

**UC SAN DIEGO
 CLINICALTRIALS.GOV INSTRUCTIONS FOR PUBLISHING RESULTS AND ADVERSE EVENTS**

The Food and Drug Administration Amendments Act (FDAAA), National Institutes of Health (NIH) and International Committee of Medical Journal Editors (ICMJE) require the publication of results for certain studies on a publicly accessible website, [ClinicalTrials.gov \(Ct.gov\)](http://ClinicalTrials.gov). After a clinical trial has been registered on ClinicalTrials.gov and the study is completed, the Responsible Party must publish the results on ClinicalTrials.gov.

What Regulatory Agencies Require Results Reporting?

	FDAAA 801 and Final Rule	ICMJE Policy	NIH Policy
Results Reporting	No later than 12 months after the Primary Completion Date (the last subject last visit)	Not required but recommended	No later than 12 months after the Primary Completion Date (the last subject last visit)

Other funding agencies may require that a clinical trial publish results on ClinicalTrials.gov. All signatories to the May 18, 2017, WHO, International Clinical Trials Registry Platform (ICTRP) require results reporting from the grantees. One signatory, for example, is the Bill and Melinda Gates Foundation. For all external funding and sponsorship, the Principal Investigator is required to review all award letters to ascertain if results publication on ClinicalTrials.gov is required.

What Kind of Clinical Trials Require Results Information to be Posted?

There are a number of regulatory bodies and other entities that require results publication on CT.gov. One or more of these polices may apply. Use the [Factsheet: registration and results decision tree](#) to help make a determination.

When Must Results be Posted?

Submission of results information is required **no later than 1 year** after the primary completion date of the clinical trial, which is defined as the date of final data collection for the primary outcome measure.

The image shows a screenshot of a web interface. At the top, there is a light blue box with the word 'Problems' and a downward-pointing triangle. Below this, a list of items is shown, with the first item being 'Late Results - per FDAAA' in red text.

ClinicalTrials.gov has a number of alerts to identify possible issues. For the results section, if a problem is identified as “Late Results- per FDAAA” the record is overdue for results publishing per FDAAA 801, based on the primary completion date entered. ClinicalTrials.gov uses a combination of data elements to calculate the results due date for each clinical trial.

What Information Must Be Posted?

It is recommended that you collect all of your data before entering information onto ClinicalTrials.gov. There are a number of module’s that must be completed within the Results Page. For additional information visit Protocol

Registration and Results System (PRS) [Help: Results Modules](#). Also, see below for an explanation of each of the Results modules.

Results Module	Minimum Required Data
Participant Flow	<ul style="list-style-type: none"> › Number starting and completing each arm (group) › Multiple periods may be required (e.g., cross-over or dose-escalation design)
Baseline Characteristics	<ul style="list-style-type: none"> › One age characteristic <ul style="list-style-type: none"> – Continuous (e.g., mean[SD]) or categorical (e.g., 0-18 years, etc.) › Either sex (biological) or gender (self-represented) › Race and ethnicity (each is required <i>if</i> collected) › Baseline measurements related to primary outcome measure(s) › <i>Must be reported by group and for all subjects (total column)</i>
Outcome Measures	<ul style="list-style-type: none"> › All registered primary and secondary outcome measures <ul style="list-style-type: none"> – At registration, all primary / secondary outcome measures in the clinical protocol document must be registered; these can be changed to reflect changes in protocol amendments during the study – Results must be entered in data tables (can't use graphs or images) › Appropriate statistical analyses (e.g., p-value, odds ratio, etc.) › <i>If outcome measures change during the study, update the registration to match</i>
Adverse Events	<ul style="list-style-type: none"> › Serious and “other” (non-serious) adverse events and <i>total affected</i> by each type (<i>know which is which</i>) › Term and organ class (e.g., Headache; Nervous System Disorders) › Must be reported according to the CT.gov definition (both related and unrelated AEs), unless otherwise defined in the clinical protocol document. › All-cause mortality (both related and unrelated to study participation)
Study Documents	<ul style="list-style-type: none"> › IRB-approved clinical protocol document or latest IRB-approved amendment <ul style="list-style-type: none"> – A printout of the IRB Protocol application is not an acceptable clinical protocol document for this purpose › Statistical analysis plan (SAP) <ul style="list-style-type: none"> – Can be part of the clinical protocol document (e.g., statistical methods section) or a separate document – If a separate document, the SAP does not need to be IRB-approved

This chart was taken from Stanford Spectrum Clinical and Translational Research and Education department:
<https://stanfordmedicine.app.box.com/s/vk39filrrjgh6fbuouzqcohiwupk5fd1>

1. Participant Flow (Subject Disposition)

- a. Documents the “flow” of subjects through different states of the study

- b. This section must account for all enrolled subjects, and should document the progression of the research subjects through each stage of the study.

Copy from: Protocol Section	Title	Description	Arm/Group	Arm/Group
Select	Drug A 100 mg	Drug A 100 mg orally twice daily for 2 weeks	Drug A 100 mg	Drug A 200 mg
Select	Drug A 200 mg	Drug A: Drug A administered as 50 mg tablets	Drug A: Drug A administered as 50 mg tablets	Drug A: Drug A administered as 50 mg tablets

Below the table, there is a 'Create: New' section with a 'Select' button and the text 'Define New Arms/Groups'.

2. **Baseline Characteristics:** Provides context for interpretation of outcome measures (endpoints)
 - a. Minimum: the age and gender requirements must be reported
 - b. Copy the arms/groups or create new arms/groups (You will see that the arms in the protocol section and the groups created in the Participant Flow module are now available to be copied)
3. **Outcome Measures:** must be specific and measurable study endpoints
 - a. Each outcome measure needs three (3) components;
 - i. Name of the specific measure,
 - ii. Description of the metric used, and
 - iii. Time points at which the measurement is assessed

Outcome Measures Overview

Results Section Add Outcome Measure Reorder Outcome Measures Help Definitions Show All

Outcome Measures copied from Protocol Section Outcome Measure Data is required for at least one primary outcome measure.

1. Primary Outcome
<p>Edit</p> <p>Title: Contact Force Through Measurement of Force-time Integral (FTI)</p> <p>Description: Determination of the average total contact force (measured in gs) achi...</p> <p>Time Frame: at time of the ablation procedure</p> <p>Outcome Measure Data Not Reported</p>

2. Secondary Outcome
<p>Edit</p> <p>Title: Changes in Impedence</p> <p>Description: Determination of the change in impedence of the catheter (measured in ...</p> <p>Time Frame: at time of the ablation procedure</p> <p>Outcome Measure Data Not Reported</p>

4. **Adverse Events (AE):** All serious and non-serious adverse events must be reported at trial completion, when the clinical trial results are being published. There are two types of adverse events that must be reported:

- (1) Serious adverse Events, and (2) non-serious adverse events, that do not qualify as serious adverse events with a frequency greater than 5 percent within at least one arm or comparison group are reported.
- The AEs will only be reported in summary format, including the number of AEs and the frequency at which they have occurred. No individual subject level data will be provided.
 - The arms/groups will be available to copy from the previous entries.
 - AEs must be reported regardless of relationship to the intervention(s).
5. **Limitations and Caveats (if any):** This section is used to describe limitations of the clinical trial such as early termination leading to small number of subjects analyzed, or technical problems with measurement leading to unreliable or uninterpretable data, etc.
6. **More Information:** This section describes agreements between the sponsor and the Principal Investigator(s), like disclosure of conflict of interest, and the “Results Point of Contact” for questions regarding the results.

Edit Results Point of Contact	
	<u>Definitions</u>
* Name or Official Title: (of Investigator)	<input type="text"/> Enter the specific person's name (e.g., Dr. Jane Smith) or a position title (e.g., Director of Clinical Trials).
* Organization Name:	<input type="text"/>
* Phone:	<input type="text"/> Ext. <input type="text"/>
* Email:	<input type="text"/>

Before Entering Results:

Before you begin, it is recommended that you review the [Simple Results Templates and Results Data Preparation Checklists](#) to ensure that you have the information needed to complete the Results Section. The results data needed are similar to the components needed for a journal publication. Preparing data for the Results Section should similarly involve individuals who are familiar with the study design and analysis (such as an investigator or statistician).

TIP: To help ensure your results are reviewed and accepted by the PRS reviewer, you can [search the public site](#) for a study similar to yours with results submitted and accepted by ClinicalTrials.gov. Review the already approved results for tips and similarities to help you formulate your information and data in a format that has already been accepted ClinicalTrials.gov.

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies About Studies Submit Studies Resources About Site

Home > Advanced Search

Advanced Search

Fill in any or all of the fields below. Click on the label to the left of each search field for more information or read the [Help](#).

Search [Help](#)

Condition or disease: [text box] X

Other terms: [text box] X

Study type: All Studies X

Study Results: All Studies X

Status: Recruitment:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn
- Unknown status

Expanded Access:

- Available
- No longer available
- Temporarily not available
- Approved for marketing

1. Click "Advanced Search"
2. Under "Condition or Disease" enter the terms relevant to your study
3. Under "Study Results" chose the drop down option "Studies with Results"
4. Click "Search"
5. Search results: studies are shown as links

Rank	Status	Study
1	Comp Has Results	Add-on Effects of Valsartan on Morbi- Mortality (KYOTO HEART Study) Conditions: Hypertension; Ischemic Heart Disease; Congestive Heart Failure; Stroke Interventions: Drug: Valsartan; Drug: Non-ARB
2	Completed Has Results	Treatment of Resistant Hypertension Using a Radiofrequency Percutaneous Transluminal Angioplasty Catheter Condition: Hypertension Intervention: Device: Renal Denervation
3	Active, not recruiting Has Results	Study to Evaluate the Clinical Performance of the Valiant Thoracic Stent Graft With the Captivia Delivery System (Valiant Captivia) for the Treatment of Acute, Complicated Type B Aortic Dissections Condition: Aortic Dissection Intervention: Device: Valiant Thoracic Stent Graft with the Captivia Delivery System

6. Click on the link (brief title) to view the study record
7. There are 3 tabs in each study record – click "Study Results" to view

Add-on Effects of Valsartan on Morbi- Mortality (KYOTO HEART Study)

This study has been completed.

Sponsor:
Kyoto Prefectural University of Medicine

Information provided by (Responsible Party):
Hiroaki Matsubara, MD., PhD, Kyoto Prefectural University of Medicine

ClinicalTrials.gov Identifier:
NCT00149227

First received: September 6, 2005
 Last updated: December 9, 2012
 Last verified: December 2012
[History of Changes](#)

Full Text View
Tabular View
Study Results
Disclaimer
? How to Read a Study Record

How to Submit Your Results:

1. If the Results Section has not been created, in the Record Summary page, click the link “Enter Results”

Results Section

[Enter Results](#) Results submission is required by FDAAA 801 for certain [applicable clinical trials](#) of drugs, biologics and devices. Note: other clinical trials may need to have results submitted based on other funder or sponsor policies

[Delay Results](#) For applicable clinical trials subject to FDAAA 801, results submission may be delayed (in limited circumstances) with a Certification or Extension Request.

For more information see: [When Do I Need to Register and Submit Results?](#)

Need help with Results? [Contact ClinicalTrials.gov PRS](#) to request one-on-one assistance from one of our experts.

2. The “Add Results Section” page follows, which has links to templates, checklists, and data entry help to assist
3. Click “Continue”
4. The “Results Section” page open with the option to edit any of the modules

ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record Summary > Results Section

Contact ClinicalTrials.gov PRS
Org: UCSDMED Admin: ctri@ucsd.edu

Results Section

[Record Summary](#) [Preview Results](#) [Download Results XML](#) [Delete Results](#) [Help](#) [Definitions](#)

[Edit](#) **Participant Flow**
Information is required

[Edit](#) **Baseline Characteristics**
Information is required

[Open](#) **Outcome Measures**
Information is required

[Edit](#) **Adverse Events**
Information is required

[Edit](#) **Limitations and Caveats**
[Not Specified]

[Open](#) **More Information**

Certain Agreements
[Relationship of Principal Investigator and Sponsor not specified.]
Information is required

Results Point of Contact

Name/Official Title	---
Organization	---
Phone	---
Email	---

Information is required

5. Click “Edit” and modify the information as necessary

Delayed Results Posting:

A study can apply for a certification of delay, which may result in the results information submission being delayed for up to two (2) additional years from the date of submission of a certification, if either of the following apply:

1. An unapproved, unlicensed, or uncleared product studied in the clinical trial is still under development by the manufacturer, or
2. Marketing approval will be sought within one (1) year after the primary completion date of the trial for a new use of an approved, licensed, or cleared product that is being studied in the clinical trial.

Following this potential extension of up to two (2) years after the primary completion date of the clinical trial, results must be posted regardless of whether the product is approved or is being sought for approval. The certification must be submitted prior to the results information submission deadline.

Further extensions to the results information submission deadlines may be granted for “good cause” (eg, the need to preserve the scientific integrity of a trial for which data collection is ongoing or emergencies, such as natural disasters or catastrophes, that would prevent timely submission of results information).

A permanent waiver of results information submission requirements may also be granted for extraordinary circumstances, consistent with the protection of the public health or in the interest of national security, but are expected to be exceedingly rare.

Results Section

[Enter Results](#) Results submission is required by FDAAA 801 for certain [applicable clinical trials](#) of drugs, biologics and devices. Note: other clinical trials may need to have results submitted based on other funder or sponsor policies.

[Delay Results](#) For applicable clinical trials subject to FDAAA 801, results submission may be delayed (in limited circumstances) with a Certification or Extension Request.

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Updating the Results Posting:

If the study is ongoing after the Primary Completion Date, the available results information must be posted, and additional information that is required can be updated as the results are complete. This can include:

1. Secondary outcome measure data not reported with the initial results because the information was not collected by the PCD. This information must be submitted within one (1) year of the date when the final data were collected (for each respective outcome measure).
2. Additional safety data that has been collected after the PCD must be reported though the Study Completion Date, including all-cause mortality, serious adverse events, and other (non-serious) adverse events.

Terminated Studies:

If you enrolled subjects but terminated the study, you are still required to publish the applicable results just as they are for completed studies.

ClinicalTrials.gov Reviewer Comments:

After information is submitted, ClinicalTrials.gov may notify the Responsible Party of apparent errors, deficiencies, and/or inconsistencies in the submitted information identified during quality control review. Comments are either *Major* or *Advisory*.

If any *Major* comments are returned by the ClinicalTrials.gov reviewer, the record must be updated to address them, then re-released. ClinicalTrials.gov will not post the submission until all *Major* comments have been addressed.

Corrections must be submitted within 25 calendar days if the submission includes results information.

Resources:

- Participant Flow-Specific Resources
 - Checklist: <https://prsinfo.clinicaltrials.gov/data-prep-checklist-pf.pdf>
- Baseline Characteristics-Specific Resources
 - Checklist: <http://prsinfo.clinicaltrials.gov/data-prep-checklist-bl.pdf>
- Outcome Measure/Statistical Analysis-Specific Resources
 - Checklist: <https://prsinfo.clinicaltrials.gov/data-prep-checklist-om-sa.pdf>
- Adverse Event-Specific Resources
 - Checklist: <https://prsinfo.clinicaltrials.gov/data-prep-checklist-ae.pdf>
- Results Data Entry:
<https://register.clinicaltrials.gov/prs/app/template/ResultsHelp.vm?popup=true&uid=U0003ACK&ts=2&cx=1ybljg>
- Example results entries for common study designs (PDF):
 - Parallel: <https://prsinfo.clinicaltrials.gov/trainTrainer/Parallel-Design-Answer-Key.pdf>
 - Crossover: <https://prsinfo.clinicaltrials.gov/trainTrainer/Crossover-Design-Answer-Key.pdf>
 - Factorial: <https://prsinfo.clinicaltrials.gov/trainTrainer/Factorial-Design-Answer-Key.pdf>
 - Dose-escalation: <https://prsinfo.clinicaltrials.gov/trainTrainer/Dose-Escalation-Design-Answer-Key.pdf>
 - Multiple-period: <https://prsinfo.clinicaltrials.gov/trainTrainer/Multiple-Period-Design-Answer-Key.pdf>
- ClinicalTrials.gov [Help: Results Data Entry](#)
- ClinicalTrials.gov Results Data Preparation Checklists and Template:
https://prsinfo.clinicaltrials.gov/results_table_layout/ResultSimpleForms.html
- ClinicalTrials.gov [FAQ](#)