COVID-19 Information

Public health information (CDC)

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History, Policies, and Laws

This page provides information on selected events, policies, and laws related to the development and expansion of ClinicalTrials.gov. It is not intended to be comprehensive.

Contents

for Public Comment

- 2015: National Cancer Institute Issues Clinical Trial Access Policy
- 2016: Final Rule for FDAAA 801 Issued
- 2016: Final NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information Issued
- 2017: Revised Common Rule (45 CFR 46) Issued
- 2020: Federal Court Decision in *Seife et al. v. HHS et al.*, 18-cv-11462 (NRB) (S.D.N.Y. Feb. 24, 2020)

1997: Congress Passes Law (FDAMA) Requiring Trial Registration

The first U.S. Federal law to require trial registration was the Food and Drug Administration Modernization Act of 1997 (FDAMA) (PDF). Section 113 of FDAMA (FDAMA 113) required the National Institutes of Health (NIH) to create a public information resource on certain clinical trials regulated by the Food and Drug Administration (FDA). Specifically, FDAMA 113 required that the registry include information about federally or privately funded clinical trials conducted under investigational new drug applications to test the effectiveness of experimental drugs for patients with serious or life-threatening diseases or conditions.

The information in the registry was intended for a wide audience, including individuals with serious or life-threatening diseases or conditions, members of the public, health care providers, and researchers.

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2000: NIH Releases ClinicalTrials.gov Web Site

With input from FDA and others, the NIH National Library of Medicine (NLM) developed ClinicalTrials.gov. The first version of ClinicalTrials.gov was made available to the public on February 29, 2000. At the time, ClinicalTrials.gov primarily included NIH-funded studies.

- NLM Press Release: National Institutes of Health Launches ClinicalTrials.gov (February 29, 2000)

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2000–2004: FDA Issues Guidance for Industry Documents

In 2000 FDA issued a draft Guidance for Industry document, which provided recommendations for researchers submitting information to ClinicalTrials.gov. A final guidance document that incorporated comments from the public was issued in 2002 and was withdrawn by FDA in September 2017.

- FDA Final Guidance, March 2002: Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (Withdrawn by FDA September 2017)

In January 2004 FDA proposed a revised draft Guidance for Industry document that included guidance

for researchers submitting information required by the Best Pharmaceuticals for Children Act of 2002. This draft guidance was withdrawn by FDA in September 2017.

- FDA Draft Guidance, January 2004: Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (Withdrawn by FDA September 2017)

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2004: ClinicalTrials.gov Wins the Innovations in American Government Award

In 2004 ClinicalTrials.gov was cited by the Ash Center for Democratic Governance and Innovation at the Harvard Kennedy School as "a successful model for the creation and maintenance of a system that processes and presents large amounts of specialized information to a wide range of users" and was selected as one of five award winners. The Innovations in American Government Awards is the Nation's preeminent program devoted to recognizing and promoting excellence and creativity in the public sector. The program highlights exemplary models of government innovation and advances efforts to address the Nation's most pressing public concerns.

- Ash Center: ClinicalTrials.gov award page
- NIH Press Release: National Institutes of Health's "ClinicalTrials.gov" Web Site Wins Prestigious Award

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2005: International Committee of Medical Journal Editors Requires Trial Registration

In 2005 the International Committee of Medical Journal Editors (ICMJE) began requiring trial registration as a condition of publication.

- ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Obligation to Register Clinical Trials
- ICMJE: Frequently Asked Questions About Clinical Trials Registration

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2005: State of Maine Passes Clinical Studies Registration Law (Repealed in 2011)

In 2005 the State of Maine passed a law requiring prescription drug manufacturers or labelers to submit clinical study registration and results information to ClinicalTrials.gov. The law applied to FDA-approved prescription drugs that are dispensed, administered, delivered, or promoted in Maine. In 2011 the law was repealed; it is no longer in effect.

- Maine State Public Law, Chapter 461: An Act To Make Certain Prescription Drug Disclosure Laws

Consistent with Federal Law (PDF) (Repealed on July 8, 2011)

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2006: World Health Organization Establishes Trial Registration Policy

In 2006 the World Health Organization (WHO) stated that all clinical trials should be registered, and it identified a minimum trial registration dataset of 20 items. In 2007 WHO launched the International Clinical Trials Registry Platform (ICTRP), which includes a search portal providing a single point of access to studies registered in various international registries. The ICTRP Search Portal includes data available on ClinicalTrials.gov.

- WHO: International Clinical Trials Registry Platform

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2007: Congress Passes Law (FDAAA) Expanding ClinicalTrials.gov Submission Requirements

In 2007 the requirements for submission to ClinicalTrials.gov were expanded after Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA) (PDF). Section 801 of FDAAA (FDAAA 801) required more types of trials to be registered; additional trial registration information; and the submission of summary results, including adverse events, for certain trials. The law also included penalties for noncompliance, such as the withholding of NIH grant funding and civil monetary penalties of up to $10,000 a day.

- FDAAA 801 and the Final Rule
- NIH Office of Extramural Research: Frequently Asked Questions: FDAAA - Further Resources for NIH Grantees

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2008: ClinicalTrials.gov Releases Results Database

In September 2008, as required by FDAAA 801, ClinicalTrials.gov began allowing sponsors and principal investigators to submit the results of clinical studies. The submission of adverse event information was optional when the results database was released but was required beginning in September 2009.

- NLM Technical Bulletin: ClinicalTrials.gov to Include Basic Results Data

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2008: Declaration of Helsinki Revision Promotes Trial Registration and Results Dissemination

In October 2008 the 59th World Medical Association (WMA) General Assembly amended the Declaration

of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. Two newly added principles (paragraphs 19 and 30) considered the prospective registration and the public disclosure of study results to be ethical obligations.

In October 2013 the 64th WMA General Assembly modified these two principles. In particular, paragraph 35 (formerly 19) required prospective registration, as follows: "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject."

Paragraph 36 (formerly 30) promotes the public disclosure of study results as an ethical obligation and states, in part, "Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties [i.e., researchers, authors, sponsors, editors, and publishers] should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available."

- WMA 2013 Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

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2009: Public Meeting Held at the National Institutes of Health

In accordance with FDAAA 801, NIH held a public meeting in April 2009 to solicit input from interested individuals about future regulations that will expand the information on ClinicalTrials.gov.

NIH gathered input on a range of issues, including the submission of adverse events information and the addition of narrative summaries to results submissions, for use in the development of draft regulations.

- NIH: Videocast and podcast of the public meeting
- Regulations.gov: Docket Folder Summary: Public Meeting on Expansion of the Clinical Trial Registry and Results Data Bank. Includes the meeting transcript, final meeting agenda, list of speakers for public statements, presentations, and public submissions.

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2013: European Medicines Agency Expands Clinical Trial Database to Include Summary Results

In October 2013 the European Medicines Agency (EMA) released a new version of the European Clinical Trials Database (EudraCT), marking "the initial step of a process through which summary clinical trial results will be made publicly available through the EU Clinical Trials Register (EU CTR)." Notably, the EudraCT summary results data requirements are "substantially aligned" with those of the ClinicalTrials.gov results database.

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