



Friends of Cancer Research Announces Results from Phase 2 of Tumor Mutational Burden Harmonization Project

Washington, DC – October 7, 2021 – Friends of Cancer Research (*Friends*) is pleased to announce findings from the final analysis of our [TMB Harmonization Project](#) published this week in *Annals of Oncology*, "[Aligning Tumor Mutational Burden \(TMB\) quantification across diagnostic platforms: Phase 2 of the Friends of Cancer Research TMB Harmonization Project](#)." Tumor mutational burden, or TMB, is a measure of the quantity of certain mutations found in a tumor.

“Recent studies have demonstrated that TMB levels may indicate if patients are more likely to respond to immunotherapies, but variability in TMB tests could complicate the use of TMB in clinical studies and ultimately in treatment decisions,” said *Friends’* President & CEO, Dr. Jeff Allen. **“Through this unique partnership we’ve determined that TMB test results can indeed vary and developed a new publicly available tool to solve for that variability, which will help improve consistency in results for patients in the future.”**

Friends works collaboratively with various stakeholders to create solutions to challenges in oncology patient care through research partnerships that tackle complex issues. The latest findings continue *Friends’* work evaluating the use of TMB as a biomarker to predict the likelihood a patient with cancer will benefit from immuno-oncology therapy, independent of their cancer type. These findings help move the field closer to the goal of ensuring every patient with cancer receiving a TMB test will receive the best care, independent of the TMB assay used.

The *Friends* TMB Harmonization Project brought together 16 different laboratories alongside experts from leading academic research institutions, drug and diagnostics developers, patient advocacy and government agencies. The collaborative effort aimed to contextualize variability across assays and to identify potential sources of variability to optimize development of TMB assays and support the development of a calibration tool to assess different panel assays in the future.

The findings from this project provide a foundation to support efforts to modernize diagnostic policy at FDA and inform development of recommendations for clinical guidelines. Additionally, this work sets the stage for additional projects focused on other biomarkers and *Friends* is currently using this framework to inform a project focused on harmonizing assays that measure homologous recombination deficiency (HRD), a biomarker used to select patients with certain cancers for treatment with PARP inhibitors.

Friends would like to thank all of the TMB Harmonization Project [partners](#).

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

Additional TMB Harmonization Project Resources

Project Overview: <https://friendsofcancerresearch.org/tmb>

Establishing guidelines to harmonize tumor mutational burden (TMB): in silico assessment of variation in TMB quantification across diagnostic platforms: phase I of the Friends of Cancer Research TMB Harmonization Project ([Friends manuscript](#))

Tumor mutational burden standardization initiatives: Recommendations for consistent tumor mutational burden assessment in clinical samples to guide immunotherapy treatment decisions ([Collaborative Manuscript](#))

Harmonization and Standardization of Panel-Based Tumor Mutational Burden (TMB)

Measurement: Real-World Results and Recommendations of the QuIP Study ([Collaborative Manuscript](#))

Spatial and Temporal Heterogeneity of Panel-Based Tumor Mutational Burden in Pulmonary Adenocarcinoma: Separating Biology From Technical Artifacts ([Collaborative Manuscript](#))

About Friends of Cancer Research

Friends of Cancer Research (*Friends*) is working to accelerate policy change, support groundbreaking science, and deliver new therapies to patients quickly and safely. We unite scientists, pharmaceutical companies, and policy makers with shared trust and guide them toward meaningful cooperation. This collaboration among partners from every healthcare sector ultimately drives advances in science, policy, and regulation that speed life-saving treatments to patients. For more information, please visit <https://friendsofcancerresearch.org/>.