BEST PRACTICE: PLASMA MASTER FILE

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 (minor reformatting only)
v7.2	04-Apr-2023	Update Best Practice for v7.2 – No Impact
v7.1	13-Jan-2022	Update Best Practice for v7.1 – No Impact
v7.0	30-Apr-2021	Update Best Practice for v7.0 – No Impact
N/A	17-Mar-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF6	21-Oct-2020	Update Best Practice for v6.2 CHF6 – No Impact
v6.2 CHF5	03-Aug-2020	Update Best Practice for v6.2 CHF5 – No 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

2 Contents

3 Document Purpose

The purpose of this document is to provide a Best Practice defining the process of managing standalone Plasma Master Files (PMF) in Ennov InSight.

3.1 Scope

The tracking and maintenance of standalone PMF dossiers submitted to health authorities outside of the Marketing Authorization Application approval by creating appropriate Applications and Events and other entities in Registrations Component of Ennov InSight.

4 Data Administration Activities

4.1 Application Category

A new Application Category should be created and named Plasma Master File.

4.2 Application Type

A new Application Type should be created named Plasma Master File, this should be mapped to the Default Application Type (Entity XML Type) and to the Plasma Master File Application Category; countries assigned should be all countries appropriate for the PMF.

Example:

- ***Application Type***: PMF
- ***Name***: Plasma Master File
- ***Display Name***: Plasma Master File
- ***Entity XML Type Name***: Default Application Type
- ***Application Category***: Plasma Master File
- ***Countries***: European Union, …

4.3 Product Family

A Product Family should be created for Plasma, in which all PMF Applications should be captured.

- ***Product Family Type***: Pharmaceutical
- ***Family Code***: <as appropriate>
- ***Family Name*:** Plasma

4.4 Product and Component

Product and Component should be created for each Plasma which requires a PMF Certification with the following Attributes:

- ***Product Name***: [Plasma Name]
- ***Component Name***: [Plasma Name]

Note: leave the Product Dosage Form and Component Form blank.

5 PMF Process

The Application is created in the Plasma Product family. Following the approval of a new or updated PMF certification application a submission may be required to the Marketing Authorisation Application (MAA).

MAA activities will follow standard processes for maintaining and updating an MAA and existing Best Practice and process documents should be used.

5.1 PMF Application

1. An Application should be created within the appropriate Plasa Product Family with the following attributes:
    a. ***Application Name:*** <Product Family Name> <Type of Application> <Country or EU procedure> <RMS / Rapp (if appropriate)> (e.g. Normal Human Immunoglobulin PMF AU)
    b. ***Application Type***: Plasma Master File
    c. ***Procedure Type***: <as appropriate>
    d. ***Reviewing Country***: <as appropriate>
    e. ***Product***: <as appropriate>
    f. Complete other fields as required by your organization.
2. Create an Event with the following attributes:
    a. ***Event Name***: follow organization naming convention (e.g. Human Immunoglobulin initial submission)
    b. Complete other fields as required by your organization.
3. Create a PDS as required by your organization.
4. Create a Sequence as required by your organization.
5. Create an Assembly as required by your organization.
6. Once approval is received:
    a. Verify PDS detail as required by your organization.
    b. Close and Approve the Initial Event.
    c. Create Reference as required by your organization.
    d. Create Registration as required by your organization.

Planning and Tracking activities will follow standard Ennov InSight processes.

5.2 Marketing Authorisation Application

As desired, a Reference can be made between the MAA Application/Event and the PMF Application/Event to provide traceability.