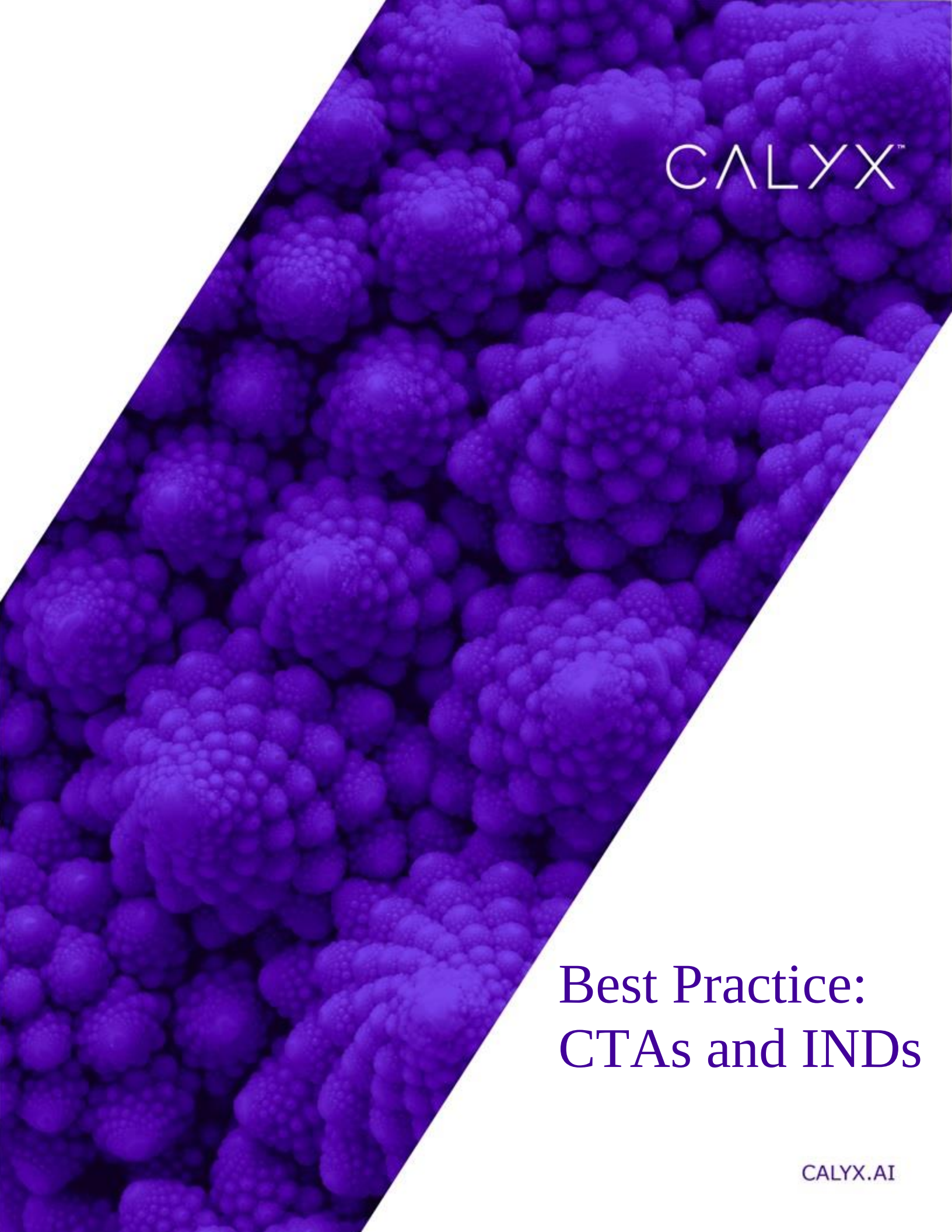

Best Practice: CTAs and INDs

CALYX.AI

1 Best Practice 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-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, 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)
N/A	30-Mar-21	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 Clinical Trial Application (CTA) and Investigational New Drug (IND) Application.

3.1 Scope

The scope of the proposed document is the process for defining the details required for CTA and IND Applications in the Registration Component of Calyx RIM.

Clinical Trial Application concept is used in countries such as European Union countries, Canada and other countries. A Clinical Trial Application can cover only one protocol.

Investigational New Drug concept is used in countries such as United States. Investigational New Drug application will cover the drug development and all protocols deployed for this new drug. New protocols will be submitted within the existing IND as an amendment.

4 Data Administration Activities

4.1 Application Category

Applications for CTA and IND will use the existing standard Application Category: Clinical Trial.

4.2 Application Type

Default Clinical Trial Authorisation Application Type will be used, with the corresponding default Clinical Trial Application Entity XML.

Default Investigational New Drug Application Type will be used, with the corresponding default Investigational New Drug Entity XML.

For each of the Application Types, appropriate countries should be selected.

4.3 CTA Product Role Values

Default **Comparator**, **IMP**, and **Placebo** should be set to Active.

4.4 Project Type

Default Clinical Trial Project Type mapped to Clinical Trial Project Internal Project type should be set to Active.

Note: Project type can be renamed as required by your organisation

5 Comparator

Comparators are used in CTA and IND Applications 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, a Comparator is treated as a separate entity that is not part of any existing Calyx RIM hierarchy.

Comparators can only be applied to Clinical Trial Authorisation (CTA) and Investigational New Drug (IND) Applications. For these Applications, Comparators are further defined by CTA Product Role Values in Data Administration. As a Best Practice, Comparator Entity is designated as a Placebo, Investigational Medicinal Product (IMP), or Comparator.

As a Best Practice, a Comparator entity is created with the appropriate value for all types of clinical supplies/products which is described in a Protocol (e.g. Placebo, Investigational Product, and Comparator Product).

To create Comparator, From the Home Page select Create a New Comparator
On the Create Comparator page:

- **Comparator Name**: <Follow Corporate Naming Convention> e.g. Active Ingredient name.
- **Product Type**: Select the CTA Product Role Values (Placebo, IMP or Comparator).
- Complete other fields as required by corporate guidance.

6 CT Shared Data

The Clinical Trial Shared Data entity (CT Shared Data) enables users to consolidate common details for a defined Protocol.

The Clinical Trial Shared Data entity is created and maintained at the Product Family level, making the information available for association with Event on CTA and/or IND Applications. Upon associating the Clinical Trial Shared Data with an Event within CTA or IND Applications, the same information applies to all Event-Countries associated with the Event without the need to continually re-enter the same information for each Event-Country.

Clinical Trial Shared Data is identified by the protocol code number. Only one CT Shared Data entity can be associated to an Event for CTA. Whereas Multiple CT Shared Data entities can be associated to an Event for IND.

Create CT Shared Data, from the Product Family:

a. ***Protocol Code Number:*** follow organisation naming convention (e.g. CT-123456).
b. ***Protocol Title:*** follow organisation naming convention.
c. ***Trial Phase:*** Select the appropriate value.
d. Complete other fields as required by your organization.

CT Shared Data entity will display the list of Events to which it's associated with the related information such as the Application Name, Country, and Event Closure information.

7 Application/Event

An individual Application should be created for each country participating in the Clinical Trial.

7.1 CTA/IND Application

As per CTA and IND regulatory definition and requirement, a CTA Application should be created for each protocol, whereas and IND Application will be created for the drug development covering multiple protocols.

Create Application, from the Product Family:

a. ***Application Name***: follow organisation naming conventions (e.g. <Product Family Name> <CC> CTA).
b. ***Application Type***: Clinical Trial Authorisation or Investigational New Drug.
c. ***Procedure Type:*** Select appropriate procedure type e.g. National.

d. ***Reviewing Country:*** *Select Country.*
e. ***Product:*** As a Best Practice leave Blank.
f. Complete other fields as required by your organization.

7.2 Submission Process

An Event is created for each regulatory objective. It can be created to support Amendment, New protocol:

1. Create an Event with the following attributes:
    a. **Event Name:** follow organisation naming convention (e.g. Initial protocol CT-12345)
    b. **CT Shared Data:** as Best Practice CT Shared Data(s) impacted by the Regulatory Objective should be selected
    c. **Comparator:** as Best Practice Comparator(s) impacted by the Regulatory Objective should be selected
    d. Complete other fields as required by your organisation
2. Create a Sequence as required by your organization.
3. Create an Assembly as required by your organization.
4. Update Event-Country Status as required by your organization
5. Close Event as required by your organization.
6. Create a Reference on the Event for the approval letter as required by your organization.

8 Global Project Plan

Global Project Plan wizard can be used for the bulk creation of Applications or Events. The Global Project Planning (GPP) *Clinical Trial* wizard will guide user to either create an Application and/or Event depending of the Regulatory Objective; For example, a new protocol will trigger new Application and Event records for CTA countries, or a single Event record for IND countries.

The Global Project Planning (GPP) *Clinical Trial* wizard enables you to create the following:

- **Clinical trial authorisation (CTA) and Investigational new drug (IND) Applications**: As a Best Practice this flow should be selected when the first protocol is identified for a New Drug.
- **CTA Applications and events for IND Applications:** As a best practice, this flow should be selected when a new protocol is identified where IND is already created in the system. As a result of the flow, CTA Applications with initial Event will be created, whereas a single Event created under existing IND applications.
- **Events for CTA Applications and IND Applications:** As a best practice, this flow should be selected when amendment (except new protocol) is submitted as part of CTA/IND Applications.

Applications and Events that the GPP wizard creates for a Clinical Trial project are associated with the same CT Shared Data and Comparators. Sequence entities can be associated with the Project.