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Participant Flow Module

Results Database Train-the-Trainer Workshop
October 2012

http://ClinicalTrials.gov

FDAAA - 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 = Food and Drug Administration Amendments Act of 2007

Description of the Participant Flow Module

- Tabular presentation of progress of research participants through each stage of trial
  - Table may consist of a single Period or multiple Periods, to represent different stages of the trial (e.g., “double-blind period,” “open-label period”)
  - Each participant is counted only once per Period
  - A participant’s progress is tracked through the trial’s sequence of events, generally in a single column, from “top” to “bottom” (on the vertical)

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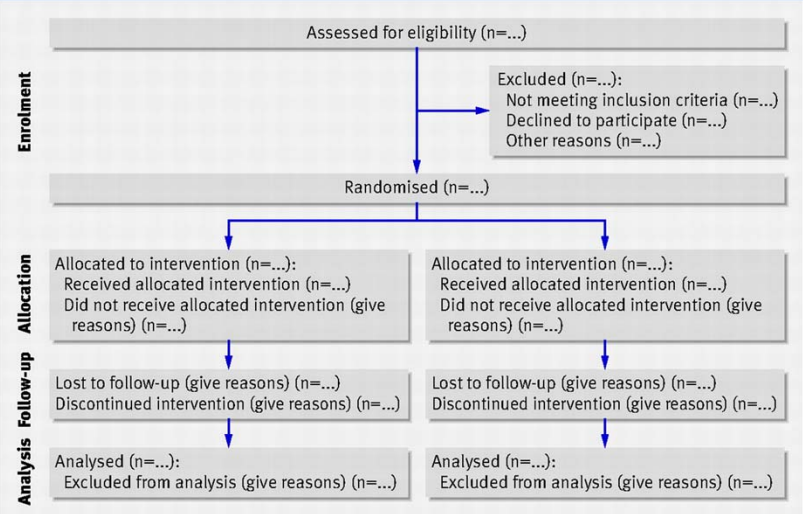
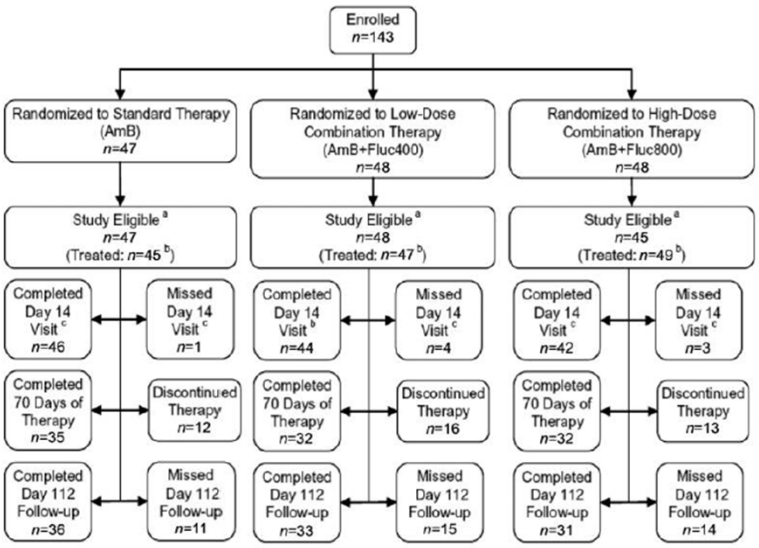
CONSORT Flow Diagram



Moher D et al. *BMJ* 2010;340:bmj.c869

BMJ

CONSORT Flow Diagram ("Figure 1")



Pappas PG, Chetchotisakd P, Larsen RA et al. Clin Infect Dis. 2009

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ClinicalTrials.gov Format

Participant Flow: Overall Study

	AmphoB Standard	AmphoB+Fluc400	AmphoB + Fluc800
STARTED	47 [1]	48 [2]	48 [3]
COMPLETED	36	33	31
NOT COMPLETED	11	15	17

[1] 47 subjects randomized; 45 subjects treated
[2] 48 subjects randomized; 47 subjects treated-2 subjects randomized to AmphoB rec'd AmphoB+Fluc400
[3] 48 subjects randomized; 49 treated-3 subjects randomized to AmphoB+Fluc400 rec'd AmphoB+Fluc800

NCT00145249

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Participant Flow Template

Recruitment Details				
Pre-assignment Details				
Period ①	Title: Overall Study			
	Arm/Group Title *	*	*	*
	Arm/Group Description ②			
		Number of Participants *	Number of Participants *	Number of Participants *
STARTED *		*	*	*
Milestone Title③	[*]	[*]	[*]	[*]
Milestone Title③	[*]	[*]	[*]	[*]
Milestone Title③	[*]	[*]	[*]	[*]
COMPLETED *		*	*	*
Reason Not Completed				
Adverse Event		[*]	[*]	[*]
Death		[*]	[*]	[*]
Lack of Efficacy		[*]	[*]	[*]
Lost to Follow-up		[*]	[*]	[*]
Physician Decision		[*]	[*]	[*]
Pregnancy		[*]	[*]	[*]
Protocol Violation		[*]	[*]	[*]
Withdrawal by Subject		[*]	[*]	[*]
Other Reason③	[*]	[*]	[*]	[*]
Other Reason③	[*]	[*]	[*]	[*]

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*

Edit Protocol Record: Enter Results

Add	**Record Log:**	None
Edit	**Unique Protocol ID:**	FDXAR -no results
	ClinicalTrials.gov ID:	
	Brief Title:	Example Parallel Study Design*****
		NOTE: A title this short may not be sufficiently descriptive.
	Official Title:	A 24-Week Double-Blind Trial of Remuverol in Adults With Condition A
	Study Type:	Interventional
	FDA Regulated Intervention?	Yes
	IND/IDE Protocol?	Yes
Edit	**Secondary IDs:**	

For completed studies: [Record must have a ClinicalTrials.gov ID (NCT number) before results can be entered.]
About Results Data Entry Delayed Results Posting...

[In PRS Test System only, results information can be entered for records that have errors or do not have an NCT number. Enter Results]

Edit	**IND/IDE Information:**	Grantor: CDER IND/IDE Number: 123456 Serial Number: Has Expanded Access? No

Pre-fill Results from Protocol

Results : Pre-fill Results from Protocol

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Results should typically be entered by someone who has detailed knowledge of the study design and anlysis (e.g. statistician, investigator.)

For additional information on the results database, see these resources:

- Guide to Results Data Entry - (CHEST. 2009 Jul;136(1):295-303) - article includes summary results reporting requirements, brief descriptions of the results database modules, and suggestions for preparing results submissions
- Results Review Criteria (DRAFT) (pdf) - describes items evaluated by ClinicalTrials.gov after results have been submitted.
- Helpful hints (pdf) - tips on entering results data, including three examples of common study models (parallel design, crossover design, and diagnostic accuracy studies), reporting measure types, including information on reporting outcomes measured with a scale.
- Presentations with audio and slides relevant to providing results data to ClinicalTrials.gov:
  - Results: Participant Flow Module
  - Results: Baseline Characteristics Module
  - Results: Outcome Measures and Statistical Analyses Module
  - Results: Adverse Events Module

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Pre-fill Results from Protocol (cont.)

The protocol information shown below will be copied into the results section of the record. Please review the information carefully. If the information is not correct, you can cancel and edit the protocol record. The information may also be edited in the results section.

Protocol Primary Outcome Measure	• **Change from baseline in pain on the 11-point Short Pain Scale (SPS-11) at week 24** [Week 24]
Protocol Secondary Outcome Measures	• **Number of patients with a 50 percent or greater reduction in pain as determined by SPS-11 at week 12** [Week 12] • **Number of patients with a 50 percent or greater reduction in pain as determined by SPS-11 at week 24** [Week 24] • **Patient's Overall Pain Relief (POPR) at week 24** [Week 24]
Protocol Other Pre-specified Outcome Measures	Protocol has no other pre-specified outcomes.

Create Results section of record FDXAR -no results?

OK Cancel

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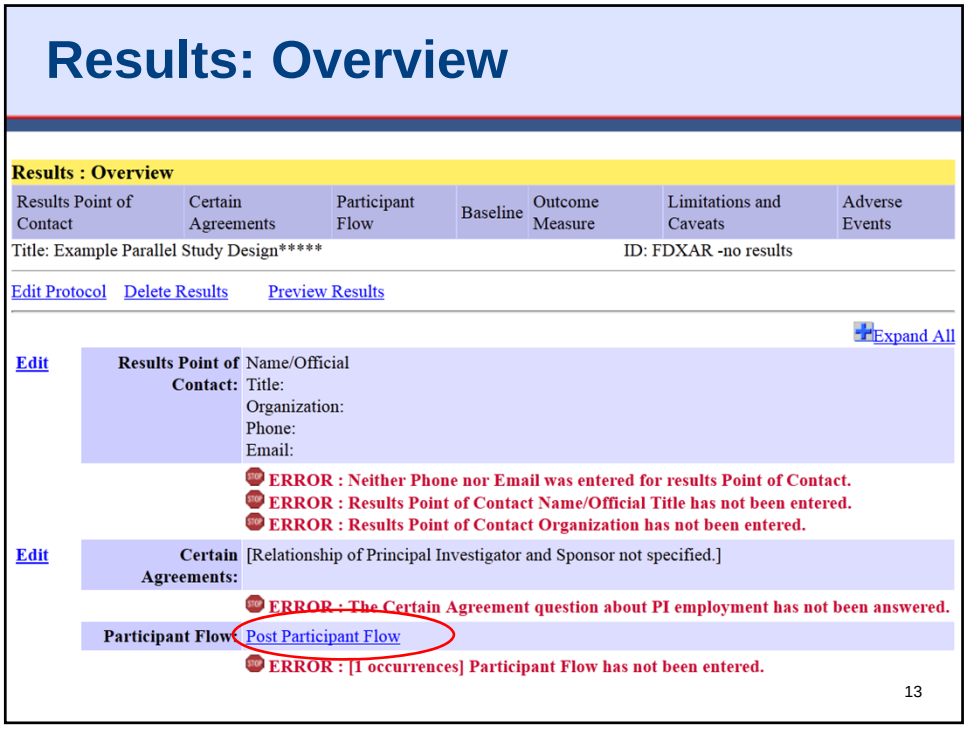
Results: Overview



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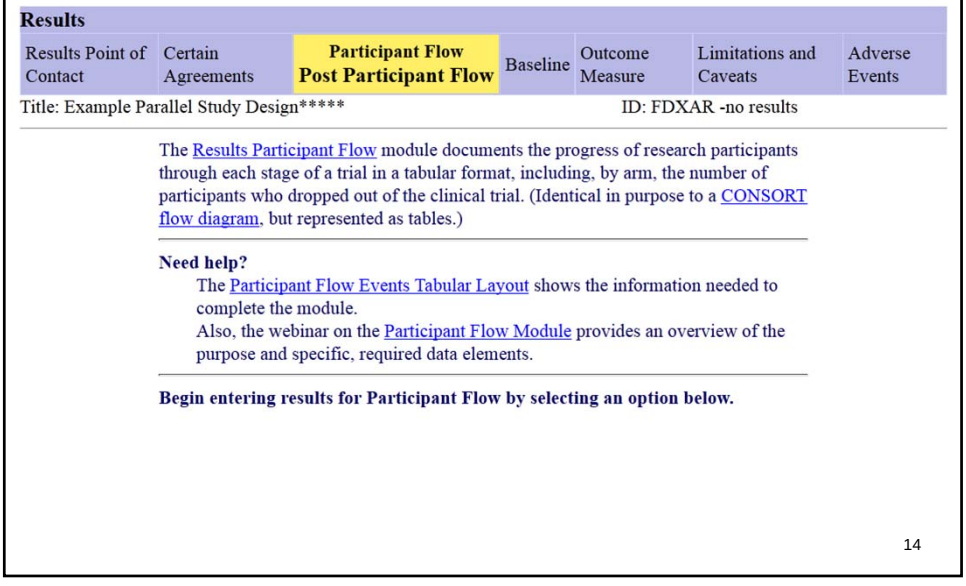
Post Participant Flow



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Post Participant Flow (cont.)

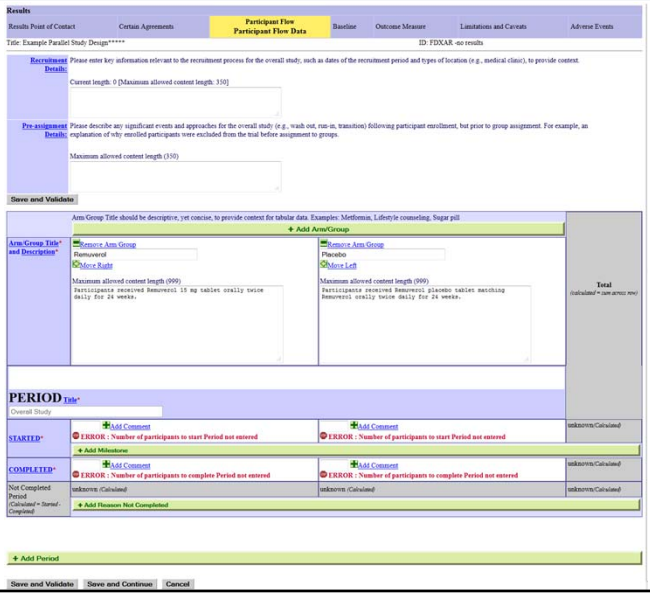
Arm/Group*

The Arm/Group Titles and Descriptions will likely require editing and you can do this on the next screen.

(•) **Use the 2 Arm/Groups** from protocol	**Arm/Group Title**	Remuverol	Placebo
	Arm/Group 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.
( ) **Use the 2 Arm/Groups and Intervention Name(s) and Description(s)** from protocol	**Arm/Group Title**	Remuverol	Placebo
	Arm/Group Description	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol : Remuverol 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo : Remuverol placebo tablet
( ) **Define New Arm/Groups**			

Continue Cancel

Participant Flow Data



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Participant Flow Data (cont.)

Recruitment Details: Please enter 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.

Maximum allowed content length (350)

```
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: Please describe any significant events and approaches for the overall study (e.g., wash out, run-in, transition) following participant enrollment, but prior to group assignment. For example, an explanation of why enrolled participants were excluded from the trial before assignment to groups.

Maximum allowed content length (350)

Save and Validate

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Participant Flow Data (cont.)

Arm/Group Title should be descriptive, yet concise, to provide context for tabular data. Examples: Metformin, Lifestyle counseling, Sugar pill

+ Add Arm/Group

Arm/Group Title* and Description*	Remove Arm/Group Remuverol Move Right Maximum allowed content length (999) Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.	Remove Arm/Group Placebo Move Left Maximum allowed content length (999) Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks.	Total (calculated = sum across row)
PERIOD Title* Overall Study			
STARTED*	Add Comment ERROR : Number of participants to start Period not entered	Add Comment ERROR : Number of participants to start Period not entered	unknown (Calculated)
x 2 →	+ Add Milestone		
COMPLETED*	Add Comment ERROR : Number of participants to complete Period not entered	Add Comment ERROR : Number of participants to complete Period not entered	unknown (Calculated)
Not Completed Period (Calculated = Started - Completed)	unknown (Calculated)	unknown (Calculated)	unknown (Calculated)
	+ Add Reason Not Completed		

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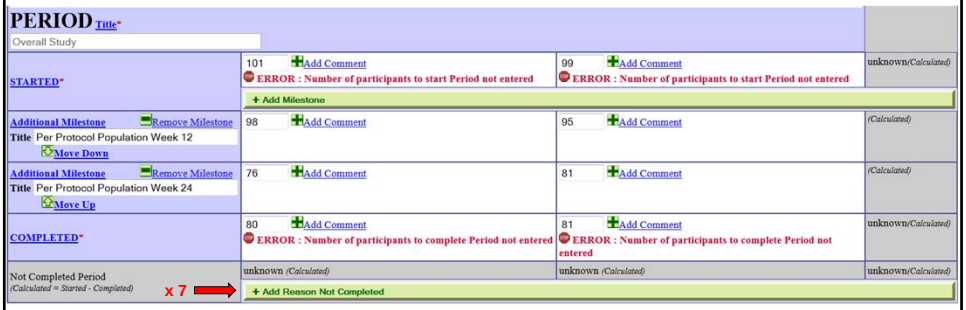
Participant Flow Data (cont.)



PERIOD Title*			
Overall Study			
STARTED*	101 Add Comment ERROR : Number of participants to start Period not entered	99 Add Comment ERROR : Number of participants to start Period not entered	unknown (Calculated)
	+ Add Milestone		
Additional Milestone Remove Milestone Title: Per Protocol Population Week 12 Move Down	98 Add Comment	95 Add Comment	(Calculated)
Additional Milestone Remove Milestone Title: Per Protocol Population Week 24 Move Up	76 Add Comment	81 Add Comment	(Calculated)
COMPLETED*	80 Add Comment ERROR : Number of participants to complete Period not entered	81 Add Comment ERROR : Number of participants to complete Period not entered	unknown (Calculated)
Not Completed Period (Calculated = Started - Completed) x 7	unknown (Calculated)	unknown (Calculated)	unknown (Calculated)
	+ Add Reason Not Completed		

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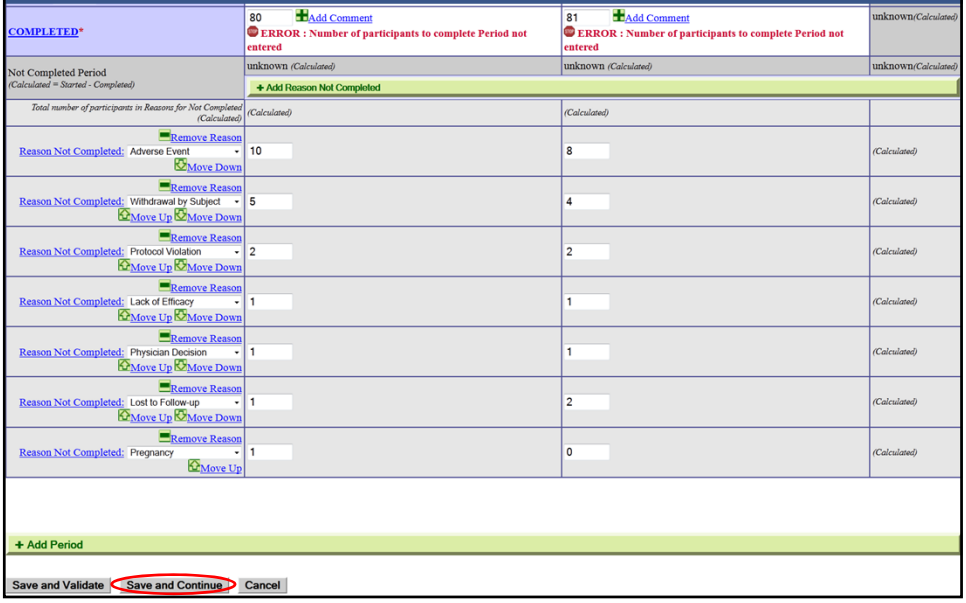
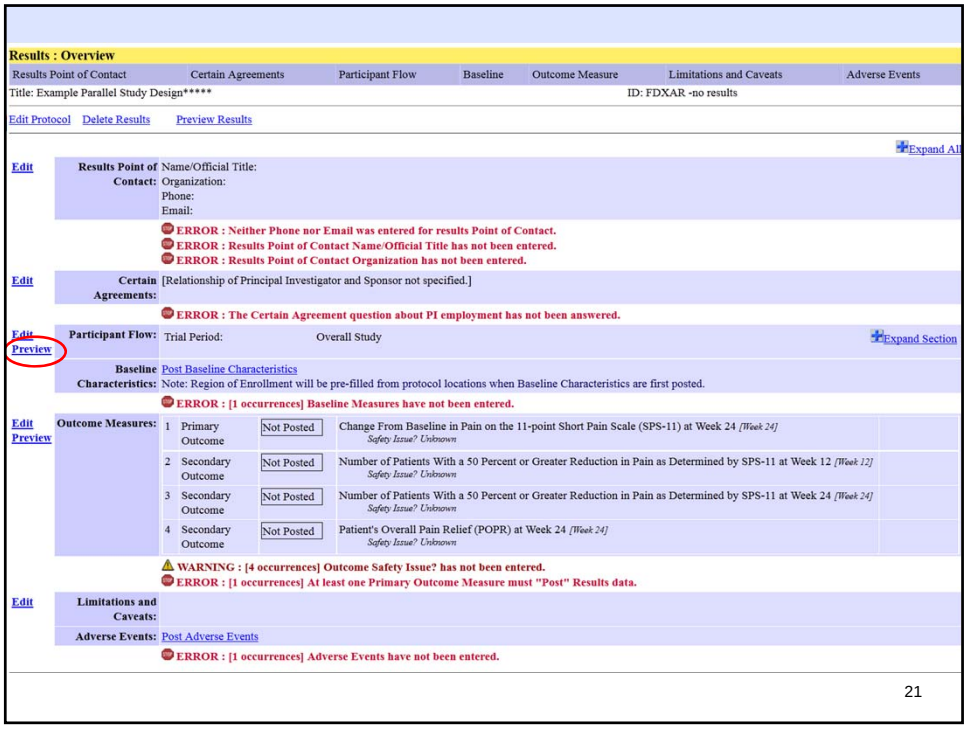
Participant Flow Data (cont.)



COMPLETED*	80 Add Comment ERROR : Number of participants to complete Period not entered	81 Add Comment ERROR : Number of participants to complete Period not entered	unknown (Calculated)
Not Completed Period (Calculated = Started - Completed)	unknown (Calculated)	unknown (Calculated)	unknown (Calculated)
	+ Add Reason Not Completed		
Total number of participants in Reasons for Not Completed (Calculated)	(Calculated)	(Calculated)	
Remove Reason Reason Not Completed: Adverse Event Move Down	10	8	(Calculated)
Remove Reason Reason Not Completed: Withdrawal by Subject Move Up Move Down	5	4	(Calculated)
Remove Reason Reason Not Completed: Protocol Violation Move Up Move Down	2	2	(Calculated)
Remove Reason Reason Not Completed: Lack of Efficacy Move Up Move Down	1	1	(Calculated)
Remove Reason Reason Not Completed: Physician Decision Move Up Move Down	1	1	(Calculated)
Remove Reason Reason Not Completed: Lost to Follow-up Move Up Move Down	1	2	(Calculated)
Remove Reason Reason Not Completed: Pregnancy Move Up	1	0	(Calculated)

+ Add Period

Save and Validate | Save and Continue | Cancel



Results : Overview

Results Point of Contact | Certain Agreements | Participant Flow | Baseline | Outcome Measure | Limitations and Caveats | Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Edit Protocol Delete Results Preview Results

Expand All

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

ERROR : Neither Phone nor Email was entered for results Point of Contact.
ERROR : Results Point of Contact Name/Official Title has not been entered.
ERROR : Results Point of Contact Organization has not been entered.

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

ERROR : The Certain Agreement question about PI employment has not been answered.

Edit Preview — **Participant Flow:** Trial Period: Overall Study — Expand Section

Baseline Characteristics: Post Baseline Characteristics
Note: Region of Enrollment will be pre-filled from protocol locations when Baseline Characteristics are first posted.

ERROR : [1 occurrences] Baseline Measures have not been entered.

Edit Preview — **Outcome Measures:**

1	Primary Outcome	Not Posted	Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24 *[Week 24]*	*Safety Issue? Unknown*
2	Secondary Outcome	Not Posted	Number of Patients With a 50 Percent or Greater Reduction in Pain as Determined by SPS-11 at Week 12 *[Week 12]*	*Safety Issue? Unknown*
3	Secondary Outcome	Not Posted	Number of Patients With a 50 Percent or Greater Reduction in Pain as Determined by SPS-11 at Week 24 *[Week 24]*	*Safety Issue? Unknown*
4	Secondary Outcome	Not Posted	Patient's Overall Pain Relief (POPR) at Week 24 *[Week 24]*	*Safety Issue? Unknown*

WARNING : [4 occurrences] Outcome Safety Issue? has not been entered.
ERROR : [1 occurrences] At least one Primary Outcome Measure must "Post" Results data.

Edit — **Limitations and Caveats:**

Adverse Events: Post Adverse Events

ERROR : [1 occurrences] Adverse Events have not been entered.

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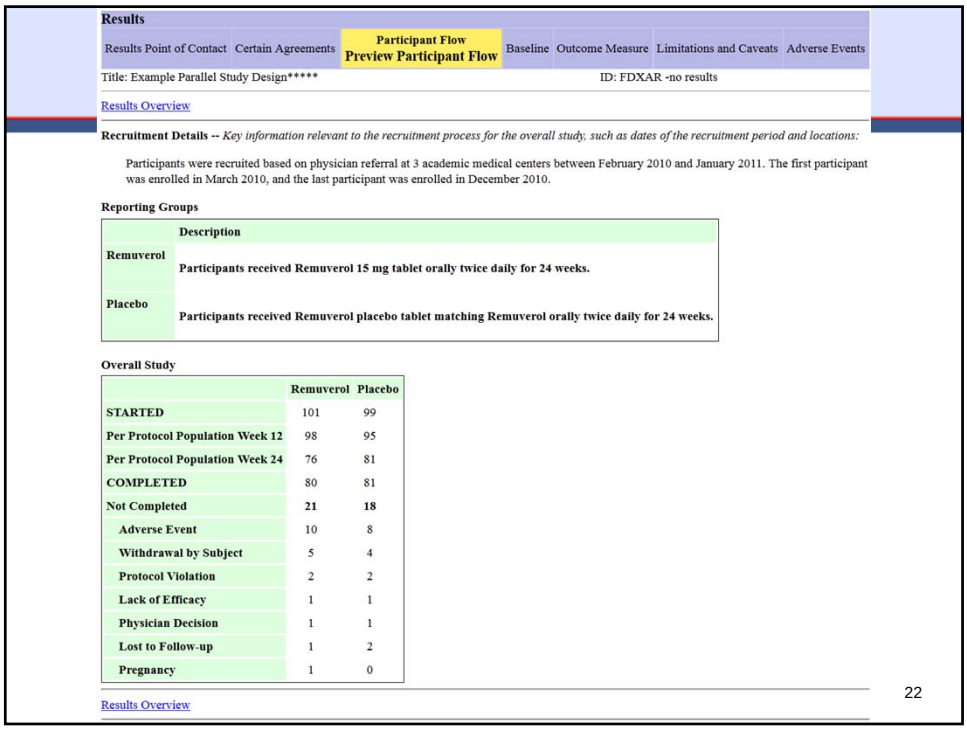

Results

Results Point of Contact | Certain Agreements | **Participant Flow** **Preview Participant Flow** | Baseline | Outcome Measure | Limitations and Caveats | Adverse Events

Title: Example Parallel Study Design***** ID: FDXAR -no results

Results Overview

Recruitment Details -- *Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations:*

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.

Reporting Groups

	Description
Remuverol	**Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.**
Placebo	**Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks.**

Overall Study

	Remuverol	Placebo
STARTED	101	99
Per Protocol Population Week 12	98	95
Per Protocol Population Week 24	76	81
COMPLETED	80	81
Not Completed	**21**	**18**
Adverse Event	10	8
Withdrawal by Subject	5	4
Protocol Violation	2	2
Lack of Efficacy	1	1
Physician Decision	1	1
Lost to Follow-up	1	2
Pregnancy	1	0

Results Overview

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Enter Participant Flow

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

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Additional Issues

- Trial reached the Primary Completion Date, but Study Completion Date not yet reached
- A different number of participants enrolled, screened, randomized, and received intervention

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