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

Login

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

OMB NO: 0925-0586
EXPIRATION DATE: 04/30/2012
Burden Statement

Organization:
Username:
Password: Forgot password

Login

PRS account registration information

Send email to ClinicalTrials.gov Administration

OMB NO: 0925-0586
EXPIRATION DATE: 04/30/2012
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, 10.0 hours per response for initial results reporting, and 5.0 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.

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Results

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

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Investigator's Name or Official Title:*	Enter the specific person's name (e.g., Dr. Jane Smith) or a position title (e.g., Director of Clinical Trials).
Organization Name:*	
Phone:*	ext.
Email:*	

OK Cancel

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Results

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

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

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" and skip the remaining questions. -- Please Select --
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" and answer the remaining question. -- Please Select -- If "No", skip the following question.
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. Maximum allowed content length (500)

OK Cancel

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Results

Results Point of Contact	Certain Agreements	**Participant Flow** **Edit Pre-assignment Description**	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

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)

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)

OK Cancel

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Results

Results Point of Contact	Certain Agreements	**Participant Flow** **Edit Milestone Data in Period**	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Please enter the **number of participants** for each milestone and any related comments

Overall Study	Combo	Placebo
STARTED	* [Add Comment]	* [Add Comment]
COMPLETED	* [Add Comment]	* [Add Comment]
Comments:		

Prefill Number of Baseline Participants: Select yes if you would like the number of baseline participants to equal the number of participants who started this period.

Yes, number of baseline participants equals number to start this period. No, change only participant flow

OK Cancel

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Results

Results Point of Contact	Certain Agreements	**Participant Flow** **Edit Reason Not Completed Data for Period**	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Please enter the number of participants to drop or withdraw due to each reason. Include each participant only once. The sum across all reasons in a group should equal the total not completed for the group.

Overall Study	Combo	Placebo
	Number Participants	**Number Participants**
Total Not Completed	10 *(Calculated=Started - Completed Milestone)*	10 *(Calculated=Started - Completed Milestone)*
Adverse Event	*	*
Lost to Follow-up	*	*

OK Cancel

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Results

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

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Number of Participants Started First Participant Flow Period	**Combo**	**Placebo**	**Total** *(calculated)*
	250	260	510

	Combo	Placebo
Overall Number of Baseline Participants *		

OK Cancel

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Results

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

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Age Categorical

Overall Number of Baseline Participants	250	260	510
Age Categorical *	**Combo**	**Placebo**	**Total** *(=sum across Arm/Groups)*
	Number	**Number**	**Number**
<=18 years *Units: participants*			*200 (Calculated)*
Between 18 and 65 years *Units: participants*			*210 (Calculated)*
>=65 years *Units: participants*			*100 (Calculated)*
Total (=sum across categories)	*250.0 (Calculated)*	*260.0 (Calculated)*	*(Calculated)*

OK Cancel Re-calculate Totals

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Results

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

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Gender, Male/Female

Overall Number of Baseline Participants	250	260	510
Gender, Male/Female *	**Combo**	**Placebo**	**Total** *(=sum across Arm/Groups)*
	Number	**Number**	**Number**
Female *Units: participants*			*310 (Calculated)*
Male *Units: participants*			*200 (Calculated)*
Total (=sum across categories)	*250.0 (Calculated)*	*260.0 (Calculated)*	*(Calculated)*

OK Cancel Re-calculate Totals

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Results

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

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Outcome Measure Type*	Post-Hoc
Outcome Measure Title*	Current length: 0 [Maximum allowed content length: 255]
Outcome Measure Description	Maximum allowed content length (600)
Outcome Measure Time Frame*	
Safety Issue (FDAAA)	Is this outcome measure assessing a safety issue? -- Please Select --

Save and Validate

Enter Outcome Data

Add Arm/Group

	Arm/Group Title should be descriptive, yet concise, to provide context for tabular data. Examples: Metformin, Lifestyle counseling, Sugar pill	
Arm/Group Title* and Description*	Remove Arm/Group Combo Maximum allowed content length (999) Drug X = Drug Y + Drug Z	Remove Arm/Group Placebo Maximum allowed content length (999) NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed:*		
	Report Units Analyzed other than participants (e.g., eyes, lesions, implants) (Not necessary for most studies)	
Analysis Population Description:	Please explain how the number of participants for analysis was determined. Maximum allowed content length (350)	
Measure Type:* Number Measure of Dispersion/Precision:* Not Applicable		

Add Category

Unit of Measure*	(e.g., mm Hg) use participants use years use units on a scale use percentage of <*something*> If the Measure Type is "Number", the Unit of Measure is typically "participants".

Save and Validate Save and Continue Cancel

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Results

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

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Posted

Post-Hoc Outcome: asdf *; Units: asdf [asdf]*

Statistical Analysis Overview:

Comparison Group Selection: *
Generally, at least 2 groups should be checked. Check all groups for an "omnibus" analysis.
☐ Combo ☐ Placebo
Please provide additional details about the analysis, such as null hypothesis and power calculation.
Maximum allowed content length (500)

Is this a non-inferiority or equivalence analysis? * Yes
If yes, please describe details of power calculation (if not previously provided), definition of non-inferiority margin, and other key parameters.
Current length: 0 [Maximum allowed content length: 500]

Statistical Test of Hypothesis:

P-Value: (e.g. <0.01)
If desired, provide additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance.
Maximum allowed content length (250)

Method: -- Please Select -- If other, please specify:

Describe any other relevant information, such as adjustments or degrees of freedom.
Maximum allowed content length (150)

What parameter did you estimate(e.g., Odds Ratio)? -- Please Select --
If other, please specify:

Estimated Value:

When the confidence interval is entered, it must be fully specified. A fully specified confidence interval includes percentage and one of the following:
- 1-sided: enter either the lower or upper limit
- 2-sided (default): enter both lower and upper limits

Also, when a confidence interval is entered, an Estimated Value and parameter must be entered.

Method of Estimation:

95 **% Confidence Interval:**
Number of sides -- Please Select --
Lower Limit:
Upper Limit:

Parameter Dispersion Type: -- Please Select --

Describe any other relevant estimation information, including the direction of the comparison (e.g., describe which Arm/Group represents the numerator and denominator for relative risk).
Maximum allowed content length (250)

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Results

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

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Overall Limitations and Caveats: 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.
Maximum allowed content length (250)

OK Cancel

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Results

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

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Time Frame for Adverse Event Reporting Please provide description of period in which adverse event data were collected (e.g., 1 year, 6 months)
Maximum allowed content length (255)

Additional Description Maximum allowed content length (350)

Source Vocabulary 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 --

OK Cancel

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Results

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

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Adverse Event Term:*	
Source Vocabulary Name:	Please enter the name and version for the term's source vocabulary, if any, (e.g., SNOMED CT, MedDRA 10.0). Blank means use table default. No current default source vocabulary
Organ System:*	-- Please Select --
Assessment Type:	Blank means use table default. No current default assessment type -- Please Select --
Additional Description:	Maximum allowed content length (250)

OK Cancel

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Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	**Adverse Events** **Edit Serious Adverse Event Total**

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Please enter the Total Number of Participants Affected and at Risk as integers.

- The Total Number of Participants at Risk is typically equal to the Number of Participants who Started the first Period in the Participant Flow.
- The Total Number of Participants Affected in an Arm/Group must be less than or equal to the sum of Participants Affected for All Adverse Events in the Arm/Group.
- The Total Number of Participants Affected in an Arm/Group must be greater than or equal to the Maximum Number of Participants Affected for any Adverse Event in the Arm/Group.

Serious Adverse Event(s)	**Combo** *Drug X = Drug Y + Drug Z*		**Placebo**	
Maximum for a single Serious Adverse Event	50 *(Calculated)*		60 *(Calculated)*	
Sum for all Serious Adverse Events	50 *(Calculated)*		60 *(Calculated)*	
	# Affected *	**# at Risk ***	**# Affected ***	**# at Risk ***
Total				

OK Cancel

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Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	**Adverse Events** **Edit Serious Adverse Event Subset Data**

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Please enter the number of participants affected and at risk as integers. Also, if available, enter the number of events as integers.

Serious Adverse Event(s)	Combo *Drug X = Drug Y + Drug Z*			Placebo		
	# Affected *		# at Risk *	# Affected *		# at Risk *
Total	50		<>	60		<>
	# Affected *	# Events	# at Risk [blank =Total]	# Affected *	# Events	# at Risk [blank =Total]
Heart Attack *Systematic Assessment*			[]			[]

OK Cancel

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Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	**Adverse Events** **Add Other (Not Including Serious) Adverse Event**

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Adverse Event Term:*	
Source Vocabulary Name:	Please enter the name and version for the term's source vocabulary, if any, (e.g., SNOMED CT, MedDRA 10.0). Blank means use table default. No current default source vocabulary
Organ System:*	-- Please Select --
Assessment Type:	Blank means use table default. No current default assessment type -- Please Select --
Additional Description:	Maximum allowed content length (250)

OK Cancel

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Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	**Adverse Events** **Edit Frequency Threshold for Reporting Other (Not Including Serious) Adverse Events**

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Frequency Threshold for Reporting Other Adverse Event: *	Enter a number for the frequency above which Other (Not Including Serious) Adverse Events are reported. The number must be less than or equal to the allowed maximum (5%) and must not include any symbol (e.g., >=). 5 %

OK Cancel

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Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	**Adverse Events** **Edit Other (Not Including Serious) Adverse Event Total**

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Please enter the Total Number of Participants Affected and at Risk as integers.

- The Total Number of Participants at Risk is typically equal to the Number of Participants who Started the first Period in the Participant Flow.
- The Total Number of Participants Affected in an Arm/Group must be less than or equal to the sum of Participants Affected for All Adverse Events in the Arm/Group.
- The Total Number of Participants Affected in an Arm/Group must be greater than or equal to the Maximum Number of Participants Affected for any Adverse Event in the Arm/Group.

Other Adverse Event(s)	**Combo** *Drug X = Drug Y + Drug Z*		**Placebo**	
Maximum for a single Other Adverse Event	50 *(Calculated)*		60 *(Calculated)*	
Sum for all Other Adverse Events	50 *(Calculated)*		60 *(Calculated)*	
	# Affected *	**# at Risk ***	**# Affected ***	**# at Risk ***
Total				

OK Cancel

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Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	**Adverse Events** **Edit Other (Not Including Serious) Adverse Event Subset Data**

Title: Food and Drug Administration Amendments Act of 2007, Title V... Org: TestOrg ID: PL110-85

Please enter the number of participants affected and at risk as integers. Also, if available, enter the number of events as integers.

Other Adverse Event(s)	Combo *Drug X = Drug Y + Drug Z*			Placebo		
	# Affected *		# at Risk *	# Affected *		# at Risk *
Total	50		<>	60		<>
	# Affected *	# Events	# at Risk [blank =Total]	# Affected *	# Events	# at Risk [blank =Total]
Allergy *Non-systematic Assessment*			[]			[]

OK Cancel