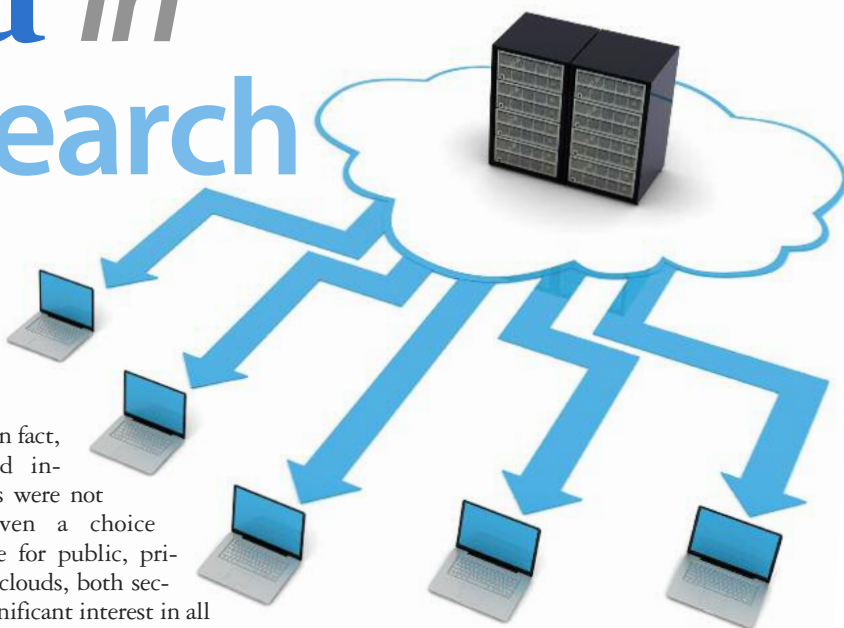# The Cloud *in* Pharma Research

Denise Myshko

The cloud has the potential to bring more efficient data management to clinical research, but pharmaceutical companies are approaching source sharing cautiously.

Web-based solutions for R&D are not new, but during the past few years, they have morphed into what many call "the cloud." The cloud, in its simplest form, uses the Internet to access resources, including hardware and software, over a network. While this is certainly not a new trend — software-as-a-service systems have been around for several years now — using the cloud for clinical research has the potential to provide more efficient and cost-effective management of data. But experts say the cloud is less about technology and more about process change.

"The word 'cloud' has become a nice descriptor for something that already happens," says Brendan Canty, technical director, IT, at INOR, the International Network for Outcomes Research. "People have had Web-based email for well over a decade. Web-based email is a cloud-based service, but we don't call it that."

Mr. Canty says generally, the cloud refers to buying space and using applications over the Internet and the physical hardware is housed outside of an organization.

Features offered by the cloud often include resource outsourcing, utility computing, large collections of inexpensive machines, automated resource management, virtualization, and parallel computing.

Public clouds offer computing in a pay-for-what-you-use format. A private cloud provides many of the advantages of the cloud model with an infrastructure contained within a company's firewall.

A third model, the hybrid cloud, allows companies to keep key data within their firewall while extending selective activities to public clouds.

In a survey last year by Insight Pharma Reports, both commercial pharma and academic respondents anticipated major growth in data processing and storage requirements during the next year, and even more so during the next three years; in fact, three-to-five fold increase predictions were not uncommon. Given a choice among preference for public, private, and hybrid clouds, both sectors expressed significant interest in all three, although commercial users gave most support to hybrid clouds while academics gave top preference to public clouds.

The cloud can be viewed as having two components, says Bryan Reynolds, managing partner at Sitrof Technologies.

"There is the storage component and an application layer component," he says. "The storage component is where the data live and the application layer involves the business processes a company is trying to achieve, in this case, managing clinical trials. An example of this might be the creation of a portal to share data with a CRO."

The cloud works best in the pharmaceutical industry in areas that have become standardized, are large scale, or where there is a mission-critical aspect to a project, says Neil de Crescenzo, senior VP and general manager at Oracle.

"Over the last decade, data have become more standardized and scalable, and a number of pharma companies have decided this is something they can trust to a vendor," he says. "Clinical trial management services, safety, pharmacovigilance, etc. are areas where the cloud can provide benefits. A lot of processes have become standardized over the past decade, and large as well as smaller companies are able to purchase that capability where it makes sense."

In the future, Mr. de Crescenzo says the adoption of cloud-based services will depend on the specific service.

"Adoption will differ based on the specific domain or area," he says. "Data capture, for example, is already a well-accepted trend with high utilization of cloud services. We also see cloud adoption increasing around clinical trial management and safety. There are also cloud-based solutions that can access healthcare data from medical centers and other data centers that can be used to make clinical R&D more efficient. These areas are growing more rapidly."

There has been a change in people's perceptions and mindsets, says Alistair Macdonald, president, clinical development services, INC Research.

> **Companies have to redefine the validation process for a true, multitenant cloud environment. Those who are blazing the trails need to put a lot of effort into documenting these efforts to eliminate a lot of fear and uncertainty.**
>
> **BRYAN REYNOLDS** / Sitrof Technologies

> **In a cloud-based environment, a request for more processing power or more storage space can be brought online much faster.**
>
> **BRENDAN CANTY** / INOR

"People have realized they don't need everything inside their company firewall," he says. "In the past, we had servers for everything, and people used to worry about service levels and how quickly they could recover from data loss. The cloud has proven to be very robust. It's proven itself over the last five to 10 years and the world of data communications and storage is very robust compared with what was expected."

But Mr. de Crescenzo points out that companies have varying perspectives about which data, which processes, and which applications they feel comfortable deploying to a cloud service.

"There are still concerns around data privacy, data security, as well as scalability and latency," he says. "At some level, data are at risk whether stored on the cloud or in a data center. At the end of the day, people, processes, and technology are the factors that determine whether data are being kept secure or not. Whether compliance and expertise exist depends on the quality of the processes and capabilities of people, regardless of whether they are inside the company or at a cloud services vendor."

Mr. Reynolds says the cloud can be just as secure as a company's internal data center.

"I think the cloud can be even more secure in that it has so many different rules and regulations covering such a large and broad customer base," he says. "There are certain fears that exist within the life sciences around how to make that leap. Regulations, for example, 21 CFR Part 11 around e-signatures and validation of a system, can be really vague. I can argue that this can be validated within the cloud as long as the rules and procedures are documented. Often, there are internal hurdles about what it means to outsource an application to the Web and what this means for the IT staff."

TRENDING NOW...

Experts offer their best practices for using the cloud in clinical trials.

MICHAEL BURTON
Director, Product Strategies, Vault eTMF
Veeva Systems

Clinical trials remain one of the most expensive and strategically important areas for life sciences. The cloud, specifically a multitenant cloud, is the best technology platform for cost-efficient, fast and secure access to content from any device in any location. Nowhere is this more evident than with the trial master file where collaboration is as critical as meeting regulatory requirements. Only a multitenant cloud application enables real-time information sharing and ongoing changes/ upgrades for fast compliance. Companies using a true cloud-based technology have a huge competitive advantage in bringing new products to market.

JOHN CLINE
VP, Client Services
Cenduit

The cloud represents a unique opportunity for the industry to lower costs in an area where research costs continue to rise. One of the most challenging areas to address is compliance. Companies must ensure they are compliant with 21CFR Part 11, GCP, and other country-specific regulations. As an example, we must follow the proper procedures for installation, verification, and validation. Given that many trials are global in nature, one should be cognizant of data storage issues that are country specific. Some countries at present require that the data be hosted in country. The cloud is here to stay and should be embraced with the same level of intention and compliance as other emerging opportunities to reduce costs and increase data visibility.

GLEN DE VRIES
President
Medidata

The "cloud" can, and should, mean something different from just using a hosted Web application for a trial. Thirty years ago we used mainframes, 20 years ago client servers, and for the last 10 years, we've used Web applications. Over the years, these technologies have made our work increasingly efficient. Now we are in the cloud era now, where convenience and speed are old news. Cloud applications shouldn't deliver just system access but increased productivity; investigators, monitors, biostatisticians, and every member of a trial team should be able to work differently and more effectively — the same way they socialize and buy things using cloud-based models outside of clinical trials.

R.J. LEWIS
President and CEO
eHealthcare Solutions

The outsourcing of the R&D function has essentially been going on for years through the conduit of biotechs. Biotechs and niche pharma invent, then big pharma buys or licenses. Open learning networks and crowdsourcing simply take it to a new and less expensive level. Many industries are having great success with open networks and shared information, from the geologic discovery of gold that had been previously difficult to find in remote areas, to the entire crowdsourcing of product innovation, development, testing, and pricing through websites such as quirky.com. While pharma R&D challenges are often more complex, it is exactly those types of problems that benefit the most from effective crowdsourcing.

Using the Cloud in Research

Adoption of cloud-computing services by pharma is still in its infancy. In fact, 54.6% of those surveyed are not currently using any cloud-based systems, according to a report last year by Insight Pharma Reports.

Of those surveyed, just 7.4% are using a public cloud solution, 7.1% are using hybrid solutions, and another 17.5% are currently evaluating solutions.

Despite its many advantages, Martin Erkens, head, early development informatics, Roche, points out that the cloud is not a miracle solution.

"The cloud does provide a huge opportunity, but one needs to be aware of the strengths and limitations of the cloud," he says. "Cloud solutions for the pharma industry are viable provided that they have the necessary level of security and quality. This is absolutely imperative since we operate in a highly regulated industry, and we have high ethical standards. We have to make sure that when we use such a service, it doesn't deviate from our policies and guidelines of security and quality."

Mr. Erkens points out that one of the advantages of the cloud is communicating with partners.

> **My philosophy is don't customize, configure. Cloud applications can be configured to address a company's individual needs without getting so out of hand that it creates an enormous, unscalable system.**
>
> **LINDA DRUMRIGHT** / IMS Health

> **The cloud makes data more accessible and more standardized, and this enables clinical trials to run faster.**
>
> **ALISTAIR MACDONALD** / INC Research

> **The cloud is challenging in a highly regulated industry like pharma, and companies shouldn't take a simplistic approach. There needs to be a thoughtful analysis of whether a cloud service in a particular area makes sense.**
>
> **NEIL DE CRESCENZO** / Oracle

"One of the challenges in the pharmaceutical industry is that science progresses very quickly," he says. "Our business model and strategy is to innovate healthcare. We know a lot of innovation is happening outside the company, and we need to tap into and link up with this innovation and, hopefully, make use of this for patients. The challenge of effective interaction between external partners can be more easily overcome with cloud-based solutions than with traditional in-house solutions."

Roche is using a variety of cloud solutions, connected through public or private networks. For example, by the end of 2013, the company will transition to using Google for email and calendar applications. This Roche Gmail and GCal environment will be separate from other publicly available Google applications, Mr. Erkens says.

In terms of clinical trials, the company is using external services and solutions on an internal network.

"This means there is an external service provider that operates a piece of hardware and a piece of software on our behalf, which we then use for our internal company purposes," Mr. Erkens says. "Typically, a virtual private network connection is established between our company and the service provider, and, in some cases, there are dedicated network lines to make sure the communications between us and the service provider are secure."

Roche is doing electronic data capture in this way, especially in early trials. With the exception of ongoing, legacy trials, all new trials capture data using hybrid cloud systems.

"The cloud provides us with a means to decouple the actual end-user devices from the underlying complex infrastructure," says Thomas Kandl, head of computing services, pharma research and early development (pRED) informatics, Roche. "We are trying to give our researchers access — from anywhere and any place — to highly specific applications that might be hosted somewhere else through a single infrastructure."

Mr. Kandl says Roche's internal cloud has a high-density data center where all virtualized applications are hosted, while at the same time accessing SaaS systems that brings the public cloud into its internal cloud.

Mr. Erkens points out this hybrid system allows for an easier way to link external partners, be they investigators, academics, or commercial partners, but still allows Roche to have control over data security and quality.

"Before we agree to a contract, we do quality and security audits to ensure that the operation meets our security and operations guidelines," he says. "As a company, we need to be very clear about what we want and what our constraints are, particularly security and quality requirements. There are a lot of regulations, particularly about patient privacy. We have to make sure that whatever solutions we put in place are in compliance with these regulations."

Advantages of the Cloud

Mr. Canty says one of the advantages of using the cloud is the potential for a lower cost of ownership.

"Buying hardware is expensive," he says. "When I buy a server, I don't just have to own the server, I have to have the space for it. I have to have power for it. I have to have air conditioning for it. I have to have security controls for where it is housed. I have to have an audit trail to maintain data, especially with sensitive health information. And I need to maintain that infrastructure to support the physical device that has a three-to-five-year life span."

Mr. Reynolds points out that initially pharma companies may not experience cost savings but there are economies of scale to be had.

"Initially the cost will be almost the same, because companies will have to cut some applications that are running inside of a data center, but when companies go to a multi-tenant or hybrid system, they can leverage a vendor's expertise and that's where the economy of scale begins," he says. "The more companies that participate, the more the cost is spread. There is a time factor associated with this evolution as we go forward, but the cloud gets cheaper the more companies start to take advantage of the cloud."

Linda Drumright, general manager, clinical trial optimization solutions, IMS Health, says for many companies it's a lease vs. buy decision.

"Moving away from proprietary systems to best-of-breed market solutions that are offered in the cloud allows pharma companies to focus on their own core competencies," she says. "They can select best-of-breed companies to deliver on noncore competencies i.e., delivering on the cloud, scalability, accessibility, performance, etc. A pharma company may need slices of expertise that don't comprise a full-time person, and purchasing hardware and continuing to upgrade that hardware over the years is expensive."

Ms. Drumright says there has been a shift over the last few years away from the home-grown, highly customized, proprietary systems of the past.

> **Cloud solutions for the pharma industry are viable provided that they have the necessary level of security and quality. This is imperative since we operate in a highly regulated industry.**
>
> **MARTIN ERKENS** / Roche

> **Roche's internal cloud has a high-density data center where all virtualized applications are hosted, while at the same time accessing SaaS systems that brings the public cloud into our internal cloud.**
>
> **THOMAS KANDL** / Roche

"Cost-cutting required many companies to look more deeply at what they could and couldn't do," she says. "Often they discovered these customized solutions added unnecessary complexity to their organizations. They needed to focus on the bottom line and make hard choices and question the philosophies they've held onto for so long."

Ms. Drumright points out there are many solutions that touch a clinical trial.

"One company went through a simplification of its IT landscape," she says. "It did an audit and found that one clinical trial touched about 158 systems in its enterprise. The company spent a lot time redesigning the landscape and pushing solutions out to the cloud. They found that the mentality and methodology both within IT and across the business had to change to begin using systems out of the box. They needed to begin to see themselves as 'less special and more like everyone else.'"

Another advantage, Mr. Canty says is the ability to ramp up fairly quickly in terms of adding servers.

"Companies are leasing space and processing power when using a cloud-based service," he says. "In a cloud-based environment, a company can put in a request for more processing power or more storage space and it can be brought online a lot faster than if it had to do this itself."

Mr. Macdonald says the cloud can allow for more efficient data management.

"We use Medidata Clinical Cloud, which connects different pieces of technology more seamlessly," he says. "It's not the cloud that actually manages this process, but the data handling system underneath. The data management model allows us to take the information we create in feasibility and study start up, pull the data all the way through the system, and then pull information from the EDC and CTMS and vice versa to create more consistent reports. This helps our monitors work more efficiently and gives them more time to focus on critical elements at the site."

Best Practices

To implement cloud-based systems, companies have to have clarity around the business process, how the solution supports that business process, and best practices for using the solution, Ms. Drumright says.

"Operating in the cloud, companies should stay away from highly customized systems," she says. "Solutions offered through the cloud can be leveraged across an enterprise, but companies have to make sure they have the appropriate processes and tools in place to leverage the full value out of the box."

Cloud Services at a Glance

» **IAAS** (infrastructure-as-a-service), a term that became popular in 2006, embodies the essence of cloud computing and allows customers to fully outsource provision of servers, software, data center space, and/or network equipment. Layered components typically include utility billing or service level agreements, an environment for running virtual machines specified by customers, computer hardware, computer networking (including firewalls and load balancing), and Internet connectivity.

» **PAAS** (platform-as-a-service), also known as cloudware, offers a hosted computing platform that allows customers to deploy applications without having to buy and manage the required hardware and underlying software layers. Typically, PaaS provides customers with everything needed to build and deliver cloud-based applications and services.

» **SAAS** (software-as-a-service), which originated around the turn of the century, refers to software licensed by a provider to customers on either a contractual or utility basis. The software may reside on the provider's network and get accessed via the Web, or be downloaded to the customer's system and disabled when the contracted use period expires.

» **CLOUD STORAGE**, employs commodity hardware linked by software to appear as a single storage device. Cloud storage may occur either in public or private clouds, but the essence remains the same, which is scaling storage capacity and performance, and providing shared access via a standard network.

Source: Insight Pharma Reports

Mr. de Crescenzo agrees that companies have to review their business processes and priorities before looking at implementing cloud-based services in clinical trials.

"Companies have to take a step back and decide which business priorities would be able to move forward faster and be more economical by using a cloud solution," he says. "In addition, there needs to be an understanding and a thoughtful examination around business risk, data privacy, data security, and regulatory compliance."

Mr. Macdonald agrees that companies need to create a plan and understand the risks before moving data to the cloud.

"There has to be a map of where everything is and how it all works, but this is no different from any other schematic system," he says. "Process mapping and structural mapping helps companies understand their business." **PV**