

Public-private research to develop more accurate ways of measuring cancer progression

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Columbia University Medical Center and NewYork-Presbyterian, in coordination with the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium, is launching a three-year research collaboration to develop new methods for analyzing digital images that track a patient's response to cancer therapy.

Many new cancer drugs fail in the latter stages of development, exposing patients who participate in early stage <u>clinical trials</u> to ineffective treatments and wasting valuable resources. In a 2012 review of 253 phase III drug clinical <u>trials</u> for treatment of solid tumors, 62 percent of the studies were unable to verify the expected positive benefit previously observed with the therapy in earlier stage trials. These results suggest that the tools used to assess drug benefit are inadequate for measuring efficacy in the early stages of development, and indicate the need for new methods of evaluating tumors.

The FNIH raised \$2.7 million from the private sector to address these issues through a new project called "Advanced metrics and modeling with Volumetric CT for Precision Analysis of Clinical Trial results" (Vol-PACT). This project is the first to use imaging data from multiple completed, pharmaceutical industry-sponsored, phase II/III clinical trials to develop drug response metrics. "Vol-PACT's goal is to identify the optimal method of measuring and assessing <u>tumor burden</u>," said Lawrence Schwartz, MD, the James Picker Professor of Radiology at



Columbia University Medical Center (CUMC), chair of the department of radiology at NewYork-Presbyterian/Columbia, and Co-Principal Investigator of Vol-PACT. "While there are general guidelines available for drug development, tumor response criteria are usually based on intuition. With this collaboration, we hope to define a data-driven methodology that more closely correlates tumor burden with patient outcomes." Binsheng Zhao, DSc, professor of radiology (physics) and Director of the Laboratory for Computational Image Analysis in the Department of Radiology at CUMC, will lead the effort to deliver quantitative tumor measurements from all of the clinical trials using labdeveloped advanced segmentation and characterization software.

The Vol-PACT project team will analyze the imaging data to measure characteristics of cancer progression and generate potential biomarkers. Since the project has access to multiple completed datasets, the team can rapidly develop robust imaging biomarker criteria and verify their utility in different settings. The project will compare the new biomarkers to the current image analysis standards used for therapies that target specific genes and proteins, as well as those that stimulate immune response. Current methods are unable to predict the efficacy of immunotherapies in many cancer types.

"This work has the potential to improve the accuracy and efficiency of future clinical trials across multiple treatments and cancer types, to accelerate the development of cancer therapies, and improve patient care," said Dr. Schwartz.

The project team, co-led by Geoffrey Oxnard, MD, of the Dana-Farber Cancer Institute, includes experts from the National Cancer Institute and the U.S. Food and Drug Administration, as well as Co-Investigators Mithat Gonen, PhD, of Memorial Sloan Kettering Cancer Center and Michael Maitland, MD, PhD, of the Inova Center for Personalized Health and the Inova Schar Cancer Institute. To date, four companies



have donated imaging and clinical trial data to support Vol-PACT and five companies have committed funding.

Provided by Columbia University Medical Center

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