What Vol-PACT partners are saying...

**Boehringer Ingelheim**

“The extension of the Vol-PACT project to include radiomics will further enhance the great potential to develop cutting-edge imaging-based biomarkers,” said Prof. Florian Gantner, Ph.D., Head of Translational Medicine and Clinical Pharmacology, Boehringer Ingelheim. “It would be great to see if imaging-based phenotyping of tumors is possible via radiomics and if that could help to predict treatment response early.”

**EMD Serono Inc.**

“There is a pressing need for improved methods of assessing and predicting tumor growth and likely response to therapy, to enable more efficient drug development, as well as more timely treatment decisions to benefit patients. EMD Serono is proud to support, sponsor and participate in this innovative FNIH initiative,” said Alise Reicin Boiarsky, M.D., Head of Global Clinical Development, EMD Serono Inc.

**Foundation for the National Institutes of Health**

“We are delighted to see Vol-PACT enter this exciting new phase to further enhance imaging biomarkers that can improve how we track and treat cancer,” said Joe Menetski, Ph.D., Associate Vice President of Research Partnerships, Foundation for the National Institutes of Health. “Using cutting-edge measurement tools, we can dig even deeper into understanding how cancer progresses, which can inform the development of future clinical trials and new, more effective therapies.”

**Merck**

“With increasing clinical experience around the use of check-point inhibitor therapies it has become apparent that there is a need for improved objective measures to evaluate immune response and progression criteria,” said Andrea Perrone, M.D., Associate Vice President of Clinical Imaging, Translational Medicine, Merck. “Vol-PACT, which will evaluate conventional and novel image-based quantification and statistical approaches, is an important step towards validating new surrogate endpoints with the potential to facilitate development of new drug regimens that bring new and meaningful options for patients. In particular, we are eager to see the results of studies to validate novel imaging criteria for immunotherapy, such as iRECIST, that improve prediction of clinical outcomes in patients with advanced disease.”

**National Cancer Institute (NCI)**

“Contemporary treatment paradigms for cancer may produce new patterns of response that require, in additions to tumor shrinkage, new methodologies for measurement,” said Gary J. Kelloff, M.D., Special Advisor, Cancer Imaging Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI). “This challenge is being met by evaluation of volumetric measurements as well as radiomics, kinetic modeling and artificial intelligence. The FNIH biomarker project, Vol-PACT, is designed to evaluate these new methods and is producing significant data and progress as the new methods are evaluated with reference to patient outcomes from completed phase III trials in which patients have received either chemotherapy, targeted agents or the newer immuno-oncology drugs.”
“Quantitative imaging measures are at the heart of proof of concept and efficacy assessments in many clinical trials,” said Dinko Gonzalez Trotter, Ph.D., Senior Director, Regeneron Pharmaceuticals, Inc. “The exploration of novel radiomics features may discover imaging measures of great utility for future clinical trials and potentially for clinical practice. The correlations of radiomics features with outcomes are of great interest as the most promising measures could be implemented proactively in upcoming clinical trials.”

**Takeda**

“The exploration and validation of novel imaging endpoints requires numerous data sets. Having multiple companies and academic centers involved provides additional credibility. Thus, the FNIH Biomarkers Consortium Vol-PACT project is uniquely positioned to satisfy both,” said Annette Schmid, Ph.D., Sr. Scientific Director, Takeda. “With respect to the particular outcomes, Takeda has been particularly interested in tumor growth kinetics as a potentially earlier, more sensitive measure and potentially a better predictor of response and progression. In the context of the expansion project, we are particularly interested in better understanding tumor features in the IO space that may allow a differentiation of flare from true progression. I very much hope that can be tackled.”