General FAQs

General Clinical Trial FAQs

My study is not yet IRB approved. Can I enter it on ClinicalTrials.gov?

Yes, you can! ClinicalTrials.gov will allow registration of the study prior to getting IRB approval if the Overall Recruitment Status of the study is “Not yet recruiting.” IRB approval must be obtained before the study’s Overall Recruitment Status is changed to “Recruiting”. When IRB approval is obtained, update the protocol registration and release the study to ClinicalTrials.gov for review and processing.

Can I register a study after it has started, has closed to recruitment, or has completed?

Yes, you can register a study on ClinicalTrials.gov at any time. However, FDAAA Section 801 requires applicable clinical trials to be registered within 21 days of enrollment of the first participant. ICMJE journals (and other journals) require registration of all clinical trials before enrollment of the first participant.

Am I required to submit the results of non-applicable clinical trials to ClinicalTrials.gov?

As of January 18, 2017, the NIH requires registration and results reporting for all NIH supported clinical trials, regardless of whether or not they are required to do so under FDAAA. Results submission for non-applicable clinical trials is not required (for example, a behavioral study) by FDAAA 801.

What about results entry if my trial is terminated and no participants were enrolled?

If no participants were ever enrolled in the trial, no results must be reported. Remember to change the Overall Recruitment Status to “Withdrawn.”

What happens if my trial is terminated, but no data were collected for one or more outcome measures?

For a trial that terminated early after participants were enrolled, provide any available data for Participant Flow, Baseline Characteristics, Outcome Measures, and Adverse Events. If no data are available for any of the Outcome Measures, specify zero (“0”) for the Number of Participants Analyzed in each Arm/Group, and leave the data fields blank. Provide an explanation in the Analysis Population Description for why zero participants were analyzed and, if appropriate, provide information in the Limitations and Caveats module. You must still provide data for Participant Flow, Baseline Characteristics, and Adverse Events.

It's time to report the results of our trial on ClinicalTrials.gov, but the principal investigator

is still analyzing the data and writing the manuscript and does not want to publicly disclose the results until accepted for publication. What should we do?

The data must be reported on ClinicalTrials.gov as soon as possible. The International Committee of Medical Journal Editors has indicated that they do not consider publishing to ClinicalTrials.gov as “pre-publication.” Here’s a link to their FAQs that may be useful.

One can ask for an extension/delay in disclosing results by contacting the ClinicalTrials.gov staff (register@clinicaltrials.gov), but the request would need to meet their definition of “good cause” and publication issues are generally excluded from that definition.

Communication with the journal regarding the legal obligatory requirements may also be useful. It’s unlikely that the journal would refuse a manuscript when the institution/investigator is mandated by law to disclose publicly. However, if the trial was not registered according to the ICMJE journal requirements (prior to enrollment of first participant), the journal may take issue with that and reject the manuscript on that basis.

What is the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information?

The new NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information is complementary to the statutory and regulatory reporting requirements of FDAAA and establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered and results information is submitted to ClinicalTrials.gov. See more FAQs for NIH Grantees.

Are data reviews or exempt research excluded from registration and results reporting?

Because data reviews are retrospective and largely observational in nature and, in general, exempt research studies are not controlled clinical trials, nor involving an FDA-regulated intervention, they would not need to be registered or reported on ClinicalTrials.gov.

However, the ICJME may have a different opinion if exempt research involves any of the following:

- Drugs:
- surgical procedures;
- devices;
- behavioral treatments;
- dietary interventions;
- process-of-care change.
- biomedical or health-related measures including pharmacokinetic measures and adverse events.

Many times studies include a mortality endpoint and could remain open for several years following the completion of the intervention under investigation. Should we wait until study is closed to enter results?

If the applicable clinical trial has reached the primary completion date, then results must be submitted by the Responsible Party no later than 12 months after the primary completion date. If the ACT is investigating mortality over a long period of time (e.g., 10 years) and the investigator chooses to analyze mortality trends over time during the course of the study, the outcome measures may be revised in the PRS according to the desired analysis timeframe while the study is still ongoing. If, in this example, the only primary outcome measure is mortality at 10 years and the investigator does not choose to analyze the data prior to the primary completion date, the study will still be considered ongoing. The record, however, should be updated regularly to accommodate for enrollment status and

protocol/amendment verification.

Regarding specification of an Outcome Measure's Time Frame , what about an oncology trial where the primary endpoint is "time to local recurrence" or a psychiatry trial where the primary endpoint is "time to relapse?"

The primary outcome measure should have an estimated time frame.
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Are clinical trials of unapproved drugs/biologics/devices required to post results to ClinicalTrials.gov?

Yes, but you may 'delay results posting' until 30 days after the product receives FDA approval or clearance. You do not qualify for this delay if you are using approved products 'off-label'. Only investigational products (i.e., no FDA approvals/clearance for any indication) qualify for delayed results posting. However, the NIH requires results reporting for all NIH supported clinical trials registered in ClinicalTrials.gov, regardless of whether or not they are required to do so under FDAAA.

Do all secondary outcome measures/endpoints need to be registered and reported on ClinicalTrials.gov?

FDAAA requires the reporting of results for all pre-specified primary and secondary outcome measures/endpoints for applicable clinical trials. Tertiary and exploratory outcomes are not captured as part of FDAAA.

The primary outcome of our trial has been completed, but secondary outcome data is still being collected. When do I need to report results of the secondary outcome(s)?

Though there is no official guidance, ClinicalTrials.gov generally advises completing data entry ASAP but not later than 12 months after data collection has ended for that measure. If data collection is ongoing, it is a good idea to provide the anticipated posting date for that measure so it is clear to the public when the information will be made available.

What about reporting results for trials where the primary outcome measure has been completed, but the study has not yet been unblinded so no ability to report the primary outcome data within required timeframe?

In a case like this, the study team may submit an extension request, indicating that the study has not been unblinded and reporting the primary outcome measure data would interfere with the scientific integrity of the study. For assistance with this request, contact the UCLA PRS Administrator.

I am not sure what ‘phase’ to choose for my behavioral trial or device trial?

For studies that do not involve a drug or biologic, such as behavioral interventional studies or device trials, select ‘Not Applicable’.

For results reporting, do we enter raw data?

FDAAA does not require that patient-level data/raw data be entered into ClinicalTrials.gov. Summary data, similar to that represented in manuscripts, is entered into ClinicalTrials.gov

Will the ClinicalTrials.gov database become more “user friendly”?

The ClinicalTrials.gov protocol registration/results reporting system interface was originally developed prior to 2000 when ‘results reporting’ was not a requirement. Since the implementation of the ICMJE requirements and FDAAA enactment, this system has been adapted in many ways to meet challenging data requirements. Continuous enhancement occurs as various users make suggestions to the ClinicalTrials.gov staff. It is likely, however, that the tool will continue to maintain a form/function similar to the current tool.

What is the definition of “ongoing at 2007”?

Trials that were “ongoing” as of December 26, 2007 (i.e., participants were being recruited, were being selected from a predetermined population, or were being treated or examined) require results reporting within one year of the Primary Completion Date. The Primary Completion Date is defined as the date the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.

Last updated: 26 Aug 2022

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