Welcome

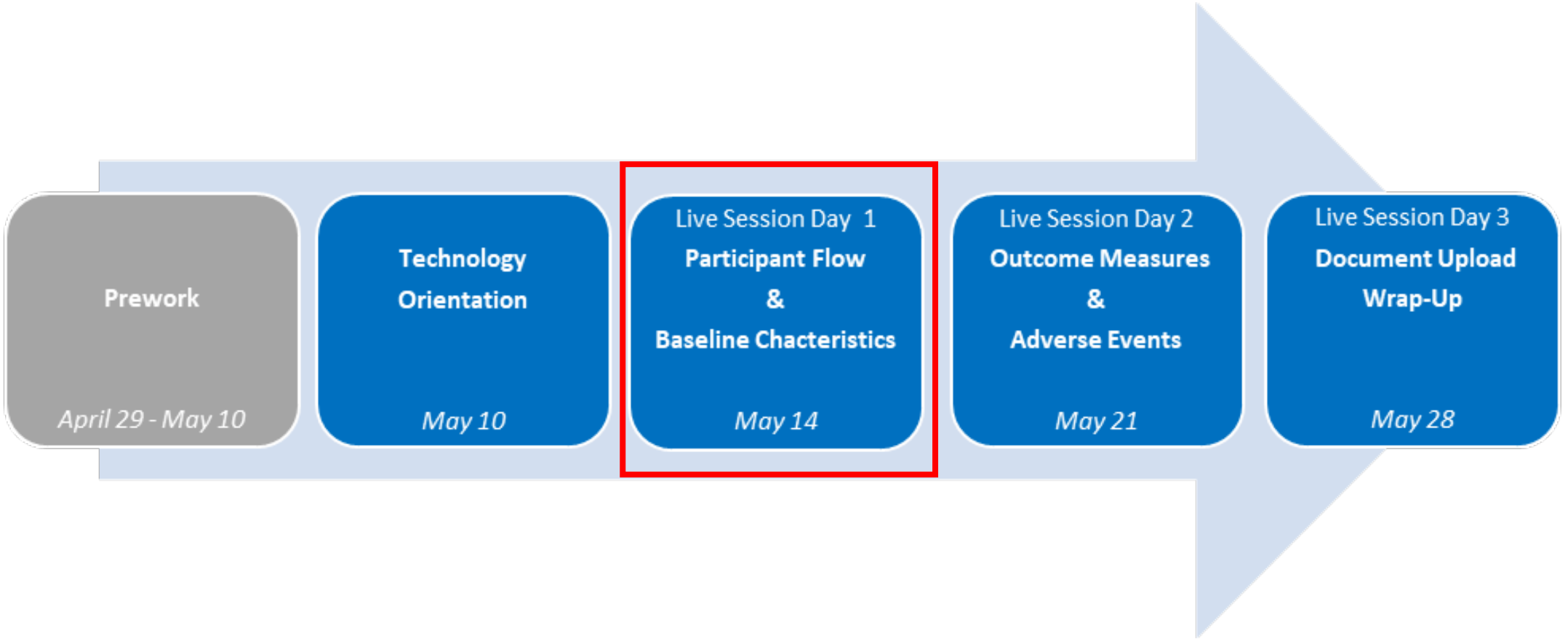
Results Database Train-the-Trainer Workshop

April 29–May 28, 2024

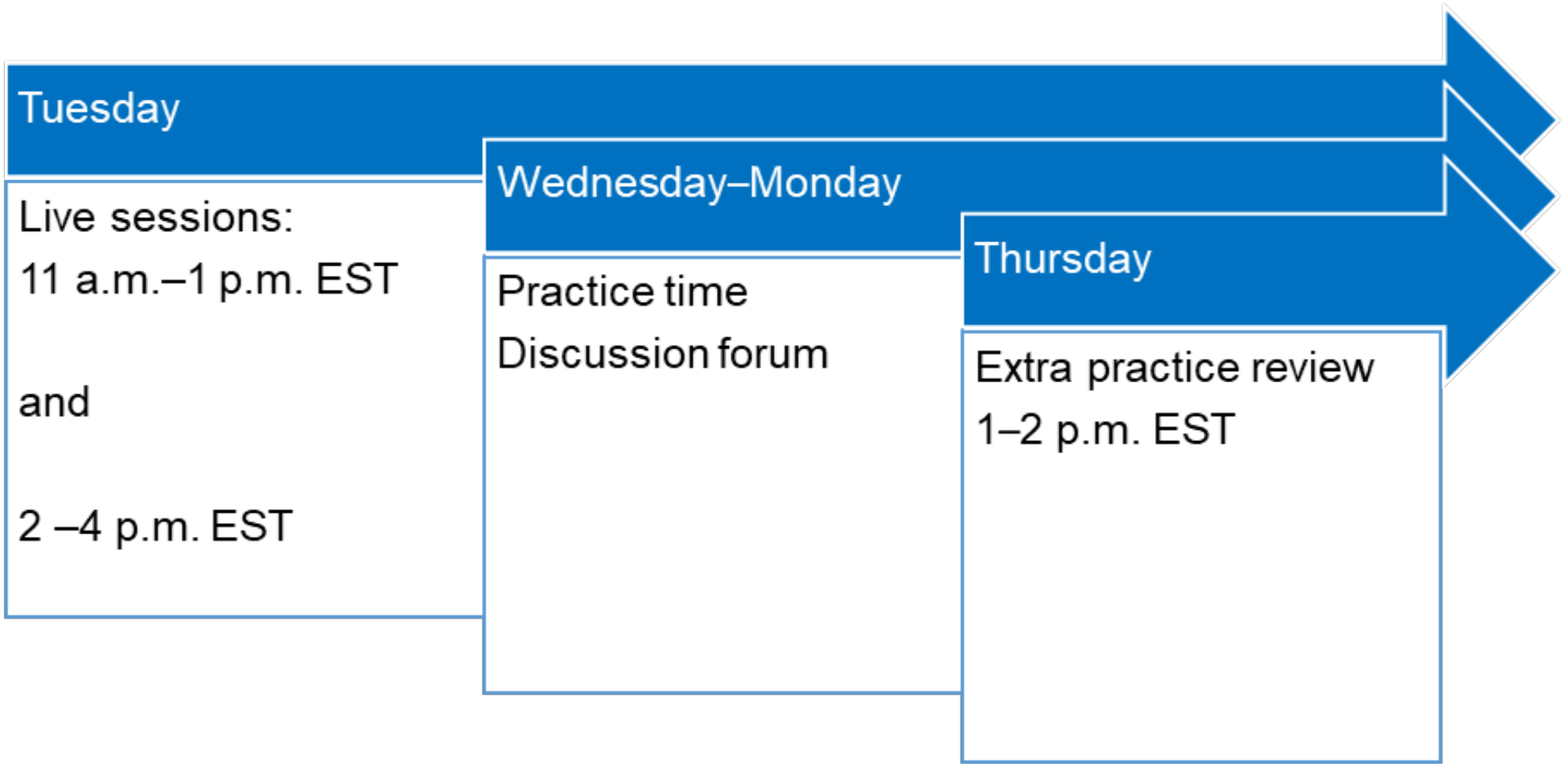
Session Agenda

- Welcome and Overview
- Participant Flow Introduction
- Parallel Study Data-Entry Tutorial
- Common Quality Control Review Issues
- Group Proto-paper Data Entry
- Review Proto-papers

Workshop Overview



Weekly Rhythm



Virtual Session Guidelines and Features

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 and unmute
- Raise hand (enable and disable)
- Chat
- Breakout rooms
- Screen sharing

Session Facilitators

Kristen Craven

Mark Basista

Praseeda Mullasseril

Santas Rosario

Ryan Whitehead

Technical Support: Brittney Davis

Results Team Members: Kristen Craven, Mark Basista, Praseeda Mullasseril, Santas Rosario, Ryan Whitehead

Participant Flow: Introduction

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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.

Recruitment Details	
Pre-assignment Details	

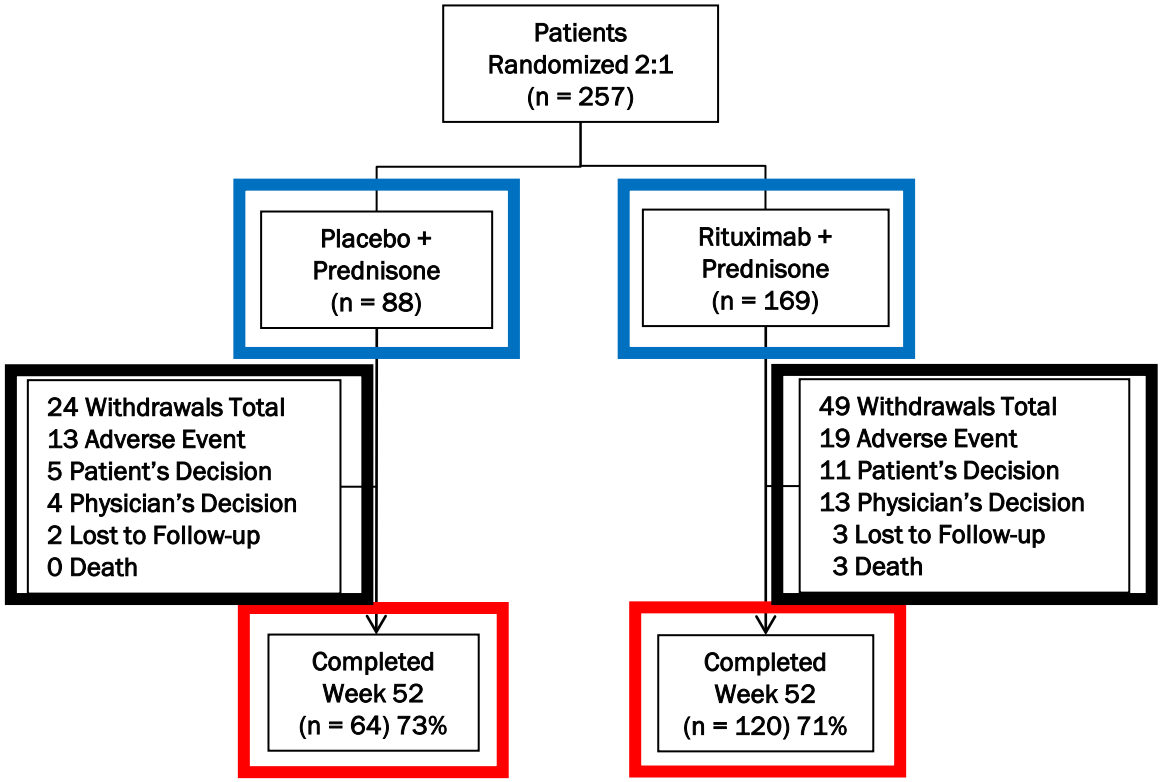
Arm/Group Title	Rituximab 1000 mg + Prednisone	Placebo + Prednisone
▼ Arm/Group Description	Participants received rituximab 1000 mg intravenously (IV) on Days 1, 15, 168, and 182. Participants also received an initial dose of prednisone (0.5, 0.75, or 1.0 mg/kg orally once a day) with tapering beginning at Day 16 for 10 weeks to a dose of ≤ 10 mg/day. Participants also received acetaminophen 1000 mg orally and diphenhydramine 50 mg orally prior to study drug infusion.	Participants received placebo intravenously on Days 1, 15, 168, and 182. Participants also received an initial dose of prednisone (0.5, 0.75, or 1.0 mg/kg orally once a day) with tapering beginning at Day 16 for 10 weeks to a dose of ≤ 10 mg/day. Participants also received acetaminophen 1000 mg orally and diphenhydramine 50 mg orally prior to study drug infusion.

Period Title: **Overall Study**		
Started	174	88
Received Study Drug	169	88
Completed	107	67
Not Completed	67	21

Results from: NCT00137969

Where Do Participant Flow Data Come From?

CONSORT Flow Diagram



ClinicalTrials.gov

Arm/Group Title	Placebo + Prednisone	Rituximab + Prednisone
▸ Arm/Group Description	Participants received placebo intra...	Participants received rituximab 100...
Period Title: **Overall Study**		
Started	88	169
Completed	64	120
Not Completed	24	49
Reason Not Completed		
Adverse Event	13	19
Withdrawal by Subject	5	11
Physician Decision	4	13
Lost to Follow-up	2	3
Death	0	3

Adapted from: Merrill JT, et al. *Arthrit Rheum*, 2010 and NCT00137969

What is the Difference Between Enrolled and Started?

- *Enrolled* – A participant or authorized representative signed an **informed consent form.** Participants who are screened but do not participate would not be considered enrolled.
- *Started* – The number of participants that initiate the period. For the first period, this includes participants who were assigned to an Arm/Group. In other words, participants who were **randomized.**

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: Phase 2/Phase 3
Interventional Study Model: Parallel Assignment
Number of Arms: 2
Masking: Double (Participant, Investigator)
Allocation: Randomized

Enrollment: 262 [Actual]

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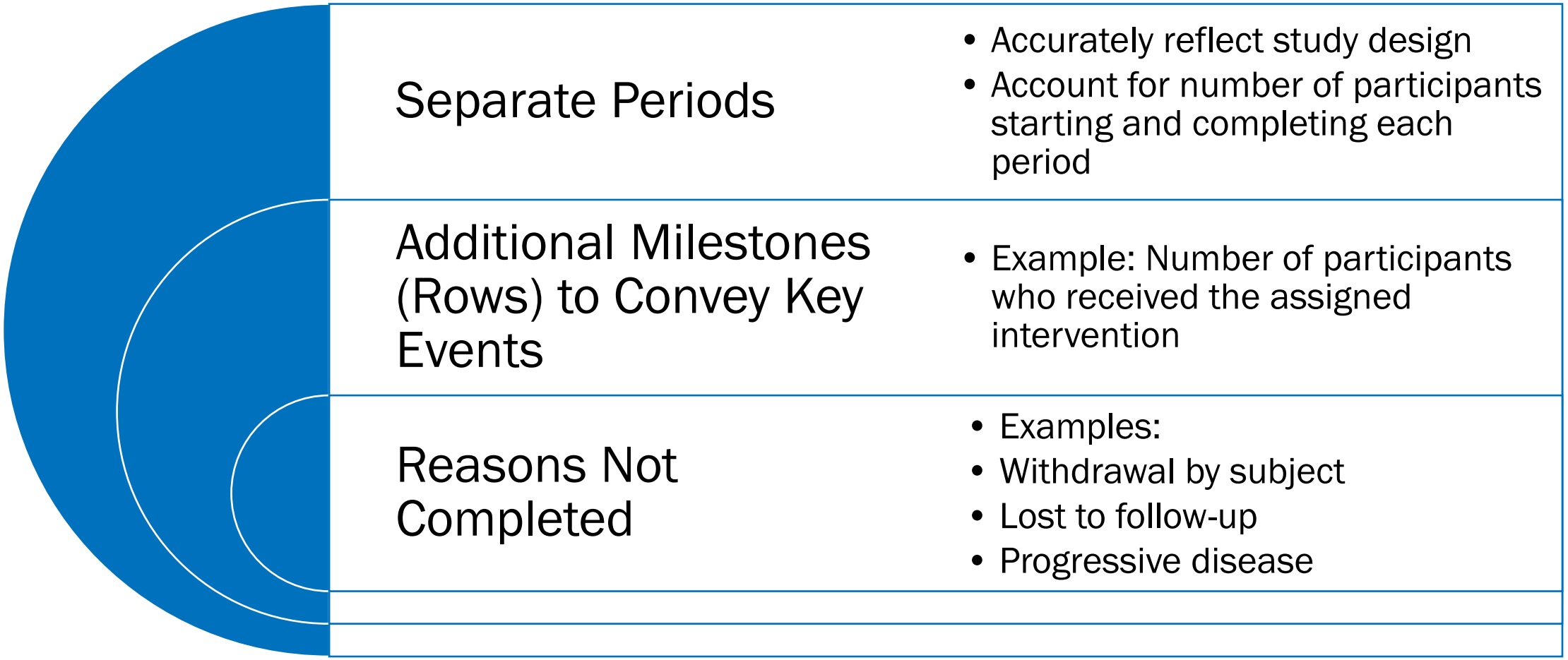
Best Practices



Separate Periods	• Accurately reflect study design • Account for number of participants starting and completing each period
Additional Milestones (Rows) to Convey Key Events	• Example: Number of participants who received the assigned intervention
Reasons Not Completed	• Examples: • Withdrawal by subject • Lost to follow-up • Progressive disease