Entering Results Using the Basic Results Data Entry Test System (August 6, 2008)

Step-by-Step Start-up Guide

Requirements

1. Existing PRS account, user name, and password
2. Existing PRS record

Note that each PRS record now has two sections: a protocol record and a results record

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Initial Steps

1. Log in to the PRS
2. Click “Modify” (under Protocol Records)
3. Click “Edit” next to the record for which results data are to be entered
4. In the Edit Protocol Record screen, click “Enter Results” (*below second “Edit,” left-hand margin*)

Pre-fill Results from Protocol

1. Carefully review the table of data elements from the protocol record that will be used to pre-populate data elements in the results record.
    - If there are errors, press “Cancel” and correct the data elements in the protocol record
    - Note that at least one Primary Outcome Measure must exist in the protocol record to create a results record
2. Press “OK” to create the results section of the PRS record.

Note that once the results section is created, any changes to data elements shared by both the protocol and results section in a record (e.g., Primary Outcome Measure) must be made in both sections of the record to maintain consistency.

Results Overview Screen

The Results Overview screen is similar in layout and purpose to the Edit Protocol Record screen. An “Edit” link appears next to each major section of the results report. Two navigation links at the top allow you to (1) return to the Edit Protocol Record screen (“Edit Protocol”) or (2) delete all data in the results record (“Delete Results”).

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

Results Point of Contact

1. Click “Edit” to view the Edit Point of Contact screen
2. Enter the relevant data
3. Press “OK” (saves data) or “Cancel” (does not save data) to return to the Results Overview screen

Certain Agreements

1. Click “Edit” to view the Edit Certain Agreements screen
2. Enter the relevant data, as appropriate. Note the instructions – for example, you may skip the remaining questions if the answer for the “Is PI an Employee of Sponsor?” data element is “Yes.”
3. Press “OK” (saves data) or “Cancel” (does not save data) to return to the Results Overview screen

Participant Flow

Click “Edit” to view the Participant Flow screen from the Results Overview screen (Click “Results Overview” to return to the Results Overview screen)

There are two types of Participant Flow information:

- Recruitment and Pre-assignment
- Post-assignment

Recruitment and Pre-assignment Information: To enter information for the Recruitment Details or Pre-assignment Details data elements

1. Click on “Edit” next to the table
2. Enter the relevant data, as appropriate
3. Press “OK” (saves data) or “Cancel” (does not save data)

Post-assignment Information: When a results report is created initially, a single default period called “Overall Study” is automatically generated. In addition, the number and label of each arm/group defined in the protocol record is represented as a column by default. Both of these defaults may be changed.

To **add** additional periods

1. Click “Create Period”
2. Enter the first and second (Next) Period Titles. Note that the first Period Title cannot be “Overall Study,” which is a title reserved for trials with only a single period
3. Press “OK” (saves data) or “Cancel” (does not save data) to return to the Results Overview screen
4. For more than two periods, click “Create Period” on the Participant Flow screen and enter Next Period Title for each additional period

To **modify** an existing period

1. Click “Modify/Delete” for the period to be modified
2. Change the Period Title and Press “OK” (saves data) or “Cancel” (does not save data)

To **delete** an existing period (Note: At least one period must remain)

1. Click “Modify/Delete” for the period to be deleted
2. Press “Delete” (Option not available if there is only one period)
3. Press “OK” (deletes period) or “Cancel” (saves period)

To **add** additional arms or groups

1. Click “Add Arm/Group”
2. Enter Arm/Group Title and Arm/Group Description
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **modify** existing arms or groups

1. Click “Modify/Delete” for the arm/group (column) to be modified
2. Modify Arm/Group Title and/or Arm/Group Description
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **delete** an existing arm or group (Note: At least one arm/group must remain)

1. Click “Modify/Delete” for the arm/group (column) to be deleted
2. Press “Delete” (Option not available if there is only one arm/group)
3. Press “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). These periods cannot be changed. However, additional milestones may be added. (Click “Participant Flow” to return to the Participant Flow screen)

To **add** a milestone

1. Click “Edit” for the period in which a milestone is to be added
2. Click “Add Milestone” on the Period screen
3. Enter Milestone Title
4. Press “OK” (saves milestone) or “Cancel” (does not save milestone) (To return to the previous screen, click “Participant Flow”)

To **modify** a milestone

1. From the Period screen, click “Modify/Delete” for the milestone to be modified
2. Update the Milestone Title
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **delete** a milestone

1. From the Period screen, click “Modify/Delete” for the milestone to be deleted
2. Press “Delete
3. Press “OK” (deletes milestone) or “Cancel” (saves milestone)

Each milestone within a period must contain the number of participants per arm/group. To enter data from the Period screen:

1. Click on “Edit”
2. Enter values
3. Add any comments, as appropriate
4. Press “OK” (saves data) or “Cancel” (does not save data)

Note: the Not Completed data element is calculated per arm/group by subtracting the COMPLETED milestone from the STARTED milestone

If the number of Not Completed is greater than zero, Drop/Withdraw Reasons may be added from the Period screen. However, once started, all numbers in the Not Completed data element must be accounted for by a Drop/Withdraw Reason.

To **add** a drop/withdraw reason

1. Click “Add Drop/Withdraw Reason” from the Period screen for the relevant period
2. Select a “Drop/Withdraw Reason” from the pull-down list
3. If “Other” is selected, enter an explanation in the “Other Reason” data element
4. Press “OK” (saves data) or “Cancel” (does not save data)

To **modify** a drop/withdraw reason

1. Click “Modify/Delete” for the relevant drop/withdraw reason
2. Select a “Drop/Withdraw Reason” from the pull-down list
3. If “Other” is selected, enter an explanation in the “Other Reason” data element
4. Press “OK” (saves data) or “Cancel” (does not save data)

To **delete** a drop/withdraw reason

1. Click “Modify/Delete” for the relevant drop/withdraw reason
2. Press “Delete”
3. Press “OK” (deletes drop/withdraw reason) or “Cancel” (saves drop/withdraw reason)

To **enter data** for a drop/withdraw reason

1. Click “Edit” for the relevant drop/withdraw reason
2. Enter values
3. Press “OK” (saves data) or “Cancel” (does not save data)

Reminder: The sum of the values for all drop/withdraw reasons per arm/group must equal the Not Completed value per arm/group once drop/withdrawal reasons are provided.

(Click “Results Overview” to return to the Results Overview screen)

Baseline Characteristics
Click “Edit” to view the Baseline Measure screen from the Results Overview screen
(Click “Results Overview” to return to the Results Overview screen)

Before adding baseline measure data, check the arm/group data.

To **add** additional arms or groups
1. Click “Add Arm/Group”
2. Enter Arm/Group Title and Arm/Group Description
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **modify** existing arms or groups
1. Click “Modify/Delete” for the arm/group (column) to be modified
2. Modify Arm/Group Title and/or Arm/Group Description
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **delete** an existing arm or group (Note: At least one arm/group must remain)
1. Click “Modify/Delete” for the arm/group (column) to be deleted
2. Press “Delete”
3. Press “OK” (deletes arm/group) or “Cancel” (saves arm/group)

While several Baseline Measures (Gender, Age, Country of Enrollment, Specific Study Characteristic) are displayed by default, only one Gender and one Age type are required.

To **enter data** for a default baseline measure
1. Click “Edit” next to the relevant baseline measure
2. Click “Edit”
3. Enter value(s) for each arm/group, either “number of participants” or a “measure of central tendency” (e.g., mean) and a “measure of dispersion” (e.g., standard deviation).
4. Press “OK” (saves data) or “Cancel” (does not save data) to return to the previous Screen
   (Click “Baseline Overview” to return to the Baseline Measure screen)

To **modify** a default baseline measure
1. Click “Modify/Delete” for the relevant baseline measure
2. Modify any of the data elements, as appropriate (e.g., Unit of Measure)
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **add** additional baseline measures

1. Click “Add Baseline Measure” on the Baseline Measure screen
2. Enter the data elements, as appropriate
3. Press “OK” (saves data) or “Cancel” (does not save data)

4. If the baseline measure is categorical, click “Edit” next to the relevant baseline measure
5. Click “Create Category”
6. Enter Category Titles
7. Press “OK” (saves data) or “Cancel” (does not save data)
8. Repeat to add additional categories for the same baseline measure (Click “Baseline Overview” to return to the Baseline Measure screen)

To **modify** a baseline measure (or a category)

1. Click “Modify/Delete” for the relevant baseline measure
2. Modify any of the data elements, as appropriate
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **delete** a baseline measure (or a category)

1. Click “Modify/Delete” for the relevant baseline measure
2. Press “Delete”
3. Press “OK” (deletes baseline measure) or “Cancel” (saves baseline measure)

To **enter data** for a baseline measure

1. Click “Edit” next to the relevant baseline measure on the Baseline Measure screen
2. Click “Edit”
3. Enter values
4. Press “OK” (saves data) or “Cancel” (does not save data) (Click “Baseline Overview” to return to the Baseline Measure screen)

(Click “Results Overview” to return to the Results Overview screen)

Outcome Measures
Click “Edit” to view the Outcome Overview screen from the Results Overview screen
(Click “Results Overview” to return to the Results Overview screen)

The first time outcome measures are entered in the results record, values from the primary and secondary outcome measures provided in the protocol record are used to pre-populate the Outcome Overview screen. Subsequent changes to the primary and secondary outcome measures must be made to **both** the protocol and results records. *Any differences in protocol or results record will result in an error message*.

To **add** an additional outcome measure
1. Click “Add Outcome Measure”
2. Enter the data elements, as appropriate
3. Press “OK” (saves data) or “Cancel” (does not save data)

4. If the outcome measure is categorical, click “Edit” next to the relevant outcome measure. If there is no “Edit” link, click “Modify/Delete” to ensure that Outcome Measure Type, Outcome Measure Title, Outcome Measure Time Frame, Measure Type, Measure of Dispersion (“Not Applicable” if Measure Type is “Number”), and Unit of Measure are entered
5. Click “Create Category”
6. Enter Category Titles
7. Press “OK” (saves data) or “Cancel” (does not save data)
8. Repeat to add additional categories for the same outcome measure (Click “Outcome Overview” to return to the Outcome Overview screen)

To **modify** an outcome measure
1. Click “Modify/Delete” for the relevant outcome measure
2. Modify any of the data elements, as appropriate
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **delete** an outcome measure
1. Click “Modify/Delete” for the relevant outcome measure
2. Press “Delete”
3. Press “OK” (deletes outcome measure) or “Cancel” (saves outcome measure)

Before adding outcome measure data, check the arm/group data. (Click “Edit” next to the relevant outcome measure on the Outcome Overview screen)

To **add** additional arms or groups
1. Click “Add Arm/Group”
2. Enter Arm/Group Title and Arm/Group Description
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **modify** existing arms or groups
1. Click “Modify/Delete” for the arm/group (column) to be modified
2. Modify Arm/Group Title and/or Arm/Group Description
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **delete** an existing arm or group (Note: At least one arm/group must remain)
1. Click “Modify/Delete” for the arm/group (column) to be deleted
2. Press “Delete”
3. Press “OK” (deletes arm/group) or “Cancel” (saves arm/group)

(Click “Outcome Overview” to return to the Outcome Overview screen

To **enter data** for an outcome measure

1. Click “Edit” next to the relevant outcome measure on the Outcome Overview screen [NOTE: If there is no “Edit” link, click “Modify/Delete” and ensure that Outcome Measure Type, Outcome Measure Title, Outcome Measure Time Frame, Measure Type (and Measure of Dispersion if Measure Type is not “Number”), and Unit of Measure have been entered.]
2. Click the upper “Edit” (*next to Number of Participants Analyzed*)
3. Enter the number of participants analyzed by arm/group
4. Enter the Analysis Population Description, as appropriate
5. Press “OK” (saves data) or “Cancel” (does not save data)
6. Press the lower “Edit”
7. Enter values
8. Press “OK” (saves data) or “Cancel” (does not save data)
   (Click “Outcome Overview” to return to the Outcome Overview screen)

Statistical Analysis

Any number of statistical analyses conducted on an outcome measure may be reported.

To **add** a statistical analysis

1. Click “Add Statistical Analysis” (*near bottom of screen for a particular outcome measure*)
2. Enter values
3. Press “OK” (saves data) or “Cancel” (does not save data)
4. Repeat to add additional statistical analyses for the same outcome measure

To **modify** a statistical analysis

1. Click “Edit” next to the relevant statistical analysis
2. Modify any of the data elements, as appropriate
3. Press “OK” (saves data) or “Cancel” (does not save data)

To **delete** a statistical analysis

1. Click “Edit” next to the relevant statistical analysis
2. Click “Delete”
3. Press “OK” (deletes statistical analysis) or “Cancel” (saves statistical analysis)

(Click “Outcome Overview” and “Results Overview” to return to the Results Overview screen)

Limitations and Caveats

1. Click “Edit” to view the Edit Limitations and Caveats screen
2. Enter data, as appropriate
3. Press “OK” (saves data) or “Cancel” (does not save data) to return to the Results Overview screen