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

	Login	
Welcome to the <u>ClinicalTrials.gov</u> Protocol Registration	and Results System (PRS).	OME NO: 0925-0586 EXPIRATION DATE: 08/31/2015 Surden Statement
Organization:	One-word organization name assigned by PRS (sent via email when acc	count was created)
Username:		
Password:	Forgot password	
See <u>Submit Studies</u> on ClinicalTrials.gov for information Send email to ClinicalTrials.gov PRS Administration	Login on how to apply for an account, how to register your study, and	d how to submit results.

OMB NO: 0925-0586

EXPIRATION DATE: 08/31/2015

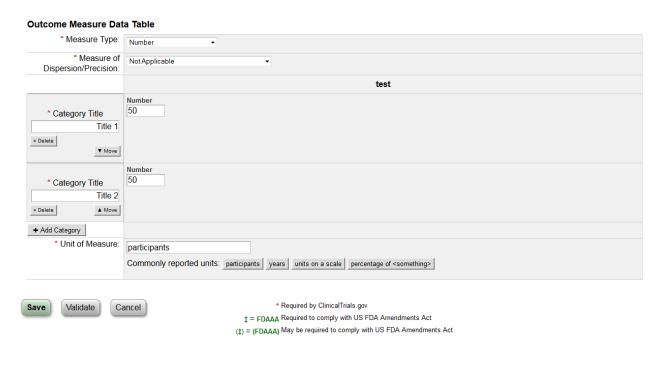
Burden Statement

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

/ID: jftest	Test Test Test Test 1	Test Test		[NCT ID not yet assigne
		Edit Participant	Flow	
	Help Definitions			
Recruitment Details:	Edit			
Pre-assignment Details:	Edit			
(0				
Arms/Groups (2)	+ Add Arm/Group			
* A (O Till	Edit	deada	Edit	
* Arm/Group Title: Arm/Group Description:	test test test	wonderdrug	placebo test test test	
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Home > F	Record Summary > F	Results Section > Baselin	e > Edit A	rms/Groups						
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					Ealt E	Baseline Arm/Grou	ps			
		+ Add Arm/Group	Help	Definitions						
* /	Arm/Group Title:	wonderdrug					placebo			
							piacooo			
Arm/Gro	oup Description:	test test test			Cha	aracters remaining: 985	test test test		Characters re	maining: 985
		× Delete				Move ▶	× Delete			◄ Move
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Save	Cancel									
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NLM	ID: jftest		Test Test						[NCT ID no	t yet assigned
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									o	
	Baseline A	Analysis Population I	Descripti	on:					Characters ren	naining: 350
Save	Cancel									

Home > Record Summary > Results Section > Baseline > Edit Measure NLM ID: jftest 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 Total placebo Overall Number of Baseline Participants: * Measure Type: * Measure of Dispersion: Standard Deviation * Category Title test 1 Standard Deviation Standard Deviation Standard Deviation + Add Category * Unit of Measure: years Commonly reported units: years Save Validate Cancel U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services Home > Record Summary > #ResultsBreadCrumbTitle() > Outcomes > Outcome Measure > Edit Data ID: jftest Test Test Test Test Test [NCT ID not yet assigned] Outcome Measure Data Help Definitions * Outcome Measure Type: Characters remaining: 227 * Outcome Measure Title: Test Outcome Measure Title 1 Characters remaining: 999 Outcome Measure Description: * Outcome Measure Time 5 weeks Frame: (‡) Safety Issue? Arms/Groups (1) + Add Arm/Group Edit * Arm/Group Title: test Arm/Group Description: test test test * Number of Participants 100 Analyzed: Type of Units Analyzed × Delete Analysis Population Characters remaining: 350 Description:



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

Add Outcome Statistical Analysis

Pr	imary Outcome
Title:	test test test test
Time Frame:	forever
Unit of Measure:	participants

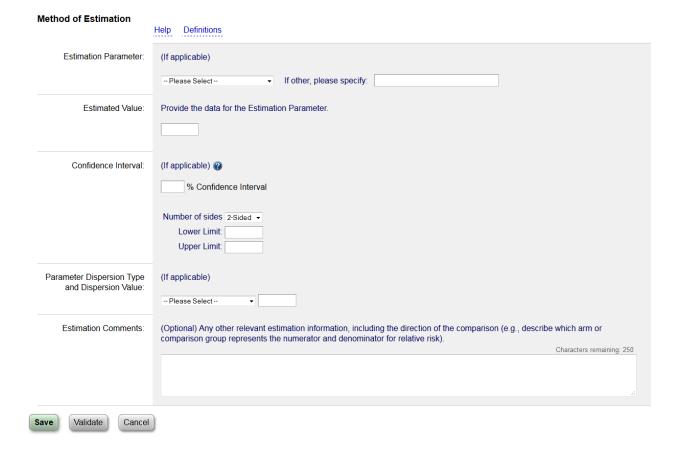
Tip: Many of the data elements are optional and may be left blank. The minimum requirements are to enter either a P-Value OR an Estimation Parameter (e.g., Mean Difference, Odds Ratio). A Confidence Interval for the Estimation Parameter may also be entered.

Statistical Analysis Overview

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



Home > Record Summary > Results Section > Adverse Events > Edit Table Defaults NLM ID: jftest Test Test Test Test Test [NCT ID not yet assigned] **Edit Adverse Event Table Defaults** Help Definitions Time Frame for Please provide description of period in which adverse event data were collected (e.g., 1 year, 6 months) Adverse Event Reporting: Characters remaining: 255 Additional Description: Characters remaining: 350 Source Vocabulary Name 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. for Table Default: (e.g., SNOMED CT, MedDRA 10.0) Assessment Type Assessment type will be applied to all adverse event terms entered in the "Serious" and "Other" adverse event tables, unless otherwise for Table Default: specified. If systematic, provide explanation of the method in Additional Description. -- Please Select --Save Cancel U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services Home > Record Summary > Results Section > Adverse Events > Edit Arms/Groups NLM ID: jftest 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 Characters remaining: 995 test test × Delete × 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

NLM	ID: jftest	Test Te	st Test Test Test			[NCT ID not yet assigned	
			Edit Seri	ious Adverse Event Total			
		Help Definition	ns .				
Serious A	dverse Event(s)		wonderdrug		pl	acebo	
* Total Nu	umber Affected:	4 partici	pants	0	participants		
* Total N	lumber At Risk:	12 partici	pants	0	participants		
		Tip: The Total Nu	mber of Participants at Risk is typically eq	ual to the Number of Participants	who Started the first Period in the Pa	rticipant Flow. Preview Participant Flow	
Save	Validate	Cancel					
			U.S. National Library of Medicine U.S. Nat	tional Institutes of Health U.S. Denartment	of Health & Human Services		
Home > Red	cord Summary > Re	sults Section > Adver	se Events > Edit Serious Data				
NLM	ID: jftest	Test Te	st Test Test Test Test			[NCT ID not yet assigned	
			Edit Seri	ious Adverse Event Data			
Table inc	ludes 1 Serious	Adverse Event te	ms				
			Help Definitions				
			wonderdru	ıg	plac	ebo	
	Total Number of Participants Affected / At Risk:		4/12		3/12		
Edit		ected /At Risk:	4 /12	Edit	3 /12	2 Edit	
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+ Add Se	rious Adverse Eve	nt					
Save	Validate	Cancel					
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			it Frequency Threshold for Repo	orting Other (Not Including	g Serious) Adverse Events	į sasta sastą sastą	
		Help	Definitions				
* F	requency Thres	hold for Enter a	number between 0 (no threshold; a	III events reported) and 5 (c	nly events occurring in greater	than 5% of participants in any	
Reportin	g Other Adverse	Event: Arm/Gro	oup are reported).				
			%				
Save	Cancel						

	Test Test Test Test Test	[NCT ID not yet assigned
	Edit Other (Not Ir	ncluding Serious) Adverse Event Total
Help	o Definitions	
Other Adverse Event(s)	Drug ABC	placebo
* Total Number Affected:	participants	participants
* Total Number At Risk:	participants	participants
	ip: The Total Number of Participants at Risk is typically ec	ual to the Number of Participants who Started the first Period in the Participant Flow. Preview Participant Flow
	U.S. National Library of Medicine U.S.	National Institutes of Health U.S. Department of Health & Human Services
Home > Record Summary > Result	ts Section > Limitations and Caveats	
NLM ID: jftest	Test Test Test Test Test	[NCT ID not yet assigned
	Edit	Limitations and Caveats
	B 6 W	
	Definitions	
Overall Limitations and C		Characters remaining: 250
Overall Limitations and C	Caveats:	ns of the trial.
Overall Limitations and C	Caveats:	ati

Home > Record Summary > Results Section > More Information > Certain Agreements NLM ID: jftest Test Test Test Test Test Test [NCT ID not yet assigned] **Fdit 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. * Are all PIs Employees of Sponsor? If all principal investigators are employees of the sponsor, select "Yes". 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 <u>Study Completion Date</u> definition). Results Disclosure Restriction on PI(s)? If there are agreements with multiple non-employee PIs and there is a disclosure restriction on at least one PI, select "Yes". Indicate which type of restriction applies. If there are varying agreements with multiple Pls, choose the type below that represents the most restrictive of the agreements (e.g., the agreement with the greatest embargo time period). PI Disclosure Restriction Type: 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 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 Cancel Save 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 adsfads Official Title: Enter the specific person's name (e.g., Dr. Jane Smith) or a position title (e.g., Director of Clinical Trials). (of Investigator)

