



BEST PRACTICE: MANAGING RISK MANAGEMENT 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 – No Impact
N/A	18-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 – Impact

2 Contents

1	Revision History	1
2	Contents	2
3	Document Purpose.....	4
4	Scope	5
5	Use of References	6
6	Risk Management Plan (RMP).....	7
6.1	Data Administration and Naming Convention Considerations.....	7
6.2	RMP Process	8
6.3	Lifecycle Maintenance of an RMP.....	8
6.4	Managing Country Differences.....	9
6.5	Local Annexes.....	9
6.6	Request from Health Authority to submit an RMP	9

3 Document Purpose

The purpose of this document is to provide best practice guidance on the management of Risk Management Plans (RMP) in Ennov InSight Registrations.

RMPs are submitted for:

- **Initial Applications:** Initial application for a Marketing Authorisation Application (MAA) or New Drug Application (NDA)
- **Changes or Modifications:** Modification to the RMP for pharmacovigilance, risk-minimization milestones or any significant changes to the benefit-risk profile
- **Periodic Submissions or Request from Health Authorities (HA)**
- **HA Request:** EMA or National Competent Authority (NCA)
- **Periodic Safety Update Report (PSUR)**

Outside of the EU, Regional requirements vary greatly and are increasing. In addition to tracking RMP statuses and dates and the current approved version, it is often important to document the type of RMP template submitted and any local country deviations from the Core or EU RMP.

4 Scope

This document covers the creation and maintenance of References to manage RMPs in Ennov InSight Registrations.

5 Use of References

References are created to capture information about the RMP and links to supporting documentation. From a Best Practice perspective, standard naming conventions should be defined and documented in operations manuals, allowing for consistency in the creation and tracking of References throughout the system.

6 Risk Management Plan (RMP)

Best Practice for routine tracking of RMPs, both current and historical, is to create a Reference at the Application level.

6.1 Data Administration and Naming Convention Considerations

The following Data Administration pick list values should be defined in the system in advance of implementing the RMP Process:

- **Reference Type:** to clearly identify the Reference as a Risk Management Plan.
- **Content:** to further identify the type of RMP submitted e.g. EU, Company Core or Local RMP.
- **Reference Status:** to identify the current status of the RMP e.g. Planned, Approved, Superseded.

For the RMP **Reference Name**, defining a consistent naming convention will ensure that key details, such as the approved version, are recorded.

Best Practice for RMP Naming Conventions are:

- < Product Family Name > < RMP Type > < Version > < Country Name >
- Calyxadone Core RMP v1.0 Brazil
- Calyxadone Core RMP v2.0 Brazil
- Calyxadone Local RMP v1.1 China
- Calyxadone Local RMP v1.1 Russia
- Calyxadone EU RMP v3.0 and Country Specific Annex Australia
- Calyxadone EU RMP v5.0 European Union

The **Reference Link** and **Origination Link** fields can be leveraged to link to the RMP content and to related Ennov InSight records.

- When creating a Reference, the Reference Link field can be used to link directly to the RMP.
- To associate the RMP with its Regulatory Objective (i.e. Event), the Event URL can be copied and pasted in the Origination Link field when creating the Reference.

The use of the **Reference Comments** and **Description** fields should also be well defined to ensure that country/regional deviations are captured.

6.2 RMP Process

The original RMP **Reference** should be created at the MAA or NDA Application. The Procedure type will determine when the Reference is created:

- EU Centralised Procedures (CP): Reference will be created upon submission to EMA.
- Mutual Recognition Procedure/Decentralised Procedure (MRP/DCP): Reference will be created upon dispatch to the Reference Member State.
- National Application: Reference will be created upon dispatch to country affiliates.

Company defined naming conventions should be followed and the relevant picklist values selected to identify the type of RMP submitted.

A **Reference** should be created within the appropriate Application with the following attributes:

- **Reference Name:** <follow organization naming convention>
- **Reference Type:** <as appropriate>
- **Content:** <as appropriate>
- **Reference Status:** <as default>
- **Reference Status Date:** <as default>
- **Reference Link:** <as required>
- Complete other fields as required by your organization.

6.3 Lifecycle Maintenance of an RMP

On Approval of the RMP:

- The **Reference Status** is updated.
- The **Reference Status Date** is updated.

- The **Reference Name** is updated with the approved RMP version number.

When a new RMP version is ready for submission, a new RMP **Reference** is created on approval of subsequent versions of the RMPs:

- The previous RMP **Reference Status** should be updated to Superseded.
- The **Reference Status Date** is updated to reflect the approval date of the latest RMP.

6.4 Managing Country Differences

Prior to submission or during the review of nationally approved products, changes may be made to the RMP. These can be introduced prior to submission by the Affiliate or during the review by the Agency. In these cases, a new Local RMP **Reference** is created and the country differences are recorded in the **Reference Comments** field. The Status of the original Reference is updated to Superseded.

6.5 Local Annexes

In some non-European markets, the RMP will be submitted with an additional Annex. In these instances, this should be included in the **Reference Name**, as defined by company naming conventions.

6.6 Request from Health Authority to submit an RMP

When an RMP is submitted as part of another Regulatory Objective (e.g. MAA, Variation, PSUR) a specific RMP **Event** is not created in Ennov InSight. However, when a request is received from the Health Authority (HA Request) to submit the current version of the RMP it is best practice to create a standalone submission. The **Event** should be created within the appropriate **Application** following organization processes. A **Reference** is created at the Application level with the attributes as described in the RMP Process above.