

Historical Highlights of ClinicalTrials.gov:

In 2000, the first version of ClinicalTrials.gov went public and included mainly NIH-funded studies. However, the importance and need for a registry for clinical trials had been discussed for decades and the first U.S. Federal law to require trial registration was the [Food and Drug Administration Modernization Act of 1997 \(FDAMA\)](#). 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).

In 2005, the [International Committee of Medical Journal Editors](#) (ICMJE) began requiring trial registration as a condition of publication that dramatically increased the number of clinical studies registered on the site.

In 2007, Congress passed the [Food and Drug Administration Amendments Act of 2007 \(FDAAA\)](#). 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 trials that met the criteria for being an [applicable clinical trial](#). Penalties for noncompliance, such as the withholding of NIH grant funding and civil monetary penalties of up to \$10,000 a day were added [which in 2019 are in excess of \$12,300/day].

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](#). It clarifies to sponsors, investigators, and the public which trials must be submitted, when they must be submitted, and whether compliance has been achieved. The regulation became effective on January 18, 2017.

[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 applies to clinical trials initiated on or after January 18, 2017.

The enactment of the Final Rule and the NIH Final Policy resulted in a large increase in the number of results posted on ClinicalTrials.gov.

In January 21, 2019, as part of the [revised Common Rule \(45 CFR 46.116\(h\)\)](#), it is now required 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. This posting must occur after recruitment closes and no later than 60 days after the last study visit. ClinicalTrials.gov and Regulations.gov were identified as the publicly available federal websites that will satisfy the consent form posting requirement