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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)]

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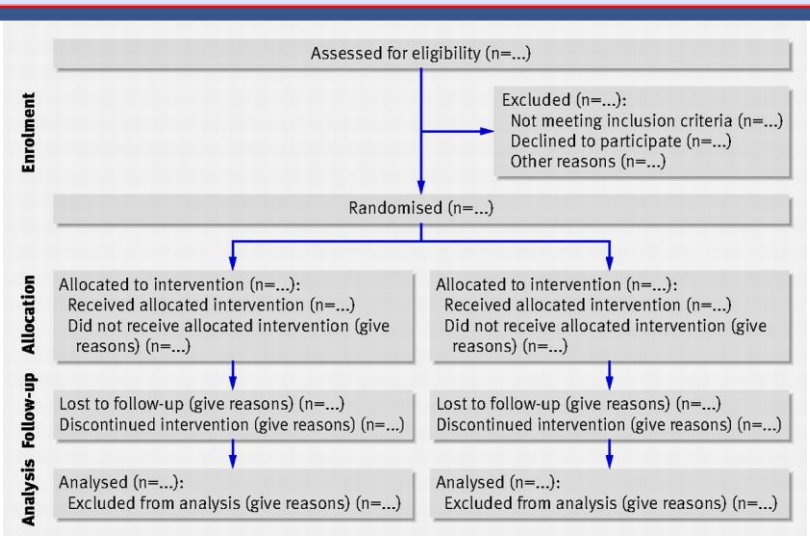
FDAAA 801 = Section 801 of the Food and Drug Administration Amendments Act of 2007

CONSORT Flow Diagram



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Shulz KF, Altman DG, Moher D. *BMJ* 2010;340:698-702.

Results: NCT00137969

ClinicalTrials.gov:

Publication:


ClinicalTrials.gov
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Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
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Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site
Home > Find Studies > Study Record Detail
Text Size
A Study to Evaluate the Efficacy and Safety of Rituximab in Patients With Severe Systemic Lupus Erythematosus (EXPLORER)
ARTHRITIS & RHEUMATISM
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, C. Michael Neuwelt, Daniel J. Wallace, Joseph C. Shanahan, Kevin M. Latinis, James C. Oates, Tammy O. Utset, Caroline Gordon, David A. Isenberg, Hsin-Ju Hsieh, David Zhang and Paul G. Brunetta
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
ClinicalTrials.gov identifier: NCT00137969
(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
alTrials.gov Identifier:
00137969
eceived: August 26, 2005
pdated: August 16, 2013
erified: August 2013
y of Changes
Disclaimer
How to Read a Study Record
s First Received: June 5, 2009
tervention Model: Parallel Assignment;
ject, Investigator); Primary Purpose: Treatment
emic

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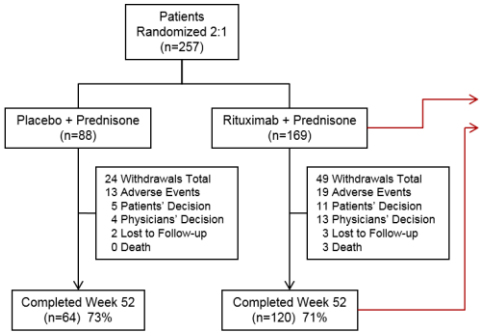
Results: Participant Flow

Publication (CONSORT Flow Diagram)



ClinicalTrials.gov

Period 1: 52 Weeks

	Placebo + Prednisone	Rituximab + Prednisone
STARTED	**88**	**169**
COMPLETED	**64**	**120**
NOT COMPLETED	**24**	**49**
Adverse Event	13	19
Patients' Decision	5	11
Physicians' Decision	4	13
Lost to Follow-up	2	3
Death	0	3

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

Web Site Resources

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

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Participant Flow Template

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

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[Δ] and Results Data Element Definitions.

	Information to have available for Participant Flow	Term
☐	• 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 CONSORT flow diagram available	Background
☐	• 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)	[Δ]Pre-assignment Details
☐	• 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
☐	• 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.	*[Δ]Arm/Group Title [Δ]Arm/Group Description
☐	• Number of distinct stages or intervals of activity in the study	Periods
☐	• 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."	*[Δ]Period Title
☐	• 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	*[Δ]Started *[Δ]Completed
☐	• For each Period, the number of participants in each group that dropped out and the reasons they dropped out	[Δ]Reason(s) Not Completed

*Required
[Δ]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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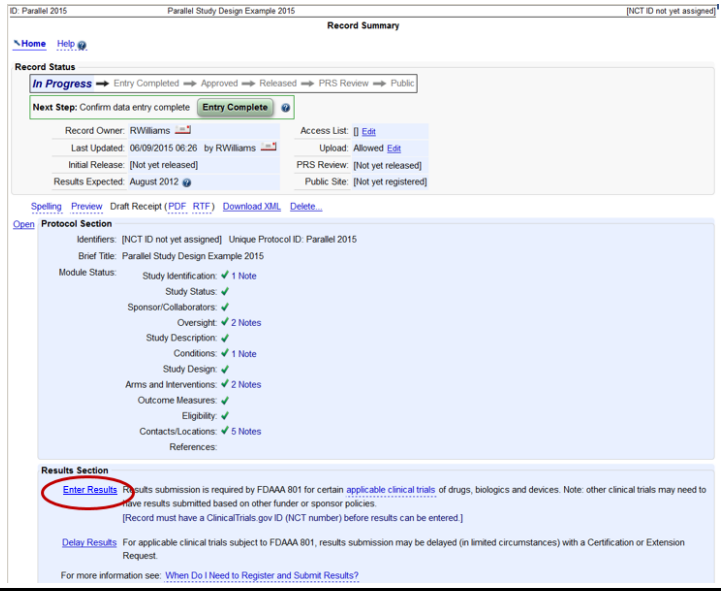
Record Summary: Enter Results



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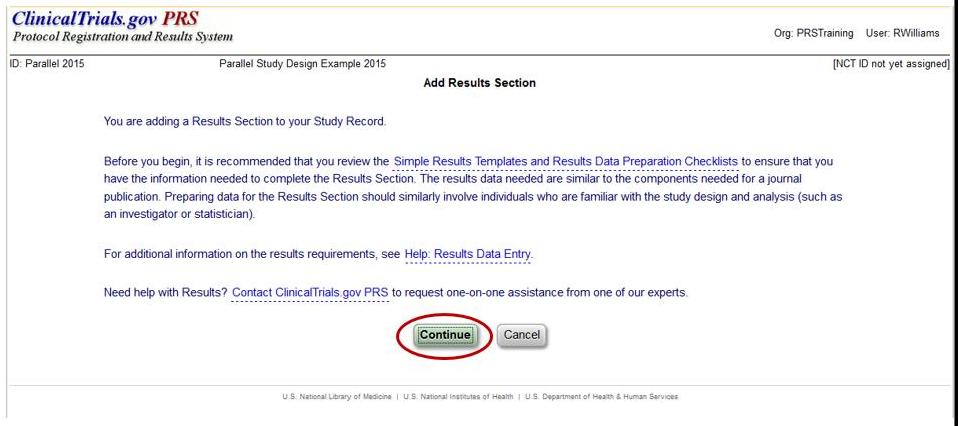
Add Results Section



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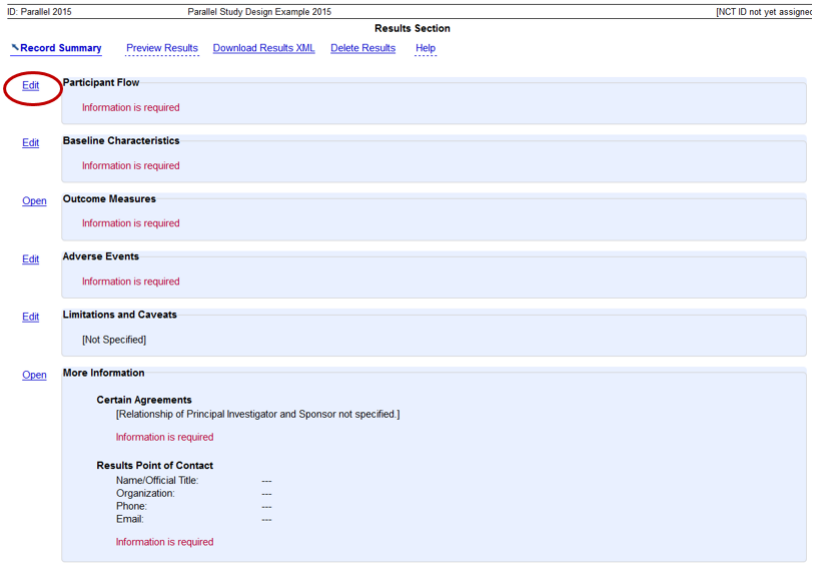
Results Section



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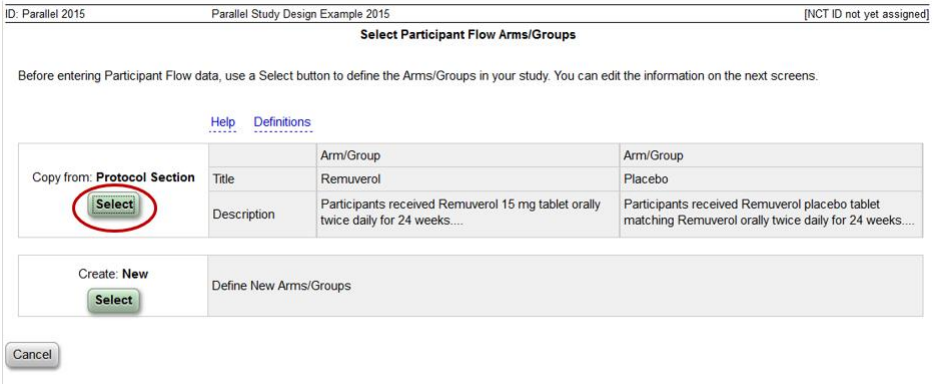
Select Participant Flow Arms/Groups



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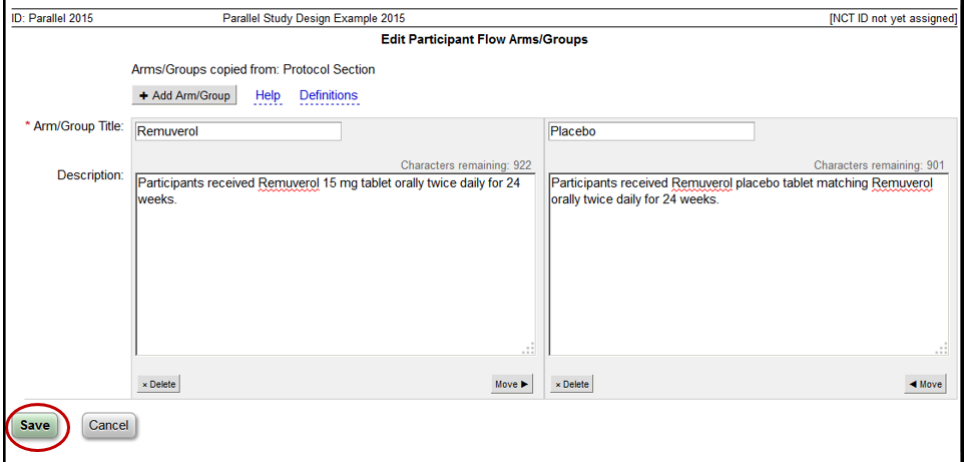
Edit Participant Flow Arms/Groups



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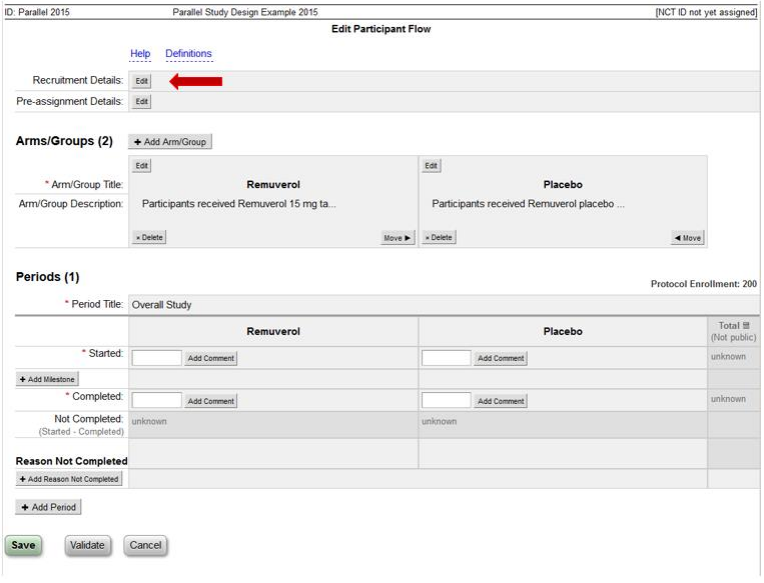
Edit Participant Flow



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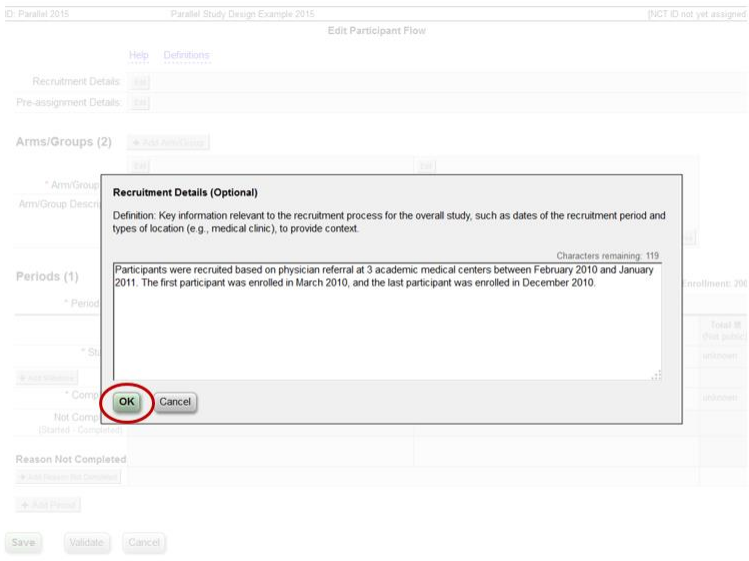
Edit Participant Flow (cont.)



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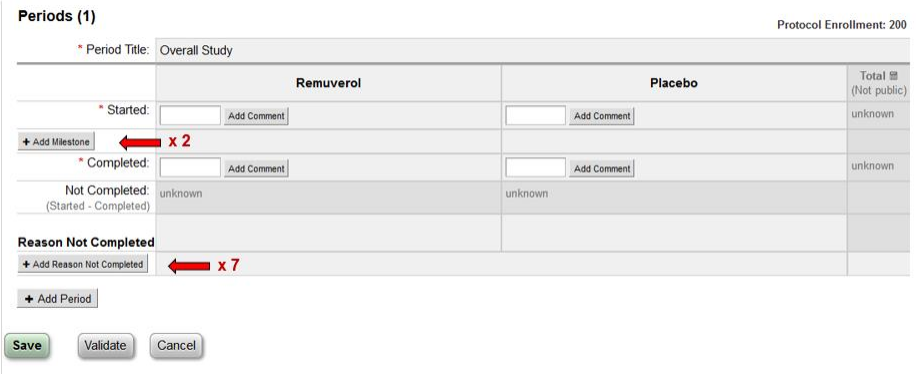
Edit Participant Flow (cont.)



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Edit Participant Flow (cont.)

Periods (1)

Protocol Enrollment: 200

* Period Title:	Overall Study		
	Remuverol	**Placebo**	**Total** (Not public)
* Started:	101 Add Comment	99 Add Comment	200
Additional Milestone: Per Protocol Population W × Delete ▼ Move	98 Add Comment	95 Add Comment	193
Additional Milestone: Per Protocol Population W × Delete ▲ Move	76 Add Comment	81 Add Comment	157
+ Add Milestone			
* Completed:	80 Add Comment	81 Add Comment	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 × Delete ▼ Move	10	8	unknown
Withdrawal by Subject × Delete ▲ Move ▼ Move	5	4	unknown
Protocol Violation × Delete ▲ Move ▼ Move	2	2	unknown
Lack of Efficacy × Delete ▲ Move ▼ Move	1	1	unknown
Physician Decision × Delete ▲ Move ▼ Move	1	1	unknown
Lost to Follow-up × Delete ▲ Move ▼ Move	1	2	unknown
Pregnancy × Delete ▲ Move	1	0	unknown
+ 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]

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 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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