UTSouthwestern Medical Center

Human Research Protection Program Office
ClinicalTrials.gov Program
ctgov@utsouthwestern.edu

ClinicalTrials.gov Quick Guide

What is Clinicaltrials.gov?

ClinicalTrials.gov, commonly known as CT.gov, is a clinical trial registry & results database run by NIH that provides clinical trial information to patients, family members, health care professionals, researchers, and the larger public.

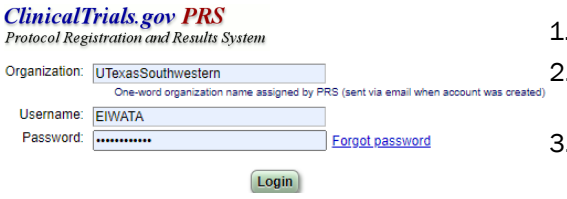
Responsible Party

UTSW PI determines whether the study requires registration. Responsible party (UTSW PI/Sponsor) register the study and submit the results information.

See the Responsible Party data element on clinicaltrials.gov for more information.

Trials are registered using a Protocol Registration and Results System (PRS) Contact your department PRS administrator or ctgov@utsouthwestern.edu for more information prior to registering a trial. In general, registration of the clinical trial must be done prior to first participant enrollment. Review the protocol review criteria before submitting your trial.

Registering Trials



1. Log in to regiter.clinicaltrials.gov
2. Enter your UTSW username and password
3. List organization as *UTexasSouthwestern*

Submitting Results

In general, results of the clinical trial must be submitted no later than 12 months after the primary completion date. How to submit your results.

The clinicaltrials.gov results database was originally implemented to meet FDAAA 801 and was expanded to meet requirements in the final rule.

Per FDAAA 801, responsible parties are required to register and submit studies and study results of clinical trials with clinicaltrials.gov. Registration is required for applicable clinical trials that were:

1. Initiated after September 27, 2007
2. Initiated on or before September 27, 2007 and ongoing as of December 26, 2007

FDAAA/Final Rule

Applicable Clinical Trials (trials of drugs/ biological products other than phase 1 trials, devices trials other than feasibility studies, & pediatric device post market surveillance) are require to be registered and result reported

ICMJE Publication Requirements

The International Committee of Medical Journal Editors (ICMJE), in 2005, required that all clinical trials be entered into the public registry and included data sharing plan

NIH Dissemination Policy

Clinical trials funded in whole or in part by the NIH initiated after January 18, 2017 are required to be registered and result reported

CMS Billing Requirements

Originally, published by the Center for Medicare and Medicaid Services (CMS) in January 2008 as a voluntary requirement, as of January 2014, the National Clinical Trial (NCT) number is required for qualified claims

Consequences for failing to register a clinical trial or submit trial results can include:

- Civil monetary penalties ($12,103/day)
- Withholding of grant funds (federally funded studies)
- Denied publication in medical journals (ICMJE - condition of consideration for publication)
- Medicare/Medicaid claims will not be paid
- Hold eIRB study activation
- Hold coverage analysis finalization

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Registering a Trial

Prior to IRB Approval

Use flowchart to determine if your clinical trial needs to be registered on CT.gov

In general, IND/IDE holder or main site PI for federally funded study is responsible party to register the trial

One trial one CT.gov record. If the trial is a multisite study, it must be registered only once, UTSW PI must coordinate with all collaborators before registration to avoid duplicate

Register a trial prior to IRB approval and enrolling your first participant

Use checklist and step-by-step instruction for registration and results reporting

Get assistance from your department PRS administrator and HRPPO CT.gov program for first time registering trial on CT.gov.
Don't have a PRS account? Email your name and UTSW User ID to **ctgov@utsouthwestern.edu**

Updating & Maintaining Trial Records

Within 15 days of Protocol Changes

Following data elements on CT.gov must be updated within 15 days of changes
- Device approval/clearance status
- Actual primary completion date
- IRB status
- Responsible party/contact information
- Overall recruitment status
- Primary completion date (final data collection date for the primary outcome)
- Study start date (first subject is enrolled)
- Study completion date (final data collection date for the study as a whole)

Intervention name
- Availability expanded access
- Expanded access status/type
- Individual site status

(recruitment status for any individual site)

Annual Updates of Record

At a minimum, at once every 12 months the responsible party must:

1. Review the CT.gov study record for accuracy and completeness, even with no changes
2. Update the Record Verification Date(and other data elements, as needed)
3. Approve and release the update to CT.gov

Reporting Trial Results

Within 12 Months

If results are required, they are due 12 months after the primary completion date
-If the study has more than one primary outcome measure, the primary completion date is the date that final data were collected for ALL primary outcome measures
-If the primary completion date and study completion date are the same, then the initial results are also the complete results, and no further results are required

Secondary outcome measure data not reported with the initial results must be submitted within 1 year of the date when the final data were collected

Protocol and statistical analysis plan must be uploaded with a cover page

Results Data Elements Definitions for interventional and observational study

Find details on how to submit results & result review criteria

Key Terms and Definitions

Data Elements	prsinfo.clinicaltrials.gov/FinalRuleChanges-12Dec2016.pdf
Record Owner	PRS account holder (PI, Dep PRS Administrator, research manager, etc) who creates a study record in the PRS
Responsible Party	Entity (UTSW) or individual (PI) responsible for conducting the trial, controlling data, verifying the accuracy of trial record, and publishing the result of the trial
UTSW (Department) PRS Administrator	Individual(s) designated by the department to manage the department's PRS account, and serve as the point of contact for PRS staff and respective study teams. Department should designate 1-2 individuals as their PRS administrator
Sponsor	The entity (UTSW) that initiates the study
Study Start Date	Actual date on which the first participant was enrolled in a clinical study
Primary Completion Date	Date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measures
Study Completion Date	Date on which the last participant in a clinical study was examined or received an intervention/treatment to collect final data for the primary outcome measures, secondary outcome measures and adverse events