



Collaborative Efforts in Biopharma: Accelerating Vaccine Development

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In the year since the pandemic struck, the world has watched one of the greatest real-life dramas of all time unfold: the quest for a vaccine. In the past, drug development and clinical trials were of interest to a relatively small group of scientists, regulators and health care professionals. But with the threat of COVID-19 looming large, time has not been a luxury. The race for a vaccine has become a true spectacle, carrying with it the potential to save untold numbers of lives, globally.

The accelerated process to develop and gain regulatory approval for multiple vaccines has also been eye-opening to biopharmaceutical insiders, as well as regulatory agencies. It's spotlighted new and exciting possibilities for quickly and collectively developing other therapies that can benefit patients in the future, while streamlining the review process to make it more efficient (that's even the topic of a recently published article in *Frontiers in Medicine, Regulatory Science*). In other words, the COVID-19 vaccine development process underscored the need to maximize digital innovations: How can industry and

regulators build a modernized, tech-savvy, interactive approval system to safely speed up the development of other novel therapies and future vaccines?

Competitors become partners

To start to answer that question, 10 biopharmaceutical companies (Pfizer, Amgen, Takeda, Bristol Myers Squibb, Astellas, Sanofi, GSK, Janssen, Roche, and Lilly) came together in July 2020 to form the nonprofit Accumulus Synergy, which is building a data-sharing platform that supports real-time exchange of information with regulators, stored safely and securely in the cloud.

Jerry Stewart, who is head of global regulatory policy with Pfizer, says COVID-19 shined a spotlight on a number of gaps in the current system. Currently, as part of the standard process to gain approval for new medications, pharmaceutical companies submit PDF documents to regulatory agencies, and then await the results. "Normally, you provide data to the FDA and, with standard processes and systems, you can wait weeks for FDA to respond and Pfizer would then take weeks to respond to that, and then weeks with each back and forth," says Stewart. "So we asked the question: what would it take for us to all communicate in real time? How could we look at data as it's available and make the best decisions that are both faster and in the best interests of patients?"

The answer is in collaboration—and the cloud. Karin Van Baelen, who is head of global regulatory affairs at Janssen, says that by using secure, technology to its full potential, communication and data exchange between biopharmaceutical companies and regulators can accelerate, and that, in turn, will accelerate medicine development and reduce lag time. "Through collaboration, we can pool our collective resources, improve efficiencies, leverage advanced technology (including data science, AI and the latest in cloud technology), and streamline communication. Since we're all advocates for global health, the regulatory improvements will get medicines to patients faster," says Van Baelen.

Bringing a sense of urgency, innovation and convenience to everyday drug development and registration are core concerns for Accumulus Synergy. Health threats such as autoimmune disorders, cancer, heart disease and other serious conditions will continue to take a toll well after the pandemic, and patients could benefit from a more efficient system that delivers new drug options, quickly. "Collectively, there will be a lot more disease morbidity in those areas than COVID-19," says Stewart. "So that really helped drive consensus around what a 'new normal' can look like across drug development, and

beyond a pandemic.”

Although the partner companies compete with each other, all have a shared interest in a more efficient approval process. It's not the first time that these players have worked together. A number of them are also partners in a non-profit called TransCelerate, which seeks to simplify and accelerate research and development processes by addressing inefficiencies in clinical trials. Accumulus Synergy builds upon lessons learned from the TransCelerate collaboration, and is working with a number of health authorities worldwide, including the U.S. Food and Drug Administration, the European Medicines Agency, the U.K. Medicines and Healthcare Products Regulatory Agency, and the Japanese Pharmaceutical and Medical Devices Agency.

Putting technology to work

This optimism must have been what it felt like in 2003 when biopharmaceutical companies converted paper documents to electronically submitted PDFs which give regulators the ability to more easily navigate through thousands of review documents. But time marches on, and Stewart says what once marked progress now can be a hindrance. "These PDF documents are stagnant," he says. By using a secure, dynamic, digital, cloud-based platform throughout the clinical trial and regulatory process, Accumulus will allow pharmaceutical companies to release the power of the data. This will also benefit regulators in their review by making it easier to run analyses to address review questions. And that's just the beginning.

"In the future, we envision using cloud technology with artificial intelligence tools that will allow us to work with the data at hand and parse out information that is of interest and meet requirements across multiple agencies," says Stewart.

This will not only cut out months-long lag times, but will also support “parallel review,” enabling multiple regulatory agencies from around the world to be involved in the process simultaneously and potentially leading to more harmonized regulatory decisions. Additionally, the data will be maintained in a more secure environment, meeting privacy requirements and protecting it from cybersecurity threats. In time, this system could offer insights to insurance plan providers, assisting them in making informed decisions about different medicines and therapies.

Ultimately, it will also benefit patients, says Van Baelen. "This collaboration is aimed at reducing time to make innovative new medicines available by collectively transforming the way the biopharma industry communicates information with health authorities

worldwide. Unity is strength. Together with our global peers, through the Accumulus collaboration, we become co-creators of a best practice model that will streamline regulatory communications, benefitting patients around the world."

Today's technologies support instantaneous exchanges of data and communication, at home and around the globe. Through the heightened urgency of the pandemic, health care institutions are examining long-standing processes and finding more efficient paths by using digital, collaborative tools. All of these advances, says Stewart, are designed with the goal of expediting the availability of safe and effective medicines so that patients can quickly access them when and where they're needed.

"In time, we hope that by making drug development and regulatory processes more efficient, we can impact countless lives," says Stewart.

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