MOLECULAR HEALTH
MHPREDICT

Accurate Prediction of Clinical Trial Success

Estimation of the success likelihood of a clinical trial plays a vital role in determining the time and investment it takes to bring efficacious drug treatment to patients to cure and manage disease. The accurate prediction of clinical trial success and failure can lead to faster drug approval times, lower costs for pharma companies, and better funding to develop new treatments. It can ultimately also benefit patients who participate in clinical trials as clinical development programs with higher success likelihood get prioritized and those unlikely to succeed can be halted or avoided altogether. Everyone involved in the clinical development process, such as regulators, biopharma companies, doctors and patients get affected by its failure. To avoid such situations, Molecular Health, a leading biomedical intelligence company, helps in predicting the technical success of clinical trials. Using proprietary data models and AI (artificial intelligence)/ML (machine learning), the company predicts the likelihood of success of clinical trials and identifies their potential success or failure factors to support informed decisions. In an interview with CIO Applications, Blanca Baez, SVP, Global Head of Pharma & Biotech, and Armin Schneider, SVP of Scientific & Medical Affairs of Molecular Health, share their insights on how the company helps in making unbiased evidence-based clinical development and portfolio decisions with its technology platform branded MH Predict, by converting clinical and molecular data and medical knowledge into actionable information.

Could you give us an overview of Molecular Health, and what are the factors that spurred the conception of the company?

Its founders recognized the trend towards and importance of enabling personalized medicine and established Molecular Health to become a transformational biomedicine intelligence company. Leveraging the understanding of disease that arose from key events in medical science such as the human reference genome and the advancement of specialized data science and technology, we want to improve health by liberating the power of biomedical data.

Codifying the clinical and molecular aspects of disease, we endeavor to empower better treatments, diagnoses and prevention through creation of intelligible data, predictive models and actionable insights to benefit drug discovery and development and treatment decisions for patients.

How does Molecular Health bring together the molecular data and provide actionable insights to the clients?

To integrate clinical and molecular data and novel data analysis technology, we have created a unique knowledge

**Blanca Baez,
SVP, Global Head of
Pharma & Biotech**
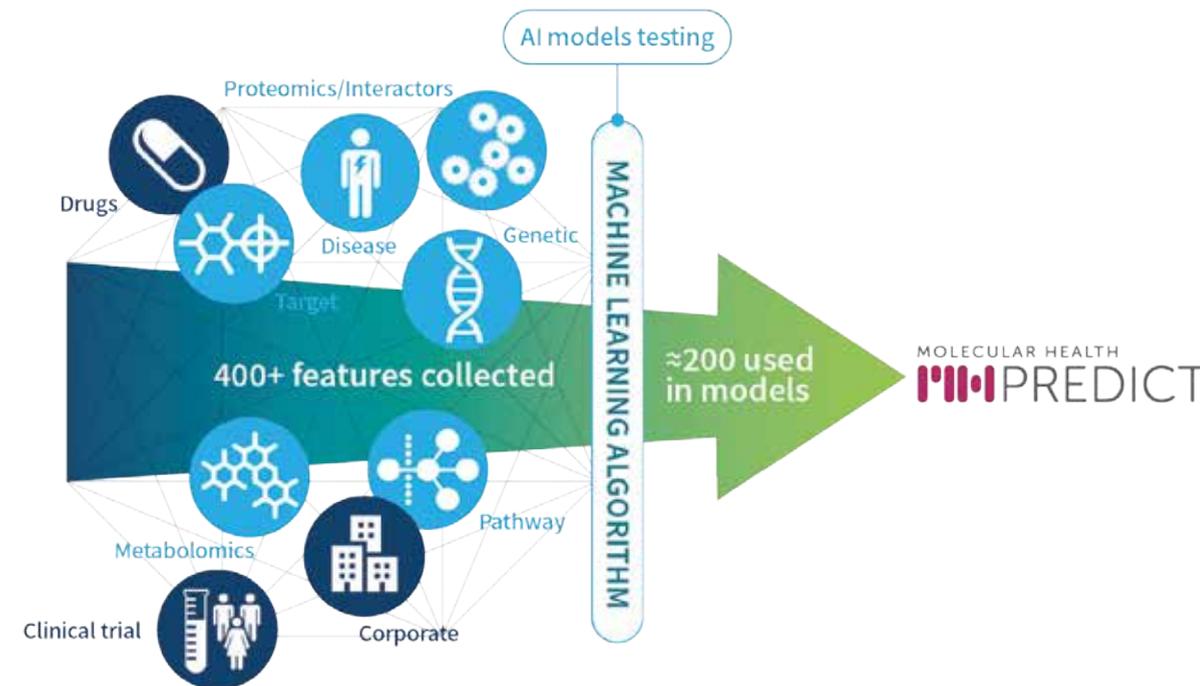
base called Dataome through which we capture and aggregate data from the molecular and clinical world to generate insights for the drug development process. The unique value proposition of Molecular Health is to perpetually capture, enrich and integrate the world´s clinical and molecular data in a quality- controlled environment, to deliver innovative solutions for the most important challenges in drug development, patient care and disease prevention. Our Dataome technology platform serves the delivery of fast clinico-molecular data interpretation, including identification of personalized treatment options for patients, patient drug response anticipation, and drug toxicity as well as side effect prediction based on referencing clinical and molecular evidence. We develop software applications from Dataome to address a series of use cases ranging from genome-guided treatment decision support, to molecular analysis of drug outcomes, drug repurposing and, as mentioned above, the prediction of clinical trial success. We work across therapeutic areas, whilst retaining a specialization in oncology and hematology with regards to the treatment decision support offering. Our product, MH Guide, serves to contextualize a patient's tumor mutational landscape with the drugs available for treatment.

What are the challenges that your clients face today, and how do you help them mitigate those?

As mentioned above, MH Guide helps oncologists, hematologists and pathologists to navigate the complexities

of treatment decision with so many approved drugs and consideration of individual characteristics of a patient's cancer. With our product MH Effect – a software application developed under a research collaboration with and utilized by the FDA - we help to make sense of and leverage drug safety data by deriving insights in a systematic way from adverse reactions captured from the real world. However, our most recent offering is MH Predict. With this product we serve the pharma and biotech industry, life science consulting, CROs, biotech investors, drug R&D academia and NGOs, and regulatory and technology appraisal bodies with the strategic and medical aspects of clinical development. The specific challenge that MH Predict addresses in drug development is the declining return on investment in Pharma R&D partially due to the stagnating success rate of clinical trials.

What are the features and functionalities of MH Predict?

MH Predict uses AI/ML and specifically engineered data to predict whether a particular clinical trial will work or not. Preferring trials with a higher success likelihood can optimize trial portfolio composition for the pharmaceutical industry, save a significant amount of money and ultimately promises better care for patients. Additionally, this may lead to faster development of drugs in particular areas of unmet medical need. Our predictive model purely focuses on the technical success of clinical trials (PTS, probability of technical success) and predicts the likelihood of a trial reaching its primary endpoint(s). This helps organizations in prioritization of

assets and making strategic decisions. Also, MH Predict helps in designing clinical trials more efficiently. Besides providing accurate probabilities of trial success, MH Predict also opens up the "black box" of AI to deliver insights into the properties of a drug or a trial that contribute to the decision of the algorithm for the assigned success probability.

Could you elaborate on the implementation of MH Predict?

MH Predict is available as a software as a service over the web (SaaS) that makes it easy to use, even for clients that have no conception of statistics or machine learning to interact with our algorithm. With a simple login, they can access the probability of success for a trial of interest that can be contextualized by the success likelihoods of the relevant neighborhood of this trial (e.g., trials targeting the same indication). The user can then "open the black box of AI" and study the influence of specific features on the prediction using state-of-the-art algorithms and simulate changes of particular values of properties to get insights on how changing some aspects of the trial would influence the probability of success. We also offer a portfolio module that provides portfolio managers or financial industries with insights on the overall outlook of a trial portfolio of a pharma company. In general, we believe that MH Predict serves as a valuable unbiased complementation of internal assessment of technical success inside an organization.

> **MH Predict uses machine learning and clinical science to predict whether a particular trial or clinical development program will work or not**

Could you share a customer success story where Molecular Health helped its clients in overcoming their clinical challenges?

We had a client that was losing value in the market due to the failure of clinical trials that were expected to be a great success. A company's financial outlook can depend on the success of trials for finding a treatment for a set of patients. Our MH Predict helped them understand the blind spot of clinical trials. We have also enabled our clients to understand and interpret the algorithm and the factors of success or failure. This analysis also supports the improvement of clinical trials as our tools give a clear representation of what would happen if the number of patients enrolled was changed to a

higher or lower number. Recently, we ran an analysis for a big pharma company on the projects that they have done over the years. We helped them understand how using MH predict as a decision support tool for their portfolio can save millions of dollars.

Usage of our product does not limit to the medical industry, it extends to the financial market as well. In one of the cases, the hedge fund makes decisions on biotech and pharma assets based on what the algorithm says. Last year, they made numerous investment decisions using MH Predict. The accuracy of our model was higher than 90 percent for their investments that allowed them to generate value for their investors.

Armin Schneider,
SVP, Scientific and
Medical Affairs

What is the future roadmap for Molecular health?

We are launching MH Predict globally throughout Q2-Q4,2020. The commercial version of the application is available now, and we are also engaging with key opinion leaders in this innovative field. The software platform includes several modules tailored to serve strategic and clinical development audience across the target markets mentioned above. Further product development is also underway. Some of the functionalities and modules we offer are: AI-driven prediction of technical success of existing clinical trials, analysis of success and failure drivers for past and upcoming trials, competitive comparison, identification and qualification of in-licensing targets and portfolio optimization. In the near future we will also add a trial design simulation module. We are continuously working on optimizations and add new data and properties that can improve accuracy further and offer valuable information on the success and failure of a trial. We are likely to advance this technology into deepening the predictive power for specific therapeutic areas to become even more specific and sophisticated in the use cases. We are also open to collaborations with potential partners that would allow us to import, extract, amalgamate, and reference further drug outcomes and data to general more predictive power and value in understanding drivers of success and failure. CA