Suggested Best Practices for ClinicalTrials.gov Activity during the COVID-19 Pandemic

Updating study records in the Protocol Registration and Results System (PRS)

This document is targeted to academic researchers and institutions, and complements the ClinicalTrials.gov help document Responses to Top Questions from Responsible Parties Related to Coronavirus (COVID-19).

Two activities are happening on ClinicalTrials.gov as a result of the COVID-19 pandemic.

1) Registration of new clinical studies of COVID-19 disease.
   - Applicable Clinical Trials (by law) and clinical trials that receive direct NIH funding (NIH policy); registration is due within 21 days of first participant enrolled. [1,2]
   - Registration should be *prior to the first participant being enrolled* to satisfy journal publication requirements.[3]

2) Updates to existing ClinicalTrials.gov records of studies that have been impacted by the situational response to the COVID-19 pandemic, including delays or pauses, and changes the design or conduct of the study.
   - In general, ClinicalTrials.gov study records should be updated within 30 days of such changes.[4]

If you are a Responsible Party or Member of a Research Team:

- **Identify and review** institutional/university guidelines related to ClinicalTrials.gov records. These guidelines may be associated with guidelines distributed from IRBs, Research Compliance, or other clinical research bodies within your organization.
- **Contact** the ClinicalTrials.gov PRS Administrator(s) at your institution. Contact ClinicalTrials.gov if you do not know the PRS administrator for your institution. PRS Administrators understand ClinicalTrials.gov requirements and can review your portfolio of study records, answer questions, and advise on actions needed for individual records.
- Include the WHO acronym "COVID-19" in the *Brief Title* of records for studies that relate to SARS-CoV-2 / COVID-19 (to aid in searchability of clinical studies related to COVID-19).
- **If you need to update your non-COVID-19 related clinical trial due to the COVID-19 situation:** Refer to the ClinicalTrials.gov *Data Element Considerations* section on the **next page** and update records with current information as needed. Address any *Errors, Problems, and Comments* associated with a record, and submit updated information to ClinicalTrials.gov according to your institution's procedure.

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[1] Applicable Clinical Trial (ACT) Checklist: https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf

[2] NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm)

[3] International Committee of Medical Journal Editors (ICMJE) Clinical Trial Recommendations (http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html)

[4] https://prsinfo.clinicaltrials.gov/FinalRuleChanges-12Dec2016.pdf (see page 11, table 3)

If you are a PRS Administrator:

- **Disseminate** relevant information (e.g., institutional policy/procedure for COVID-19, ClinicalTrials.gov FAQ) as appropriate to investigators and leadership at your institution(s).
- Using the Planning Report, **identify** studies that are likely to be suspended according to local guidance.
- Actively **communicate** with Investigators and research teams. Direct questions to research staff first when possible and the Responsible Party if necessary (to minimize impact on clinically based investigators).
- **Assist** researchers and teams for COVID-19 study records if possible (e.g., institutions that normally designate an investigator as Responsible Party may set that data element to *Sponsor* to help maintain the record).

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Data Element Considerations for Records Experiencing Delay or Pause Due to the COVID-19 Pandemic

Evaluate each study record separately. These suggestions are in line with the PRS data element definitions.

OVERALL RECRUITMENT STATUS

- For delays in study starts, the status can remain ***Not yet recruiting***.
- ***Active, not recruiting*** if there is any ongoing interaction with or evaluation of participants in the study (e.g., remote visit; or data still being collected over time although visits are delayed).
- ***Suspended*** if the study is considered (by institutional policy or the Responsible Party) to be temporarily halted or on a clinical hold due to COVID-19.

  Why Study Stopped? (Character max: 160)

  - This data element appears if the Overall Recruitment Status is ***Suspended***, ***Terminated***, or ***Withdrawn***.
  - Sample reason for ***Suspended*** due to COVID-19 (modify as appropriate):
    Temporarily paused due to COVID-19 and expected to resume. This is not a suspension of IRB approval.
  - Similar reasons can be given if a study is ***Terminated*** or ***Withdrawn*** due to COVID-19.
  - "COVID-19" entered here is not captured in search results for the term on the ClinicalTrials.gov public site.

STUDY START DATE (anticipated) (definition)

- If the study has not begun recruiting or no participants have been enrolled, enter the best estimate of the date when recruitment will start.

PRIMARY COMPLETION DATE (anticipated) (definition)

- Enter the best estimate of the date when the last data for the primary outcome measure(s) will be collected.

STUDY COMPLETION DATE (anticipated) (definition)

- Enter the best estimate of the date when the last data for the overall study will be collected.

  Note: All milestone dates can be changed again later as needed. The Primary and Study Completion Dates are the same date if primary outcome data are collected during the entire study.

ENROLLMENT (anticipated) (definition): Update if there is any change to the planned sample size.

OUTCOME MEASURES (definition - primary or secondary): If the protocol is amended, such that outcome measures are added, removed, or modified, update the study record to reflect those changes, ensuring that all prespecified primary and secondary outcome measures are included in the record.