



CALYX™

# Best Practice: Creating EU PSUR Events

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# 1 Best Practice Revision History

When Parexel releases a new version of Calyx RIM, they issue Release Notes which explain the new features and updates. Parexel 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, Parexel 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..0	30-Apr-2021	Update Best Practice for 7.0 - No Impact
N/A	13-Apr-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

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### 3 Document Purpose

The purpose of this document is to provide a Best Practice guide for the creation of PSUR Events for EU Applications. The creation of this document was triggered by the EMA's PSUR Repository which became mandatory in June 2016.

### 4 Scope

This document covers the creation of PSUR Events for EU Applications.

### 5 General Considerations

PSUR dates can be tracked in different ways in Calyx RIM depending on the products themselves:

- Product Family – for those Active Ingredients, or groups of active Ingredients that have harmonised PSUR dates using fields “PSUR Due Date” and “PSUR Data lock date”
- Application – for those Active Ingredients, or groups of active Ingredients that do not have harmonised PSUR dates using fields “Local PSUR Date” and “Local PSUR Data lock date”.

TIP: The Local PSUR Due date and data lock date can be added / maintained by using the wizard Update Applications if it is common across multiple applications.

PSUR Events are typically created at 2 points in time:

- When the initial Application is approved future PSUR Event/s are created and the Projected Submittal Date is completed. Multiple PSUR Events may be created when the timetable for the submission is known in advance.
- When the immediately previous PSUR is submitted the next PSUR Event is created and the Projected Submittal Date is completed

While PSURs will be submitted to the EMA via the eSubmission gateway, it is not recommended that users create Event and Sequence records for a Reviewing Country = European Union to represent the transmission of data. Instead it is recommended that a single Event with its Sequence is created under the appropriate Marketing Authorisation Application/s. The Event should include the Reviewing Country and all applicable CMSs where necessary.

Additionally, even if the PSUR could be submitted as a single submission, the eCTD lifecycle of the individual Application should be taken into consideration therefore an Event, Sequence and Assembly should also be representative through all Applications impacted by the single PSUR submission.

## 6 Best Practice for creating PSUR Events

### 6.1 A PSUR covering a single Marketing Authorisation Application (National, MRP/DCP or Centralised Procedure)

1. Create an Event with the following attributes:
  - Event Name: follow organisation naming convention (e.g. PSUR May 2019)
  - Associate CMS countries if applicable
  - Complete other fields as required by your organization.
2. Create a Sequence as required by your organization:
  - Complete fields as required by your organization.
3. Create Assembly as required.

### 6.2 A PSUR covering multiple Applications (National, MRP/DCP and/or Centralised Procedure)

1. Create a Global Project Plan either using the 'Create New Events Only – Package Set Registration' or the 'Update Product Detail Set' flow.
  - Complete fields as required by your organisation.
2. On the Search by Product, Country and Application Status screen, select the Product Family Type and Product Family, then choose the Product(s) and all Countries where the PSUR is applicable.
3. Click Next.
4. On the Select Applications screen select all Applications where the PSUR is applicable.
5. Click Next.
6. Complete the GPP wizard by creating Events and Sequences and associating PDS as required by your organisation.
7. Navigate to any MRP/DCP Applications to associate the corresponding CMS for the PSUR event (See 'Adding countries to MRP, DCP & CP Events created via GPP\_Calyx RIM for Registrations Best Practice').
8. Create Assemblies for each Sequence as required.