ClinicalTrials.gov

Submitting Results Information

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Clinical Trials Office
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Learn About ClinicalTrials.gov Results Database

- What is the results database and do I need to submit results?
- What information is expected on the results database?
- Steps for submitting results and PRS review process
- Identify and address common questions
- PRS Tutorial

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What is the Results Database?

- Repository of information about federally and privately supported **clinical studies and their results**, which includes any initiated, ongoing, and completed or terminated research.
- Web-based resource of self-reported data by study sponsors or investigators to demonstrate protocol adherence and complement medical literature.
- Free service of the U.S. National Institutes of Health (NIH), maintained by the National Library of Medicine (NLM), to make study findings available to the public and different audiences.

Why Should I Submit Results?

- Satisfy legal requirements
  - Food and Drug Administration Amendments Act of 2007 (FDAAA)
    - U.S. Public Law 110-85, Title VII (also known as FDAAA 801)
  - Final Rule 2016 (42 CFR Part 11)
- Satisfy funding requirements
  - NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
- Condition for publication, scientific practices
  - ICMJE Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals

Do I Need to Submit Results Information?

Reporting Requirement	FDAAA (Effective in 2007) Final Rule (January 18, 2017)	NIH Policy (January 18, 2017)	ICMJE (Effective in 2005)
Scope	Registration and Results Reporting	Registration and Results Reporting	Registration (Results Reporting encouraged)
Phase	Not Phase 1	All	All
Intervention Type	Drug, biologic and device products regulated by FDA	All, including behavioral intervention	All
Funding Source	Any	NIH	Any
Enforcement	• Criminal and civil penalties (up to $11,569/day) • Loss of HHS funding	Loss of NIH funding	Refusal to publish

Results Required?

Example 1: Phase 1 trial that tests a drug intervention funded by NIH

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Results Required?

Example 2: AHA awarded mobile health behavioral interventional trial

Reporting Requirement	FDAAA (Effective in 2007) Final Rule (January 18, 2017)	NIH Policy (January 18, 2017)	ICMJE (Effective in 2005)
Scope	Registration and Results Reporting	Registration and Results Reporting	Registration (Results Reporting encouraged)
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When Do I Need to Submit Results?

- Results information **due date** is determined by the **completion (final) date** of data collection.
- In general, results information must be submitted no later than 1 year after the completion date of an Applicable Clinical Trial.
- Two types of completion dates: Primary Completion Date and Study Completion Date.

  Reminder: Responsible Party must update the Primary Completion Date and Study Completion Date on ClinicalTrials.gov to reflect any change to or the actual completion dates once they have been reached within 30 calendar days.

When Do I Need to Submit Results?

	Primary Completion Date	**Study Completion Date**
	Definition: Final data collection date for primary outcome measure [anticipated or actual].	*Definition: Final data collection date for study [anticipated or actual].*
Scope	**Primary Outcome Measure**	**Secondary Outcome Measure Adverse Event Information**
	Definition: Data measure(s) of greatest importance specified in the protocol.	*Definition: Data measure(s) of lesser importance but pre-specified in the protocol.*
Example	Maximum Tolerated Dose	Overall Survival Rate
Completion Date	June 2020	June 2025
Results Expected Date	June 2021	June 2026

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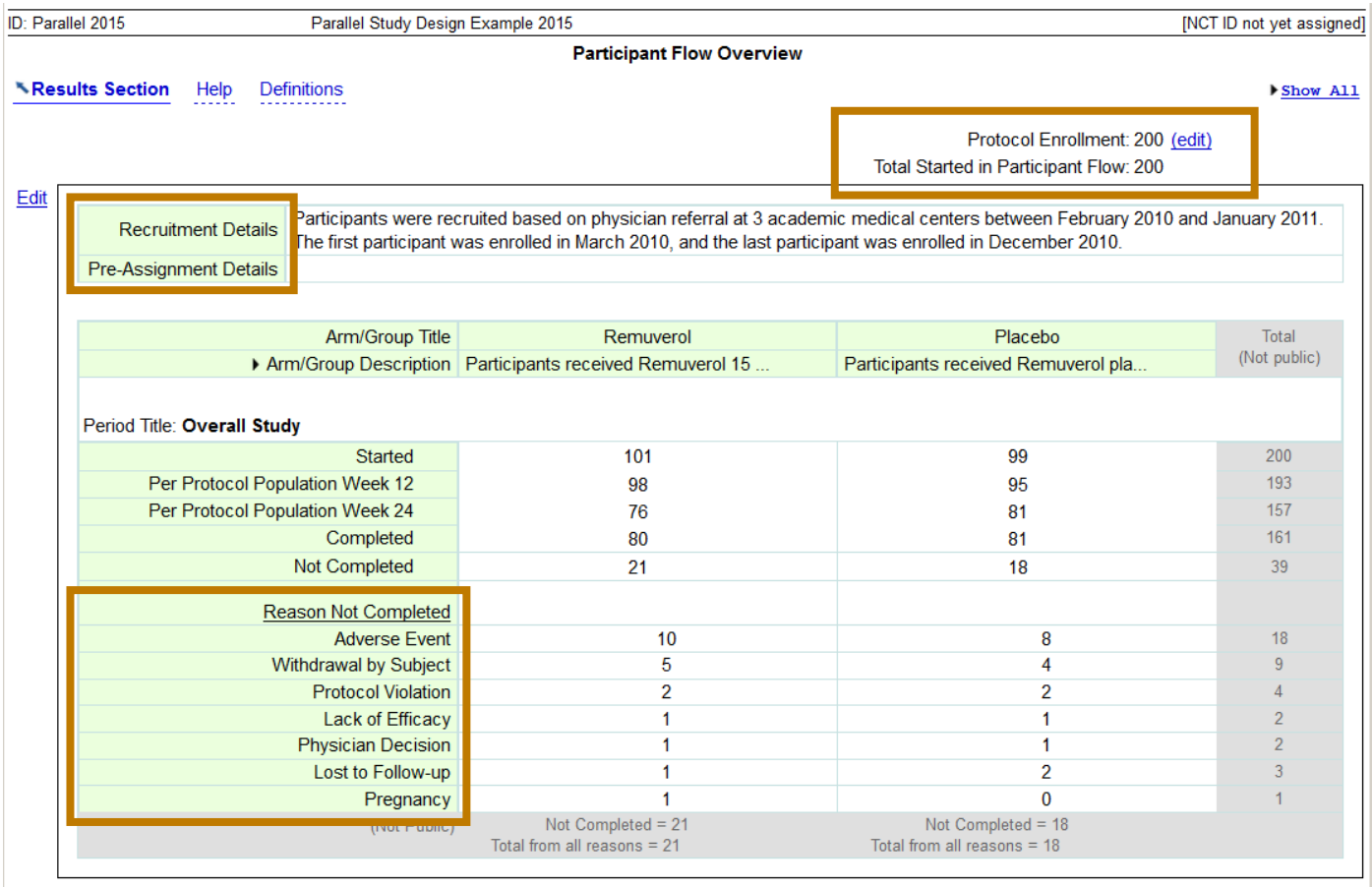
“Basic Results” Expected in ClinicalTrials.gov

The Results Section includes:

- Participant Flow
- Baseline Characteristics
- Outcome Measures (and Statistical Analyses)
- Adverse Events
- Limitations and Caveats
- Administrative Information

Participants Flow Module



ID: Parallel 2015 | Parallel Study Design Example 2015 | [NCT ID not yet assigned]

Participant Flow Overview

Results Section Help Definitions ▸ Show All

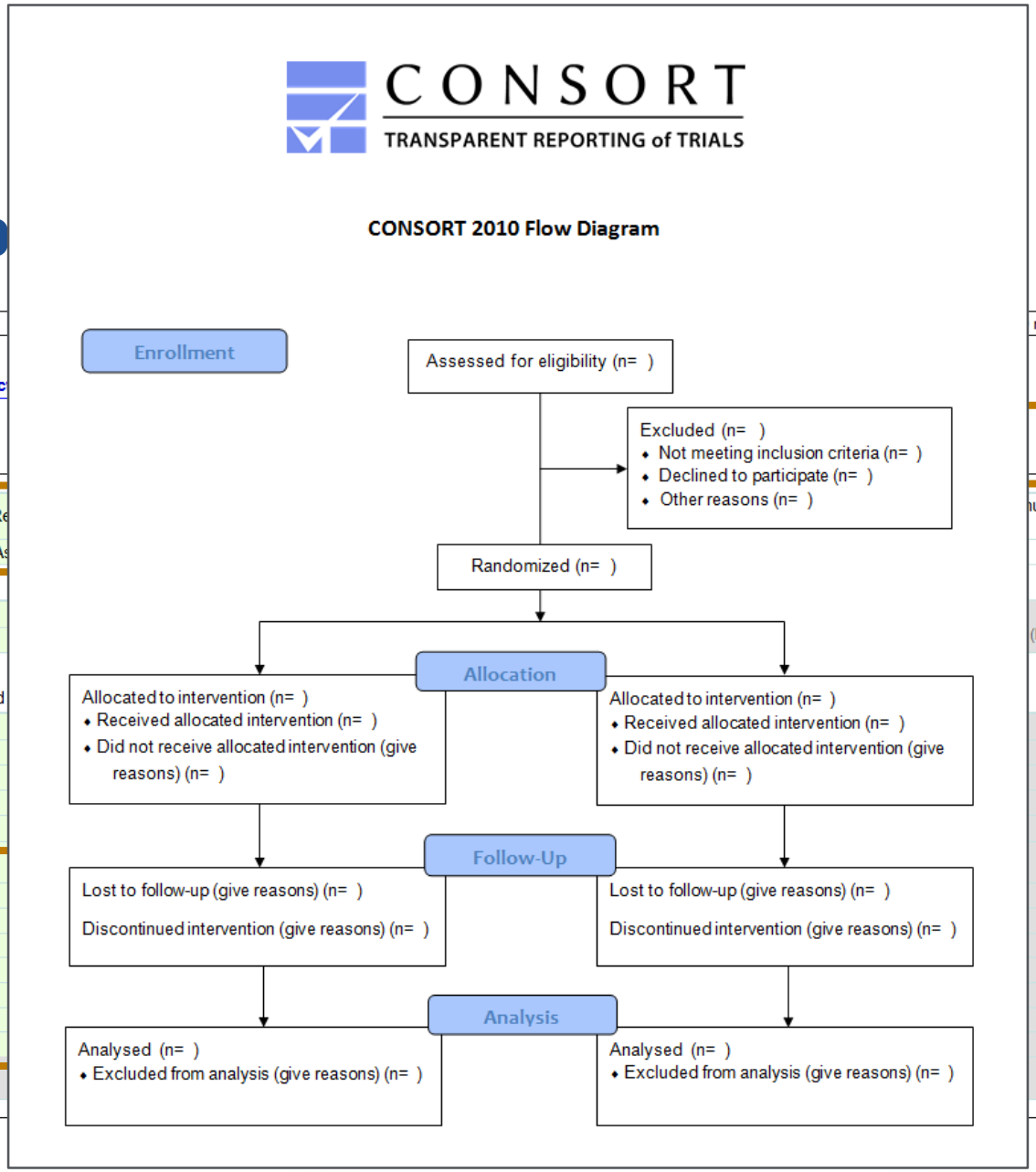
Protocol Enrollment: 200 (edit)
Total Started in Participant Flow: 200

Edit

Recruitment Details	Participants were recruited based on physician referral at 3 academic medical centers between February 2010 and January 2011. The first participant was enrolled in March 2010, and the last participant was enrolled in December 2010.
Pre-Assignment Details	

Arm/Group Title	Remuverol	Placebo	Total (Not public)
▸ Arm/Group Description	Participants received Remuverol 15 ...	Participants received Remuverol pla...	
Period Title: **Overall Study**			
Started	101	99	200
Per Protocol Population Week 12	98	95	193
Per Protocol Population Week 24	76	81	157
Completed	80	81	161
Not Completed	21	18	39
Reason Not Completed			
Adverse Event	10	8	18
Withdrawal by Subject	5	4	9
Protocol Violation	2	2	4
Lack of Efficacy	1	1	2
Physician Decision	1	1	2
Lost to Follow-up	1	2	3
Pregnancy	1	0	1
(Not Public)	Not Completed = 21 Total from all reasons = 21	Not Completed = 18 Total from all reasons = 18	

Particip


CONSORT
TRANSPARENT REPORTING of TRIALS
CONSORT 2010 Flow Diagram
Enrollment
Assessed for eligibility (n=)
Excluded (n=)
Not meeting inclusion criteria (n=)
Declined to participate (n=)
Other reasons (n=)
Randomized (n=)
Allocation
Allocated to intervention (n=)
Received allocated intervention (n=)
Did not receive allocated intervention (give reasons) (n=)
Allocated to intervention (n=)
Received allocated intervention (n=)
Did not receive allocated intervention (give reasons) (n=)
Follow-Up
Lost to follow-up (give reasons) (n=)
Discontinued intervention (give reasons) (n=)
Lost to follow-up (give reasons) (n=)
Discontinued intervention (give reasons) (n=)
Analysis
Analysed (n=)
Excluded from analysis (give reasons) (n=)
Analysed (n=)
Excluded from analysis (give reasons) (n=)

Baseline Characteristics Module

ID: ParallelR 2015 | Parallel Study Design Example (With Results) 2015 | [NCT ID not yet assigned]

Baseline Measures Overview

Results Section | Add Baseline Measure | Reorder Baseline Measures | Help | Definitions | Show All

Edit	Arm/Group Title	Remuverol	Placebo	Total
	▸ Arm/Group Description	Participants received Remuverol 15 ...	Participants received Remuverol pla...	
Edit	**Overall Number of Baseline Participants**	101	99	**200**
	▸ Baseline Analysis Population Description			
Edit Delete	Age, Continuous Mean (Standard Deviation) Units: years	34.78 (9.72)	35.34 (10.71)	34.98 (9.89)
Edit Delete	Gender, Male/Female Measure Type: Number Units: participants			
	Female	60	63	123
	Male	41	36	77
Edit Delete	Quebec Task Force Classification of Spinal Disorders [1] Measure Type: Number Units: participants			
	Class 0 (no pain)	16	14	30
	Class 1 (pain without radiation)	73	68	141
	Class 2 (pain with proximal extremity radiation)	12	17	29

[1] Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from Class 0 (no pain) to Class 7 (spinal stenosis).

Baseline Characteristics Module

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Baseline Measures Overview

Results Section | Add Baseline Measure | Reorder Baseline Measures | Help | Definitions | Show All

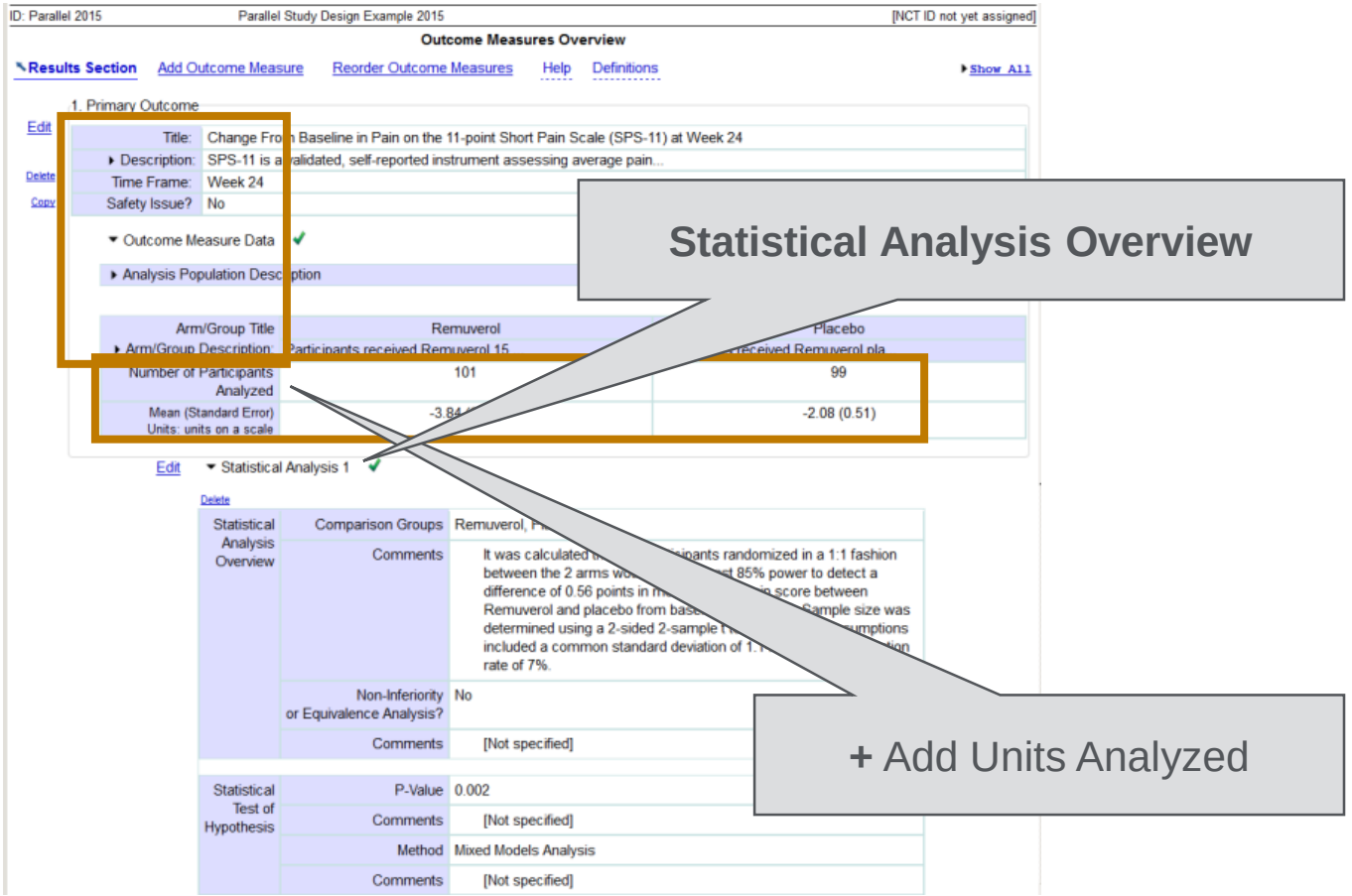
Edit	Arm/Group Title	Remuverol	Placebo	Total
	▸ Arm/Group Description	Participants received Remuverol 15 ...	Participants received Remuverol pla...	
Edit	**Overall Number of Baseline Participants**	101	99	**200**
	▸ Baseline Analysis Population Description			
Edit Delete	Age, Continuous Mean (Standard Deviation) Units: years	34.78 (9.72)	35.34 (10.71)	34.98 (9.89)
Edit Delete	Gender, Male/Female Measure Type: Number Units: participants			
	Female			
	Male			
Edit Delete	Quebec Task Force Classification of Spinal Disorders [1] Measure Type: Number Units: participants			
	Class 0 (no pain)			
	Class 1 (pain without radiation)			
	Class 2 (pain with proximal extremity radiation)			
		[1]		

Major Issues:

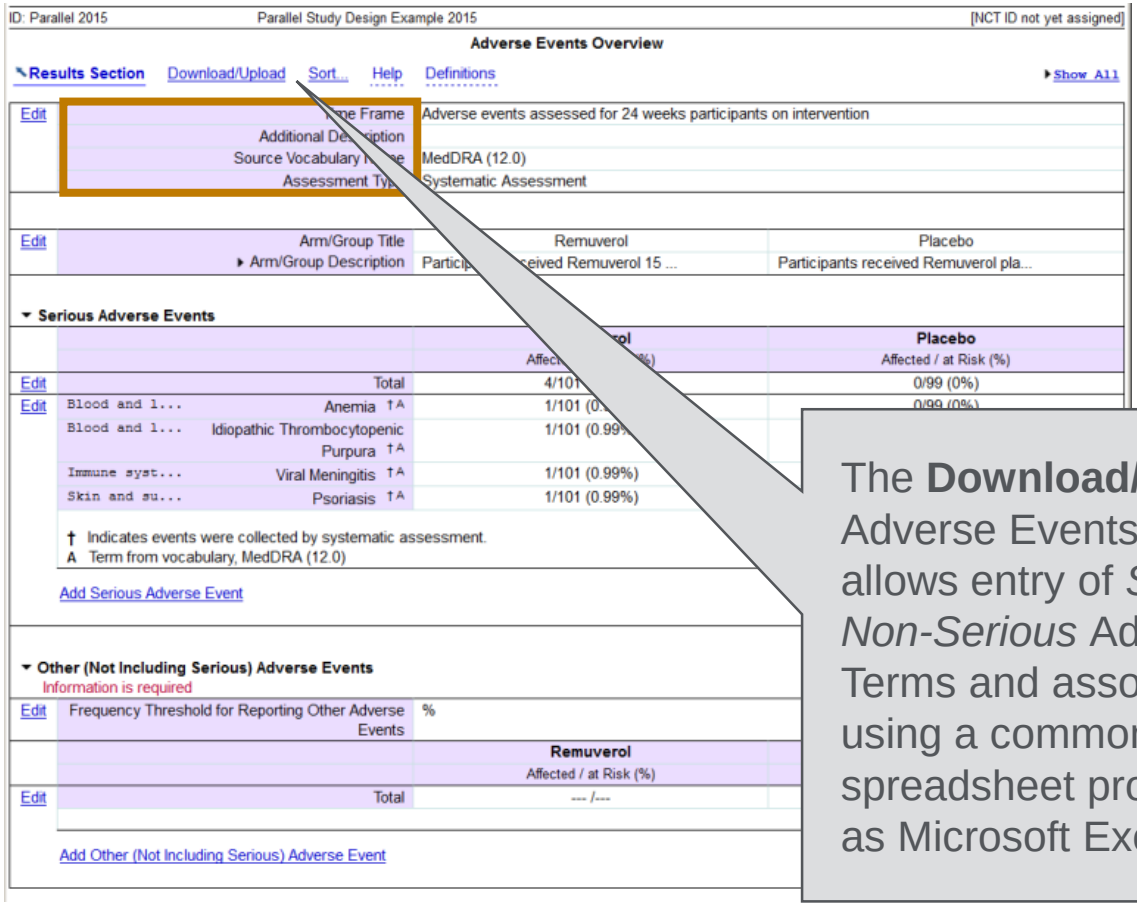
1) **Required information appears to be missing without a valid explanation.**

Please note that it is a PRS requirement that values be calculated for the Total column in the Baseline Characteristics module. In this case, it appears the Total should be calculable since data for both individual Arms/Groups are available. Please review and revise, as appropriate.

Outcome Measures Module



Adverse Event Information Module



The **Download/Upload** Adverse Events feature allows entry of *Serious* and *Non-Serious* Adverse Event Terms and associated data using a common spreadsheet program such as Microsoft Excel.

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ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the ClinicalTrials.gov Protocol Registration and Results System (PRS).

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: Forgot password

Login

See Submit Studies on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.

Send email to ClinicalTrials.gov PRS Administration

Steps for Submitting Results

1. Login to the Protocol Registration and Results System (PRS).

   Reminder: **Forgot password** link on the PRS Login Page

2. Update the Protocol Section.

   Reminder: Ensure that the information in the Protocol Section is up-to-date before starting the Results Section

3. Enter the required and optional results data elements.

   Reminder: If available, **cite your publication** in the Protocol Section

   Reminder: Upload **full study protocol and statistical analysis plan**

4. Preview, inspect, and release (submit) the record.

Steps for Submitting Resu

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PRS Results Information Review Process

1. ClinicalTrials.gov staff may takes up to 30 days to review the submitted results and identify potential errors, deficiencies and/or inconsistencies.
2. Responsible Party may be asked to clarify items or make corrections to the Protocol and/or Results Sections of the record.

   Reminder: Correct or address PRS comments related to results information within 25 calendar days
3. Upon acceptance, the **Results Section will be displayed with the corresponding registered Protocol Section** under different tabs.
4. After the Results Section has been initially posted, the record may be updated and edited at any time.

   Reminder: A history of changes is available on ClinicalTrials.gov archive site.

PRS Quality Assurance Review Criteria

Review Criterion	Example
Lack of apparent validity	Data: 263 hours of sleep per day
Meaningless entry	Outcome: Clinical evaluation of adverse events
Data mismatch	Outcome: Time to disease progression (months)
Internal inconsistency	Total enrollment does not match total analyzed
Trial design unclear	Participant flow and baseline characteristics entered as a two-group study with a total of 200 participants; outcomes entered for three comparison groups with 100 participants

Delayed Submission of Results

- Results submission may be delayed (in limited circumstances) with a Certification or Extension Request.
  - **Certification:** The trial 1) reached its completion date before the drug, biologic, or device is initially approved, licensed, or cleared by FDA for *any use*; or 2) studies a *new use* of an FDA-approved drug, biologic, or device.
  - **Extension Request:** The Responsible Party demonstrates a good cause for the delay and provides an anticipated submission date (Note: Pending publication is not considered good cause for an extension).

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5 Do's of Results Submission

- Do plan ahead to meet specified timeframes
- Do enlist extra help from qualified personnel, such as a statistician to assist
- Do retain your data per study protocol (and study arms)
- Do check on the status of your results submission until it is posted
- Do contact your CU PRS Administrators if you experience issues

Frequently Asked Questions

- I inherited a bunch of ClinicalTrials.gov records, some of which are really “old,” do I still need to help my investigator enter results?
- I received PRS comments that I cannot seem to correct or address, who can help me?
- A study was terminated early and none of the results were analyzed, what should I do?

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Breakout Session

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