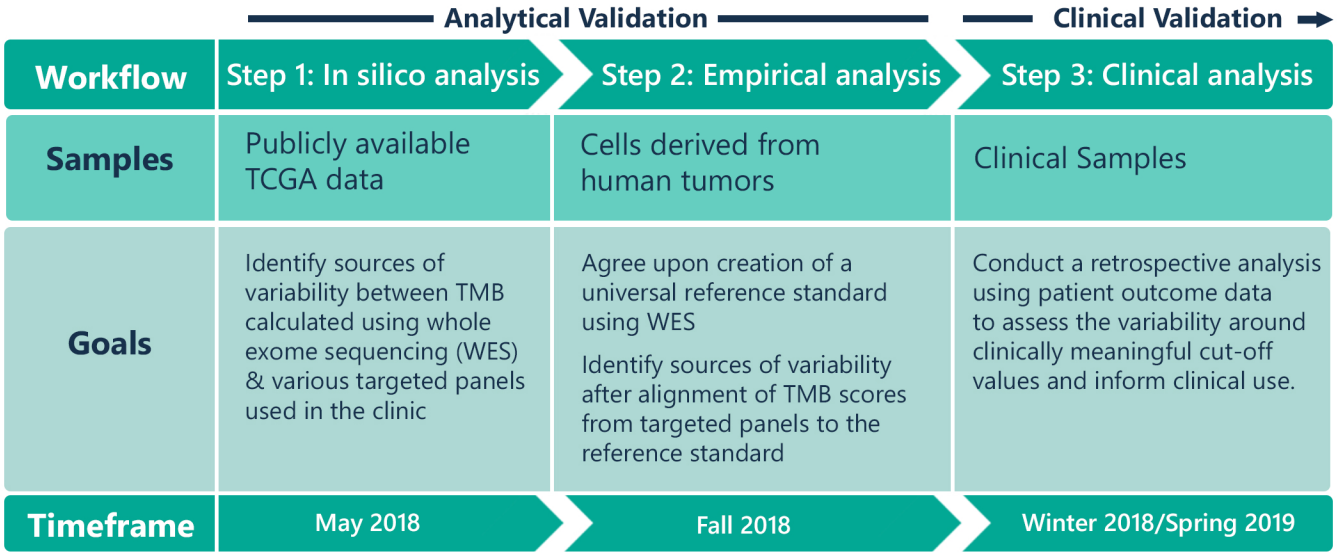
TMB Harmonization Project

The Definition: Tumor mutational burden (TMB) measures the quantity of mutations found in a tumor. This type of biomarker is currently under study to evaluate whether it may help predict the likelihood a patient with cancer will benefit from immuno-oncology (IO) therapies.

The Problem: Currently, there is a lack of standardization for TMB calculation and reporting. Different tests may report different measurements, and since there is currently no one way of calculating TMB it is difficult to use as a biomarker. To achieve consistency and accurate reporting across tests, it is imperative to create some sort of standardization to arrive at clinically-meaningful results, which will support informed decision-making for patients.

The Solution: There needs to be a standardized way of calculating and reporting TMB. Friends of Cancer Research (*Friends*) will convene stakeholders across all health sectors to review the current methods of TMB calculation and reporting and create a consensus solution on how best to standardize them. The group will propose analytical and clinical validation studies to support a standardized method of TMB measurement, which will help improve patient care through consistent TMB reporting in a clinical setting despite differences in the testing panel used. Ultimately, this project will help ensure consistent identification of patients who are likely to respond to IO therapies.

TMB Harmonization Project Overview



The Background:

- The use of IO therapies has increased dramatically in recent years. Immune checkpoint inhibitors (ICIs) are drugs that harness the patient's own immune system to fight cancer and have demonstrated a durable response and improved survival in a limited fraction of patients with cancers of the lung, head and neck, bladder, and melanoma.
- Recent discoveries have shown an association between a higher number of mutations found in a patient's tumor and an elevated immune response. This was also observed in patients who received ICIs. The higher the number of tumor mutations, the better the patient's outcome.
- Measuring the tumor's mutation burden may be a good predictor of which patients would most likely benefit from treatment from ICIs.

Partnering Organizations: National Cancer Institute (NCI), U.S. Food and Drug Administration (FDA), Memorial Sloan Kettering Cancer Center, AstraZeneca, Bristol-Myers Squibb Company, EMD Serono, Inc., Genentech, Inc., Merck & Co., Inc., Pfizer, Inc., Foundation Medicine, Inc., Guardant Health, Inc., Illumina, Inc., NeoGenomics Laboratories, Inc., OmniSeq, Personal Genome Diagnostics (PGDx), QIAGEN, Inc., Thermo Fisher Scientific