ClinicalTrials.Gov

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Registration for Clinical Research Trials

Interventional studies with health outcomes must be registered, and may be required to report results, in ClinicalTrials.gov. Those responsible for conducting a clinical trial must make sure that they are in compliance with these requirements for:

All NIH-funded trials including phase 1 studies and clinical trials of behavioral or non-FDA-regulated interventions (Registration and Results required)

- The US National Institutes of Health (NIH) Policy on the Dissemination of NIH-Funded Clinical Trial Information of 2016 establishes the expectation that all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by the NIH, will register their NIH-funded clinical trial, and submit summary results information to, clinicaltrials.gov for public posting.
    - Click here to see if your clinical trial meets the NIH definition of a clinical trial.

- Compliance with NIH Policy is a legal requirement and a term and condition of the NIH award, where applications or proposals are received by NIH on or after the policy's effective date [**January 18, 2017**].
    - Consequences of noncompliance may include the suspension or termination of Federal awards and other penalties as described in the Code of Federal Regulations (§ 75.371 Remedies for noncompliance). All competing applications (new and renewal) and progress reports for NIH grants (including cooperative agreements) supporting clinical trials must certify compliance with registration and results reporting requirements.

- NIH Application Guide, Section 4.7, Dissemination Plan: A link to this webpage (https://www.researchgo.ucla.edu/clinicaltrialsgov) will suffice in addressing this requirement.

Clinical trials involving FDA-regulated drug, biologic and device products (Registration and Results required).

- Section 801 of the Food and Drug Amendments Act, known as FDAAA 801, requires registration and results reporting on the government web site called ClinicalTrials.gov for studies that meet the definition of “Applicable Clinical Trial”. Click here to evaluate whether your study is an **Applicable Clinical Trial** (ACT) under 42 CFR 11.22(b).
- Under the statute, responsible parties, including, for example, investigators and grantee institutions, could be held accountable for noncompliance, with the potential for substantial civil monetary penalties (exceeding $10,000/day), the suspension or termination of grant or contract funding from HHS agencies, and public identification of clinical trial record as non-compliant in ClinicalTrials.gov.

Studies that will bill routine costs to Medicare or any other insurer (Registration required)

Effective January 1, 2015, Center for Medicare and Medicaid Services (CMS) requires a clinical trial identifier (NCT#) to be reported on all billing claims for items/ services related to a qualifying clinical trial(s). If your study will bill routine costs to Medicare or any other insurer, the study must be registered on ClinicalTrials.gov to obtain the NCT#.

Clinical trials intended for publication in a journal recognized by the ICMJE (Registration required).

The International Committee of Medical Journal Editors (ICMJE) requires, and recommends that all medical journal editors require, as a condition of consideration for publication, registration of [all] clinical trials in a public trials registry at or before the time of first patient enrollment.

Studies may be required to comply with clinical trial registration policies of other organizations.

Informed Consent Statement

Under new 21 CFR 50.25(c), a ClinicalTrials.gov consent statement must be reproduced word-for-word in informed consent documents for clinical trials registered under the requirements of FDAAA 801 or NIH Policy. In the UCLA IRB consent form in the section “WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY,” include the following:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Please see the following links for more information:

- UCLA Guidance on ClinicalTrial.Gov Registration and Reporting Requirements - Updated Guidance on ClinicalTrial.Gov Registration and Reporting Requirements
- Registering in the ClinicalTrials.gov Registry - Guidance for UCLA Sponsor-Investigators
- UCLA Creating a New Study Record - Tips on how to initiate a new record
- Resolving Problem Records - This guide explains the types of problem and how to resolve
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
- Clinical Trial Registration for NIH Grantees **Frequently Asked Questions (FAQs)**
- Steps to Compliance for NIH Awardees
- Changes from Current Practice Described in the Final Rule (PDF) (December 2016)

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

Last updated: 16 Sep 2025

Definition of a Clinical Trial

1. The U.S. National Institutes of Health (NIH) defines a clinical trial as: "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

- Click here to evaluate whether your NIH-funded study meets the NIH definition of a clinical trial

2. The FDA defines an Applicable Clinical Trial (ACT) as follows:

- Trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation.
- Trials of biomedical devices: 1) controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric post-market surveillance.
- Click here to evaluate whether your study is an Applicable Clinical Trial (ACT) under 42 CFR 11.22(b)

3. The International Committee of Medical Journal Editors (ICMJE) defines a clinical trial as “any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.”

For complete statutory definitions and more information on the meaning of Applicable Clinical Trial, see Elaboration of Definitions of Responsible Party and Applicable Clinical Trial (PDF).

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

Last updated: 26 Aug 2022

Why Register My Study?

According to the World Health Organization (WHO), “The registration of all interventional trials is a scientific, ethical and moral responsibility.”

According to the World Medical Association (WMA) Declaration of Helsinki (2013): it is stated that “Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.” and that “Researchers have a duty to make publicly available the results of their research .... Negative and inconclusive as well as positive results must be published or otherwise made publicly available”.

Registration may be required by law and/or policy if any one (or more) of the following is true:

Required by Law

Your study involves a drug or device:

FDAAA (U.S. Public Law 110-85, Food and Drug Amendments Act of 2007) requires registration of all Applicable Clinical Trials in ClinicalTrials.gov

- Applicable clinical trials generally include interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the U.S, involves a drug, biologic, or device that is manufactured in the US (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE).

- FDAAA establishes penalties for failure to comply with registration or results submission requirements. Penalties include civil monetary penalties and, for federally funded studies, the withholding of grant funds.

Required by Your Funding Source

The NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (effective January 2017) 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.

All competing applications (new and renewal) and progress reports for NIH grants (including cooperative agreements) supporting applicable clinical trials must include a certification of compliance with FDAAA. This includes applications where the trial has not yet begun (e.g. is proposed) or is not yet required to be registered (e.g. less than 21 days since first subject was enrolled), as well as applications and progress reports that include an on-going trial that is already registered in ClinicalTrials.gov.

Required for Journal Publication

- Required for Journal Publication: You intend to publish an article about your study methods and/or outcomes. The International Committee of Medical Journal Editors (ICMJE) requires, and recommends that all medical journal editors require, as a condition of consideration for publication, registration of [all] clinical trials in a public trials registry at or before the time of first patient enrollment.

- ICMJE defines a clinical trial as “any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect

relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioural treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events."

Required for Billing

For a Qualifying Clinical Trial (QCT): You intend to bill insurance for routine costs of care for study participants.

The Center for Medicare and Medicaid Services (CMS) requires a clinical trial identifier (NCT#) be reported on all billing claims for items/ services related to a qualifying clinical trial. If your study will bill routine costs to Medicare or any other insurer, the study must be registered on ClinicalTrials.gov to obtain the NCT#.

Qualifying Criteria (All three criteria must be "Yes"):

1. Evaluates a medicare benefit
2. Has therapeutic intent
3. Enrolls diagnosed beneficiaries

Deemed Automatically Qualifying Trial (Any one criteria must be "Yes"):

- Is funded/supported by NIH, CDC, AHRQ, CMS, DOD or VA
- Is supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA
- Has an IND number: Trial conducted under an investigational new drug application (IND) reviewed by the FDA
- Trial is exempt from having an IND

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

Last updated: 9 Dec 2024

How to Register a Study

The "Guidance for Registering in the ClinicalTrials.gov Registry" document provides guidance for UCLA investigators, plus selected tips on how to initiate a new record. Please review the UCLA Creating a New Study Record document. Detailed instructions, examples, data entry tips and a review checklist are also available by logging in to your PRS user account and selecting Help > Protocol Data Entry.

The Clinical and Translational Science Institute (CTSI) Office of Regulatory Affairs (ORA) assists investigators conducting non-oncology related research with the process of registering trials with clinicaltrials.gov. Please contact the UCLA PRS Administrator for more details.

The JCCC Office of Regulatory Compliance (ORC) assists investigators conducting oncology related research with the process of registering trials with clinicaltrials.gov.

Timelines & Deadlines

Registration:

- Not later than 21 calendar days after enrollment of the first participant (Applicable Clinical Trials under FDAAA 801 and NIH-funded clinical trials)
- Prior to enrollment of the first participant (for publication in journals adhering to ICMJE standards).

Required Updates:

- Within 30 days of a change to Recruitment Status, or Completion Date data elements
- Within 15 calendar days of a change to Device Approval Status
- General updates to the record (or verification of no changes) must be made at least every 12 months

Correction of errors, deficiencies:

- **Registration:** 15 calendar days after Review Comments
- **Results:** 25 calendar days after Review Comments

Results:

- Not later than 12 months after 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, whether the clinical study concluded according to the pre-specified protocol or was terminated.)

Last updated: 29 Aug 2022

Qualifying Clinical Trials

The National Coverage Decision (NCD) offers specific guidance concerning Clinical Trials Billing.

Under the National Coverage Decision (NCD), Medicare will cover those routine costs of qualifying clinical trials and the costs of items and services that are reasonable and necessary* to diagnose and treat complications arising from participation in all clinical trials (Centers for Medicare and Medicaid Publication 100-3, Ch 1, Part 4, Section 310.1).

What is a Qualifying Clinical Trial?

Deemed Automatically Qualifying Trial (Any one criterion must be "Yes"):

- Is funded/supported by NIH, CDC, AHRQ, CMS, DOD or VA
- Is supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA
- Has an IND number: Trial conducted under an investigational new drug application (IND) reviewed by the FDA
- Trial is exempt from having an IND

Qualifying Criteria (All three criteria must be "Yes"):

- Evaluates a Medicare benefit
- Has therapeutic intent
- Enrolls diagnosed beneficiaries

*Some commonly ordered tests may not be considered “reasonable and necessary” under the NCD, or may be reasonable and necessary at some frequency less than that required by the sponsor in a protocol. See the NCD Alphabetical Index for CMS’ indications and limitations for common procedures.

Routine Costs Provided to Qualifying Clinical Trials

- Items or services required solely for the provision of the investigational item or service (e.g., infusion)
- Items or services typically provided absent a clinical trial
- Clinically appropriate monitoring of the effects of the item or service (e.g., monitoring side effects or complications)
- Prevention of complications
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service (e.g., hydration fluids as part of chemotherapy treatment)

Items Excluded from Routine Costs Provided to Qualifying Clinical Trials

- Items or services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient or not used to monitor the effects of the item or service (e.g., plasma biomarkers)
- An investigational item or service itself if used in a non-FDA approved way
- Items or services customarily provided by the sponsors free of charge
- Items or services provided solely to determine trial eligibility
- Treatment of healthy volunteers unless used as controls
- Cosmetic surgery, some prosthetics, herbal remedies, relaxation therapies, etc.

Learn more about Qualifying Clinical Trials for Devices.

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

Last updated: 26 Aug 2022

Applicable Clinical Trials

Definition of a Clinical Trial

The World Health Organization (WHO) defines a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc."

The U.S. National Institutes of Health (NIH) defines a clinical trial as: "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

Consistent with the definition developed by the WHO, The International Committee of Medical Journal Editors (ICMJE) defines a clinical trial as "any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioural treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events."

The FDA defines an Applicable Clinical Trial (ACT) as follows:

- Trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation.
- Trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.

For complete statutory definitions and more information on the meaning of Applicable Clinical Trial, see Elaboration of Definitions of Responsible Party and Applicable Clinical Trial (PDF).Definition of a Clinical Trial

What is a Qualifying Trial

Under the National Coverage Decision (NCD), Medicare will cover those routine costs of qualifying clinical trials and the costs of items and services that are reasonable and necessary to diagnose and treat complications arising from participation in all clinical trials (Centers for Medicare and Medicaid Publication 100-3, Ch 1, Part 4, Section 310.1).

The trial may be "Qualifying" if it:

- Is funded/supported by NIH, CDC, AHRQ, CMS, DOD or VA
- Is supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA
- Has an IND number
- Is conducted under an IND/IDE reviewed by the FDA
- Is exempt from having an IND/IDE
- Is conducted an abbreviated IDE

-OR-

Your trial (All three criteria must be "Yes"):

- Evaluates a Medicare benefit

- Has therapeutic intent
- Enrolls diagnosed beneficiaries

For additional information regarding “Qualifying Trials” please refer to Qualifying Clinical Trials on ResearchGO.

Do I need to register my “Qualifying Trial” even if it is not an “Applicable Clinical Trial” under FDAAA?

Yes, your trial must be registered in ClinicalTrials.gov if it is a “qualifying trial” even if it doesn’t meet the definition of an “Applicable Clinical Trial.” According to a recent CMS mandate, a clinical trial number must be reported on claims for items and services provided in clinical trials that are qualified for coverage as specified in the “Medicare National Coverage Determination (NCD) Manual, “ Section 310.1.

The clinical trials number to be reported is the number assigned by the National Library of Medicine (NLM) http://clinicaltrials.gov website (an 8-digit # preceded by “NCT”, a.k.a. “the NCT #”) when a study appears in the NLM Clinical Trials database.

When must my ‘Qualifying Trial” be registered in ClinicalTrials.gov?

Your “Qualifying Trial” must be registered in ClinicalTrials.gov prior to IRB approval

What are the penalties for failing to register?

According to the ICMJE:

Unregistered trials will not be considered for publication in journals that adhere to ICMJE standards. This penalty has not changed over time.

According to the FDA/NIH (Food and Drug Amendments Act of 2007):

Penalties may include civil monetary penalties up to $10,000 fine for failing to submit or for submitting fraudulent information to ClinicalTrials.gov. After notification of noncompliance, the fine may go up to $10,000 per day until resolved. For federally funded grants, penalties may include the withholding or recovery of grant funds.

What is an applicable clinical trial according to the Food and Drug Administration Amendments Act (FDAAA) Section 801?

Applicable Clinical Trial (ACT) is the term used in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (PL 110-85) to designate the scope of trials that may be subject to the registration and reporting requirements in FDAAA. FDAAA defines the term using two other terms defined in the Act, namely an “applicable drug clinical trial” or an “applicable device clinical trial.”

Detailed definitions can be found in the Elaboration of Definitions of Responsible Party and Applicable Clinical Trials document.

In general, a study is likely subject to the requirements of FDAAA if YES is answered to all five questions below:

1. Was the study initiated after September 27, 2007 (OR ongoing as of December 26, 2007)?
2. Is the study 'interventional' (i.e., participants are assigned to interventions by protocol)?
3. Does the study intervention include a 'drug', 'biological product', or 'medical device' (whether or not approved for marketing in the United States)?
4. Is the study not considered a phase I clinical investigation (e.g., a phase 2 study) OR not considered a 'small feasibility' device trial (e.g., a pivotal study)?
5. Does the study have at least one site located in the United States OR is the study conducted under an IND or IDE?

Are investigator-initiated trials applicable clinical trials?

Yes, investigator-initiated trials are applicable clinical trials if they meet the criteria outlined above.

Can non-randomized trials be considered ACTs?

Yes – non-randomized trials can be "Applicable Clinical Trials" if they meet the other criteria. In non-randomized trials, participants are expressly assigned to intervention groups through a non-random method, such as physician choice. Keep in mind, a single –arm study often uses a historical comparison. See below for details regarding 'controlled' studies.

What does 'controlled' mean when it comes to deciding if a study is an ACT or not?

A study where a control is not expressly outlined in the protocol may still be considered an applicable clinical trial if it meets the other criteria outlined above. A controlled clinical investigation is one that is designed to permit a comparison of a test intervention with a control to provide a quantitative assessment of the drug effect. The purpose of the control is to distinguish the effect of a drug from other influences. The control provides data about what happens to human subjects who have not received the test intervention or who have received a different intervention. Generally, the types of control that are used in clinical investigations are (1) placebo concurrent control; (2) dose-comparison control; (3) no intervention concurrent control; (4) active intervention concurrent control; and (5) historical control.

What clinical trials are specifically excluded from the definition applicable clinical trials according to FDAAA?

- Phase 0 and phase I drug trials (however, these trials may still require registration per FDAMA Section 113).
- Small feasibility device trials and larger clinical trials of prototype devices with a primary measure of feasibility rather than health outcomes.
- Trials that include only de-identified human specimens and do not include human subjects.

Additional information can be found in the Elaboration of Definitions of Responsible Party and Applicable Clinical Trials document.

Who is responsible for registering protocols and reporting results for applicable clinical trials?

The “Responsible Party” is the entity or individual responsible for meeting FDAAA requirements for registering protocols and reporting results of ACTs. The responsible party is generally either the regulatory sponsor or the principal investigator. Note that the regulatory sponsor and financial sponsor are sometimes the same entity (i.e., a pharmaceutical company).

Generally speaking, the regulatory sponsor of an ACT will register and report the results of the trial if they:

- Are the company/organization that initiates the trial (multicenter or otherwise) and its employees conduct the trial;
- Are an individual who initiates a trial, but has someone else conduct the investigation;
- Hold the IND or IDE.

Generally speaking, Principal Investigators of applicable clinical trials will register and report the results of the trial if:

- The obligation is delegated to the principal investigator by the regulatory sponsor;
- The principal investigator is responsible for conducting the trial, analyzing the data, has rights to publish results and has the ability to meet all of FDAAA’s requirements for the submission of clinical trial information.

Note: For investigator-initiated ACTs, where a UCLA PI holds the IND/IDE, the IND/IDE holder (sponsor-investigator) must serve as the responsible party. For investigator-initiated ACTs where there is no IND or IDE holder and UCLA is the regulatory sponsor, the PI will be the designated responsible party. [UCLA Policy Pending]

If there is more than one award supporting a non-IND/IDE ACT, who is the Responsible Party?

Investigators and institutional officials associated with the trial should work together to determine the Responsible Party and ensure that the other grantees are aware of the designation. For assistance in these situations, please contact the UCLA PRS Administrator.

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

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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.
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.

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.

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Resources and Regulations

DHHS:

- Final Rule for FDAAA 801 (effective January 18, 2017)
- Summary information on FDAAA 801 (U.S. Public Law 110-85) requirements
- General information about the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11)
- Checklist for Evaluating Whether a Clinical Study is an Applicable Clinical Trial (PDF) (October 2017)
- FAQs for Applicable Clinical Trials (ACTs)
- FDA's Role: ClinicalTrials.gov Information
- U.S. Public Law 110-85 - FDA Amendments Act of 2007
- ClinicalTrials.gov Protocol Data Element Definitions
- ClinicalTrials.gov Results Data Element Definitions

NIH:

- 2016 NIH Policy on the Dissemination of NIH-funded Clinical Trial Information
- NIH Definition of a Clinical Trial
- NIH Clinical Trial Case Studies (Examples)
- NIMH human subject research subject to NIH Clinical Trial Requirements
- Refining Case Studies and FAQs about the NIH Definition of a Clinical Trial (1/04/2018)
- Clarification regarding basic health research involving fMRI (1/22/2018)
- FAQs for NIH-Funded Clinical Trials and FDAAA
- NIH Office of Science Policy – Clinical Trials
- NOT-OD-16-147 NIH Policy on Funding Opportunity Announcements (FOA) for Clinical Trials (9/16/2016)
- NOT-OD-17-043 NIH Update on Clinical Trial Funding Opportunity Announcement Policy (2/17/2017)

CMS:

- Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims

ICMJE (International Committee of Medical Journal Editors):

- ICMJE FAQs on Clinical Trials Registration

Additional Tools & Guidance

- UCLA Guidance on ClinicalTrial.Gov Registration and Reporting Requirements
- How to Register a Study at UCLA
- Resolving Problem Records
- Outcome Measures Guidance
- Registration and Results Reporting Time Estimates (OMB Burden Statement)

Results Reporting Tools

- Common Errors
- Pre-Submission Checklist
- Results Examples
- How to Submit Results
- Submitting Results Webinar-May 14, 2013
- Sample Results Template (single-arm study)
- Sample Results Template (2-arm study)
- Sample Results Template (3-arm study)
- Checklists, templates, and examples to help gather information needed to report results to ClinicalTrials.gov

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

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