

Takeda, MiTest Health to launch innovative Disease Risk Prediction Tool

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The validated predictive tool - an important advancement in precision medicine for CD will evaluate individual risk for developing complications and help support personalized clinical decision-making



Takeda Pharmaceuticals USA and MiTest Health LLC ("MiTest"), a pioneering health technology company, have announced an exclusive partnership to optimize MiTest's personalized risk and outcome prediction tool for widespread use in patients with Crohn's disease (CD). The validated tool can help predict a patient's individual potential risk for CD-related complications based on clinical, serologic and genetic variables and create a visual report to support informed, shared decision-making with their healthcare providers.

Devastating complications from CD - such as fistulas, abscesses, strictures, and intestinal obstruction - can be common, yet the course of CD is highly variable and difficult to predict. Prognostic tools that can identify the potential risk for complication early are essential when considering the most appropriate management approach for an individual patient. With the goal of advancing personalized treatment in CD, Takeda and MiTest Health plan to make the validated predictive tool readily available for use by gastroenterologists to enhance informed clinical decision-making.

"Crohn's disease can cause severe complications and irreversible damage to the bowels. The tool has the potential to help tailor the approach for patients with Crohn's disease by better informing them and their physicians about their individual potential risks for developing complications early on, before disease complications occur," said Corey Siegel, MD, MS, MiTest co-founder, section chief of gastroenterology and hepatology and co-director of the IBD Center at the Dartmouth-Hitchcock Medical Center, NH. "The tool will help initiate conversation around potential disease progression and options based on predicted outcomes."

"Physicians using the validated predictive tool will be better able to support their patients with Crohn's disease, who face significant challenges, by developing a disease management plan based on a shared understanding of their individual prognosis," said Marla Dubinsky, MD, MiTest co-founder, chief of pediatric gastroenterology and nutrition, co-director of the Susan and Leonard Feinstein IBD Clinical Center at Icahn School of Medicine at Mount Sinai in New York. "We look forward to our continued work with Takeda to bring this important resource to physicians and patients."

This tool predicts an individual's potential risk for disease progression before he or she develops severe complications using a blood sample that is analyzed for patient-specific serologic markers and NOD2 status, combined with clinical phenotype

information. Based on the results, the tool will create a patient-friendly graphical risk score. Health care providers will then receive a report that can facilitate discussions with patients to determine an appropriate course of action.

"Takeda is dedicated to shaping the future of gastroenterology, and we are excited to help advance the use of personalized treatment in Crohn's disease. By bringing a deep understanding of unmet clinical needs to our collaborations with strategic partners, we're focused on delivering original and meaningful tools to support patients through their journey," said Uthra Sundaram, Senior Vice President, GI Business Unit, Takeda Pharmaceuticals U.S.A., Inc. "In partnership with MiTest Health, Takeda looks forward to broadening the use of this tool, allowing more patients and physicians to benefit from discussions and shared decision-making prompted from its insights."

This validated predictive tool was developed by MiTest in 2014, has been validated via analysis of a well-characterized cohort of adult patients with CD and predictive modelling, and has been used on a limited basis in clinical settings to date. Takeda will provide support in scaling up and operationalizing the tool to more broadly support providers and patients.