FDAAA 801 - 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.”

[Sec. 282(j)(3)(C)(i)]
CONSORT Flow Diagram

Assessed for eligibility (n=...)
- Excluded (n=...): Not meeting inclusion criteria (n=...)
- Declined to participate (n=...)
- Other reasons (n=...)

Randomised (n=...)

Allocated to Intervention (n=...):
- Received allocated intervention (n=...)
- Did not receive allocated intervention (give reasons) (n=...)

Allocated to Intervention (n=...):
- Received allocated intervention (n=...)
- Did not receive allocated intervention (give reasons) (n=...)

Lost to follow-up (give reasons) (n=...)
- Discontinued intervention (give reasons) (n=...)

Lost to follow-up (give reasons) (n=...)
- Discontinued intervention (give reasons) (n=...)

Analysed (n=...):
- Excluded from analysis (give reasons) (n=...)

Analysed (n=...):
- Excluded from analysis (give reasons) (n=...)

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Results: NCT00137969

ClinicalTrials.gov:

Efficacy and Safety of Rituximab in Moderately-to-Severely Active Systemic Lupus Erythematosus Evaluation of Rituximab Trial

Objective: The trial tested the efficacy and safety of actively treating lupus patients with moderate-to-severely active disease.

Participants: 108 participants were treated with rituximab.

Follow-up: 6 months.

Results: The trial achieved its primary endpoint of non-inferiority compared to the control group.

Conclusion: Rituximab is effective in treating moderate-to-severely active lupus.
Results: Participant Flow

Publication (CONSORT Flow Diagram)

ClinicalTrials.gov

Period 1: 52 Weeks

<table>
<thead>
<tr>
<th>Condition</th>
<th>Placebo + Prednisone</th>
<th>Rituximab + Prednisone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STARTED</strong></td>
<td>88</td>
<td>169</td>
</tr>
<tr>
<td><strong>COMPLETED</strong></td>
<td>64</td>
<td>120</td>
</tr>
<tr>
<td><strong>NOT COMPLETED</strong></td>
<td>24</td>
<td>49</td>
</tr>
<tr>
<td><strong>Adverse Event</strong></td>
<td>13</td>
<td>19</td>
</tr>
<tr>
<td><strong>Patients' Decision</strong></td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td><strong>Physicians' Decision</strong></td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td><strong>Lost to Follow-up</strong></td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

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

Web Site Resources
Best Practices

• Specific Periods to reflect study design and to account for number of participants starting and completing each Period

• Use of Milestones to convey key events
  – e.g., number of participants that received the assigned intervention

• Provide Reasons for Non-completion

Participant Flow Tutorial
Record Summary: Enter Results

Add Results Section
Results Section

Select Participant Flow Arms/Groups

Before entering Participant Flow data, use a Select button to define the Arms/Groups in your study. You can edit the information on the next screens:
**Edit Participant Flow Arms/Groups**

- **Remivaclo**: Participants received Remivaclo 15 mg tablet orally twice daily for 24 weeks.
- **Placebo**: Participants received Remivaclo placebo tablet matching Remivaclo orally twice daily for 24 weeks.

**Edit Participant Flow**

- **Remivaclo**: Participants received Remivaclo 15 mg tablet orally twice daily for 24 weeks.
- **Placebo**: Participants received Remivaclo placebo tablet matching Remivaclo orally twice daily for 24 weeks.
**Edit Participant Flow (cont.)**

- **Periodes (1)**
  - Overall Study
  - Removerol
    - Started: Add Comment
    - Completed: Add Comment
  - Placebo
    - Started: Add Comment
    - Completed: Add Comment

- **Reason Not Completed**
  - Add Reason Not Completed

- **Protocol Enrollment:** 200
  - Total: unknown
  - Not Public: unknown

**Recruitment Details (Optional)**

Definition: Key information relevant to the recruitment process for the overall study, such as details of the recruitment period and types of location (e.g., medical clinic) to provide context.

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.
### Edit Participant Flow (cont.)

#### Periods (1)

<table>
<thead>
<tr>
<th>Period</th>
<th>Overall Study</th>
<th>Protocol Enrollment: 200</th>
</tr>
</thead>
</table>
|        | Total | Placebo | Total
|        | Started | 101 | 99 | 200 |
|        | Add Event | 101 | 99 | 200 |
|        | Per Protocol Population | 150 |
|        | | 150 |
|        | Additional Milestone | 157 |
|        | Not Completed | 161 |
|        | Completed | 161 |

#### Edit Participant Flow (cont.)

<table>
<thead>
<tr>
<th>Reason Not Completed</th>
<th>Not Completed (Started - Completed)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Event</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Events</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Protocol Violation</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Lack of Eligibility</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Physician Decision</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Lack of Follow-up</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Total not completed = 21
Total from all reasons = unknown
Total from all reasons = unknown

Save | Update | Cancel
Participant Flow Overview

Enter Participant Flow

- Example Study Designs
  - Factorial
  - Crossover
  - Cluster Randomized
  - Dose Escalation
  - Multiple Period