Clinical Trial Application Submission Guidance

Purpose:

The purpose of this guidance document is to outline DAIDS' requirements regarding the submission of Clinical Trials Applications (CTAs) to DAIDS to ensure compliance with ICH E6. This document provides guidance to In-Country Sponsor Representatives that prepare and submit CTAs to the competent National Regulatory Authority(ies) for authorization to conduct a clinical trial in a specific country.

Background:

According to ICH E6 (R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) Current Step 4 version dated 9 November 2016, "applications/submissions are required to be verified for accuracy, timeliness, legibility and that they are dated and accurately identify the trial".

To accomplish this verification, DAIDS requires that a copy of the CTA submitted to the competent National Regulatory Authority(ies) be submitted to the DAIDS Regulatory Support Center (DAIDS RSC) to verify the accuracy of the application/submission prior to sites being allowed to complete the initial protocol registration process for a protocol.

A **Clinical Trials Application (CTA)** is the application/submission to the competent National Regulatory Authority(ies) for authorization to conduct a clinical trial in a specific country. Examples of submissions to competent National Regulatory Authorities may include but are not limited to:

1. Investigational New Drug Application (IND) for any product filed with the U.S. Food and Drug Administration (FDA) pursuant to Title 21 of the Code of Federal Regulations, Part 312 (U.S. sites)*

2. Application/submission to a competent National Regulatory Authority within the European Union (EU) to request an authorization concerning a clinical trial, as envisaged in Article 9, paragraph 2, of Directive 2001/20/EC

3. Any comparable application/submission to a National Regulatory Authority in another country or territory other than the U.S. or the EU.

**As DAIDS submits the IND Applications, these are already on file and are not required for submission from U.S. sites.*

An **In-Country Sponsor Representative** is the individual or group that prepares and submits the CTA to the competent National Regulatory Authority(ies) for authorization to conduct a clinical trial in a specific country. Examples of In-Country Sponsor Representatives include but are not limited to:

1. Central Clinical Research Site

2. Clinical Trials Unit

3. Network representative or contracted third party

NOTE - If an individual CRS is not responsible for submitting the CTA, the In-Country Sponsor Representative which created the application/submission must provide the application/submission to the DAIDS RSC or must provide the application to the CRS for submission to the DAIDS RSC.

Document Requirements:

The CTA, must include the following information at a minimum:

- Full Protocol Title
- DAIDS Protocol Number
- DAIDS Protocol Version/Date
- Accurate identification of the Study Sponsor
- Identification of the site(s) for which the application applies (when applicable – see Submission Requirements below for additional information)

If any of the above protocol and/or site information is not included, the In-Country Sponsor Representative must include a memo/letter or other documentation that allows DAIDS (or an inspector) to link the application/submission to the correct protocol in order to verify the accuracy of the application/submission.

Submission Requirements:

It is recommended that Clinical Trials application/submission be submitted to the DAIDS RSC prior to the submission of an initial protocol registration submission to the DAIDS Protocol Registration Office (DAIDS PRO). Below are the steps In-Country Sponsor Representatives should follow when submitting Clinical Trials application/submission to the DAIDS RSC.

1. Complete the CTA checklist - https://rsc.niaid.nih.gov/clinical-research-sites/protocol-registration-forms

2. Submit the CTA checklist and Clinical Trials application/submission as pdf documents to the DAIDS RSC at ClinicalTrialApplication@tech-res.com.

NOTE - The subject line of the email to the DAIDS RSC must include the DAIDS Protocol Number that the Clinical Trials application/submission is being submitted for.

NOTE - If additional sites are added during the course of a trial the amended Clinical Trials application/submission must be submitted to the DAIDS RSC following the steps outlined above.

NOTE – If the DAIDS RSC has not received a complete and accurate Clinical Trails application/submission by the time of initial protocol registration, the Clinical Research site will receive a Required Corrections notification from the DAIDS PRO.

References:

ICH E6 (R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) - https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf