MDIC Launches Initiative to Improve Accuracy of Next-Generation Sequencing-Based Cancer Diagnostics
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This article has been updated from a previous version to provide more detailed information about the nature of the program launch.

NEW YORK – The Medical Device Innovation Consortium (MDIC), a public-private partnership working to advance medical device regulatory science, said on Monday that it has launched the next phase of the Somatic Reference Samples (SRS) Initiative with a pilot project to improve the validation and regulatory review process for cancer diagnostics based on next-generation sequencing (NGS).

As part of the initiative, MDIC will lead a collaboration with the US Food and Drug Administration, the National Institute of Standards and Technology (NIST), the National Institutes of Health, and industry stakeholders to manufacture, validate, and distribute SRSs to simplify and support the validation of NGS-based cancer diagnostics. The initiative also aims to create a publicly available global genomic data resource library of datasets with the potential to be used by sponsors and regulators, the consortium said.

According to MDIC, the goal of the pilot project is to individually engineer 10 gene variants clinically associated with cancer into a highly characterized human cell line, GM24385, using CRISPR. Horizon Discovery, a PerkinElmer company, is tasked with developing and manufacturing these reference samples.

MDIC said the fully characterized reference samples will be commercially available to end users from Horizon while the characterization data will be accessible through public databases, including precisionFDA, an FDA-sponsored site for data information, sequencing, and bioinformatics.

"[W]ell-characterized and widely accepted reference materials do not exist for NGS-based diagnostics, complicating the development and validation process," said MDIC President and CEO Andrew Fish in a statement. "Through the MDIC SRS Initiative, we are developing reference samples and datasets that can be used globally by test developers and regulators to bring more consistency to NGS-based cancer diagnostic development, increasing the confidence and accuracy of these tests, which will ultimately lead to more accuracy in diagnosis and treatment for patients."

The initiative is funded in part by the Gordon and Betty Moore Foundation, the National Philanthropic Trust, Illumina, and Quidel.

The new pilot builds on an earlier phase of the project, which included "landscape analysis, project definition, and requests for proposals for a manufacturing partner," a
spokesperson said in an email. The spokesperson added that this week the consortium is announcing the formal launch of the pilot project to make and characterize somatic reference samples, establish a steering committee with key stakeholders to guide the project, and disclose a manufacturing agreement with Horizon Discovery and a CRADA with the National Institute of Standards and Technology.