BEST PRACTICE: PEDIATRIC PLANS

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 – Impact
v6.2 CHF6	25-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 guide defining the process of capturing Paediatric Investigation Plan (PIP) Application and Pediatric Submission Plan (PSP) in Ennov InSight.

4 Scope

The scope of the proposed document is the process for defining the details required for PIP Application and PSP submission in the Registration Component of Ennov InSight.

PIP is used in countries such as European Union. A PIP Application will cover the development of a new indication for a development product or an authorized product.

PSP is used in countries such as United States. It is part of Investigational New Drug application which will cover the drug development and all protocols deployed for this new drug.

5 Data Administration Activities

5.1 Application Category

A new Application Category should be created and named Pediatric Investigation.

5.2 Application Type

A new Application Type should be created named Paediatric Investigation Plan. This should be mapped to the Clinical Trial Application Entity xml (Entity XML Type) and to the Pediatric Investigation Application Category, countries assigned should be all countries appropriate for the PIP.

Example:

- ***Application Type***: PIP
- ***Name***: Paediatric Investigation Plan
- ***Display Name***: Paediatric Investigation Plan
- ***Entity XML Type Name***: Clinical Trial Application
- ***Application Category***: Pediatric Investigation
- ***Countries***: European Union, …

5.3 Event Type

A new Event Type should be created named 'Pediatric Investigation/Study Plan' should be created . This Event Type will be used to capture PIP and PSP submissions.

5.4 Secondary Event Type

Secondary Event Types should be created named 'Product Specific Waiver', 'Complete Deferral'… as required by your organization and mapped to Event Type 'Pediatric Investigation/Study Plan'.

5.5 Product Family

Product Family should follow standard Ennov InSight Best Practice.

5.6 Product

Product should follow standard Ennov InSight Best Practice.

6 PIP Process

The PIP Application is created in the appropriate Product Family.

1. An Application should be created within the appropriate Product Family with the following attributes:
    a. ***Application Code***: Paediatric Procedure number
    b. ***Study Number***: follow organization naming convention (e.g. PIP Liquentymacine EU)
    c. ***Application Type***: Paediatric Investigation Plan
    d. ***Procedure Type***: <as appropriate> (e.g. EU CP for European Union)
    e. ***Reviewing Country***: <as appropriate> (e.g. Rapporteur)
    f. ***Countries***: (Only For EU CP procedure Type)
    g. Select all of the appropriate. **Ensure that European Union is selected from the Reference country list**
    h. ***Product(s)***: **<**select as appropriate>
    i. 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. ***Event Type***: Pediatric Investigation/Study Plan
    c. ***Secondary Event type***: <as appropriate>
    d. ***Product(s)***; <as appropriate>
    e. Complete other fields as required by your organization
3. Create a Sequence as required by your organization.
4. Create an Assembly as required by your organization.
5. After approval is received:
    a. Close and Approve the Initial Event.
    b. Create Reference as required by your organization.

Planning and Tracking activities will follow standard Ennov InSight processes.

7 PSP Process

The PSP process is covered under an existing IND Application in the appropriate Product family. If the IND doesn't exist, create IND Application following standard Ennov InSight Best Practice.

1. An Event should be created within the appropriate IND Application with the following attributes:
    a. ***Event Name***: follow organization naming convention (e.g. Human Immunoglobulin initial submission)
    b. ***Event Type***: Pediatric Investigation/Study Plan
    c. ***Secondary Event type***: <as appropriate>
    d. ***Product(s)***: <as appropriate>
    e. Complete other fields as required by your organization
2. Create a Sequence as required by your organization.
3. Create an Assembly as required by your organization.
4. Once approval is received:
    a. Close and Approve the Initial Event.
    b. Create Reference as required by your organization.

Planning and Tracking activities will follow standard Ennov InSight processes.