Best Practice: VHP Best Practice

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-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)
v7.0	30-Apr-2021	Update Best Practice for 7.0 - 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 – No Impact

2 Contents

3 Document Purpose

The purpose of this document is to provide a Best Practice guidance for tracking Registration data in *Calyx RIM for Registrations* for the specific Voluntary Harmonisation Procedure (VHP) related to the assessment of the multinational Clinical trial in Europe.

4 General Considerations

This section describes the basic process for the assessment of a multinational clinical trial in Europe assessed part of a Voluntary Harmonisation Procedure (VHP). (For a complete process refer to the Clinical Trials Facilitation Group, Guidance document for sponsors for a Voluntary Harmonisation Procedure (VHP) for the assessment of multinational Clinical Trial Applications,

http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2014_12_HMA_CTFG_VHP_sponsors.pdf)

The VHP allows the application and assessment process to be harmonised so that multinational clinical trials can be conducted in several Member States. As each Member State competent authority remains responsible for their national decisions on clinical trial authorisations (CTAs) the procedure operates by reviewing a pre-submission application. This enables Member States to share the assessment (for initial application and amendment) of the pre-submission application and to provide a harmonised opinion, which will facilitate quick approval at the national level.

Referring to the current legal framework (Directive 2001/20/EC), each National Competent Authority remains responsible for the approval of a CTA in its own country. Therefore, the assessment of the multinational clinical trial applications is proposed before the initial phase of the national process, on a voluntary basis.

NOTE: Be aware Regulation (EU) No 536/2014 published in May-2014 updates and will repeal the Clinical Trials Directive 2001/20/EC (IDRAC 28709). Therefore, please ensure VHP is still applicable for your country.

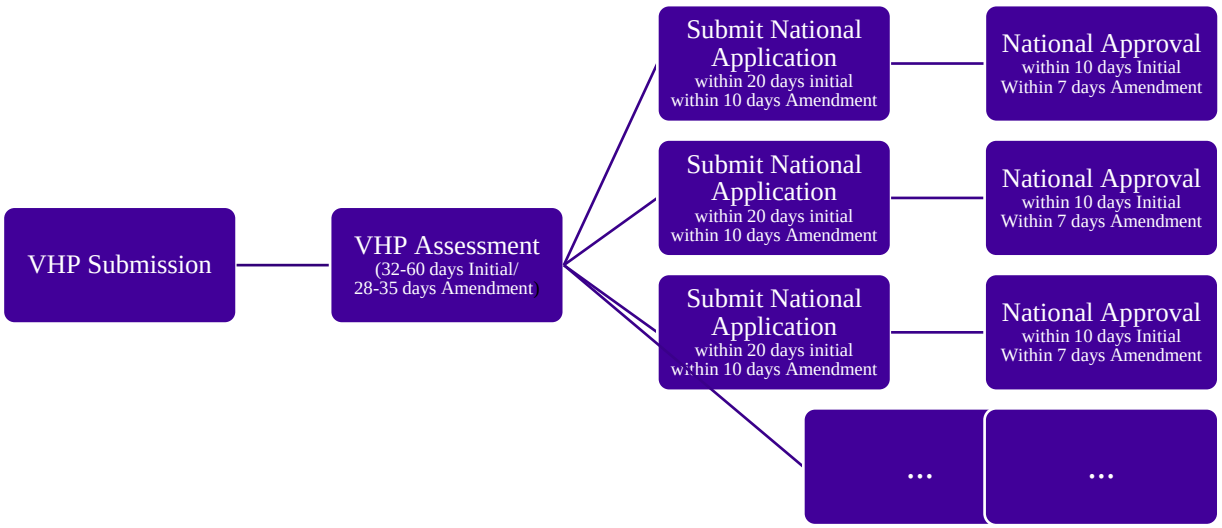

Figure 1: High Level process for Multinational Clinical trial application with VHP assessment

Today, the VHP assessment is a pre-cursor to a National Approval. Following the VHP assessment a national dossier needs to be submitted to align with the national requirement (Figure 1). The concept of a common dossier does not exist

and evaluation is nationally independent. For these reasons, each country needs its own Assembly Lifecycle and hence its own Calyx RIM Application.

As a best practice, an individual Application for each country part of the VHP will be created with a procedure type EU-National. Usual Best Practice for Clinical Trial should be followed.

NOTE: VHP can be part of the naming convention at the Application Name or Application Code.

5 Data Administration Activities

5.1 Procedure Type

Create New Procedure Types for VHP and associate European Union countries with the Internal Procedure Code = MRP.

6 Best Practice for VHP

As usual Best Practice, Application, Event, Sequence, Assembly (as required) and PDS are created for VHP Assessment and for each National Application part of the VHP which can be created via a Project.

6.1 VHP Assessment

1. An Application should be created to track VHP Assessment
    a. ***Application Name***: follow organisation naming conventions (e.g. <Product Family Name> VHP Assessment)
    b. ***Application Type***: Clinical Trial Authorisation
    c. ***Procedure Type:*** VHP
    d. ***Reviewing Country:*** *Reference Member States*
    e. ***Countries:*** <each Member State part of VHP>
    f. ***Product*** *<as appropriate>*
    g. 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. VHP Initial Assessment)
    b. Complete other fields as required by your organisation
3. Create a Sequence as required by your organisation
4. Create an Assembly as required by your organisation

Note: only the Reference Member State is associated to the Event

5. Create a Reference on the Initial Event and Application for the approval letter as required by your organisation

6.2 National CTA Applications

Note: CTA National Applications and Events can be created by using the Global Project Plan feature.

1. An Application should be created for Member State
    a. ***Application Name***: follow organisation naming conventions (e.g. <Product Family Name> VHP National Phase <country code>)
    b. ***Application Type***: Clinical Trial Authorisation

c. ***Procedure Type:*** EU - National
d. ***Reviewing Country:*** *<Concerned member State>*
e. ***Product*** *<as appropriate>*
f. Complete other fields as required by your organisation

2. Create an Event with the following attributes
   a. **Event Name:** follow organisation naming convention
   b. Complete other fields as required by your organisation
3. Create a Reference on Project or Event to capture the VHP Assessment approval
4. Create a PDS as required by your organisation
5. Create a Sequence as required by your organisation
6. Create an Assembly as required by your organisation
7. Create a Reference on the Event and the Application for the approval letter as required by your organisation

7 Lifecycle management process

The process to maintain the Clinical Trial under the VHP procedure is always initiated with a VHP assessment. This would follow the same process as above, with an Event created under the VHP Application and after approval an Event under each National Application

8 References

- Cortellis database
  - https://cortellis.thomsonreuterslifesciences.com/ngg/home.do

- Clinical Trials Facilitation Group, Guidance document for sponsors for a Voluntary Harmonisation Procedure (VHP) for the assessment of multinational Clinical Trial Applications
  - http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2014_12_HMA_CTFG_VHP_sponsors.pdf
  - Cortellis database, IDRAC Number – 207277

- INITIATION AND CONDUCT OF CLINICAL TRIALS,
  - Cortellis database, IDRAC Number – 21417