Workshop Overview

Pre-work: Preparing for the Workshop

Live Session 1
Participant Flow
Aug 3

Live Session 2
Baseline Characteristics
Aug 10

Live Session 3
Outcome Measures
Aug 17

Live Session 4
Adverse Events
Aug 24

Live Session 5
Open Session
Aug 31
Weekly Rhythm

Tuesday
Live session
1-3 pm

Wed-Fri
Practice time
Discussion board

Thursday
Office hours
1-2 pm
Today's Agenda

Welcome

Participant Flow Intro

Parallel Study Data Entry Tutorial

Common QC Review Issues

Group Protopaper Data Entry

Review Protopapers
Virtual Session Guidelines

Virtual Norms

• Eliminate distractions by closing all email and chat programs
• Avoid multitasking
• Mute your line when not speaking

Features Used in Today’s Session

• Mute/unmute
• Raise hand (enable and disable)
• Chat
• Breakout rooms
• Screen sharing
Session Facilitators

Kristen Craven
Alexandria Scott
Nachiket Dharker
Stacey Arnold
Amanda Burton

Technical Support: Brittney Davis

Results Team Members: Mark Basista, Zachary Feiger, Swapna Mohan, Praseeda Mullasseril, Julianne Nelson, Hetal Pandya, Yvonne Puplampu-Dove, Santas Rosario, Emma Shaw
Participant Flow: Introduction

Results Database Train-the-Trainer Workshop
August 2021
Results Information Submission

42 CFR Part 11 – Subpart C

§ 11.48 – What constitutes clinical trial results information?

42 CFR 11.48(a) applies to applicable clinical trials that are required to register and have a Primary Completion Date on or after January 18, 2017 (effective date).

Results information consists of the following:

- **Participant flow**
- Demographic and baseline characteristics
- Outcomes and statistical analyses
- Adverse event information
- Protocol and statistical analysis plan
- Administrative information
- Additional clinical trial results information for applicable device clinical trials of unapproved or uncleared device products
What Is the Participant Flow?

“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.”

From: FDAAA 801, Sec. 282(j)(3)(C)(i)
What Is Included in the Participant Flow?

42 CFR 11.48(a)(1)

- Participant/Flow Arm Information
  - Title and Description

- Pre-assignment Information
  - Significant events that occur after enrollment and prior to assignment to an arm

- Participant Data
  - Number of human subjects that started and completed the clinical trial, by arm
  - If assignment is based on a unit other than participants, also include a description of the unit of assignment (e.g., eyes, lesions, implants) and number of units that started and completed the clinical trial, by arm

Results from: NCT00137969
Where Do Participant Flow Data Come From?

CONSORT Flow Diagram

Patients Randomized 2:1 (n = 257)

Placebo + Prednisone (n = 169)

Completed Week 52 (n = 120) 71%

24 Withdrawals Total
13 Adverse Event
5 Patient’s Decision
4 Physician’s Decision
2 Lost to Follow-up
0 Death

49 Withdrawals Total
19 Adverse Event
11 Patient’s Decision
13 Physician’s Decision
3 Lost to Follow-up
3 Death

Completed Week 52 (n = 64) 73%

Rituximab + Prednisone (n = 88)

ClinicalTrials.gov

<table>
<thead>
<tr>
<th>Arm/Group Title</th>
<th>Placebo + Prednisone</th>
<th>Rituximab + Prednisone</th>
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</thead>
<tbody>
<tr>
<td>Arm/Group Description</td>
<td>Participants received placebo intra...</td>
<td>Participants received rituximab 100...</td>
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</table>

Period Title: Overall Study

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<tr>
<th></th>
<th>Started</th>
<th>Completed</th>
<th>Not Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo + Prednisone</td>
<td>88</td>
<td>64</td>
<td>24</td>
</tr>
<tr>
<td>Rituximab + Prednisone</td>
<td>169</td>
<td>120</td>
<td>49</td>
</tr>
</tbody>
</table>

Reason Not Completed

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<tr>
<th>Reason Not Completed</th>
<th>Placebo + Prednisone</th>
<th>Rituximab + Prednisone</th>
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</thead>
<tbody>
<tr>
<td>Adverse Event</td>
<td>13</td>
<td>19</td>
</tr>
<tr>
<td>Withdrawal by Subject</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Physician Decision</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Lost to Follow-up</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Death</td>
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<td>3</td>
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Adapted from: Merrill JT, et al. Arthritis Rheum, 2010 and NCT00137969
# Best Practices

<table>
<thead>
<tr>
<th>Separate Periods</th>
<th>Additional Milestones (Rows) to Convey Key Events</th>
<th>Provide Reasons Not Completed</th>
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<tbody>
<tr>
<td>• Accurately reflect study design</td>
<td>• Example: Number of participants who received the assigned intervention</td>
<td>• Examples:</td>
</tr>
<tr>
<td>• Account for number of participants starting and completing each period</td>
<td></td>
<td>• Withdrawal by subject</td>
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<tr>
<td></td>
<td></td>
<td>• Lost to follow-up</td>
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<tr>
<td></td>
<td></td>
<td>• Progressive Disease</td>
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