How Bayer, Oracle, and Accenture Are Bringing Clinical Trials Into the Device-Driven Future

BY MARGARET LINDQUIST

As usual, Raj Pallapothu woke before dawn in his Dallas, Texas, home and picked up his phone to check WhatsApp. The first message was from a neighbor—a man who by chance had borrowed a mobile ECG, or echocardiogram from Pallapothu. The neighbor had tested himself, seen some results that didn't look right, and was feeling some discomfort. He messaged Pallapothu, who ran over immediately, ran the test again, and called 911 for an ambulance.

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> —RAJ PALLAPOTHU, M.D.
> Business Lead for Mobile Health
> Bayer Pharmaceuticals, USA

"In 29 minutes he was in the hospital," says Pallapothu. "In one hour he was in surgery for two major heart blockages. An hour after that he woke up, and I was working next to him in a chair." The device the neighbor used received FDA approval just days later.

The whole experience was all in a day's work for Pallapothu, who is the business lead for the mHealth (mobile health) project at Bayer Pharmaceuticals, USA, and a medical doctor with extensive experience with crisis intervention for infectious diseases. His neighbor's episode is just one example of how technology has the potential to transform the way the healthcare and life sciences industries interact with patients, develop treatments, and bring them to market. The explosion in personal devices, from cell phones to step monitors to mobile ECGs, is opening opportunities for clinical research. Other advances in software and hardware are changing the clinical trials process, allowing manufacturers to bring drugs to market faster. Pallapothu is watching it all unfold around him—and helping to lead the charge.

Pallapothu's interest in transforming the patient experience began early, when he started working in Australia right after medical school. "Australia is a huge continent, and the healthcare people I worked with talked a lot about how we could provide services for people in remote locations," he says. In the late 1990s, that distance was a particularly difficult challenge. The internet boom that would soon connect much of the world with high-speed data access was just beginning, but even then Pallapothu could see the seeds of technologies that would eventually revolutionize the patient experience—even for those in remote locations.

His work today is helping to turn his vision from the '90s into today's reality. Pallapothu is part of a team made up of clinical trial leaders from Bayer, industry and business process and implementation experts from Accenture, and technology professionals from Oracle, all focused on creating the first mHealth platform for clinical trials, based on Oracle mHealth Connector Cloud Service technology. Once complete, the platform will provide a platform and business processes to enable digital monitoring and interactions with patients using biosensors, wearables, and mobile applications. Clinical trial teams will be able to connect to easily embrace new innovative biosensors and patient centric engagement apps to help gain deeper insight into the patient in the day-to-day world.

Bayer's Raj Pallapothu is working on creating the first mHealth platform for clinical trials, based on Oracle mHealth Connector Cloud Service technology. (Photo by Paul S. Howell)

In conjunction with Oracle Analytics Cloud, Accenture INTIENT Clinical platform, and other supporting systems, Bayer clinical trial project teams will gain deep understanding of the patient to support their clinical research. The ultimate goal: improved patient safety, better care for patients and access to a broad range of rich, objective, high-quality data that can provide insights into patient behavior and physiology. Those insights, in turn, could help prove the efficacy and safety of specific drugs and treatments.

"We're looking at how can we take advantage of these technologies and get better data into our clinical trials, get it faster, get richer data, and make it easier for the patients," says Pallapothu. Another key consideration, he adds, is the non-negotiable need for devices and systems that ensure patient privacy. "Even with devices that have been certified by government agencies," says Pallapothu, "I look to make sure they have the highest levels of data privacy and security features." The end result, he adds, will be a platform where patients have more autonomy and agency during the course of a clinical trial—without sacrificing their right to keep their medical data private.

Guido Radack is vice president of strategic initiatives in clinical operations at Bayer. (Photo by Michael Danner/Getty Images for Oracle)

The Initial Requirements

To create this patient-centric platform, four distinct challenges needed to be addressed. The first was data privacy and standardization. Second was bringing together all the people who make up a clinical trial, from the sponsor, to the doctor, to the patient, the data statisticians, and more, to ensure that everyone is active on the platform. For example, patients must actively use the sensors and apps, and doctors must know how to interact with the data the trial produces.

The third challenge focuses on data capture. If Bayer is able to collect everything a sensor can produce, researchers must determine whether it makes sense to collect a particular data point. According to Guido Radack, vice president of strategic initiatives in clinical operations at Bayer, there are two possibilities. “One is we only measure what we need for that particular study. You keep the number of data points low, as each data point comes at a cost. But if the same sensor produces 20 other data points that we don't need now, what if we have a question five years later? Do we then run another trial to get that data, or could we collect all the data right now, and say it’s for future use?" There are pros and cons for each way.

The last challenge was regulatory compliance, which is why Bayer is working closely with federal regulators to ensure that the systems and devices will be compliant with government regulations—and that device approvals will carry over from trial to trial, without the need for lengthy reapprovals.

Modernizing Medical Models

The models for clinical research and disease management commonly used today are based on practices set in the 1960s. Those models were developed in response to public disclosures at that time of ethical failings in the conduct of clinical trials as well as the disastrous consequences of the use of drugs that had not been sufficiently tested, such as the severe birth defects that resulted from the prescribing of Thalidomide in the late 1950s and early 1960s. “After Thalidomide, a lot of rigor and governance and compliance was put into place in the 60s, but only minimal, incremental changes in core processes have happened since then,” says Jonathan Palmer, senior director of product strategy for clinical trials at Oracle.

Today’s standard practice in most clinical trials is labor-intensive, often with fragmented manual data entry of information, creating disparate data silos. And that data may take months or even a year to be pulled together. Creating clinical trial systems that allow real-time data flow is a radical change, one that would help Bayer achieve its paramount goal—rigorous patient safety—by giving trial sponsors previously unheard-of insight into their data from the trial. And what they learn could help them course-correct as necessary, for example, by providing patients with reminders to take their study drug, complete their daily questionnaire, or perform their daily walk test. More importantly, clinical trials researchers can gain insight into any safety signals that may indicate the patient needs to consult with the study nurse or investigator sooner than their next scheduled visit.

Another benefit would be lower costs. Clinical trials are very expensive. There are typically three phases, with increasing numbers of patients and complexity necessary to prove the effectiveness and safety of a new drug or device. No matter what phase, however, losing a patient from a trial is costly. By embracing new technologies and using remote monitoring, the number of physical visits to the clinic could be reduced and patients’ ability to have more ad hoc, on-demand interactions with the investigator would increase.

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Bayer researchers examine cell cultures. (Photo courtesy of Bayer AG)

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Rolling Out the Digital Trial

By the end of 2019, Bayer, Accenture, and Oracle plan to run a pilot of the mHealth platform in a simulated clinical trial setting, to give insight into all the processes involved and help the team make sure the data it collects can be used by sponsors and participants. "We know what works, [and] what doesn't work, because we already tested the waters with devices in clinical research, but now we need everyone to embrace digital trials so we can roll this out across the company," says Pallapothu.

Rolling this out to a number of the clinical trials at Bayer won't be a simple process—doing so is requiring Bayer to engineer a digital clinical process that involves 20 different domain areas within the company. But Pallapothu believes the effort will be worthwhile, ultimately allowing Bayer to gather and leverage the huge amounts of data that will be created and discover hidden signals in it. "It's the classic big data story that advanced analytics are primed for," says Palmer. "How can Bayer find those signals that are going to provide new insights? With richer, high granularity, objective data, correlated to the complete patient record, we may find some previously hidden signals." For example, adds Palmer, maybe during the later stages of a trial it's apparent that some of the female patients who have a history of arthritis are showing significant signs of increased mobility, compared to their condition during the first half of the trial and the condition of other participants. New signals can suddenly become highly visible.

Essentially, the platform is a service offering, a process, and an organizational structure that could enable this set of capabilities for any enterprise study team across the global clinical research organization. Once the data has been collected, the team can perform analytics that can determine, for example, if the patient is actually wearing the device or the healthcare provider in the clinic is performing the required tests. "We need to make sure the data flows as per our expectations, and we can integrate that data into our systems," says Pallapothu. The initial pilot involved integration of a number of digital data sources—wearables, medical devices, mobile apps—and flowed the data from patient to transactional clinical systems and analytics.

One of the unique elements of the platform is the validation of a business process. "If it is a validation limited to a device, it's already done. If it is a validation limited to data capture, it's already done. But validation of a business process, nobody has done that. Not within Bayer. Not within the industry. Nobody is doing it yet," says Pallapothu. The clinical trial process, from trial design and start-up through to trial endpoints, is a global and complex one with a great deal of regulatory oversight, and the task of bringing all that data together and analyzing it is challenging.

But Louis Kauffman, management consulting manager in pharmaceutical research and development at Accenture, emphasizes that rather than just installing new technology, it's critical that they focus on developing the end-to-end digital clinical trials operating model. "Oracle has created a great technology—it's easy to use, it meets the requirements of the business—the real challenge is to define how this new technology will be utilized by the trial sites and research teams, and what will Bayer do with the data. In other words, the ultimate goal is to establish a digital clinical trial operating model that ensures study team adoption and business value," Kauffman says.

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Accenture

Guido Radack is looking into the future at another challenge that needs to be resolved around data capture—the requirement that clinical trial data be retained for 30 years. That, says Radack, was a requirement set at a time when clinical trials were small and the amount of data collected could fit on a single hard drive or even a CD-ROM disc. That's no longer the case—typically a large trial will accumulate around a terabyte of data. “What do we do with that data? How can we even make sure that we can read that data in 30 years? We know how fast technology is evolving. We don’t have an answer to that question—and neither does any other pharmaceutical company.”

Bayer's platform is designed to be patient-centric. (Photo courtesy of Bayer AG)

The Road Ahead

By the end of the year, Bayer, Accenture, and Oracle will kick off the next phase of the project: The new processes will be finalized, and a real study team will take advantage of them. They’ll also validate the end-to-end data flow. According to Kauffman, the idea is that actual Bayer clinical staff will execute end-to-end platform validation in order to prepare for utilization at an enterprise level. After validation Bayer will be able to quickly iterate its processes to optimize usage of the platform for early adopter studies.

Pallapothu also emphasizes the role of coalitions in this space. Bayer is part of a group called the Accenture Life Sciences Coalition—which includes Oracle—where pharma and technology companies share technologies, precompetitive knowledge, and new process optimizations. Bayer is also supporting startup accelerators that are bringing new ideas—Pallapothu regards this type of partnership with startups as critical to the evolution of clinical trials. “A lot of real innovation,” says Pallapothu, “will be driven by startups. It’s not that big pharma or tech companies can’t come up with innovations, but they can’t do everything. You need to bring some sort of startup enthusiasm.”

Pallapothu expects that the treatment areas most likely to be the subjects of initial real-time studies with the new platform include pulmonology, cardiology, and oncology. “Then we have some specialized areas like Parkinson’s and psychiatric treatments.” But, he adds, at the end of the day, it’s the patient that’s important. “Touch the patient. From the bottom of my heart, I ask that you be empathetic. Millions of patients who sign up for trials are looking for hope. They have faith that something is coming at the end of the tunnel but they want to visualize it. They want to feel it.”

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