Oracle's Unified Cloud Platform Promises to Shorten Clinical Trials

BY ROB PRESTON

Oracle's Clinical One Platform will enable pharmaceutical companies to manage every trial function—from randomizing patient participants and collecting and analyzing data to tracking budgets and ensuring trial safety—from a single user interface.

The process of standing up clinical trials has come a long way in 20 years, moving from paper forms and faxes to a much more automated, data-intensive endeavor. Still complicating the process, however, is the collection of independent systems that support a clinical trial's many functions—systems that were developed by multiple vendors on different IT platforms and stitched together piecemeal over the years.

As such, the trial setup process remains a lengthy, expensive ordeal with lots of redundant steps, holding up potentially life-saving treatments.

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>
> — STEVE ROSENBERG
> Senior Vice President and General Manager, Oracle Health Sciences

To address that challenge, Oracle Health Sciences is developing the Clinical One Platform, a unified cloud environment that will enable pharmaceutical companies to manage every clinical trial function—from randomizing patient participants and collecting and analyzing data to tracking budgets and ensuring trial safety—from a single user interface. And because the platform is cloud-based, it will bring all the benefits associated with cloud computing: cost efficiency, high availability, configurability, robust security, and the ability to scale up and down as trial demands dictate.

The logistics of clinical trials, which are designed to evaluate the effectiveness and safety of new drugs in human test subjects, are more complex than ever. Trials can entail multiple phases; the selection of hundreds of trial sites in multiple countries; the enrollment of hundreds or thousands of patients; the training of specialists in those countries, each with its own acceptable-care and safety practices; coordination with various contract research organizations (CROs) and other partners; and the analysis of reams of original and third-party data.

It now takes three to five months for a pharma company just to stand up a trial, with much of that time spent on setting up and connecting the underlying systems and coordinating vendors, notes Steve Rosenberg, senior vice president and general manager of Oracle Health Sciences. And considering that some drugs require 30, 40, or sometimes as many as 70 trials before they receive regulatory approval, those months can add up to years quickly, Rosenberg says.

Because Oracle Health Sciences is building the Clinical One Platform from the ground up as a single, integrated cloud environment, it intends to cut the study setup time by 50 to 80 percent, he says, ultimately helping pharma companies get their drugs to market faster.

"That's an enormous time savings," Rosenberg says. "We are reimagining, if you will, the way that the software is consumed by pharmaceutical companies and CROs."

Flexible Architecture

Oracle Health Sciences has identified common functions that clinical trial teams can use to manage different parts of the trial process. "There's a function, for example, for 'display a form,' and that function can be used in your [interactive response technology] process, in your electronic data capture process, in your local lab management process," he says. "These functions become the micro–building blocks of these bigger capabilities."

The first Clinical One Platform capability, for randomizing the selection of trial patients and coordinating drug supplies, is due to be available as early as July. Other capabilities, such as electronic data capture, clinical trial management, and data management, will follow.

"We may very well license those different capabilities separately, in a vernacular that the market understands," Rosenberg says. "But underneath the covers, Oracle's Clinical One Platform will be a single cloud environment that is flexible and brings to bear the functions that are needed for a specific trial."

Oracle's Clinical One Platform should also make it easier for pharma companies to meet another one of their main challenges: enlisting the many sites needed to conduct these clinical trials worldwide. Some sites choose their pharma partners based on, at least in part, the sophistication of their underlying systems, Rosenberg says.

Oracle Health Sciences, which has been developing its Clinical One Platform for almost two years, is uniquely positioned against a range of smaller competitors—many of which added system capabilities through acquisitions—to deliver this kind of interoperable platform, he says.

"No $400 million, $500 million company can invest the kind of money we invest to redo its platform from the ground up," Rosenberg says. And the reason Oracle Health Sciences is so efficient at it, he says, "is because we're taking advantage of all the Oracle tools—Oracle Cloud, Oracle's development environment, Oracle's scalability, Oracle's 12*c* database, Oracle's identity management," he says. "All of that stuff we get for free. We're focused just on the application services."

As Oracle Health Sciences builds out its Clinical One Platform's electronic data capture, clinical trial management, and other capabilities, "we envision our current customer base using them as part of their upgrade," Rosenberg says. The two main, complementary clinical trial platforms customers now use are Oracle Health Sciences InForm Cloud Service and Siebel Clinical Trial Management System Cloud Service.

While clinical research technology has come a long way during the past two decades, the industry is in need of a fresh perspective on how to "make the whole better than the sum of its technology parts," Rosenberg says. Oracle Health Sciences is doing just that with the Clinical One Platform, he says, unifying data and processes and bringing the benefits of the cloud to the entire clinical development lifecycle.

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