

**Results Reporting for VA Office of Research and Development (ORD)
Sponsored Clinical Trials
Frequently Asked Questions
Updated August 2015**

- **Why am I required to report results of my clinical trial to ClinicalTrials.gov?**

As a condition of funding, ORD requires clinical trials it supports to be registered on ClinicalTrials.gov. ORD also requires Principal Investigators (PIs) to report results to ClinicalTrials.gov to enable public access to activities related to the study. Reporting results in a public trial registry helps fulfill ORD's commitment to informing Veterans and the public about its research and helps maximize the impact of the research it supports. The reporting requirement applies to all ORD trials which includes, but is not limited to, "Applicable Clinical Trials" as described in Section 801 of the Food and Drug Administration Amendments Act ([FDAAA 801](#)).

- **What is the due date for reporting summary results to ClinicalTrials.gov?**

Results must be submitted no later than 12 months after the [primary completion date](#) as indicated by the PI. This date is when the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome measure, whether the clinical trial concluded according to the pre-specified protocol or was terminated. Results information includes Participant Flow, Baseline Characteristics, all pre-specified Primary and Secondary Outcomes and Adverse Events.

- **How do I submit summary results to ClinicalTrials.gov?**

Results are submitted using the National Library of Medicine's ClinicalTrials.gov Protocol Registration and Results System (PRS). The VA ART Program sends the PI an automated email notification approximately 3 months prior to the results submission due date. The email will include PRS login information and instructions for submitting summary results.

Note that results are not submitted through the VA ART Website. Only protocol registration information is submitted and updated through ART.

- **I would like to learn more about what's required and how to enter it. Who can I contact?**

ClinicalTrials.gov provides one-on-one assistance to investigators throughout the results submission process. As part of the process, a member of the ClinicalTrials.gov results team will help prepare you for results submission, orient you to the PRS and walk you through the data entry process. To take advantage of this assistance, please send a request to register@clinicaltrials.gov. Indicate that you are a VA investigator and include available dates/times (including time zone) for an introductory call and the best phone number at which to reach you.

- **What results information must be submitted?**

To help investigators understand and gather the data needed to complete each results module, ClinicalTrials.gov has developed data preparation checklists and templates. See the table below for the available checklists and templates. All checklists and templates are found on ClinicalTrials.gov:

http://prsinfo.clinicaltrials.gov/results_table_layout/ResultSimpleForms.html

Results Data Preparation Checklists	
Participant Flow Data Preparation Checklist	<ul style="list-style-type: none"> • Participant Flow Template
Baseline Characteristics Data Preparation Checklist	<ul style="list-style-type: none"> • Baseline Characteristics Template - Age • Baseline Characteristics Template - Gender • Baseline Characteristics Template - Race, Ethnicity, Region • Baseline Characteristics Template - Study Specific Measure
Outcome Measure and Statistical Analysis Data Preparation Checklist	<ul style="list-style-type: none"> • Outcome Measure Template • Outcome Measure Template Examples
Adverse Events Data Preparation Checklist	<ul style="list-style-type: none"> • Serious Adverse Events Template • Other (Not Including Serious) Adverse Events Template

- **Are there training or help materials available for results submission?**

Information providing an overview of [How to Submit Your Results](#) is available on ClinicalTrials.gov. The available materials include: data preparation checklists, simple results templates, data element definitions, online presentations and review criteria.

Additional training materials are available on ClinicalTrials.gov at:

<https://clinicaltrials.gov/ct2/manage-recs/present>. These training materials include online presentations, workshop slides, and fictional study records and papers for common study models (e.g., Parallel, Cross-Over, Dose-Escalation, Factorial and Multiple Period Study Designs). The latter help illustrate key concepts for results data entry in PRS.

In addition, there are help links and data element definitions available in PRS that can be accessed during results entry or while editing results. The “Definitions” and “Help” links are located at the top of each page. The Data Element Definitions describe the results data items (required and optional) that are entered in the PRS. The Help Links offer “per module” help and provide an overview of the current module that is being edited.

- **After I enter the summary results, how do I submit them?**

When you complete data entry, click on the Entry Complete button at the top of the Record Summary screen. An ART Program team member will be notified that data entry is complete and will submit the results information to ClinicalTrials.gov on your behalf.

- **What happens once the results are submitted?**

A ClinicalTrials.gov results team member will review the record after it is submitted and prior to posting to ClinicalTrials.gov. This review will focus on content validity (when possible), meaningful entries, logic and internal consistency and formatting. Ensuring that the record is consistent with the [ClinicalTrials.gov protocol review criteria](#) (PDF) and the [ClinicalTrials.gov results review criteria](#) (PDF) before indicating Entry Complete will expedite its posting on the site.

- **How will I know when the results are accepted for posting on the site?**

The ClinicalTrials.gov review time will vary. It may take up to 30 days.

- a) When the review is completed, you may be asked to clarify items or make corrections to the Protocol and/or Results Sections of the record before the study record is posted. You will receive an email notification that instructs you to log-in to the PRS and view the comments provided. The ART team will send email reminders to the PI, every two weeks, until the questions or problems have been resolved (i.e., record updated and PI indicates Entry Complete).
- b) If the results are accepted and posted to ClinicalTrials.gov then the PI will receive a confirmation email from both ClinicalTrials.gov and the ART Program. At that time, the PI or designee's permissions to the record in PRS will be removed by the ART Program.

- **I don't know how to address the comments from the ClinicalTrials.gov review. Is there someone I can contact?**

Contact the ClinicalTrials.gov results team at register@clinicaltrials.gov.

- **My clinical trial was terminated. Do I still need to report results?**

Yes, if the trial ended prematurely and participants were enrolled (i.e., terminated status) then you are required to submit summary results to ClinicalTrials.gov. If the trial ended prematurely but participants were not enrolled (i.e., withdrawn status) then you do not need to submit summary results.

Additional information on submitting results for terminated trials is described in the ClinicalTrials.gov FAQ: [How do I submit results information if the trial is terminated \(that is, stopped prematurely\) and no data were collected for one or more Outcome Measures?](#)

- **Will posting results on ClinicalTrials.gov jeopardize the ability to publish my clinical trial in a journal?**

The International Committee of Medical Journal Editors (ICJME) supports clinical trials registration and its policy requires prospective registration of all interventional clinical studies. It has indicated that results data posted in the tabular format required by

ClinicalTrials.gov will not be considered to be prior publication. For more information, please see: <http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>.

- **My study is completed and results have been posted on ClinicalTrials.gov. Why do I continue to receive emails from the ART Program requesting publication updates?**

ORD expects investigators to submit publications on the background and/or results of the trial to ClinicalTrials.gov. Providing up-to-date information on publications helps ensure that Veterans and the general public are receiving the full benefit of the research investment that was made.

- **Who should I contact if I think my study is not a clinical trial and therefore reporting results to ClinicalTrials.gov should not be required?**

Please contact the trials registry point of contact for the ORD Service that funded the study. See contacts at:

http://www.research.va.gov/resources/ORD_Admin/clinical_trials/default.cfm.