



Implementing Clinical Solutions in the Cloud



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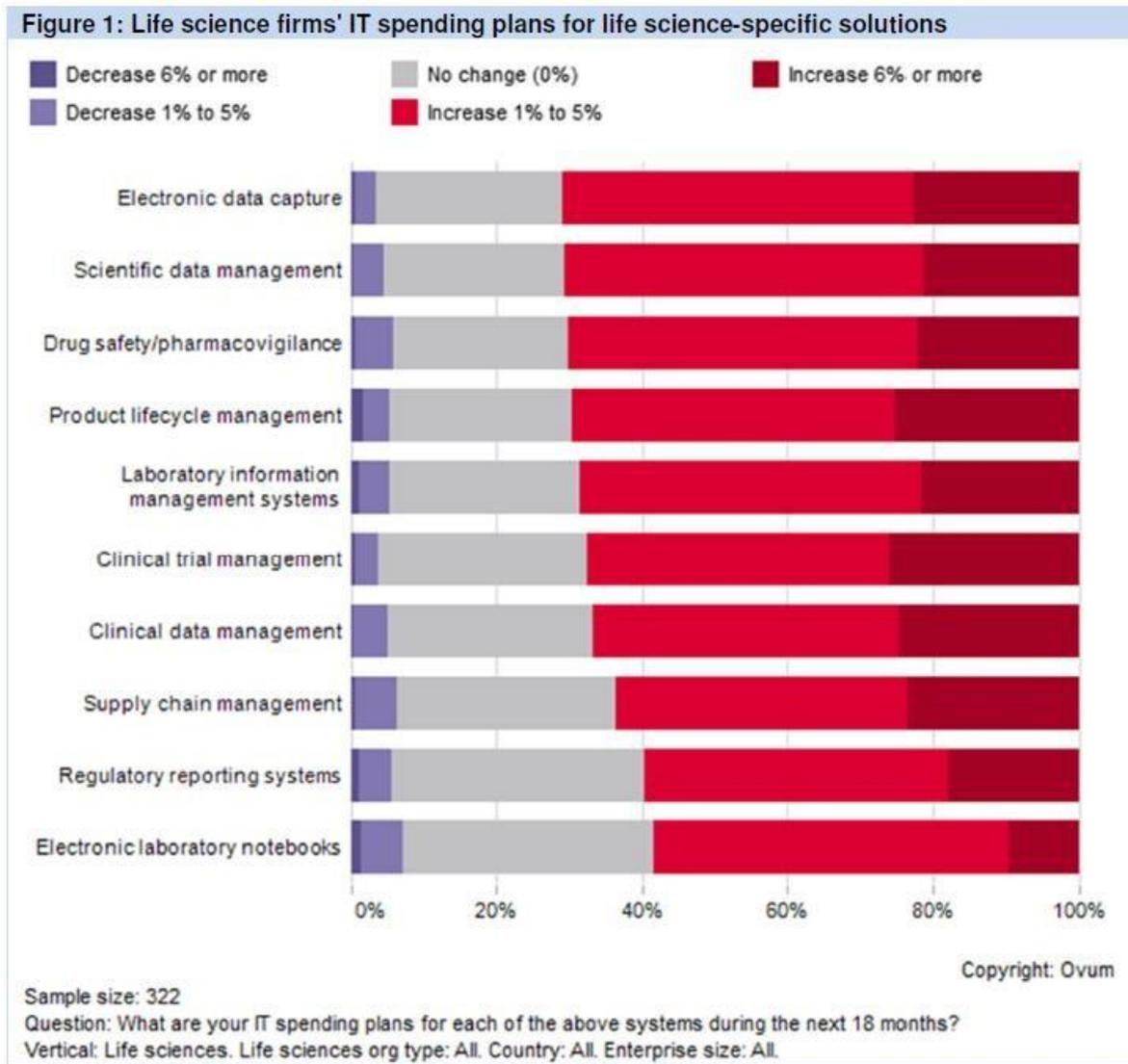
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Introduction

Over the next few years, the global clinical trials market is expected to substantially expand. At the same time, the cost incurred to conduct a clinical trial has been increasing steadily and is putting new compounds at risk due to it no longer economically feasible. This whitepaper discusses cloud-based clinical solutions to determine their economic impact on the costs to conducting Clinical studies.

Latest research by Ovum research concludes that biopharma companies are looking to advances in technology to disrupt the drug development process and open new doors to clinical trial management. Per Ovum’s Decision matrix Report: Selecting a CTMS, IT budgets are up and expected to increase;



Source: Ovum ICT Enterprise Insights

Based on the chart above, it is evident that Clinical Executives are ready and willing to spend money on IT systems which can improve their businesses. Over the last few years, there has been a major push to remove information siloes and make their systems as close to real-time as possible. By doing so, we are seeing more Clinical I.T. automation, business intelligence and advanced analytics.

As observed in the Ovum report, we can identify the current shortcomings of existing clinical systems and extract the important aspects that need to be improved upon in order to improve the clinical process and reduce clinical trial costs. The current industry trends and concerns for clinical I.T. solutions are as follows;

1. Due to many complexities of clinical trials, the design, planning and execution is more difficult and costly with today's disparate tools
2. More business intelligence and advance analytics are needed
3. The goal is to have real-time information or as close to real time as possible.
4. There is a need/desire to have all clinical information available in one system

Can cloud-based clinical solutions fill in the above mentioned gaps? Let's explore the topic but first let's become familiar with what a cloud is.

What is the Cloud?

When researching the cloud, you will come across many definitions where most of it is just marketing lore. In simplest terms, the cloud can be broken down into:

Service Models – the Product You are Buying

Infrastructure as a Service (IaaS)

As its name implies, IaaS provides an infrastructure to an organization. Products may include networks, servers, storage, and staffing and more. You are responsible for maintaining the servers such as patches. An example of this is Cloudshare (www.cloudshare.com)

Platform as a Service (PaaS)

With PaaS, you publish and manage your applications whereas the infrastructure is maintained by the vendor. An example of this is Salesforce.com/Force.com (www.salesforce.com).

Software as a Service (SaaS)

With SaaS, you are provided access to use software, usually on a monthly basis. You do not manage the application or the infrastructure. An example of this is Office365. (www.office365.com)

Delivery Models – How that Product is Setup, Permissioned, and Distributed

Public Cloud

Typically, the most cost effective cloud, end users share resources with other organizations over the public internet.

Community Cloud

Similar to a public cloud, except that the number of organizations using it are limited.

Hybrid Cloud

Two or more distinct clouds are joined from a technology perspective, but the data remains split.

Private Cloud

A cloud model that is open to only one organization and is typical located within the company’s own data center.

Cloud Challenges

As most of us already know, pharmaceutical companies and healthcare organizations are late technology adopters. There should no surprise that cloud technology uptake has been slow in this industry. This slow uptake has been the direct result of certain challenges that the pharmaceutical and healthcare industries face.

For instance, privacy concerns top the list because abiding by patient privacy laws is left to a 3rd party which is located in remote location outside the company. This puts the data at a potential risk for being stolen or lost altogether. If patient data is stolen, the healthcare company would be in violation of patient confidentiality laws which carry some hefty fines and even the possibility of imprisonment. Below is a summary of the fines/penalties;

Civil monetary penalties

| Tier | Penalty |
|---|--|
| 1. Covered entity or individual did not know (and by exercising reasonable diligence would not have known) the act was a HIPAA violation. | \$100-\$50,000 for each violation, up to a maximum of \$1.5 million for identical provisions during a calendar year |
| 2. The HIPAA violation had a reasonable cause and was not due to willful neglect. | \$1,000-\$50,000 for each violation, up to a maximum of \$1.5 million for identical provisions during a calendar year |
| 3. The HIPAA violation was due to willful neglect but the violation was corrected within the required time period. | \$10,000-\$50,000 for each violation, up to a maximum of \$1.5 million for identical provisions during a calendar year |
| 4. The HIPAA violation was due to willful neglect and was not corrected. | \$50,000 or more for each violation, up to a maximum of \$1.5 million for identical provisions during a calendar year |

Criminal penalties

| Tier | Potential jail sentence |
|--|-------------------------|
| Unknowingly or with reasonable cause | Up to one year |
| Under false pretenses | Up to five years |
| For personal gain or malicious reasons | Up to ten years |

Figure 1: HIPAA Violations and Penalties

That being said, we can make the case that the security challenges of cloud solutions are being blown out of proportion. Many of today's cloud technologies are HIPAA and ISO certified. Take office365.com for example, where security and privacy have been verified by third party companies¹. Regardless, if security and privacy are still roadblocks, then implementing a private cloud would alleviate those concerns.

Additionally, security concerns have been a roadblock in the adoption of cloud solutions for clinical - be it security of the underlying hardware (think servers) or security of the server operating system software. Cloud providers today staff security experts that monitor their networks, patch systems, and implement policies to protect their assets and ensure data security. By using cloud-based solutions, all data is stored in the cloud, and we can make the argument that the data is more protected than it would be if it were sitting on a physician's laptop waiting to be stolen. Not too long ago, a veteran's affairs contractor had their laptop stolen which contained the medical histories of 644 veterans².

Change management is another big problem area for cloud adoption. Many clinical practices still incorporate the use of paper based procedures. The skillsets of the I.T. employees of pharma and healthcare companies will need to be retooled. Training programs will need to be put into place as new cloud technologies are implemented. Employees who once managed the servers in the organization may find themselves supporting clinical applications in the cloud. Organizations need to take a step back and evaluate the ROI and risk/benefits of transitioning to the cloud instead of using it as a reason to not progress forward.

The Benefits of a Clinical Cloud

Cloud-based architectures offer both clinical and business benefits. From a clinical perspective, cloud technologies tear down the communication barrier and allow external parties to access applications, and more importantly access data. This remote (centralized) access has a direct effect on patient care because data is in a central place, and can be collaborated on by multiple parties much faster than traditional systems. Moreover, cloud vendors support or can help create accessible web services that can be utilized by the big data industry.

From a business perspective, organizations will not need to focus on training I.T. people and instead focus on patient care. Typically, a cloud provider will have in-house experts for just about anything related to their service; storage experts, network experts, application experts, etc.

Also, cloud technologies are business favorable when it comes to procurement. Budgeting for cloud is much more streamlined and easier to manage because it utilizes a "pay for what you use" approach with unlimited scalability. Contrast that with the typical 5-year capital expenditures process typical of a healthcare organization where you need to request funding for 5 years while predicting how much storage you will need. On top of that, at some point you are going to need to replace those systems, whereas with cloud the vendor is on the hook.

¹ <http://office.microsoft.com/en-us/business/office-365-trust-center-cloud-computing-securityFX103030390.aspx#compliance>

² <http://www.nextgov.com/health/2010/05/laptop-stolen-from-va-contractor-contains-veterans-personaldata/46684/>

Cloud technologies offer a level of high availability with Service level agreements typically offering 99.9% uptime. Considering the healthcare and pharmaceutical industry need this for their mission critical applications, it may be beneficial for these organizations to utilize more cloud-based solutions.

Cloud Financials

Not all clouds are created the same, nor do they all cost the same. Different clouds have different pricing structures. Most the most part, a private cloud is going to be the most expensive because you are providing the datacenter and electricity to cool the center. That is why it is important to consider the Total Cost of Ownership (TCO) which incorporates all costs associated with using a cloud. Outside of typical the costs identified above, data breach remediation agreements need to be put into place which identify which party is responsible.

Cloud Considerations

When evaluating cloud providers, it is important to thoroughly vet all aspects of the service they provide. With respect to the healthcare and pharmaceutical industries, be sure to mitigate risks by looking carefully at the following;

- **Standards-based data management:** DICOM/HL7, XML metadata, NIST 800-146 Cloud Computing recommendations, and IHE
- **Time to Provision additional units**
- **Availability:** downtime, latency, and redundancy
- **Security**
- **External Access**
- **Service Level Agreements**
- **Contractual obligations**

Retracing back to the beginning of this white paper, we posed a few challenges with the current suite of disparate tools. Let's see if cloud technologies can help fill in those gaps;

1. Due to many complexities of clinical trials, the design, planning and execution is more difficult and costly with today's disparate tools.

The use of cloud-based solutions for EDC, CTMS, and patient safety can greatly reduce costs for running a clinical. DatStat, INC offers cloud-based EDC and patient care systems enable companies to reduce queries, improve quality, and get to lock faster. These all add up to costs savings.

2. The goal is to have real-time information or as close to real time as possible.

Part of the sell with cloud solutions is that all data is in the cloud, essentially making it as real time as it gets. External parties like Physicians can have direct access to critical patient information with waiting.

3. There is a need/desire to have all clinical information available in one system

Instead of using disparate systems to collect data coupled with complex extract, transform, and load routines, cloud suites such as Veeva Systems offer a suite of tools that are already linked.

4. More Business intelligence and advance analytics are needed

Cloud solutions/providers offer access to real time information as part of their service, and assuming the solutions are implemented using standard-based data models like XML, DICOM/HL7, and IHE then data is available via web services. This web services data layer provides the foundation for advanced analytics and business intelligence.

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