# Sample Results Data Entry Participant Flow Module

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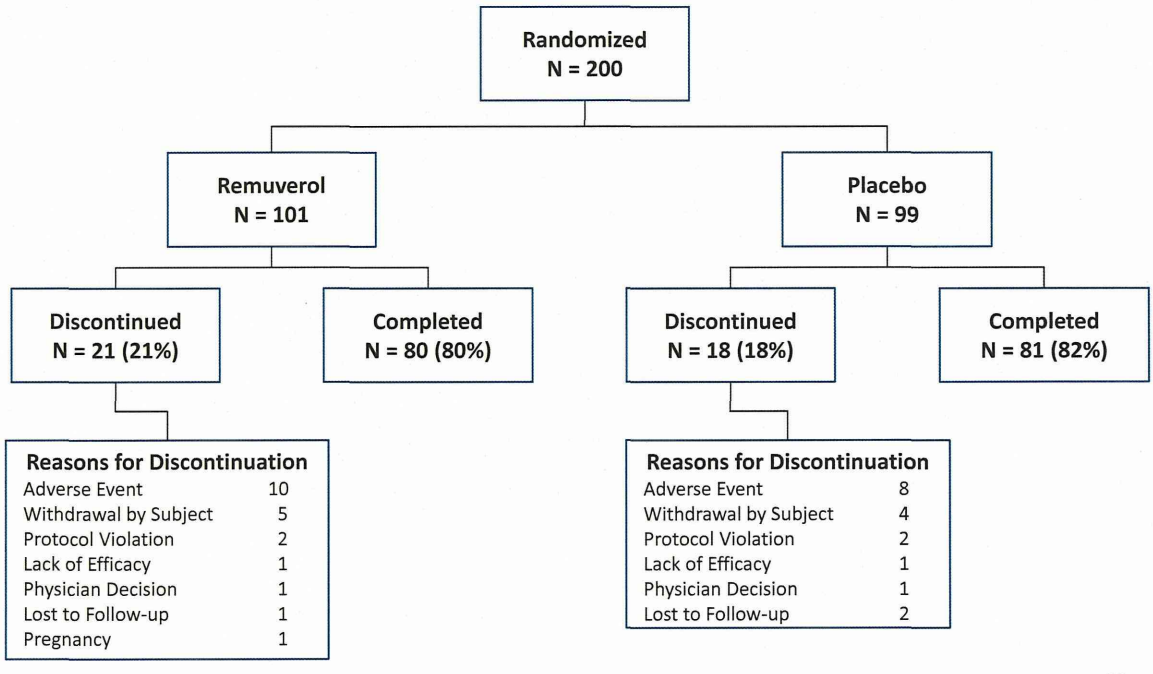
## Figure 1. Enrollment, Randomization, and Retention of Study Participants

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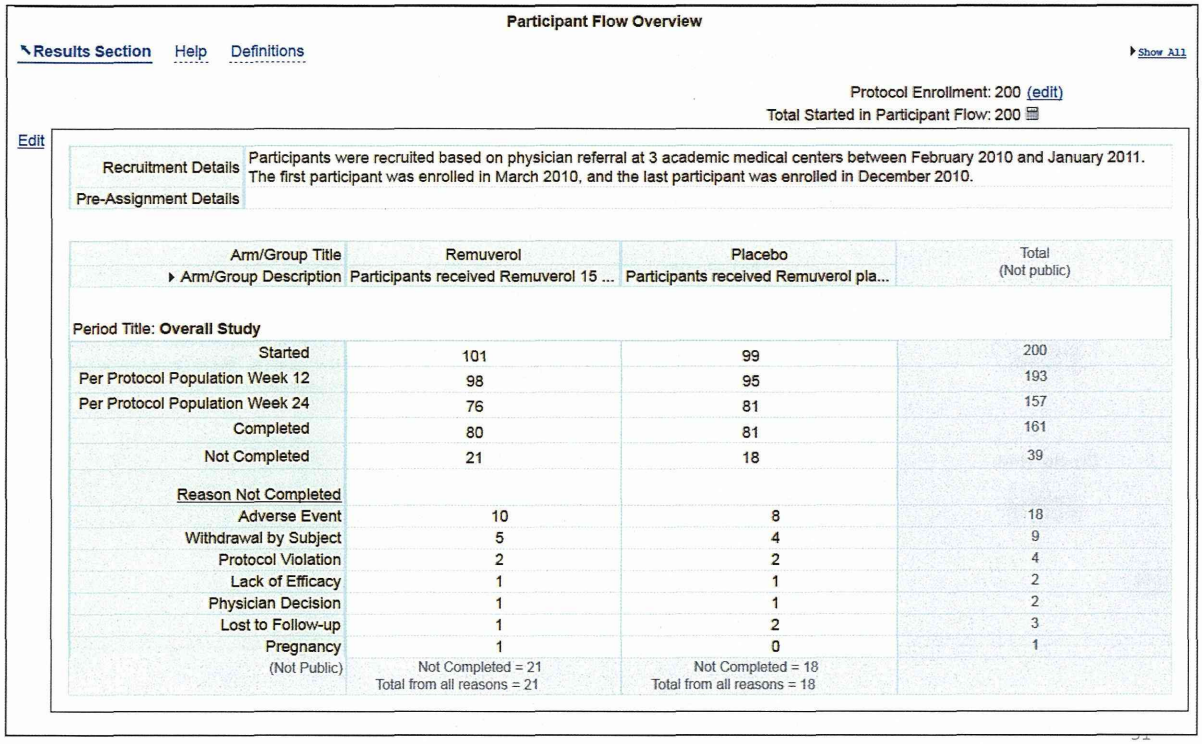
# PRS: Participant Flow Overview



**Participant Flow Overview**

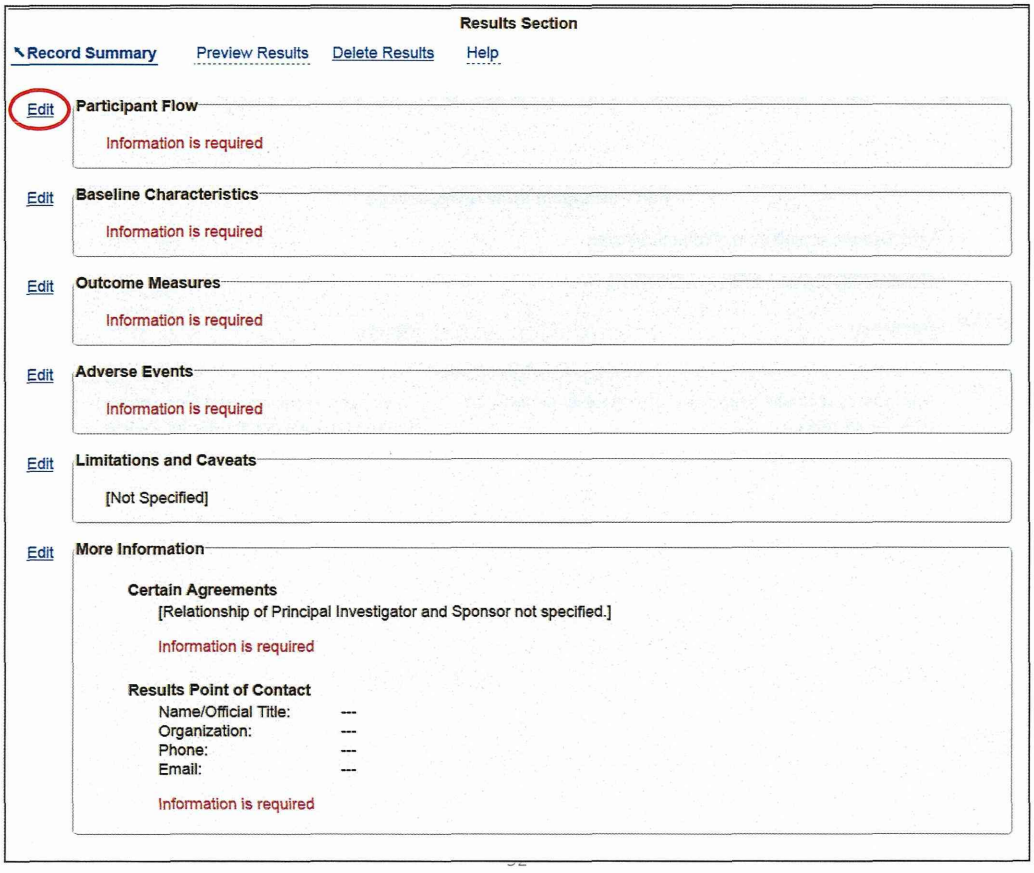
Results Section | Help | Definitions | Show All

Protocol Enrollment: 200 (edit)
Total Started in Participant Flow: 200

Edit

| | |
|---|---|
| Recruitment Details | Participants were recruited based on physician referral at 3 academic medical centers between February 2010 and January 2011. The first participant was enrolled in March 2010, and the last participant was enrolled in December 2010. |
| Pre-Assignment Details | |

| Arm/Group Title | Remuverol | Placebo | Total (Not public) |
|---|---|---|---|
| Arm/Group Description | Participants received Remuverol 15 ... | Participants received Remuverol pla... | |
| Period Title: **Overall Study** | | | |
| Started | 101 | 99 | 200 |
| Per Protocol Population Week 12 | 98 | 95 | 193 |
| Per Protocol Population Week 24 | 76 | 81 | 157 |
| Completed | 80 | 81 | 161 |
| Not Completed | 21 | 18 | 39 |
| Reason Not Completed | | | |
| Adverse Event | 10 | 8 | 18 |
| Withdrawal by Subject | 5 | 4 | 9 |
| Protocol Violation | 2 | 2 | 4 |
| Lack of Efficacy | 1 | 1 | 2 |
| Physician Decision | 1 | 1 | 2 |
| Lost to Follow-up | 1 | 2 | 3 |
| Pregnancy | 1 | 0 | 1 |
| (Not Public) | Not Completed = 21<br>Total from all reasons = 21 | Not Completed = 18<br>Total from all reasons = 18 | |



**Results Section**

Record Summary | Preview Results | Delete Results | Help

Edit **Participant Flow**
Information is required

Edit **Baseline Characteristics**
Information is required

Edit **Outcome Measures**
Information is required

Edit **Adverse Events**
Information is required

Edit **Limitations and Caveats**
[Not Specified]

Edit **More Information**

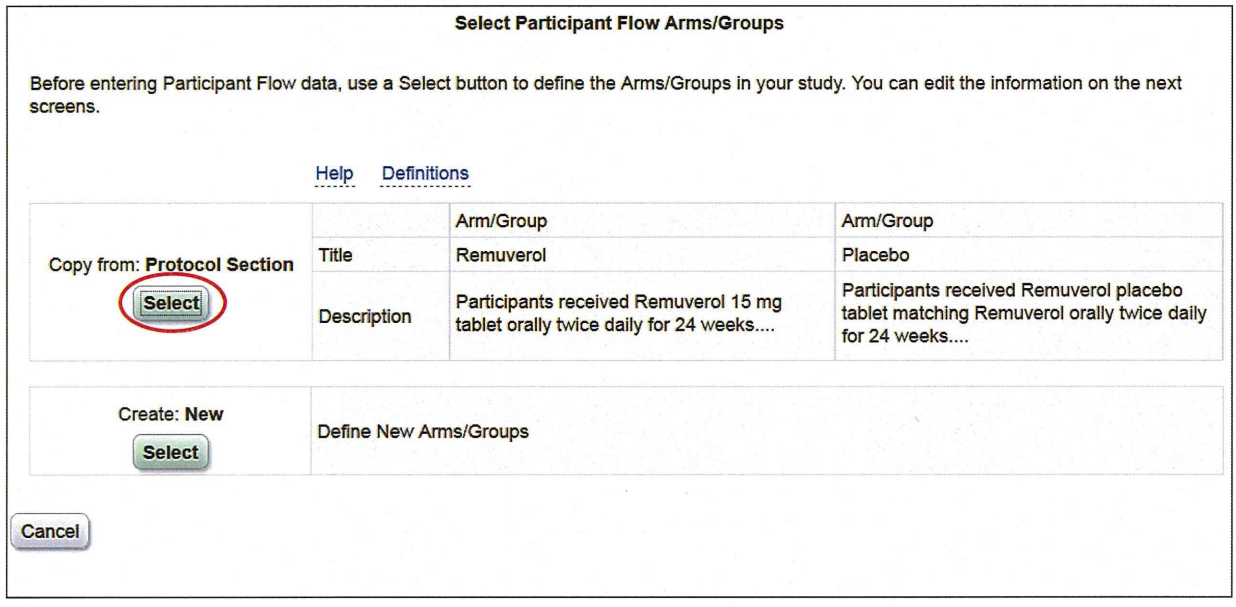
**Certain Agreements**
[Relationship of Principal Investigator and Sponsor not specified.]

Information is required

**Results Point of Contact**
Name/Official Title: ---
Organization: ---
Phone: ---
Email: ---

Information is required

# Select Participant Flow Arms/Groups

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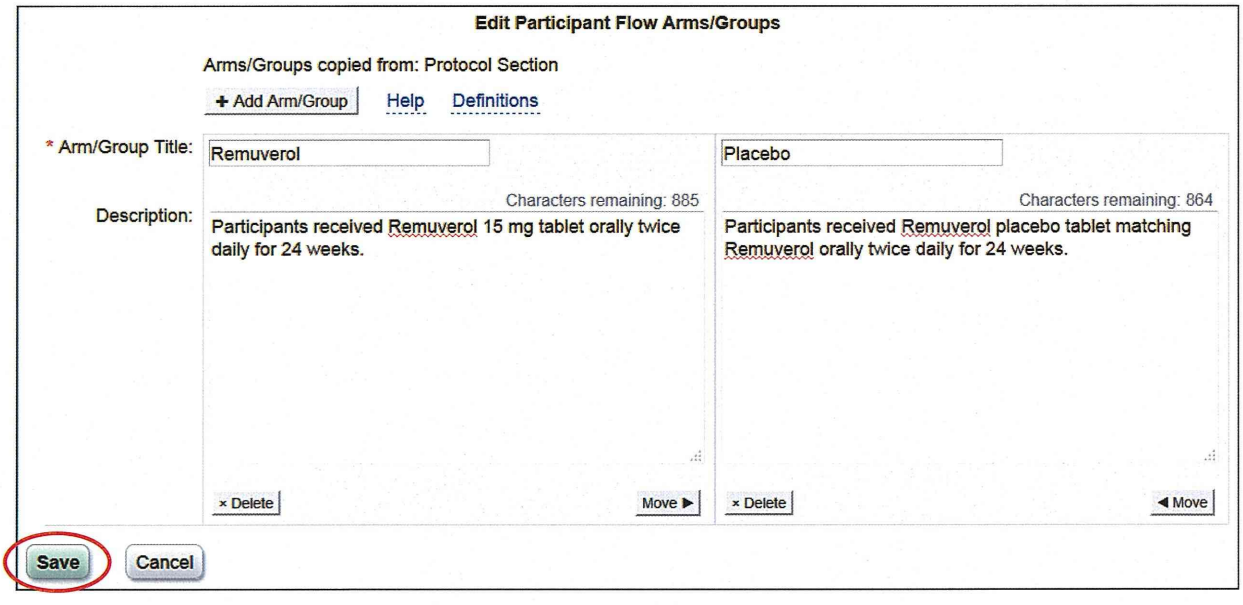
# Edit Participant Flow Arms/Groups

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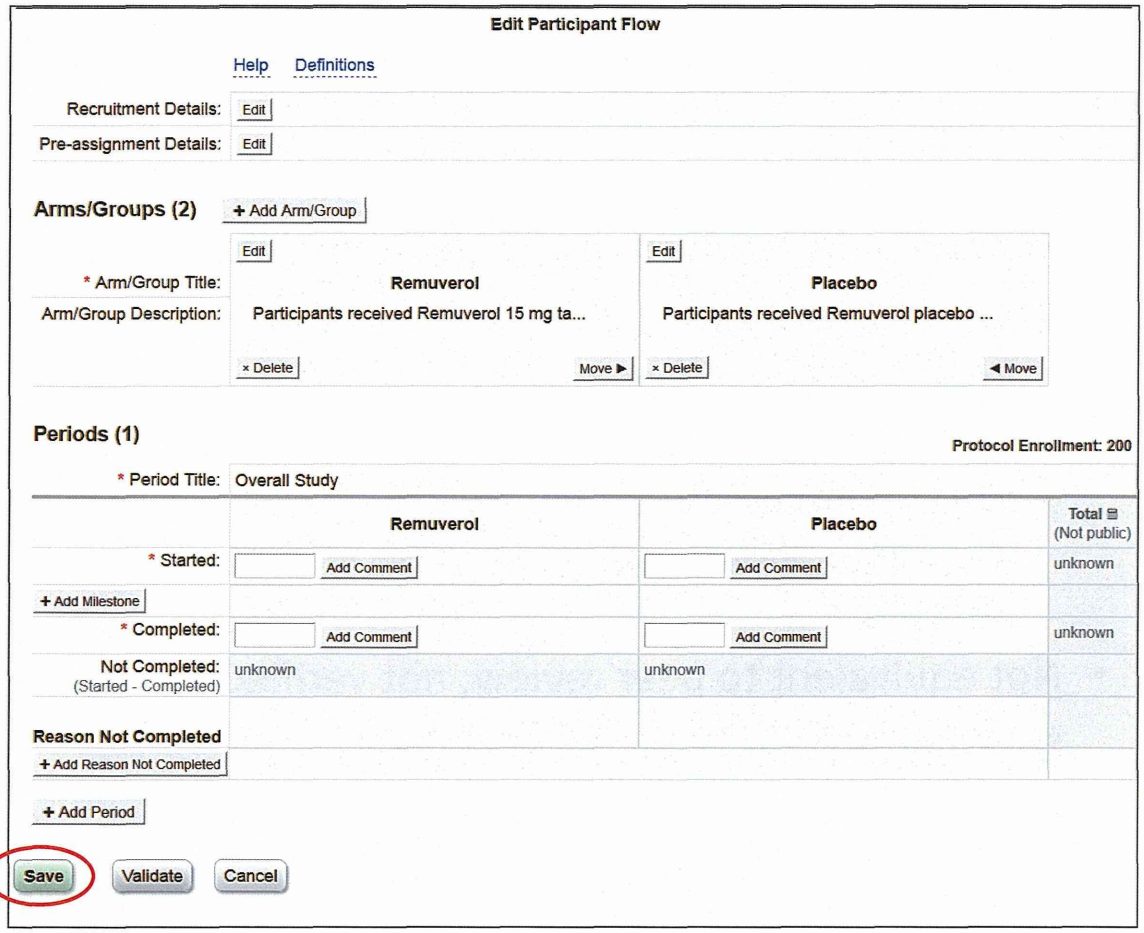


Edit Participant Flow

Help Definitions

Recruitment Details: Edit

Pre-assignment Details: Edit

**Arms/Groups (2)** + Add Arm/Group

| | Edit | Edit |
|---|---|---|
| * Arm/Group Title: | **Remuverol** | **Placebo** |
| Arm/Group Description: | Participants received Remuverol 15 mg ta... | Participants received Remuverol placebo ... |
| | × Delete Move ▶ | × Delete ◀ Move |

**Periods (1)**

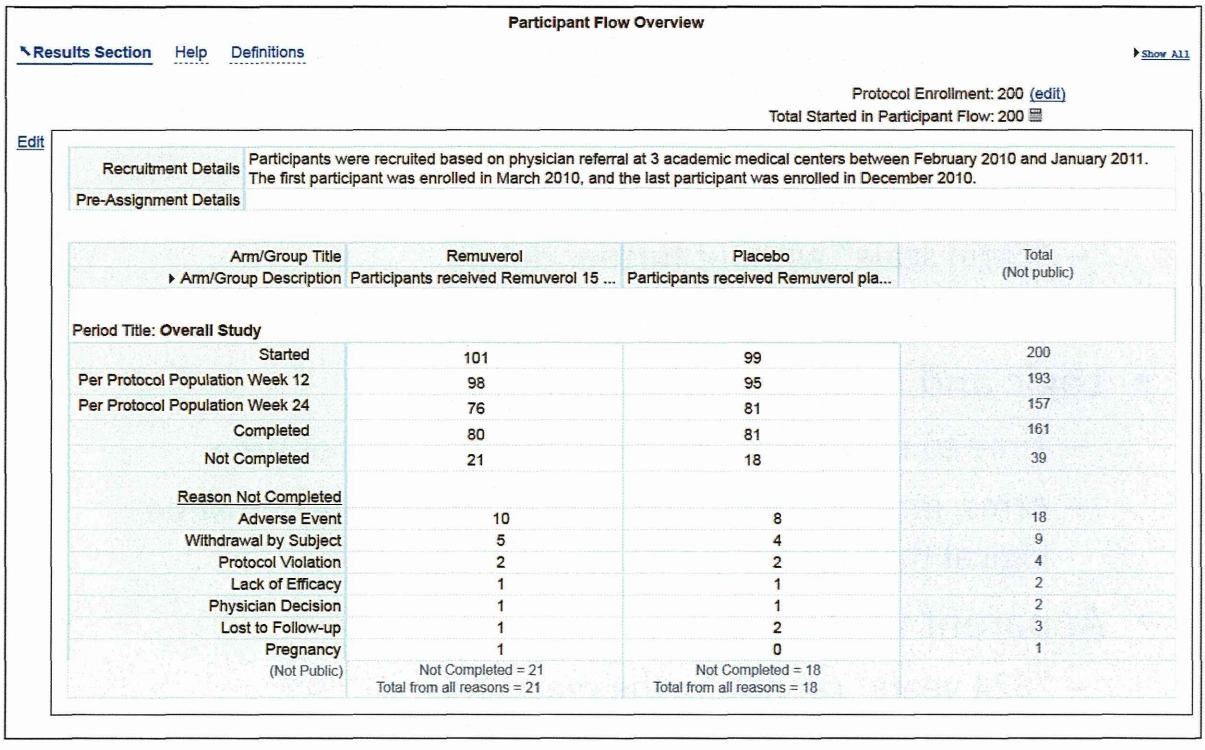
**Protocol Enrollment: 200**

* Period Title: Overall Study

| | Remuverol | Placebo | Total (Not public) |
|---|---|---|---|
| * Started: | Add Comment | Add Comment | unknown |
| + Add Milestone | | | |
| * Completed: | Add Comment | Add Comment | unknown |
| Not Completed: (Started - Completed) | unknown | unknown | |
| **Reason Not Completed** | | | |
| + Add Reason Not Completed | | | |

+ Add Period

Save Validate Cancel



Participant Flow Overview

Results Section Help Definitions Show All

Protocol Enrollment: 200 (edit)
Total Started in Participant Flow: 200

Edit

| | |
|---|---|
| Recruitment Details | Participants were recruited based on physician referral at 3 academic medical centers between February 2010 and January 2011. The first participant was enrolled in March 2010, and the last participant was enrolled in December 2010. |
| Pre-Assignment Details | |

| Arm/Group Title | Remuverol | Placebo | Total (Not public) |
|---|---|---|---|
| ▸ Arm/Group Description | Participants received Remuverol 15 ... | Participants received Remuverol pla... | |
| Period Title: **Overall Study** | | | |
| Started | 101 | 99 | 200 |
| Per Protocol Population Week 12 | 98 | 95 | 193 |
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| Withdrawal by Subject | 5 | 4 | 9 |
| Protocol Violation | 2 | 2 | 4 |
| Lack of Efficacy | 1 | 1 | 2 |
| Physician Decision | 1 | 1 | 2 |
| Lost to Follow-up | 1 | 2 | 3 |
| Pregnancy | 1 | 0 | 1 |
| (Not Public) | Not Completed = 21<br>Total from all reasons = 21 | Not Completed = 18<br>Total from all reasons = 18 | |

# General Review Criteria

- Protocol and results must be clear and informative
- Review focuses on:
  - Logic and internal consistency
  - Apparent validity
  - Meaningful entries
  - Formatting, including appropriate use of database structure
- Not equivalent to peer review; not verified against external sources (e.g., full protocol)

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Review Criteria: http://clinicaltrials.gov/ct2/manage-recs/resources

# Review Criteria Overview

- Complete and meaningful entries
  - "Zarin scale" without further detail;
  - "IOP" without explanation
- Logic and internal consistency
  - Time to event must be measured in a unit of time
  - Arms, interventions, numbers of participants must be logical throughout modules
- Apparent validity, e.g.
  - "624 years" cannot be the mean age

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# Baseline Measure - Example

**Baseline Measures**

| | Drug X |
|---|---|
| **GOG Performance Status** [units: participants] | |
| **0** | 48 |
| **1** | 27 |
| **2** | 4 |



# Baseline Measure - Example Corrected

**Baseline Measures**

| | Drug X |
|---|---|
| **Gynecological Oncology Group (GOG) Performance Status** [1] [units: participants] | |
| **0 – Fully Active** | 48 |
| **1 – Restricted Strenuous Activity, Ambulatory** | 27 |
| **2 – Ambulatory, Difficulty Walking** | 4 |
| **3 – Limited Self-Care, Partly Confined to Bed** | 0 |
| **4 – Completely Disabled, No Self-Care** | 0 |

[1] 5-point, ordinal scale specifying patient's ability to perform activities from 0 (fully active) to 4 (completely disabled, no self-care)

# Outcomes Conceptual Framework

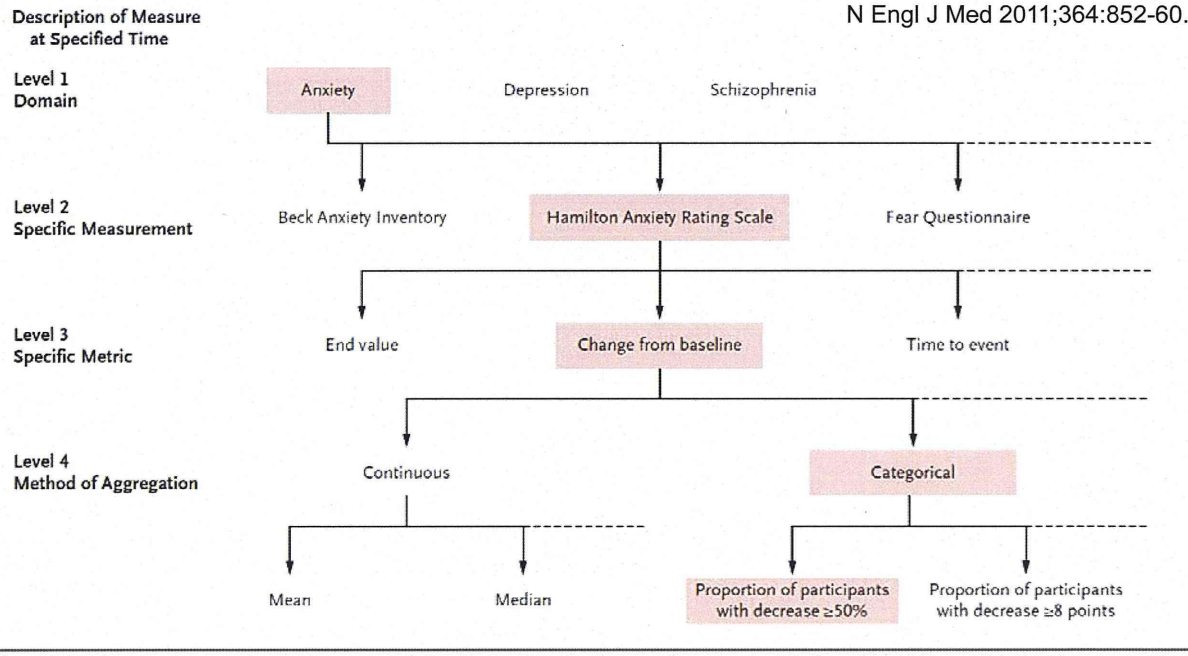


**Figure 1.** An Example of the Four Levels of Specification in Reporting Outcome Measures.

# Level of Outcome Measure Specification in Registration

Primary Outcome Measures registered in ClinicalTrials.gov

| Level | Primary Outcome Measures (% Total); n=100 |
|---|---|
| 1 – Domain only | 36% |
| 2 – Specific Measurement | 25% |
| 3 – Specific Metric | 26% |
| 4 – Method of Aggregation | 13% |
| | |
| Specific Time Frame | 72% |

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Zarin DA et al. *N Engl J Med 2011*;364: 852-60.

# Review Comments

## Reviewer Perspective

hide

Period Title: **First Intervention**

| Arm/Group Title | Hypertena Then Placebo | Placebo Then Hypertena | Total (Not public) |
|---|---|---|---|
| Started | 65 | 65 | 130 |
| Completed | 65 | 63 | 128 |
| Not Completed | 0 | 2 | 2 |
| Reason Not Completed | | | |
| Withdrawal by Subject | 0 | 1 | 1 |
| myocardial infarction | 0 | 1 | 1 |
| (Not Public) | Not Completed = 0<br>Total from all reasons = 0 | Not Completed = 2<br>Total from all reasons = 2 | |

**Comments :**

-- Add Comment Stamp --
Acronyms and Abbreviations - Spell Out
Arm Titles not Informative
Cross-over Study
Detailed Review of Results Submission
Earlier Comments
Irrelevant Information
None or N/A
Not Understandable
Number Started Inconsistent with Protocol Enrollment
Pending Records Require Review
Results Helpful Hints and Common Errors
Results Pre-submission checklist
Spelling

Characters remaining: 2999

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# Review Comments

## Reviewer Perspective

hide

Period Title: **First Intervention**

| Arm/Group Title | Hypertena Then Placebo | Placebo Then Hypertena | Total (Not public) |
|---|---|---|---|
| Started | 65 | 65 | 130 |
| Completed | 65 | 63 | 128 |
| Not Completed | 0 | 2 | 2 |
| Reason Not Completed | | | |
| Withdrawal by Subject | 0 | 1 | 1 |
| myocardial infarction | 0 | 1 | 1 |
| (Not Public) | Not Completed = 0<br>Total from all reasons = 0 | Not Completed = 2<br>Total from all reasons = 2 | |

**Comments :**

-- Add Comment Stamp --

Characters remaining: 2717

The Enrollment number in the protocol section conflicts with the number of participants Started in the Participant Flow module. Please verify and correct either or both of these data elements, or otherwise explain the apparent discrepancy in Pre-Assignment Details, as appropriate.

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# Review Comments

## Data Provider Perspective

**Participant Flow**

Protocol Enrollment: 124
Total Started in Participant Flow: 100

hide

| | |
|---|---|
| Recruitment Details | |
| Pre-Assignment Details | |

| Arm/Group Title | Placebo | Aliskiren | Total (Not public) |
|---|---|---|---|
| Arm/Group Description | Placebo: 0mg tablet, taken orally for 12 weeks daily | Aliskiren: 150mg tablet, taken orally for 12 weeks daily | |

**Comments [1] :**

**The Enrollment number in the protocol section (124) conflicts with the number of participants Started in the Participant Flow module (100). Please verify and correct either or both of these data elements, or otherwise explain the apparent discrepancy in Pre-Assignment Details, as appropriate.**

hide

Period Title: **Overall Study**

| Arm/Group Title | Placebo | Aliskiren | Total (Not public) |
|---|---|---|---|
| Started | 50 | 50 | 100 |
| Completed | 45 | 43 | 88 |
| Not Completed | 5 | 7 | 12 |

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# ClinicalTrials.gov and Journal Publication

- Substantial number of trials not published 4+ years after completion
- 57% of ClinicalTrials.gov results entries not available elsewhere
- Structured data entry leads to powerful search capability
  - E.g., “six minute walk” as outcome measure
- Quality Assurance is not Peer Review
  - Require complete, internally consistent and logical entries
  - Review does not (cannot) depend on domain knowledge
  - We do not (cannot) reject based on quality or relevance of the study
  - No discussion or interpretation in ClinicalTrials.gov
- Journals do not reject based on ClinicalTrials.gov entry

# International Landscape

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# Issues in Preventing Publication Bias

- Journal editors
  - Require trial registration
  - Use trial registry identifier (e.g., NCT #)
  - Check for "denominator" when considering a manuscript
- Registries
  - Ensure that search functions allow for identification of all trials relevant to a given search
  - Facilitate examination of publication practices by enabling "cohort identification" and facilitating the detection of publications

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