Prevencio
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Revolutionizing biomarker blood tests using artificial intelligence

By combining machine learning with multiple proteins and proprietary algorithms, Prevencio has developed a portfolio of HART tests that accurately diagnose cardiovascular diseases. Prevencio also offers custom diagnostic services.

The accurate diagnosis of disease and prediction of patients who may develop a disease are key for clinicians to prescribe personalized treatment plans, and for pharmaceutical companies to develop effective drugs. Prevencio, based in Kirkland, Washington, has developed a platform utilizing machine learning, a subset of artificial intelligence (AI), to develop multi-protein and clinical variable panels specific to a disease. The multiple proteins and clinical variables are combined in a proprietary HART algorithm and highly accurate scoring system for cardiovascular diagnosis and prognosis. Prevencio also offers custom panel development for clinical trial enrichment and orphan diseases.

Building multi-protein, algorithmically scored novel cardiac panels

Many laboratories use assays that test for a single protein, but cardiovascular disease is complex and assessing a single marker, such as troponin or BNP (B-type natriuretic peptide), often fails to provide a complete picture for accurate diagnosis or prognosis. Prevencio's machine learning approach eliminates bias and selects clinically significant proteins and clinical variables that comprise a panel to pinpoint disease or prognosis (Fig. 1). Accurate data allow physicians and researchers to stratify patient risk according to a HART risk score. Prevencio's original research was conducted in collaboration with Massachusetts General Hospital, and included 109 protein biomarkers, and more than 250 clinical variables from more than 1,200 patients. The panels demonstrated higher accuracy than nuclear treadmill tests, single proteins, and clinical risk scores. The HART tests have potential to reduce expense and patient exposure to radiation from non-invasive cardiac testing. The HART tests have been externally validated at University Heart and Vascular Center, Hamburg, Germany, as well as Inova Healthcare, in Northern Virginia.

Accurate diagnosis, tailored treatment and treatment monitoring

With the HART tests, patients receive accurate diagnosis, tailored drug treatment and follow-up at earlier stages of disease, as well as monitoring impact of treatment.

Prevencio has a development pipeline of 8 HART blood tests, with 2 tests currently being used by physicians for patients as laboratory developed tests (LDTs): HART CADhs for obstructive coronary artery disease diagnosis and HART CVE for 1-year risk of heart attack, stroke or cardiovascular death. The other tests are for research use only and include: HART PAD for peripheral artery disease diagnosis; HART AS for aortic valve stenosis diagnosis; HART AKI for predicting acute kidney injury risk; HART AMP for predicting amputation risk; and, most recently, the HART KD for the rare and sometimes fatal childhood disorder, Kawasaki disease. There is a possible link between COVID-19 and Kawasaki disease symptoms in some children. Prevencio plans to obtain US Food and Drug Administration (FDA) clearance for HART KD between 2021 and 2022, and EU CE marking and FDA approval for HART CADhs and HART CVE around 2024 or 2025.

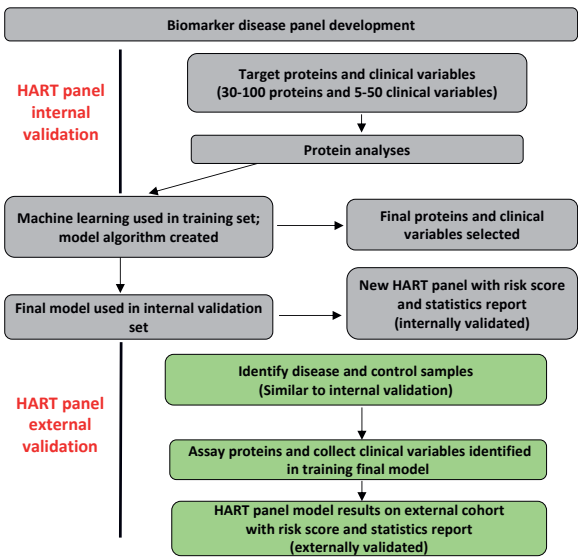

Fig. 1 | HART panel development and validation process.

Clinical trial support

According to a March 2020 study, the average cost to bring a drug to market is $1.3 billion. There have been significant efforts to reduce drug development costs and timelines. One of the most promising strategies is the use of biomarkers in clinical trials. Biomarkers enable the identification of patient risk profiles, such as patients with higher risk of events compared to those with lower risk of events. This enables pharmaceutical companies to streamline clinical trials by enrolling only high-risk patients in the screening process (known as clinical trial enrichment), thereby realizing immense economic and time savings. Biomarkers have also been used for predicting unanticipated drug effects and toxicity, as well as pre-treatment and post-treatment effects. These biomarker strategies can reduce the cost of development, optimize time for completion of clinical trials, and increase by 3-fold the probability of drug success from phase 1 to regulatory approval.

Prevencio's HART tests play several roles in drug development. They can be used to identify and screen target populations, for example, higher risk patients for clinical trial recruitment; identify patients most likely to respond to treatment or develop adverse effects; or select individuals at higher risk of cardiovascular events who are therefore more likely to benefit from the drug. During clinical trials, Prevencio's HART assays can be used to monitor responses to different doses of the drug during dose-escalation efficacy studies.

Prevencio offers custom panels for specific disease diagnosis and prognosis, including orphan diseases, using blood samples and clinical information. Prevencio provides vital information on clinical trial participants to partners in drug development at screening, during treatment and after treatment phases on drug effects and toxicity. Pharmaceutical partners have access to the custom panel on an exclusive or non-exclusive basis, depending on the terms of the agreement.

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