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ClinicalTrials.gov: Results Reporting, Unique Evidence and the Role of Medical Librarians

Training Materials

ClinicalTrials.gov How to Read a Study Record: https://clinicaltrials.gov/ct2/help/how-read-study

- Provides information on how to read a study record including record tabs, search term highlighting, historical views of records, and viewing study records in Extensible Markup Language (XML).

ClinicalTrials.gov Training Materials: https://clinicaltrials.gov/ct2/manage-recs/present

- Training materials including the Final Rule Webinar Series, Updated Quality Control and Posting Procedures webinar, PRS Guided Tutorials, materials from the Train-the-Trainer Workshop, and example studies for results data entry.

ClinicalTrials.gov Additional Resources: https://clinicaltrials.gov/ct2/manage-recs/resources

- Support materials including Protocol Registration and Results System (PRS) information, U.S. laws, regulations, and guidance, key U.S. policies, and international policies.

Additional ClinicalTrials.gov Resources

Final Rule Information: https://prsinfo.clinicaltrials.gov

- Final Rule Webinar Series
- Applicable Clinical Trial Checklist and Elaboration (ACT Checklist)
- Frequently Asked Questions
- Planned Updates to PRS
- “Coming Soon”

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Submit Studies: https://clinicaltrials.gov/ct2/manage-recs

- FDAAA 801 and the Final Rule Requirements
- Frequently Asked Questions
- Training Materials – recorded presentations, example study records
- Support Materials

Readings and Articles

ClinicalTrials.gov FDAAA 801 Requirements [Internet]. Bethesda (MD): National Library of Medicine (US); c2012. Available from: http://clinicaltrials.gov/ct2/manage-recs/fdaaa.

ClinicalTrials.gov Why Should I Register and Submit Results? [Internet]. Bethesda (MD): National Library of Medicine (US); c2012. Available from: http://clinicaltrials.gov/ct2/manage-recs/background.

Gøtzsche PC. Why we need easy access to all data from all clinical trials and how to accomplish it. Trials. 2011 Nov 23;12:249. doi: 10.1186/1745-6215-12-249.

Grady, Denise. Patients Lose Sight After Stem Cells Are Injected Into Their Eyes. New York Times. 15 Mar. 2017. https://www.nytimes.com/2017/03/15/health/eyes-stem-cells-injections.html?_r=0.

McGauran N, Wieseler B, Kreis J, Schüler YB, Kölsch H, Kaiser T. Reporting bias in medical research - a narrative review. Trials. 2010 Apr 13;11:37. doi: 10.1186/1745-6215-11-37.

National Institutes of Health News Releases: "HHS takes steps to provide more information about clinical trials to the public." Bethesda (MD): National Institutes of Health; c2017. Available from: https://www.nih.gov/news-events/news-releases/hhs-takes-steps-provide-more-information-about-clinical-trials-public.

Ross JS, Tse T, Zarin DA, Xu H, Zhou L, Krumholtz HM. Publication of NIH funded trials registered in ClinicalTrials.gov: cross sectional analysis. BMJ. 2012 Jan 3;344:d7292. doi: 10.1136/bmj.d7292.

Tse T, Zarin DA, Williams RJ, Ide NC. The Role and Importance of Clinical Trial Registries and Results Databases. In: Gallin JI, Ognibene FP, editors. Principles and Practice of Clinical Research. London: Academic Press; c2012. p. 171-181.

Zarin DA, Tse T. Moving Toward Transparency of Clinical Trials. Science. 2008 Mar 7;319(5868):1340-2. doi: 10.1126/science.1153632.

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