



Friends of Cancer Research Releases Results from Phase 2 of the TMB Harmonization Project

Press Contact:

Ryan Hohman, VP - Public Affairs, Friends of Cancer Research
rhohman@focr.org; 202-944-6708

Washington, DC - April 28, 2020 - Today, Friends of Cancer Research (*Friends*) released the findings from Phase 2 of its [TMB Harmonization Project](#) at the [AACR Virtual Annual Meeting I](#). These results are the outcome of the large-scale project led by *Friends*, which is leading the standardization of tumor mutational burden (TMB) calculation and reporting, in order to more effectively evaluate whether TMB may be used as a predictive biomarker.

Overview of Results:

- The TMB Harmonization Project demonstrates the variability in the association between the panel TMB values and whole exome sequencing determined (WES) TMB in a series of clinical samples.
- Multiple calibration approaches were developed to help align TMB values across next-generation sequencing (NGS) panels, reduce the spread between tests, and ultimately enhance consistency in the application of TMB.

“Through this unique collaboration, we have been able to utilize a standardized approach to TMB measurement to provide alignment between different tests,” said *Friends*’ President & CEO, Dr. Jeff Allen. “Ultimately, this project will help ensure consistent identification of patients who are likely to respond to immuno-oncology therapies.”

The main goal of Phase 2 was to create a universal reference standard to help calibrate or align TMB scores obtained from different NGS panels and better understand the sources of

variability across panels. The primary objective of the 15 participating labs was to assess the empirical variability in the association between panel TMB values and WES TMB in the clinical samples used for study. Using clinical data to further investigate three calibration approaches that may help align TMB values across NGS panels was the secondary objective.

In Phase 1 of the TMB Harmonization Project an in silico approach used publicly available WES data from the TCGA project. Eleven labs participated and a strong correlation between WES TMB and the panel TMB values was found.

“As complex biomarkers like TMB become more readily incorporated into oncology care, scientific and regulatory approaches are necessary for alignment on optimal performance thresholds and standards development,” Allen said.

Friends of Cancer Research would like to thank all of its [partners](#) without whom the TMB Harmonization Project would not be the success it is today.

Project Partners

Government: National Cancer Institute (NCI), U.S. Food and Drug Administration (FDA)

Academia: Brigham & Women’s Hospital, College of American Pathologists, Columbia University, EORTC, Genomic Testing Cooperative, Hartwig Medical Foundation, Johns Hopkins University, Massachusetts General Hospital, MD Anderson Cancer Center, Memorial Sloan Kettering Cancer Center, Quality in Pathology (QuIP), University of Heidelberg

Diagnostics: ACT Genomics, Biodesix, Caris Life Sciences, Foundation Medicine, Inc., Guardant Health, Inc., Illumina, Inc., Intermountain Precision Genomics, NeoGenomics Laboratories, Inc., OmniSeq, Personal Genome Diagnostics (PGDx), Q2 Solutions, QIAGEN, Inc., Quest

Diagnosics, RocheDx, Thermo Fisher Scientific, Thrive **Industry:** AstraZeneca, Bristol-Myers Squibb Company, EMD Serono, Inc., Genentech, Merck & Co., Inc., Pfizer, Inc., Regeneron Pharmaceuticals **Operational:** precisionFDA, SeraCare

For the full presentation from AACR, [click HERE](#).

###

About Friends of Cancer Research

Friends of Cancer Research (*Friends*) drives collaboration among partners from every healthcare sector to power advances in science, policy and regulation that speed lifesaving treatments to patients. For more information, please visit www.focr.org.