



# Speeding Pharma's Time to Market with Managed Cloud Services

**Drug developers need an IT infrastructure that enables their organizations to focus on innovation and stay competitive, and the cloud is more than ready.**

Bringing a new drug to market is an expensive undertaking.

Over the past few years, the cost has inched closer to \$3 billion, according to Tufts Center for the Study of Drug Development. That's for drugs that successfully pass through the various phases of clinical trials where failure is commonplace. PwC found that 46 percent of drugs in phase 1, 66 percent of drugs in phase 2, and 30 percent of drugs in phase 3 failed in 2010.

However, drug development is evolving thanks to changes in government regulation and the availability of new technologies.

Earlier this month, the Food and Drug Administration (FDA) revealed updates to its oversight of digital health products through its framework for reviewing the safety and efficacy of digital therapeutics under a precertification pilot program. Johnson & Johnson and Roche were two of the nine participants in its digital health software precertification pilot program.

"Our new actions will promote the development of novel, beneficial technology while ensuring that patients have access to high quality, safe and effective digital health devices," said FDA Commissioner Scott Gottlieb, MD.

Pharmaceutical companies will be working to get new drugs and software products to market more swiftly and conversely to recognize failure sooner and avoid sunk costs.

"One of the unique challenges facing pharma is that its business in general is changing," says Jim Gibson, MBA, Vice President of Growth and Innovation at ClearDATA. "The traditional pharma lifecycle process used to be measured in multiple years, with drug development spanning seven to ten years. Now, as many look to expand their portfolios to include software solutions, product lifecycles are measured in months or weeks. They're trying to get products out the door."

Cloud is a technology already revolutionizing drug development. The cloud offers flexibility, agility, security, and compliance with regulation governing industry standards and practices. These qualities have attracted many suitors in pharma with industry leaders such as Roche, Sanofi, GlaxoKlineSmith, and Johnson & Johnson actively working with prominent cloud service providers.

Data from KPMG showed that the cloud provides an opportunity for organizations to shrink their IT infrastructure costs dramatically. “With typical IT organizations spending over 30% of their budget on infrastructure (primarily data centers and data networks), shifting some or all of this work to the cloud can save organizations anywhere from 10-20% of their annual IT budget, savings that can either be returned to the firm or reinvested in growth and innovation,” the KPMG researchers noted.

Similarly, Gartner researchers predicted that more than 75 percent of life science research and development (R&D) IT organizations would adopt “cloud-first application deployment strategies” by 2019.

In many ways, the cloud is a requirement for today’s drug development and broader go-to-market strategy. Beyond its ability to reduce costs, the cloud enables collaborators to work together in a secure and centralized environment, promotes communication between stakeholders (e.g., patients, investigators, regulators) irrespective of geography, and ensures the safety of patients through its compliance with regulation at the federal, state, and regional level.

A significant challenge for pharma to address when moving to the cloud is to avoid reproducing inefficiencies in this digital ecosystem.

“You want to take a measured approach,” Gibson advises. “And then the more mature your team becomes, the greater the likelihood that your organization can start accelerating migrations and more effectively leveraging the cloud. But this should be done with a ‘cloud’ mentality. If you simply replicate an on-prem architecture, tooling and solution in the cloud, you are also going to replicate the inefficiencies and issues you have today. Unless you design a deploy a more true cloud solution you will not be taking advantage of the benefits the cloud offers.”

According to Gibson, the work of transitioning to the cloud begins with assessing organizational readiness and moves to road mapping and migration planning. The focus then shifts to identifying the right candidate projects to green light.

“The beauty of the cloud for clinical trials is you can spin something up very quickly so that the research can begin almost immediately,” says Gibson. “Once you have a secure, compliant platform in place and understand the overall requirements, success depends on the ability of individual research environments to perform. It’s also important to note that if a trial ends or fails, the underlying infrastructure can quickly and easily be turned down so no further costs are incurred.”

In other words, a strategic approach doesn’t merely push everything to the cloud. Instead, it paves the way toward making more significant and more targeted use of the cloud’s ability to work with emerging technologies as needed at an affordable cost.

“The largest companies in the world would be able to make the investment in computing power that’s required of data science such as machine learning. But the cloud makes it a simple service. AWS, Google, and Microsoft have spent the money. They have created the underlying infrastructure and have developers working purely on machine learning, many specifically for healthcare use cases, and those resources are becoming more and more cost effective. Organizations leveraging these services will be on a faster track to improving healthcare through initiatives such as personalized medicine” adds Gibson.

To stay competitive, drug developers need an IT infrastructure that enables their organizations to focus on innovation. Given the abundance of available cloud offerings, pharma would benefit from having a business partner that understands the technology performance demands of drug developers and ensures compliance with regulation and conformance with industry practice.

“They’re trying to be agile and innovative so they can more rapidly improve healthcare, and we enable them to do that,” concludes Gibson.

## About ClearDATA

Healthcare professionals across the globe trust the ClearDATA HITRUST 9.1 -certified cloud to safeguard their sensitive data and power their critical applications available across the major public cloud platforms. For healthcare organizations, customers receive one of the most comprehensive Business Associate Agreements (BAA) in the industry, combined with market-leading healthcare-exclusive security and compliance solutions. ClearDATA’s innovative solutions protect customers from data privacy risks, improve their data management, and scale their healthcare IT infrastructure, enabling the industry to focus on making healthcare better by improving healthcare delivery.