

Marker Assay Use - Include v4.5

- **Integral.** Tests that must be performed for the trial to proceed. Includes biomarkers evaluated for the purpose of eligibility/enrollment, stratification, and treatment assignment.
- **Integrated.** Integrated assays include assays that will be performed on all samples or cases (for imaging studies) from an appropriate statistically prespecified subset of patients, are not required for the trial to proceed, will not inform treatment decisions or actions within the current trial but are intended to inform development of assays for subsequent trials.
- **Research.** Systematic investigation into a subject in order to discover facts, establish or revise a theory, or develop a plan of action based on the facts discovered.
- **Correlative.** Correlative studies include all other laboratory biomarker or translational research studies that are not performed on all patients within a clinical trial.