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## Participant Flow Module

Results Database Train-the-Trainer Workshop  
September 2015



<http://ClinicalTrials.gov>

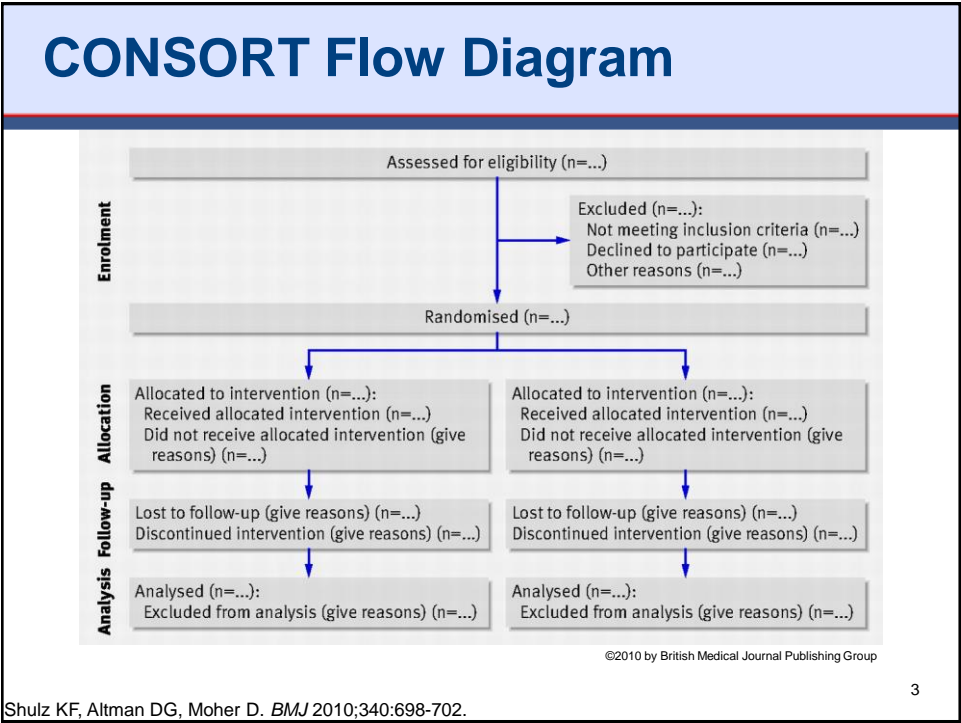
## FDAAA 801 - Participant Flow

“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)]

FDAAA 801 = Section 801 of the Food and Drug Administration Amendments Act of 2007

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Results: NCT00137969

ClinicalTrials.gov

ARTHRITIS & RHEUMATISM

Vol. 52, No. 1, January 2010, pp 222-233

DOI: 10.1002/art.21723

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

The Randomized, Double-Blind, Phase II/III Systemic Lupus Erythematosus Evaluation of Rituximab Trial

Joan T. Merrill,<sup>1</sup> C. Michael Newwitt,<sup>2</sup> Daniel J. Wallace,<sup>3</sup> Joseph C. Shanahan,<sup>4</sup> Kevin M. Latinis,<sup>5</sup> James C. Oates,<sup>6</sup> Tammy O. Utset,<sup>7</sup> Caroline Gordon,<sup>8</sup> David A. Isenberg,<sup>9</sup> Hsin-Ju Hsieh,<sup>10</sup> David Zhang,<sup>10</sup> and Paul G. Brunetta<sup>10</sup>

Objective. B cells are likely to contribute to the pathogenesis of systemic lupus erythematosus (SLE), and rituximab induces depletion of B cells. The Exploratory Phase II/III SLE Evaluation of Rituximab (EXPLORER) trial tested the efficacy and safety of rituximab versus placebo in patients with moderately-to-severely active extrarenal SLE.

Methods. Patients entered with ≥1 British Isles Lupus Assessment Group (BILAG) A score or ≥2 BILAG B scores despite background immunosuppressant therapy, which was continued during the trial. Prednisone was added and subsequently tapered. Patients were

Search for studies:  Search

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Home > Find Studies > Study Record Detail

Text Size

Publication: A Study to Evaluate the Efficacy and Safety of Rituximab in Patients With Severe Systemic Lupus Erythematosus (EXPLORER)

alTrials.gov Identifier: N0137969

received August 26, 2005

updated August 16, 2013

verified August 2013

History of Changes

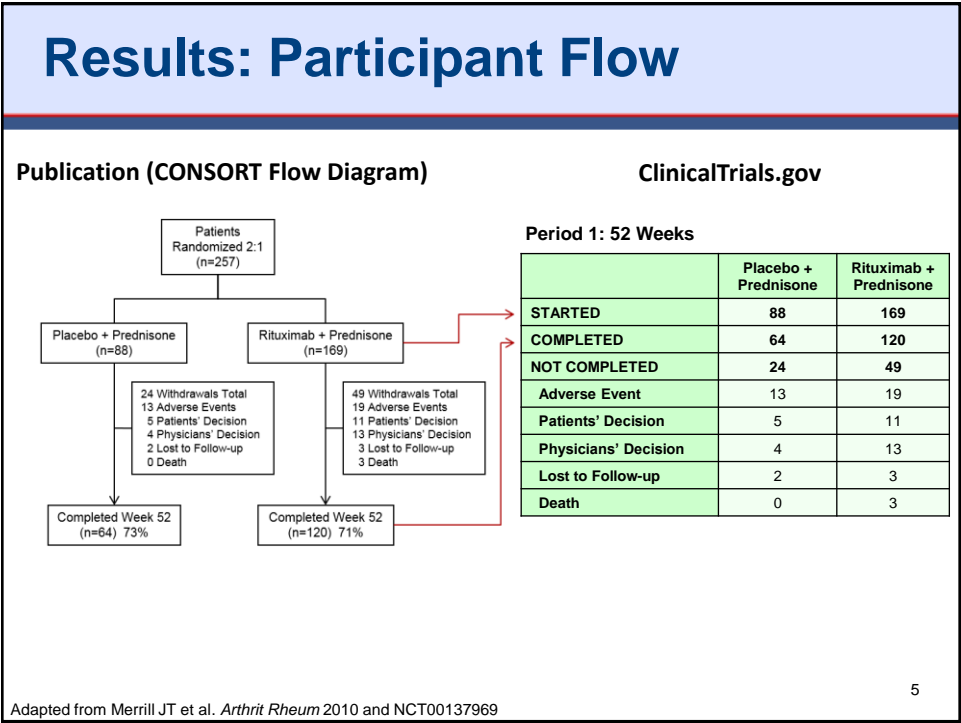
Disclaimer | How to Read a Study Record

First Received: June 5, 2009

Intervention Model: Parallel Assignment; Subject, Investigator; Primary Purpose: Treatment

emic

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Web Site Resources

<http://www.clinicaltrials.gov/ct2/manage-recs/how-report>

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Search for studies:

Example: "Heart attack" AND "Los Angeles"

Search

Advanced Search

Help

Studies by Topic

Glossary

Find Studies

About Clinical Studies

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Home

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Submit Studies

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How to Submit Your Results

Text Size

▼

Do you want to participate in a clinical study? See information for patients and families.

How to Submit Your Results

Contents

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Scientific Information

Administrative Information

Steps for Submitting Results

Learn About Requirements for Submitting Results

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Update the Protocol Section and Release (Submit) the Record

Enter the Required and Optional Results Data Elements

Preview, Inspect, and Release (Submit) the Record

ClinicalTrials.gov Results Information Review Process

Viewing Your Record

Editing and Updating Your Record

Related Pages

Protocol Registration System (PRS)

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Participant Flow Template

[http://prsinfo.clinicaltrials.gov/results\\_table\\_layout/ResultSimpleForms.html](http://prsinfo.clinicaltrials.gov/results_table_layout/ResultSimpleForms.html)

* Period Title	Overall Study	①		
* Arm/Group Title				
Arm/Group Description ②				
		Number of Participants	Number of Participants	Number of Participants
* Started				
[*] Milestone Title ③				
[*] Milestone Title ③				
[*] Milestone Title ③				
* Completed				
Reason Not Completed				
[*] Adverse Event				
[*] Death				
[*] Lack of Efficacy				
[*] Lost to Follow-up				
[*] Physician Decision				
[*] Pregnancy				
[*] Protocol Violation				
[*] Withdrawal by Subject				
[*] Other Reason ③				
[*] Other Reason ③				
[*] Other Reason ③				

\* Required by ClinicalTrials.gov

[\*] Conditionally required by ClinicalTrials.gov

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Participant Flow Checklist

[http://prsinfo.clinicaltrials.gov/results\\_table\\_layout/ResultSimpleForms.html](http://prsinfo.clinicaltrials.gov/results_table_layout/ResultSimpleForms.html)

Participant Flow Data Preparation Checklist

Overview: A tabular summary of the participants' progression through each stage of a study by group. Use this checklist with the [Participant Flow Template](#) and [Results Data Element Definitions](#).

Information to have available for Participant Flow	Term
<input type="checkbox"/> • Conceptual overview of the study design, including the type (e.g., single-group, cross-over, parallel) and any distinct stages (e.g., double-blind then open-label) • Tip: Have a <a href="#">CONSORT flow diagram</a> available	Background
<input type="checkbox"/> • A description of any study events that occurred before participants were assigned to a study group (e.g., run-in phase, number of screen failures)	<sup>a</sup> Pre-assignment Details
<input type="checkbox"/> • Number of groups that accurately describes the study design from participant assignment to completion. Each group will be reported as a table column. • Tip: The number of groups is typically equal to the number of unique paths (participant experiences) in a CONSORT flow diagram, from beginning to end.	Arms/Groups
<input type="checkbox"/> • For each group, a detailed explanation of the participants and/or interventions o Title—A descriptive label for the group (header for the table column). Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1"). o Description—A detailed explanation of the interventions administered or the groups observed during each stage of the study. Include details about the intervention and the frequency and time period of administration or observation.	<sup>a,b</sup> Arm/Group Title <sup>a</sup> Arm/Group Description
<input type="checkbox"/> • Number of distinct stages or intervals of activity in the study	Periods
<input type="checkbox"/> • If there is more than one stage (Period), each Period will need a unique Title (the default for one Period is "Overall Study"). o A Period Title should be a descriptive label. For example, "Double-blind (0 to 24 weeks)" and "Open-label (24 to 48 weeks)" are more descriptive than "Period 1" and "Period 2."	<sup>a,b</sup> Period Title
<input type="checkbox"/> • For each Period, the number of participants in each group that: o Started—Generally, the participants assigned (or randomized) to each group ▪ Additional Milestone (optional)—Any important event(s) during study o Completed—As defined for the study • Tip: If the number of participants starting the first Period is different from the total enrolled in the study, explain why in Pre-assignment Details	<sup>a,b</sup> Started <sup>a,b</sup> Completed
<input type="checkbox"/> • For each Period, the number of participants in each group that dropped out and the reasons they dropped out	<sup>a</sup> Reason(s) Not Completed <sup>a</sup> Required <sup>b</sup> Template Field

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## 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

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## Participant Flow *Tutorial*

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# Record Summary: Enter Results

Parallel 2015

Parallel Study Design Example 2015

[NCT ID not yet assigned]

Home

Help

Record Status

In Progress

Entry Completed

Approved

Released

PRS Review

Public

Next Step: Confirm data entry complete

Entry Complete

Record Owner: RWilliams

Last Updated: 06/09/2015 06:26 by RWilliams

Initial Release: [Not yet released]

Results Expected: August 2012

Access List: [Edit]

Upload: Allowed [Edit]

PRS Review: [Not yet released]

Public Site: [Not yet registered]

Spelling

Preview

Draft Receipt [PDF] [RTF]

Download XML

Delete

Open

Protocol Section

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: Parallel 2015

Brief Title: Parallel Study Design Example 2015

Module Status: Study Identification: ✓ 1 Note

Study Status: ✓

Sponsor/Collaborators: ✓

Oversight: ✓ 2 Notes

Study Description: ✓

Conditions: ✓ 1 Note

Study Design: ✓

Arms and Interventions: ✓ 2 Notes

Outcome Measures: ✓

Eligibility: ✓

Contacts/Locations: ✓ 5 Notes

References:

Results Section

Enter Results

Results submission is required by FDAAA 801 for certain applicable clinical trials of drugs, biologics and devices. Note: other clinical trials may need to have results submitted based on other funder or sponsor policies.  
[Record must have a ClinicalTrials.gov ID (NCT number) before results can be entered.]

Delay Results

For applicable clinical trials subject to FDAAA 801, results submission may be delayed (in limited circumstances) with a Certification or Extension Request.

For more information see: When Do I Need to Register and Submit Results?

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# Add Results Section

ClinicalTrials.gov PRS

Protocol Registration and Results System

Org: PRSTraining

User: RWilliams

Parallel 2015

Parallel Study Design Example 2015

[NCT ID not yet assigned]

Add Results Section

You are adding a Results Section to your Study Record.

Before you begin, it is recommended that you review the Simple Results Templates and Results Data Preparation Checklists to ensure that you have the information needed to complete the Results Section. The results data needed are similar to the components needed for a journal publication. Preparing data for the Results Section should similarly involve individuals who are familiar with the study design and analysis (such as an investigator or statistician).

For additional information on the results requirements, see Help: Results Data Entry.

Need help with Results? Contact ClinicalTrials.gov PRS to request one-on-one assistance from one of our experts.

Continue

Cancel

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

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# Results Section

ID: Parallel 2015Parallel Study Design Example 2015[NCT ID not yet assigned]

Record Summary

Preview Results

Download Results XML

Delete Results

Help

Edit

Participant Flow

Information is required

Edit

Baseline Characteristics

Information is required

Open

Outcome Measures

Information is required

Edit

Adverse Events

Information is required

Edit

Limitations and Caveats

[Not Specified]

Open

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

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# Select Participant Flow Arms/Groups

ID: Parallel 2015Parallel Study Design Example 2015[NCT ID not yet assigned]

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.

Help

Definitions

Copy from: Protocol Section

Select

	Arm/Group	Arm/Group
Title	Remuverol	Placebo
Description	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks....	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks....

Create: New

Select

Define New Arms/Groups

Cancel

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## Edit Participant Flow Arms/Groups

ID: Parallel 2015Parallel Study Design Example 2015[NCT ID not yet assigned]

### Edit Participant Flow Arms/Groups

Arms/Groups copied from: Protocol Section

+ Add Arm/Group

Help

Definitions

\* Arm/Group Title:

Remuverol

Placebo

Description:

Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.

Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks.

x Delete

Move ▶

x Delete

◀ Move

Save

Cancel

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## Edit Participant Flow

ID: Parallel 2015Parallel Study Design Example 2015[NCT ID not yet assigned]

Help

Definitions

Recruitment Details:

Pre-assignment Details:

Arms/Groups (2)

+ Add Arm/Group

Remuverol

Placebo

\* Arm/Group Title:

Arm/Group Description:

x Delete

Move ▶

x Delete

◀ Move

Periods (1)

Protocol Enrollment: 200

\* Period Title:

Overall Study

	Remuverol	Placebo	Total # (Not public)
* Started:	<div><div></div><div>Add Comment</div></div>	<div><div></div><div>Add Comment</div></div>	unknown
+ Add Wilestone			
* Completed:	<div><div></div><div>Add Comment</div></div>	<div><div></div><div>Add Comment</div></div>	unknown
Not Completed: (Started - Completed)	unknown	unknown	
Reason Not Completed			
+ Add Reason Not Completed			
+ Add Period			

Save

Validate

Cancel

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Edit Participant Flow (cont.)

ID: Parallel 2015

Parallel Study Design Example 2015

[NCT ID not yet assigned]

Help

Definitions

Recruitment Details

Pre-assignment Details

Arms/Groups (2)

+ Add New Group

\* Arm/Group

Arm/Group Description

Periods (1)

\* Period

\* Start

\* End

\* Completion Date

\* Comment

Not Completed

(Started - Completed)

Reason Not Completed

+ Add Reason Not Completed

+ Add Period

Save

Validate

Cancel

Recruitment Details (Optional)

Definition: Key information relevant to the recruitment process for the overall study, such as dates 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.

Characters remaining: 119

OK

Cancel

Enrollment: 200

Total # (Not public)

unknown

unknown

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Edit Participant Flow (cont.)

Periods (1)

Protocol Enrollment: 200

\* Period Title: Overall Study

	Remuverol	Placebo	Total # (Not public)
* Started:	<input type="text"/> <div>Add Comment</div>	<input type="text"/> <div>Add Comment</div>	unknown
+ Add Milestone	x 2		
* Completed:	<input type="text"/> <div>Add Comment</div>	<input type="text"/> <div>Add Comment</div>	unknown
Not Completed: (Started - Completed)	unknown	unknown	
Reason Not Completed			
+ Add Reason Not Completed	x 7		
+ Add Period			

Save

Validate

Cancel

















18

## Edit Participant Flow (cont.)

Periods (1)






































Protocol Enrollment: 200

Period Title: Overall Study

	Remuverol	Placebo	Total  (Not public)
* Started:	101 	99 	200
Additional Milestone			193
Per Protocol Population V 	98 	95 	
 Delete  Move			
Additional Milestone			157
Per Protocol Population V 	76 	81 	
 Delete  Move			
 Add Milestone			
* Completed:	80 	81 	161
Not Completed: (Started - Completed)	21	18	

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## Edit Participant Flow (cont.)

Not Completed: (Started - Completed)	21	18	
Reason Not Completed			
Adverse Event 	10 	8 	unknown
 Delete  Move			
Withdrawal by Subject 	5 	4 	unknown
 Delete  Move			
Protocol Violation 	2 	2 	unknown
 Delete  Move			
Lack of Efficacy 	1 	1 	unknown
 Delete  Move			
Physician Decision 	1 	1 	unknown
 Delete  Move			
Lost to Follow-up 	1 	2 	unknown
 Delete  Move			
Pregnancy 	1 	0 	unknown
 Delete  Move			
 Add Reason Not Completed	Not Completed = 21 Total from all reasons = unknown	Not Completed = 18 Total from all reasons = unknown	
 Add Period			

Save

Validate

Cancel

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## Participant Flow Overview

ID: Parallel 2015

Parallel Study Design Example 2015

[NCT ID not yet assigned]

Results Section

Help

Definitions

Show All

Protocol Enrollment: 200

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
Arm/Group Description	Participants received Remuverol 15 ...	Participants received Remuverol pla...	(Not public)
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 Total from all reasons = 21	Not Completed = 18 Total from all reasons = 18	

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## Enter Participant Flow

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

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