

How a Novel 'Incubation Sandbox' Helped Speed Up Data Analysis in Pfizer's COVID-19 Vaccine Trial

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As Pfizer scientists raced to develop their COVID-19 vaccine at record-breaking speed these past few months, they turned to an innovative artificial intelligence (AI) tool to help achieve this mission.

Normally, when a clinical trial or trial phase ends, it can take more than 30 days for the patient data to be "cleaned up," so scientists can then analyze the results. This process involves data scientists manually inspecting the data sets to check for coding errors and other inconsistencies that naturally occur when collecting tens of millions of data points. But thanks to process and technology optimizations, including a new machine learning tool known as Smart Data Query (SDQ), the COVID-19 vaccine clinical trial data was ready to be reviewed a mere 22 hours after meeting the primary efficacy case counts. The technology enabled the team to maintain an exceptional level of data quality throughout the trial, leaving minimal discrepancies to resolve during the final steps.

"It saved us an entire month," says Demetris Zambas, Vice President and Head of Data Monitoring and Management at Pfizer. "It really has had a significant impact on the firstpass quality of our clinical data and the speed through which we can move things along and make decisions."

Incubation sandbox

Across the industry, experts have long been attempting to find faster ways to manage clinical trial data. Pfizer was able to quickly create its SDQ tool thanks to its Breakthrough Change Accelerator, a novel "incubation sandbox" that invites startups, larger technology companies, individuals and other institutions to help solve complex research challenges. The inaugural competition, to develop an Al-powered tool to quickly clean clinical data, was won earlier this year by Saama Technologies, a California-based software company.

"Developing such technology normally would take a long time, but in six weeks they solved it and produced a viable tool," says Zambas. "From there, we collaborated with them to build it out to meet our needs."

Traditionally, when Pfizer partners with outside companies to develop tech solutions and other research tools, it can take months of negotiations and technical assessments to agree upon contractual terms and ensure that access to Pfizer's data is protected from a legal and privacy standpoint. But with this new technology model and using a highlyabbreviated contracting framework, partners who are accepted into the challenge are given immediate access to relevant anonymized Pfizer data and software on a secure cloud server, cutting down on the months of back and forth. At the end of the challenge period (usually six to eight weeks), the winning company is offered an opportunity to work with Pfizer to develop the technology into a full-fledged solution.

In the months ahead, the Breakthrough Change Accelerator expects to host competitions to tackle a variety of business challenges, from medicine labeling to diversity in clinical trials, speeding up the pace of problem-solving.

Next challenge: More patient-friendly labels

In an upcoming challenge, potential partners will compete to develop a tool using AI that can convert the physician version of a drug label into a patient-friendly version that is easy to read and understand. Typically, label conversion is labor-intensive work that requires experts to manually translate scientific language into lay-friendly terms. Across all of Pfizer products globally, that adds up to thousands of label updates per year. But with a potential AI tool, the process is optimized, freeing up employees to focus on problems that require critical thinking and to help understand patient needs more indepth.

"It's really improving our efficiency so we can use our colleagues' talents to concentrate on what matters to patients and healthcare professionals," says Shimon Yoshida, Executive Director, Head of International Labeling Group at Pfizer, based in the U.K.

Advances in digital health have exploded in recent years, and the team sees this project as just one of many to take drug label information into the digital age. "Understanding drug labels is an important part of health literacy and has a significant impact on adherence and patient outcomes," says Yoshida. "By addressing these needs and bringing together disparate information from electronic health records, e-prescriptions, and telemedicine resources, we can create a patient experience which is truly intuitive and valuable, improving health literacy along the way."

And as AI and other machine-learning tools help solve many of our challenges, Zambas says it frees up creative minds to focus on innovation. "On my own team, the same folks who were spending all these hours looking for errors, now they're the same folks looking for innovative ways to capture data in clinical trials."

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