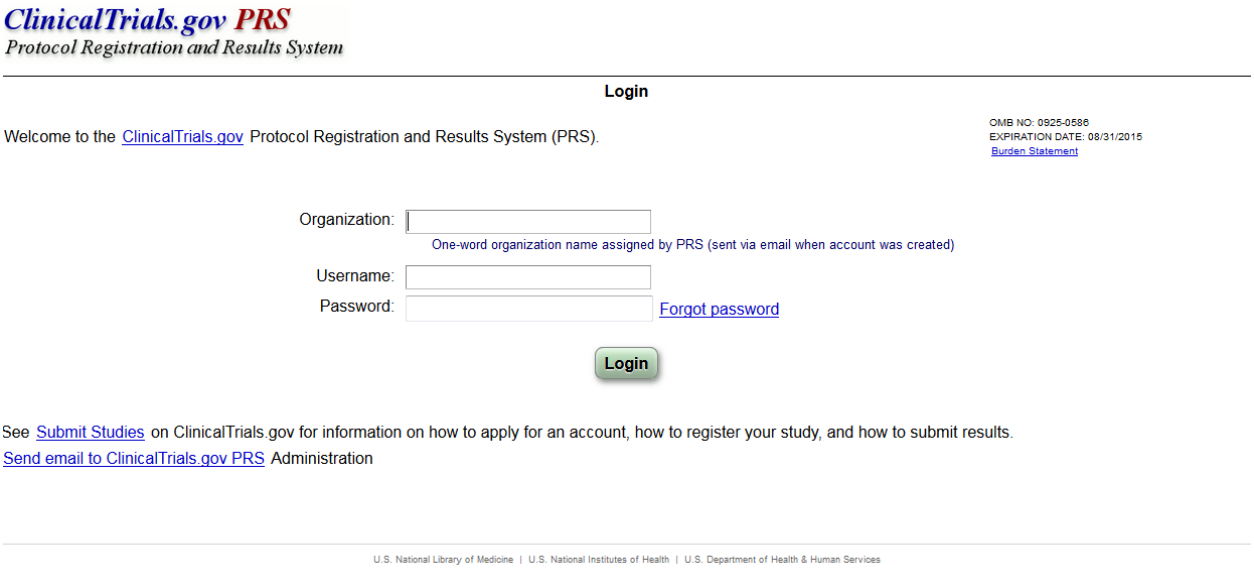
Attachment 4 - ClinicalTrials.gov Results Reporting Data Entry Screen Shots



ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the ClinicalTrials.gov Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 08/31/2015
Burden Statement

Organization:
One-word organization name assigned by PRS (sent via email when account was created)
Username:
Password: Forgot password

Login

See Submit Studies on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.
Send email to ClinicalTrials.gov PRS Administration

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OMB NO: 0925-0586
EXPIRATION DATE: 08/31/2015
Burden Statement

Public reporting burden for this collection of information is estimated to average 7.0 hours per response for initial registration, 2.0 hours for each of 8 updates to the registration information during the course of the trial, 25.0 hours per response for initial results submission, 8.0 hours for two substantive updates to the results information. These estimates include the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0586). Do not return the completed form to this address

Home > Record Summary > Results Section > Participant Flow > Edit

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Participant Flow

Help Definitions

Recruitment Details:	Edit
Pre-assignment Details:	Edit

Arms/Groups (2) + Add Arm/Group

	Edit	Edit
* Arm/Group Title:	**wonderdrug**	**placebo**
Arm/Group Description:	test test test	test test test
	× Delete Move ►	× Delete ◄ Move

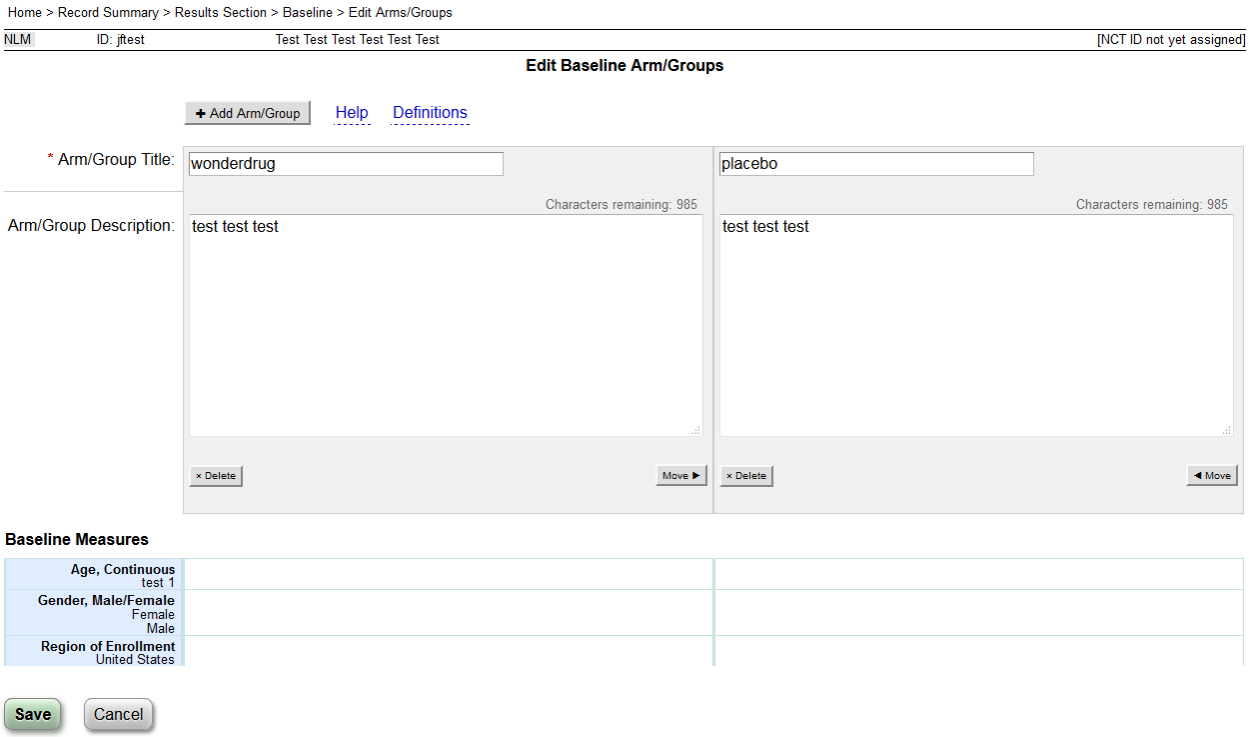
Periods (1)

Protocol Enrollment: 200

* Period Title:	Overall Study		
	wonderdrug	**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			
-- Select Reason Type -- × Delete			unknown
+ Add Reason Not Completed	Not Completed = unknown Total from all reasons = unknown	Not Completed = unknown Total from all reasons = unknown	

+ Add Period

Save Validate Cancel



Home > Record Summary > Results Section > Baseline > Edit Arms/Groups

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Baseline Arm/Groups

+ Add Arm/Group Help Definitions

	* Arm/Group Title:	Arm/Group Description:	
	wonderdrug	Characters remaining: 985 test test test	× Delete Move ►
	placebo	Characters remaining: 985 test test test	× Delete ◄ Move

Baseline Measures

Age, Continuous test 1		
Gender, Male/Female Female Male		
Region of Enrollment United States		

Save Cancel

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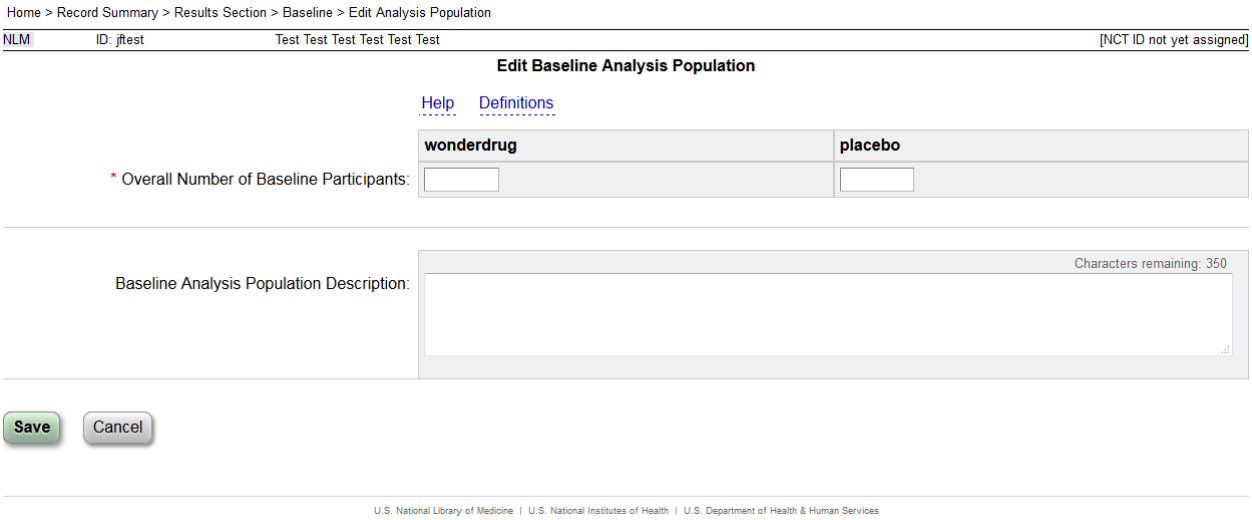

Home > Record Summary > Results Section > Baseline > Edit Analysis Population

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Baseline Analysis Population

Help Definitions

* Overall Number of Baseline Participants:	wonderdrug	placebo

Baseline Analysis Population Description:

Characters remaining: 350

Save Cancel

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Home > Record Summary > Results Section > Baseline > Edit Measure

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Baseline Measure

Help Definitions

* Baseline Measure Title:	Age, Continuous		
Baseline Measure Description:	Edit Additional information about the measure (e.g., description of scale)		
	wonderdrug	placebo	Total
Overall Number of Baseline Participants:	---	---	---
* Measure Type:	Mean		
* Measure of Dispersion:	Standard Deviation		
* Category Title: test 1	Mean / Standard Deviation	Mean / Standard Deviation	Mean / Standard Deviation
+ Add Category			
* Unit of Measure:	years Commonly reported units: years		

Save Validate Cancel

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Home > Record Summary > #ResultsBreadCrumbTitle() > Outcomes > Outcome Measure > Edit Data

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Outcome Measure Data

Help Definitions

* Outcome Measure Type:	Primary
* Outcome Measure Title:	Characters remaining: 227 Test Outcome Measure Title 1
Outcome Measure Description:	Characters remaining: 999
* Outcome Measure Time Frame:	5 weeks
(‡) Safety Issue?	No

Arms/Groups (1) + Add Arm/Group

* Arm/Group Title:	Edit **test**
Arm/Group Description:	test test test
* Number of Participants Analyzed:	100
Type of Units Analyzed	× Delete
Analysis Population Description:	Characters remaining: 350

Outcome Measure Data Table

* Measure Type:	Number
* Measure of Dispersion/Precision:	Not Applicable
	test
* Category Title: Title 1 (× Delete, ▼ Move)	**Number** 50
* Category Title: Title 2 (× Delete, ▲ Move)	**Number** 50
+ Add Category	
* Unit of Measure:	participants Commonly reported units: participants | years | units on a scale | percentage of <something>

Save | Validate | Cancel

* Required by ClinicalTrials.gov
‡ = FDAAA Required to comply with US FDA Amendments Act
(‡) = (FDAAA) May be required to comply with US FDA Amendments Act

Home > Record Summary > Results Section > Outcomes > Outcome Measure > Add Statistical Analysis

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Add Outcome Statistical Analysis

Primary Outcome	
Title:	test test test test test
Time Frame:	forever
Unit of Measure:	participants

Tip: Many of the data elements are optional and may be left blank. The minimum requirements are to enter either a P-Value OR an Estimation Parameter (e.g., Mean Difference, Odds Ratio). A Confidence Interval for the Estimation Parameter may also be entered.

Statistical Analysis Overview

Help Definitions

* Comparison Group Selection: Select the Outcome Measure Arms/Groups involved in the statistical analysis.
☐ test

Comments: (Optional) Additional details about the statistical analysis, such as null hypothesis and description of power calculation.
Characters remaining: 500

* Non-inferiority or Equivalence Analysis? -- Please Select --

Comments: If "Yes" (non-inferiority or equivalence analysis), describe details of the power calculation (if not previously provided), definition of non-inferiority margin, and other key parameters.
Characters remaining: 500

Statistical Test of Hypothesis

Help Definitions

P-Value: (If applicable)
(e.g. <0.01)

Comments: (Optional) Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the *a priori* threshold for statistical significance.
Characters remaining: 250

Method: (Required if a P-Value is entered)
-- Please Select -- If other, please specify:

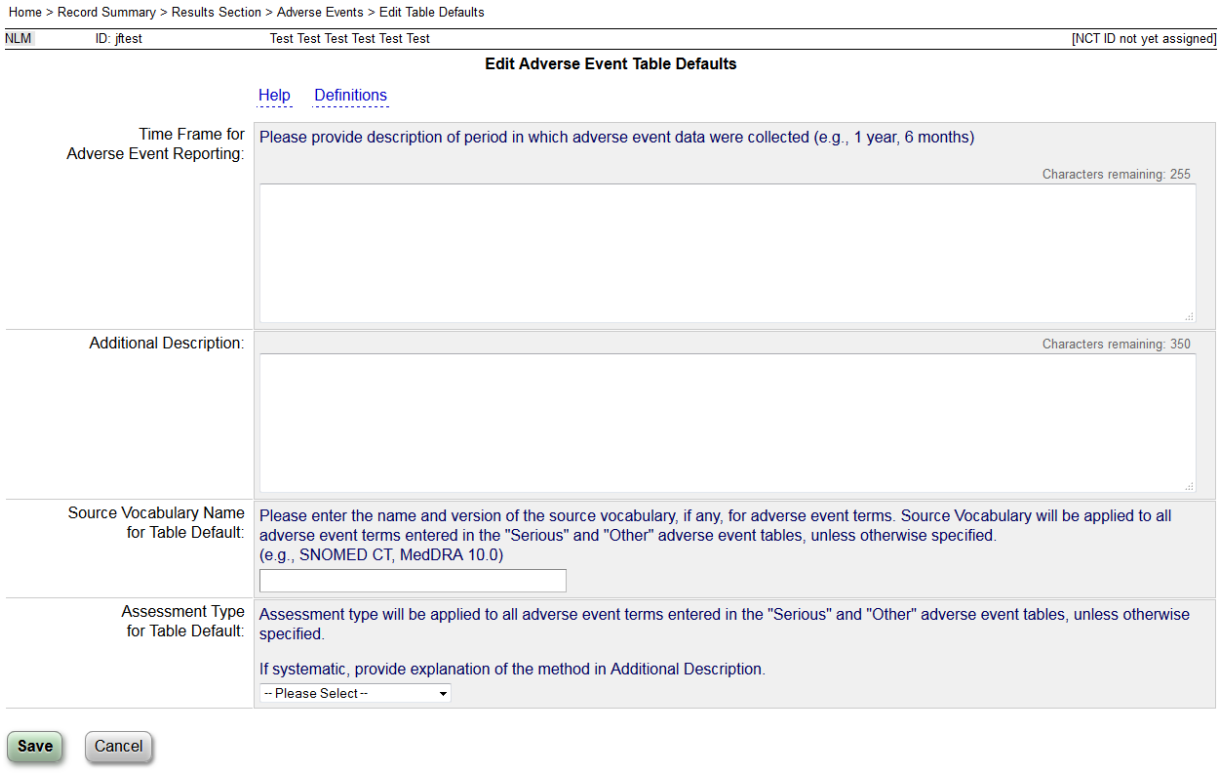
Comments: (Optional) Any other relevant information, such as adjustments or degrees of freedom.
Characters remaining: 150

Method of Estimation

Help Definitions

Estimation Parameter:	(If applicable) -- Please Select -- If other, please specify:
Estimated Value:	Provide the data for the Estimation Parameter.
Confidence Interval:	(If applicable) % Confidence Interval Number of sides 2-Sided Lower Limit: Upper Limit:
Parameter Dispersion Type and Dispersion Value:	(If applicable) -- Please Select --
Estimation Comments:	(Optional) Any other relevant estimation information, including the direction of the comparison (e.g., describe which arm or comparison group represents the numerator and denominator for relative risk). Characters remaining: 250

Save Validate Cancel


Home > Record Summary > Results Section > Adverse Events > Edit Table Defaults
NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]
Edit Adverse Event Table Defaults
Help Definitions
Time Frame for Adverse Event Reporting:
Please provide description of period in which adverse event data were collected (e.g., 1 year, 6 months)
Characters remaining: 255
Additional Description:
Characters remaining: 350
Source Vocabulary Name for Table Default:
Please enter the name and version of the source vocabulary, if any, for adverse event terms. Source Vocabulary will be applied to all adverse event terms entered in the "Serious" and "Other" adverse event tables, unless otherwise specified.
(e.g., SNOMED CT, MedDRA 10.0)
Assessment Type for Table Default:
Assessment type will be applied to all adverse event terms entered in the "Serious" and "Other" adverse event tables, unless otherwise specified.
If systematic, provide explanation of the method in Additional Description.
-- Please Select --
Save
Cancel
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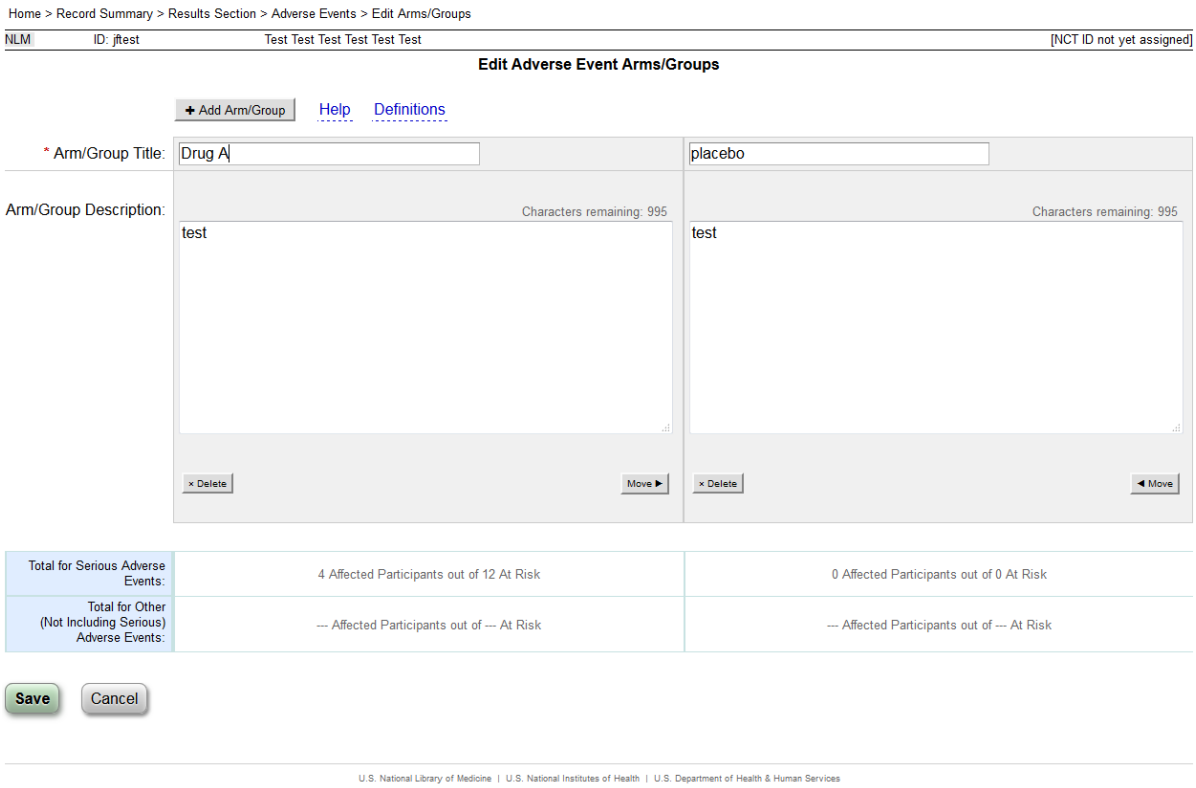
Home > Record Summary > Results Section > Adverse Events > Edit Arms/Groups
NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]
Edit Adverse Event Arms/Groups
+ Add Arm/Group
Help Definitions
* Arm/Group Title:
Drug A
placebo
Arm/Group Description:
Characters remaining: 995
test
Characters remaining: 995
test
× Delete
Move ▶
× Delete
◀ Move
Total for Serious Adverse Events:
4 Affected Participants out of 12 At Risk
0 Affected Participants out of 0 At Risk
Total for Other (Not Including Serious) Adverse Events:
--- Affected Participants out of --- At Risk
--- Affected Participants out of --- At Risk
Save
Cancel
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Home > Record Summary > Results Section > Adverse Events > Edit Serious Total

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Serious Adverse Event Total

Help Definitions

Serious Adverse Event(s)	wonderdrug	placebo
* Total Number Affected:	4 participants	0 participants
* Total Number At Risk:	12 participants	0 participants

Tip: The Total Number of Participants at Risk is typically equal to the Number of Participants who Started the first Period in the Participant Flow. Preview Participant Flow

Save Validate Cancel

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Home > Record Summary > Results Section > Adverse Events > Edit Serious Data

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Serious Adverse Event Data

Table includes 1 Serious Adverse Event terms

Help Definitions

		wonderdrug	placebo
	Total Number of Participants Affected/At Risk:	**4/12**	**3/12**
Edit death Blood and lymphati... × Delete	* Affected /At Risk:	4 /12 Edit	3 /12 Edit
	Number of Events:		

✚ Add Serious Adverse Event

Save Validate Cancel

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Home > Record Summary > Results Section > Adverse Events > Edit Threshold

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Frequency Threshold for Reporting Other (Not Including Serious) Adverse Events

Help Definitions

* Frequency Threshold for Reporting Other Adverse Event:	Enter a number between 0 (no threshold; all events reported) and 5 (only events occurring in greater than 5% of participants in any Arm/Group are reported). %

Save Cancel

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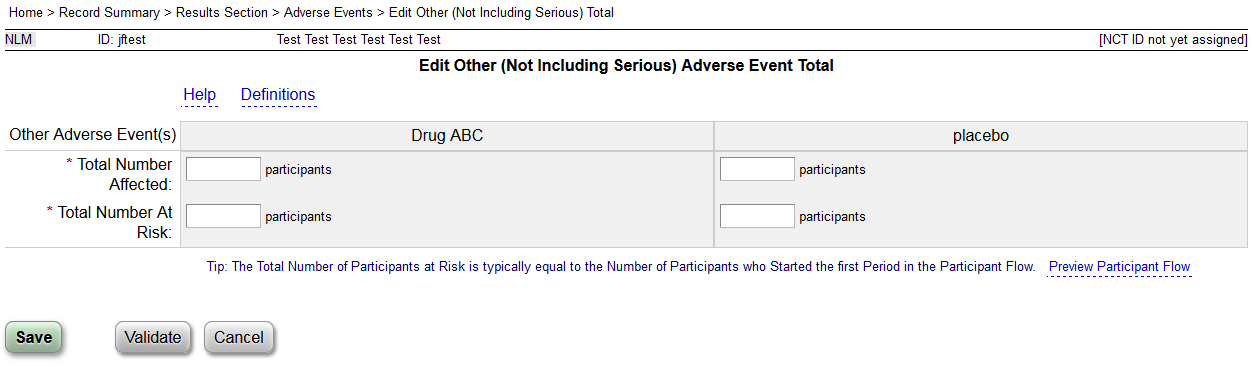

Home > Record Summary > Results Section > Adverse Events > Edit Other (Not Including Serious) Total

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Other (Not Including Serious) Adverse Event Total

Help Definitions

Other Adverse Event(s)	Drug ABC	placebo
* Total Number Affected:	participants	participants
* Total Number At Risk:	participants	participants

Tip: The Total Number of Participants at Risk is typically equal to the Number of Participants who Started the first Period in the Participant Flow. Preview Participant Flow

Save Validate Cancel

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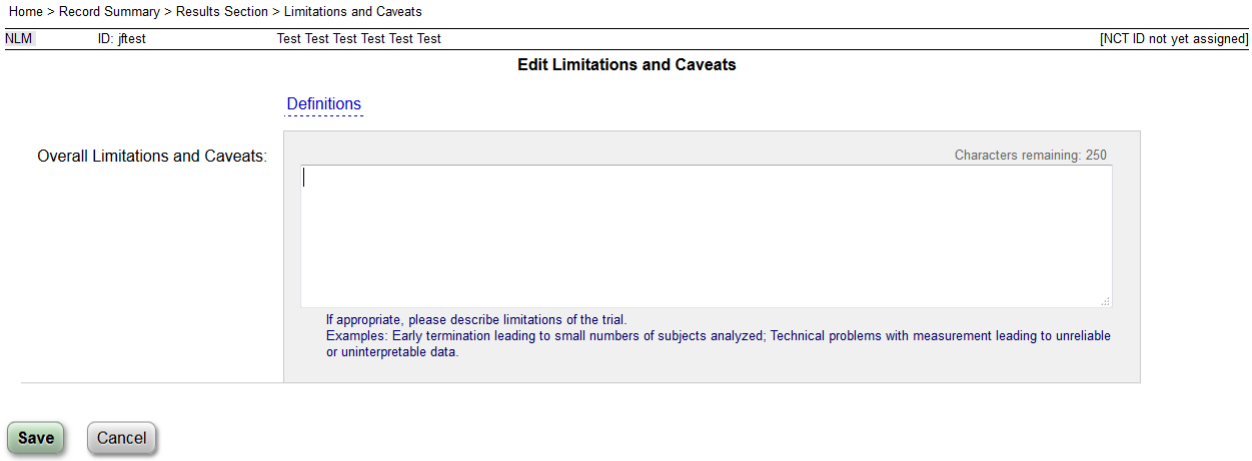

Home > Record Summary > Results Section > Limitations and Caveats

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Limitations and Caveats

Definitions

Overall Limitations and Caveats:

Characters remaining: 250

If appropriate, please describe limitations of the trial.
Examples: Early termination leading to small numbers of subjects analyzed; Technical problems with measurement leading to unreliable or uninterpretable data.

Save Cancel

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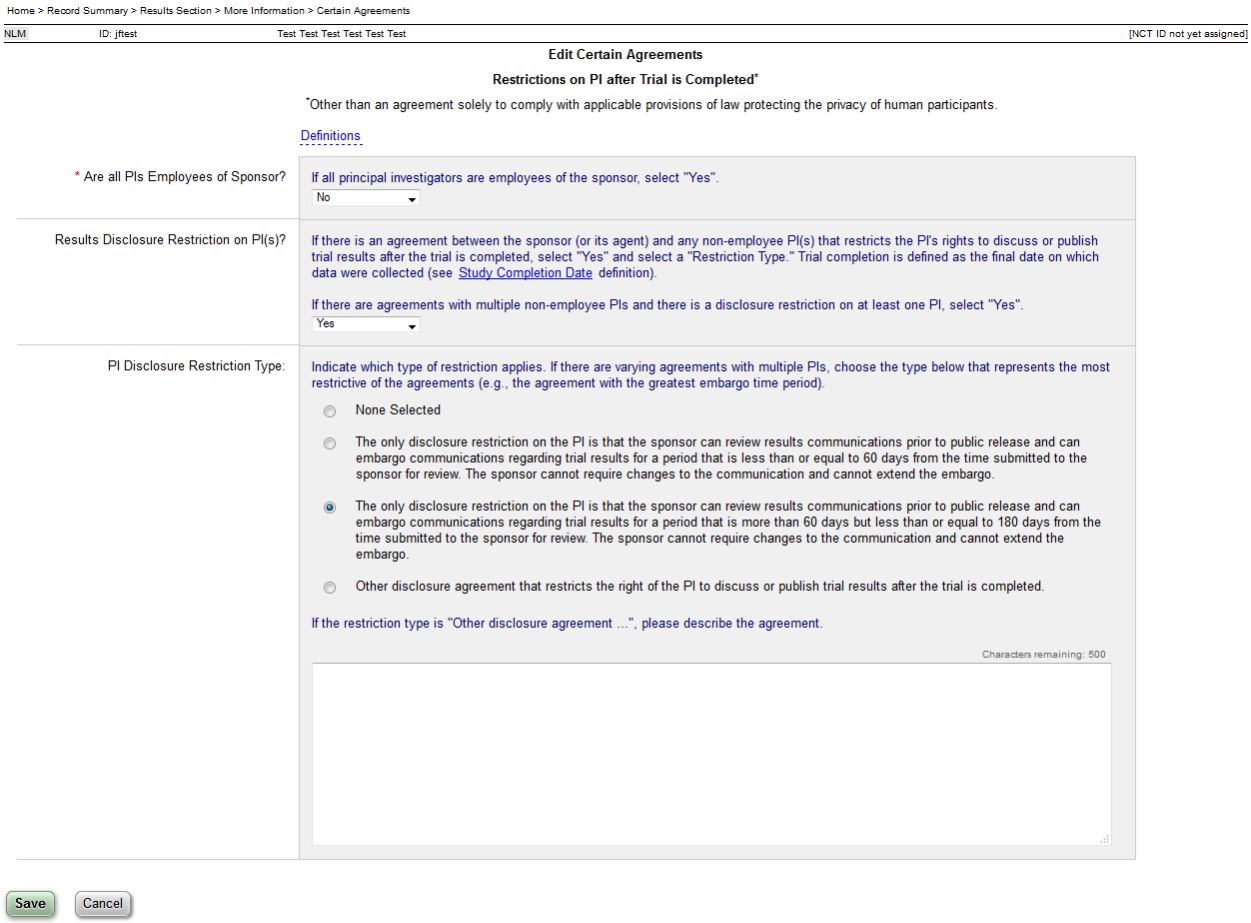

Home > Record Summary > Results Section > More Information > Certain Agreements

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Certain Agreements

Restrictions on PI after Trial is Completed*

*Other than an agreement solely to comply with applicable provisions of law protecting the privacy of human participants.

Definitions

* Are all PIs Employees of Sponsor?

If all principal investigators are employees of the sponsor, select "Yes".

No

Results Disclosure Restriction on PI(s)?

If there is an agreement between the sponsor (or its agent) and any non-employee PI(s) that restricts the PI's rights to discuss or publish trial results after the trial is completed, select "Yes" and select a "Restriction Type." Trial completion is defined as the final date on which data were collected (see Study Completion Date definition).

If there are agreements with multiple non-employee PIs and there is a disclosure restriction on at least one PI, select "Yes".

Yes

PI Disclosure Restriction Type:

Indicate which type of restriction applies. If there are varying agreements with multiple PIs, choose the type below that represents the most restrictive of the agreements (e.g., the agreement with the greatest embargo time period).

- None Selected
- The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.
- The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.
- Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

If the restriction type is "Other disclosure agreement ...", please describe the agreement.

Characters remaining: 500

Save Cancel

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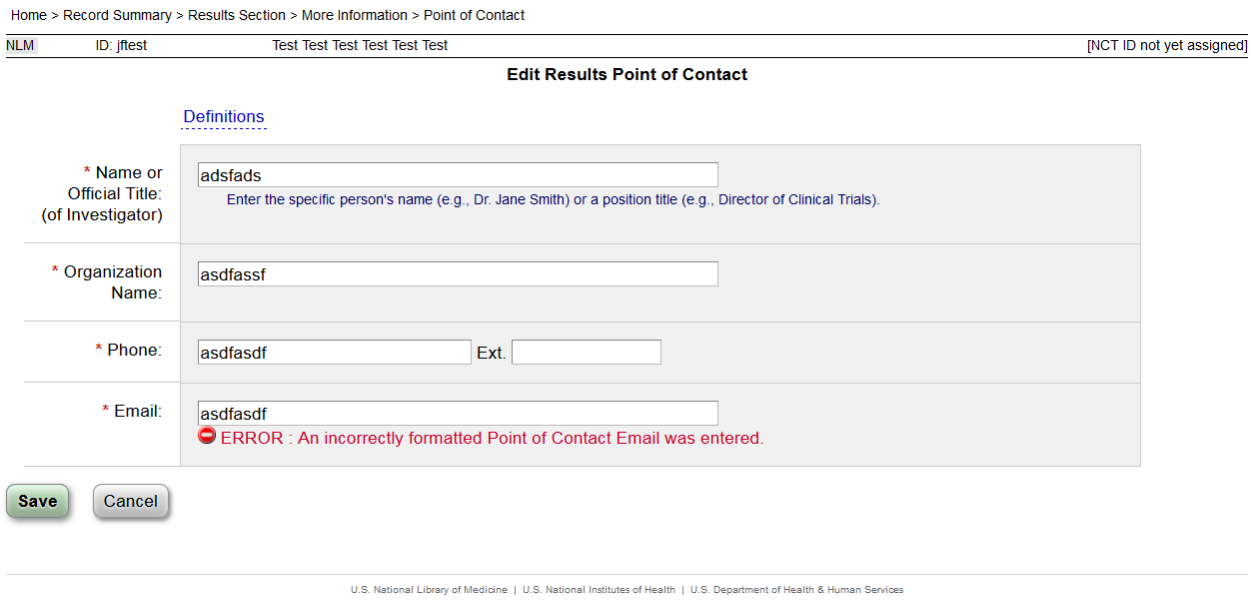

Home > Record Summary > Results Section > More Information > Point of Contact

NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned]

Edit Results Point of Contact

Definitions

* Name or Official Title: (of Investigator)

adsfads

Enter the specific person's name (e.g., Dr. Jane Smith) or a position title (e.g., Director of Clinical Trials).

* Organization Name:

asdfassf

* Phone:

asdfasdf Ext.

* Email:

asdfasdf

ERROR : An incorrectly formatted Point of Contact Email was entered.

Save Cancel

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