MEMO re: How to Initiate the ClinicalTrials.gov Initial Registration Process

BACKGROUND

This memo is being provided to clarify how to initiate the ClinicalTrials.gov (CT.gov) initial registration of a new protocol. The initial registration of a protocol to ClinicalTrials.gov is completed by the PPD Regulatory Affairs Specialist Team. Below is a description of how to request the initial registration of a new protocol on ClinicalTrials.gov.

PROCESS

The registration process is triggered by a study team member (DAIDS Medical Officer [MO] or Network Point of Contact [Network POC, a person who can review and approve the submission]) sending an email to naractgov.sm@ppd.com with daids-trials@nih.gov in copy requesting that a protocol be registered.

This email is the ONLY way the PPD team will be alerted that a protocol is ready for CT.gov registration and will begin work on the initial registration.

** Please note that copying PPD on emails, such a Full Regulatory Review email, does not constitute a request for registration. **

The email requesting registration should contain the information outlined below:

- Email recipients: naractgov.sm@ppd.com AND daids-trials@nih.gov

- Title of email: DAIDS CRSS Initial Registration Request: [*Insert Protocol Number*] (Example: DAIDS CRSS Initial Registration Request: X1234)

- Required attachments:
    - Completed CT.gov checklist (See Appendix 1)
    - Copy of final protocol
    - Final Site Assignment Memo (Must contain the site name, address and site contact name, phone number and email)

- Optional attachment:
    - IRB approval letter (If available at time of request)

- Additional information to be included in body of email (See Appendix 2 for definitions):
    - Name and email address of the individual who will be the point of contact during the review process and who will provide approval of the draft record for release.
    - Anticipated Study Start Date
    - Anticipated Primary Completion Date
    - Anticipated Study Completion Date

The PPD Regulatory Affairs Specialist creates the draft ClinicalTrials.gov record based on the information provided and may request additional information from the email originator (Network POC or MO) once the “DAIDS CRSS Initial Registration Request” email is received.

NOTE: The NCT number is assigned only after the record is approved by the PRS Admin team with no further major comments/feedback (minor comments/warnings may be given but are not required to be edited).

Please share this memo with others, as appropriate.

Appendices

Appendix 1: CT.gov Checklist Revised 20200810_1

Appendix 2: CT.gov Date Definitions

Appendix 1: CT.gov Checklist Revised 20200810_1: DAIDS Clinicaltrials.gov Protocol Checklist | DAIDS Regulatory Support Center (RSC) (nih.gov)

Division of AIDS ClinicalTrials.gov Protocol Checklist

This form is intended to be filled out electronically. This form will identify which conditions must be met to fulfill requirements set forth by the Food and Drug Administration Amendments Act of 2007 (FDAAA) and the NIH Policy on Dissemination of NIH-funded Clinical Trial Information. This form should be submitted along with to-be Version 1.0 main protocol documents at the time of Full Regulatory Review.

Contact Email | Protocol Number | Today's Date

Contact Name | DAIDS-ES ID (if known)

Contact Role:

☐ Central Contact ☐ Principal Investigator ☐ Sponsor ☐ Sponsor-Investigator ☐ Results point of contact

Please answer all 6 questions to determine whether reporting to ClinicalTrials.gov is required.

FDAAA Applicable Clinical Trial (ACT) Determination* (Questions 1-4)

Questions	Yes	No
1. Is the study interventional (a clinical trial) per FDAAA?	☐	☐
2. Do ANY of the following apply (is the answer "Yes" to at least one of the following sub-questions: 2a, 2b, OR 2c)? a. Is at least one study facility located in the United States or a U.S. territory? b. Is the study conducted under a United States Food and Drug Administration (U.S. FDA) Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country?	☐	☐
3. Does the study evaluate at least one drug, biological, or device product that is regulated by the U.S. FDA?	☐	☐
4. Is the study: (a) higher than a Phase 1 trial of a drug and/or biological product, or (b) a device study other than a device feasibility study?	☐	☐

If "Yes" is selected for questions 1-4 and the study was initiated on or after January 18, 2017, the trial meets the definition of an ACT that is required to be registered under 42 CFR 11.22. See https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf for additional information.

NIH Policy on the Dissemination of NIH-Funded Clinical Trials Information** (Questions 5-6)

Questions	Yes	No
5. Is the study a clinical trial per the NIH policy? For help in determining, please see the NIH Grants Decision Tool found at https://grants.nih.gov/ct-decision/index.htm.	☐	☐
6. Is the clinical trial funded in whole or in part by the NIH? Note: NIH Policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct. See https://grants.nih.gov/grants/guide/notice-files/not-od-16-149.html for additional information.	☐	☐

Sub-Study Results Submission:

None: ☐ Separate: ☐ Part of a parent study: ☐

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ClinicalTrials.gov Results Reporting Required

If "Yes" is selected for questions 1-4, the clinical trial information must be posted on ClinicalTrials.gov. Please complete the box below.

If "Yes" is selected for questions 5 and 6 (even if one of the questions in 1-4 is "No"), the clinical trial information must be posted on ClinicalTrials.gov. Please complete the box below.

For voluntary basic results reporting not subject to FDAAA regulations or the NIH Policy on the Dissemination of NIH-Funded Clinical Trials Information requirements, please complete the box below.

Clinical Trials determined to be applicable per FDAAA requirements or required per NIH Policy on the Dissemination of NIH-Funded Clinical Trials Information must be registered to ClinicalTrials.gov, must post basic results, and must include mandatory language in the informed consent form regarding ClinicalTrials.gov.

Please include the below information:

Sponsor: DAIDS ☐ OR Other:

Anticipated Primary Completion Date (APCD):

The APCD is a projected date and allowed to be updated as the study progresses. Updates should be sent to CSIO@tech-res.com.

Note: For DAIDS-held IND studies, the responsibility to meet the requirements falls within DAIDS ("Responsible Party"). For other studies (e.g., Network Non-IND, non-DAIDS held IND, non-network non-IND, etc.), the responsibility generally lies with the grantee institution, organization, and/or IND holder.

*For the complete statutory definitions and more detailed information on NIH's current thinking on FDAAA, please visit: http://prsinfo.clinicaltrials.gov/.

**For information about the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information, please visit: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html. Policy effective for competing applications and contract proposals submitted on or after January 18, 2017 (https://grants.nih.gov/policy/clinical-trials/reporting/understanding.htm).

Please note this checklist does not address International Committee of Medical Journal Editors (ICMJE) requirements. For information on ICMJE requirements, please visit: http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/.

For questions regarding this form, please contact CSIO@tech-res.com.

Appendix 2: CT.gov Date Definitions

Anticipated Study Start Date: The estimated date on which the clinical study will be open for recruitment of participants, or the actual date on which the first participant was enrolled.

Anticipated Primary Completion Date: The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome.

Anticipated Study Completion Date: The date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events.