Business White Paper

How The Cloud Will Determine The Pharma Company Of The Future

ClearDATA
SECURE • HEALTHCARE • CLOUD

How The Cloud Will Determine The Pharma Company Of The Future

Table of Contents

The drug development landscape is changing in promising and challenging ways. Mobile technology offers the ability to collect more data for analysis and introduces transformative workflow efficiencies. Breakthroughs in medical research make it newly possible to target the root causes of diseases. And patient advocacy groups are increasing their capabilities to share resources in an effort to develop powerful new therapies. All this is happening as healthcare's transition from fee-for-service to value-based care puts significant pressure on the pharma industry to prove value and efficacy. Providers facing substantial reductions in revenue are looking everywhere for savings, as are patients confronted with increasingly high deductibles and co-insurance. In a parallel development, payers are looking for real-world evidence to align pricing and risk.

As these new realities converge, pharma can expect heightened focus on drug cost and efficacy at exactly the same time the stakes have never been higher to develop new and better drugs faster. In this white paper we explain how managed data services in the cloud can enable the pharmaceutical industry to take advantage of these new trends and shifts, all of which are driven by massive new sources of patient data. Organizations that can leverage the cloud to access, secure and analyze this data will emerge as the winners in an exciting but highly competitive future.

What the cloud means for pharma

Broadly defined, cloud computing is the hosting of data and applications on virtual or Internet-based servers. When offered by a third party vendor, typically within the vendor's own data centers, they are referred to as cloud managed services and can include data aggregation and migration, security, backup and disaster recovery, and even analytics. Pharma companies should seek out cloud managed services vendors with a deep understanding of healthcare, as these will be the partners who understand how to meet and exceed HIPAA requirements for protecting patient confidentiality.

Some top tier cloud vendors even offer "analytics-as-a-service." This includes data standardization, presentation and visualization services that help pharma companies, clinical research organizations (CROs) and other partner organizations integrate, share and analyze data from clinical trials. Like other managed services in the cloud, these are typically available on a pay-as-you-go model, much like a monthly utility. This turns what would otherwise be a costly capital expenditure into a manageable operating expense. Read on for a detailed look at even more benefits of using the cloud managed services model for access to a modern and highly flexible IT infrastructure for drug development.

Pharma companies that leverage the cloud managed services model to nimbly access, secure and analyze data will emerge as the winners in an exciting but rapidly changing industry.

Why the Cloud is Set to Ignite a Clinical Research Revolution

Clinical research is transforming from a paper-driven model into one that is almost wholly electronic. This goes well beyond the electronic transcribing of data. Wearables and smart phone technology now make it possible to electronically collect data directly from clinical research trial participants, skipping many manual and middle steps. With the advent of this "remote patient-centered" model for clinical research, clinical trials can increasingly cover a much more representative sample of patients than the tiny market percentage they historically have.

Presently, these trials still take a long time and cost a lot of money.[1] Even with high speed computers and software applications that replace paper-based work, it is still a significant undertaking to manage a clinical trial, especially one with multiple sites and remote participants. To that end, cloud management of a clinical trial can streamline a number of critical tasks:

1. Institute of Medicine (US). Envisioning a Transformed Clinical Trials Enterprise in the United States: Establishing an Agenda for 2020: Workshop Summary. Washington (DC): National Academies Press (US); 2012. Appendix F, Discussion Paper: Transforming the Economics of Clinical Trials. Available from: http://www.ncbi.nlm.nih.gov/books/NBK114653/

- **Developing the clinical trial concept.** In the initial concept evaluation phase, researchers rely on expert and peer feedback. Having one centralized "console" in the cloud from which to query, receive and archive feedback and input can vastly speed up this communication.
- **Developing the clinical trial protocol.** The benefits of centralized collaboration apply even more so during protocol development. Keeping the latest document with all the most recent amendments in one central location can circumvent the confusion that ensues when everyone is trying to keep track of the latest version on their own.
- **Conducting and monitoring the research.** Centralized cloud management especially saves time for clinical trials with complex logistics - such as multiple sites enrolled; thousands or even tens of thousands of remotely monitored participants; and other large, random studies. Further, standardization of data collection, structure and presentation is facilitated with centralized aggregation of localized data.
- **Intervening to make adjustments to the protocol.** While a protocol based on the "adaptive design" model for clinical trials will allow for changes, the reality is these tweaks aren't easily made when data is in disparate locations. Centralizing this data in the cloud, by contrast, will facilitate nimble and quick action with robust auditing.
- **Protecting the confidentiality of study participants.** Among the most important responsibilities a clinical researcher has, protecting study participant privacy is also stringently covered under the HIPAA Security and Privacy Rule.[2] Perhaps the biggest benefit of a centralized cloud, located in a secure data center, is how it can apply multiple layers of security to sensitive patient data. More on this in the next section.

Beyond HIPAA: Defense-in-depth security in the cloud

Here's a painful reality about personal health data: it's just as valuable to hackers as it is to researchers. That's because a medical record typically includes a social security number and other

2. https://www.nichd.nih.gov/health/clinicalresearch/clinical-researchers/steps/Pages/protectparticipants.aspx

information that criminals can use to embark on a profitable and years-long theft of a patient's identity. Pharma companies and CROs can expect to become targets for this type of crime as they acquire ever larger sets of patient data.

The good news is they won't have to take on the daunting (and many would say futile) task of making IT security a core internal competency. They can opt instead for the choice a growing number of healthcare organizations have made: partner with a cloud managed services vendor who is already an expert in the professional-grade security required to fend off today's cyber-criminals. And this is indeed a requirement. Hackers frequently change up the kinds of attempts they make to steal protected health information (widely referred to by its acronym PHI). To bar them from access to this lucrative data, there must be multiple layers of defense in place.

A cloud managed services partner should be able to take on the bulk or all of the work involved in each of the following layers of security.

1. **Physical.** PHI should reside in a fortress-like setting with, at a minimum, 24/7 perimeter sensor-monitoring and badged or biometric entry into secure areas.

2. **Network.** Preventing entrance into the network that houses PHI requires multiple tactics, some of which are generally present in many organizations, but often out of date. These include enterprise-grade hardware, advanced firewall configuration, SSL VPN security, intrusion detection and prevention, and threat management response.

3. **Application.** Security for EHRs, analytics dashboards and other applications that house PHI should include data encryption (for static and in-transit data), anti-virus protection, patching, two-factor authentication, malware protection, and log management. This layer can easily fall behind if patches and upgrades are infrequently applied, as they often are in internal IT departments with strained resources.

4 **Server.** Essential security responsibilities at this layer include file integrity monitoring, patching and role-based access controls.

5 **Data.** Backup, static and in-transit encryption, retention, destruction; archiving, and data lifecycle management are critical security tasks at the PHI or data level. Often the primary focus of internal security efforts, but if a breach does occur it becomes difficult to mitigate without security at other layers.

6 **Devices.** This includes security for mobile and medical devices, as well as BYOD security options. Often the Achilles heel for internal IT security personnel as personal employee devices are outside their control and distribution of devices to patients stretch human and capital resources further.

7 **User.** This layer of security requires changing behaviors along with upgrading technology. It includes two-factor authentication, policies related to passwords and BYOD, corporate policy, continuous education and ethical hacking. This layer of security should pay close to attention to new standards for authentication, such as those by The FIDO Alliance.

Recovery in the cloud

Pharma companies must also have established plans for protecting clinical trial data that would be difficult—more likely, impossible—to acquire again in the event of a natural or deliberately-caused disaster. Real-time data replication, backup and disaster recovery services should be on the "must" list when choosing services from a cloud data vendor's portfolio.

The cloud's scalability and security benefits aren't restricted to pre-market trials. Pharma companies can also take advantage of the cloud's flexibility for post-approval studies as drugs are tested on new groups and broader populations.

Using Managed Data Services to Speed Personalized Medicine to Market

Personalized medicine is a term that is expanding beyond its original definition of drugs tailored to an individual or small group's genetic makeup. It increasingly applies to a wider range of medical interventions, even software-related, such as remote monitoring algorithms developed specifically to a chronically ill patient's unique symptoms and that detect deterioration in advance of an acute event.

One thing that hasn't changed since the advent of personalized medicine is the question of how to make a profit on a therapy that, in the end, will only be marketed to a relative few. Driving up the price to stratospheric heights will not be an option in the value-based era. Pharma companies must look instead to driving down the costs of development, specifically by sharing them.

How the Cloud Facilitates Faster Collaboration

The story of the Kalydeco™ breakthrough therapy for cystic fibrosis is well-known in the pharma and non-profit research worlds. Working together, Vertex and the patient advocacy non-profit group The Cystic Fibrosis Foundation developed the first approved drug for the condition that makes repairs at the cellular level instead of treating only the symptoms. It is also a huge financial success story for a charity; the Cystic Fibrosis Foundation has since cashed out its stake in the drug for a cool $3 billion.[3]

As such, we can expect more and stronger partnerships between pharma companies and non-profits, including patient advocacy and academic organizations. But take heed. For all the excitement surrounding collaboration success stories, human factors frequently get in the way when diverse stakeholders with different interests attempt to actually collaborate. There must be common accord on a number of issues, but most essentially, on how the data is handled. This is, after all, the foundation of clinical research and other joint initiatives. The chief questions that must be answered:

3. http://www.bloomberg.com/news/features/2015-07-07/this-medical-charity-made-3-3-billion-from-a-single-pill

- **Who will host the data?**
- **Who will be responsible for acquiring, maintaining and distributing it?**
- **Most importantly, who will keep the data secure?**

If the answer is a neutral, trusted and capable third party, the project's chances of success are immeasurably increased as projects stakeholders can stay focused on their own competencies and roles instead of becoming data logistics managers. This in turn neutralizes potential control issues that might otherwise doom the project's success.

A cloud managed services vendor can host the data and perform a number of key data management services. These can include:

- Pulling data from disparate sources into a single cloud-based repository for collaborative use
- Pulling data "as-needed" from disparate sources for collaborative use when time sensitivity is low
- Curation of data using a "clean-once/use-many" process that is repeatable and transferable
- Stripping the data of patient identifiable information
- Providing data visualization tools including dashboards and reports
- Maintaining audit trails of who accessed what, when and from where
- Scaling storage as the data volume increases

Managed services for massive data sets

In addition to providing neutral and central ground for collaboration, the cloud offers a nimble IT infrastructure to host the large volumes of data that accumulate when developing targeted therapies. As noted in an FDA report, these therapies frequently use or depend on actual devices, which in turn run on software; from a personalized tracheal splint that was created based on a CT image, to software-based EEG analysis that predicts responses to different psychotropic drugs.[4]

4. http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf

Development on such innovative treatments can quickly come to a halt if there aren't enough servers in place to contain all the data they amass. Commissioning more servers, however, has historically been a time intensive process. The organization that instead uses quickly scalable, virtual servers in the cloud will have a powerfully responsive tool to aid faster time to market for breakthrough drugs and other therapies. Further, strategies to incorporate data on an as-needed basis and a dynamic data mart for temporary and repeatable analysis provides a second mitigation strategy and potential cost savings.

Putting Patient Engagement To Use

Patient engagement has long been a top if elusive objective for the pharmaceutical industry. Regulatory and other barriers make it difficult to directly communicate with patients, which means many drugs are developed from assessing only a tiny percentage of the market. This is set to change, however, with the entrance of wearable health tracking devices and digital health forums that collect and sell (with patients' permission) insightful patient data. That said, there are still some technical barriers that must be cleared to acquire these newly available treasure troves of information:

- How to aggregate patient data from disparate locations and device?
- How to make the data breach-proof and HIPAA compliant?
- How to make the data meaningful for analytics?

Cloud Partner for Data

A cloud managed services vendor with a healthcare-exclusive focus will know how to aggregate data, including PHI, from different sources without putting it at risk of security breaches. As described in an earlier section, such a vendor will be knowledgeable about applying HIPAA security and privacy requirements, including strong access controls of data whether it's in transit or "at rest" in the data

center. A top-tier vendor can even offer additional data analytics capabilities that enable deep dives into these vast new data lakes, essential for speeding up clinical trial findings and time to market.

A cloud partner can also facilitate data aggregation between pharma companies as they consolidate with each other or acquire vertical entities that have access to patient audiences. As each new deal adds more valuable data assets to the parent company's assets, data inventory and aggregation will be needed skill sets. Rather than depend internally on this expertise, pharma companies can turn to an able cloud managed services partner instead.

Conclusion

As much as technology has helped to replace manual processes at collecting and analyzing data for pharmaceutical research, a good deal of it is trapped in an internal IT infrastructure - and mindset, that it's time to move away from. The emergence of value-based care and personalized medicine are changing how drugs will be developed. Accordingly, the pharma industry must change the technology methods that facilitate clinical trials and other major projects. Indeed, without a nimble IT infrastructure, it will simply become too expensive and cumbersome to develop drugs.

By contrast, cloud technology will enable far more efficiency and much better analysis of the data that can lead to targeted therapeutics and unequivocally prove their value. Those companies that opt to harness this cloud managed services model will be the ones who sprint ahead.

About Us

ClearDATA is the nation's fastest growing healthcare cloud computing company. More than 310,000 healthcare professionals rely on ClearDATA's HIPAA compliant cloud computing HealthDATA platform and infrastructure to store, manage, protect and share their patient data and critical applications.

For more information

1600 W. Broadway Road, Tempe AZ
(800) 804-6052
www.cleardata.com

ClearDATA
SECURE • HEALTHCARE • CLOUD