



cogitativo

Real-World Disease Progression Intelligence

Position Your Therapeutic Product for Success Through Advanced Machine Learning

Early access to real-world evidence (RWE) in the developmental stages of new therapeutics is crucial for expediting the delivery of solutions. RWE allows pharmaceutical developers to address critical medical needs and mitigate the expenses and delays associated with post-market research requirements. Additionally, combining RWE and validated machine learning solutions can reveal innovative applications for therapeutics for expanded use. Successfully incorporating RWE is essential for a more efficient launch, commercial adoption, and growth of therapeutics.

Real-World Evidence and Therapeutics for Chronic Disease Management

Chronic disease is the leading cause of death and disability in the United States, where nearly half of the population suffers from a chronic illness.^{1,2} Most people with chronic diseases do not receive adequate medical therapies, which leads to complications, hospitalizations, and costs that would be preventable with proper care.² This increases demand for therapeutics to help patients manage and prevent disease progression. However, clinical trials for medications can be costly, time-consuming, and unrepresentative of the whole population needing medications. Post-market study growth is primarily driven by complex regulator and payor demands for

more RWE of safety and clinical efficacy. Payor coverage standards are typically more demanding than regulators' approval standards, as they require evidence of quantifiable improvement in patient outcomes, cost-effectiveness, and overall value versus existing and new alternatives. These foregoing factors contribute to ineffectiveness in our healthcare system, where they have created a feedback loop reflected in deteriorating health status and escalating health-related costs. Medications that could be helping the majority of Americans with chronic diseases are stuck in a holding pattern of testing.

Cogitativo's response: personalized unseen comorbidity risks and predictions

A Platform That Leverages Diverse Real-World Evidence

Powered by advanced machine learning models

Cogitativo has deployed a predictive disease progression platform that detects vulnerable individuals with imminent and emerging clinical risks. Cogitativo's Disease Prediction Index (DPI) produces probabilities that individual patients will endure disease progression or acute events. The DPI analyzes key RWE inputs such as demographics, clinical conditions, medical procedures, specific medications, laboratory results, and social determinants of health (SDoH).

Cogitativo has advanced predictive health science to render unseen patient-level disease progression risk, even for individuals with multiple chronic conditions. Simultaneously, Cogitativo can evaluate the effectiveness of therapeutics on these patients' health. This capability will allow developers to assess their products in real-world settings beyond basic clinical trials. Additionally, the evaluations can be conducted while patients use their existing medications so that the effectiveness and efficiency of the medications can be assessed beyond FDA approval.



Cogitativo's Machine Learning Insights

Forecasting of health-related events to optimize medical intervention.

These predictive outputs enable systems of care to identify the most clinically vulnerable and deliver personalized optimal medical therapeutics, thereby improving effectiveness, outcomes, and benefit design value proposition. By delivering faster, higher value care, providers can practice at the top of their value care to the license, which enables the alignment of acuity of required care to specialist resources. Applying this to the future, life science organizations can now accurately deploy care capabilities to meet high-probability future care needs.

Proactive improvements in care quality and customization.

While making clear the ideal timing and order of care delivery, Cogitativo's platform also generates novel predictive insights into individual risk factors and the type of care that will be most advantageous for each patient. Specifically, the platform captures the

subtleties of patient responses to treatments and guides providers to make the most effective therapy recommendations based on each patient's unique biological, social, and clinical characteristics. This data also provides unique insights into provider-patient level performance of care, which can be used to communicate the value of differentiated therapies.

In addition to providing a snapshot of a patient's health, using the DPI to monitor patients' health over time provides further insight into the performance of interventions, care providers, and health systems, which can inform future medical therapeutic decisions. The DPI can also detect and mitigate health disparities at a societal level through its sensitivity to social determinants of health (SDoH) factors.

The future release of DPI will incorporate the ability to ingest voice, video, actigraphy data, and waveforms from remote patient monitoring devices in inpatient, step-down, or at-home care locations. These additional biomarkers will give a more complete, comprehensive, and timely view of a person's health status.

DPI is Solving Pressing Chronic Health Challenges in Real-World Settings

Cogitativo's DPI was developed using Clarivate's heterogeneous dataset from over 200 million individuals, including PBM and specialty therapeutics. The data include a longitudinal view of patients and their biomarkers as well as both clinical and nonclinical data. RWE clinical data include patient details and data related to claims, pharmacies, providers, and electronic medical records (EMRs). Nonclinical data include the EPA's Environmental Justice Index and the CDC/ATSDR Social Vulnerability Index. Cogitativo's platform incorporates clinical expertise, peer-reviewed clinical research, and nationally accepted medical guidelines to ensure that output variables are comprehensive and reflect the latest medical knowledge.

Cogitativo's condition library currently includes atherosclerotic cardiovascular disease (ASCVD), diabetic complications, chronic kidney disease (CKD), and chronic obstructive pulmonary disease (COPD). An individual patient's likelihood of experiencing unfavorable outcomes related to these conditions can be scored in single or multi-morbidity conditions.



Cogitativo's DPI has been used to facilitate and improve care in the face of healthcare emergencies.

Improving care and vaccination rates during the COVID-19 pandemic.

- A prominent West Coast payor utilized Cogitativo's DPI to identify their most at-risk members during the pandemic and match them with beneficial personalized medical care and support.
- The Department of Health and Human Services (HHS) partnered with Cogitativo to identify patients for whom COVID-19 posed the greatest risk, map their optimal vaccine pathways, and determine the locations for pop-up COVID-19 vaccine centers accordingly.

Mitigating effects of deferred care among Veterans.

- Based on their observations of the detrimental impacts of deferring care in the context of cardiovascular disease, chronic kidney disease, and diabetes, the Veterans Health Administration (VHA) has used DPI to identify Veterans at high risk for disease progression and to develop healthcare strategies to boost Veteran wellbeing.

Takeaway

Protecting patients' health and the nation's financial stability requires efficient prevention and treatment of chronic conditions, often with medications. Efficiently developing, validating, and delivering these therapeutics to the right patients requires an optimal machine-learning approach that utilizes RWE. Cogitativo's DPI empowers pharmaceutical developers to get the proper medications to the right patients.

RWE is more likely to reveal potentially novel uses for a therapeutic, yielding hypotheses that target a broader range of indications, resulting in more efficient clinical trials that are better aligned with the needs of payors.

Cogitativo's advanced machine learning solution transforms noisy and incomplete patient data into actionable data that:

- Accelerates time-to-patient by delivering patient-provider RWE insights faster
- Reveals innovative applications for alternative care pathways
- Facilitates payor reimbursement discussions, based on RWE of product effectiveness and value

References

1. Boersma P, Black LI, Ward BW. Prevalence of Multiple Chronic Conditions Among US Adults, 2018. *Prev Chronic Dis.* 2020;17. doi:10.5888/PCD17.200130
2. Saude J, Baker ML, Axman LM, Swider SM. Applying the Chronic Care Model to Improve Patient Activation at a Nurse-Managed Student-Run Free Clinic for Medically Underserved People. *SAGE Open Nurs.* 2020;6. doi:10.1177/2377960820902612

