Overview | ClinicalTrials.gov

Registration for Clinical Research Trials

Interventional studies with health outcomes must be registered, and may be required to report results, in ClinicalTrials.gov. This requirement applies to:

1. All NIH-funded trials, including phase 1 studies and clinical trials of behavioral or non-FDA-regulated interventions (Registration and Results required).
2. Clinical trials involving FDA-regulated drug, biologic and device products (Registration and Results required).
3. Studies that will bill routine costs to Medicare or any other insurer (Registration required).
4. Any study intended for publication in a journal recognized by the ICMJE (Registration required).

Those responsible for conducting a clinical trial must make sure that they are in compliance with the trial registration requirements of the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the International Committee of Medical Journal Editors (ICMJE), and as required by other organizations with policies on clinical trial registration for transparency and publication.

Section 801 of the Food and Drug Amendments Act, known as FDAAA 801, requires registration of studies meeting the definition of "Applicable Clinical Trial" on a government web site called ClinicalTrials.gov.

The US National Institutes of Health (NIH) final policy of 2016 established the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered and results information is submitted to ClinicalTrials.gov. Compliance with FDAAA is a legal requirement and a term and condition of the NIH award. All competing applications (new and renewal) and progress reports for NIH grants (including cooperative agreements) supporting clinical trials must include a certification of compliance with FDAAA.

The International Committee of Medical Journal Editors (ICMJE) requires, and recommends that all medical journal editors require, as a condition of consideration for publication, registration of [all] clinical trials in a public trials registry at or before the time of first patient enrollment.

Effective January 1, 2015, Center for Medicare and Medicaid Services (CMS) will require a clinical trial identifier (NCT#) be reported on all billing claims for items/ services related to a qualifying clinical trial(s). If your study will bill routine costs to Medicare or any other insurer, the study must be registered on ClinicalTrials.gov to obtain the NCT#.

ClinicalTrials.Gov Registration and Results Reporting of Clinical Studies

Last updated: 17 Sep 2019

Drupal.jQueryUiFilter.globalOptions('accordion');