

## ClinicalTrials.gov Required Results Reporting Data Elements Overview

Section	Description
<b>Participant Flow</b>	<ul style="list-style-type: none"> <li>-Number of participants starting each milestone of the study by arm</li> <li>-Number of participants completing the overall study by arm</li> <li>-The reason not completed for each participant not completing the overall study</li> </ul>
<b>Baseline Characteristics</b>	<p><b>Age: (choose at least 1):</b> Categorical ages or continuous age (i.e. mean/median and a measure of dispersion, e.g. 95% CI, SD, or full range)</p> <p><b>Sex/Gender:</b> Summary of the count of participants by sex and/or gender</p> <p><b>Race/ethnicity:</b> Summary of the count of participants by race and/or ethnicity (NIH/OMB classifications or custom categories) if collected</p> <p><b>Study specific baseline measure:</b> Any additional baseline measures recorded. Must include any measures used in evaluation of end-points</p>
<b>Outcome Measures</b> (For all primary and secondary outcomes)	<p><b>Descriptive outcome measure title:</b> Needs to specifically indicate what was measured and what will be reported as data</p> <ul style="list-style-type: none"> <li>-An additional <b>outcome measure description</b> is often also needed to fully explain what was measured, how it was measured, and what data are being reported</li> </ul> <p><b>Time Frame:</b> The specific duration over which the participants were assessed for the measure. Needs to include the specific timepoint(s) or duration over which the assessment(s) occurred. If a relative time frame is used (e.g. until study end), an absolute measure of time must also be included (e.g. up to 2-years)</p> <p><b>Number of participants analyzed</b> per arm for the outcome measure</p> <p><b>Measure Type:</b> Count of participants, mean, median, least squares mean, geometric mean, geometric LSM, or number</p> <p><b>Measure of dispersion:</b> Standard deviation, standard error, inter-quartile range, full range, or confidence interval (as appropriate)</p> <p><b>Unit of measure:</b> Specific unit associated with the numerical data (e.g. mg, participants, percent, etc.)</p>
<b>Statistical Analysis</b>	<p>If a test of statistical significance was performed for the outcome measure, a tabular summary of the statistical test or other parameter estimated from the outcome measure data is needed. If a statistical analysis is provided, it must include either a P-value, estimation parameter, or other statistical analysis. Multiple statistical analyses per outcome measure may be included if necessary.</p>
<b>Adverse Events/ Toxicity</b>	<p><b>All Grade/Attribution Adverse Events</b> must be reported in the adverse events section. The adverse events section includes:</p> <p><b>Time Frame</b> over which the adverse events were assessed</p> <p><b>Number of participant deaths</b>, during AE assessment time frame</p> <p><b>Serious Adverse Events:</b> summary of the specific serious adverse events experienced by participants shown as the total number of participants that had SAE's, the number of participants that experienced each specific SAE (and optionally the number of events)</p> <p><b>All other adverse events:</b> Summary of all other adverse events (not including those already listed in the SAE section). Reporting threshold cannot exceed 5% of participants.</p>

More detailed results reporting checklists are available from ClinicalTrials.gov at [https://prsinfo.clinicaltrials.gov/results\\_table\\_layout/ResultSimpleForms.html](https://prsinfo.clinicaltrials.gov/results_table_layout/ResultSimpleForms.html)