ClinicalTrials.gov
Protocol Registration System

Send message to PRS

# PRS User's Guide

**September 2009**

| Section | Audience |
|---|---|
| Overview | All PRS Users |
| Procedures for Protocol | All PRS Users |
| Procedures for Results | All PRS Users |
| XML File Transfer | All PRS Users |

## Overview

The ClinicalTrials.gov Protocol Registration System (PRS) is a web-based tool developed for submitting clinical trials information to ClinicalTrials.gov. This document provides step-by-step instructions for entering, modifying, and releasing protocol records using the PRS. Records submitted through the PRS (http://register.clinicaltrials.gov) are available to the public at ClinicalTrials.gov (http://clinicaltrials.gov). A guided tour of the PRS and account application information are available at http://prsinfo.clinicaltrials.gov/

PRS users enter information about their clinical trials, ensuring that the information is correct, readily understood by members of the public, and updated in a timely manner.

PRS Administrators are responsible for the process by which clinical trial information is released to ClinicalTrials.gov on behalf of their organization. This process includes creating accounts for PRS users and editing and approving clinical trial records prior to initial release and after record updates. They serve as points of contact for the ClinicalTrials.gov team and resolve questions associated with the information that is provided.

The ClinicalTrials.gov team maintains the PRS and the ClinicalTrials.gov site and may make minor corrections to records.

## Procedures for Protocol



## Protocol-A. Log In to PRS

1. Go to http://register.clinicaltrials.gov.
2. Complete the three fields on the **Login** screen:

- Organization: organization login name
- Username: user login name
- Password: (case-sensitive)

3. Click [Login] and the **Main Menu** of the PRS appears.
4. To log out of the PRS, select [Logout] from the **Main Menu** screen.

## Protocol-B. Create a ClinicalTrials.gov Record

A record may be created at a single session or created and saved for completion at later sessions. To create a record during a single session:

1. Click [Create] from the **Main Menu** screen.
2. Enter the Unique Protocol ID and Brief Title for your record on the **Create New Protocol Record** screen.
3. Click [Continue] to save data and proceed to the next screen. Repeat data entry and [Continue] for successive screens.
4. After clicking [Continue] on the final data entry screen (**Links**), click [OK] on the **Study Completed** screen.

To create a record and save for completion at later sessions, after step 2. (above) or any successive screen, click [Quit] to stop data entry

- Click [Save Protocol Record] to keep your data. The record is saved for later sessions.
- Click [Delete Protocol Record] to erase the record.

**Data entry tips:**

Use language that is easily understood in Brief Summary.

Paragraph separation: leave a blank line between paragraphs (press enter twice).

Create lists:

- Keep each item on a separate line (press return after entering text for each line)
- Bullet items by starting each line with two spaces, a hyphen, and a space before entering the text
- Press return after text for each item

All of the data screens are clustered into 11 groups (by topic).

Click on any data entry field name to obtain a description of the field.

All fields may be modified at a later date.

Protocol records progress through the PRS with record status values as explained in the table below.

| Description | Record Status |
|---|---|
| User is creating (or modifying) the record. | In Progress |
| User has finished - record is ready for review. | Completed |
| Administrator has reviewed record and has made any necessary changes. | Approved |
| Administrator has released the record to ClinicalTrials.gov. | Released |

## Protocol-C. Submit Record to Your Administrator

1. Click [Modify] from the Main Menu.
2. Click [Edit] next to the record you wish to submit.
3. Review and make any necessary changes indicated by messages below the data fields on the **Edit Protocol Record** screen:

   **ERROR** messages indicate serious problems that need to be addressed.

   **ALERT** messages indicate problems that need to be addressed.

   **NOTE** messages indicate potential problems that should be reviewed and corrected as needed.

4. After data entry for a record has been completed, click [Complete] in the Record Status area of the Edit Protocol screen. This generates automatic e-mail notification to the Administrator that the record is complete.

Your Administrator will review the record. Approved records are released to ClinicalTrials.gov.

## Protocol-D. Modify Record

1. Click [Modify] on the **Main Menu**.
2. Click [Edit] next to the record to be modified on the **Select Protocol Record - Edit** screen
*Repeat steps 3-6 for all data fields to be modified.*
3. Locate the data field to be modified on the **Edit Protocol Record** screen.
4. Click on the corresponding [Edit] for that field.
5. Make changes on the data entry screen.
6. Click [OK] to save the changes and return to **Edit Protocol Record**.
7. Update Record Verification Date (using steps 3-6 above).

## Protocol-E. View Record

1. Click [View] on the **Main Menu**.
2. Click [View] next to record to be displayed on the **Select Protocol Record - View** screen.
3. **View Protocol Record** is *read-only*. To edit records see Protocol-D. Modify Record.

## Protocol-F. Preview Record as it Appears on ClinicalTrials.gov

1. Click [Modify] on the **Main Menu**.
2. Click [Edit] next to the record to be previewed.
3. Click [Preview] to see the record displayed similar to how it appears on ClinicalTrials.gov.
4. Click [Continue] to return to the **Edit Protocol Record** screen.

## Protocol-G. Delete Record

*NOTE: Protocol information is made available on ClinicalTrials.gov for completed studies as well as those that are actively recruiting, thus the Delete function is only provided for records which have never been released.*

1. Click [Modify] on the **Main Menu**.
2. Click [Edit] next to the record to be deleted.
3. Click [Delete].
4. Click [OK] on the **Delete Protocol** screen or click [Cancel] to return to the **Edit Protocol Record** screen without deleting the record.

A deleted record can be recovered via the [Undelete] option on the **Main Menu**.

### Protocol-H. Change Your Password

1. Click [Change password] on the **Main Menu**.
2. Enter:

- old password
- new password
- new password again for verification

3. Click [Change Password] to save the new password.

Contact your Administrator if you forget your password.

---

# Procedures for Results



### Results-A. Requirements

1. Existing PRS account. (see Protocol-A. Log In to PRS)
2. Existing PRS record.

Note that each PRS record consists of a protocol section and a results section. Once a results section is created, all PRS actions (e.g., Release) apply to both sections. For example, the record **preview** feature will provide a rough approximation of how the protocol data, followed by the results data, will appear on ClinicalTrials.gov. After a record with results section data is released for the first time, the Initial Results Release Date is shown in the status area of the **Edit Protocol** screen.

### Results-B. Create a Results Section

Do not create a results section unless results data for at least one Primary Outcome Measure specified in the protocol section are ready to be entered and submitted to ClinicalTrials.gov for public posting.

1. Log in to the PRS
2. Click [Modify] on the **Main Menu** (under Protocol Records)
3. Click [Edit] next to the record for which results data are to be entered
4. Click [Enter Results] (below second [Edit], under the "IND/IDE Protocol?" data field) in the **Edit Protocol Record** screen.
5. Carefully review the information from the protocol section that will be used to pre-populate data elements in the results section.

- If there are any errors, click [Cancel] and correct the data in the protocol section.
- Note that at least one Primary Outcome Measure must be provided in the protocol section in order to create a results section

6. Click [OK] to create the results section of the PRS record.

*Note: After the results section is created, any changes to Arms/Groups must be made in both the protocol and results sections of the record to maintain consistency. However, because the Primary and Secondary Outcome Measure will be accessible only through the results section, any changes to these data elements will also be displayed in the protocol section of the record at ClinicalTrials.gov.*

## Results-C. Navigate the Results Section

The **Results Overview** screen is similar in layout and purpose to the **Edit Protocol Record** screen.

- An "Edit" link appears next to each category of results data elements.
- Click [Edit Protocol] (near the top of the screen) to return to the **Edit Protocol Record** screen.
- Click [Delete Results] to erase all the results section data.

The following seven results data modules, described in the sections below, are accessible from the **Results Overview** screen:

1. Results Point of Contact
2. Certain Agreements
3. Participant Flow
4. Baseline Characteristics
5. Outcome Measures
6. Limitations and Caveats
7. Adverse Events

*Note: Upon creation of a new results section, there will be numerous* ***ERROR****,* ***WARNING****, and* ***NOTE*** *messages. As results data are entered, the number of such messages will decrease.*

## Results-D. Results Point of Contact

1. Click [Edit] to view the **Edit Point of Contact** screen.
2. Enter data.
3. Click [OK] (saves data) or [Cancel] (does not save data) to return to the **Results Overview** screen.

## Results-E. Certain Agreements

1. Click [Edit] to view the **Edit Certain Agreements** screen.
2. Enter data.
3. Click [OK] (saves data) or [Cancel] (does not save data) to return to the **Results Overview** screen.

## Results-F. Participant Flow

1. Navigate the Participant Flow module from the **Results Overview** screen

- Click [Edit] to view the **Participant Flow** screen.
- To return to the **Results Overview** screen, click [Results Overview] near the top of the **Participant Flow** screen.

2. Enter information about participants before assignment to an intervention(s)

- Click [Edit] next to "Recruitment Details" on the **Participant Flow** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).

When a results section is created, a single default Period called "Overall Study" is generated for

information about participant flow after assignment to an intervention(s). Periods are represented as tables.

- The rows consist of Milestones; "STARTED" and "COMPLETED" are the two default Milestones.
- The columns each represent an Arm or Comparison Group ("Arm/Group"). The default column headings are pre-populated with values from the "Arm Number or Label" and "Arm Description" data elements in the protocol section (renamed "Arm/Group Title" and "Arm/Group Description," respectively, in the results section).

In each "cell" of the Period, enter the number of participants in an Arm/Group to reach a Milestone.

3. Add a Period

- Click [Create Period] on the **Participant Flow** screen.
- Rename the "Period Title" ("Overall Study" is reserved for trials with only a single period).
- Enter a "New Period Title."
- Click [OK] (saves data) or [Cancel] (does not save data) to return to the **Participant Flow** screen.
- Repeat for each additional Period

4. Modify a Period

- Click [Modify/Delete] for the Period to be modified on the **Participant Flow** screen.
- Modify the Period Title.
- Click [OK] (saves data) or [Cancel] (does not save data).

5. Delete a Period
*Note that the results section must include at least one Period.*

- Click [Modify/Delete] for the Period to be deleted on the **Participant Flow** screen.
- Click [Delete]. (Option not available if there is only one Period.)
- Click [OK] (deletes period) or [Cancel] (saves period)

6. Add an Arm/Group

- Click [Add Arm/Group] on the **Participant Flow** screen.
- Enter data.
- Other module(s) containing identical Arm/Groups (e.g., Outcome Measures) are listed under "Modify Similar Arm/Groups." Select [Yes] (adds new Arm/Group to listed module(s)) or [No] (adds Arm/Group to Participant Flow only).
- Click [OK] (saves data) or [Cancel] (does not save data).

7. Modify an Arm/Group

- Click [Modify/Delete] for the Arm/Group to be modified on the **Participant Flow** screen.
- Modify data.
- Other module(s) containing identical Arm/Groups (e.g., Outcome Measures) are listed under "Modify Similar Arm/Groups." Select [Yes] (modifies Arm/Group in each listed module) or [No] (modifies Arm/Group in Participant Flow only).
- Click [OK] (saves data) or [Cancel] (does not save data).

8. Delete an Arm/Group
*Note that the results section must include at least one Arm/Group.*

- Click [Modify/Delete] for the Arm/Group to be deleted on the **Participant Flow** screen.
- Other module(s) containing identical Arm/Groups (e.g., Outcome Measures) are listed under "Modify Similar Arm/Groups." Select [Yes] (deletes Arm/Group in each listed module) or [No] (deletes Arm/Group in Participant Flow only).
- Click [Delete]. (Option not available if there is only one Arm/Group.)

- Click [OK] (deletes Arm/Group) or [Cancel] (saves Arm/Group).

Each Period consists of two default Milestones, STARTED and COMPLETED, which represent the number of participants starting and ending the Period (per Arm/Group). While default Milestones cannot be changed, additional Milestones may be added.

9. Add a Milestone

- Click [Edit] for the Period in which a Milestone is to be added on the **Participant Flow** screen.
- Click [Add Milestone] on the **Period** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).
- Click [Participant Flow] to return to the **Participant Flow** screen.

10. Modify a Milestone

- Click [Modify/Delete] for the Milestone to be modified from the **Period** screen.
- Modify data.
- Click [OK] (saves data) or [Cancel] (does not save data)
- Click [Participant Flow] to return to the **Participant Flow** screen.

11. Delete a Milestone

- Click [Modify/Delete] for the Milestone to be deleted from the **Period** screen.
- Click [Delete].
- Click [OK] (deletes Milestone) or [Cancel] (saves Milestone).
- Click [Participant Flow] to return to the **Participant Flow** screen.

12. Enter number of participants per Arm/Group that reached each Milestone

- Click [Edit] for the Period in which data are to be entered on the **Participant Flow** screen.
- Click [Edit] on the **Period** screen.
- Enter data.
- Use the "Prefill Number of Baseline Participants" feature to copy values from the **STARTED** milestone into the "Overall Number of Baseline Participants" data element in the Baseline Characteristics module. Select [Yes] (copies values to Baseline Characteristics) or [No] (does not copy values).
  **Note**: This does not apply if the Baseline Characteristics module has not yet been "posted" (see Results-G. Baseline Characteristics, 1: Navigate the Baseline Characteristics module from the Results Overview Screen); or if the Baseline Characteristics module has been "posted" but the Arm/Groups or the entered values for "Overall Number of Baseline Participants" and "STARTED" milestone are different.
- Click [OK] (saves data) or [Cancel] (does not save data).
- Click [Participant Flow] to return to the **Participant Flow** screen.

*Note that "Not Completed" is calculated per arm/group by subtracting COMPLETED Milestone values from STARTED Milestone values.*

If "Not Completed" is greater than zero (i.e., participants did not complete the Period), the reasons for participant non-completion may be described. However, if any reasons are provided, the sum total of participants listed under each Reason for Not Completed must equal the number of participants listed under "Not Completed" within each Arm/Group in a Period.

13. Add a Reason for Not Completed

- Click [Add Reason for Not Completed] from the appropriate **Period** screen.
- Select from the drop-down list. Enter data in "Other Reason" if "Other" is selected.

- Click [OK] (saves data) or [Cancel] (does not save data).
- Repeat for each additional Reason for Not Completed.

14. Modify a Reason for Not Completed

- Click [Modify/Delete] for the relevant "Reason for Not Completed" on the **Period** screen.
- Select from the drop-down list. Enter data in "Other Reason" if "Other" is selected.
- Click [OK] (saves data) or [Cancel] (does not save data).

15. Delete a Reason for Not Completed

- Click [Modify/Delete] for the relevant "Reason for Not Completed" on the **Period** screen.
- Click [Delete].
- Click [OK] (deletes Reason for Not Completed) or [Cancel] (saves Reason for Not Completed).

16. Enter number of participants per Arm/Group for each Reason for Not Completed

- Click [Edit] for the relevant Period on the **Participant Flow** screen.
- Click [Edit] next to the Reasons table on the **Period** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).

Reminder: Providing "Reasons for Not Completed" is optional. If provided, the sum of the values for all Reasons for Not Completed per Arm/Group must equal the corresponding value for Not Completed per Arm/Group.

## Results-G. Baseline Characteristics

1. Navigate the Baseline Characteristics module from the Results Overview screen

- *First time only*: Click [Post Baseline Characteristics] to create the Baseline Overview screen. *Note: "Arm/Group" information and "Overall Number of Baseline Participants" will be pre-populated with "Arm/Group" and "STARTED" milestone data, respectively, from the Participant Flow module.*
- Thereafter, click [Edit] to view the **Baseline Overview** screen.
- To return to the **Results Overview** screen, click [Results Overview] near the top of the **Baseline Overview** screen.

2. Modify Overall Number of Baseline Participants

- Click [Edit] next to "Overall Number of Baseline Participants"
- Modify data.
- Click [OK] (saves data) or [Cancel] (does not save data).

3. Enter Baseline Measure data
While a number of Baseline Measures (i.e., Age, Gender, and Region of Enrollment) are displayed by default, only one "Age" and one "Gender" Baseline Measure are required. The remaining are optional.

- Click [Edit] next to a Baseline Measure (e.g., Age Categorical) on the **Baseline Overview** screen.
- Click [Edit] on the **Baseline Measure** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).
- Click [Baseline Overview] to return to the **Baseline Overview** screen.

4. Add a Baseline Measure

- Click [Add Baseline Measure] on the **Baseline Overview** screen
- Enter data. (Tip: Use the Baseline Measure Title, "Study Specific Characteristic," to define a

customized Baseline Measure used in the study.)
- Click [OK] (saves data) or [Cancel] (does not save data).
- If the Baseline Measure is categorical
  - Click [Edit] for the relevant Baseline Measure on the **Baseline Overview** screen.
  - Click [Create Categories] on the **Baseline Measure** screen.
  - Enter data.
  - Click [OK] (saves data) or [Cancel] (does not save data).
  - Repeat for each additional Category.
  - Click [Baseline Overview] to return to the **Baseline Overview** screen.

5. Modify or Delete a Baseline Measure

- Click [Modify/Delete] for the relevant Baseline Measure on the **Baseline Overview** screen.
- Modify data.
- Click [OK] (saves data), [Cancel] (does not save data), or [Delete] (erases all data).

6. Modify or Delete a Category for a Baseline Measure

- Click [Edit] for the relevant Baseline Measure on the **Baseline Overview** screen.
- Click [Modify/Delete] for the Category to be modified or deleted on the **Baseline Measure** screen.
- Modify the "Category Title."
- Click [OK] (saves data), [Cancel] (does not save data), or [Delete] (erases all data).
- Click [Baseline Overview] to return to the **Baseline Overview** screen.

7. Add an Arm/Group

- Click [Add Arm/Group] on the **Baseline Overview** screen.
- Enter data.
- Other module(s) containing identical Arm/Groups (e.g., Participant Flow) are listed under "Modify Similar Arm/Groups." Select [Yes] (adds new Arm/Group to listed module(s)) or [No] (adds Arm/Group to the Baseline Measure only).
- Click [OK] (saves data) or [Cancel] (does not save data).

8. Modify an Arm/Group

- Click [Modify/Delete] for the Arm/Group to be modified on the **Baseline Overview** screen.
- Modify data.
- Other module(s) containing identical Arm/Groups (e.g., Participant Flow) are listed under "Modify Similar Arm/Groups." Select [Yes] (modifies Arm/Group in each listed module) or [No] (modifies Arm/Group in Baseline Measure only).
- Click [OK] (saves data) or [Cancel] (does not save data).

9. Delete an Arm/Group
*Note that the results section must include at least one Arm/Group.*

- Click [Modify/Delete] for the Arm/Group to be deleted on the **Baseline Overview** screen.
- Other module(s) containing identical Arm/Groups (e.g., Participant Flow) are listed under "Modify Similar Arm/Groups." Select [Yes] (deletes Arm/Group in each listed module) or [No] (deletes Arm/Group in Baseline Measure only).
- Click [Delete]. (Option not available if there is only one Arm/Group.)
- Click [OK] (deletes Arm/Group) or [Cancel] (saves Arm/Group).

## Results-H. Outcome Measures

1. Navigate the Outcome Measures module from the **Results Overview** screen

- Click [Edit] to view the **Outcome Overview** screen.

- To return to the **Results Overview** screen, click [Results Overview] near the top of the **Outcome Overview** screen.

When the results section is created, information from Primary and Secondary Outcome Measures of the protocol section of the PRS record are moved to the results section and will no longer be accessible from the protocol section. Please Note: If you don't have results, use "Not Posted" rather than deleting it. Otherwise, deleting also removes from protocol display.

*Note: At least one Primary Outcome Measure must have the Outcome Measure Reporting Status value of "Posted" in order to "release" the record.*

2. Add an Outcome Measure

- Click [Add Outcome Measure] on the **Outcome Overview** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).
- If the Outcome Measure is categorical (and Outcome Measure Reporting Status is "Posted")
  - Click [Edit] for the relevant Outcome Measure on the **Outcome Overview** screen.
  - (If there is no [Edit] link, click [Modify/Delete] to ensure that Outcome Measure Reporting Status is set to "Posted" and the combination of Measure Type and Measure of Dispersion is valid)
  - Click [Create Categories].
  - Enter Category Titles.
  - Click [OK] (saves data) or [Cancel] (does not save data).
  - Repeat for each additional Category.
  - Click [Outcome Overview] to return to the **Outcome Overview** screen.

3. Modify or Delete an Outcome Measure

- Click [Modify/Delete] for the relevant Outcome Measure on the **Outcome Overview** screen.
- Modify data.
- Click [OK] (saves data), [Cancel] (does not save data), or [Delete] (erases all data).

*Note: If the modification of an Outcome Measure includes changing the Outcome Measure Reporting Status to "Not Posted," a [Clear Posted Data] link and an* ***ERROR*** *message appears next to the Outcome Measure on the* ***Outcome Overview*** *screen. All Outcome Measure data, including Statistical Analysis data, for an Outcome Measure that is "Not Posted" must be deleted.*

To correct the Error message, either:

- Click [Clear Posted Data] to erase the previously entered data for the Outcome Measure OR
- Change the Outcome Measure Reporting Status to "Posted"
  - Click [Modify/Delete] for the Outcome Measure
  - Selected "Posted" for the Outcome Measure Reporting Status
  - Click [OK] (saves data).

4. Enter Outcome Measure data
*Note: Outcome Measure Reporting Status must be set to "Posted"*

- Click [Edit] for the relevant Outcome Measure on the **Outcome Overview** screen.
- Click [Edit] next to "Number of Participants Analyzed" on the **Outcome Measure** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).
- Click [Edit] next to the Outcome Measure table on the **Outcome Measure** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).
- Click [Outcome Overview] to return to the **Outcome Overview** screen.

5. Add an Arm/Group

- Click [Add Arm/Group] on the **Outcome Measure** screen.
- Enter data.
- Other module(s) containing identical Arm/Groups (e.g., Participant Flow) are listed under "Modify Similar Arm/Groups." Select [Yes] (adds new Arm/Group to listed module(s)) or [No] (adds Arm/Group to that particular Outcome Measure only).
- Click [OK] (saves data) or [Cancel] (does not save data).

6. Modify an Arm/Group

- Click [Modify/Delete] for the Arm/Group to be modified on the **Outcome Measure** screen.
- Modify data.
- Other module(s) containing identical Arm/Groups (e.g., Participant Flow) are listed under "Modify Similar Arm/Groups." Select [Yes] (modifies Arm/Group in each listed module) or [No] (modifies Arm/Group for that particular Outcome Measure only).
- Click [OK] (saves data) or [Cancel] (does not save data).

7. Delete an Arm/Group
*Note that the results section must include at least one Arm/Group.*

- Click [Modify/Delete] for the Arm/Group to be deleted on the **Outcome Measure** screen.
- Other module(s) containing identical Arm/Groups (e.g., Participant Flow) are listed under "Modify Similar Arm/Groups." Select [Yes] (deletes Arm/Group in each listed module) or [No] (deletes Arm/Group in that particular Outcome Measure only).
- Click [Delete]. (Option not available if there is only one Arm/Group.)
- Click [OK] (deletes Arm/Group) or [Cancel] (saves Arm/Group).

8. Enter Statistical Analysis data
Any number of statistical analyses conducted on an outcome measure may be reported.
*Note: Outcome Measure Reporting Status must be set to "Posted."*

- Click [Edit] for the relevant Outcome Measure on the **Outcome Overview** screen.
- Click [Add Statistical Analysis] on the **Outcome Measure** screen (near the bottom of the screen).
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).
- Repeat for each additional Statistical Analysis.

9. Modify or Delete Statistical Analysis data

- Click [Edit] for the relevant Statistical Analysis on the **Outcome Measure** screen.
- Modify data.
- Click [OK] (saves data), [Cancel] (does not save data), or [Delete] (erases all data).

## Results-I. Limitations and Caveats

1. Click [Edit] to view **Overall Limitations and Caveats** screen.
2. Enter data.
3. Click [OK] (saves data) or [Cancel] (does not save data) to return to the **Results Overview** screen.

## Results-J. Adverse Events

*Note: Starting on September 27, 2009, data providers will be required to report adverse events. They will be required to report all other (non-serious) adverse events that exceed a frequency threshold of 5 percent within any arm of the study. Data providers may voluntarily use a reporting threshold that is lower than 5 percent, if desired.*

1. Navigate the Adverse Events module from the **Results Overview** screen

- *First time only*: Click [Post Adverse Events] to create the **Adverse Events** screen. *Note: "Arm/Group" information will be pre-populated with "Arm/Group" data from the Participant Flow module.*
- Thereafter, click [Edit] to view the **Adverse Events** screen.
- To return to the **Results Overview** screen, click [Results Overview] near the top of the **Adverse Events** screen.

2. Enter Adverse Event Report information

- Click [Edit] next to "Time Frame" on the **Adverse Events** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).

3. Add a Serious Adverse Event

- Click [Add Serious Adverse Event] on the **Adverse Events** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).
- Repeat for each additional Serious Adverse Event.

4. Modify or Delete a Serious Adverse Event

- Click [Modify/Delete] for the relevant Serious Adverse Event on the **Adverse Events** screen.
- Modify data.
- Click [OK] (saves data), [Cancel] (does not save data), or [Delete] (erases all data).

5. Enter Serious Adverse Event data

- Click [Edit] next to "Total for Serious Adverse Events" on the **Adverse Events** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).
- (Hint: Click [Sort Adverse Events] on the **Adverse Events** screen to arrange adverse event terms alphabetically to facilitate data entry.)

6. Enter "Frequency Threshold for reporting Other Adverse Event"

- Click [Edit] next to "Frequency Threshold for reporting Other Adverse Event"
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).

7. Add an Other (Not Including Serious) Adverse Event

- Click [Add Other Adverse Event] on the **Adverse Events** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).
- Repeat for each Other (Not Including Serious) Adverse Event.

8. Modify or Delete an Other (Not Including Serious) Adverse Event

- Click [Modify/Delete] for the relevant Other (Not Including Serious) Adverse Event on the **Adverse Events** screen.
- Modify data.
- Click [OK] (saves data), [Cancel] (does not save data), or [Delete] (erases all data).

9. Enter Other (Not Including Serious) Adverse Event data

- Click [Edit] next to "Total for Other Adverse Events" on the **Adverse Events** screen.
- Enter data.
- Click [OK] (saves data) or [Cancel] (does not save data).
- (Hint: Click [Sort Adverse Events] on the **Adverse Events** screen to arrange adverse event terms alphabetically to facilitate data entry.)

10. Add an Arm/Group

- Click [Add Arm/Group] on the **Adverse Events** screen.
- Enter data.
- Other module(s) containing identical Arm/Groups (e.g., Participant Flow) are listed under "Modify Similar Arm/Groups." Select [Yes] (adds new Arm/Group to listed module(s)) or [No] (adds Arm/Group to Adverse Events only).
- Click [OK] (saves data) or [Cancel] (does not save data).

11. Modify an Arm/Group

- Click [Modify/Delete] for the Arm/Group to be modified on the **Adverse Events** screen.
- Modify data.
- Other module(s) containing identical Arm/Groups (e.g., Participant Flow) are listed under "Modify Similar Arm/Groups." Select [Yes] (modifies Arm/Group in each listed module) or [No] (modifies Arm/Group in Adverse Events only).
- Click [OK] (saves data) or [Cancel] (does not save data).

12. Delete an Arm/Group
*Note that the results section must include at least one Arm/Group.*

- Click [Modify/Delete] for the Arm/Group to be deleted on the **Adverse Events** screen.
- Other module(s) containing identical Arm/Groups (e.g., Participant Flow) are listed under "Modify Similar Arm/Groups." Select [Yes] (deletes Arm/Group in each listed module) or [No] (deletes Arm/Group in Adverse Events only).
- Click [Delete]. (Option not available if there is only one Arm/Group.)
- Click [OK] (deletes Arm/Group) or [Cancel] (saves Arm/Group).

### Results-K. Preview Results as it Appears on ClinicalTrials.gov

See Protocol-F. Preview Record as it Appears on ClinicalTrials.gov. The entire PRS record (i.e., protocol section followed by results section) is displayed, similar to how it appears on ClinicalTrials.gov.

### Results-L. Delete the Results Section

If a results section has been created in error for a particular trial or there are error messages that will not allow for the protocol section of the record to be published (and results are not currently required), the results section may be deleted. The entire PRS record (i.e., protocol section followed by results section) is displayed, similar to how it appears on ClinicalTrials.gov.

- Click [Edit] next to "Results" on the Edit Protocol Record screen
- Click [Delete Results]
- Click [OK] (deletes results section) or [Cancel] (does not delete results section)

---

# XML File Transfer

The XML file transfer (upload) capability is provided to facilitate the transfer of data into

ClinicalTrials.gov from data providers' computer systems. This capability is not required for most organizations.

## XML-A. XML Upload

XML files, which may contain either protocol or results information, or both, to be uploaded into the PRS are subject to the same validation process as protocol records created using the PRS web interface.

The PRS Document Type Definition (DTD), available via the PRS main menu, defines the specific required and optional tags associated with a protocol record. The DTD also contains comments outlining some of the key validation rules which cannot be expressed in the form of a DTD. For more details on what constitutes valid content, refer to the PRS Data Element Definitions, also accessible via the main menu.

Similarly, the Results XML Schema, available via the PRS main menu, defines the results portion of the clinical trial record.

Multiple records can be uploaded from a single file by simply concatenating the XML for the records and placing the concatenated XML within a "<study_collection>" tag.

Once the XML file is prepared, upload is accomplished by selecting the "Upload protocol records" option from the main menu and following the instructions provided on that screen.

## XML-B. XML Download

Data from one or more protocol records, including results, if any, can be downloaded from the PRS into an XML file on the data provider's computer. To download a single file, use the Download XML link on the Edit Protocol screen.

Multiple protocol records may be downloaded into a single XML file, via the Select Protocol Record screen's Download XML link. It may be necessary to change selection criteria to get the desired list of protocol records before downloading.

Data from the results sections of a single protocol record can be downloaded from the PRS. To download, use the Download Results XML link listed in the Results section on the Edit Protocol screen.