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## [Related Guidance, Tools and Templates](#)

### 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 ClinicalTrials.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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