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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.

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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In 2000 FDA issued a draft Guidance for Industry document, which provided recommendations for researchers submitting information to ClinicalTrials.gov. A final guidance document that incorporated comments from the public was issued in 2002 and was withdrawn by FDA in September 2017.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Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (Withdrawn by FDA September 2017)

In January 2004 FDA proposed a revised draft Guidance for Industry document that included guidance for researchers submitting information required by the Best Pharmaceuticals for Children Act of 2002. This draft guidance was withdrawn by FDA in September 2017.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.

- EMA Press Release: [European Medicines Agency launches a new version of EudraCT: Summary results of clinical trials soon to be available to the public](#)

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2014: Notice of Proposed Rulemaking (NPRM) for FDAAA 801 Issued for Public Comment

In November 2014 the [U.S. Department of Health and Human Services](#) issued a [notice of proposed rulemaking](#) (NPRM) describing the proposed requirements and procedures for registering and submitting the results, including adverse events, of clinical trials on ClinicalTrials.gov, in accordance with [FDAAA 801](#). It also considers regulations intended to provide more complete results information and enhance patients' access to the results of clinical trials, by proposing to expand the requirement for submission of results information for Applicable Clinical Trials of unapproved products (i.e., drugs, biological products, or devices that have not been approved, licensed, or cleared by FDA). Public comments on the proposed rule were accepted until March 23, 2015. All substantive comments will be carefully reviewed and considered in drafting a final rule.

- NIH News Release: [HHS and NIH take steps to enhance transparency of clinical trial results](#) (November 19, 2014)
 - Publication: Zarin DA, Tse T, Sheehan J. [The proposed rule for U.S. clinical trial registration and results submission](#). *N Engl J Med*. 2015 Jan 8;372(2):174-80. [\[Full Text\]](#)
 - Publication: Hudson KL, Collins FS. [Sharing and reporting the results of clinical trials](#). *JAMA*. 2015 Jan 27;313(4):355-6. [\[Full Text\]](#)
- Office of the Federal Register: [Clinical Trials Registration and Results Submission Notice of Proposed Rulemaking](#) (November 2014)
 - NIH: [What Changes From Current Practice Are Proposed in the NPRM?](#) (PDF) (November 2014)
 - NIH: [NPRM at a Glance: Summary of Key Proposals](#) (PDF) (November 2014)
- Reginfo.gov: [U.S. Department of Health and Human Services Unified Agenda - Clinical Trials Registration and Results Submission \(RIN:0925-AA55\)](#). Describes the public process for the expansion of ClinicalTrials.gov under FDAAA 801.
 - OMB: [EO 12866 Regulatory Review](#) for Notice of Proposed Rulemaking (NPRM): OIRA received the NPRM on March 11, 2014, for regulatory review and concluded its review on August 29, 2014.
- HHS.gov: [HHS Regulations Toolkit - Information about the rulemaking process](#)

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2014: NIH Draft Policy on Registration and Results Submission of NIH-Funded Clinical Trials Issued for Public Comment

In November 2014 [NIH](#) proposed a [policy](#) to ensure that every clinical trial (see the [Revised NIH Definition of "Clinical Trial"](#)) that receives NIH funding is registered on ClinicalTrials.gov and has summary results submitted and posted in a timely manner, whether subject to [FDAAA 801](#) or not. Public comments on the proposed rule were accepted until March 23, 2015. All substantive comments will be carefully reviewed and considered in drafting a final policy.

- NIH News Release: [HHS and NIH take steps to enhance transparency of clinical trial results](#) (November 19, 2014)
 - Publication: Hudson KL, Collins FS. [Sharing and reporting the results of clinical trials](#). *JAMA*. 2015 Jan 27;313(4):355-6. [\[Full Text\]](#)
- NIH: [Request for Public Comments on the Draft NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#) (November 2014)

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2015: National Cancer Institute Issues Clinical Trial Access Policy

In January 2015 the NIH National Cancer Institute (NCI) issued its [Policy Ensuring Public Availability of Results from NCI-supported Clinical Trials](#). Generally, for "all initiated or commenced NCI-Supported Interventional Clinical Trials whether extramural or intramural" (i.e., Covered Trials), "Final Trial Results are expected to be reported in a publicly accessible manner within twelve (12) months of the Trial's Primary Completion Date regardless of whether the clinical trial was completed as planned or terminated earlier." This policy will be incorporated as a term and condition of any award supporting a Covered Trial.

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2016: Final Rule for FDAAA 801 Issued

In September 2016, the U.S. Department of Health and Human Services issued a [Final Rule for Clinical Trials Registration and Results Information Submission](#) (42 CFR Part 11) that clarifies and expands the regulatory requirements and procedures for submitting registration and summary results information of clinical trials on ClinicalTrials.gov, in accordance with [FDAAA 801](#). The final rule is intended to make it clear to sponsors, investigators, and the public which trials must be submitted, when they must be submitted, and whether compliance has been achieved. For example, the final rule clarifies the definition of an Applicable Clinical Trial and provides structured criteria for determining which studies are considered to meet the definition. The final rule also expands the FDAAA 801 requirements by requiring the submission of results information for trials of unapproved products. The regulation is effective on January 18, 2017 and responsible parties are expected to be in compliance as of April 18, 2017.

- NIH News Release: [HHS takes steps to provide more information about clinical trials to the public](#) (September 16, 2016)
 - Publication: Zarin DA, Tse T, Williams RJ, Carr S. [Trial reporting in ClinicalTrials.gov - the final rule](#). *N Engl J Med*. 2016 Nov 17;375(20):1998-2004. [\[Full Text\]](#)
 - Publication: Hudson KL, Lauer MS, Collins FS. [Toward a new era of trust and transparency in clinical trials](#). *JAMA*. 2016 Oct4;316(13):1353-1354. [\[Full Text\]](#)

- Office of the Federal Register: [Final Rule for Clinical Trials Registration and Results Information Submission](#) (September 2016)
 - NIH: [Changes from Current Practice Described in the Final Rule](#)
 - Office of Management and Budget (OMB): [EO 12866 Regulatory Review](#) for Final Rule: OMB's Office of Information and Regulatory Affairs (OIRA) received the final rule on August 1, 2016, and concluded its review on September 15, 2016.

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2016: Final NIH Policy on the Dissemination of NIH-funded Clinical Trial Information Issued

In September 2016, [NIH](#) issued a [final policy](#) to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Under this policy, every clinical trial funded in whole or in part by NIH is expected to be registered on ClinicalTrials.gov and have summary results information submitted and posted in a timely manner, whether subject to [FDAAA 801](#) or not. This policy is effective for applications for funding, including grants, other transactions, and contracts submitted on or after January 18, 2017. For the NIH intramural program, the policy applies to clinical trials initiated on or after January 18, 2017.

- NIH News Release: [HHS takes steps to provide more information about clinical trials to the public](#) (September 16, 2016)
 - Publication: Hudson KL, Lauer MS, Collins FS. [Toward a new era of trust and transparency in clinical trials](#). *JAMA*; 2016 Oct4;316(13):1353-1354. [\[Full Text\]](#)
- [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#) (September 2016)
- NIH OER: [Continued Extension of Certain Flexibilities for Prospective Basic Experimental Studies With Human Participants](#) (March 2021)

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2017: Revised Common Rule (45 CFR 46) Issued

In January 2017, [nearly 20 Federal department and agencies](#) issued a [revised Federal Policy for the Protection of Human Subjects](#) (also known as subpart A of 45 CFR part 46, or the "Common Rule"). The revisions were designed to modernize, strengthen, and make more effective the Common Rule originally promulgated in 1991. The revised Common Rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. It became effective on July 19, 2018, [as amended](#).

The [revised Common Rule \(45 CFR 46.116\(h\)\)](#) requires that for any clinical trial conducted or supported by a Common Rule department or agency, one consent form used in enrolling participants be posted on a publicly available Federal website within a specific time frame. In an August 2018 announcement, ClinicalTrials.gov and Regulations.gov were identified as the publicly available federal websites that will satisfy the consent form posting requirement.

- Office of Human Research Protections (OHRP): [Announcement: Federal websites that will satisfy the revised Common Rule's requirement to post clinical trial consent forms \(45 CFR 46.116\(h\)\)](#) (August 2018) (PDF)

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2020: Federal Court Decision in *Seife et al. v. HHS et al.*, 18-cv-11462 (NRB) (S.D.N.Y. Feb. 24, 2020)

On February 24, 2020, a Federal court held that Section 801 of the [Food and Drug Administration Amendments Act of 2007 \(FDAAA 801\)](#) (PDF) requires submission of results information for an "applicable clinical trial" ("ACT") that was initiated after September 27, 2007, or that was ongoing as of December 26, 2007, if the ACT studies a product that is approved, licensed, or cleared by the Food and Drug Administration (FDA) at any time, including after the ACT's primary completion date.

On September 21, 2016, the Department of Health and Human Services ("HHS") published the [Final Rule for Clinical Trials Registration and Results Information Submission](#) (81 FR 64981). The preamble to the Final Rule states that a responsible party is not required to submit to the ClinicalTrials.gov data bank results information under sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service (PHS) Act for an ACT that was completed before January 18, 2017, the effective date of the Final Rule, if the ACT studied a product that was not approved, licensed, or cleared for any use until after the ACT's primary completion date (81 FR 65067).

On February 24, 2020, a Federal court rejected this interpretation, holding that FDAAA 801 requires responsible parties to submit to the ClinicalTrials.gov data bank results information required under section 402(j)(3)(C) of the PHS Act, which includes information required under section 402(j)(3)(I) of the PHS Act, for ACTs subject to the registration requirements and with a primary completion date before January 18, 2017, if the ACT studies a product that is approved, licensed, or cleared after the ACT's primary completion date. The Court set aside HHS's contrary interpretation in the preamble to the Final Rule but did not change the regulations promulgated in 2016. *Seife et al. v. HHS, et al.*, No. 18-cv-11462-NRB, 2020 WL 883478 (S.D.N.Y. February 24, 2020).

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