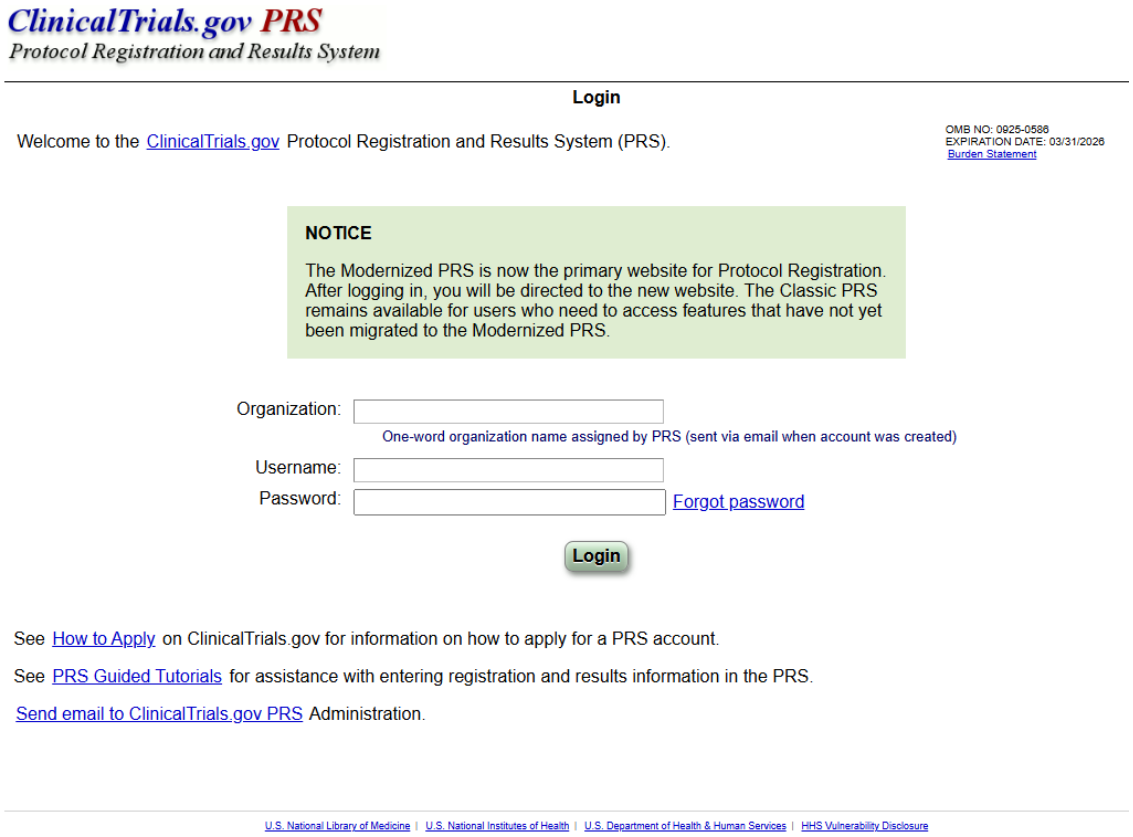
Attachment 5 - ClinicalTrials.gov Results Reporting Data Entry Screenshots



OMB No: 0925-0586
EXPIRATION DATE: 03/31/2026

Public reporting burden for this collection of information is estimated to average from 15 minutes to 45 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining 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 current 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.

Classic PRS

Edit Participant Flow

Help Definitions

Protocol Enrollment:	Enrollment is a Protocol Section data element (Protocol Registration Data Element Definitions). Changing the value here will change the value in the Protocol Section.
Recruitment Details:	Edit
[*] Pre-assignment Details:	Edit

Arms/Groups (2) + Add Arm/Group

* Arm/Group Title:	Edit **Arm 1**	Edit **Arm 2**	Total (Not public)
* § Arm/Group Description:	× Delete Move ▶	× Delete ◀ Move	
[*] Type of Units Assigned:	+ Add Units Assigned (Optional) Use only if assigned units other than participants (e.g., eyes, lesions, implants).		

Periods (1)

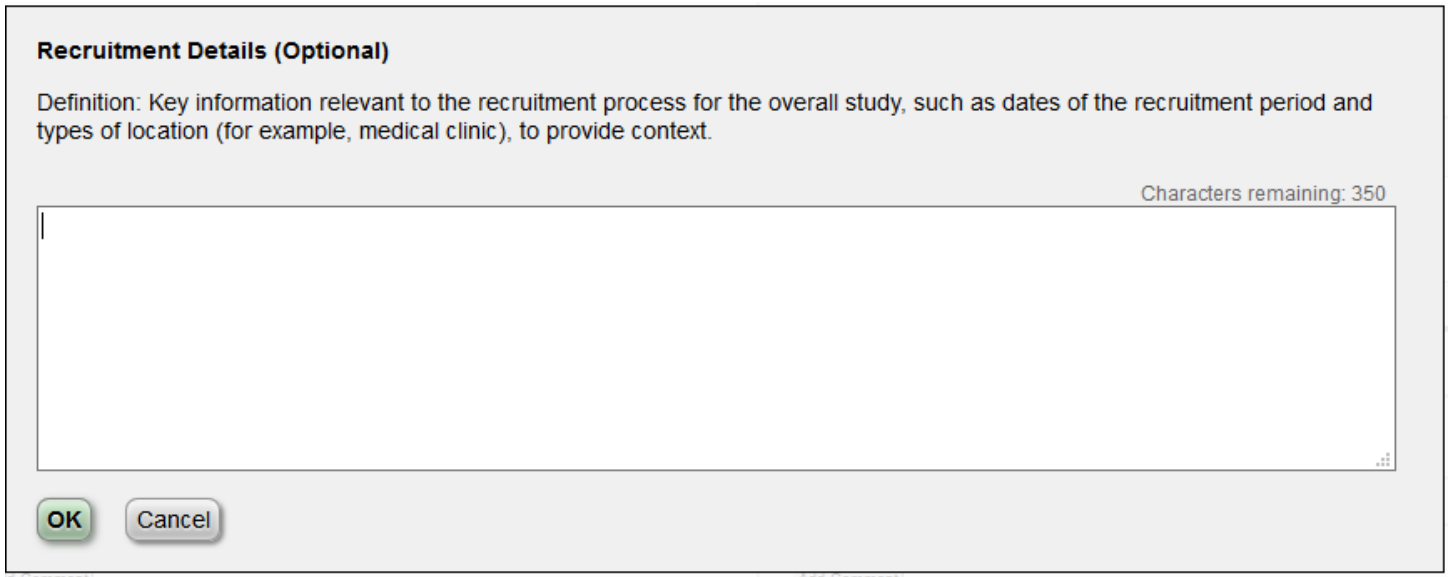
Protocol Enrollment:

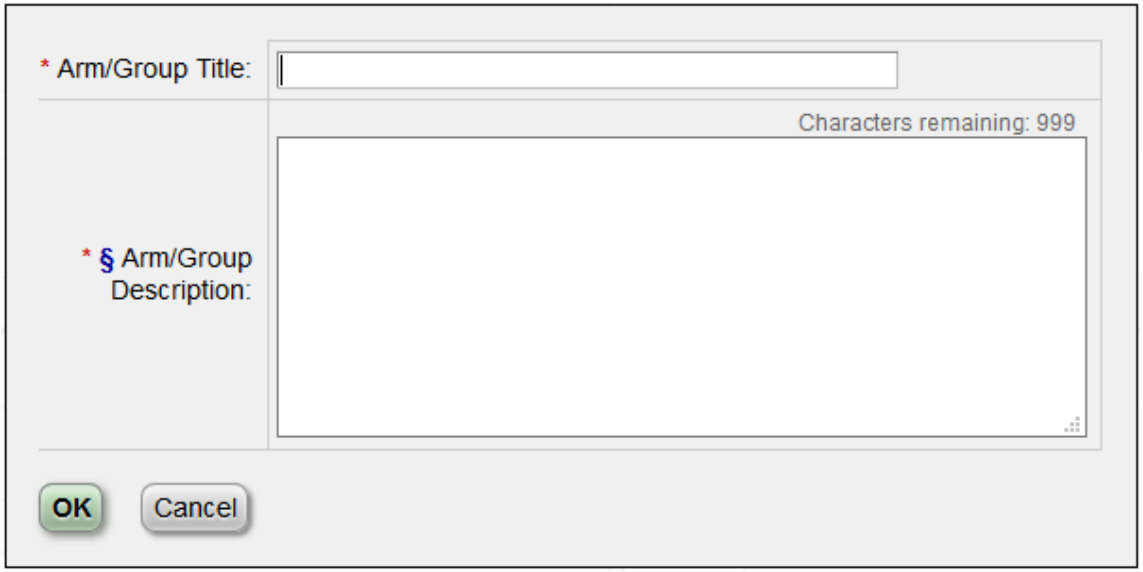
* Period Title:	Overall Study		
	Arm 1	**Arm 2**	Total (Not public)
* Started: Add Comment	Add Comment	Add Comment	unknown
+ Add Milestone			
* Completed: Add Comment	Add Comment	Add Comment	unknown
Not Completed: (Started - Completed)	unknown	unknown	
Reason Not Completed			
+ Add Reason Not Completed			

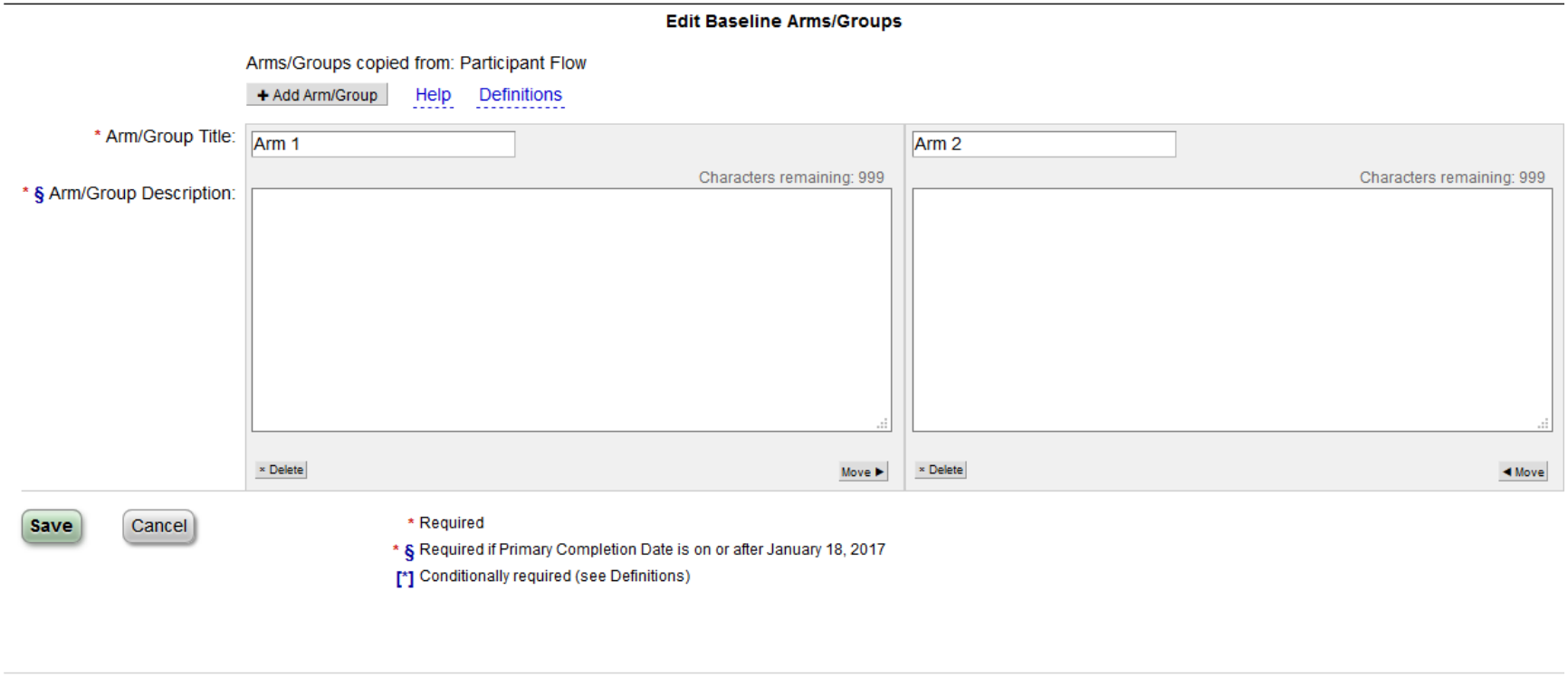
+ Add Period

Save Validate Cancel

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)


Recruitment Details (Optional)
Definition: Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (for example, medical clinic), to provide context.
Characters remaining: 350
OK
Cancel


* Arm/Group Title:
Characters remaining: 999
* § Arm/Group Description:
OK
Cancel


Edit Baseline Arms/Groups
Arms/Groups copied from: Participant Flow
+ Add Arm/Group
Help
Definitions
* Arm/Group Title:
* § Arm/Group Description:
Arm 1
Characters remaining: 999
Arm 2
Characters remaining: 999
× Delete
Move ▶
× Delete
◀ Move
Save
Cancel
* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Add Baseline Measures

Help Definitions

		* Baseline Measure Title:	
* **Age** At least 1 is Required	☑	Age, Continuous	Example
	☑	Age, Categorical ≤18 years; 18 to 65 years; ≥65 years	Example
	☐	Age, Customized	Example
* **Sex/Gender** At least 1 is Required	☑	Sex: Female, Male	Example
	☐	Sex/Gender, Customized	Example
* § **Race and Ethnicity**	☐	Race (NIH/OMB)	Example
	☐	Ethnicity (NIH/OMB)	Example
	☐	Race/Ethnicity, Customized	Example
	☐	Race and Ethnicity Not Collected	Example
Region of Enrollment Pre-filled with countries from Locations in Protocol	☑	Region of Enrollment	Example
* § **Study-Specific Measures** Additional Baseline Measures assessed in the study, if any.	+ Add		Example

Save Cancel

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Baseline Measure

Help Definitions

* Baseline Measure Title:	Age, Categorical
Baseline Measure Description:	Edit Additional information about the measure (e.g., description of scale)

	Arm 1	Arm 2	Total
Overall Number of Baseline Participants:	---	---	unknown
Baseline Analysis Population Description:			

* Measure Type: Count of Participants — Hide calculated percentage

* Measure of Dispersion: Not Applicable

	Arm 1	Arm 2	Total
Number Analyzed: Participants	--- participants Edit	--- participants Edit	unknown
<=18 years	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
Between 18 and 65 years	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
>=65 years	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%

+ Add Row

* Unit of Measure: participants

Save Validate Cancel

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Baseline Measure

Help Definitions

* Baseline Measure Title:	Sex: Female, Male
Baseline Measure Description:	Edit Additional information about the measure (e.g., description of scale)

	Arm 1	Arm 2	Total
Overall Number of Baseline Participants:	---	---	unknown
Baseline Analysis Population Description:			

* Measure Type:	Count of Participants	Hide calculated percentage		
* Measure of Dispersion:	Not Applicable			
	Number Analyzed: Participants	--- participants Edit	--- participants Edit	unknown
	Female	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
	Male	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
+ Add Row				
* Unit of Measure:	participants			

Save Validate Cancel

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Baseline Measure

Help Definitions

Information is required

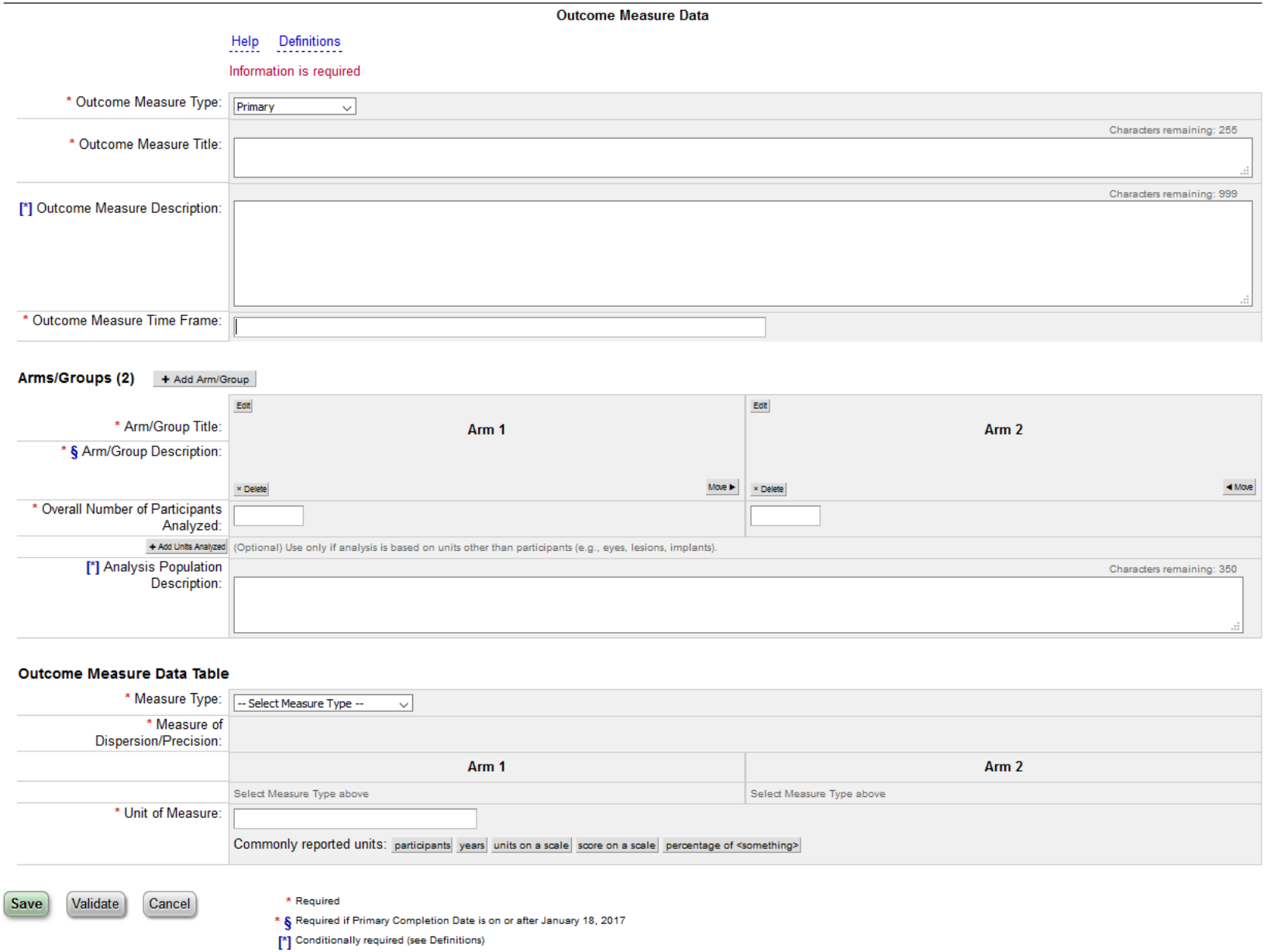
* Study-Specific Baseline Measure Title:	
Baseline Measure Description:	Edit Additional information about the measure (e.g., description of scale)

	Arm 1	Arm 2	Total
Overall Number of Baseline Participants:	---	---	unknown
Baseline Analysis Population Description:			

* Measure Type:	-- Select Measure Type --			
* Measure of Dispersion:	-- Select Measure of Dispersion --			
	Number Analyzed: Participants	--- participants Edit	--- participants Edit	unknown
		Select Measure Type above	Select Measure Type above	Select Measure Type above
+ Add Row				
* Unit of Measure:	Commonly reported units: years / units on a scale / participants			

Save Validate Cancel

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)



Outcome Measure Data

Help Definitions

Information is required

* Outcome Measure Type: Primary

* Outcome Measure Title: Characters remaining: 255

[*] Outcome Measure Description: Characters remaining: 999

* Outcome Measure Time Frame:

Arms/Groups (2) + Add Arm/Group

	Edit Arm 1 × Delete Move ▶	Edit Arm 2 × Delete ◀ Move
* Arm/Group Title:	Arm 1	Arm 2
* § Arm/Group Description:		
* Overall Number of Participants Analyzed:		

+ Add Units Analyzed (Optional) Use only if analysis is based on units other than participants (e.g., eyes, lesions, implants).

[*] Analysis Population Description: Characters remaining: 350

Outcome Measure Data Table

* Measure Type: -- Select Measure Type --

* Measure of Dispersion/Precision:

	Arm 1	Arm 2
	Select Measure Type above	Select Measure Type above

* Unit of Measure:

Commonly reported units: participants | years | units on a scale | score on a scale | percentage of <something>

Save Validate Cancel

* Required

* § Required if Primary Completion Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Edit Adverse Event Table Defaults

Help Definitions

* § Time Frame:	Provide a description of the specific period of time over which adverse event data were collected (e.g., 1 year, 6 months) Characters remaining: 500
[*] Adverse Event Reporting Description:	If the definition of adverse event and/or serious adverse event, used to collect adverse event information, differs from the clinicaltrials.gov Definitions, describe how the definitions differ. Also, optionally provide additional relevant information about adverse event collection. Characters remaining: 500
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)
* § Collection Approach 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 Adverse Event Reporting Description. -- Please Select --

Save Cancel

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit All-Cause Mortality

Help Definitions

All-Cause Mortality	Arm 1	Arm 2
* § Total Number Affected:	participants	participants
* § Total Number At Risk:	participants	participants

Save Validate Cancel

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Serious Adverse Event Total

Help Definitions

Serious Adverse Event(s)	Arm 1	Arm 2
* 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

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Other (Not Including Serious) Adverse Event Total

Help Definitions

Other Adverse Event(s)	Arm 1	Arm 2
* 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

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

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

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 Primary Completion Date, select "Yes." 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

* Required

* § Required if Primary Completion Date is on or after January 18, 2017

Edit Results Point of Contact

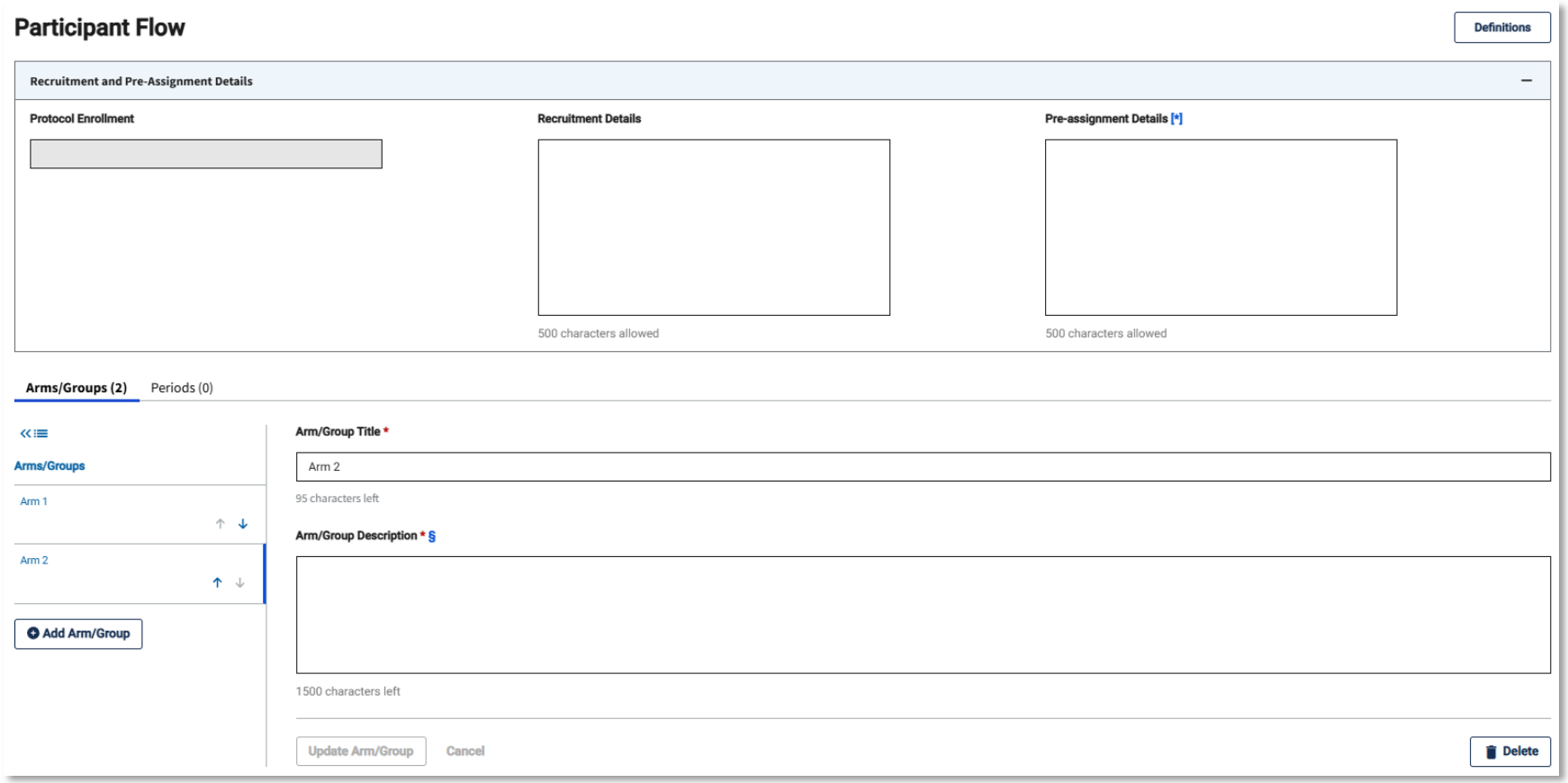
Definitions

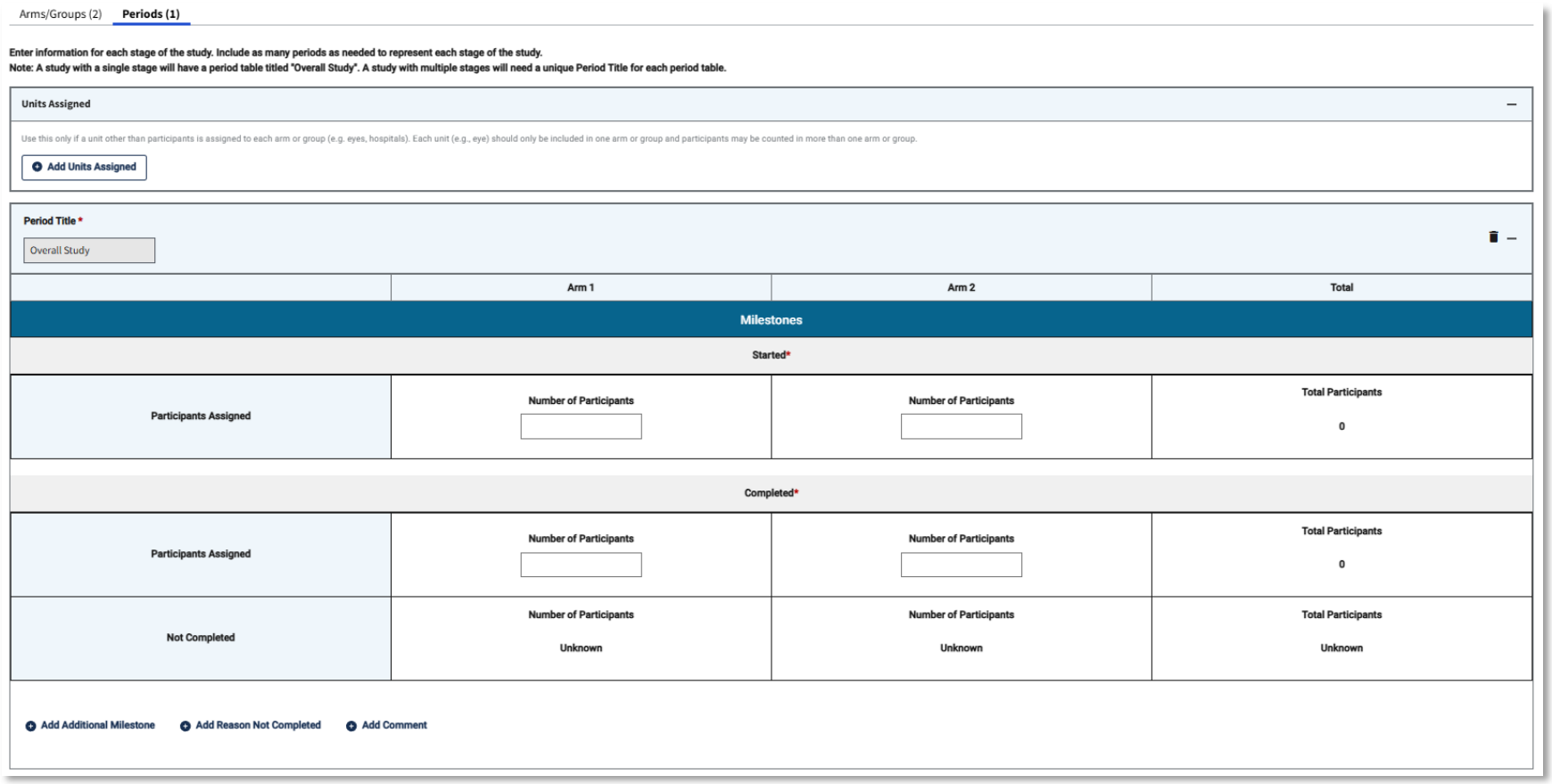
* Name or Official Title:	Enter the specific person's name (e.g., Dr. Jane Smith) or a position title (e.g., Director of Clinical Trials).
* Organization Name:	
* § Phone:	Ext.
* § Email:	

Save Cancel

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Modernized PRS





Arms/Groups (2) **Periods (1)**

Enter information for each stage of the study. Include as many periods as needed to represent each stage of the study.
Note: A study with a single stage will have a period table titled "Overall Study". A study with multiple stages will need a unique Period Title for each period table.

Units Assigned –

Use this only if a unit other than participants is assigned to each arm or group (e.g. eyes, hospitals). Each unit (e.g., eye) should only be included in one arm or group and participants may be counted in more than one arm or group.

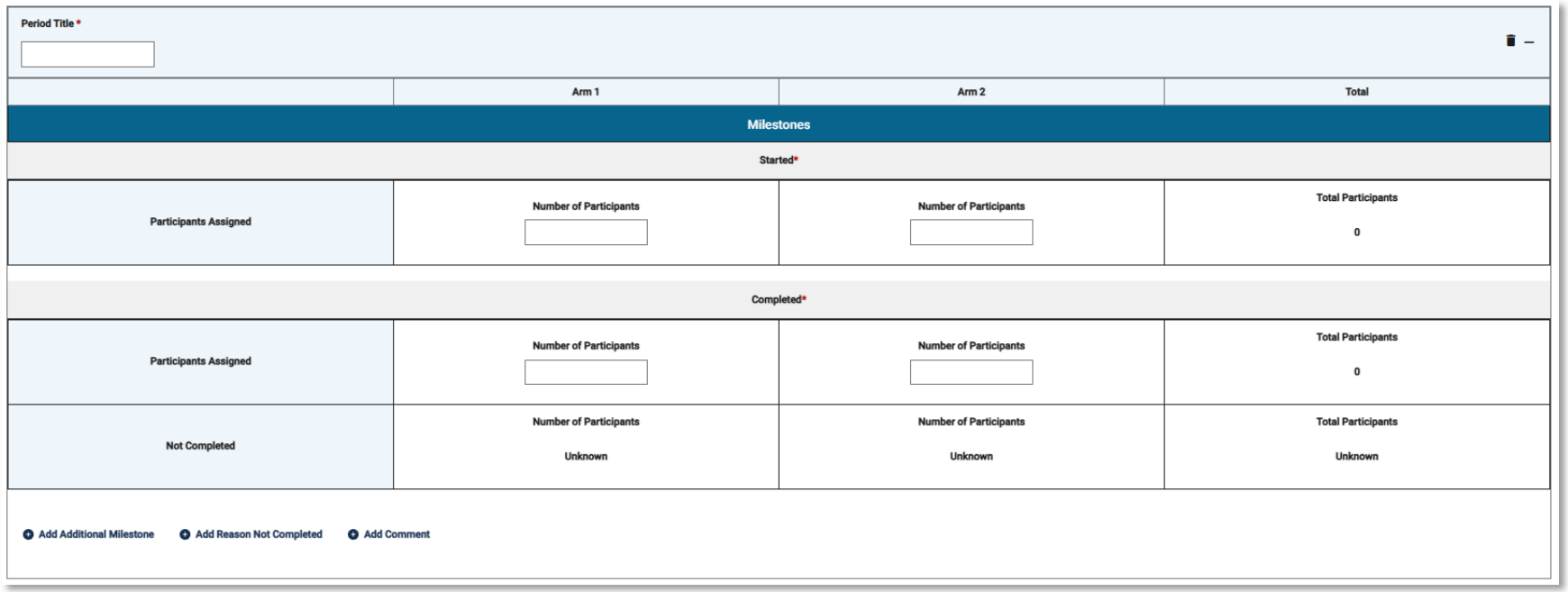
Add Units Assigned

Period Title *

Overall Study

	Arm 1	Arm 2	Total
Milestones			
Started*			
Participants Assigned	Number of Participants	Number of Participants	Total Participants 0
Completed*			
Participants Assigned	Number of Participants	Number of Participants	Total Participants 0
Not Completed	Number of Participants Unknown	Number of Participants Unknown	Total Participants Unknown

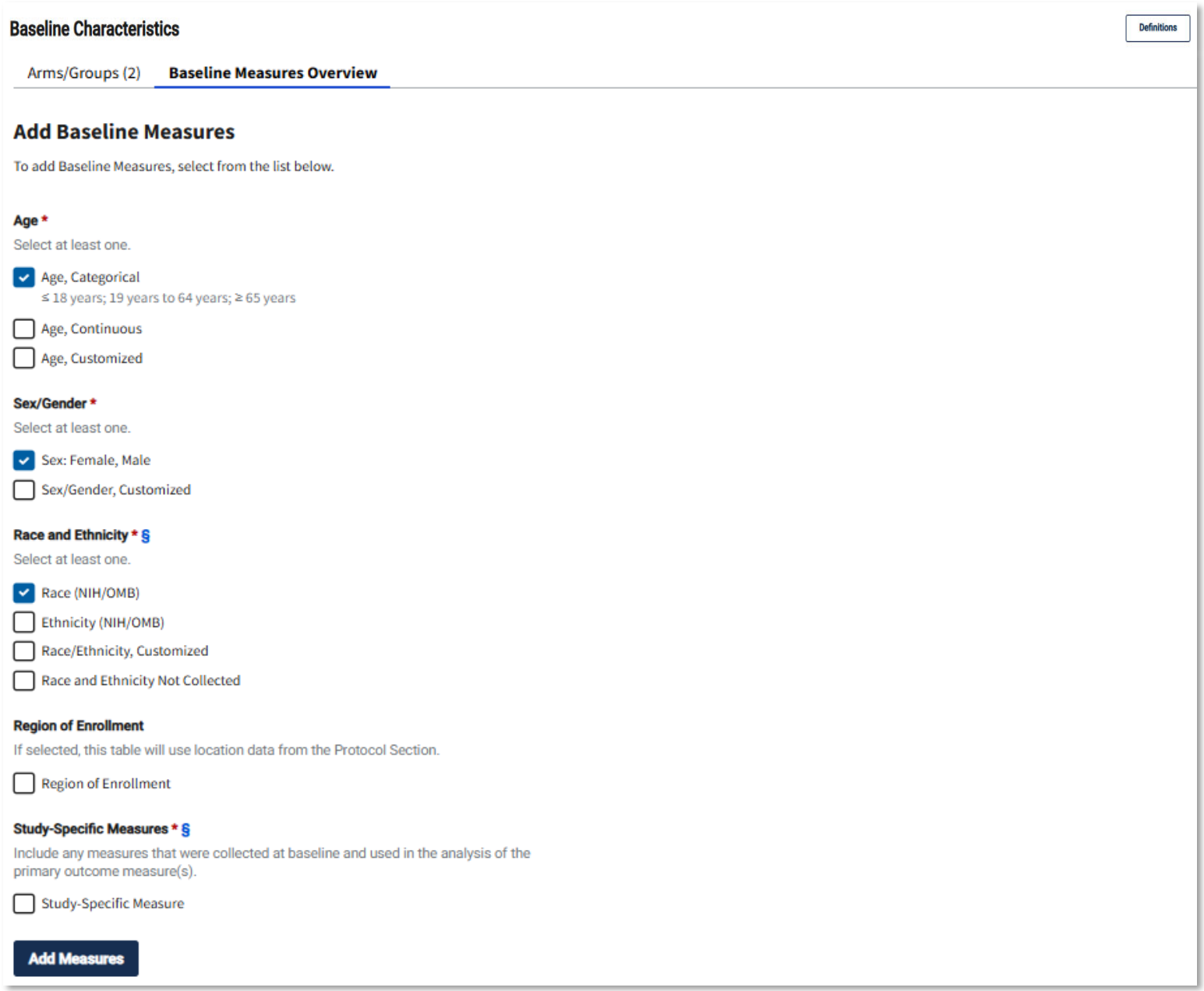
Add Additional Milestone Add Reason Not Completed Add Comment

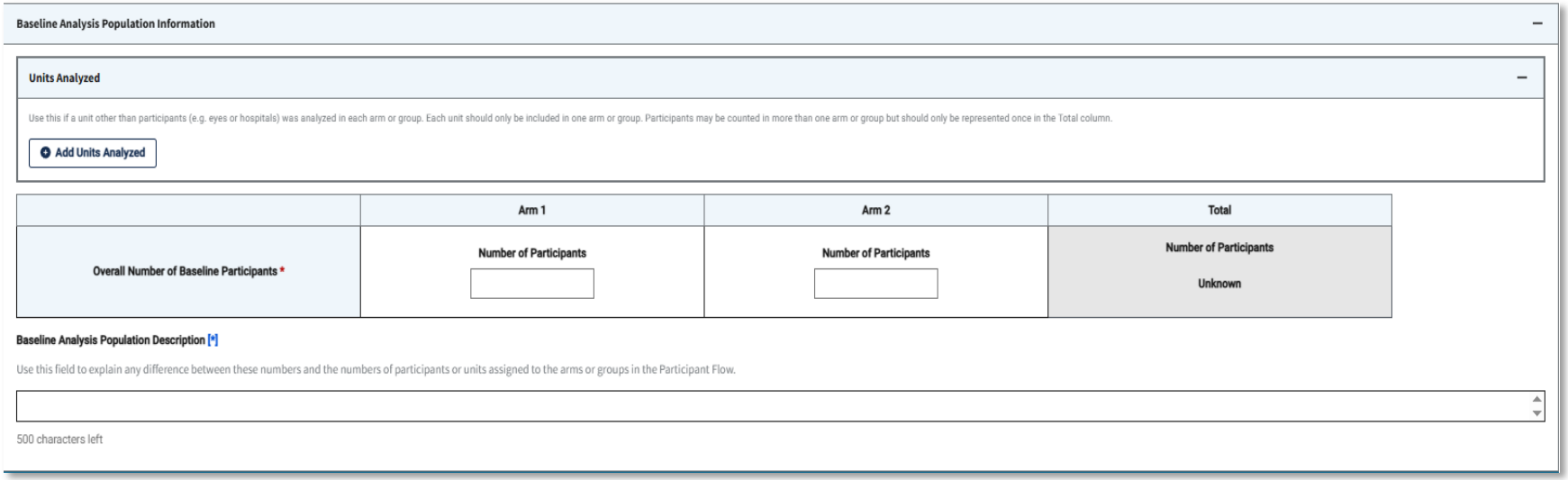


Period Title *

	Arm 1	Arm 2	Total
Milestones			
Started*			
Participants Assigned	Number of Participants	Number of Participants	Total Participants 0
Completed*			
Participants Assigned	Number of Participants	Number of Participants	Total Participants 0
Not Completed	Number of Participants Unknown	Number of Participants Unknown	Total Participants Unknown

Add Additional Milestone Add Reason Not Completed Add Comment


Baseline Characteristics
Definitions
Arms/Groups (2)
Baseline Measures Overview
Add Baseline Measures
To add Baseline Measures, select from the list below.
Age *
Select at least one.
Age, Categorical
≤ 18 years; 19 years to 64 years; ≥ 65 years
Age, Continuous
Age, Customized
Sex/Gender *
Select at least one.
Sex: Female, Male
Sex/Gender, Customized
Race and Ethnicity * §
Select at least one.
Race (NIH/OMB)
Ethnicity (NIH/OMB)
Race/Ethnicity, Customized
Race and Ethnicity Not Collected
Region of Enrollment
If selected, this table will use location data from the Protocol Section.
Region of Enrollment
Study-Specific Measures * §
Include any measures that were collected at baseline and used in the analysis of the primary outcome measure(s).
Study-Specific Measure
Add Measures



Baseline Analysis Population Information

Units Analyzed

Use this if a unit other than participants (e.g. eyes or hospitals) was analyzed in each arm or group. Each unit should only be included in one arm or group. Participants may be counted in more than one arm or group but should only be represented once in the Total column.

Add Units Analyzed

	Arm 1	Arm 2	Total
Overall Number of Baseline Participants *	Number of Participants	Number of Participants	Number of Participants Unknown

Baseline Analysis Population Description [*]

Use this field to explain any difference between these numbers and the numbers of participants or units assigned to the arms or groups in the Participant Flow.

500 characters left

Age, Categorical

Measure Settings

Baseline Measure Description

Use this field to provide additional details about the measure that could help with the interpretation of the data, e.g. information about a scale.

600 characters left

Measure Type *

Count of Participants

Unit of Measure *

Participants

	Arm 1	Arm 2	Total
Number of Participants Analyzed [*]	**Number of Participants**	**Number of Participants**	**Number of Participants** **Unknown**
≤ 18 years	**Count of Participants** **Percentage of Participants** **NA%**	**Count of Participants** **Percentage of Participants** **NA%**	**Count of Participants** **Unknown** **Percentage of Participants** **NA%**
19 years to 64 years	**Count of Participants** **Percentage of Participants** **NA%**	**Count of Participants** **Percentage of Participants** **NA%**	**Count of Participants** **Unknown** **Percentage of Participants** **NA%**
≥ 65 years	**Count of Participants** **Percentage of Participants** **NA%**	**Count of Participants** **Percentage of Participants** **NA%**	**Count of Participants** **Unknown** **Percentage of Participants** **NA%**

Sex: Female, Male

Measure Settings

Baseline Measure Description

Use this field to provide additional details about the measure that could help with the interpretation of the data, e.g. information about a scale.

600 characters left

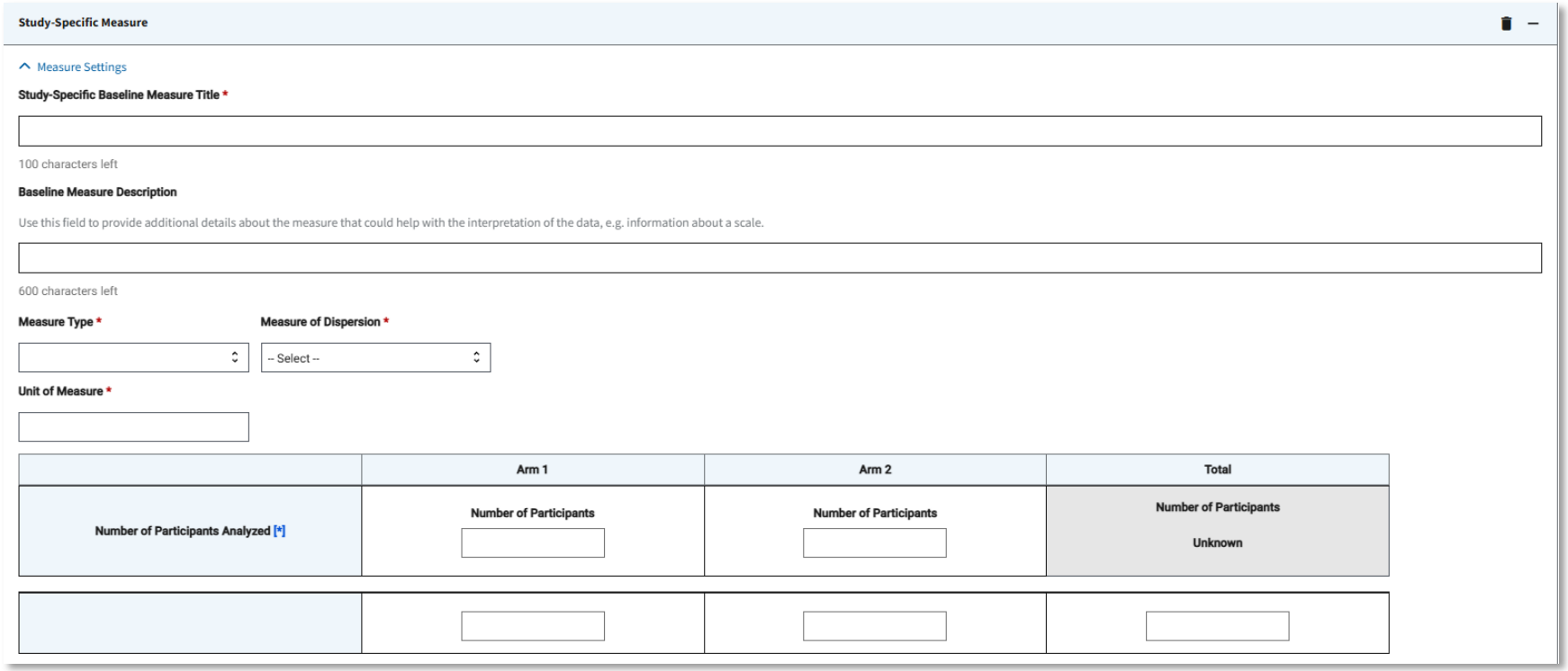
Measure Type *

Count of Participants

Unit of Measure *

Participants

	Arm 1	Arm 2	Total
Number of Participants Analyzed [*]	**Number of Participants**	**Number of Participants**	**Number of Participants** **Unknown**
Female	**Count of Participants** **Percentage of Participants** **NA%**	**Count of Participants** **Percentage of Participants** **NA%**	**Count of Participants** **Unknown** **Percentage of Participants** **NA%**
Male	**Count of Participants** **Percentage of Participants** **NA%**	**Count of Participants** **Percentage of Participants** **NA%**	**Count of Participants** **Unknown** **Percentage of Participants** **NA%**



Study-Specific Measure

Measure Settings

Study-Specific Baseline Measure Title *

100 characters left

Baseline Measure Description

Use this field to provide additional details about the measure that could help with the interpretation of the data, e.g. information about a scale.

600 characters left

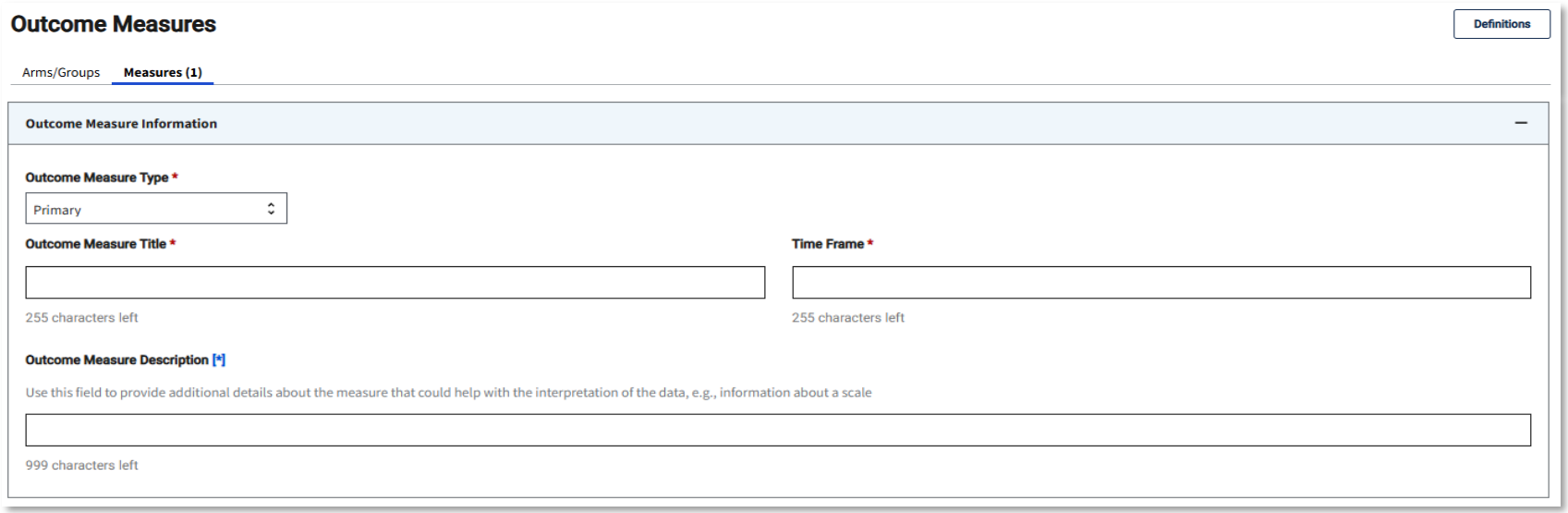
Measure Type *

Measure of Dispersion *

-- Select --

Unit of Measure *

	Arm 1	Arm 2	Total
Number of Participants Analyzed [*]	Number of Participants	Number of Participants	Number of Participants Unknown



Outcome Measures

Definitions

Arms/Groups | **Measures (1)**

Outcome Measure Information

Outcome Measure Type *

Primary

Outcome Measure Title *

255 characters left

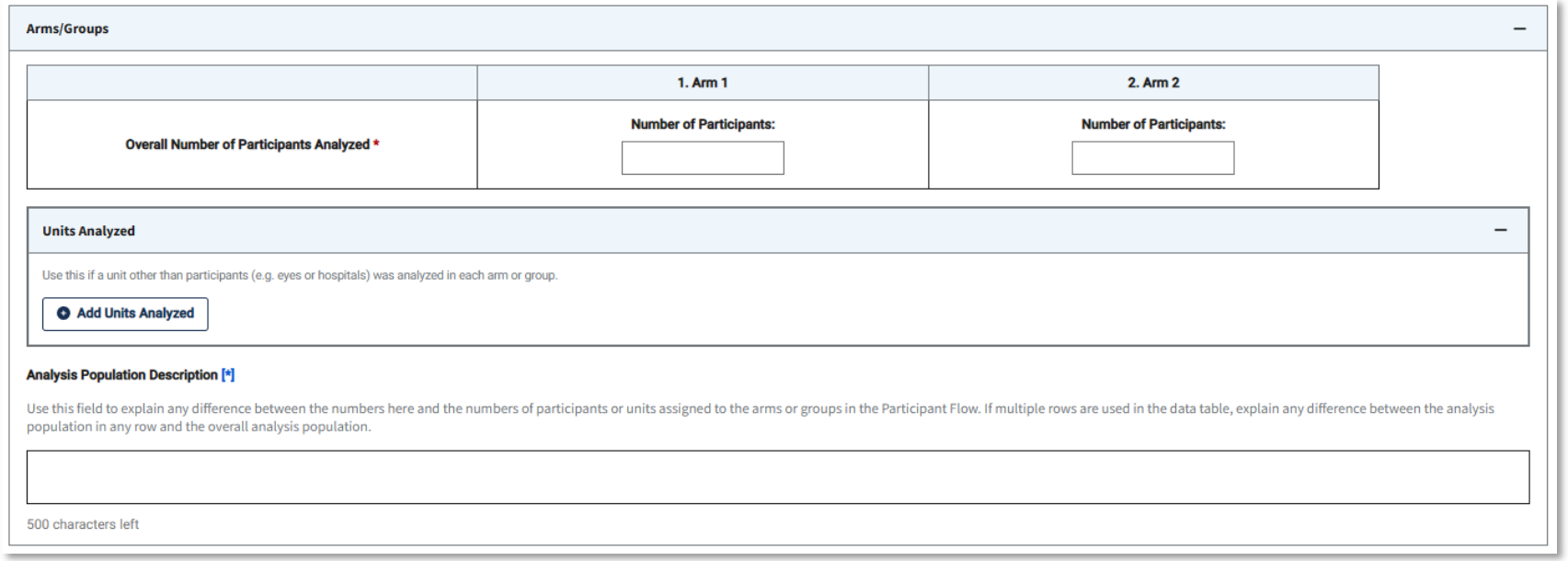
Time Frame *

255 characters left

Outcome Measure Description [*]

Use this field to provide additional details about the measure that could help with the interpretation of the data, e.g., information about a scale

999 characters left



Arms/Groups

	1. Arm 1	2. Arm 2
Overall Number of Participants Analyzed *	**Number of Participants:**	**Number of Participants:**

Units Analyzed

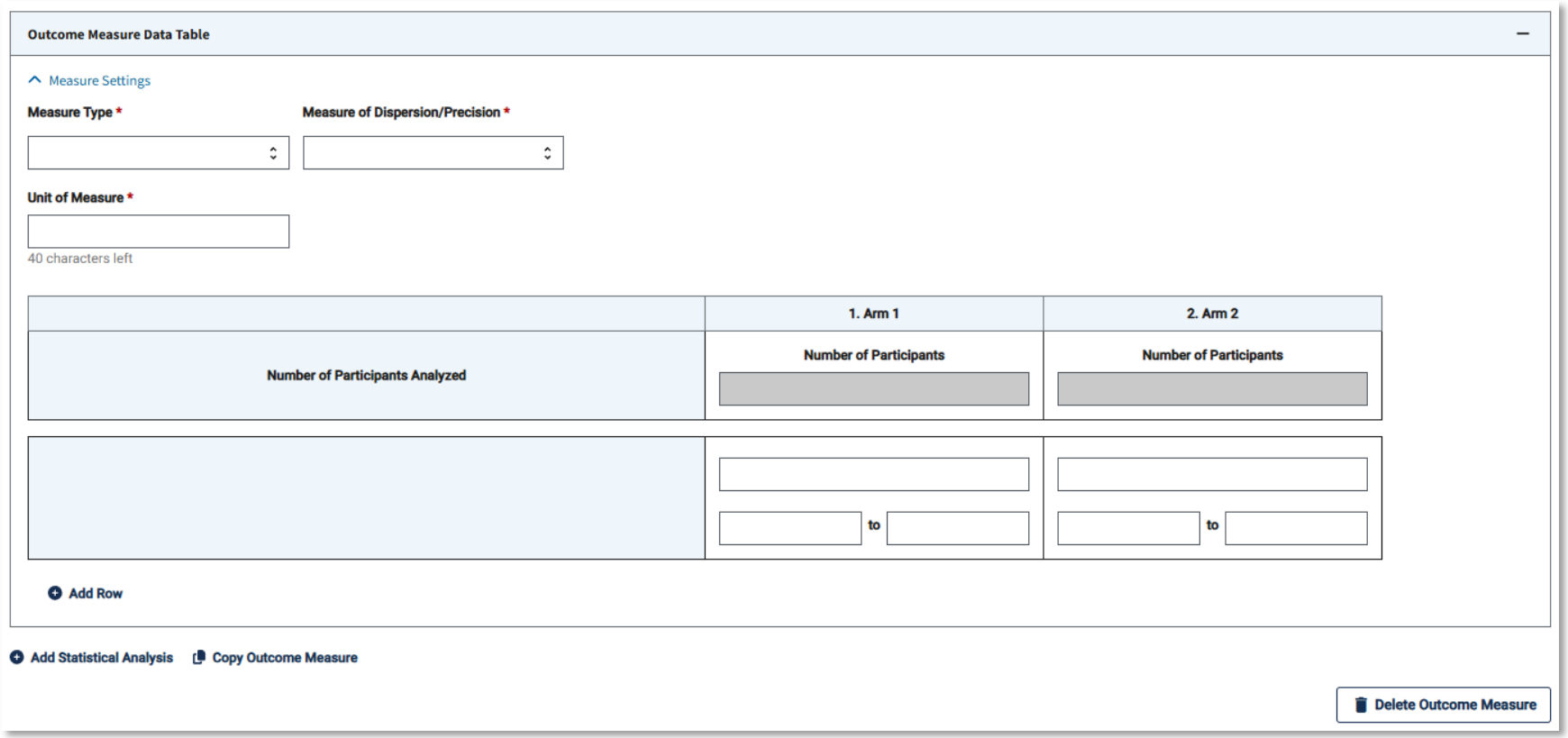
Use this if a unit other than participants (e.g. eyes or hospitals) was analyzed in each arm or group.

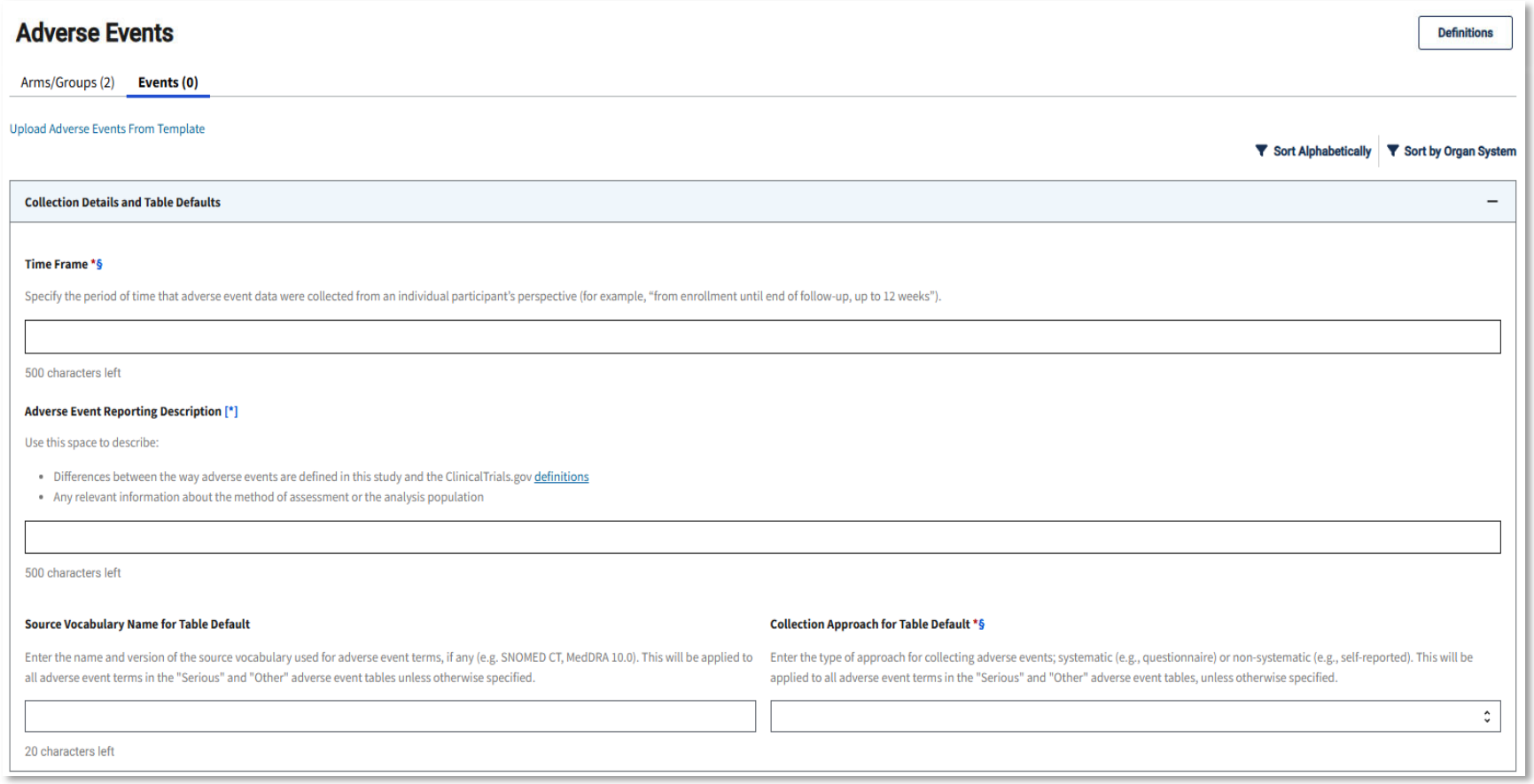
Add Units Analyzed

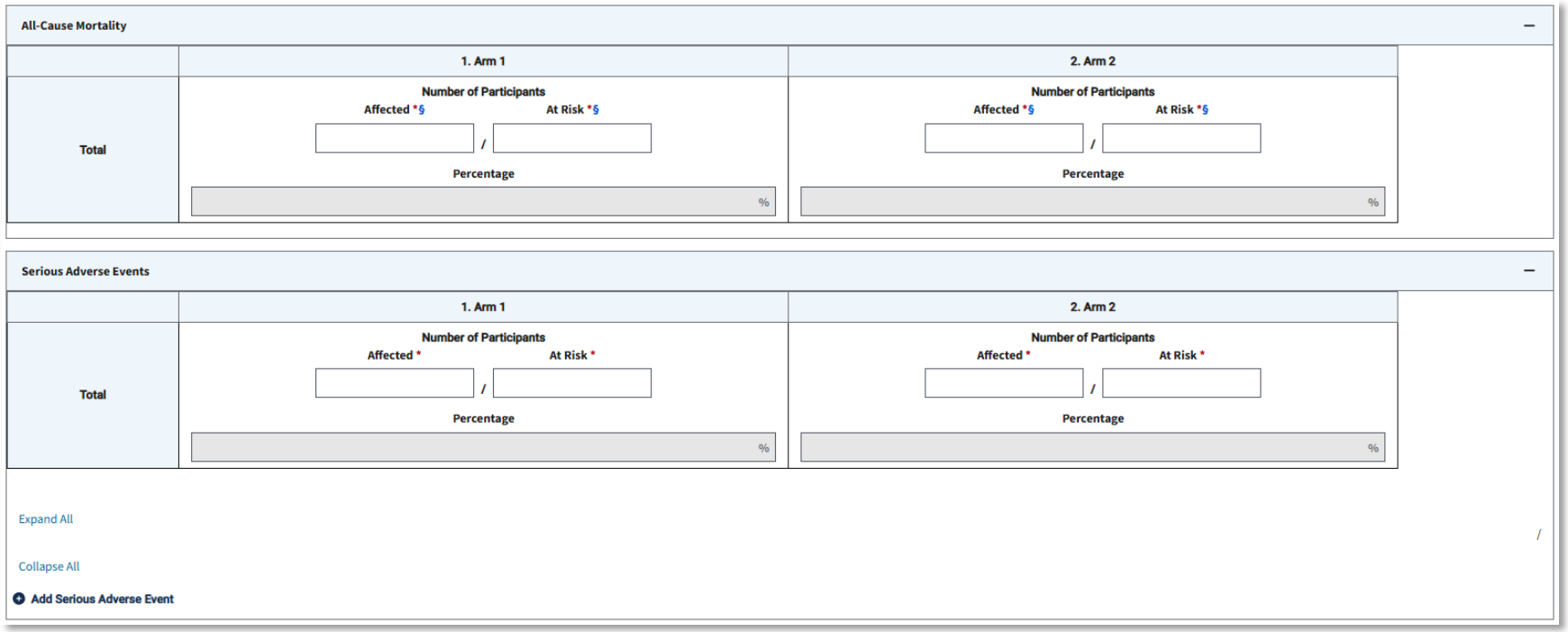
Analysis Population Description [*]

Use this field to explain any difference between the numbers here and the numbers of participants or units assigned to the arms or groups in the Participant Flow. If multiple rows are used in the data table, explain any difference between the analysis population in any row and the overall analysis population.

500 characters left


Outcome Measure Data Table
Measure Settings
Measure Type *
Measure of Dispersion/Precision *
Unit of Measure *
40 characters left
1. Arm 1
2. Arm 2
Number of Participants Analyzed
Number of Participants
Number of Participants
to
to
Add Row
Add Statistical Analysis
Copy Outcome Measure
Delete Outcome Measure


Adverse Events
Definitions
Arms/Groups (2)
Events (0)
Upload Adverse Events From Template
Sort Alphabetically
Sort by Organ System
Collection Details and Table Defaults
Time Frame *§
Specify the period of time that adverse event data were collected from an individual participant's perspective (for example, "from enrollment until end of follow-up, up to 12 weeks").
500 characters left
Adverse Event Reporting Description [*]
Use this space to describe:
Differences between the way adverse events are defined in this study and the ClinicalTrials.gov definitions
Any relevant information about the method of assessment or the analysis population
500 characters left
Source Vocabulary Name for Table Default
Enter the name and version of the source vocabulary used for adverse event terms, if any (e.g. SNOMED CT, MedDRA 10.0). This will be applied to all adverse event terms in the "Serious" and "Other" adverse event tables unless otherwise specified.
20 characters left
Collection Approach for Table Default *§
Enter the type of approach for collecting adverse events; systematic (e.g., questionnaire) or non-systematic (e.g., self-reported). This will be applied to all adverse event terms in the "Serious" and "Other" adverse event tables, unless otherwise specified.



All-Cause Mortality

	1. Arm 1	2. Arm 2
Total	Number of Participants Affected *§ / At Risk *§ Percentage %	Number of Participants Affected *§ / At Risk *§ Percentage %

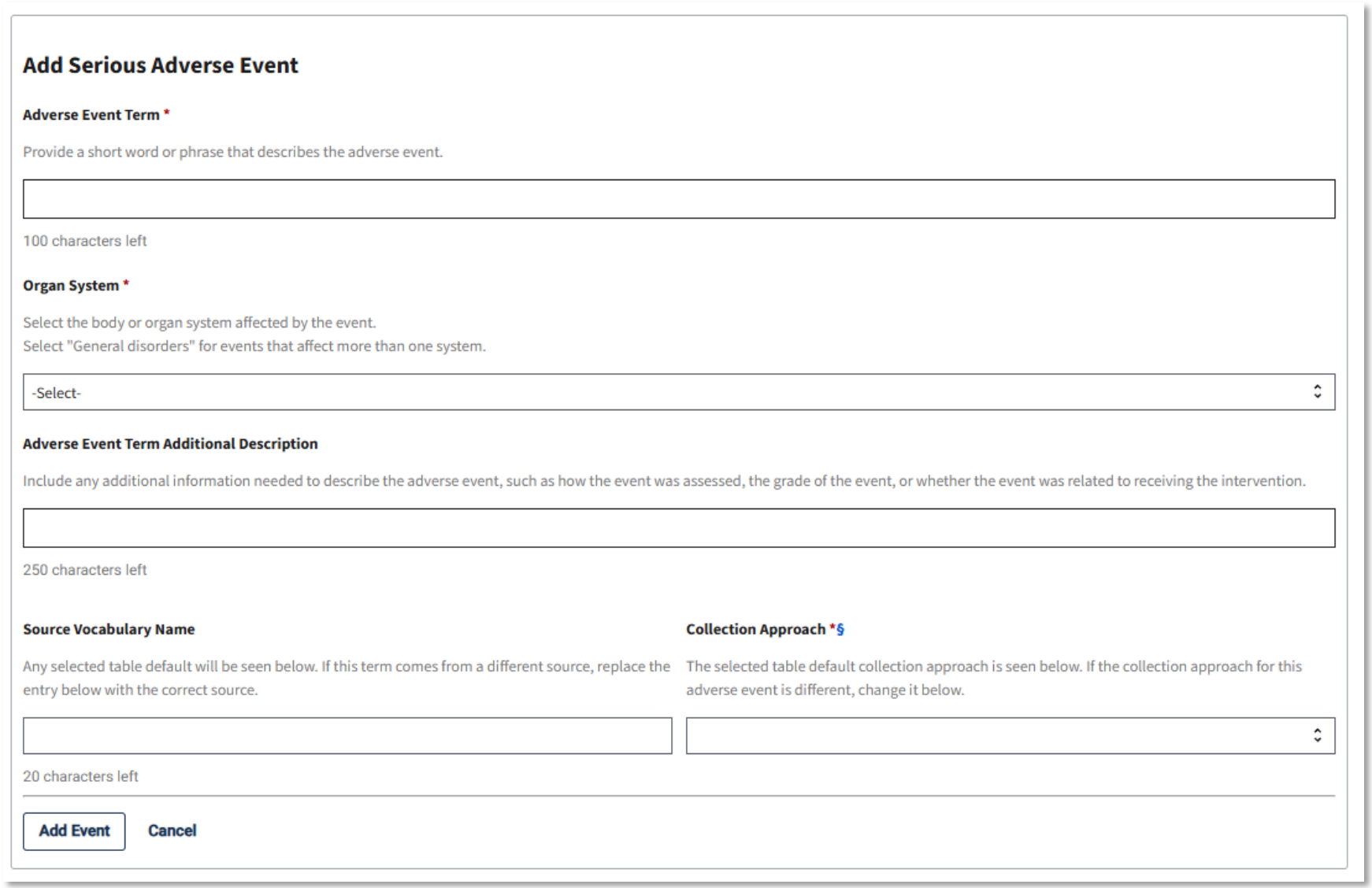
Serious Adverse Events

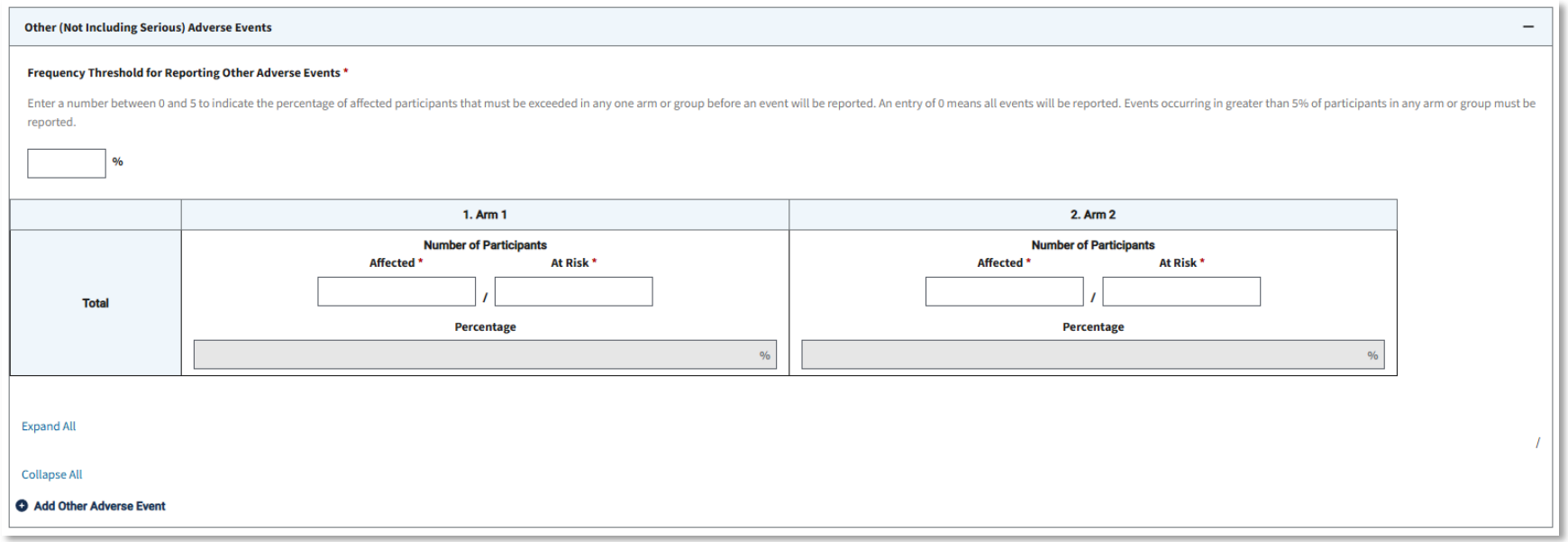
	1. Arm 1	2. Arm 2
Total	Number of Participants Affected * / At Risk * Percentage %	Number of Participants Affected * / At Risk * Percentage %

Expand All

Collapse All

Add Serious Adverse Event


Add Serious Adverse Event
Adverse Event Term *
Provide a short word or phrase that describes the adverse event.
100 characters left
Organ System *
Select the body or organ system affected by the event.
Select "General disorders" for events that affect more than one system.
-Select-
Adverse Event Term Additional Description
Include any additional information needed to describe the adverse event, such as how the event was assessed, the grade of the event, or whether the event was related to receiving the intervention.
250 characters left
Source Vocabulary Name
Any selected table default will be seen below. If this term comes from a different source, replace the entry below with the correct source.
Collection Approach *§
The selected table default collection approach is seen below. If the collection approach for this adverse event is different, change it below.
20 characters left
Add Event
Cancel



Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events *

Enter a number between 0 and 5 to indicate the percentage of affected participants that must be exceeded in any one arm or group before an event will be reported. An entry of 0 means all events will be reported. Events occurring in greater than 5% of participants in any arm or group must be reported.

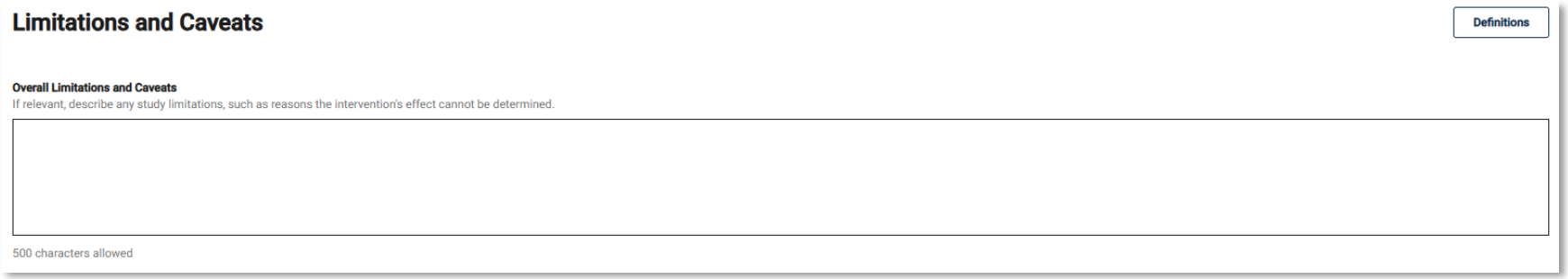
%

	1. Arm 1	2. Arm 2
Total	Number of Participants Affected * / At Risk * Percentage %	Number of Participants Affected * / At Risk * Percentage %

Expand All

Collapse All

Add Other Adverse Event



Limitations and Caveats

Definitions

Overall Limitations and Caveats

If relevant, describe any study limitations, such as reasons the intervention's effect cannot be determined.

500 characters allowed

More Information

Definitions

Certain Agreements

Agreements That Restrict the PI After the 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".

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

- ◯ Yes
- ◯ No

Results Point of Contact

Name or Official Title *

Enter the name or title of the person who can answer scientific questions about the clinical study results.

100 characters allowed

Organization Name *

Enter the full name of the organization the point of contact is affiliated with.

255 characters allowed

Phone *§ **Ext.**

Email *§

254 characters allowed