THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

ClinicalTrials.gov Questions and Answers (Q&A)

What is ClinicalTrials.gov?
A web-based resource for patients, their families, health care professionals, researchers, and the public with access to information on publicly and privately funded clinical studies. Clinicaltrials.gov is the largest registry in the world.

Which trials must be registered on ClinicalTrials.gov?
Registration is required for studies that meet the definition of an "applicable clinical trial" (ACT) and either were initiated after September 27, 2007, or initiated on or before that date, and were still ongoing as of December 26, 2007. Please see Checklist and Elaboration for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT) ("ACT Checklist"), which follow the criteria specified in Title 42 CFR Part 11.22(b), to determine whether a study initiated on or after January 18, 2017, is an ACT subject to the expanded registration requirements under the Final Rule.

Why is it important to register and report results on ClinicalTrials.gov?
Clinical trials are not abstract research projects; they are large, expensive, practical evaluations that aim to directly inform clinical practice. Efforts to synthesize evidence into systematic reviews or inform guidelines are compromised by missing trial data. Patients and clinicians cannot make informed choices when the results of clinical trials are routinely withheld. Liberati A. An unfinished trip through uncertainties. BMJ 2004; 328: 531

Failure to report the results of a clinical trial can distort the evidence base for clinical practice, breaches researchers' ethical obligations to participants, and represents an important source of research waste. Moher D, Glasziou P, Chalmers I, et al. Increasing value and reducing waste in biomedical research: who's listening? Lancet 2016; 387: 1573–86.

Why must studies be registered on ClinicalTrials.gov?
It is required by law. The Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11) defines the regulatory requirements and procedures for submitting registration and results information for certain clinical trials to ClinicalTrials.gov, in accordance with Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801). The Final Rule has been in effect since January 18, 2017.

The revised (effective July 19, 2018) Federal Policy for the Protection of Human Subjects, also known as the Common Rule, codified at 45 CFR 46, states that for clinical trials (including those not meeting the regulatory definition of ACT) conducted or supported by a federal department or agency, one IRB-approved informed consent form (ICF) will be posted on a publicly available federal website in accordance with (IAW) 45 CFR 46.102(b), 46.116(h). The ICF will be posted on the federal website after the

clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

While there are two federal websites (ClinicalTrials.gov is one) available for this purpose, COM expects that researchers will adhere to this federal requirement using ClinicalTrials.gov.

Some scientific journals require ClinicalTrials.gov registration and compliance as a condition of publication (including those not meeting the regulatory definition of ACT). For example, the International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition of the publication of research results generated by a clinical trial.

What is the responsibility of the department and division points of contact (POC)?

- Release study records
- Review records for compliance (i.e., updated within one year, results submitted on time, queries addressed and answered by responsible party)
- Notify responsible party of noncompliance and help reduce noncompliant problem records
- Create/disable user accounts, reset passwords
- Transfer records as needed

Who is the Responsible Party (RP)?

If a study was initiated and written by an investigator at Ohio State, the Principal Investigator (PI) of the study should be listed as the Responsible Party, whether listed as “Principal Investigator” or “Sponsor-Investigator.”

What are the responsibilities of the RP?

- Register the trial on ClinicalTrials.gov and submit results
- Update the record, minimally, on an annual basis

How often should records be updated?

The study record needs to be updated at least once a year until the study is completed and/or the Protocol Registration and Results System (PRS) review process has ended for submitted results information. Some data elements require more frequent updates, such as a change in responsible party, overall recruitment status, and after the clinical trial reaches actual study completion date. Please see ClinicalTrials.gov for additional information.

What is a problem record?

Records may have issues with data entry errors or FDAAA 801. Records may not have been updated recently or have missing information. FDAAA results may be late,

incomplete, or missing information. A user can view the problems associated with a record in the Problems column within a ClinicalTrials.gov record.

Which Ohio State internal department provides ClinicalTrials.gov administrator contact information?
The Center for Clinical and Translational Science (CCTS) maintains several documents regarding ClinicalTrials.gov registration and contact information for ClinicalTrials.gov administrators. The Office of Responsible Research Practices (ORRP) also maintains contact information for Ohio State administrators.

How often does the ClinicalTrials.gov PRS send emails regarding problem records?
Problems notifications are sent twice yearly (approximately every six months) to each organization. These notifications are sent to Record Owners, Responsible Parties, and the organization's Administrator(s), alerting them to records that list any type of record problem.

A PI departed/joined Ohio State. How do I transfer a record to/from a different institution?
Email the ClinicalTrials.gov PRS staff at register@clinicaltrials.gov and they can provide the contact information for the administrators at the other institution. The other institution must agree to the transfer. To coordinate a transfer, you must include the following information: Study title, National Clinical Trial (NCT) #, organization, and new record owner. After obtaining this information, email the ClinicalTrials.gov PRS staff and they can complete the transfer.

In accordance with COM Standard Operating Procedure (SOP) 1, *ClinicalTrials.gov Compliance*, when a PI plans to depart Ohio State, they must update their ClinicalTrials.gov records accordingly as part of their COM offboarding responsibilities. This includes ensuring that the record is in good standing and: completing the record; or updating the record to reflect transfer to a new PI; or transferring the record to the PI's new institution.

Where can I find ClinicalTrials.gov training?
The Collaborative Institutional Training Initiative (CITI) offers, *ClinicalTrials.gov Registration and Results Summary Disclosure in ClinicalTrials.gov.* This course provides a video-enhanced guide to compliance with the FDAAA Final Rule and e National Institutes of Health (NIH) Policy on clinical trial disclosure in ClinicalTrials.gov. The course guides learners through critical parts of the regulations and provides a step-by-step guide to data entry, thus helping organizations avoid the risk of significant civil monetary penalties or loss of NIH grant funding. Ohio State does not subscribe to this course, and as such, there is an independent learner fee associated.
https://www.citiprogram.org/.

The ClinicalTrials.gov PRS has guided tutorials with step-by-step instructions for entering registration and results information.
https://prsinfo.clinicaltrials.gov/tutorial/content/index.html#/

What is the ClinicalTrials.gov Taskforce?
The Clinical Trials Registration and Results Reporting Taskforce is a national consortium of members of academic medical centers, universities, hospitals, and non-profit organizations focused on the implementation of domestic clinical trials registration and results reporting requirements in the ClinicalTrials.gov public repository. The objectives of the group are to identify best practices, develop solutions and tools for regulatory support and investigators, and serve as a communication forum. To join, complete a membership form on their website. https://ctrrtaskforce.org/

Who is subject to penalties for noncompliance with ClinicalTrials.gov?
Responsible Parties who violate regulations and fail to submit clinical trial registration and/or results are subject to financial penalties. Violations not corrected within 30 days following notification may be fined up to $13,237 each day until the violation is corrected.

In addition to civil money penalties, violations of § 301(jj) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 USC 331 (jj)) could result in other regulatory action, such as injunction and/or criminal prosecution.

If there is a failure to submit a certification under § 402(j)(5)(B) of the PHS Act or knowingly submitting a false certification, the applicant or submitter of the relevant submission to FDA would be subject to the potential consequences set forth.

If, however, there is a failure to submit required clinical trial information under § 402(j) of the PHS Act or submitting clinical trial information that is false or misleading, the RP (as identified in the ClinicalTrials.gov record for the ACT) would be subject to the potential consequences set forth.

Who may I contact with questions regarding ClinicalTrials.gov?
The ClinicalTrials.gov staff quickly responds to emails at register@clinicaltrials.gov.

Is there a ClinicalTrials.gov Frequently Asked Questions (FAQ) resource?
Yes! For the most current information, please visit this link.
https://clinicaltrials.gov/ct2/manage-recs/faq