About the Results Database

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What Is the Results Database?

The ClinicalTrials.gov results database was launched in September 2008 to implement Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (PDF), which requires the submission of "basic results" for certain clinical trials, generally no later than 1 year after their Completion Date (see Primary Completion Date on ClinicalTrials.gov). The submission of adverse event information was optional when the results database was first released but was required beginning in September 2009. Results information for registered and completed studies is submitted by the study sponsor or principal investigator in a standard, tabular format without discussions or conclusions. The information is considered summary information and does not include individual patient data. The "basic" results information required by FDAAA 801 includes the following:

- **Participant Flow.** A tabular summary of the progress of participants through each stage of a study, by study arm or comparison group. It includes the numbers of participants who started, completed, and dropped out of each period of the study based on the sequence in which interventions were assigned.
- **Baseline Characteristics.** A tabular summary of the data collected at the beginning of a study for all participants, by study arm or comparison group. These data include demographics, such as age and gender, and study-specific measures (for example, systolic blood pressure, prior antidepressant treatment).
- **Outcome Measures and Statistical Analyses.** A tabular summary of Outcome measure values, by study arm or comparison group. It includes tables for each prespecified Primary Outcome and Secondary Outcome and may also include other prespecified outcomes, post hoc outcomes, and any appropriate statistical analyses.
- **Adverse Events.** A tabular summary of all anticipated and unanticipated Serious adverse event and a tabular summary of anticipated and unanticipated other adverse events exceeding a specific frequency threshold. For each serious or other adverse event, the summary includes the adverse event term, affected organ system, number of participants at risk, and number of participants affected, by study arm or comparison group.

The Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11), was issued in September 2016 and is effective in January 2017. It expands the scope of the results database by requiring the submission of results information for trials of unapproved products and additional information for summarizing trial results. For more information, also see Regulations Implementing FDAAA 801.

ClinicalTrials.gov staff review results submissions to ensure that they are clear and informative before posting them to the Web site. However, ClinicalTrials.gov cannot ensure scientific accuracy. Data providers are responsible for ensuring that their submitted information is accurate and complete.

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Display of Results on ClinicalTrials.gov

ClinicalTrials.gov organizes information for each registered study as an integrated unit, displaying the study protocol information and, if available, the corresponding results information on the same page under different tabs.

Study Results Posted

When available, study results information is included in the study record under the Study Results tab. See How to Find Results of Studies for more information on finding results entered in the results database.

Results Submitted

After study results information has been submitted to ClinicalTrials.gov, but before it is posted, the results tab in the study record is labeled "Results Submitted." Results may not yet be posted because they are pending quality control (QC) review by the National Library of Medicine (NLM) or the sponsor or investigator is addressing QC review comments provided by NLM. For additional information, see the Results Submitted Tab section of the December 18, 2017 NLM Technical Bulletin article.

No Results Posted

When results are not available for a study, the results tab is labeled "No Results Posted." Results of a study may not be posted on ClinicalTrials.gov for any of the following reasons:

- The study may not be subject to U.S. Federal requirements to submit results. See FDAAA 801 and the Final Rule: When Do I Need to Register and Submit Results?
- The study is ongoing.
- The study has been completed, but the deadline for results submission has not passed.
- The submission of results information has been delayed by the submission of a certification or a request to extend the results submission deadline. See FDAAA 801 and the Final Rule: When Do I Need to Register and Submit Results?

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Learn More

For the General Public

- ClinicalTrials.gov Background: Learn about the mandate and mission of ClinicalTrials.gov, who supplies the study record data found on the Web site, and how to use the site.

For Study Sponsors and Data Providers

- Why Should I Register and Submit Results?: Learn about the purpose of study registration and results submission. This page includes an overview of applicable laws and policies.
- How to Submit Your Results: Review the basic steps for submitting results, find out what information must be included, and learn about the review process.
- FDAAA 801 and the Final Rule: Learn about FDAAA 801 and the basic requirements for registering clinical studies and submitting results, including information about Responsible Parties, Applicable Clinical Trials, deadlines, and penalties.

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