AI-Driven twoXAR and Ono Pharma COLLABORATE ON DRUG DISCOVERY RESEARCH

▶ *Trend Watch: Partnerships and Collaborations Advance AI Capabilities*

Ono Pharmaceutical, a Japanese pharmaceutical research and development company, and twoXAR Inc., an AI-driven biopharmaceutical company, have teamed up to jointly discover and develop novel, efficacious treatments to address unmet medical needs in a specific neurological disease.

By combining Ono's drug discovery experience and twoXAR's AI technology, the companies aim to increase the speed and probability of success in discovering and developing innovative first-in-class drugs to expand its neurological disease pipeline.

Under the agreement, twoXAR will use its proprietary AI technology to identify a set of lead compounds, which demonstrate a novel mechanism of action and will be further optimized by Ono for potential drug candidates. twoXAR will also predict a set of hypotheses that suggest the efficacy and safety of such lead compounds for the therapy. The two companies will select several compounds with their hypotheses from this set to test in further validation studies. Ono will retain exclusive rights to develop and commercialize the compounds obtained through this collaboration throughout the world, and in return twoXAR will receive research and license fees from Ono as well as development and sales milestones.

Roche/Genentech Study Shows AI Can DETECT SEVERITY OF DIABETIC MACULAR EDEMA

A new study published in Investigative Ophthalmology & Visual Science suggests AI could be used to provide widespread, cost-effective eye screenings via telemedicine to assist ophthalmologists in improving vision outcomes for millions of people with diabetes who may not be getting regular eye exams.

The study, led by Roche and Genentech scientists, demonstrated for the very first time that AI, specifically deep learning technology, can detect swelling in the macula (the part of the eye responsible for central vision and allowing people to see color and details) and the severity of the swelling in individuals with diabetes. This swelling in the macula is known as diabetic macular edema (DME), a sight-stealing condition that impacts about 10% of the 425 million people around the world living with diabetes.

In the Roche/Genentech study, scientists used almost 18,000 CFPs and their associated OCT images captured during Genentech's past Phase III DME studies to develop and assess the performance of deep learning algorithms. Results of the study showed that the best deep learning algorithm was up to 97% accurate in detecting DME severity using CFP images alone. Such results underscore the promising potential of AI in increasing screening capacity via telemedicine with appropriate triage to assist ophthalmologists in improving vision outcomes for a large population of patients who may not be getting comprehensive eye exams.

The study adds to the growing literature about the use of AI in ophthalmology. It also sheds light on how Roche/Genentech can use its vast clinical trial database to develop AI algorithms to predict the presence of disease, risk of disease progression, and response to treatment, all of which could be supplied to ophthalmologists to deliver higher quality personalized healthcare.

FDA Creating new Review Framework for ARTIFICIAL INTELLIGENCE-BASED MEDICAL DEVICES

The FDA has announced steps to consider a new regulatory framework specifically tailored to promote the development of safe and effective medical devices that use advanced artificial intelligence algorithms.

The goal of the framework is to assure that ongoing algorithm changes follow pre-specified performance objectives and change control plans, use a validation process that ensures improvements to the performance, safety, and effectiveness of the artificial intelligence software, and includes real-world monitoring of performance once the device is on the market to ensure safety and effectiveness are maintained.

Former FDA Commissioner Scott Gottlieb unveiled the proposed framework to allow ongoing artificial intelligence algorithm changes based on real-world learning. Modifications to traditional software as a medical device (SaMD) that could have a significant impact on the safety or effectiveness of a device would still require a submission to FDA.

Approved AI products to date generally have locked algorithms and do not automatically change over time as new data is collected. The agency suggests relying on periodic modifications by manufacturers may delay the promise of AI to actively learn and potentially improve intervention timeliness and outcomes.

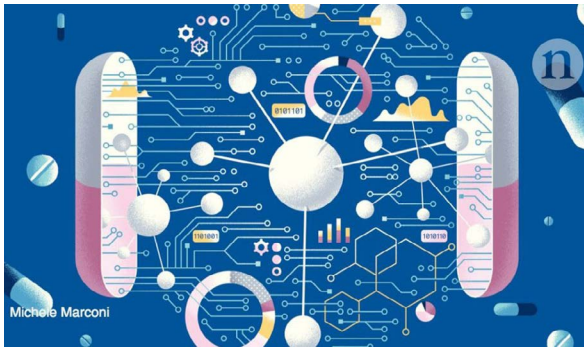
The idea, laid out in a discussion paper, is to determine what type of AI/machine learning-based SaMD modifications, if any, could potentially be exempted from premarket submission requirements. The FDA is formally asking for feedback in a request for information on the discussion paper by June 3.

In addition, the agency is exploring a framework that would allow for modifications to algorithms to be made from real-world learning and adaptation, while still ensuring safety and effectiveness of the software as a medical device is maintained.

In the future, the agency will include issuing draft guidance that will be informed by the input it receives.

Last year, the FDA authorized an artificial intelligence based device for detecting diabetic retinopathy, an eye disease that can cause vision loss. The agency also authorized a second artificial intelligence based device for alerting providers of a potential stroke in patients.

Exscientia Achieves Molecule Discovery Milestone as Part of GSK Collaboration



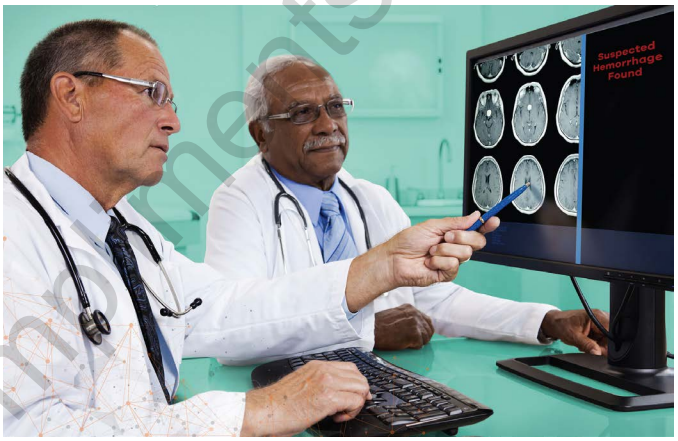
Exscientia, an AI-driven drug discovery company, has delivered a highly potent in vivo active lead molecule, targeting a novel pathway for the treatment of chronic obstructive pulmonary disease (COPD). By delivering the candidate, it has reached the first major milestone in its AI-drug discovery collaboration with GSK.

The molecule was developed through the application of Exscientia's Centaur Chemist AI-driven automated drug discovery platform. This approach has delivered a lead molecule with fewer compounds synthesized in comparison to conventional industry benchmarks. The in vivo lead was identified de novo from 85 project compounds and was synthesized and tested within five iterative design and screening cycles.

Exscientia entered a strategic AI-drug discovery collaboration with GSK, with the aim of combining its AI enabled platform with GSK's long-standing expertise to accelerate the discovery of quality new molecules. Exscientia is learning from the wealth of biological and chemistry data resources to drive its AI algorithms to design novel molecules with exacting product criteria as the objectives.

Exscientia's approach has already proved itself by delivering preclinical drug candidate molecules in roughly one-quarter of the time, and at one-quarter of the cost of traditional approaches, within partnerships with a variety of major pharmaceutical companies.

MaxQ Accelerates Artificial Intelligence Performance with Intel



A collaboration with Intel is expected to accelerate the computational flow of MaxQ AI's Accipio Medical Diagnostics Platform. MaxQ AI has tripled the computational performance of its Accipio intracranial hemorrhage (ICH) and stroke detection platform, enabling clinicians to prioritize critical patients and provide faster, near real-time ICH diagnosis. MaxQ's Accipio Ix reduces the time needed to detect hemorrhages, enabling physicians to prioritize patient care when time is of the utmost importance. MaxQ AI's Accipio Ix can now achieve more than 300% acceleration in the computational flow of algorithms on Intel AI, without impacting detection accuracy.

MaxQ AI's Accipio platform uses vision algorithms comprised of machine learning neural networks capable of reading all major CT OEMs' non-contrast CT with a goal of providing speed and confidence in diagnosing suspected ICH. Accipio Ix has received both FDA clearance and CE Mark certification, and is being deployed through major OEM CT and PACS partners to the global acute healthcare space.

Based on deep-learning technologies, the Accipio Ix software platform is trained to automatically analyze CT images for ICH. The acute imaging AI engine leverages deep vision and cognitive analytics to compare billions of data points to identify even rare, long-tail anomalies. The platform is capable of combining the full richness of medical imaging along with other relevant patient data.

AI-Based App Could Screen for Cervical Cancer

Scientists are developing an app to use artificial intelligence to identify precancerous or cancerous cells with just a photograph. The app is being developed by researchers at the National Institutes of Health and Global Good; the latter is a joint effort by Bill Gates and invention firm Intellectual Ventures. Their preliminary results, published online in January in the Journal of the National Cancer Institute, suggest that such an approach could significantly improve cervical cancer diagnosis in low-resource settings.

Over a seven-year period NIH researchers routinely photographed the cervixes of more than 9,400 women in Costa Rica. They used these images to train an AI algorithm to recognize characteristics of abnormal tissue — and to predict later cancer development. When the algorithm analyzed new images, it performed better than a clinical expert did by visual inspection.

"We were surprised to see that computers could see much more sensitively and clearly which cervixes are or are not precancerous," says Mark Schiffman, a molecular epidemiologist at the National Cancer Institute and senior author of the paper. The scientists ultimately plan to implement their algorithm on mobile phones and aim to train future iterations of the program with digital camera photos.

Iktos and Merck KGaA Partner in Drug Design

Merck KGaA and tech firm Iktos team up to use generative modeling technology to speed up the discovery and design of promising new compounds. Iktos' AI tech automatically designs virtual novel molecules that have desired activities for treating a given disease.

"Artificial intelligence is emerging as a pillar in the biopharmaceutical R&D model, giving us exponential opportunity to complement our existing expertise with further speed and better precision. For patients, this could mean faster access to novel treatment options," says Belén Garijo, a member of the executive board and CEO of healthcare at Merck.

This is Merck's second foray into AI: late last year the German firm began a year-long agreement with Cyclica using AI to uncover new drug targets and predict any side effects.