

Why Register?

- **US Public Law 110-85, Title VIII (FDA Amendments Act of 2007 or FDAAA)**. The law:
 - Requires Responsible Parties to register and submit summary results of certain clinical trials with ClinicalTrials.gov.
 - Applies to [Applicable Clinical Trials \(ACTs\)](#), generally including interventional studies of FDA-regulated drugs, biological products, or devices, be registered no later than 21 days after first subject enrollment.
 - Imposes significant penalties for noncompliance.
 - [Click here to view the ClinicalTrials.gov Registration FACT SHEET as required by PL 110-85](#) for more details.
 - [Click here to view ClinicalTrials.gov FDAAA Section 801 Requirements](#) for additional information.
- **NIH** requires all grantees, regardless of whether or not they are the “responsible party”, to certify compliance with FDAAA in competing grant applications and progress reports that the responsible party has made all required submissions to ClinicalTrials.gov for ACTs funded in whole or in part by the NIH.
 - [Click here for more details about Certifying Compliance with FDAAA in NIH Applications and Progress Reports](#)
- The **International Committee of Medical Journal Editors (ICMJE)** policy requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry prior to first subject enrollment, as a condition of consideration for publication.
 - [Click here for more details about ICMJE Requirements.](#)
- The **Center for Medicare & Medicaid Services (CMS)** requires providers and suppliers to report an 8-digit clinical trial *NCT number* assigned by ClinicalTrials.gov on claims for items/services provided furnished pursuant to clinical trials that qualify for coverage as set forth in the Medicare National Coverage Determination Manual, effective 1/1/2014.
 - Claims submitted without the ClinicalTrials.gov NCT number will be returned to providers for reprocessing and inclusion of the ClinicalTrials.gov NCT trial number.