* **Participant Flow.** A tabular summary of the progress of participants through each stage of a study, by study arm or comparison group. It includes the numbers of participants who started, completed, and dropped out of each period of the study based on the sequence in which interventions were assigned. The module accommodates a wide range of study designs and allows for the description of key events following study enrollment but prior to group assignment. For more information, see:
  + [Participant Flow Data Preparation Checklist](https://prsinfo.clinicaltrials.gov/data-prep-checklist-pf.pdf) (PDF)
  + Simple results template: [Participant Flow Template](https://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_PopFlowForm.pdf) (PDF)
* **Baseline Characteristics.** A tabular summary of the data collected at the beginning of a study for all participants, by study arm or comparison group. These data include demographics, such as age and gender, and study-specific measures (for example, systolic blood pressure, prior antidepressant treatment). For more information, see:
  + [Baseline Characteristics Data Preparation Checklist](https://prsinfo.clinicaltrials.gov/data-prep-checklist-bl.pdf) (PDF)
  + Simple results templates:
    - [Baseline Characteristics Template—Age](https://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_BaselineAgeForm.pdf) (PDF)
    - [Baseline Characteristics Template—Sex/Gender](https://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_BaselineGenderForm.pdf) (PDF)
    - [Baseline Characteristics Template—Race, Ethnicity, Region](https://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_BaselineRegionRaceEthnicityForm.pdf) (PDF)
    - [Baseline Characteristics Template—Study-Specific Characteristic](https://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_BaselineSpecificCharForm.pdf) (PDF)
* **Outcome Measures and Statistical Analyses.** A tabular summary of Outcome measure values, by study arm or comparison group. It includes tables for each prespecified Primary Outcome and Secondary Outcome and may also include other prespecified outcomes, post hoc outcomes, and any appropriate statistical analyses. For more information, see:
  + [Outcome Measure Data Preparation Checklist](https://prsinfo.clinicaltrials.gov/data-prep-checklist-om-sa.pdf) (PDF)
  + Simple results template and examples:
    - [Outcome Measure Template](https://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_OMForm.pdf) (PDF)
    - [Examples - Outcome Measure Template](https://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_OMExamples.pdf) (PDF)
    - [Statistical Analysis Template](https://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_StatAnalysisForm.pdf) (PDF)
* **Adverse Events.** A tabular summary of all anticipated and unanticipated Serious adverse event and a tabular summary of anticipated and unanticipated other adverse events exceeding a specific frequency threshold. For each serious or other adverse event, the summary includes the adverse event term, affected organ system, number of participants at risk, and number of participants affected, by study arm or comparison group. For more information, see:
  + [Adverse Event Data Preparation Checklist](https://prsinfo.clinicaltrials.gov/data-prep-checklist-ae.pdf) (PDF)
  + Simple results templates:
    - [Serious Adverse Events Template](https://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_SAEForm.pdf) (PDF)
    - [Other (Not Including Serious) Adverse Events Template](https://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_FreqAEForm.pdf) (PDF)