Clinical Trials.gov Results Entry Work Aid and Checklist

Elements	Guidance	
Results Point of Contact		**Done**
*Name	Enter the name of the Principal Investigator	☐
*Organization	Enter "University of Michigan "	☐
*Phone	Enter the PI's Phone #	☐
*Email	Enter the PI's Email	☐
Certain Agreements		
*Are PIs Employed by the Sponsor?	Refer to the sponsor listed for the CT.gov registration. If the sponsor was listed as the University of Michigan, enter "Yes."	☐
Results Disclosure	If the Sponsor is not the University of Michigan, you will have to state whether or not there is an agreement with the sponsor that restricts the PI's rights to publish results. Check with ORSP to look in the contract if you do not know. If "Yes", you will have to select the type of agreement.	☐
Protocol Enrollment		
*Enrollment	This will pre-populate if you have entered the "actual" accrual number on the registration page.	☐
Participant Flow		
Recruitment Details	Enter any details from the protocol or publication that describes where and how the participants were recruited (i.e. sites, time period). *NOT A REQUIRED FIELD.	☐
Pre-Assignment Details	Enter details for any events that occur after enrollment but prior to randomization. If patients were enrolled but not treated (randomized) enter an explanation here. *NOT A REQUIRED FIELD.	☐

*Arm/Group Title/Description	Select the available Arm/Group or create a new one. You may need to edit the description (sometimes it pulls in both the arm and intervention description from the registration).	☐
*Period Title	This will automatically populate with "Overall Study" unless you specify more than one period. ONLY THE NUMBER STARTED AND NUMBER COMPLETED IS REQUIRED. You may enter in additional periods if needed to show stages of the study, e.g. a washout period or crossovers of the treatments. The participant flow should tell the whole story regarding people's departures IF YOU ENTER MORE THAN ONE PERIOD, THE NUMBER COMPLETED IN THE PREVIOUS PERIOD MUST EQUAL THE NUMBER STARTED IN THE FOLLOWING PERIOD. IF THE NUMBER COMPLETED DOES NOT EQUAL THE NUMBER STARTED WITHIN A PERIOD YOU ARE REQUIRED TO ENTER A REASON FOR EACH SUBJECT NOT COMPLETED.	☐
*Started	Number of participants starting a period (If one period this will be the number of participants that started the study).	☐
*Completed	The number of participants completing a period. (If there was only one period, "overall study", this will usually be the number of patients that were treated.)	☐
Reason Not Completed	Required if the number of participants completing the period does not equal the number of participants starting a period. There must be a reason for each subject that does not complete.	☐
Baseline Characteristics For this and Outcome measures, be sure to consult with the PI for the important variables and information s/he wishes to convey. The Clinicaltrials.gov templates will assist in that data gathering and preparation.		
*Arm/Group Title/Description	Select the available Arm/Group or create a new one. You will generally select the Arm/Group from "Participant Flow"	☐
*Overall Number of Baseline Participants	Enter the number of Participants	☐
Baseline Analysis Population Description	Provide an explanation for number of participants analyzed in the Baseline Measures section if different the number analyzed is different than the number enrolled.	☐

	*NOT REQUIRED	
Baseline Measures		
*Baseline Measure Title	AGE AND GENDER ARE REQUIRED BASELINE MEASURES. Showing age in a single table is sufficient. You don't need to use multiple versions. And you don't have to list age with one of their default tables. You can and should make these make sense for your trial. Thus a pediatric trial might have categories for ages that are 1 – 5 years; 6- 10 years and 11 – 16 years. You should add additional Baseline Measures as necessary to show important characteristics of the population studied. This is very comparable to a "Table 1" in many articles.	☐
Baseline Measure Description	Provide a Baseline Measure Description if the measure is something that may not be commonly known (i.e. ECOG; provide a description of what performance status is and describe the scale). *NOT REQUIRED	☐
*Measure Type	This will usually be "Number" but can be something else. Choose from the drop down. You may add more than one Category. For example if the Baseline Measure is Prior Surgery, you may add a category: one category title will be "Yes" and one title will be "No."	☐
*Measure of Dispersion	This will usually be "N/A" (if the Measure Type is Number). Choose from the drop down.	☐
*Unit of Measure	This will normally be "Participants", unless your baseline measures are mean measures of specific variables such as weight, BMI, etc.	☐
Outcome Measures		
*Outcome Measures	Outcome measures are pre-populated from the registration. You are required to post at least one primary outcome measure. If, there are outcomes measures that are not completed at the 1 year after Primary completion date, they are not required to be posted until 1 year after their last data collection IF statistical analysis CANNOT be provided either because study size was inadequate to support the power originally required,	☐

	or for some other critical reason, If the study was not completed OR the primary objective was not analyzed, post the results and enter "0" for the number of patients analyzed. Also provide an explanation under the Analysis Population Description.	
Outcomes		
*Measure Type	This should pre-populate unless you are adding a new outcome measure.	☐
*Outcome Measure Title	This should pre-populate. The outcome measure title may need to be revised to concisely state a measurable outcome (i.e. Percentage of patients with progressive disease OR number of participants that experienced grades 2-4 adverse events) If you make changes to the title to make the outcome measurable (if the title is different from the title listed under the original registration), try to include the original title under the Outcome Measure Description. For example if the original title was "To establish the rate of acute GVHD following prophylactic cellular immunotherapy", and the title was changed to "Percentage of participants with Acute GVHD", enter "The primary objective of this study was to establish the rate of acute GVHD following prophylactic cellular immunotherapy. To establish the rate of GVHD, the percentage of participants with acute GVHD was calculated."	☐
Outcome Measure Description	Describe the outcome measure or provide additional information if necessary. For example if the outcome measure is the "Number of Serious Adverse Events", you may want to describe what qualifies as a Serious Adverse Event and provide the Source Vocabulary Name (i.e. CTCAE 3.0).	☐
*Outcome Measure Time Frame	Specific time point at which the outcome measure was assessed. CT.gov will not accept "3 months after treatment end". Instead enter "3 months".	☐
Safety Issue	Select "Yes" if the outcome measure is a measurement of drug safety (i.e. measuring number of AEs).	☐
*Arm/Group Title Description	You will select from the list of Arm/Group titles when you post the outcome measure. You will generally select the Arm/Group from "Participant Flow"	☐

*Number of Participants Analyzed	Enter the number of participants that were used to calculate the outcome measure. If this number is not the same as the number of participants enrolled, provide an explanation under Analysis Population Description If the study was not completed OR the primary objective was not analyzed, post the results and enter "0" for the number of patients analyzed. Also provide an explanation under the Analysis Population Description.	☐
Analysis Population Description	Enter a description when this number or participants analyzed is not the same as the number of participants enrolled, provide an explanation under Analysis Population Description * NOT REQUIRED	☐
*Measure Type	Select from the dropdown. If the measure type is number, a measure of dispersion is not required. More than one category may be entered (i.e. Outcome Measure was number of Grade 2-4 AEs and the results were listed by event name).	☐
*Unit of Measure	Enter the unit of measure for the primary outcome (i.e. participants or percentage of participants).	☐
Limitations and Caveats		
Overall Limitations and Caveats	Enter any limitations of the study. For example, if the study was not completed or the study under accrued, enter the reason here.	☐
Adverse Events		
Time Frame	Description of period in which adverse event data were collected. * NOT REQUIRED	☐
Additional Description	Any additional information regarding what and how AEs were recorded. If the number of participants analyzed is different than the number of participants enrolled, enter an explanation here. * NOT REQUIRED	☐
Source Vocabulary Default	Enter the source vocabulary used (i.e. CTCAE,	

	MedDRA) * NOT REQUIRED	☐
Assessment Type for Table Default	Choose “Systematic or “Non-Systematic” for the default. * NOT REQUIRED. IT IS ALSO NOT REQUIRED TO CHOOSE THE ASSESSMENT TYPE FOR EACH AE LISTED.	☐
Arms/Groups	Select from the list of Arm/Group titles. You will generally select the Arm/Group from “Participant Flow”	☐
Serious Adverse Events		
Total # Affected	The total number of participants that experienced a SAE.	☐
Total # at Risk	The number of participants analyzed for serious adverse events. If the number of participants analyzed is different than the number of participants enrolled, enter an explanation under Additional Description for the Adverse Events section.	☐
Adding SAEs	All SAEs must be listed. To add an SAE, select the “Add Serious Adverse Event” link. You are required to enter the Adverse Event Term, the Organ System for that Term using CTCAE 4.0, and the Number of Participants Effected. To upload all SAEs from an excel file see “Comments” below.	☐
Other Adverse Events		
Frequency Threshold for Reporting Other Adverse Events	Enter any frequency from 1-5%. Typically 5% is used.	☐
Total # Affected	The total number of participants that experienced an AE.	☐
Total # at Risk	The number of participants analyzed for adverse events. If the number of participants analyzed is different than the number of participants enrolled, enter an explanation under Additional Description for the Adverse Events section.	☐
Adding AEs	At minimum all AEs that occur in more than 5% of the	

	patient's must be listed (i.e. if 100 patients were treated, any adverse event experienced by 6 or more patients must be reported). To add an AE, select the "Add Other Adverse Event" link. You are required to enter the Adverse Event Term, the Organ System for that Term using CTCAE 4.0, and the Number of Participants Effected. To upload all AEs from an excel file see "Comments" below.	☐

Comments

Uploading AEs and SAEs

Prior to uploading events you must enter the Total Number Affected and Total Number at Risk and add one AE and one SAE as described above.

Once an event has been added, select the "Download/Upload" link at the top of the Adverse Events Page.

First download the Excel template: Select the AE type and File format and click on "Download".

Complete the Excel template by cutting and pasting reportable events from the CERVANT report. You are only required to complete the columns for AE Event Type, Organ System Name, Term, and Number of Subjects Effected.

*You must use the Organ Systems from CTCAE 4.0, located at:

https://register.clinicaltrials.gov/prs/html/results_definitions.html#OrganSystem

When you have completed the Excel Template, upload the file on the same page where the template was downloaded. Select the file, select the AE Type and File Format and click on "Upload".

You will see a message at the top of the AE page that will state whether or not the download was successful.

Make sure to double check that the AEs were uploaded correctly by viewing several events.

Adding Citations

If there is a corresponding publication for the results, you should enter the citation on the Protocol Registration page.

At the bottom of the Registration page, select "Edit" next to the Citations section.

Select "Add" and enter in the MEDLINE Identifier (this publication specific number can be found on the PubMed Website. Locate the publication on PubMed. The PMID can be located beneath the abstract.) and select "Save". The citation text will be generated automatically.

Makes sure the citation text is correct and click on "Done".

If the PMID is not available, you may enter the citation text by selected “enter the citation text”

It is NOT required, but RPs are free to add additional citations at any point even after the full results are posted.