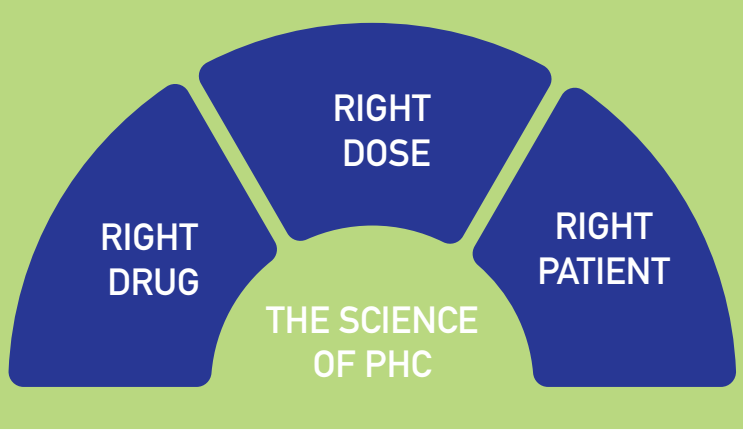

DEVELOPMENT SCIENCES

bTMB

LEARN MORE ABOUT BLOOD TUMOR MUTATIONAL BURDEN (bTMB) AND FIND OUT HOW THE SCIENTISTS IN DEVSCI ARE USING IT TO BRING PERSONALIZED MEDICINES TO PATIENTS.

the science

WHAT IS IT?

Blood-based testing delivers the potential to assess mutations in a broad range of patients, including those with unattainable tumor tissue. This may facilitate serial testing as patients' cancers progress. Tumor mutational burden (TMB) is an emerging biomarker that quantitatively measures the number of somatic mutations within a tumor genome. (bTMB) testing is an investigational approach to inform treatment decisions in cancer immunotherapy.

- Blood testing addresses several barriers to increasing treatment rates:
  - Offers a less-invasive alternative to biopsy for mutation analysis in patients with advanced Non-small cell lung cancer (NSCLC) for improved and timely patient testing.
  - Can be performed in patients who are unsuitable or unwilling to undergo a biopsy due to their health status
  - Spares tissue for additional biomarker testing
  - While tissue biopsies are standard in clinical practice, new methodologies may enable comprehensive biomarker testing in blood. Blood-based testing delivers the potential to assess mutations in a broad range of patients, including those with unattainable tumor tissue. Additionally, may facilitate serial testing as patients' cancers progress. National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology for NSCLC recommend that blood-based testing should be considered if tissue biopsy is not feasible.

Higher TMB levels are correlated with HIGHER LEVELS OF NEOANTIGENS which help our immune system to recognize tumors.

- DAVID SHAMES, STAFF SCIENTIST, OBD

our work

A FEW HIGHLIGHTS OF OUR SCIENTIST'S WORK ON bTMB:

INFORMING TREATMENT
We are currently investigating the potential of TMB and bTMB to inform cancer immunotherapy treatment decisions for patients with various cancers

BLOOD BASED TMB ASSAY
Our deep experience with blood-based mutation profiling (e.g., with Tarceva and EGFR mutations), coupled with our work in tissue-based TMB led us to pursue the development of a blood based TMB assay (bTMB).

PREDICT RESPONSE
In 2018 we published data in Nature Medicine showing that bTMB could predict response to Tecentriq based on retrospective analysis of data from two of Tecentriq's clinical trials. We're now validating the test prospectively in two ongoing clinical trials of Tecentriq in non-small cell lung cancer (NSCLC).

"Our goal is to partner with FMI to ensure that this type of blood-based test can report out results for all our actionable biomarkers to help patients receive earlier diagnoses and make informed medical decisions."

DAVID SHAMES, STAFF SCIENTIST, OBD

the future

We continue to test and optimize the clinical validity of our novel bTMB assay. It is being prospectively evaluated in two ongoing clinical trials:

- The Phase III Blood First Assay Screening Trial (BFAST), as a companion diagnostic to validate bTMB as a noninvasive biomarker of response to first-line atezolizumab in advanced non-small cell lung cancer (NSCLC) patients
- In the single-arm Phase II Blood First-Line Ready Screening Trial (B-F1RST) evaluating atezolizumab monotherapy in first-line NSCLC. Preliminary data from the B-F1RST trial presented at the 2018 American Society of Clinical Oncology (ASCO) meeting showed that progression-free survival in NSCLC patients was three times longer in those with high bTMB compared to those with low bTMB.

A version of our liquid biopsy assay was also granted Breakthrough Device designation, and if approved, could be the first FDA-approved liquid biopsy assay to incorporate multiple companion diagnostics (CDx) and multiple biomarkers, including bTMB, to inform the use of both targeted oncology therapies and immunotherapies.

Development Sciences