Tips for Entering Study Results in UPittsburgh ClinicalTrials.gov PRS

Please note the following submission deadlines for Applicable Clinical Trials (ACTs) and studies subject to the NIH Policy that are required to submit results:

- By 1 year after the primary completion date, for initial results (includes all primary outcomes)
- If partial submissions, by 1 year after the…
  - Final data collection date, for each secondary outcome
  - Collection date, for adverse event data collected after initial submission
  - Study completion date, for the final submission

Results Expected Date on the Record Summary page:

- This date will only display for studies entered as Applicable Clinical Trials (ACTs) required to submit results.
- This date will not display for studies required to submit results under the NIH Policy that are not also ACTs required to submit results.
- Until results information for all primary outcomes has posted to the public study record, the Results Expected date is one year from the entered primary completion date.
- If, after results information for all primary outcomes has posted, there are still secondary outcomes for which results information has not posted, the Results Expected Date switches to one year from the entered study completion date. This is the deadline for the final results submission; additional partial submissions may be due in between, as per the deadlines listed above.

Important Note: This guidance document does not cover all modules and data elements required for results submission. You should consult the “Help” and “Definitions” links at the top of each page within the Results section. Other help resources include:

- “Help” dropdown list at the top of your PRS homepage
- The Results Review Criteria
- Materials at https://clinicaltrials.gov/ Submit Studies
  - How to Submit Your Results
  - FAQs
  - Support Materials
  - Training Materials

The results section of your study record is meant to mimic the results section of a journal publication. Therefore, the following will result in the issuance of QC review comments requiring corrections:

- Study results data entered in narrative form in the free text fields in lieu of the tabular format.
- Inclusion of narrative discussion or conclusions of the results data.
Results Section Modules

Participant Flow
- Remember that for CTgov purposes, an enrolled participant is one who agreed to participate, was screened for eligibility and began participation in the study. If a participant agreed to participate but did not begin the study following confirmation of eligibility (as applicable), you should not count the participant in the actual total enrollment. If your protocol defines enrollment differently, explain this using Pre-Assignment Details and the Add Comment feature, as appropriate. Edit your Protocol Enrollment number, if necessary.

Baseline Characteristics
- Age and Sex/Gender are required. Race and Ethnicity are required, if collected per protocol. Also, include any other measures assessed at baseline and used in analysis of the primary outcome measure(s).
- Overall Number of Baseline Participants: If this differs from the number of participants (or units) assigned to the arm or comparison group and overall, provide an explanation in the Baseline Analysis Population Description.

Outcome Measures

Any interested party can easily compare for consistency: the public study record (all outcome changes tracked), uploaded protocol document, and publication, as applicable. Avoid outcome reporting bias (i.e., outcome switching). Instead of deleting a pre-specified outcome after study initiation, explain any changes or why results will not be available. Also, explain the addition of any new outcomes. (Note: “Post-Hoc” is selectable for Outcome Measure Type upon creating the Results section for a study record.)

- All outcome measure components must be specific and precise:
  - The title is what is being measured (e.g., Pain Level).
  - The description is how it is being measured (e.g., XYZ Pain Scale, a participant reported rating of pain level ranging from 0 = no pain to 10 = severe pain).
  - The time frame is the timepoints at which, or the time span over which, the outcome is being assessed (e.g., At 6 months from study start).
  - Explanation of why it was measured or what you expected to find (hypothesis/prediction statements) is not allowed and will result in QC review comments requiring corrections.

- Results information is required for all pre-specified Primary and Secondary Outcome Measures for Applicable Clinical Trials (ACTs) and studies subject to the NIH Policy that are required to submit results.
  - If data collection is complete or will not occur for an outcome measure, there are 3 possible entries:
1. If outcome measure data were collected on any participants and can be reported, the data must be reported. The components of a fully reported outcome measure minimally include:
   - Overall Number of Participants Analyzed: If this differs from the number of participants or units assigned to the arm or comparison group, provide an explanation in the Analysis Population Description.
   - Measure Type (count of participants, mean, median, number, etc.) and the data value
   - Measure of Dispersion/Precision (standard deviation, full range, etc.) and the data value
   - Unit of Measure
   - Statistical Analyses: If completed, include information about scientifically appropriate tests of statistical significance of the primary and secondary outcome measures. Such analyses include: pre-specified in the protocol and/or statistical analysis plan; made public by the sponsor or responsible party; conducted on a primary outcome measure in response to a request made by FDA.

2. If outcome measure data were collected but cannot be reported:
   - Overall Number of Participants Analyzed: Enter the number of participants for which data were collected.
   - Select the Measure Type and Measure of Dispersion that apply to the outcome.
   - Enter NA in each of the data boxes and an explanation in the box provided for why the values are not available.
   - Enter the unit of measure that applies to the outcome.
3. If outcome measure data were not collected on any participants, enter 0 for the Overall Number of Participants Analyzed and provide an explanation in the Analysis Population Description element for why no data were collected.
If data collection is not yet completed for an outcome measure, but results information will be provided at a later date, click “edit” next to the outcome measure, click “save” and you will be prompted to enter the anticipated reporting date for the results. This date should be between the anticipated final data collection date and the deadline for results reporting (e.g., between the anticipated final data collection date for a secondary outcome and 1 year from then). If this date passes and results have not been entered for the outcome, an error message will be triggered on the record.

Adverse Events

- Please carefully read the definitions provided for Adverse Event and Serious Adverse Event within CTgov. Note that an event need only be temporally associated with participation in the research to be considered an Adverse Event, regardless of severity or suspected cause.
  - If different definitions were used for your study, provide an explanation in the Adverse Event Reporting Description.
- All Serious Adverse Events must be reported. For Other (Not including Serious) Adverse Events, a Frequency Threshold for Reporting Other Adverse Events (between > 0% and > 5%) must be specified. Note that whether an event was anticipated is not a factor in determining whether it is required to be reported.
- Time Frame: The specific time period over which adverse event data were collected (typically at the individual participant level).
- Each adverse event entry must minimally contain the Adverse Event Term, associated Organ System and Total Number of Participants Affected/At Risk.
- If any entry for Number of Participants at Risk differs from the number of participants assigned to the arm or comparison group, provide an explanation in the Adverse Event Reporting Description.
- If a default source vocabulary for Adverse Event Terms (e.g., MedDRA, CTCAE, etc.) was used in the study, this can be specified in the Source Vocabulary Name for Table Default.
- If you have many adverse events to report, you may find the adverse event batch upload feature to be helpful. To use this feature, click Download/Upload at the top of the Adverse Events Overview page, and follow the instructions provided.

Limitations and Caveats

- As the name implies, use this module to describe any limitations and caveats of the results information. Again, do not include results data here in narrative form in lieu of the other modules provided, and do not enter narrative discussion or conclusions of the results data.

More Information

- Certain Agreements: “Sponsor” here is referring to the Sponsor Organization (i.e., University of Pittsburgh).
Documents Section
• Results submissions for studies that have a Primary Completion Date on or after January 18, 2017 must include a copy of the protocol and the statistical analysis plan, which will be posted for public access.
  ➢ An updated version, if applicable, is required with each partial results submission.
• Required format: Portable Document Format Archival (PDF/A)
• Each document must include a cover page with the Official Title of the study, NCT number, and date of the document.
• “Advanced” feature: Use this to upload more than one document of the same Document Type. Do not use this feature to upload a new version of a document already uploaded.
• Refer to the “Results Submission” tab on our website for additional guidance.