OVERVIEW

The ClinicalTrials.gov Protocol Registration System (PRS) is a web-based tool developed for submitting clinical trials information to ClinicalTrials.gov. This document provides step-by-step instructions for entering, modifying, and releasing study results records using the PRS. Initial entry of a study (protocol) is the subject of a separate job aid document.

The screen shots provided below for your review and assistance are step by step guidance to enter study results. What appear to be broken images occurred when the original page was greater than one full screen at capture, and in this document the cropped screen images are shown together on one page for continuity.

Due to system limitations, capture of screens was required to occur in edit mode rather than initial entry of data. This resulted in the appearance of summary screens that may differ when initial results entry occurs. The system has provided links to additional information for most fields that require entry; it is suggested they be selected (by double-click) whenever there is need.

The results section of a clinicaltrials.gov file is divided into discrete parts, each of which includes nested series of data entry screens.

1. Results Point of Contact	**5. Outcome Measure**
2. Certain Agreements	**6. Limitations and Caveats**
3. Participant Flow	**7. Adverse Events**
4. Baseline	

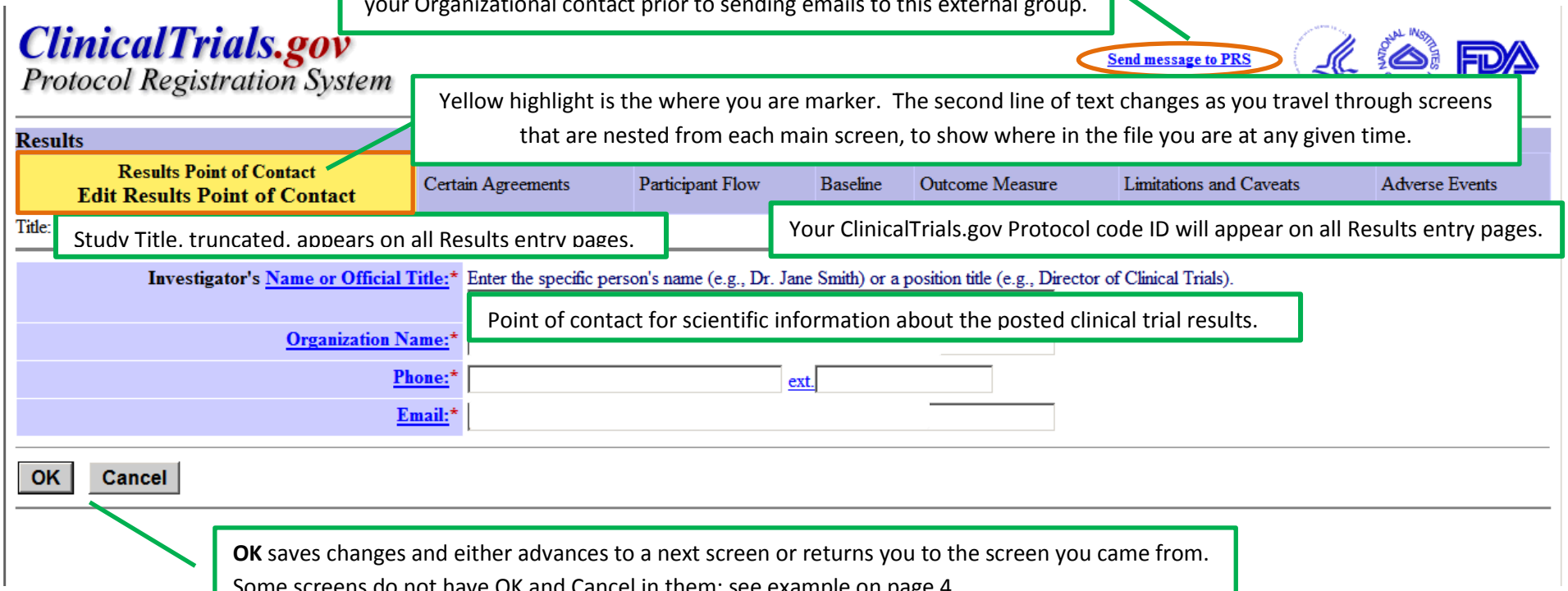
You will see these as form section headers across the top of each main screen page, useful for navigation though they are not jump-to links. The 'where you are now' marker is yellow highlight on these area labels that is applied by the system.

Color Key Code used on subsequent pages:

Green = Text explanation

Orange = Highlighted information on form

RED = Please take note



Red asterisks mark required fields.

Underlined texts in blue are links. Some are navigational, and move you to other screens, especially Add, Create and Edit. Other blue underlined text next to a box for data entry are field labels that take you to helpful descriptions of what it is that the system is looking for.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Results

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

Title:

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.

No

Indicate Yes or No, here.

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.

No

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.

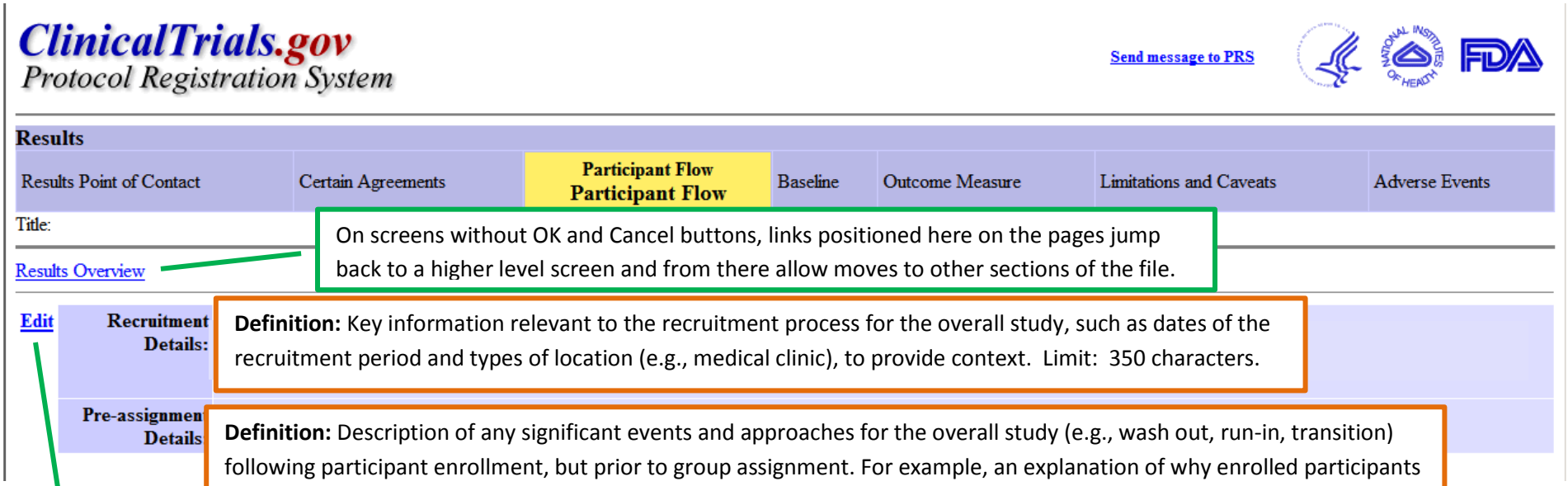
Maximum allowed content length (500)

OK Cancel

Information certifying whether there exists an agreement between the sponsor or its agent and the principal investigators (unless the sponsor is an employer of the principal investigators) that restricts in any manner the ability of the principal investigators (PIs), after the completion of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial. This does not include an agreement solely to comply with applicable provisions of law protecting the privacy of participants.

Participant Flow: Progress of research participants through each stage of a trial in a tabular format, including the number of participants who dropped out of the clinical trial. (Identical in purpose to a CONSORT flow diagram, but represented as tables.)

The tabular presentation may be separated into "periods," each of which comprises an interval of trial activity. Each period consists of "milestones" for reporting numbers of participants at particular points in time within that period.



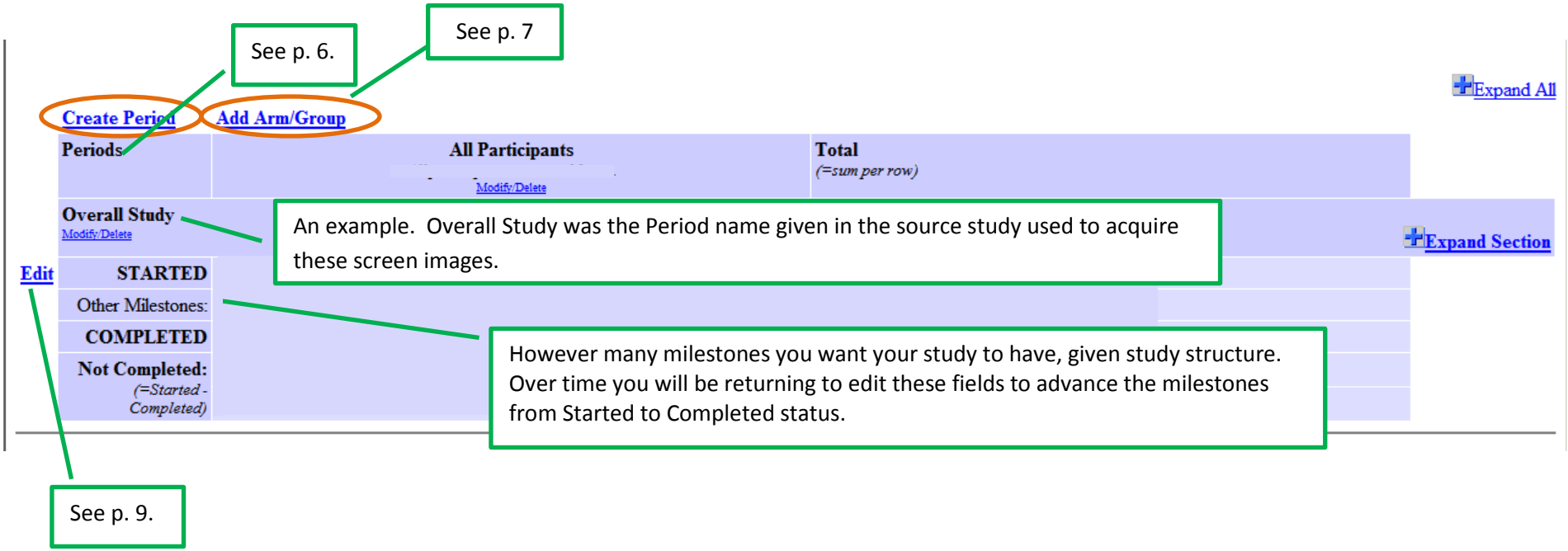
On screens without OK and Cancel buttons, links positioned here on the pages jump back to a higher level screen and from there allow moves to other sections of the file.

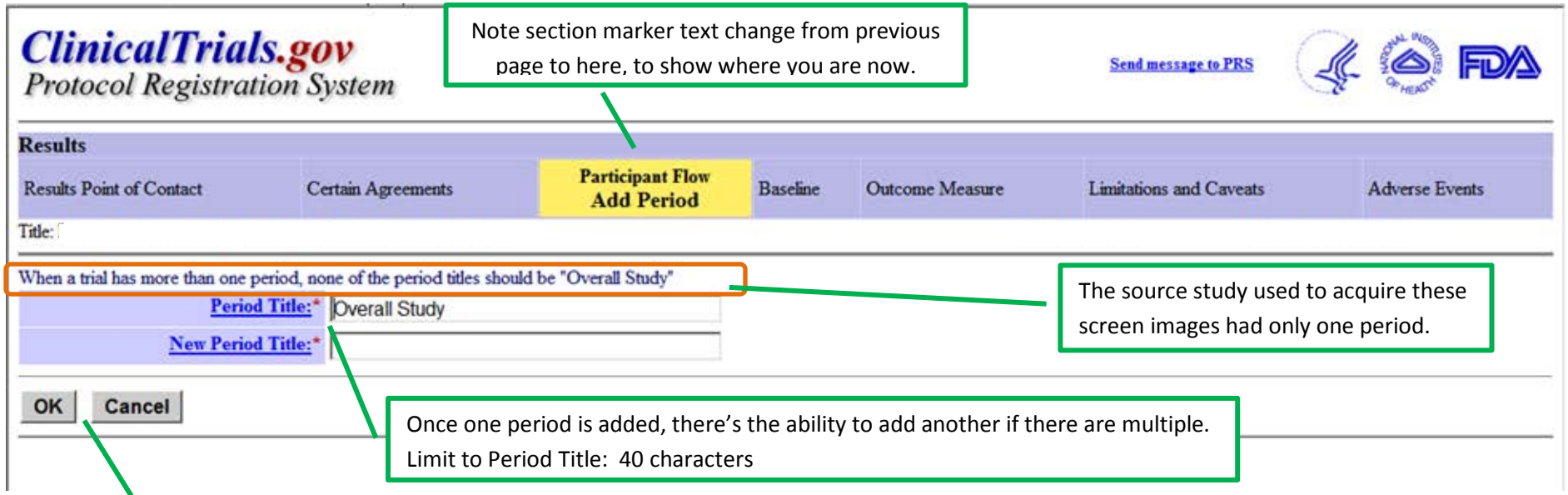
Definition: Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (e.g., medical clinic), to provide context. Limit: 350 characters.

Definition: Description of 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. Limit: 350 characters.

See p. 8.

[Participant Flow main screen continues on page 5]

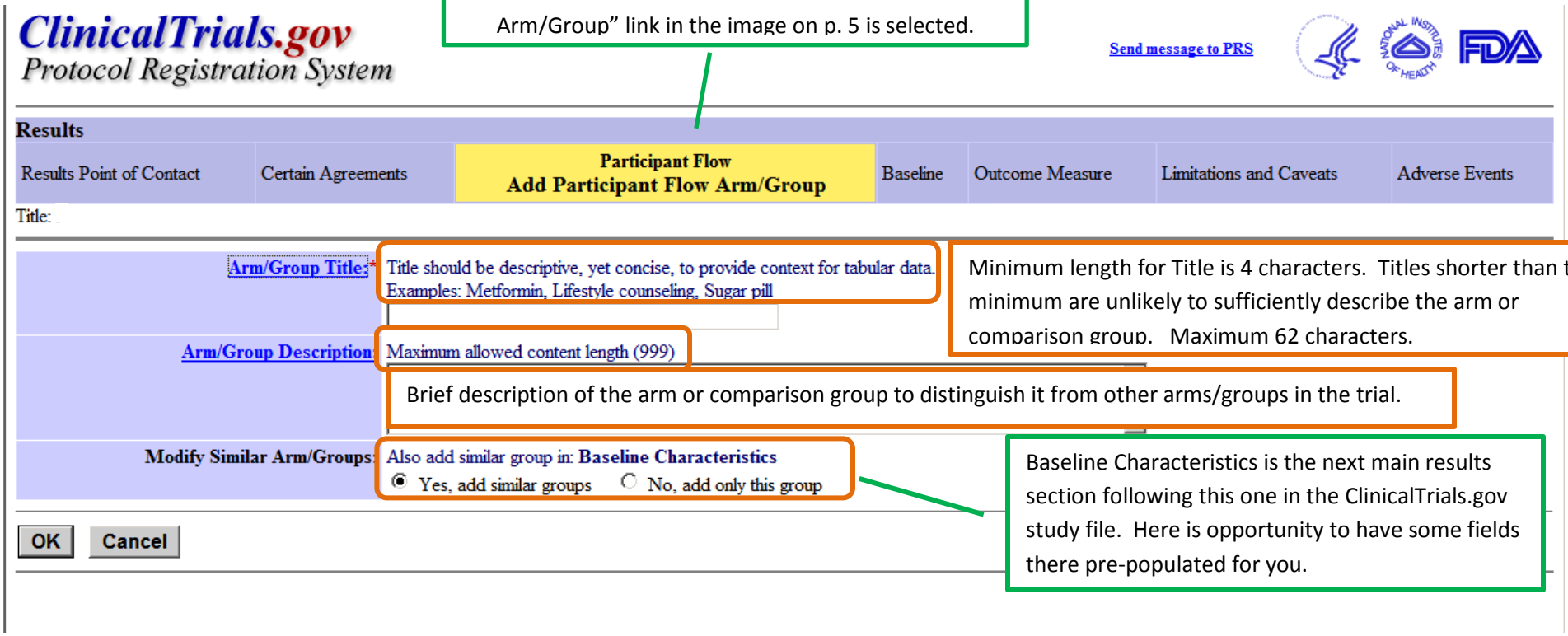

See p. 6.
See p. 7
Create Period
Add Arm/Group
Expand All
Periods
All Participants
Modify/Delete
Total
(=sum per row)
Overall Study
Modify/Delete
An example. Overall Study was the Period name given in the source study used to acquire these screen images.
Expand Section
Edit
STARTED
Other Milestones:
COMPLETED
Not Completed:
(=Started - Completed)
However many milestones you want your study to have, given study structure. Over time you will be returning to edit these fields to advance the milestones from Started to Completed status.
See p. 9.



Definition of Period: Discrete stages of a clinical trial during which numbers of participants at specific significant events or points of time are reported. If only one period, use Overall Study for "Period Title."

There is no limit to the number of periods that may be used to describe a single trial. Each subsequent period represents a trial stage following the previous period. That is, participants "flow" from earlier to later periods. All results sections must cover participant flow from initial assignment to arms/groups to completion of the trial.

This screen is the destination when the "Add Arm/Group" link in the image on p. 5 is selected.



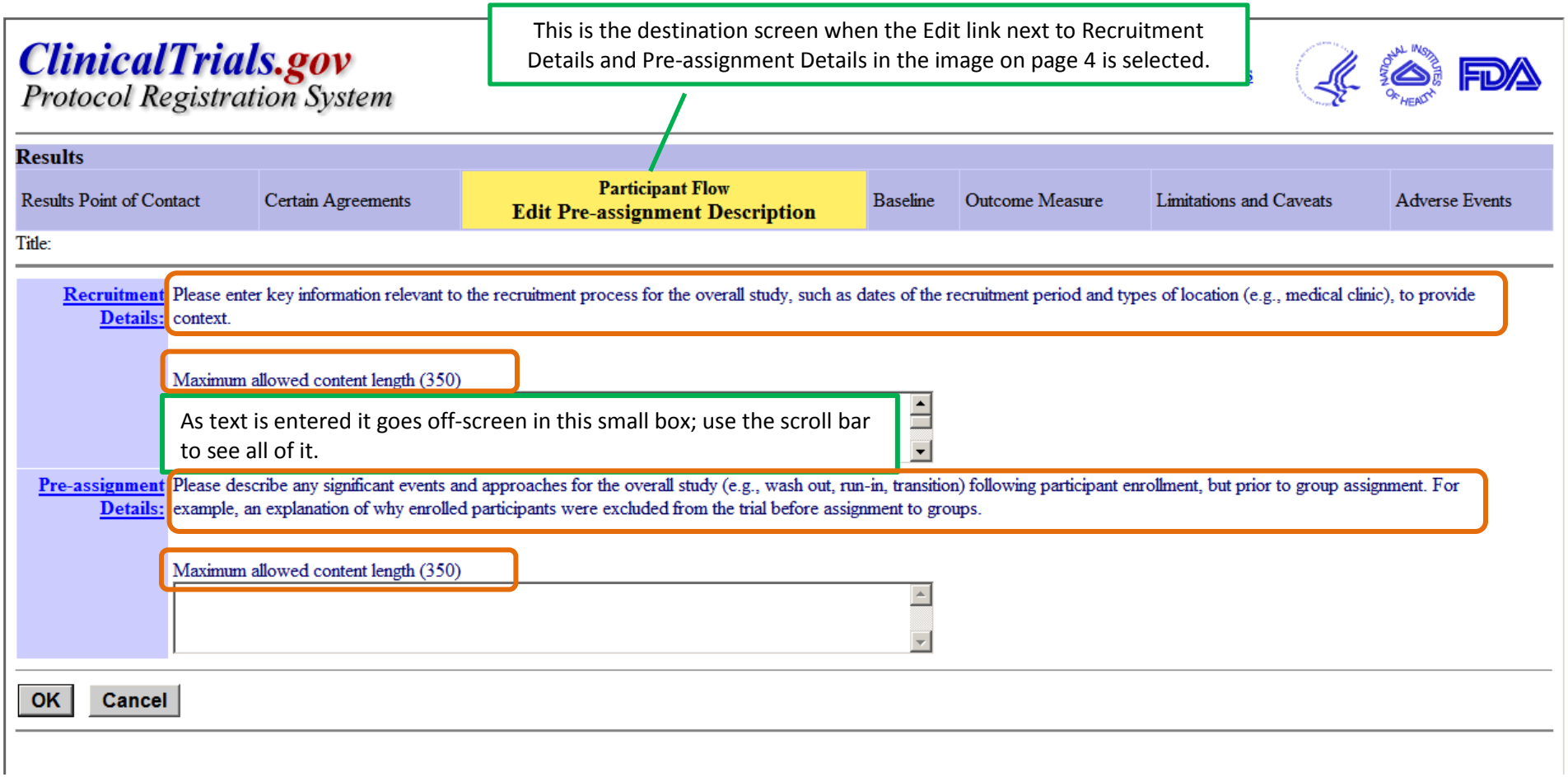
Minimum length for Title is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Maximum 62 characters.

Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial.

Baseline Characteristics is the next main results section following this one in the ClinicalTrials.gov study file. Here is opportunity to have some fields there pre-populated for you.

(Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)

This is the destination screen when the Edit link next to Recruitment Details and Pre-assignment Details in the image on page 4 is selected.



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Protocol Registration System

This link will jump back to the main Participant Flow screen.

Send message to PRS

Results

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

Title:

Participant Flow

See the upper part of p. 10.

Add Milestone

Edit	**Overall Study**	**All Participants**	**Total** *(=sum per row)*
	STARTED	96	96 *(Calculated)*
	Received Placebo Modify/Delete	93	93 *(Calculated)*
	Received Low Dosage Modify/Delete	93	93 *(Calculated)*
	Received Medium Dosage Modify/Delete	93	93 *(Calculated)*
	Received High Dosage Modify/Delete	93	93 *(Calculated)*
	COMPLETED	93	93 *(Calculated)*
	Not Completed: *(=Started - Completed)*	3 *(Calculated)*	3 *(Calculated)*

See p. 11.

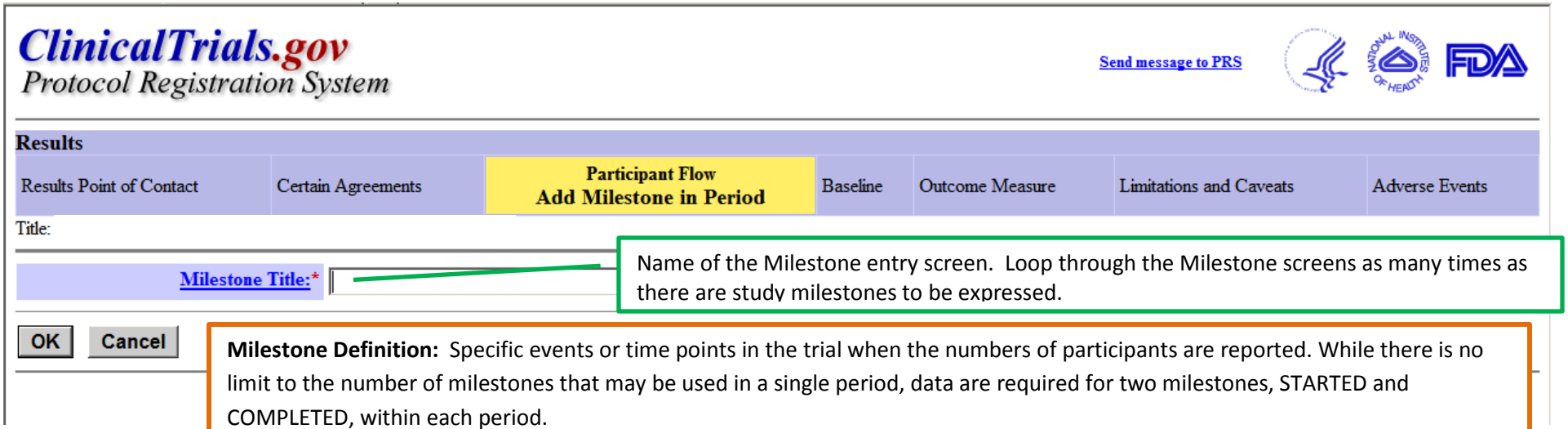
Values on this screen are from the study used to source the images.

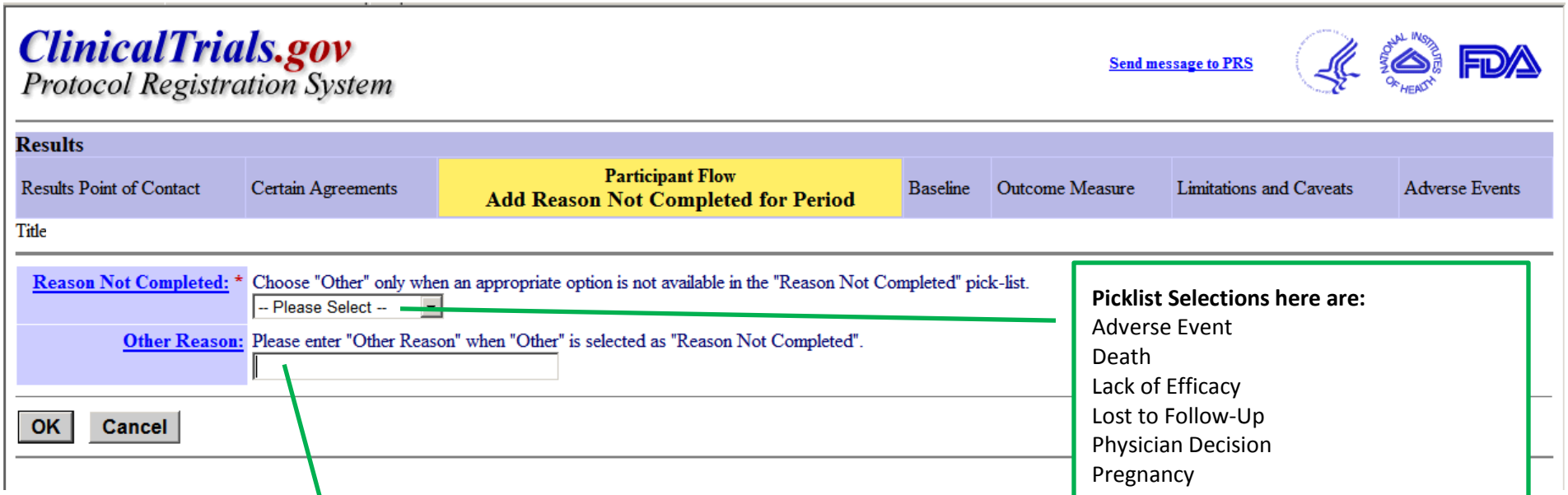
See the lower part of p. 10.

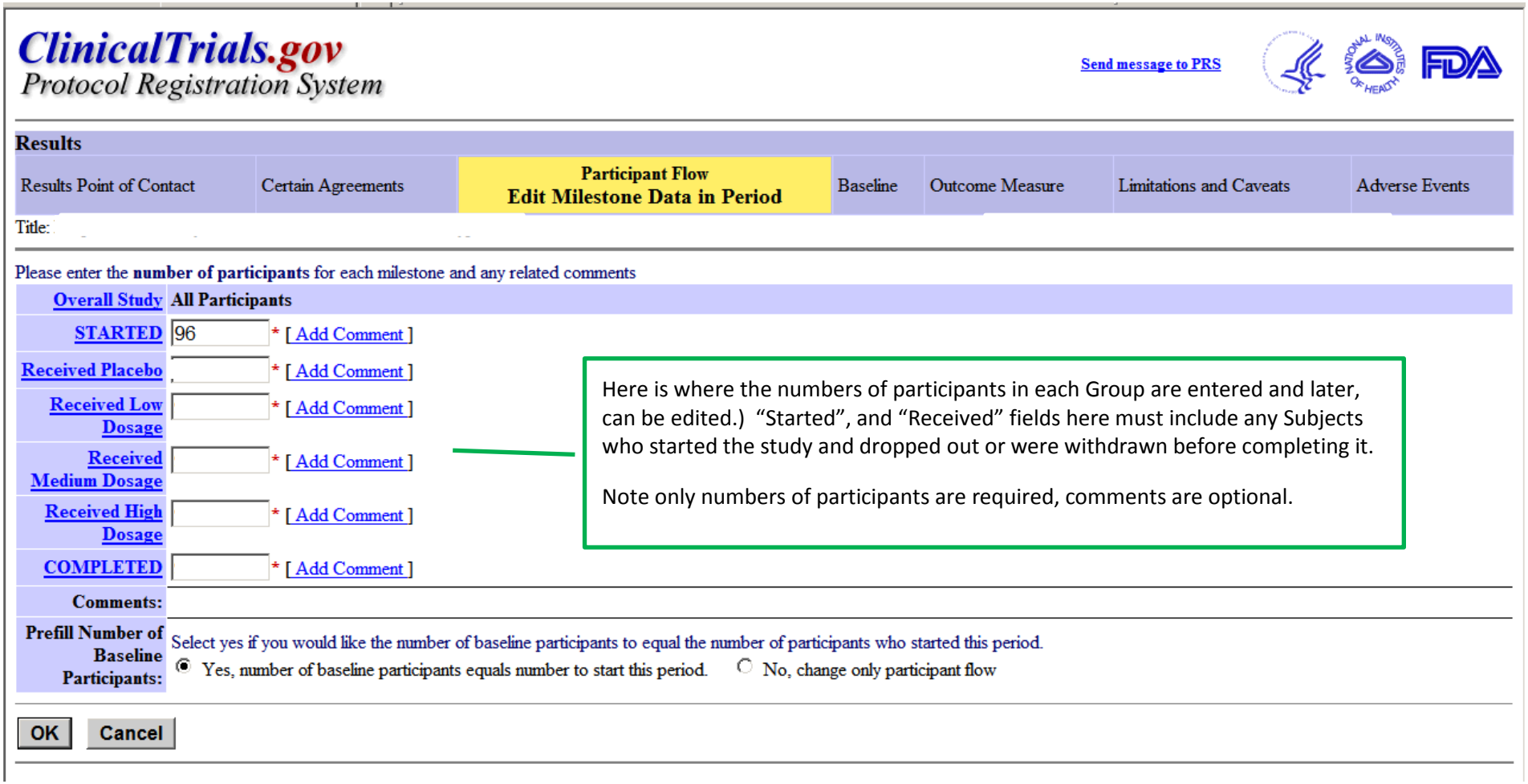
Add Reason for Not Completed

Edit	**Overall Study**	**All Participants**	**Total** *(=sum per row)*
	Total *(=sum per column)*	3 *(Calculated)*	3 *(Calculated)*
	Other [REASON] Modify/Delete	3	3 *(Calculated)*

See p. 12.


ClinicalTrials.gov
Protocol Registration System
Send message to PRS
Results
Results Point of Contact
Certain Agreements
Participant Flow
Add Milestone in Period
Baseline
Outcome Measure
Limitations and Caveats
Adverse Events
Title:
Milestone Title:*
OK
Cancel
Name of the Milestone entry screen. Loop through the Milestone screens as many times as there are study milestones to be expressed.
Milestone Definition: Specific events or time points in the trial when the numbers of participants are reported. While there is no limit to the number of milestones that may be used in a single period, data are required for two milestones, STARTED and COMPLETED, within each period.

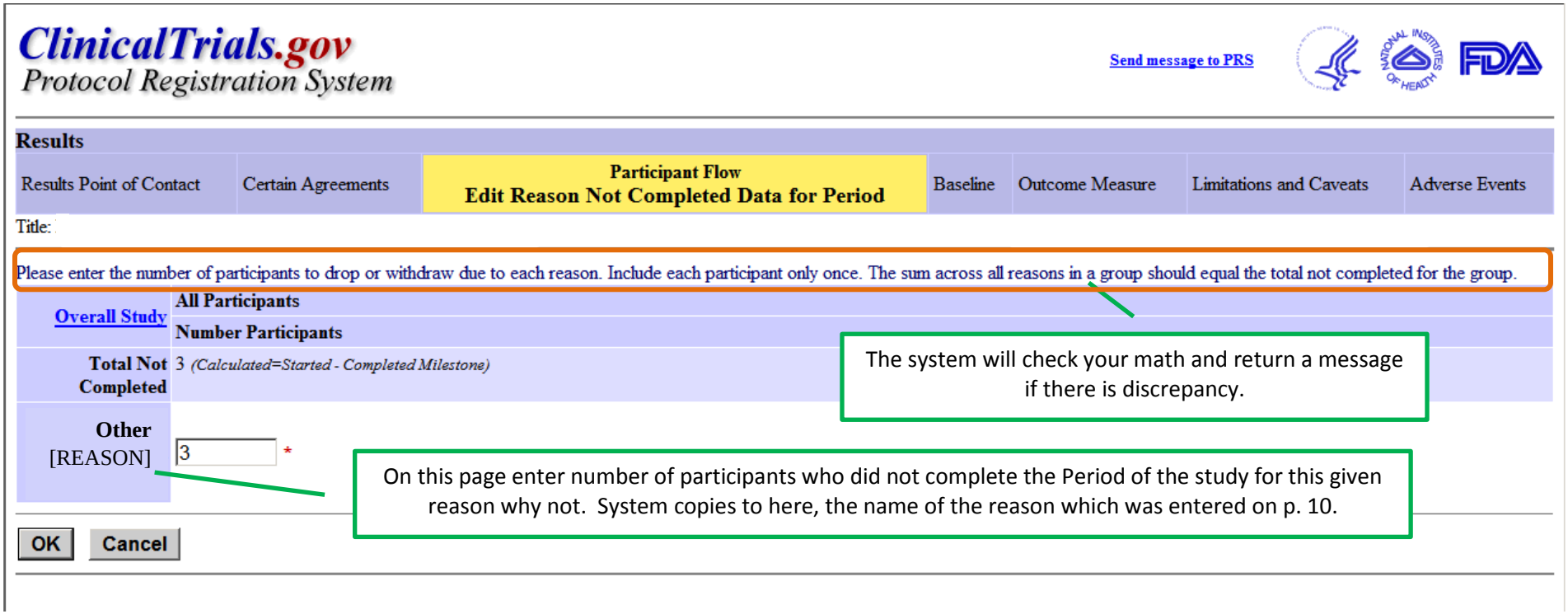

ClinicalTrials.gov
Protocol Registration System
Send message to PRS
Results
Results Point of Contact
Certain Agreements
Participant Flow
Add Reason Not Completed for Period
Baseline
Outcome Measure
Limitations and Caveats
Adverse Events
Title
Reason Not Completed: *
Choose "Other" only when an appropriate option is not available in the "Reason Not Completed" pick-list.
-- Please Select --
Other Reason:
Please enter "Other Reason" when "Other" is selected as "Reason Not Completed".
OK
Cancel
Free text field for when the pick list choices do not fit.
Picklist Selections here are:
Adverse Event
Death
Lack of Efficacy
Lost to Follow-Up
Physician Decision
Pregnancy
Protocol Violation
Withdrawal by Subject
Other

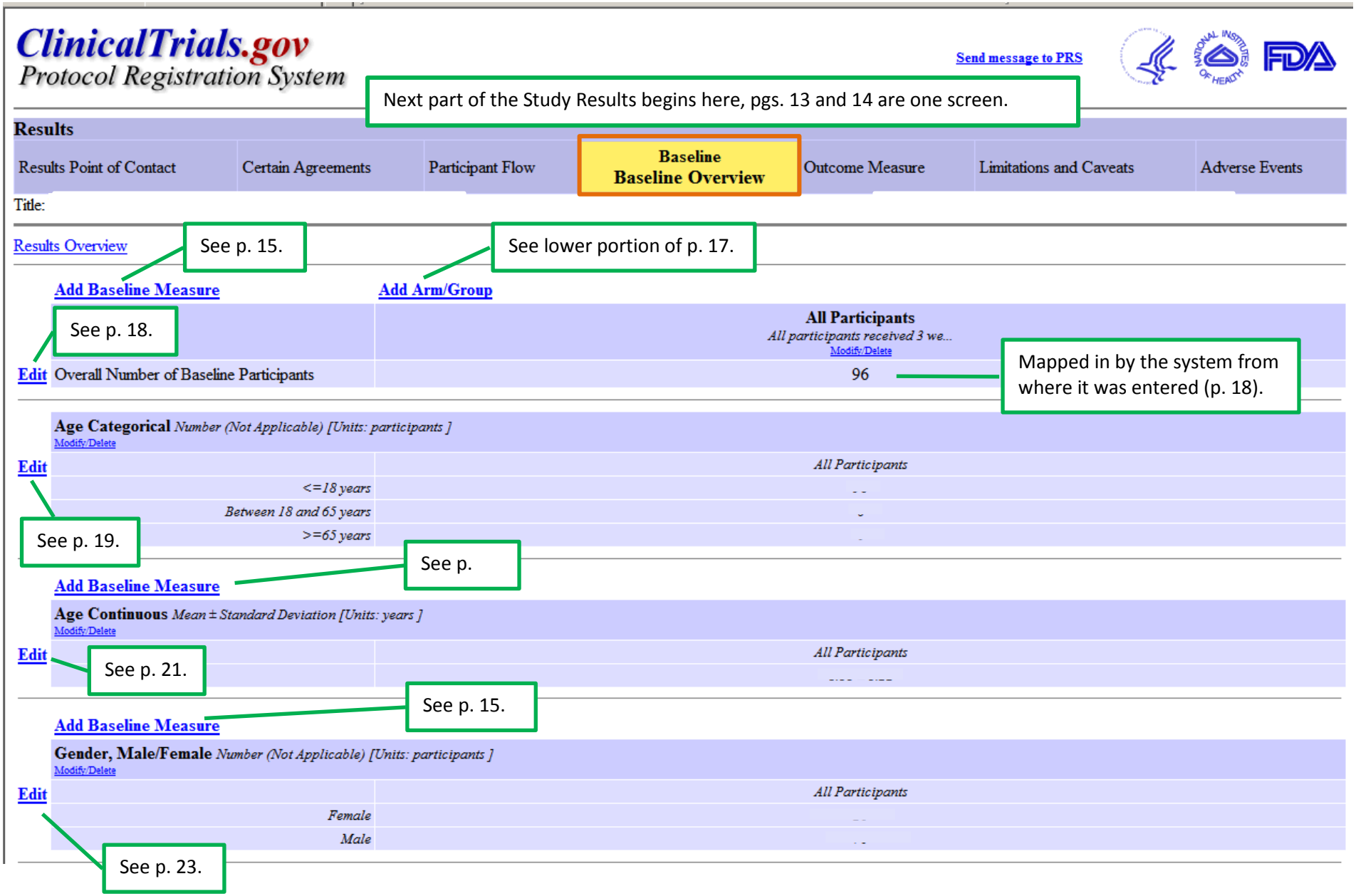


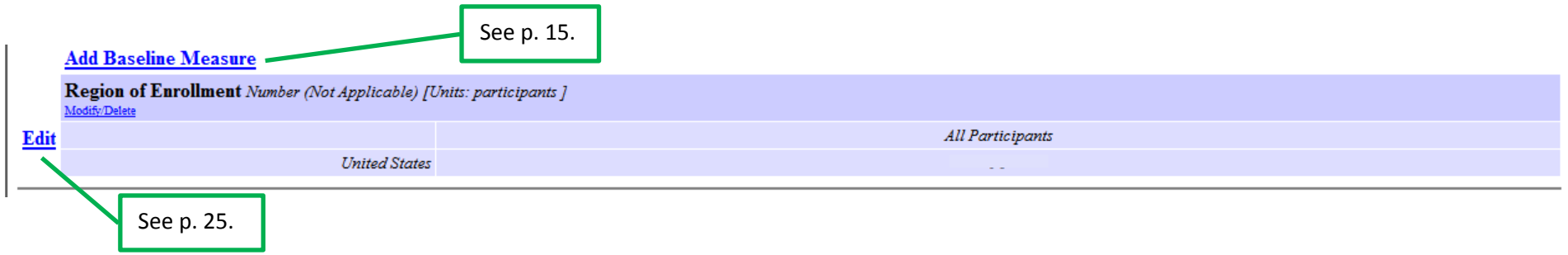
Here is where the numbers of participants in each Group are entered and later, can be edited.) "Started", and "Received" fields here must include any Subjects who started the study and dropped out or were withdrawn before completing it.

Note only numbers of participants are required, comments are optional.

Links in the left-hand blue column on this page take you to informational text.


ClinicalTrials.gov
Protocol Registration System
Send message to PRS
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:
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
All Participants
Number Participants
Total Not Completed
3 (Calculated=Started - Completed Milestone)
Other [REASON]
3
*
OK
Cancel
The system will check your math and return a message if there is discrepancy.
On this page enter number of participants who did not complete the Period of the study for this given reason why not. System copies to here, the name of the reason which was entered on p. 10.

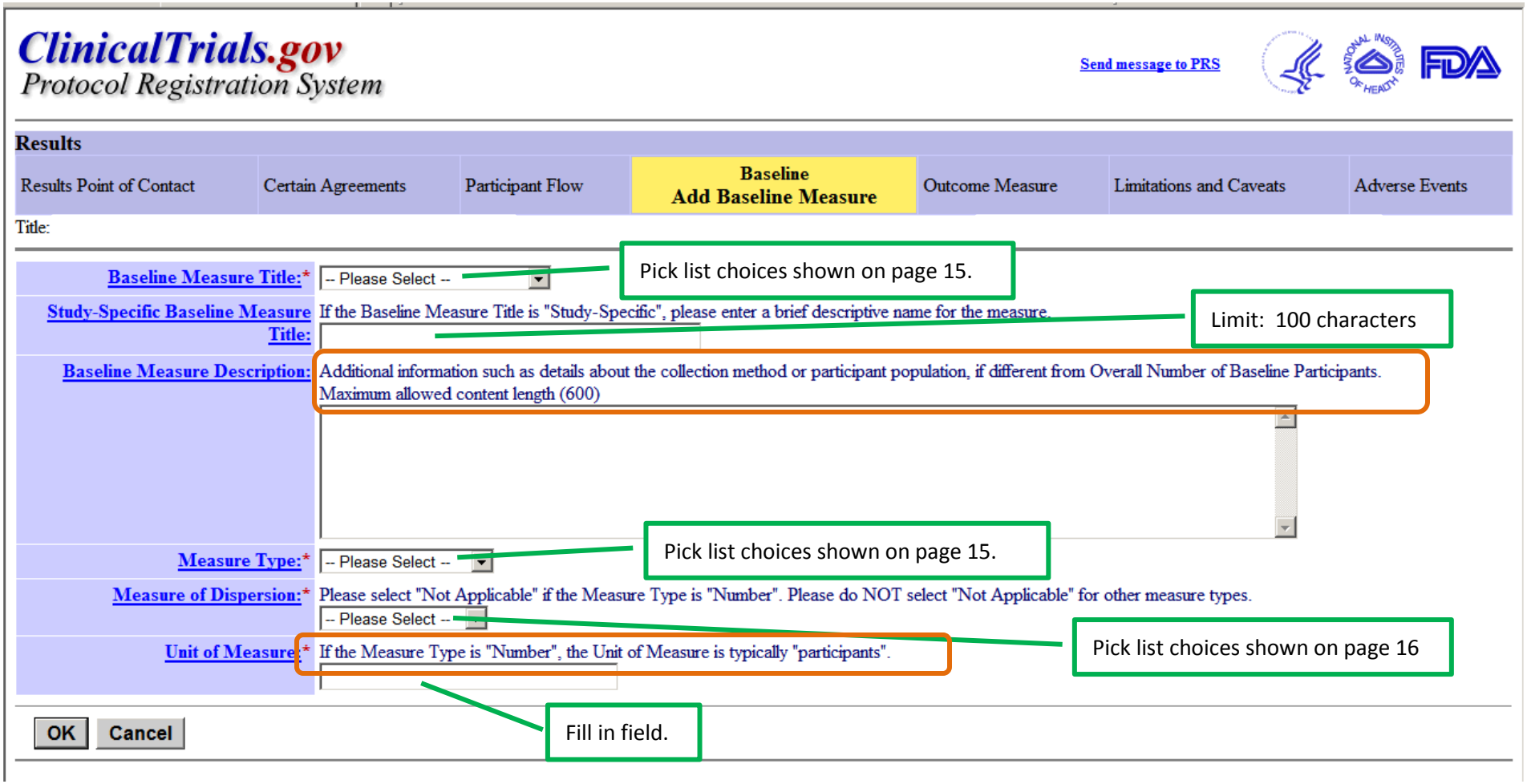

ClinicalTrials.gov
Protocol Registration System
Send message to PRS
Next part of the Study Results begins here, pgs. 13 and 14 are one screen.
Results
Results Point of Contact
Certain Agreements
Participant Flow
Baseline
Baseline Overview
Outcome Measure
Limitations and Caveats
Adverse Events
Title:
Results Overview
See p. 15.
See lower portion of p. 17.
Add Baseline Measure
Add Arm/Group
See p. 18.
All Participants
All participants received 3 we...
Modify/Delete
Edit
Overall Number of Baseline Participants
96
Mapped in by the system from where it was entered (p. 18).
Age Categorical Number (Not Applicable) [Units: participants]
Modify/Delete
Edit
All Participants
<=18 years
Between 18 and 65 years
>=65 years
See p. 19.
See p.
Add Baseline Measure
Age Continuous Mean ± Standard Deviation [Units: years]
Modify/Delete
Edit
All Participants
See p. 21.
See p. 15.
Add Baseline Measure
Gender, Male/Female Number (Not Applicable) [Units: participants]
Modify/Delete
Edit
All Participants
Female
Male
See p. 23.



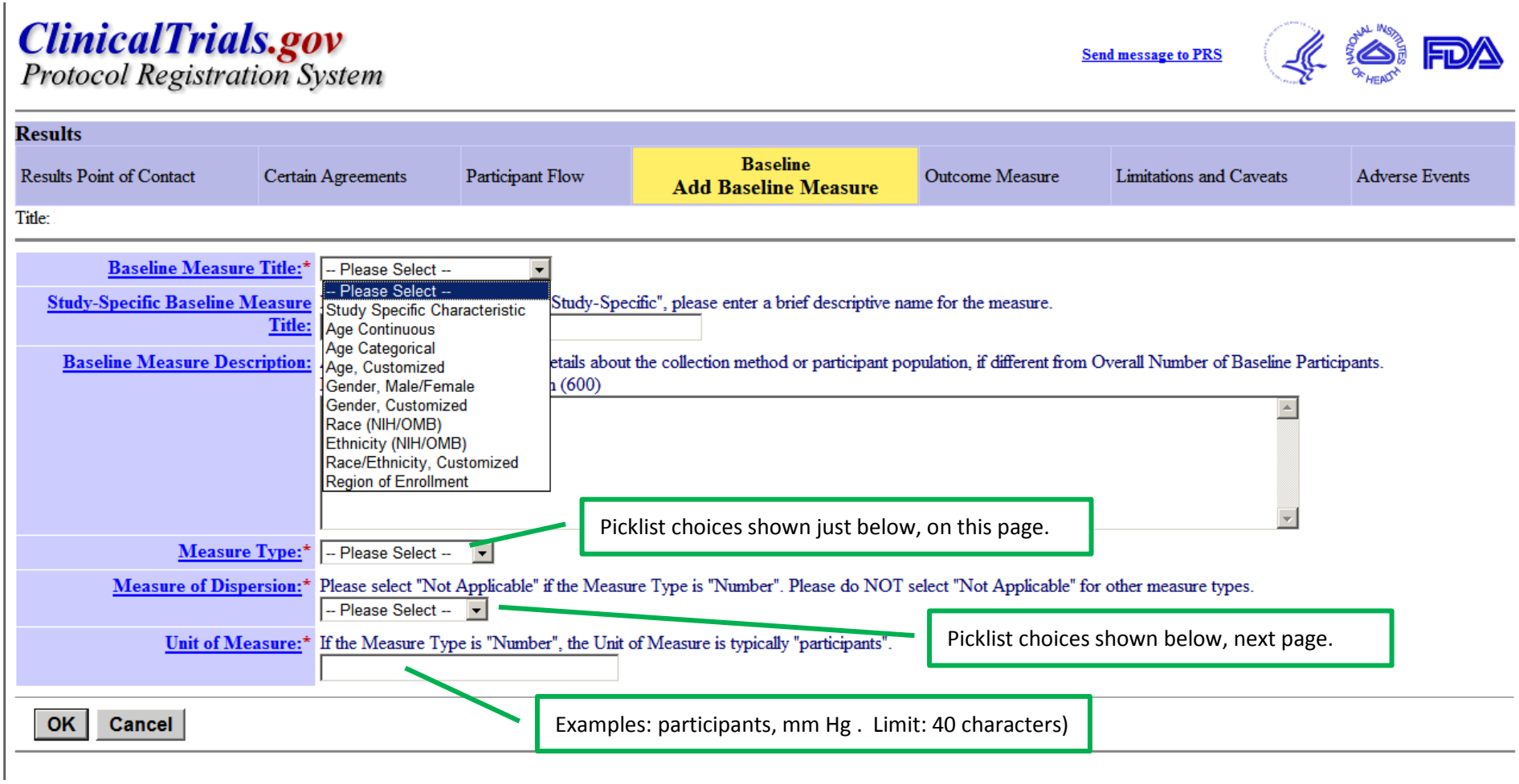
Baseline Characteristic : A table of demographic and baseline data for the entire trial population and for each arm or comparison group. Note that only baseline measures for Age and Gender are required; all other baseline measures are optional. The table cells accommodate different types of data:

- Categorical - create customized categories and then report a count or a measure of central tendency and a measure of dispersion for each category by arm or comparison group
- Continuous - report a measure of central tendency and a measure of dispersion for each arm or comparison group
- Time-to-Event Data - report as either (1) continuous data (e.g., mean time to event with measure of dispersion) or (2) categorical data at different time points by arm or comparison group

Overall Number of Baseline Participants (per arm/group) : Overall number of participants for which baseline characteristics were measured for all baseline measures reported. Note that if the participant population differs for a particular baseline measure, the number of participants should be included in the Baseline Measure Description.



Baseline Measure Definition: Name and description of a characteristic measured at the beginning of the trial. Note that baseline measure data for "Age" (at least one of the three types) and "Gender" are required. There is no limit to the number of additional "Study-Specific Measures" that may be provided.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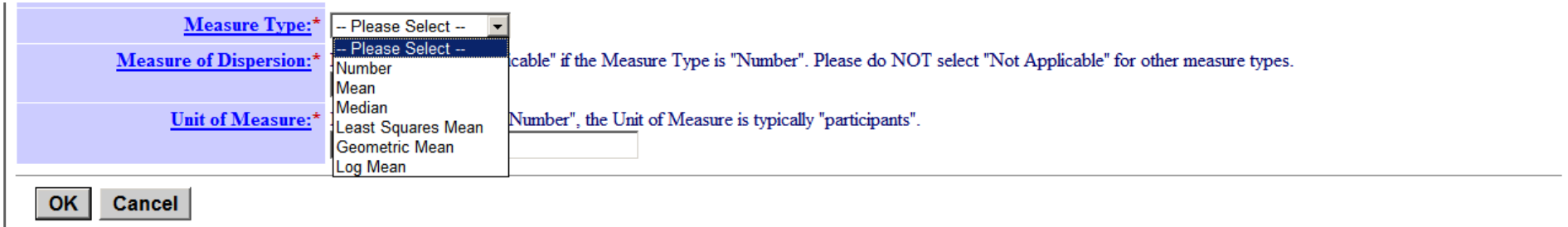
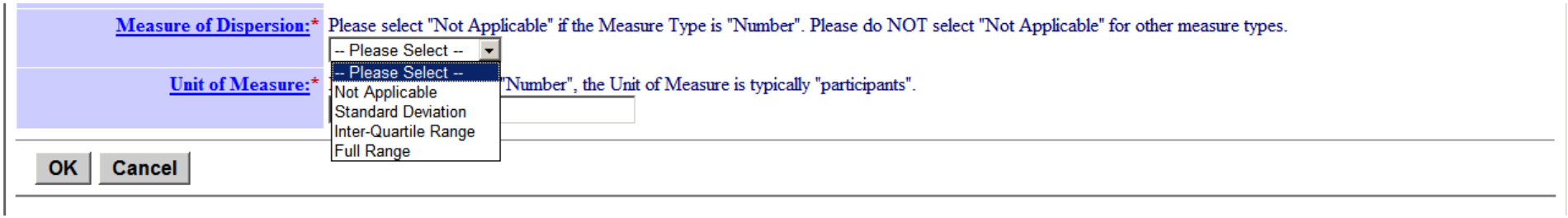
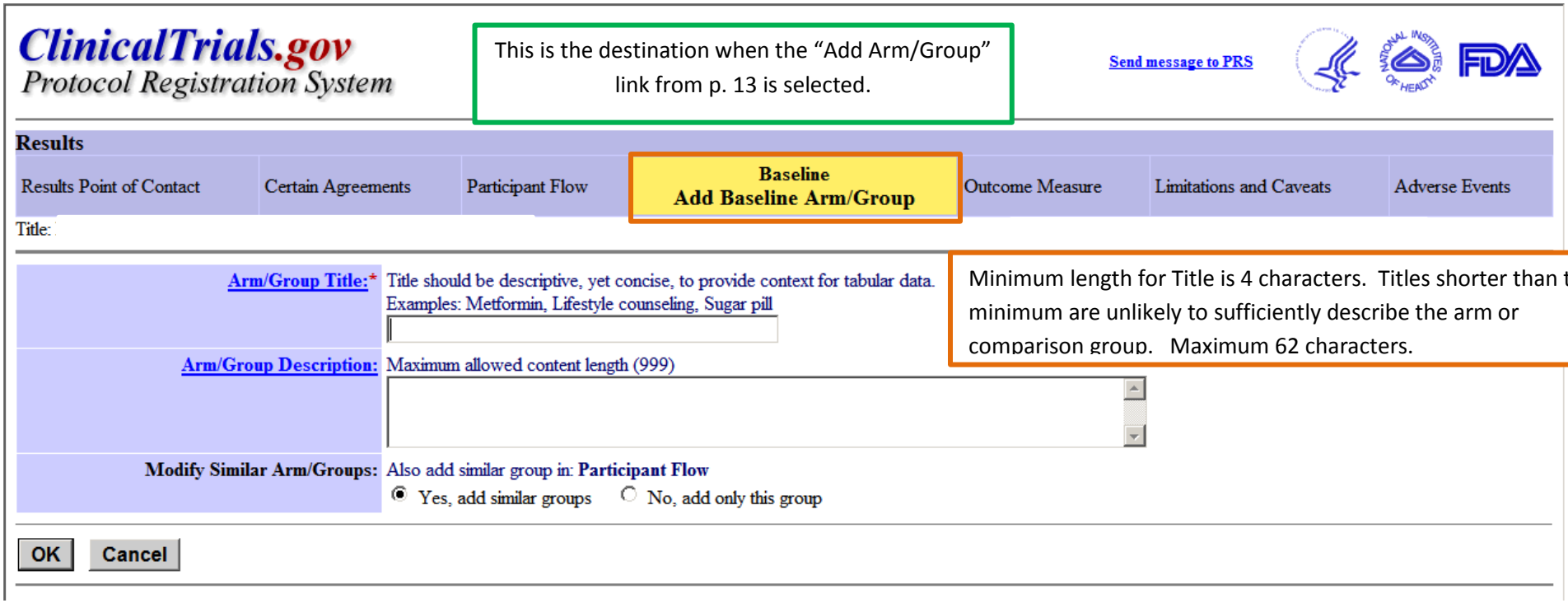
Protocol Registration System
Send message to PRS
Results
Results Point of Contact
Certain Agreements
Participant Flow
Baseline
Add Baseline Measure
Outcome Measure
Limitations and Caveats
Adverse Events
Title:
Baseline Measure Title:*
-- Please Select --
-- Please Select --
Study Specific Characteristic
Age Continuous
Age Categorical
Age, Customized
Gender, Male/Female
Gender, Customized
Race (NIH/OMB)
Ethnicity (NIH/OMB)
Race/Ethnicity, Customized
Region of Enrollment
Study-Specific Baseline Measure Title:
Study-Specific", please enter a brief descriptive name for the measure.
Baseline Measure Description:
etails about the collection method or participant population, if different from Overall Number of Baseline Participants.
n (600)
Picklist choices shown just below, on this page.
Measure Type:*
-- Please Select --
Measure of Dispersion:*
Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types.
-- Please Select --
Picklist choices shown below, next page.
Unit of Measure:*
If the Measure Type is "Number", the Unit of Measure is typically "participants".
Examples: participants, mm Hg . Limit: 40 characters)
OK
Cancel


Measure Type:*
-- Please Select --
-- Please Select --
Number
Mean
Median
Least Squares Mean
Geometric Mean
Log Mean
Measure of Dispersion:*
cable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types.
Unit of Measure:*
Number", the Unit of Measure is typically "participants".
OK
Cancel


Measure of Dispersion:*
Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types.
-- Please Select --
Unit of Measure:*
-- Please Select --
Not Applicable
Standard Deviation
Inter-Quartile Range
Full Range
"Number", the Unit of Measure is typically "participants".
OK
Cancel


ClinicalTrials.gov
Protocol Registration System
This is the destination when the "Add Arm/Group" link from p. 13 is selected.
Send message to PRS
Results
Results Point of Contact
Certain Agreements
Participant Flow
Baseline
Add Baseline Arm/Group
Outcome Measure
Limitations and Caveats
Adverse Events
Title:
Arm/Group Title:*
Title should be descriptive, yet concise, to provide context for tabular data.
Examples: Metformin, Lifestyle counseling, Sugar pill
Minimum length for Title is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Maximum 62 characters.
Arm/Group Description:
Maximum allowed content length (999)
Modify Similar Arm/Groups:
Also add similar group in: Participant Flow
Yes, add similar groups
No, add only this group
OK
Cancel

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Results

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

Title:

Number of Participants Started First Participant Flow Period	**All Participants**	**Total** *(calculated)*
	96	96

	All Participants
Overall Number of Baseline Participants *	96

OK Cancel

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Results

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

Title:

Baseline Overview

Age Categorical

	Overall Number of Baseline Participants	96
	Age Categorical *Number (Not Applicable) [Units: participants]*	**All Participants** *All participants received 3 we...*
Edit	**<=18 years**	
	Between 18 and 65 years	
	>=65 years	
	Total (=sum across categories)	*96.0 (Calculated)*

See p. 20 where data entries may be made.

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Protocol Registration System

Send message to PRS

Results

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

Title:

Age Categorical

Overall Number of Baseline Participants	96
Age Categorical *	**All Participants**
	Number
<=18 years *Units: participants*	
Between 18 and 65 years *Units: participants*	
>=65 years *Units: participants*	
Total (=sum across categories)	*96.0 (Calculated)*

OK Cancel

Enter the number of participants in these fields.

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Protocol Registration System

Send message to PRS

Results

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

Title:

Baseline Overview

See p. 22.

Age Continuous

Create Categories Create Categories if you wish to report categorical data (e.g., low, medium, or high).

Overall Number of Baseline Participants	96
Age Continuous *Mean ± Standard Deviation [Units: years]*	**All Participants** *All participants received 3 we...*

Edit

See the screen below on this page.

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Protocol Registration System

Send message to PRS

Results

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

Title:

Age Continuous

Overall Number of Baseline Participants	96	
Age Continuous *	**All Participants**	
	Mean	**Standard Deviation**
Units: years		

OK Cancel

Data entry screens here.

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Protocol Registration System

Send message to PRS

Results

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

Title:

Age Continuous

Please enter category titles and click "OK". If more categories are needed, please click "Create Category" on the next screen.
Category Title is required ONLY when reporting categorical data (i.e., more than one category or row of data per measure).

Category Title*	
New Category Title*	

OK Cancel

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Results

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

Title

Baseline Overview

Gender, Male/Female

	Overall Number of Baseline Participants	96
	Gender, Male/Female *Number (Not Applicable) [Units: participants]*	**All Participants** *All participants received 3 we...*
Edit	**Female**	_ _
	Male	. .
	Total (=sum across categories)	*96.0 (Calculated)*

See the screen below on the next page.

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Protocol Registration System

Send message to PRS

Results

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

Title:

Gender, Male/Female

Overall Number of Baseline Participants	96
Gender, Male/Female *	**All Participants**
	Number
Female *Units: participants*	
Male *Units: participants*	
Total (=sum across categories)	*96.0 (Calculated)*

OK Cancel

Data entry screens here.

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Protocol Registration System

Send message to PRS

Results

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

Title:

Baseline Overview

Region of Enrollment

Add Country/Region

	Overall Number of Baseline Participants	96
	Region of Enrollment *Number (Not Applicable) [Units: participants]*	**All Participants** *All participants received 3 we...*
Edit	**United States** Modify/Delete	96
	Total (=sum across categories)	*96.0 (Calculated)*

See the screen below on the next page.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Results

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

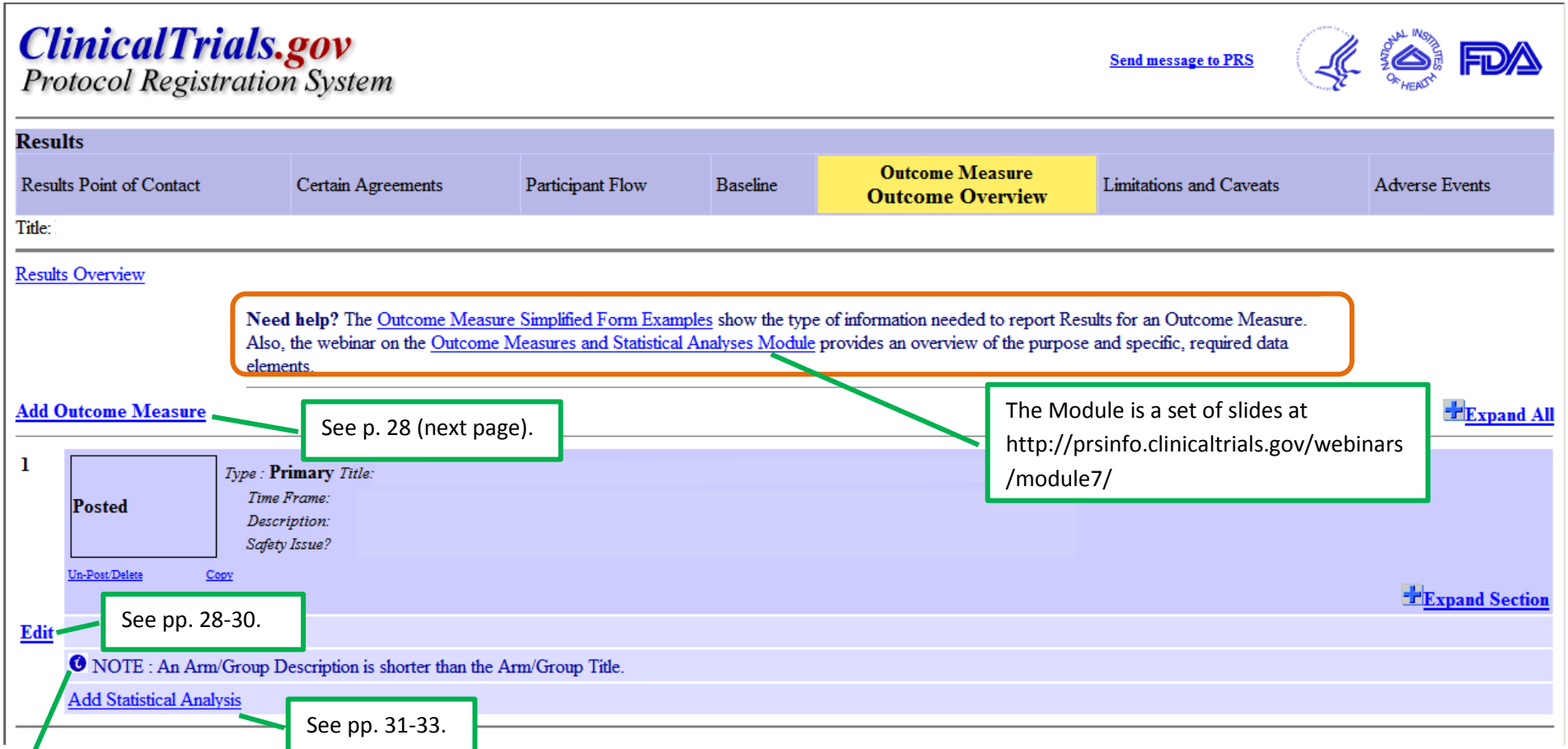
Title:

Region of Enrollment

Overall Number of Baseline Participants	96
Region of Enrollment *	**All Participants**
	Number
United States *Units: participants*	96
Total (=sum across categories)	*96.0 (Calculated)*

OK Cancel

Data entry screen here.



See p. 28 (next page).

The Module is a set of slides at http://prsinfo.clinicaltrials.gov/webinars/module7/

See pp. 28-30.

See pp. 31-33.

The blue-circle-i NOTE Information messages won't stop you from proceeding.

Your Administrator will be checking to see that you have provided some information for each note that you have.

If additional information is required, you will receive a notification from PRS.

(Note that primary and secondary outcome measure information from the protocol section of the record will be copied into the results section the first time results are created. After that, "Outcome Measure Type," "Outcome Measure Title," "Outcome Measure Time Frame" and "Outcome Measure Safety Issue? (Y/N)" for primary or secondary outcome measures may only be changed in the results section.)

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	**Outcome Measure** **Initial Outcome Measure Arm/Groups**	Limitations and Caveats	Adverse Events

Title:

This link is informational, to help text.

Arm/Group*

Select the Arm/Groups for this Outcome Measure. The Arm/Groups define columns for reporting tabular Outcome Measure data. You will be able to edit the Arm/Group Titles and Descriptions later, if desired.

○ **Use Arm/Groups (i.e., columns) from** Participant Flow

Arm/Group Title	All Participants
Arm/Group Description	All participants received 3 weekly doses of *drugname* at a low dose (18 mg), medium dosage (27 mg or 36 mg depending on weight) and a high dosage (52 mg or 36 mg depending on weight) and another week of placebo.

○ **Use Arm/Groups (i.e., columns) from** Adverse Events

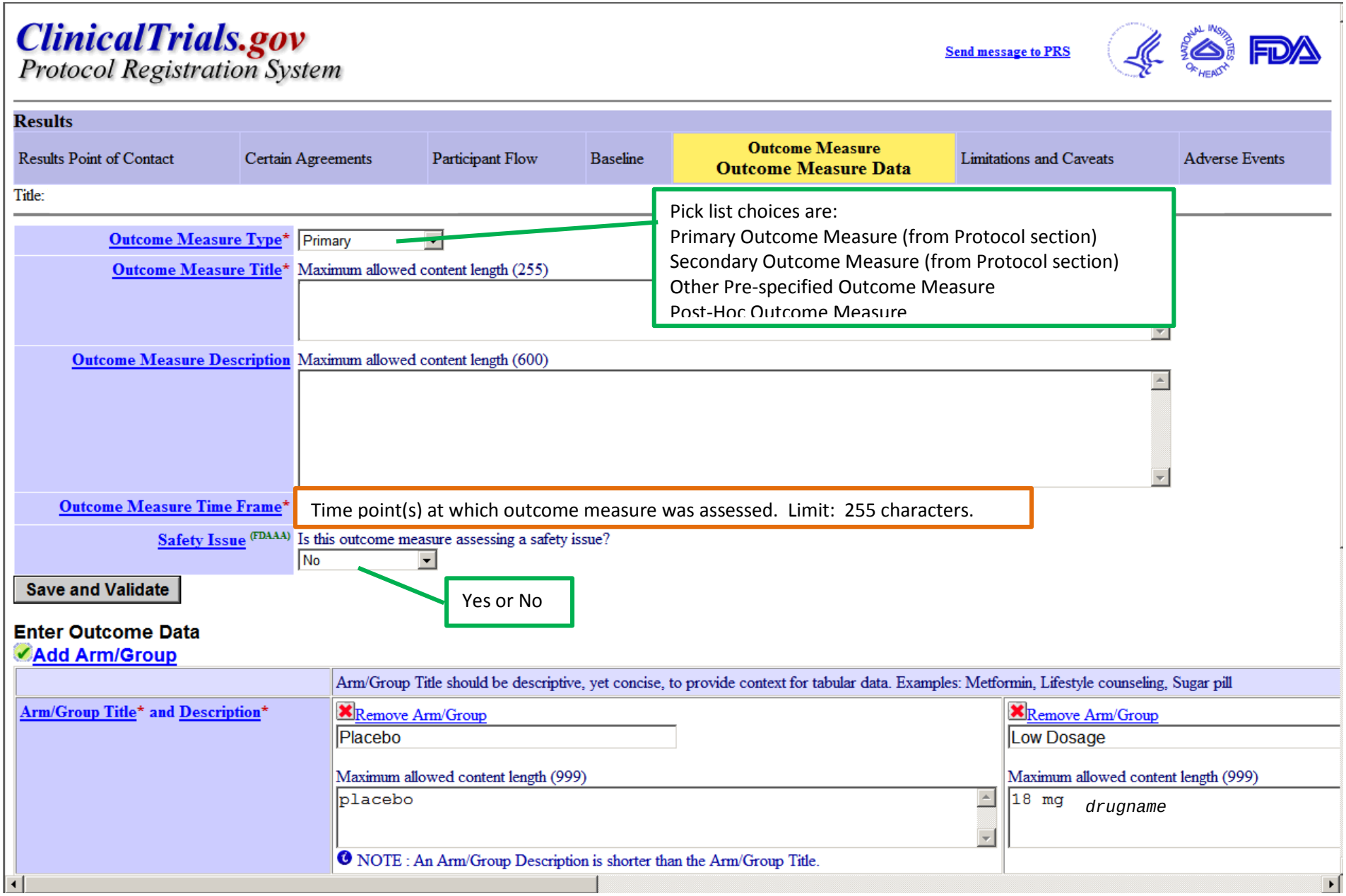
Arm/Group Title	Placebo	Low dosage	Medium Dosage	High Dosage
Arm/Group Description		Low dose: 18 mg *drugname*	Medium Dosage: 36 mg *drugname*	54 mg *drugname*

○ **Use Arm/Groups (i.e., columns) from** Outcome Measure

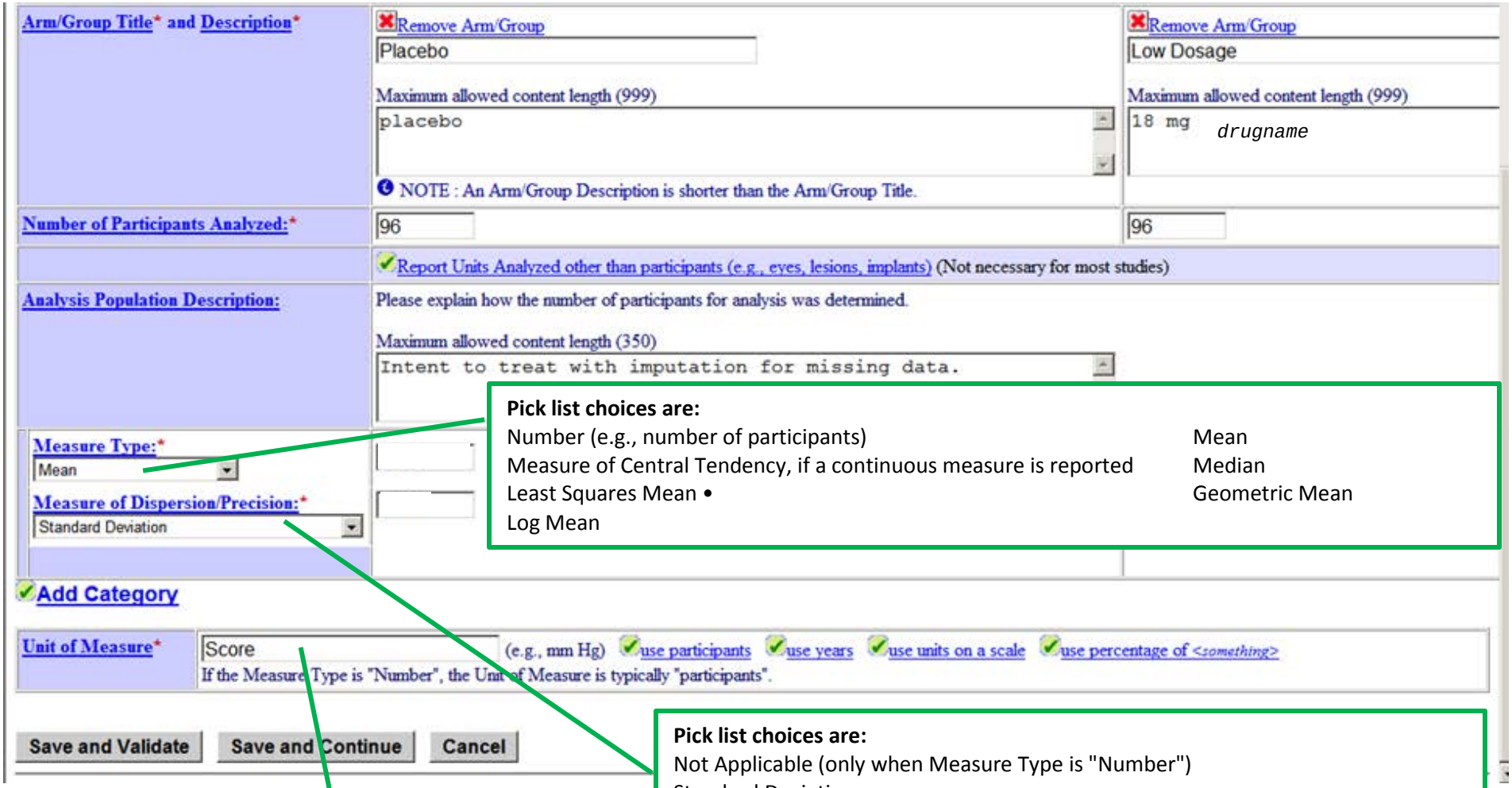
Arm/Group Title	Placebo	Low Dosage	Medium Dosage	High Dosage
Arm/Group Description	placebo	18 mg *drugname*	36 mg *Drugname* if >25 kg; 27 mg *drugname* if < 25 kg.	54 mg *Drugname* if >25 kg; 36 mg *drugname* if < 25 kg.

◉ **Define New Arm/Groups (columns)**

Continue **Cancel**



[In the model study there is a sideways portion to this page that holds data from additional study groups – omitted here.]



Pick list choices are:

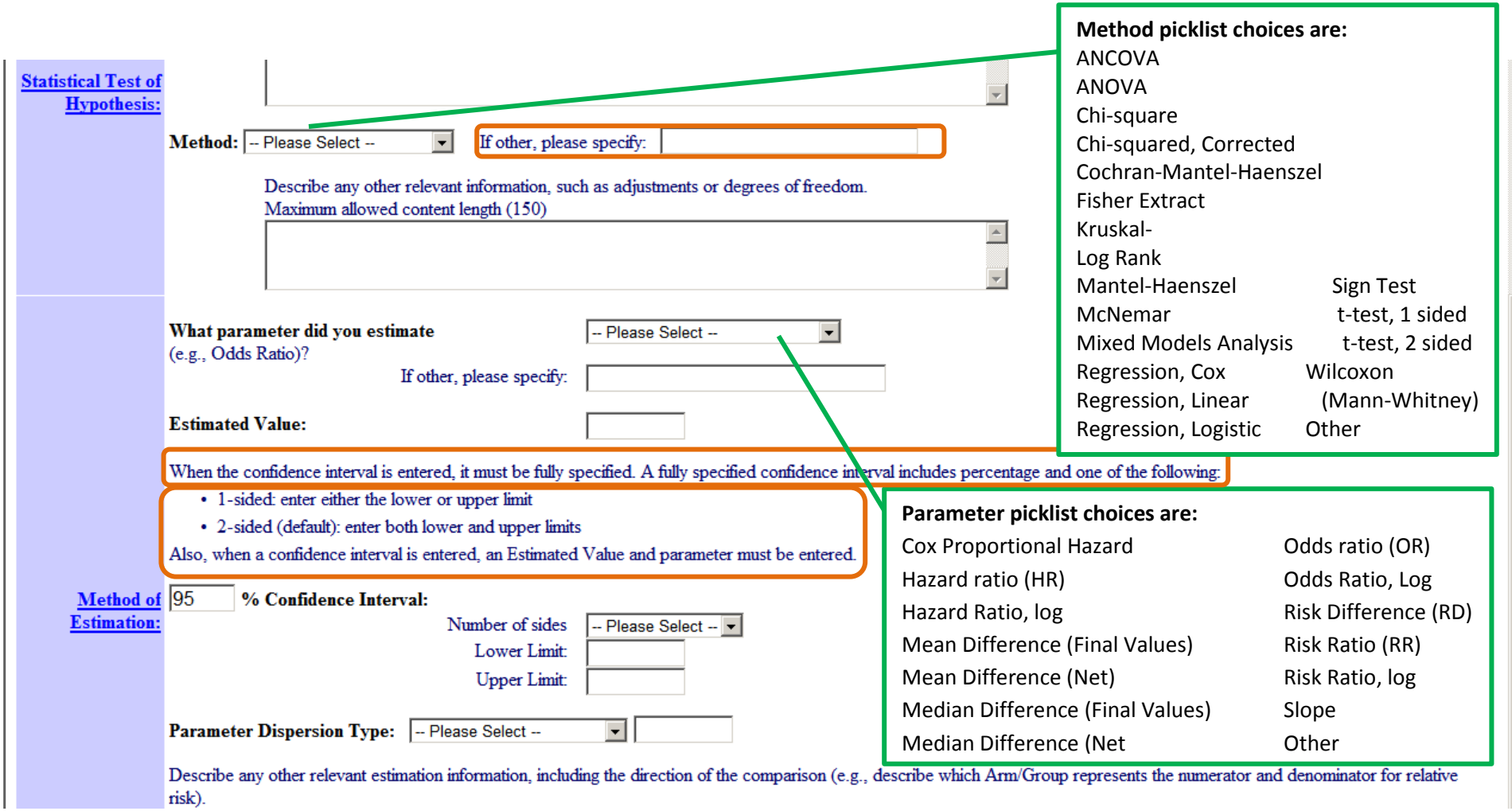
Number (e.g., number of participants)
Measure of Central Tendency, if a continuous measure is reported
Least Squares Mean •
Log Mean
Mean
Median
Geometric Mean

Fill-in field, not picklist. Pre-programmed suggestions are provided in smaller blue font to the right (see green check marks).

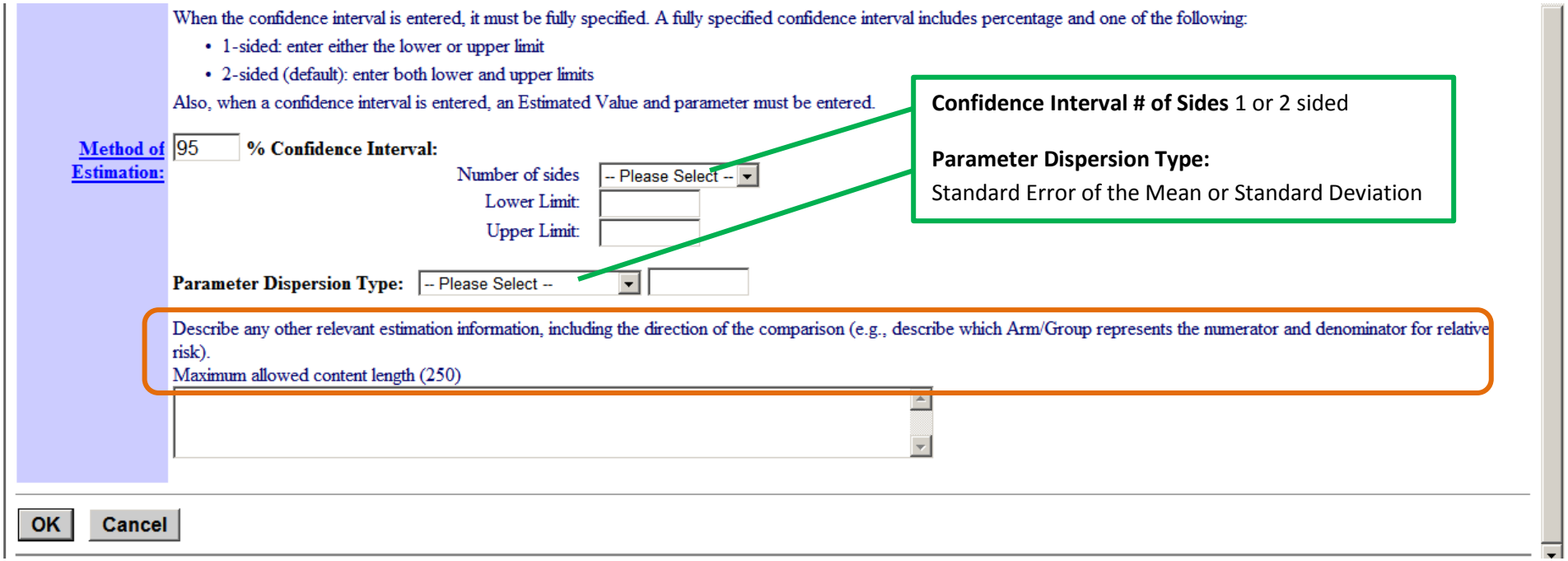
Pick list choices are:

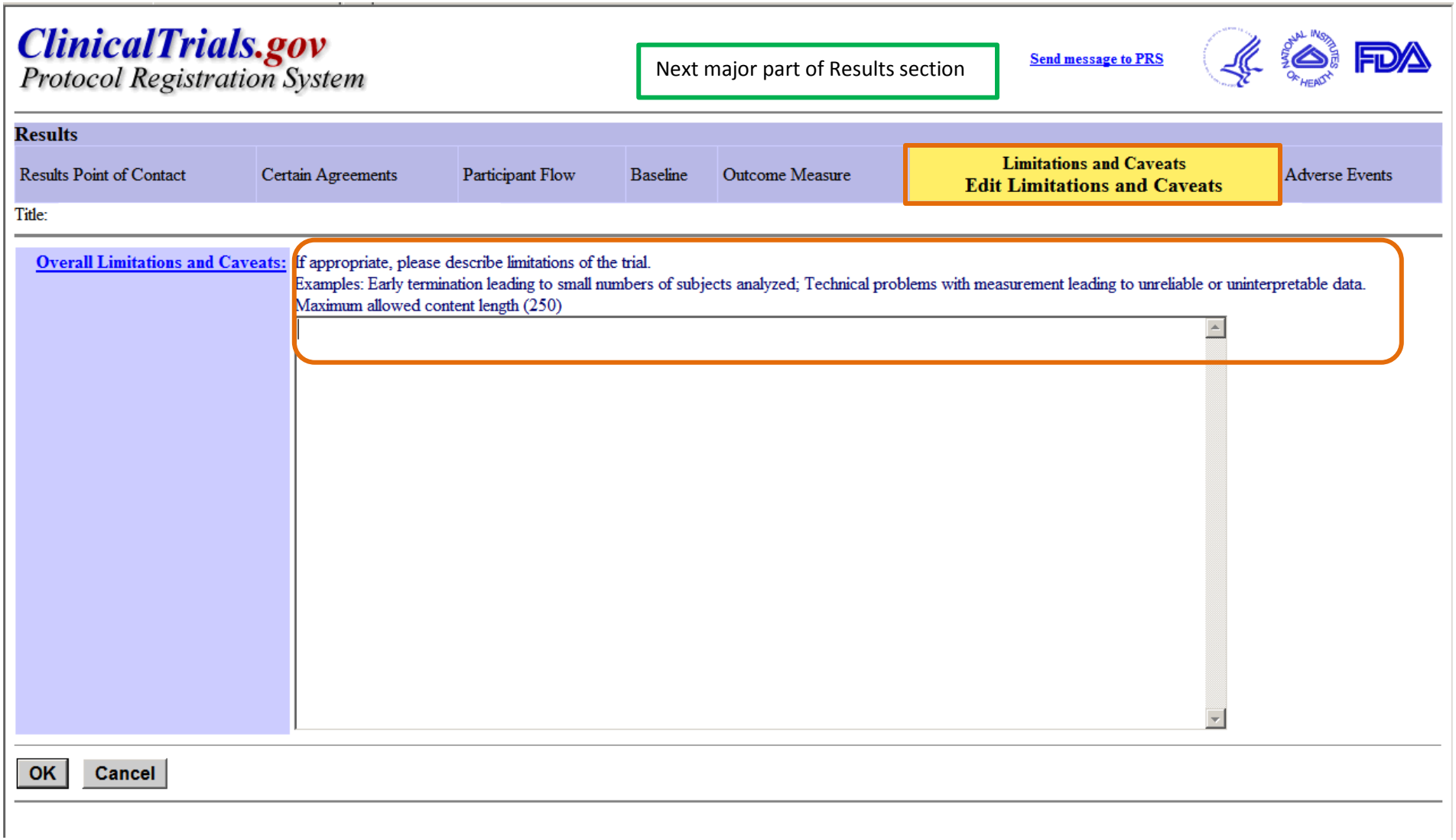
Not Applicable (only when Measure Type is "Number")
Standard Deviation
Inter-Quartile Range
Full Range
Standard Error
95% Confidence Interval
90% Confidence Interval
Geometric Coefficient of Variation (only when Measure Type is "Geometric Mean")

This screen continues on p. 32 (scroll down when live).



Screen Image continues below on next page.


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)
OK
Cancel
Confidence Interval # of Sides 1 or 2 sided
Parameter Dispersion Type:
Standard Error of the Mean or Standard Deviation


ClinicalTrials.gov
Protocol Registration System
Next major part of Results section
Send message to PRS
Results
Results Point of Contact
Certain Agreements
Participant Flow
Baseline
Outcome Measure
Limitations and Caveats
Edit Limitations and Caveats
Adverse Events
Title:
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

ClinicalTrials.gov
Protocol Registration System

Next major part of Results.
This example includes only 4 nonserious AEs.

Send message to PRS

Results

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

Title:

Results Overview

See p. 37

Edit	**Time Frame**	
	Additional Description	
	Source Vocabulary for Table Default	
	Assessment Type for Table Default	

(Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)

See p. 38.

See pp. 39-40

Sort Adverse Events Alphabetically - a productivity aid to facilitate Adverse Event (AE) data entry
Sorts Adverse Event Terms alphabetically within each Table ("Serious" and "Other")
NOTE: Order of AEs displayed within tables in the ClinicalTrials.gov public Web site may differ.

Add Arm/Group

Add Serious Adverse Event List all Serious Adverse Events.

See p. 41

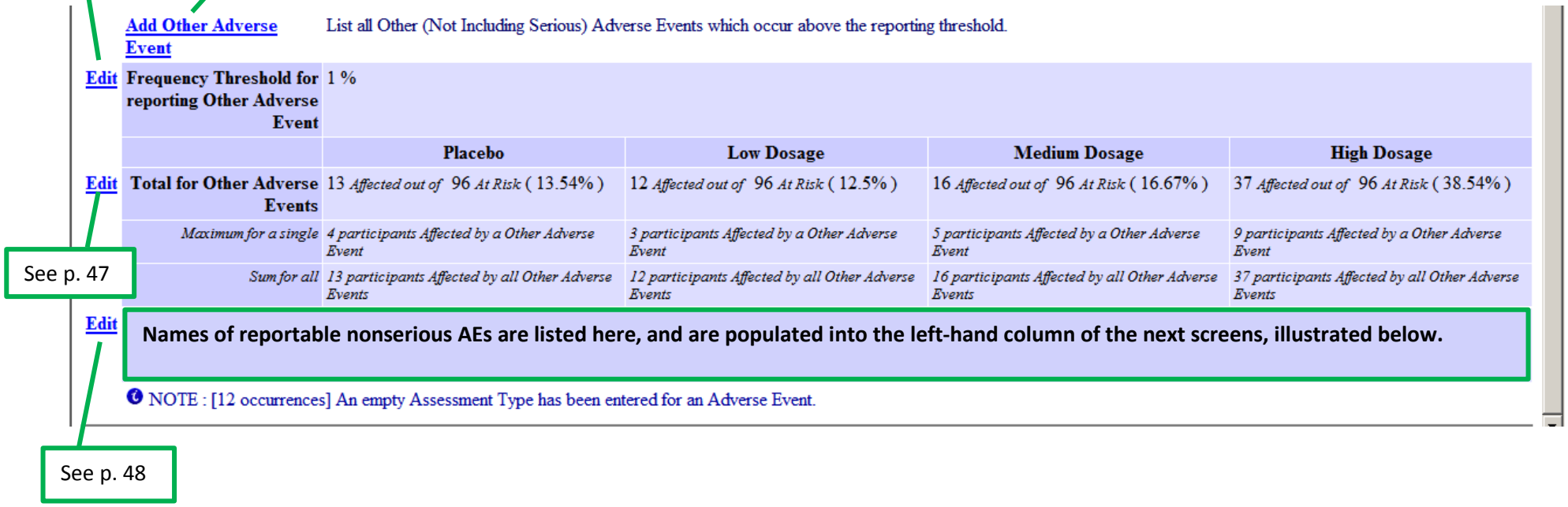
		Placebo Modify/Delete NOTE : An entry in Arm/Group Description is recommended.	Low Dosage *Low dose: 18 mg* Modify/Delete	Medium Dosage *Medium Dosage: 36 mg* Modify/Delete	High Dosage *54 mg* Modify/Delete
Edit	**Total for Serious Adverse Events**	0 *Affected out of* 96 *At Risk* (0%)	0 *Affected out of* 96 *At Risk* (0%)	1 *Affected out of* 96 *At Risk* (1.04%)	0 *Affected out of* 96 *At Risk* (0%)
	Maximum for a single	*0 participants Affected by a Serious Adverse Event*	*0 participants Affected by a Serious Adverse Event*	*1 participants Affected by a Serious Adverse Event*	*0 participants Affected by a Serious Adverse Event*
	Sum for all	*0 participants Affected by all Serious Adverse Events*	*0 participants Affected by all Serious Adverse Events*	*1 participants Affected by all Serious Adverse Events*	*0 participants Affected by all Serious Adverse Events*
Edit	Name of SAE				

See p. 42

[Non-Serious AEs are shown below the SAEs on this same screen, image on page 36 immediately below.]

See p. 44.

See p. 46.



Add Other Adverse Event | List all Other (Not Including Serious) Adverse Events which occur above the reporting threshold.

Edit	**Frequency Threshold for reporting Other Adverse Event**	1 %			
		Placebo	**Low Dosage**	**Medium Dosage**	**High Dosage**
Edit	**Total for Other Adverse Events**	13 *Affected out of* 96 *At Risk* (13.54%)	12 *Affected out of* 96 *At Risk* (12.5%)	16 *Affected out of* 96 *At Risk* (16.67%)	37 *Affected out of* 96 *At Risk* (38.54%)
	Maximum for a single	*4 participants Affected by a Other Adverse Event*	*3 participants Affected by a Other Adverse Event*	*5 participants Affected by a Other Adverse Event*	*9 participants Affected by a Other Adverse Event*
	Sum for all	*13 participants Affected by all Other Adverse Events*	*12 participants Affected by all Other Adverse Events*	*16 participants Affected by all Other Adverse Events*	*37 participants Affected by all Other Adverse Events*

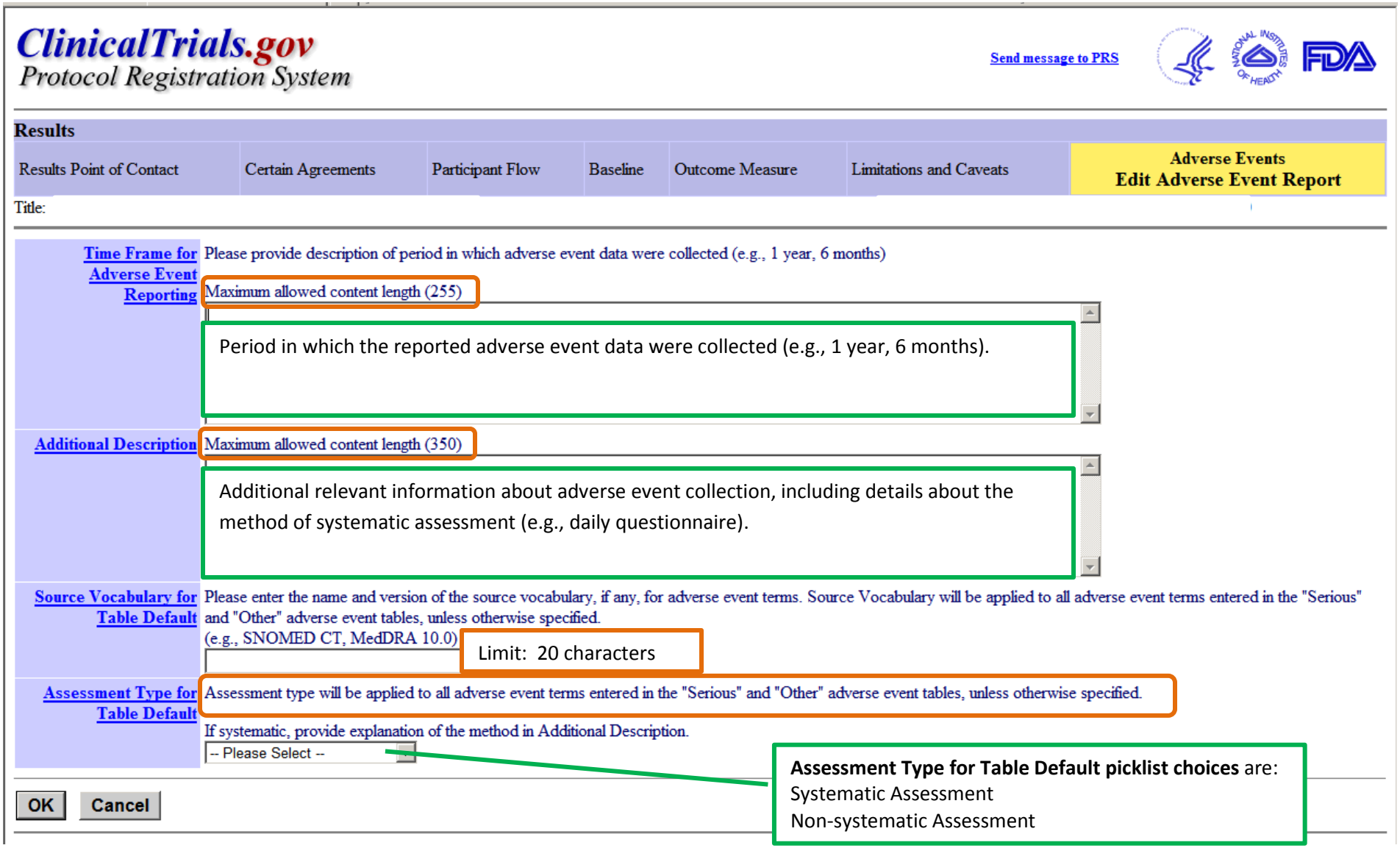
Edit

Names of reportable nonserious AEs are listed here, and are populated into the left-hand column of the next screens, illustrated below.

NOTE : [12 occurrences] An empty Assessment Type has been entered for an Adverse Event.

See p. 47

See p. 48


ClinicalTrials.gov
Protocol Registration System
Send message to PRS
Results
Results Point of Contact
Certain Agreements
Participant Flow
Baseline
Outcome Measure
Limitations and Caveats
Adverse Events
Edit Adverse Event Report
Title:
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)
Period in which the reported adverse event data were collected (e.g., 1 year, 6 months).
Additional Description
Maximum allowed content length (350)
Additional relevant information about adverse event collection, including details about the method of systematic assessment (e.g., daily questionnaire).
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)
Limit: 20 characters
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
Assessment Type for Table Default picklist choices are:
Systematic Assessment
Non-systematic Assessment

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

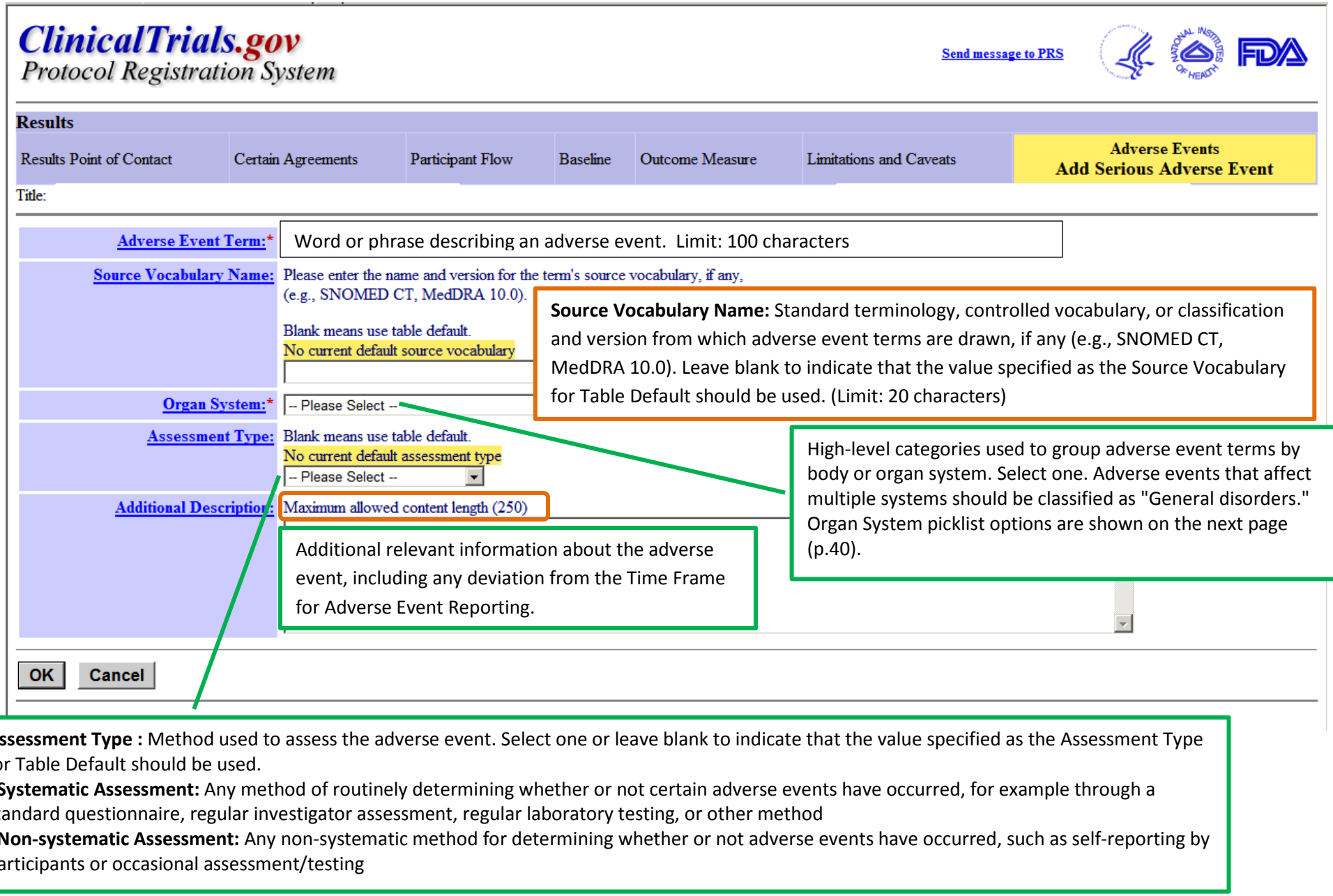
Results

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

Title

Arm/Group Title:*	Title should be descriptive, yet concise, to provide context for tabular data. Examples: Metformin, Lifestyle counseling, Sugar pill
Arm/Group Description:	Maximum allowed content length (999)

OK Cancel



Assessment Type : Method used to assess the adverse event. Select one or leave blank to indicate that the value specified as the Assessment Type for Table Default should be used.

- **Systematic Assessment:** Any method of routinely determining whether or not certain adverse events have occurred, for example through a standard questionnaire, regular investigator assessment, regular laboratory testing, or other method
- **Non-systematic Assessment:** Any non-systematic method for determining whether or not adverse events have occurred, such as self-reporting by participants or occasional assessment/testing

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Results

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

Title:

Adverse Event Term:* Word or phrase describing an adverse event. Limit: 100 characters

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

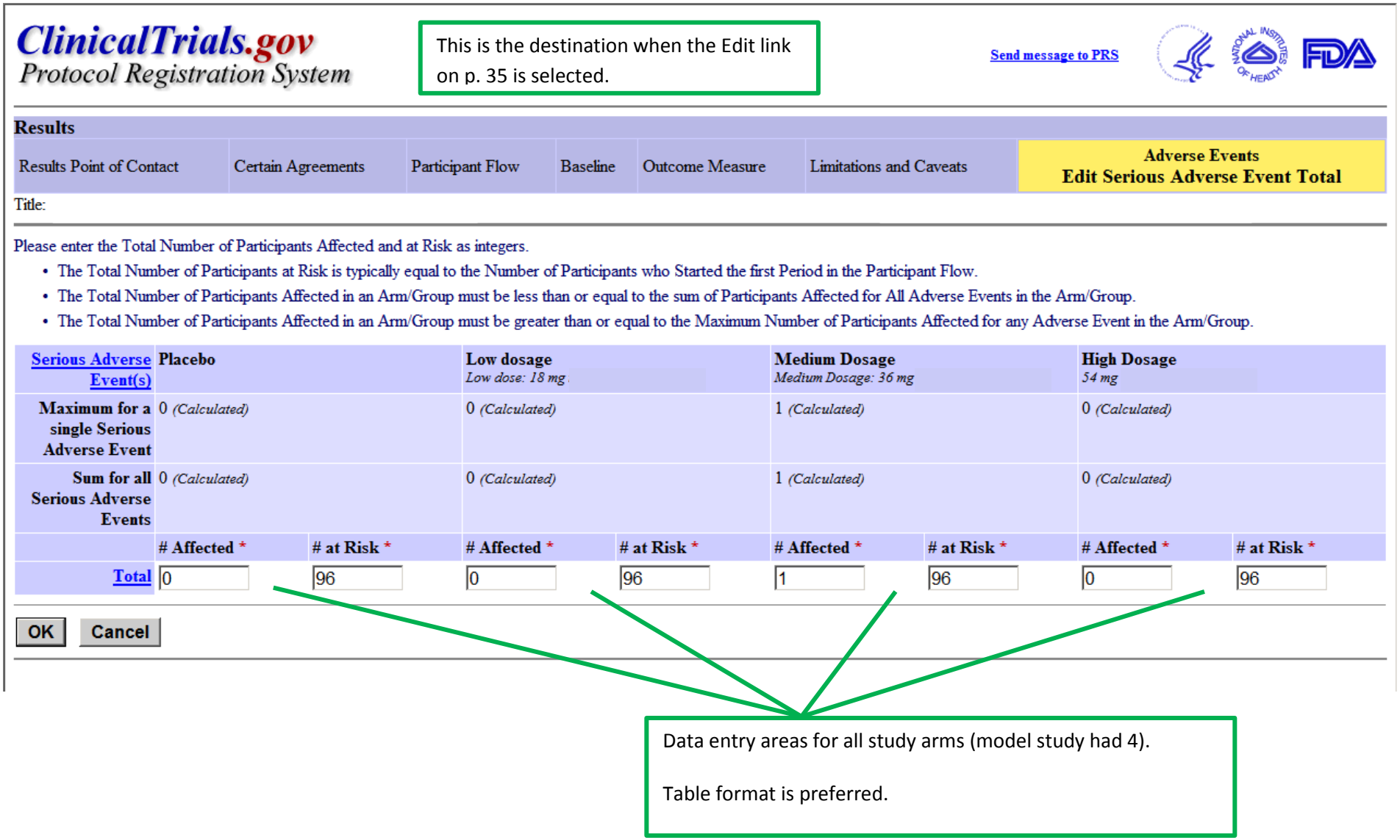
Organ System:* -- Please Select --

Assessment Type:

Additional Description:

- -- Please Select --
- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders

OK Cancel


ClinicalTrials.gov
Protocol Registration System
This is the destination when the Edit link on p. 35 is selected.
Send message to PRS
Results
Results Point of Contact
Certain Agreements
Participant Flow
Baseline
Outcome Measure
Limitations and Caveats
Adverse Events
Edit Serious Adverse Event Total
Title:
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)
Placebo
Low dosage
Low dose: 18 mg
Medium Dosage
Medium Dosage: 36 mg
High Dosage
54 mg
Maximum for a single Serious Adverse Event
0 (Calculated)
0 (Calculated)
1 (Calculated)
0 (Calculated)
Sum for all Serious Adverse Events
0 (Calculated)
0 (Calculated)
1 (Calculated)
0 (Calculated)
Affected *
at Risk *
Affected *
at Risk *
Affected *
at Risk *
Affected *
at Risk *
Total
0
96
0
96
1
96
0
96
OK
Cancel
Data entry areas for all study arms (model study had 4).
Table format is preferred.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Results

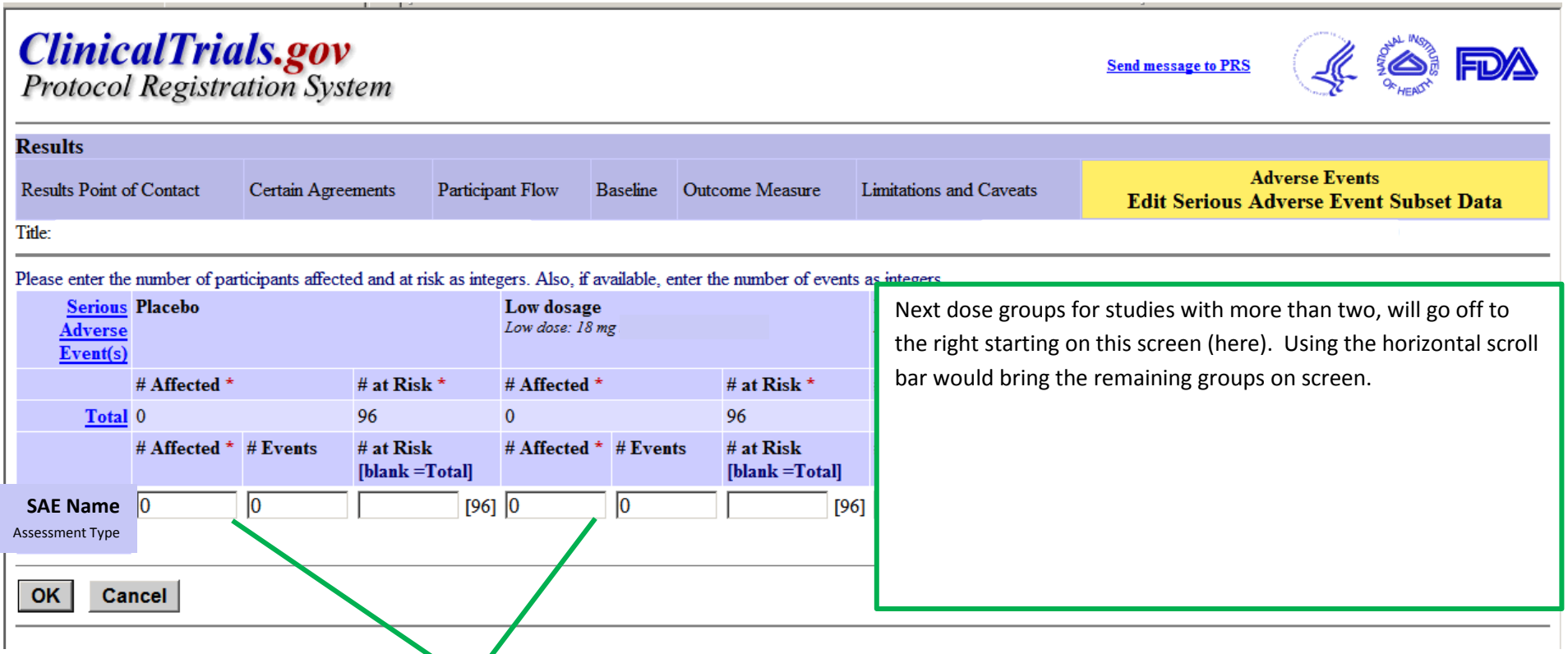
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	**Adverse Events** **Adverse Event Subset**

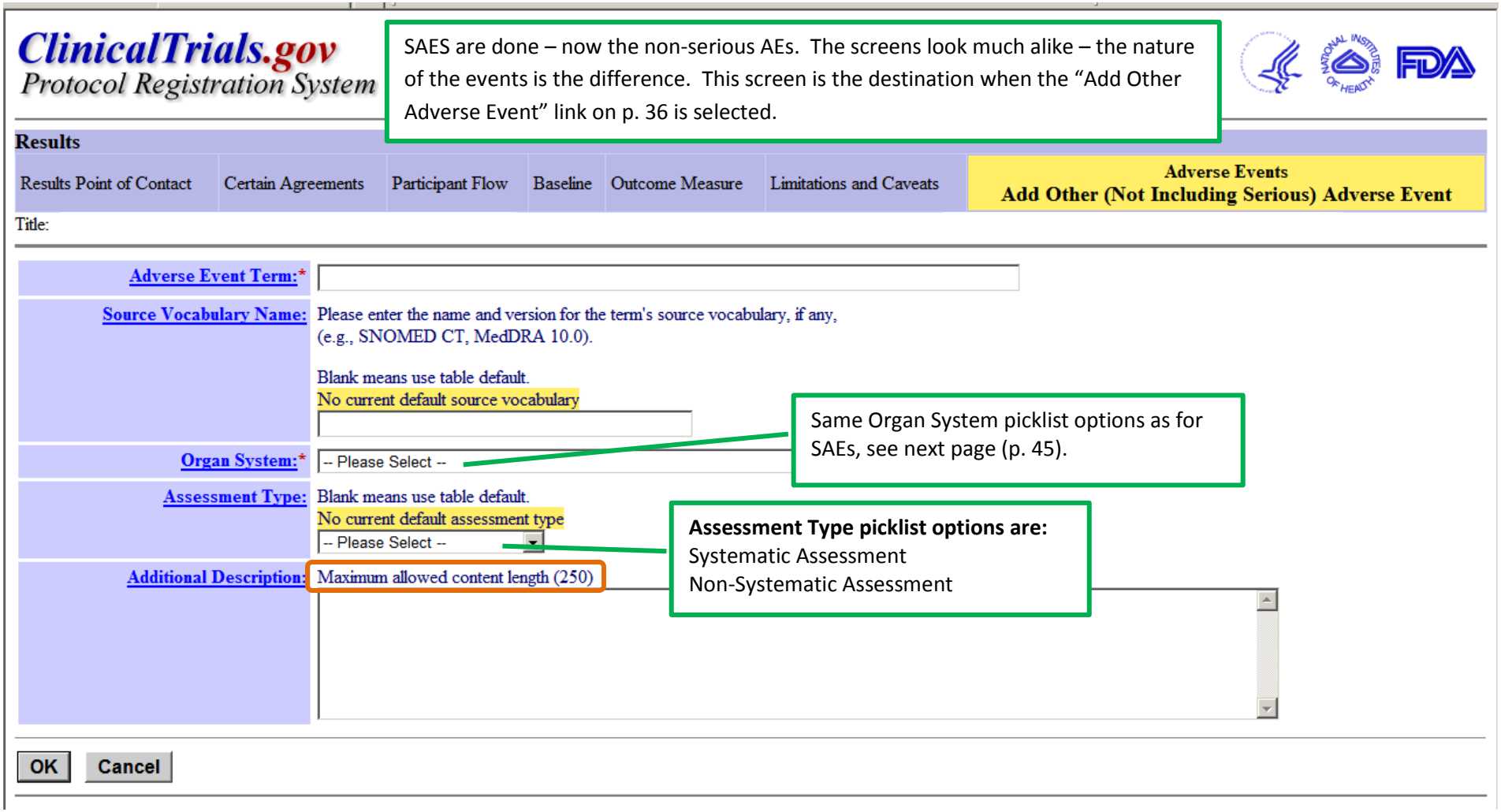
Title:

Adverse Event Overview

		Placebo	Low Dosage	Medium Dosage	High Dosage
Edit	**Total for Serious Adverse Events**	0 *Affected out of* 96 *At Risk* (0%)	0 *Affected out of* 96 *At Risk* (0%)	1 *Affected out of* 96 *At Risk* (1.04%)	0 *Affected out of* 96 *At Risk* (0%)
	Name of SAE Category Assessment Type	0 *Affected out of* 96 *At Risk* (0%) 0 *Events*	0 *Affected out of* 96 *At Risk* (0%) 0 *Events*	1 *Affected out of* 96 *At Risk* (1.04%) 1 *Events*	0 *Affected out of* 96 *At Risk* (0%) 0 *Events*

See p. 43, which is where the entry screens are, for numbers of Subjects who incurred the named SAE.


ClinicalTrials.gov
Protocol Registration System
Send message to PRS
Results
Results Point of Contact
Certain Agreements
Participant Flow
Baseline
Outcome Measure
Limitations and Caveats
Adverse Events
Edit Serious Adverse Event Subset Data
Title:
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)
Placebo
Low dosage
Low dose: 18 mg
Affected *
at Risk *
Affected *
at Risk *
Total
0
96
0
96
Affected *
Events
at Risk [blank =Total]
Affected *
Events
at Risk [blank =Total]
SAE Name
Assessment Type
0
0
[96]
0
0
[96]
OK
Cancel
Next dose groups for studies with more than two, will go off to the right starting on this screen (here). Using the horizontal scroll bar would bring the remaining groups on screen.
Data entry areas for study arms, 2 of 4 shown.


ClinicalTrials.gov
Protocol Registration System
SAES are done – now the non-serious AEs. The screens look much alike – the nature of the events is the difference. This screen is the destination when the "Add Other Adverse Event" link on p. 36 is selected.
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:
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 --
Same Organ System picklist options as for SAEs, see next page (p. 45).
Assessment Type:
Blank means use table default.
No current default assessment type
-- Please Select --
Assessment Type picklist options are:
Systematic Assessment
Non-Systematic Assessment
Additional Description:
Maximum allowed content length (250)
OK
Cancel

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

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:

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

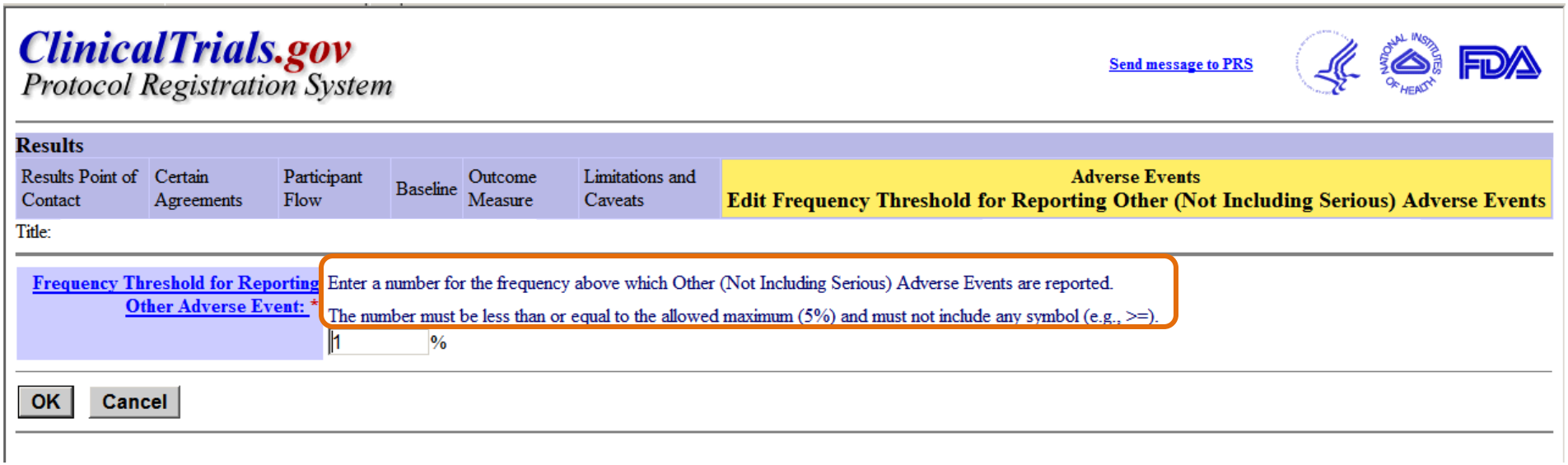
Organ System:* -- Please Select --

Assessment Type:

Additional Description:

- -- Please Select --
- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders

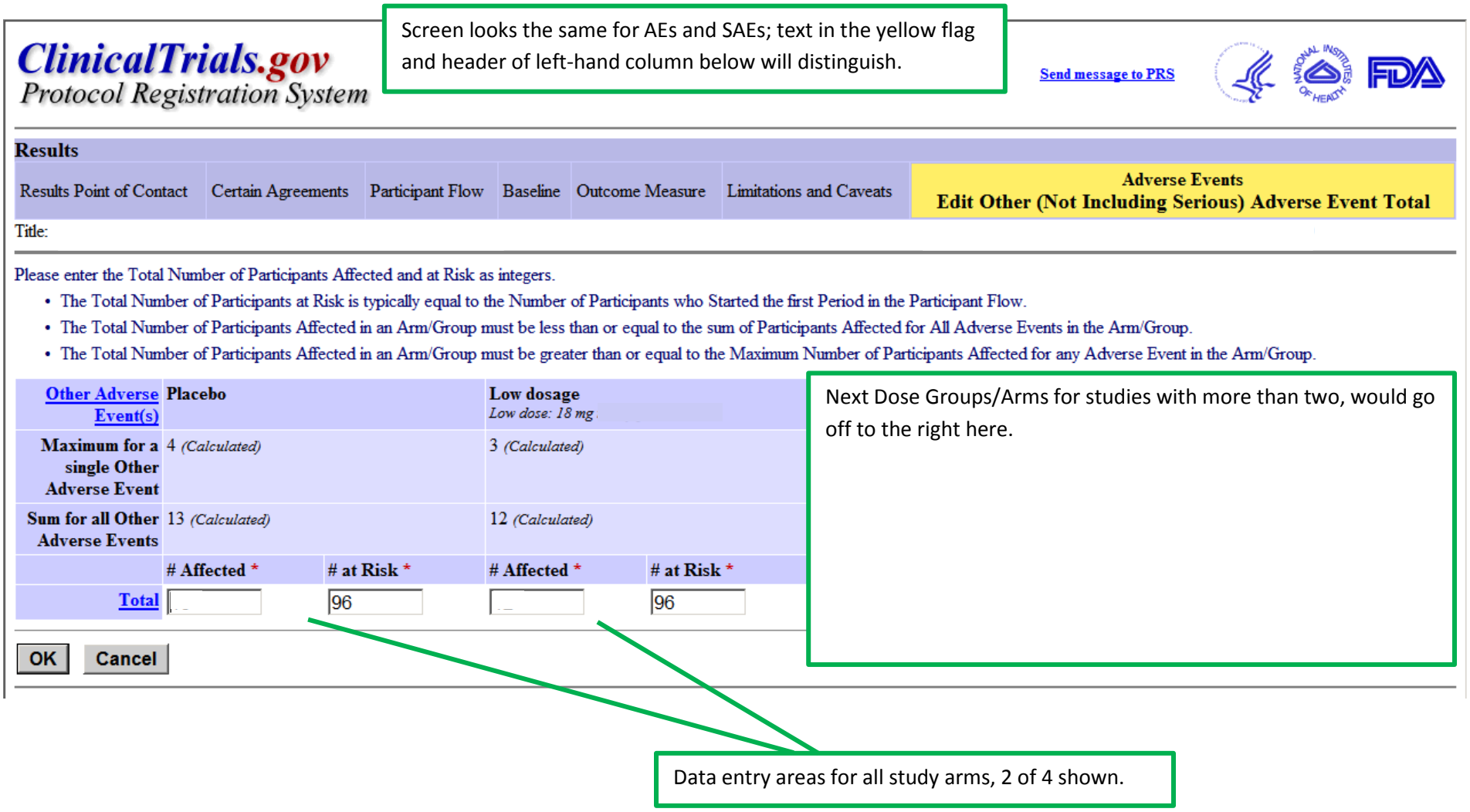
OK Cancel



The frequency of Other (Not Including Serious) Adverse Events that, when exceeded within any arm or comparison group, are reported in the results database for all arms or comparison groups. T

The number must be less than or equal to the allowed maximum (5%), and must not include any symbols (e.g., >= , %).

For example, a threshold of 5 percent indicates that all Other (Not Including Serious) Adverse Events with a frequency greater than 5 percent within at least one arm or comparison group are reported.


ClinicalTrials.gov
Protocol Registration System
Screen looks the same for AEs and SAEs; text in the yellow flag and header of left-hand column below will distinguish.
Send message to PRS
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:
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)
Placebo
Low dosage
Low dose: 18 mg
Maximum for a single Other Adverse Event
4 (Calculated)
3 (Calculated)
Sum for all Other Adverse Events
13 (Calculated)
12 (Calculated)
Affected *
at Risk *
Affected *
at Risk *
Total
96
96
OK
Cancel
Next Dose Groups/Arms for studies with more than two, would go off to the right here.
Data entry areas for all study arms, 2 of 4 shown.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Results

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

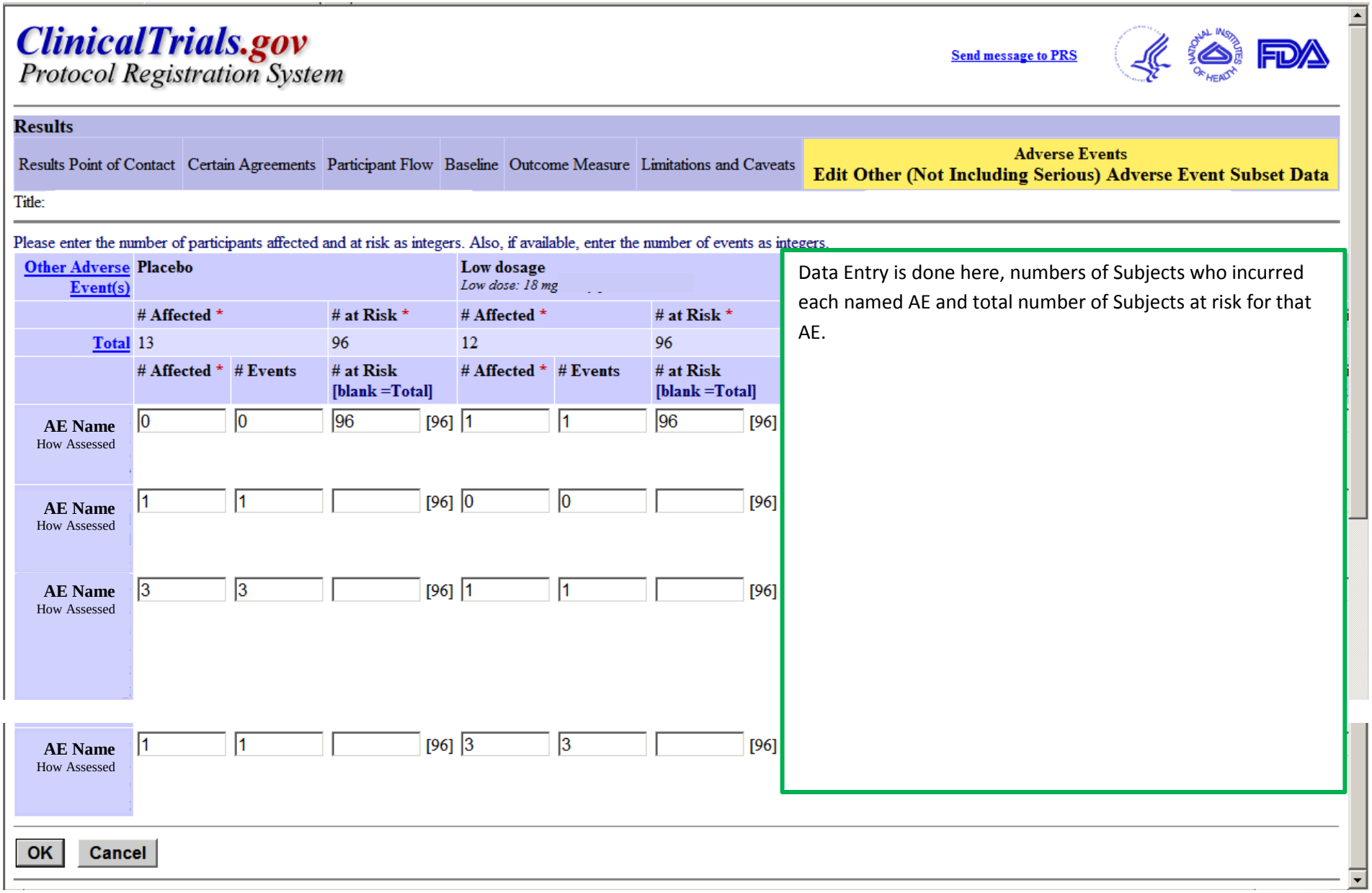
Title:

Adverse Event Overview

See p. 49 for actual data entry screens.

		Placebo	Low Dosage
Edit	**Total for Other Adverse Events**	13 *Affected out of* 96 *At Risk* (13.54%)	12 *Affected out of* 96 *At Risk* (12.5%)
	Name of AE Category How Assessed Number rated 4 (severe) Modify/Delete	0 *Affected out of* 96 *At Risk* (0%) 0 *Events*	1 *Affected out of* 96 *At Risk* (1.04%) 1 *Events*
	Name of AE Category How Assessed Number rated 4 (severe) Modify/Delete NOTE : An empty Assessment Type has been entered for an Adverse Event.	1 *Affected out of* 96 *At Risk* (1.04%) 1 *Events*	0 *Affected out of* 96 *At Risk* (0%) 0 *Events*
	Name of AE Category How Assessed Number rated 4 (severe) Modify/Delete	3 *Affected out of* 96 *At Risk* (3.12%) 3 *Events*	1 *Affected out of* 96 *At Risk* (1.04%) 1 *Events*
	Name of AE Category How Assessed Number rated 4 (severe) Modify/Delete	1 *Affected out of* 96 *At Risk* (1.04%) 1 *Events*	3 *Affected out of* 96 *At Risk* (3.12%) 3 *Events*

For brevity, four AEs from a longer list and only 2 arms of the four that the study had are illustrated here.



Only with study ownership in the clinicaltrials.gov system are the screens shown in this illustration visible. These illustrations would have not been possible without the kind permission of the model study's PI, who allowed the image extractor temporary ownership of the study in the ClinicalTrials.gov system.