Preparing for ClinicalTrials.gov Results Reporting and Module 1: Participant Flow

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ICTR Research Navigators
Content Overview

Introduction

- Results Reporting Requirements
- Preparing for Results Reporting

The First Results Module

- Participant Flow
Required for:

- FDAAA “Applicable Clinical Trials” that study drugs, biologics, and devices which are approved, licensed, or cleared by FDA (for any use).

When:

- Within 12 months of Primary Completion Date (the final data collection for the primary endpoint)
- If product not approved by Primary Completion Date but is approved later, then results due 30 days after approval
- Delays are possible, primarily for manufacturer or under limited special circumstances

NOTE: Pending publication is NOT considered a good cause for delay

See:

http://clinicaltrials.gov/ct2/manage-recs/fdaaa
How are Results Reported?

Tables are constructed by data providers

- “Stand alone” tables - must be meaningful to people who are not already familiar with the study
- No narrative conclusions
- Columns are study arms
- Rows are measures
- Type of measure determines specific design of cells
**How are Results Reported?**

### Results Data Table – General Structure

<table>
<thead>
<tr>
<th>Measure 1</th>
<th>Arm 1</th>
<th>Arm 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Columns** represent "arms" or "groups".
- **Rows** represent "measures" or "categories" of a measure.
- A cell represents the value (e.g., mean and standard deviation) of a measure for an arm or group.

These general resources are available and will help you prepare for results reporting:

1. *How to Submit Your Results* homepage
   

2. *Basic Results Data Elements Definitions*
   
   [http://prsinfo.clinicaltrials.gov/results_definitions.html](http://prsinfo.clinicaltrials.gov/results_definitions.html)

3. *PRS User Guide*
   
   Located on Main Menu in database

4. 10 minute webinars for each results module
   

5. *Helpful Hints* (with common study designs examples)
   
   [http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf](http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf)
Preparing for Results Reporting: Tips

• **Accurate registration entry is essential for results reporting.**

• Be sure your registration is as accurate and complete before entering results.

• Registration inaccuracies will be replicated in the results reporting module as some fields auto populate.

• If outcomes in the initial registration were copied directly from protocol “Aims”, as described for NIH grant applications, they may be too general for use in results reporting and should be fixed in the initial registration so that they carry over more directly into results reporting.
Preparing for Results Reporting: Tips

• Populating the “Detailed Description” field in your Registration record may assist in the reader’s understanding of the study and will make your Quality Assurance review more effective. Remember, the ultimate goal is clarity for the public.

• If time allows, release your registration one final time to the ClinicalTrials.gov QA review team to ensure you have addressed any errors before inputting results.
Preparing for Results Reporting

- Different Modules have Different Structures.
- The ClinicalTrials.gov PRS system software is frequently updated to improve ease of use. Changes in functionality and design of data entry fields are common.

See the “What’s New” link on the main menu to learn about updates to the system.
Participant Flow
FDAAA: Participant Flow Definition

“A table…, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.”

FDAAA[Sec. 282(j)(3)(c)(i)],
Module 1: Participant Flow

Participant Flow Purpose

- Describe data such as # subjects enrolled, completed, terminated, lost to follow-up etc.

- Provide information about the study design by documenting the “flow” of participants through different stages of the study.

- The module should account for all enrolled participants, and make it clear which participants were analyzed.

Module 1: Participant Flow

Participant Flow Data Elements

- **Recruitment Details:** Brief description of recruitment process (i.e., dates of recruitment process, types of locations (medical center) to provide any needed context.

- **Pre-assignment Details:** Description of any significant events/approaches for study (i.e., Wash-out, run-in) following participant enrollment but prior to group assignment. That is, provide an explanation of why enrolled subjects were dropped, excluded, etc.

- **Arm/Group**
  - Title
  - Description

- **Period Title(s)**
  - “Overall Study” (default) if a single period

- **Milestones**
  - Milestone Title
  - STARTED Data*  
  - COMPLETED Data*
  - Reason Not Completed
    - Type (e.g., Death)
    - Data

*Required by ClinicalTrials.gov

For definitions of these elements, see the “Basic Results Data Elements Definitions” at: [http://prsinfo.clinicaltrials.gov/results_definitions.html](http://prsinfo.clinicaltrials.gov/results_definitions.html)
**Participant Flow**

**Recruitment Details**

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations.

- Subjects were screened and enrolled at 10 sites in the US and 5 sites in Thailand.

**Pre-Assignment Details**

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment.

- No text entered.

**Reporting Groups**

<table>
<thead>
<tr>
<th>Reporting Groups</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AmphoB Standard</strong></td>
<td>Amphotericin B 0.7 mg/kg for 14 day followed by fluconazole 400 mg daily for 8 weeks. For subjects in the standard therapy arm whose AmphoB dose is continued beyond 14 days, fluconazole initiation will be delayed.</td>
</tr>
<tr>
<td><strong>AmphoB+Fluc400</strong></td>
<td>Amphotericin B 0.7 mg/kg and the randomized dose of fluconazole at 400 mg/day for the first 14 days, then the randomized dose of fluconazole at 400 mg/day respectively for an additional 8 weeks.</td>
</tr>
<tr>
<td><strong>AmphoB + Fluc800</strong></td>
<td>Amphotericin B 0.7 mg/kg and the randomized dose of fluconazole at 800 mg/day for the first 14 days, then the randomized dose of fluconazole at 800 mg/day respectively for an additional 8 weeks.</td>
</tr>
</tbody>
</table>

Module 1: Participant Flow

Participant Flow Structure

- **Tabular Format**
- **Arms/Groups** – pre-populated from Protocol Section.
- **Period(s)** – Represent different stages of study.
- **Milestones** – Specific events/time points when # of subjects reported. Must have STARTED and COMPLETED.

Example:
If your study only has one period than you would provide the title of “Overall Study” to the period and only one Participant Flow table would be needed for your record.

<table>
<thead>
<tr>
<th>Participant Flow: Overall Study</th>
<th>AmphoB Standard</th>
<th>AmphoB+Fluc400</th>
<th>AmphoB + Fluc800</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMPLETED</strong></td>
<td>36</td>
<td>33</td>
<td>31</td>
</tr>
<tr>
<td><strong>NOT COMPLETED</strong></td>
<td>11</td>
<td>15</td>
<td>17</td>
</tr>
</tbody>
</table>

This is an example of a basic Participant Flow table for parallel design study. (For examples of other study designs, see ClinicalTrials.gov’s Helpful Hints: Basic Results at: http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf)
Module 1: Participant Flow

Participant Flow Structure (Multiple Periods)

**EXAMPLE:** If your study has 3 different periods, you would create 3 tables and provide a descriptive title for each.

**STARTED & COMPLETED** are required milestones. You can add others milestones to show specific events when the # of participants was reported.

You will track the # of participants that do not complete the period and provide a reason why.

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**Participant Flow for 3 periods**

<table>
<thead>
<tr>
<th>Period: First Intervention</th>
<th>Placebo First, then Drug A</th>
<th>Drug A First, then Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>STARTED</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Received at Least One Dose of Drug</td>
<td>65</td>
<td>64</td>
</tr>
<tr>
<td>COMPLETED</td>
<td>65</td>
<td>63</td>
</tr>
<tr>
<td>NOT COMPLETED</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Withdrawal by Subject</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Period: Washout Period of 2 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo First, then Drug A</td>
</tr>
<tr>
<td>STARTED</td>
</tr>
<tr>
<td>COMPLETED</td>
</tr>
<tr>
<td>NOT COMPLETED</td>
</tr>
<tr>
<td>Disease relapse</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Period: Second Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo First, then Drug A</td>
</tr>
<tr>
<td>STARTED</td>
</tr>
<tr>
<td>COMPLETED</td>
</tr>
<tr>
<td>NOT COMPLETED</td>
</tr>
<tr>
<td>Adverse Event</td>
</tr>
<tr>
<td>Lost to Follow-up</td>
</tr>
</tbody>
</table>

Example adapted from ClinicalTrials.gov’s Basic Results Helpful Hints, p.13 at [http://prainfo.clinicaltrials.gov/ResultsExamples.pdf](http://prainfo.clinicaltrials.gov/ResultsExamples.pdf)
Module 1: Participant Flow

Participant Flow: *What is wrong with this?*

<table>
<thead>
<tr>
<th>Period: First Intervention</th>
<th>Arm A: Drug Bupropion, then placebo</th>
<th>Arm B: Placebo, then Drug Bupropion</th>
</tr>
</thead>
<tbody>
<tr>
<td>STARTED</td>
<td>92</td>
<td>95</td>
</tr>
<tr>
<td>COMPLETED</td>
<td>88</td>
<td>95</td>
</tr>
<tr>
<td>NOT COMPLETED</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Period: Second Intervention</th>
<th>Arm A: Placebo, then Drug Bupropion</th>
<th>Arm B: Drug Bupropion, then placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>STARTED</td>
<td>88</td>
<td>93</td>
</tr>
<tr>
<td>COMPLETED</td>
<td>88</td>
<td>93</td>
</tr>
<tr>
<td>NOT COMPLETED</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

For the 1\textsuperscript{st} period, there is no explanation of why some subjects did not complete the period.

In the 2\textsuperscript{nd} period, the # of subjects that started does not match the # that finished the 1\textsuperscript{st} period. This may be a data error. Or if there was a washout period between the two periods, you may want to add that as a separate period and explain what happened to the subjects that dropped out.
**Module 1: Participant Flow**

**Participant Flow: Get Organized Using the Simple Form**

Use one form for each period in your study to gather your data for the Participant Flow module.

One helpful tool to use to get organized before inputting results is to use the simple form. For Participant flow, each sheet of paper represents 1 period (which will be organized as 1 table within the database).

Print out as many simple forms as you have periods.

**Participant Flow Summary Form**

<table>
<thead>
<tr>
<th>Period</th>
<th>Title: Overall Study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Arm/Group Title *</td>
</tr>
<tr>
<td></td>
<td>Arm/Group Description 2</td>
</tr>
<tr>
<td></td>
<td>Number of Participants *</td>
</tr>
<tr>
<td></td>
<td>Number of Participants *</td>
</tr>
<tr>
<td></td>
<td>Number of Participants *</td>
</tr>
</tbody>
</table>

**Milestone Title**

- Milestone Title 3
- Milestone Title 4
- Milestone Title 5

**Reason Not Completed**

- Adverse Event
- Death
- Lack of Efficacy
- Lost to Follow-up
- Physician Decision
- Pregnancy
- Protocol Violation
- Withdrawal by Subject

* Required by ClinicalTrials.gov

Source: http://prainfo.clinicaltrials.gov/results_table_layout/ResultSimpleForms.html
This Results Overview page is your home base for inputting results. You can access the 4 Results modules from here.

Click on “edit” next to Participant Flow to edit that module.

### Results: Overview

<table>
<thead>
<tr>
<th>Back to Protocol</th>
<th>Preview Results</th>
<th>Delete Results</th>
<th>Help</th>
</tr>
</thead>
</table>

#### Results Point of Contact
Name/Official Title: Rebecca Williams
Organization: ClinicalTrials.gov
Phone: 123-456-7890
Email: register@clinicaltrials.gov

#### Certain Agreements
Principal Investigators are NOT employed by the organization sponsoring the study.
There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PIs' rights to discuss or publish trial results after the trial is completed.

#### Protocol Enrollment
- **53**

#### Participant Flow
- **Pre-assignment Details**
  - Trial Period: First Intervention (12 Weeks)
  - Trial Period: Second Intervention (12 Weeks)
  - Total STARTED: 53
  - Total STARTED: 49

#### Baseline Characteristics
- Overall Number of Baseline Participants: 53
- Age, Categorical
- Age, Continuous
- Gender, Male/Female
- Race/Ethnicity, Customized
Within “edit mode”, you can scroll up and down to edit various parts of the Participant Flow.

The screen is only partially shown in this snapshot.
Participant Flow: Edit Mode

Within “edit mode”, you can scroll up and down to edit various parts of the Participant Flow.

The screen is only partially shown in this snapshot.

<table>
<thead>
<tr>
<th>Recruitment Details</th>
<th>Pre-assignment Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Arm/Group Title</em></td>
<td></td>
</tr>
<tr>
<td><em>Arm/Group Description</em></td>
<td>125 subjects were screened. 50 were excluded due to undetectable HIV-1 RNA, 11 for not meeting inclusion criteria and 11 for other reasons.</td>
</tr>
</tbody>
</table>

### Arms/Groups (2)

<table>
<thead>
<tr>
<th>Arm/Group Title</th>
<th>Arm/Group Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir Then Placebo (Arm A)</td>
<td>400 mg raltegravir (MK-0518) administered...</td>
</tr>
<tr>
<td>Placebo Then Raltegravir (Arm B)</td>
<td>Placebo administered twice daily in addi...</td>
</tr>
</tbody>
</table>

### Periods (2)

<table>
<thead>
<tr>
<th><em>Period Title</em></th>
<th>First intervention (12 weeks)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>* Started*</th>
<th>27</th>
<th>Add Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Completed*</td>
<td>25</td>
<td>Add Comment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not Completed (Started - Completed)</th>
<th>2</th>
</tr>
</thead>
</table>
In edit mode, you can edit the Arm/Group as needed.

For example, you can add an arm/group, delete an arm/group or edit the title and description of the arm/group.
After clicking on the “edit” button to update the arm/group title and description, a text box pops up. Here is a snapshot of Arm A text box. Edit as needed and click on “OK” to save changes.
Here you can edit information about the Period such as Period Title, # of participants that started and completed the period. You can also note the # that did not complete the period and why.
Module 1: Participant Flow

Participant Flow: Edit Mode – Edit Arm/Group Description

After clicking on the “edit” button to update the arm/group title and description, a text box pops up.

Here is a snapshot of Arm A text box.

Edit as needed and click on “OK” to save changes.

NOTE: There is a button at the bottom of the page to “add a period” if needed.

NOTE: Always click on “save” at the bottom of the page!
Within the Period, use the dropdown box when selecting a reason why a subject did not complete a period. There is an “other” option to select if the reason isn’t listed.
If you select “other”, then a blank field appears where you would explain why a subject dropped out.
Participant Flow: Edit Mode – Simple but Important

At the bottom of each page in edit mode:

**Save**: Saves your work and brings you back to the “Results Overview page.”

**Validate**: Activates display of Errors, Warnings and Notes, but does not save entered data.

**Cancel**: Does not save changes and brings you back to the “Results Overview page.”
Module 1: Participant Flow

Participant Flow: Quick Tips

• Number of participants “started” should match “Enrollment, Actual” in protocol section
  – Pre-Assignment Details can be used to explain any discrepancies in Enrollment, Actual and total number of participants Started.
• Specific Periods to reflect study design and to account for # of participants starting and completing each Period
• Use of Milestones to convey key events
  – For example, number who received intervention
• Reasons for non-completion

See http://prsinfo.clinicaltrials.gov/ResultsDetailedReviewItems.pdf
Module 1: Participant Flow

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