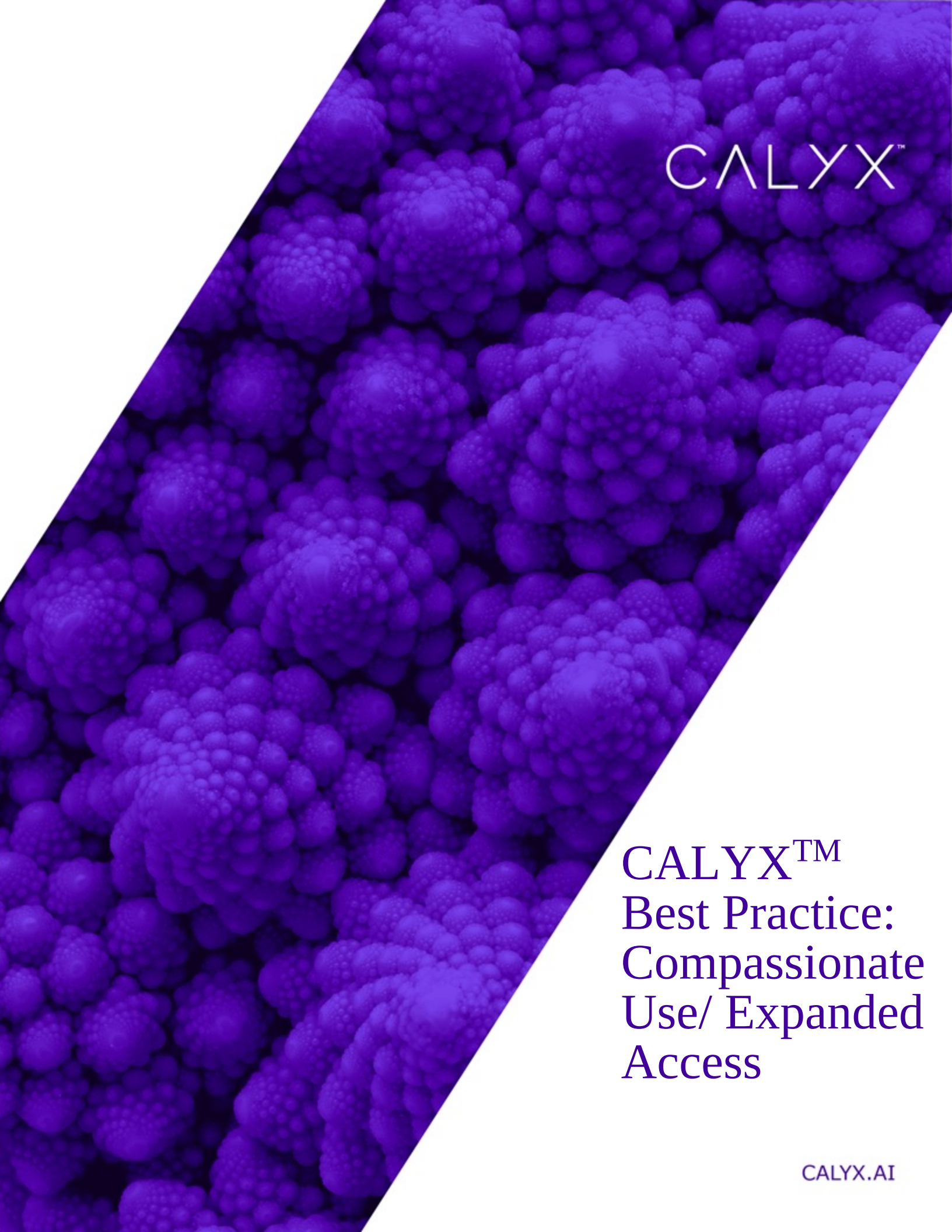

CALYX™ Best Practice: Compassionate Use/ Expanded Access

CALYX.AI

1 Revision History

When Calyx releases a new version of Calyx RIM, they issue Release Notes which explain the new features and updates. Calyx reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes change this Best Practice
- No Impact = Release notes do not change this Best Practice

When Release Notes impact Best Practice documentation, Calyx 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 v7.0 – Impact
N/A	09-Apr-2021	Update Best Practice for Calyx Rebranding – No Impact
N/A	21-Oct-2020	Update Best Practice for v6.2 CHF6 – No Impact
N/A	03-Aug-2020	Update Best Practice for v6.2 CHF5 – No Impact
N/A	28-Feb-2020	Update Best Practice for v6.2 CHF4 – No Impact
N/A	27-Jun-2019	Update Best Practice for v6.2 CHF3 – No Impact
N/A	15-Feb-2019	Update Best Practice for v6.2 CHF2 – No Impact

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2 Contents

3 Document Purpose

The purpose of this document is to provide a Best Practice guide for the management of Compassionate Use/Expanded Programs in Calyx RIM for Registrations.

4 Scope

This document only defines the set up and management of the following activities in Calyx RIM for Registrations.

1. Compassionate Use
2. Expanded Access

5 General Considerations

The Compassionate Use and the Expanded Access programmes are potential pathways for patients to gain access to development products (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. i.e. this treatment option allows the use of unauthorised medicinal products.

Medicinal products used for Compassionate Use and Expanded Access programmes are mainly development products undergoing CTA's or IND's.

The management of development products undergoing CTA's or IND's are defined in the Calyx RIM for Registrations Best Practice – "Clinical Trial Application and Investigational New Drug Application".

The Calyx RIM for Registrations "Comparator" entity is used to capture additional details about the development product. Comparators are used to identify the study supplies that are included in a clinical trial to ensure the success of a medicine to another medicine or placebo. In Calyx RIM for Registrations, Comparators are treated as a separate entity that is not part of any existing Calyx RIM for Registrations hierarchy.

Therefore, a prerequisite for the management of development products in the Compassionate Use and Expanded Access programmes is that the Comparator entity has been created for the Investigational Medicinal Product (IMP) and is available for use.

6 Data Administration Activities

6.1 Application Category

An Application Category = "Compassionate Use" must be created/available.

6.2 Application Type

Appropriate Application Type must be created/available.

For EU countries and all other applicable countries:

Application Type = Compassionate Use

Name = Compassionate Use

Display Name = Compassionate Use

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Entity XML Type Name = Clinical Trial Application

Application Category = Compassionate Use

Countries = All applicable countries.

For the US and other applicable countries

Application Type = Expanded Access

Name = Expanded Access

Display Name = Expanded Access

Entity XML Type Name = Investigational New Drug

Application Category = Compassionate Use

Countries = US and other applicable countries.

7 Best Practice

1. Create a Compassionate Use Clinical Trial Application (CTA) or an Expanded Access Investigational New Drug (IND) Application, for the country where the development product will be supplied to meet the medicinal needs under the Compassionate Use/Expanded Use programmes.
    a. ***Application Name***: Follow organisation naming conventions (e.g. <Product Family Name> <CC> Compassionate Use or Expanded Access).
    b. ***Application Type***: Compassionate Use or Expanded Access.
    c. ***Procedure Type:*** Select the appropriate procedure type, e.g. National.
    d. ***Reviewing Country:*** *Select Country.*
    e. ***Product:*** As appropriate – associate IMP Product
    f. Complete other fields as required by your organisation.

2. Create an Event with the following attributes:
    a. **Event Name:** Follow organisation naming convention (e.g Application for Compassionate Use/Expanded Access of <IMP Name>).
    b. **Comparator:** As best practice, Comparator(s) impacted by the Regulatory Objective should be selected e.g. Placebos and Comparator Products
    c. Complete other fields as required by your organisation.

3. Create a Sequence entity as required by your organization to capture the submission of the application package for the request to supply the development product on an Compassionate Use/Expanded Access programme. Create an Assembly as required by your organisation.

4. Update Event-Country Status as required by your organisation.

5. Upon receipt from the respective HA that the application has been approved/accepted:
    a. Create a Reference on the Event for the approval letter or equivalent as required by your organisation.
    b. Approve and Close the Event as required by your organisation.

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6. OPTIONAL. Create a Registration record as required by your organisation. (Note: this is not a conventional authorisation, but the entity can be used to capture the additional HA details that are applicable to the Compassionate Use/Expanded Access product). As there is no PDS and consequently no Package Set – the registration entity is created without the Package Set being associated.

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