



Friends of Cancer Research Releases Results of TMB Harmonization Project - Phase I

Results to be Presented at the Society for Immunotherapy of Cancer's (SITC) 33rd Annual Meeting

November 6, 2018 - Washington, DC - Friends of Cancer Research (*Friends*) is pleased to announce that the results of Phase I of the [tumor mutational burden \(TMB\) Harmonization Project](#) will be presented as a late-breaking abstract at the [Society for Immunotherapy of Cancer's \(SITC\) 33rd Annual Meeting](#). The abstract, "In silico assessment of variation in TMB quantification across diagnostic platforms: Phase 1 of the Friends of Cancer Research Harmonization Project," will be presented as an oral presentation on **Friday, November 9, 2018, from 12:15pm - 12:30pm in Hall D**, and as a poster presentation on **Saturday, November 10, 2018, from 12:20pm - 1:50pm and 7:00pm - 8:30pm in Hall E**.

Objectives of Phase I included identifying sources of variability between TMB calculated using whole-exome sequencing (WES) and 11 different targeted panels. The working group analyzed publicly available data from The Cancer Genome Atlas and used an agreed upon method to calculate WES-derived TMB values, which served as the "gold standard" for the analysis. The finalized results of Phase I allowed project partners to formulate several conclusions based on these analyses. In general, the in silico analysis demonstrated that there is a strong correlation between panel-derived TMB and WES-derived TMB and that the methods used to calculate TMB can impact this correlation.

"It is vital that TMB measurement is harmonized to help reduce variability and optimize its use in cancer research and care," said *Friends'* President & CEO, Dr. Jeff Allen. "We've convened a group of partners to tackle the lack of consistent clinical interpretation of TMB since recent data has shown there is a role for TMB to play in identifying patients who are likely to respond to immunotherapies."

Earlier this year, *Friends* partnered with Quality Initiative in Pathology (QuIP), a German organization, upon realizing QuIP was working on a complementary approach to TMB

standardization and harmonization. A poster showcasing *Friends'* and QULP's approaches to TMB harmonization and joint recommendations between the two groups was presented at the 2018 European Society for Medical Oncology Congress in Munich, Germany on Saturday, October 20, 2018. Additionally, the abstract will be presented as an oral presentation at the upcoming International Association for the Study of Lung Cancer Asia Conference on Lung Care on Thursday, November 8, 2018.

“By working together with QULP, we are able to tackle a critical issue for patients by working collaboratively both here in the United States and abroad,” said Dr. Allen. “We are extremely grateful to all the participants in these initiatives. Bringing experts together from this many different organizations and agencies takes a true commitment from all.”

The [next phase](#) of the [TMB Harmonization Project](#) has begun and consists of an empirical analysis of cells derived from human tumors. Establishing a universal reference standard that can be used to assess the variability of TMB assays in development is the primary objective. The group will additionally identify sources of variability after alignment of TMB scores from targeted panels to the reference standard, which can help inform best practices. Phase II is expected to be completed in early 2019.

TMB measures the quantity of mutations found in a tumor. Currently, there are no standards for calculating and reporting TMB, which leaves a significant gap in the reliability of TMB measurement. *Friends* has convened stakeholders across all health sectors to review the current methods of calculation and reporting that can impact the clinical implementation of TMB to come to a consensus solution on how these approaches can be best standardized.

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.