



**GENERAL INSTRUCTIONS**

Laboratory tests are routinely administered in clinical trials of pharmacological interventions to assess participant/subject safety.

Laboratory tests may also be used to determine an individual's eligibility for a study.

Laboratory results may be received via electronic files directly from central study laboratories or recorded manually on case report forms if the study is using a local lab. In either scenario, it is recommended that the Laboratory Test Tracking form be used to record when samples were collected (date and time) so that the laboratory tests results can be matched with the samples collected for each participant/subject.

**SPECIFIC INSTRUCTIONS**

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

- **Lab Panel** – Choose the lab panel that was performed.
- **Date and Time Collected** – Indicate the date and time the specimen was collected.
- **Accession Number** – Provide the accession number or bar code number that is assigned to the specimen.
- **Results Reported** – Indicate if any laboratory test results were reported for the specimen.
- **Test** – Indicate the name of each laboratory test that is run on the specimen.
- **Result** – Record the numeric results for each laboratory test.
- **Unit for Result** – Record the units the numeric results for each laboratory test are measured in.
- **Abnormal Result** – Indicate if the laboratory test result is abnormal. Abnormal means the test result falls outside the normal range.
- **Clinical Significance** – If the laboratory test result is abnormal, indicate if the physician considers the result clinically significant.