all Products within that Product Family (even if Products are not being captured).

The following example demonstrates how different Products with the same active ingredients are handled in Ennov InSight Product Families. Even though the licenses of Ennov InSight Publisher and Ennov InSight Submission Planning and Tracking do not allow for products and active ingredients to be created the grouping of all Product Families should be handled in the same way as Ennov InSight for Registrations.

Care should be given to ensure that Products within the Product Family could realistically be included within the same MAA or NDA. In this example, the Acetaminophen + Diphenhydramine hydrochloride capsules would never be considered in the same application as the Diphenhydramine hydrochloride tablet and are therefore tracked in a separate Product Family.

Figure 1 Product Family example schematic



More Product Family examples are provided in **Appendix 1: Product Family Scenarios**.

7.3 Veterinary Product Families

When defining a Veterinary Product Family, the same rules apply as with Pharmaceutical Product Families. There are some fields that are different when comparing a Veterinary Product Family to a Pharmaceutical Product Family. Details on fields can be found in the Ennov InSight for Registrations System Configuration Specification documentation.

7.4 Medical Device Product Families

When defining a Medical Device Family, most of the same rules apply as with Pharmaceutical and Veterinary Product Families. The exceptions are that there are no active ingredients, substances or species for a medical device. Even with these exceptions, best practices are similar. Products with the same mode of action are grouped together. Typical examples of Medical Devices Product Families are:

- Syringes
- Heart pacemakers
- X-ray machine
- Scalpels
- Insulin packs (even if that pack contains a Syringe captured in the Syringes Product Family)
- Medicated plasters
- Heart valves
- Bone cement

7.5 Pharma-Med Device Product Families

When defining a Pharma-Med Device Family, most of the same rules apply as with Pharmaceutical Product Families and Medical Device Product Families.

7.6 Flu Vaccine Product Families

When defining a Flu Vaccine Product Family, most of the same rules apply as with Pharmaceutical Product Families unless specifically described within this document. At the Product Family level substitute active ingredients (of type AI Placeholder) are assigned rather than the specific Flu strain itself. This allows for the annual strain updates while still maintaining the restrictions of the active ingredient at the Product Family Level.

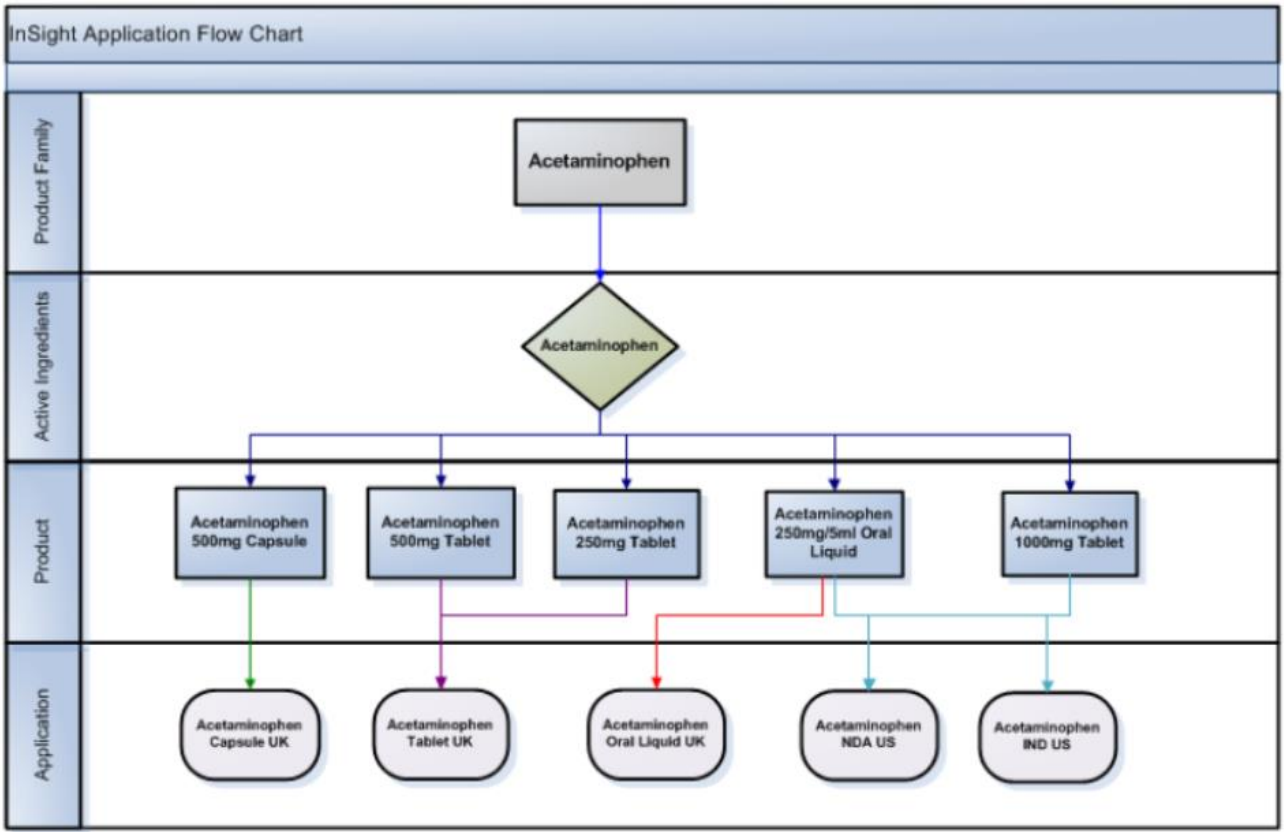
8 Further Best Practice for Product Families

1. Product Trade Names are defined in Data Administration, assigned at the Product Family Level and associated at the Product Detail Set that falls below the Application in the Ennov InSight for Registrations hierarchy. Product Trade Name is the short trade mark name known within a country without describing the strength and the form of the product, it is often link to a trademark. It is therefore not best practice to create separate Product Families for products that are marketed with different names, even if they are marketed in the same country under different names.
2. A Product that spans both Human and Animal health must be managed separately under two different Product Families to accommodate the way Ennov InSight for Registrations handles the two Product Family Types.
3. A Product that is registered as a Pharmaceutical in some countries and as a Medical Device in other countries may be tracked in a Pharma-Med Device Product Family or Pharmaceutical Product Family, depending on the type of data that needs to be tracked. The Pharma-Med Device Product Family Type is a Product Family that captures a combination of all the data tracked in a pharmaceutical product or a medical device product. During the SSW the Ennov consultants will assess the Product Family types required to support the Client's portfolio.

9 Application

Applications are captured at the country or region (EU, GCC, etc.) level. This level facilitates tracking the lifecycle of a product as it is approved by the regulatory authority. Products with different strengths and/or dosage forms can be associated with an Application if they share a common dossier that is maintained through the same lifecycle. The association of a Product (or Products) to an Application may differ depending on specific country regulations. Where possible the Application and its association with products should match the regulatory process in each country, even where Ennov InSight is not being used to capture Product information.

Figure 2 Application example schematic



9.1 Internal Code

The Internal Code should only be used if the organization has an established internal coding mechanism for identifying an Application. If this does not exist, best practice would be to hide the field from the user.

9.2 Application Code

9.2.1 Pharmaceutical, Flu Vaccine and Veterinary Applications

Best practice for the Application Code is to use the code provided by the regulatory body or organization being applied to for Marketing Authorization. If the Application Code is not known at the creation of the Application entity best practice would be to use the Application Name until such time as the Application Code is known. The Application Code is used within Ennov InSight Publisher to create the parent folder for the output file of a submission. Therefore, it is not recommended to use the special character '/'.

Some best practice examples:

- FR-H-0450-001-003
- EMEA-H-C-002835

9.2.2 Medical Device Applications

Best practice for the Application Code for Medical Device Applications is to use the code provided by the regulatory body or the organization seeking marketing approval. If the Application Code is not known at the creation of the Application entity best practice would be to use the Application Name until such time as the Application Code is known.

9.3 Application Name

Regardless of the Product Family Type, when determining the Name for an Application, apply a consistent naming convention. These naming conventions should be appropriate to the organization and should be as short as possible while still maintaining the convention and providing clarity to the users.

9.3.1 Pharmaceutical, Flu Vaccine, and Veterinary Applications

The Pharmaceutical and Veterinary Application Name should conform to a naming convention that can be applied across all Pharmaceutical or Veterinary Applications and should have some logical meaning to the users. It may also take into consideration the organizations registration strategy.

Pharmaceutical, Flu Vaccine and Veterinary Application Name Examples
<Product Family Name> <Type of Application> <Country or EU Procedure> <RMS/Rapp (if appropriate)
Ibuprofen + Caffeine MAA UK

- Ibuprofen + Caffeine MAA CP DK
- Ibuprofen + Caffeine MAA MRP BE
- Ibuprofen + Caffeine MAA DCP DE
- Ibuprofen + Caffeine NDA US
- Ibuprofen + Caffeine ABNDS CA
- Ibuprofen + Caffeine IND US
- Ibuprofen + Caffeine CTA BE
- Ivermectin + Pyrantel Pamoate ANADA US

9.3.2 Medical Device Applications

The Medical Device Application Name should conform to a naming convention that can be applied across all Medical Device Applications and should have some logical meaning to the users.

Medical Device Application Name Examples:

- <Product Family Name> <Type of Application> <Country/Region>
- Stainless V-Clamp PMA US
- Pacemaker 510K US
- Stainless V-Clamp CE-Cert EU

9.4 UUID

The UUID field is captured on the Application to support the requirements of European Union countries for eCTD submissions. The UUID is a universal unique identifier that is automatically generated on creation of the Application entity and at the Application level is only modifiable to those with Administration rights to Application Country. The UUID field is only available to countries that belong to the European Union or Undefined region. The UUID is required to be 32 digits separated by 4 hyphens: (xxxxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx).

NB: To meet the needs of Supporting Sequences, the UUID field is modifiable in the eCTD wizard, although in most cases the UUID should not change as the same UUID should be used for all Sequences supporting the same eCTD application.

9.5 Procedure Identifier

Best practice for the Procedure Identifier is to use the code provided by the regulatory body that is common to all products that are part of the Application.

Note: For a European MRP / DCP, the Procedure Indentifier should contain the country code of the Reference Member State + Human or Veterinary indicator + the medicinal product number. Whereas the speciality number characterizing the strength or pharmaceutical form will be tracked at the PDS level under the Speciality Number field.
Examples:

- FR/H/0450/
- EMEA/H/C/002835

9.6 Basic Considerations

When using the Copy Application or the Create New Application in Global Project Planning (SPT) functionality, Ennov InSight will append the 2-digit country code to the Internal Code, Application Code and Application Name to add uniqueness to those fields. If using the Copy Application functionality, it is suggested that the Application being used to copy from does NOT include a country identifier until after the copy is performed.

10 Event

Events are used to track the Regulatory Actions (Variations, Supplements, etc.) that occur against each Application. An Event represents a regulatory objective that can group multiple actions (Change Details) depending on country requirement. Note that this section applies to all Product Family Types.

10.1 Event Code

The Event Code may be used if the organization has an established internal coding mechanism for identifying an Event. If not, the best practice would be to hide the field from the user.

10.2 Event Name

The Event Name should conform to a naming convention that can be applied across all Events/Applications and should have some logical meaning to the users. It may also take into consideration the organization's registration strategy. The Event has additional fields to help in identifying the type of Event, so adding detail specific to the Event can be helpful when querying. Since adding this detail can also make it difficult to define the naming convention clearly, is considered best practice to come up with an example of the Events that happen most often so users can follow the convention as closely as possible. Event Code and Event Name within an Application must be unique. When Event Code is hidden Event Name must be unique.

Some best practice examples:

<Basic Type> followed by one of the following

- <Name of Manufacturer>
- <Type Detail>

Examples:

- Initial Filing
- Mar 2017 Safety Report – 6 months
- New Manufacturer – Vandelay Industries
- Labeling – Storage Condition to 18 months
- New Packaging – 24 count blister
- March 2017 Renewal
- New Strength – 500 mg
- 513(g) Request – Jun 2017
- 30 Day Notice – Dec 2016
- Class III Period Report – Sep

10.3 Event Type and Secondary Event Type

These fields allow for easier querying on "like" Events. Regional differences should be taken into consideration when defining these types, although wherever possible it is best practice to agree on a global definition of Event Types and Secondary Event Types. Some out of the box Types from a best practice perspective are:

- Primary: New Application
- Secondary: Full Filing
- Secondary: Abridged Filing

- Primary: Extension
- Secondary: Active Substance
- Secondary: Indication
- Secondary: Strength/Form/Route

- Primary: Type I Variation
- Secondary: Deletion of an indication
- Secondary: Type IA
- Secondary: Type IB
- Secondary: Change in content – manuf. Author
- Secondary: Change in shelf life after first opening
- Secondary: Change to markings on tablet

10.4 Basic Considerations

Event Codes and Event Names must be unique within an Application. Naming convention should be considered to ensure uniqueness constraint. For repeating Events (like Annual Reports, PSUR or Renewals) it is considered best practice to add a date to provide more clarity to the Event. Just as with Applications, when determining the Name for an Event it is best practice to apply a consistent naming convention. These naming conventions should be appropriate to the organization and should be as short as possible while still maintaining the convention and providing clarity to the users.

10.5 Event Status Schedules (SPT)

Event Status Schedules are used for tracking the milestones planned and achieved for each Event (Regulatory Action). It is considered best practice to use the Event Planning functionality to assist in the tracking of these milestones. Timeline/Event Plans are created in the Data Administration section of Ennov InSight. Timeline/Event Plans are either Procedure Type or Event Type specific; this determination is made at the time of creation and will depend on the type of Timeline/ Event Plan being created.

Timeline/Event Plans are defined ahead of time for the various types of Events that occur. The statuses (milestones, e.g. Dispatch, Submission, Approval) are defined with the appropriate lead times. When Events are created, an Event Plan is used to automatically add the milestones and include the projected dates on which the milestones are expected to be reached. (See the Ennov InSight for Registrations User Guide for instructions on the use of this feature). A standard plan should be available for selection for Events that will often follow the same path and the same approval times for a country. Since Plans are created in Data Administration, it is Business Administrators who will need to apply a naming convention and users would be trained to understand which plans should be used when.

Timeline / Event Plan Names should conform to naming conventions and be easily understood by the user so that the desired Plan is selected. To help users conform to the naming conventions, define examples based on the Events that happen most often so users can follow the convention as closely as possible.

Examples:

- Initial Filing <country> or <region> or <"global"> or <procedure>
- New Manufacturer <country> or <region> or <"global"> or <procedure>
- Labeling Update <country> or <region> or <"global"> or <procedure>
- New Packaging <country> or <region> or <"global"> or <procedure>
- New Strength <country> or <region> or <"global"> or <procedure>

10.6 Countries

For national Applications, InSight automatically selects the national country as the Event country. For multi-country applications, such as MRPs and DCPs, InSight automatically associates the Reference Member State (RMS) to the Event. Best practice is to supplement this selection by associating all countries affected by the regulatory action to the Event. Following this practice allows InSight to mirror regulatory reality. In a CP application, unless specific National submission or approval dates need to be tracked (e.g. RMM submissions) only the European Union Country needs to be associated.

11 Sequences

Sequences are used to track the actual submissions (document set) sent to a regulatory authority for the purposes of gaining approval for the Event (Regulatory Action). There can be multiple Sequences that occur for each Event.

Although it is ultimately up to individual organizations, it is considered best practice to track the submissions at the Sequence level and as part of that best practice to attach the Sequence to only 1 Event whereas each Event may have multiple Change Details. This provides the organization with the ability to know the status of submissions at any given time. Historically, it helps in the planning of new submissions because it shows exactly how long it took to obtain approvals of the various types of changes. Currently Ennov InSight will allow one Sequence to be associated to multiple Events, however this is not recommended. Logic developed within the system assumes one Event per Sequence.

Note: If Ennov InSight is already being used for Assembly tracking and Publishing, the conventions for Sequences should follow the rules that have been established for the Publishing process. If one Sequence is linked to multiple Events, it will require careful handling of the Wizards used.

11.1 Sequence Code

Sequence Code must be unique within an Application. It is considered best practice to use the eCTD conventions for Sequence Code values where relevant for eCTD or NeeS. If an Application is not under eCTD publishing rules care should be taken to not use eCTD numbering in case of future conflicts. When eCTD will be implemented the sequence numbering will continue.

11.2 Sequence Name

The Sequence Name should conform to a naming convention that can be applied across all Sequences, regardless of the Application and Event, and should have some logical meaning to the users. Including the Sequence Code (if an eCTD) and a simple description of the filing reason and a filing type can help in showing the logical progression of the Sequences when looking at the name. Examples of this are:
<Sequence Code> <Filing Description> <Filing Type >

Examples:

- 0000 Safety Report – 6 months – Safety Filing
- 0003 New Manufacturer-label change – Vandelay Industries – Variation Filing
- New Manufacturer-label change – Vandelay Industries Supplement Filing
- Labeling – Storage Condition to 18 months – Variation Filing
- New Packaging – 24 count blister – Variation Filing
- New Packaging – 24 count blister – Reformat Filing
- Renewal – Renewal Filing
- New Strength – 500 mg – Extension Filing

12 Clinical Trial Submissions

Ennov InSight functionality supports the 2 main methods of submitting data in support of a clinical trial authorization:

- One Application detailing all clinical trials in a rolling submission (like the US IND)
- Individual Applications each detailing one clinical trial in one or more (EU procedure) countries (like the European CTA).

12.1 Clinical Trial Comparators (SPT)

Comparators are used to capture specific details about comparators used in clinical trials across the Ennov InSight hierarchy. To that end the comparators are not assigned to an individual Product Family. Comparators can be any of 3 types: Comparator, Placebo, or IMP. As a best practice, minimally the suppliers for each Comparator should be tracked.

Clinical Trial Comparator Names

Clinical Trial Comparators may be named to match the investigational product they represent or will be compared with, for example:

- Ibuprofen comparator
- Ibuprofen placebo matched capsule

12.2 Clinical Trial Shared Data (SPT)

The Clinical Trial Shared Data entity captures information about a specific clinical trial protocol. Since the Clinical Trial Shared Data entity is assigned to an Application's Event, it captures information that is relevant across all Application types (IND –like or CTA-like). As a best practice, the following information should be tracked:

- Protocol Code Number
- Protocol Title
- EUDRACT number (if applicable)

12.3 Clinical Trial Application

Clinical Trial Applications are captured at the country or region (EU procedures) level. This level facilitates tracking the lifecycle of a Clinical Trial (or group of Clinical Trials as in the US IND) as it is approved by the regulatory authority. As a best practice the following information should be captured at the Clinical Trial IND/CTA Application.

12.4 Application Code

Best practice for the Application Code is to use the code provided by the regulatory body or organization being applied to for Marketing Authorization. If the Application Code is not known at the creation of the

Application entity best practice would be to use the Application Name until such time as the Application Code is known.

12.5 Study Number (CTA only)

Best practice for the Study Number is to use the internal Clinical Protocol Number.

12.6 Application Name (IND only)

Best practice for the Application Name is to apply a consistent naming convention. These naming conventions should be appropriate to the organization and should be as short as possible while still maintaining the convention and providing clarity to the users.

13 References (SPT)

References are used to help clients link external documents to specific entities based on their individual processes. In the System Setup Workshop (not covered in this document), clients will determine the right place for their users to attach references. In the workshop, clients will also decide the appropriate values to be used in the various drop-down selections. From a best practice perspective, clients should keep in mind that standard naming conventions should be considered, and examples should be provided in their Operations Manual. This will allow for consistency in the creation and tracking of References throughout the system. Reference Name must be unique within its association.

14 Tasks (SPT)

References are used to help clients link external documents to specific entities based on their individual processes. In the System Setup Workshop (not covered in this document), clients will determine the right place for their users to attach references. In the workshop, clients will also decide the appropriate values to be used in the various drop-down selections. From a best practice perspective, clients should keep in mind that standard naming conventions should be considered, and examples should be provided in their Operations Manual. This will allow for consistency in the creation and tracking of References throughout the system. Reference Name must be unique within its association.

14.1 Assembly

Following our best practice (naming conventions are handled during SSW) the assembly name should be named like the sequence name.

14.1.1 DMS Search & Grid View

From a data management perspective, it makes sense to reuse fields which are commonly used within the client's DMS. DMS field attribute values can be configured to allow for better search capabilities and for query results.

14.1.2 Data Mapping

On leaf and document level 'keywords', 'descriptions' and 'comments' may be reused for DMS data mapping.

14.1.3 Assembly Templates

Further information about Assembly Template Structures best practice can be found on help.Liquent.com.

The naming convention for assembly templates should remain as OOTB to ensure Ennov InSight will find the appropriate DTD when running the eCTD wizard.

In case additional eCTD templates have to be created to reflect regional specifications these should be renamed and mapped with the eCTD properties file to ensure that the eCTD wizard will work appropriately.

14.1.4 US Grouped Submissions

Further details about the US Grouped Submissions can be found on help.Liquent.com.

One topic to consider is the metadata differences for the applications within the grouped submission (application containing file and the other application pointing to the ACF).The metadata for primary application (ACF) and the other application(s) within the grouped submission need to be handled on the form attributes level for each application separately to ensure that the appropriate metadata gets entered correctly for each application.

15 Appendices

15.1 Appendix 1: Product Family Scenarios

15.1.1 Scenario 1

Active ingredient: Ennovamycin
2 different Manufacturers (one to support EU one for US) each with its own manufacturing site
2 different Products: Ennovamycin tablets and Ennovamycin liquid
Products may be sold as competitors by the same company (e.g. Ennovamycin tablet made in US is marketed in UK)

1 Product Family, 2 Products, 2 PDSs

15.1.2 Scenario 2

Active ingredients: Brown Spider venom, Black Spider venom, Yellow spider venom
3 different products: One for each spider venom product, never included in same MAA

3 Product Families (Black Spider Venom, Brown Spider Venom and Yellow Spider Venom), 1 Product per Product Family, 1 PDS per Product

15.1.3 Scenario 3

1 active ingredient
3 different flavors
Separate Registrations for each flavor

1 Product Family, 3 Products (each flavor), 3 PDSs

15.1.4 Scenario 4

Active ingredient: Ennovamycin
Registered in humans and horses

2 Product Families (1 Veterinary, 1 Pharmaceutical), 2 Products, 2 PDSs