



Friends of Cancer Research Announces Launch of Phase II TMB Harmonization Project

September 18, 2018 - Washington, DC - Today, Friends of Cancer Research (*Friends*) announced the launch of Phase II of its tumor mutational burden or TMB Harmonization Project as the TMB harmonization team finalizes data collected from the Phase I in silico analysis.

"Recent data shows a role for TMB in identifying patients more likely to respond to immunotherapy," said *Friends'* President & CEO, Jeff Allen. "However, harmonizing the measurement of TMB will be an important step in helping to reduce variability and optimize its use in cancer research and care. As we begin Phase II, I look forward to working with our partners and the team maneuvering through the data to come to consensus solutions. This has been a truly collaborative effort."

Phase II of the TMB Harmonization Project will be an empirical analysis of cells derived from human tumors. The working group will aim to agree upon the creation of a universal reference standard using whole exome sequencing (WES). Additionally, they will identify sources of variability after alignment of TMB scores from targeted panels to the reference standard.

Phase II logistics will involve the National Cancer Institute, which will serve as the reference lab and anchor the results generated from the diagnostic partners. Additionally, SeraCare will perform the necessary sample preparations for input material, and DNAnexus will provide its cloud-based services to host the sequencing data for analyses. Completion of Phase II is anticipated in early 2019.

At a September 13, 2018 meeting, the partners came together and finalized Phase I by arriving at high-level conclusions on the analyses. The conclusions from this phase will be presented at an upcoming scientific meeting.

In the first phase of the project, the working group reviewed publicly available data from The Cancer Genome Atlas. The aim of Phase I was to identify sources of variability between TMB calculated using WES and various targeted panels used in the clinic.

TMB measures the quantity of mutations found in a tumor. Currently, there are no standards for calculating and reporting TMB, which leaves a critical hole in the field. *Friends* has convened stakeholders across all health sectors to review the current methods of calculation and reporting that can impact TMB assessment in order to come to a consensus solution on how they can best be standardized. For updates on this three-phase project visit: <https://www.focr.org/tmb>.

Partners participating in this project include:

- ACT Genomics
- AstraZeneca
- Bristol-Myers Squibb Company
- Caris Life Sciences
- Columbia University
- DNAnexus
- EMD Serono, Inc.
- Foundation Medicine, Inc.
- Genentech
- Guardant Health, Inc.
- Illumina, Inc.
- Johns Hopkins University
- Memorial Sloan Kettering Cancer Center
- Merck & Co., Inc.
- National Cancer Institute (NCI)
- NeoGenomics Laboratories, Inc.
- OmniSeq
- Personal Genome Diagnostics
- Pfizer, Inc.
- QIAGEN, Inc.
- Regeneron Pharmaceuticals
- SeraCare
- Thermo Fisher Scientific
- U.S. Food and Drug Administration

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.