

Communications of the IIMA

Volume 13 | Issue 3

Article 3

2013

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Recommended Citation

Sommer, Thomas (2013) "Cloud Computing in Emerging Biotech and Pharmaceutical Companies," *Communications of the IIMA*: Vol. 13: Iss. 3, Article 3.
Available at: <http://scholarworks.lib.csusb.edu/ciima/vol13/iss3/3>

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Cloud Computing in Emerging Biotech and Pharmaceutical Companies

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ABSTRACT

The purpose of this research is to determine the qualitative advantages and disadvantages of cloud computing in emerging biotech and pharmaceutical companies. From the perspective of four small biotech and pharmaceutical organizations the research investigated the positive and negative aspects of cloud computing and how it impacted the way these organizations conduct business in an increasingly complex global community. The research techniques were mixed qualitative methods that provided cross-examination and included action research, observations, interviews, surveys, and case studies. The analysis used triangulation and resulted in the discovery of patterns and themes, which provided separate interpretations and assertions of perceived benefits and obstacles. The research indicated that small biotech and pharmaceutical companies find cloud computing very attractive with some relatively minor drawbacks, which can be mitigated with adequate planning and proper implementation.

Keywords: Cloud computing, biotech, pharmaceutical, SaaS, IaaS, PaaS

INTRODUCTION

In today's global economic climate, start-up and emerging biotech and pharmaceutical organizations are seeking greater cost-saving measures, increased agility, and the type of scalability that responds to the rapid changes in both technology and business. Cloud computing, with its low cost pay-as-you-grow business model, could potentially help these companies manage similar changes while transforming Information Technology (IT) into an engine that drives business (Roehrig, 2010). The immediate benefits from on-demand clouds seem to provide users with enhanced portability and the capacity to have secure access to information from virtually anywhere, with almost any mobile device, regardless of location or time of day, whether it be from a lab, a client location, when traveling, or while in a meeting at the office. Additionally, small and medium business (SMB) life science companies represent a unique market that could potentially benefit from this new computing paradigm. These organizations could then economically scale their businesses as needed while rapidly completing complex research-to-market tasks they simply could not accomplish on their own (Bowers, 2011).

Cloud Computing Model

The idea of cloud computing mystifies many organizations, especially those dealing with a deluge of data being generated by life science companies. Similar terms are often used to describe cloud computing, such as grid, distributed, on-demand, cluster, utility, virtualization,

and software-as-a-service. More directly, cloud computing refers to end-users connecting with applications or services running on sets of shared servers, often hosted and virtualized, instead of traditional dedicated servers. For over 30 years, client-server computing has provided applications that were assigned to specific hardware, often residing in on-premise data centers. On-demand cloud computing empowers its end-users by allowing them to use their choice of Internet-connected devices, on any day or at any time (Knorr & Gruman, 2009).

REVIEW OF LITERATURE

Prior research in this area focused on the viability and outcomes of using cloud computing in life sciences, both internally and outsourced to cloud service providers (CSPs). This literature review helps establish a theoretical framework for the research topic. Independent authors used a variety of qualitative and quantitative methods to arrive at their results, although none included the distinct qualitative mixed methods used by this researcher.

Reduced Cost at Greater Speed

According to Proffitt (2009), early adopters of cloud computing such as Pfizer, Johnson & Johnson, and Eli Lilly all used Amazon Web Services (AWS) and Amazon EC2 (Elastic Compute Cloud). These pharmaceutical companies were able to perform R&D using the cloud, and process proteomics, bioinformatics, statistics and adaptive trial design more rapidly with predictable time and costs. Davies (2009) illustrated the relative low cost of cloud computing for early adopters by describing reactions of members at the inaugural Bio-IT World European Conference in 2009. BioTeam co-founder and technology director Chris Dagdigian argued Amazon impressed users by starting at 10 cents/hr. Dagdigian later pronounced a traditional 100 CPU-hour research problem could be solved using EC2 in 1 hour for \$40, and what he called the "Aha" moment (Davies, 2009).

Better Connectivity

Effective connectivity is a major factor in life science research and development. Kubick (2011) argued cloud computing, using a solitary Internet connection, could reduce the effort of individually integrating each research system at various locations yet provide availability to all. Bowers (2011) suggested CSPs could provide SMB life science organizations with best practices they generally could not afford. These cloud CSPs utilize multiple connections to massive networks of interconnected servers that include comprehensive data protection, 24x7 disaster recovery, multi-site replication, real-time monitoring, and state-of-the-art emergency response systems, all from user-friendly, front-end interfaces (Bowers, 2011).

Improved Scalability and Performance

According to May (2010), most life science companies lack the necessary computing infrastructure required to analyze and store their research data. In order to increase their computational power, many life science researchers are searching beyond their own organizations and turning to decentralized systems, like supercomputers or grids of many smaller

computers working together. May (2010) contended scientists are uploading and analyzing their data using cloud computing with what he called, "near-limitless processing and storage capacity on a pay-as-you-go basis." In the same manner, Taylor (2010) argued that bioinformatics researchers, using ultra large data sets, had better performance using cloud-based systems. Taylor (2010) also suggested life science researchers could see significant performance benefits with regard to management of failures, data analysis, and computational jobs. Afgan et al. (2010) illustrated how to deploy a compute cluster using the Amazon EC2 cloud and Galaxy CloudMan. According to Afgan et al. (2010), their system was simple to use and made it possible for small groups of researchers to deploy the amount of computational resources needed without requiring support from skilled bioinformatics personnel.

Collaborative Drug Discovery and Microarray Data Analysis

According to McCarthy (2012), CSPs are now providing cloud-based drug discovery software platforms that increase the power of collaboration. These private, secure cloud architectures create a barrier-free virtual world that permits researchers in remote areas, sometimes with few technological resources, to participate fully in research projects (McCarthy, 2012). Vandeweyer, Reyniers, Wuyts, Rooms, and Kooy (2011) expounded on the collaborative advantages of cloud computing and suggested that open-source web based platforms, such as CNV-WebStore, are being used in clinical practice by both lab technicians and clinicians to compare results against clinical information without producing overwhelming amounts of data.

Cloud Databases

Taylor (2010) also argued that cloud computing and open source software have created a programming paradigm that already has considerable use in the field of next-generation sequencing analysis and in bioinformatics communities. Apache Hadoop, Hbase, and MapReduce are cost-effective software that is reliable, scalable, and distributed. This type of software framework in the cloud provides SMB life science companies with distributed processing of large data sets across clusters of computers using a simple programming model (Taylor, 2010). Do, Esteves, Karten, and Bier (2010) researched Booly, a similar cloud-based relational database that runs on multiple load balanced servers and can easily be accessed through a graphical user interface using a web browser. Do et al. (2010) argued Booly is a comprehensive platform for the creation, storage, and integration of biological databases that can assist researchers in developing novel discoveries in the laboratory. Qiu et al. (2010) maintained a hybrid cloud that utilizes MapReduce combined with Message-Passing Interface (MPI) standard, for programming parallel computers, offers an appealing production environment for life sciences applications. Qiu et al. (2010) used three cloud-based computational infrastructures in their study (Azure, Amazon and FutureGrid) and showed how life science organizations with few resources could successfully create this environment.

Cloud Security

Sansom (2010) maintained cloud computing may offer compelling solutions for small companies that struggle with large data sets, but security issues may limit its use in life science research. Sansom (2010) argued that only "precompetitive or non-confidential" data would be used in the

cloud; however, CSPs are currently helping small life science start-up companies manage their public and private clouds using Amazon and Google. Kubick (2011) suggested a fear of relinquishing control and the term “cloud computing” would cause protests about security concerns, even from current hosted cloud customers. Yet Kubick (2011) argued that in most cases a CSP provides much higher degrees of disaster recovery and auditable security than most internal IT departments, because cloud computing is that CSP's primary business. Kubick (2011) concluded that cloud security requires risk assessments and that detailed mitigation plans are necessary precautions, which build internal confidence. Bowers (2011) expanded on these ideas and suggested data security in the cloud must be strong, extensive, and dependable. Bowers (2011) argued clinical operations alone have legal and regulatory requirements with the U. S. Food and Drug Administration (FDA), such as 21 Code of Federal Regulations (CFR) Part 11, and Electronic Records/Electronic Signatures rules requiring computer systems and their controls be available for FDA inspection. Bowers (2011) concluded that life science companies using cloud computing should consider SAS 70 Type II and ISO-27001 certifications, and ensure adequate security controls are provided in these main areas: application security, data security, infrastructure security, process security, personnel security, and product development security. Additionally, in a recent a study, Gartner Inc. (2008) suggested that security delivered, as a cloud-based service, would more than triple in life science organizations by 2013.

Regulations

Besides cloud security, another concern of many life science organizations is the typical regulatory concerns. Kubick (2011) suggested regulatory agencies and their lack of definitive regulatory positions can negatively influence attitudes regarding cloud adoption, thus making small life science companies wary of cloud computing. Kubick (2011) acknowledged that CSPs should also comply with Health Insurance Portability and Accountability Act (HIPAA), and Good Clinical Practice (GCP) standards, along with having their cloud services verified by regular audits. Bowers (2011) expanded on these ideas and suggested cloud computing is helping streamline heavily regulated clinical trials by overhauling once labor-intensive procedures into controlled, secure, and efficient processes. Bowers (2011) argued that clinicians and investigators are no longer shackled by mountains of paper, instead cloud computing has moved the focus toward the data itself, freeing it to be analyzed, tracked, or instantly reused whenever necessary. Gorban (2012) maintained regulated environments that utilize cloud computing can manage compliance with the use of strong controls and auditable documentation, thereby mitigating associated risks. Gorban suggested, with proper planning, there are real benefits to taking an evolutionary approach and systematically developing a compliant cloud environment.

Life Sciences Efficiency

Shurell (2010) maintained that clinical trials at life science companies have become more global and that regulatory examination has continued to climb, making paper-based processes even more difficult. Clinical trials, in particular, require the tracking of documents being sent between multiple sites, sponsors, contract research organizations (CROs), and stakeholders. Shurell (2010) argued that by using a SaaS-based solution in the cloud electronic documents can be securely tracked globally, which can accelerate contract negotiations, patient recruitment,

protocol design, clinical trials, and other activities of pharmaceutical companies. Shurell (2010) suggested the outcome was quicker, more intelligent, and more efficient clinical research.

Bowers (2011) cited examples of life science organizations that use cloud computing in fundamental research, to speed up the development process at times when their IT infrastructure was functioning at maximum capacity, while requiring little IT involvement. Bowers (2011) suggested companies were able to bring down fixed IT costs without undermining service levels, while significantly expanding computing and storage capabilities. One company cited by Bowers (2011) moved research projects to the cloud and planned to analyze filing data for actual drug approval.

Cloud Adoption

Bowers (2011) argued SMB life science companies could experience remarkable economic advantages and timesaving by migrating to a SaaS provider. The process of implementing a SaaS solution could take days/weeks instead of months/years when compared to traditional in-house solutions, without interrupting normal business. Bowers (2011) maintained cloud-based systems require minimal in-house IT support, which liberates infrastructure and resources for other activities. Bowers (2011) added cloud computing requires smaller upfront investment and provides predictable cost management that is based on operating budgets instead of capital budgets, which is particularly attractive to start-up companies. Kubick (2011) acknowledged pharmaceutical and biotechnology companies have adopted IaaS and PaaS for computationally heavy research such as molecular modeling, proteomics, and bioinformatics. These companies had immediate access to on-demand processing and storage services along with hosted environments for developing custom applications. Kubick (2011) added these types of services are especially attractive to start-ups, considering they can avoid capital investments and instead rent the computing infrastructure needed during product development. Cloud computing also reduces start-up times and can be made available much faster than it takes to build infrastructure internally, without bureaucratic hurdles or delays.

METHODOLOGY

The methodology used in this study was qualitative action research in a mixed mode, which provided research techniques that were used to collect and analyze primary data. Both interpretive and aggregative data were collected using action research, first hand observations, surveys, interviews, case studies, and peer reviewed literary sources. This approach used multiple data sources and methods, to maintain the credibility of the research, and provide more comprehensive and reliable analysis based on triangulation, or cross-examination.

Action Research in a Mixed Mode

Lau (1999) argued qualitative research in information systems works best with diverse approaches such as case study, ethnography, action research, grounded theory, and other multi-method triangulation. Lau (1999) also suggested action research in information systems could provide unique opportunities that link theory with practice, allowing solutions to real-world

problems. This research assists the organizations being studied as a reflective process that helps them improve the way they address cloud computing. The researcher actively participated as the organizations changed while conducting this research. Furthermore, the action research methodology used in this study is appropriate because it is collaborative and later assisted the organizations being studied to make necessary changes in their unique cloud environments.

Population

The population in this research included four emerging biotech and pharmaceutical companies, each with less than 100 employees. Three organizations are private companies and one is public, with current market value of less than \$25 per share. All four companies are considered SMB life science companies with market capitalization of less than \$100 million. All organizations and participants utilized cloud computing prior to the beginning of this research, ranging from one to seven years.

Due to non-disclosure and privacy agreements signed by the researcher, no company names or employee names are used in this research, instead organizations are described in an anonymous manner, such as “Company A” and the title of a participant being referenced.

Sample Population and Selection Process

The sample population was chosen using purposeful sampling/stratified sampling based on the participant or stakeholder's experience. The researcher obtained prior permission whenever gathering data within the organizations and all participation was voluntary. Specific sample groups included managers and senior management, with an understanding of the strategic goals and corporate business plan, technical staff, with an understanding of cloud mechanics, and cloud end-users (also known as “internal customers”) within the organization. The sample population consisted of 47 total participants within the four companies: 11 participants were managers or senior managers, 17 participants were technical staff, and 19 participants were cloud end-users.

Research Questions

Ten research questions in Appendix Figure A-1 were designed to reveal the advantages and disadvantages of cloud computing and to illicit clusters of opinions and overall themes from research participants. The questions were posed to sample population participants electronically in survey form and verbally during structured interviews, conducted by the researcher. The surveys allowed the researcher to reach a large majority of the sample population, while the interviews were held independently with approximately 10 percent of the sample population.

Surveys were conducted electronically using SurveyMonkey.com and each included a proviso asking participants to respond as thoroughly as possible to each question. The interview protocol utilized the same research questions except participants provided verbal responses based on their individual experiences. (Appendix Figure A-1)

Validity of Methodology and Bias

According to Lincoln and Guba (1985), there are many different ways to establish validity, credibility, and dependability in qualitative research. Validity in this research was determined using interviewer corroboration and member check, or respondent validation, by verifying the quality of the researcher's data and conclusions when compared with the experiences of the research participants. Survey responses were given to respondents for verification of their accuracy. Interviews were electronically recorded and later transcribed, then given to participants for verification of content and meaning. Notes from first hand observations, case studies, and peer-reviewed literature were captured electronically and verified by repetitive review and cross-examination. Additionally, a concept map was created, using Wordle.net, with the electronic data that was collected from the various methods.

Bias was a consideration because the researcher had personal experience with the research topic and the companies being studied, prior to the research. Stake (2010) argued the greatest concern about bias in qualitative research is it may be self-serving and promotional, protecting the ideas of the home team. Janesick (2000) suggested bias is virtually unavoidable in qualitative research. Whereas, Glasser (1992) argued bias is not only unavoidable, but also considering that the researcher is the principal instrument of research, the data he/she collects will be biased, regardless of research method. In order to lessen or diminish the effects of bias in this qualitative research, the researcher intentionally used multiple points of view and data collection methods. Bias was minimized during the analysis process through the use of electronic data gathering and analysis, and all participant responses were validated using member check. The interpretations and subsequent reporting of research results were based on those validated responses.

Data Collection

All primary research data was collected electronically first-hand, using SurveyMonkey.com, one laptop, one iPhone, and one iPad. The various data types collected (text, audio, images, etc.) were then input into TAMS Analyzer, a computer assisted qualitative data analysis software (CAQDAS) system, which aided in coding and the identification of themes.

RESULTS

Analysis

This study used an inquiry process of research, analysis, and synthesis. A meta-analysis was conducted from reading and reviewing research data, the literature review, observations, notes, interviews, surveys, transcripts, case studies, and research documentation provided by the participant companies. Obvious patterns that reflect the advantages and disadvantages of cloud computing were gathered. Interpretive and aggregative data from micro-research, personal experiences, interview responses, case studies, and the literature review were sorted and catalogued. The concept map was regularly updated, which helped visually classify, code, and sort clusters of meaning. The researcher was then able to recognize and interpret various patterns and the major issues and sub-issues. Through additional sorting and organizing, patterns and

themes emerged that were categorized, and eventually provided interpretations of the advantages and disadvantages. During the analysis process the researcher continually reviewed, discerned, examined, compared, and contrasted the research data. Triangulation from multiple perspectives, and multiple data types, was completed, adding credibility and reliability to the results.

Surveys and Interviews

The results and data collected from research questions (Appendix Figure A-1) represent feedback from a majority or plurality of respondents:

- Participants indicated cloud computing has both advantages and disadvantages, but overall they are growing more positive in their experience as worldwide cloud adoption continues and the CSP industry matures.
- Participants most frequently cited as why participant organizations use cloud computing were reduced cost; to avoid capital expenditures in hardware, software, IT support, or information security; and flexibility or scalability of IT resources.
- Participants indicated the cloud service models most frequently utilized were SaaS - hosted software packages; and PaaS - complete operating systems and software packages for application development.
- Participants indicated the cloud deployment models most frequently utilized were Hybrid Cloud (a federation of clouds provided by various sources (partner, private, etc.); and Public Cloud (owned and managed by an unrelated business).
- Participants indicated the organizations that most frequently host and manage their cloud computing environments were Amazon, Rackspace, Google Apps, Comcast Business, and Egnyte.
- Participants indicated the IT services or applications that most frequently support their business processes via cloud computing were: payroll, CRM/sales management, accounting and finance, project management, scientific collaboration, data analysis, research analysis, development analysis, life sciences research and development, and DNA sequencing.
- Participants indicated that most companies in this research would outsource to multiple cloud service providers (CSPs).
- Participants indicated in their assessment of the feasibility and profitability of their cloud-computing environment, the biggest advantages were cost, flexibility, and agility.
- Participants indicated in their assessment of the feasibility and profitability of their cloud-computing environment, the biggest disadvantages were security, reliability of key systems, and lack of organizational control.
- Participants indicated their main concerns regarding their organization's approach to cloud computing were privacy issues, availability of services or data, confidentiality of corporate data, loss of control of services or data, legal ramifications (including government regulations, compliance and auditing), and cloud vendor lock-in.

Researcher Observations

The researcher had personal experience with all the organizations being studied prior to the research and is thoroughly familiar with their use of cloud computing. The researcher made the following observations during the study, creating additional clusters of meaning and themes, which apply to a majority or plurality of the participants and organizations being studied:

Change Management. Participants in this study acknowledged they depend on automatic change management with no additional expenditures for future updates, in terms of software and hardware. Participants expressed concerns about reliability in terms of changes made by CSPs and how these changes will affect their business needs and/or might negatively impact their e-discovery and production environments. A majority of organizations requires advance notice from CSPs prior to patches or updates being applied and that they have redundancy in place, including management procedures, which ensure these risks are minimal.

Security Conundrum. Participants in this study cited most often confidentiality and security, and their complexity, as the greatest concerns of cloud computing. However, security of their cloud service providers (CSPs) was considered an advantage by most organizations that utilize strong SLAs and appropriate security controls. All organizations in this study mitigate risks by requiring CSPs or themselves to use strong encryption and privately controlled encryption keys, during data transit and when at rest inside cloud infrastructure. Frequently participants cited the need for enhanced security in the following areas: corporate data security, application security, process security, infrastructure security, R&D security, and personnel security. A majority of these organizations also maintained they require comprehensive security standards be used by their CSPs, such as: HIPAA, SAS70 Type II or SSAE 16, Safe Harbor Compliance, FIPS 200 / SP 800-53, ISO 27001, ISO 27002, SOC 2 & 3, WebTrust and SysTrust, and Certificate of Cloud Security Knowledge (CCSK). "HIPAA requires our patient data be safe and we're always concerned about security, so we've integrated our security and compliance efforts by adopting easier and more secure online platforms," argued Director of Clinical Operations from Company B, (personal communication, June 14, 2012). A majority of organizations view security controls in cloud computing as no different from security controls in any IT environment. As the Vice President of Finance from Company A described it, ". . . our frequent audits and security are backed by strong controls, very high level security standards, and a security framework that specifies which security services are provided how and where" (personal communication, June 11, 2012).

Regulatory Proficiency. Organizations in this study must comply with various regulatory agencies and auditors, both inside and outside the United States. Their use of cloud computing provides them with regulatory proficiency that is compliant, scalable, and on-demand. "All of our cloud providers support our audit requirements for compliance," responded the Vice President, Research & Development at Company A, (personal communication, June 8, 2012). The Senior Director Regulatory Affairs and Quality Assurance at Company C provided additional evidence, "Our most critical systems in the cloud that are regulated have very high audit and data retention requirements," (personal communication, June 20, 2012).

Legal Ramifications. A majority of participants cited legal issues as a major concern of cloud computing. All participant organizations require clear legal definitions in their CSP agreements on what is/is not being provided by CSPs, ownership of information/system, as well as what should happen in case the vendor files for bankruptcy. A majority of organizations indicated that when CSPs are clearly aware of the consequences for violating these policies, it motivates them to execute successfully their agreements. Furthermore, these organizations avoid SLAs or contracts that limit, ignore, or gloss over potential data loss, privacy, security and e-discovery issues. These organizations expect CSPs to assume responsibility and liability in case of network

outages and data loss. "We have even required indemnification clauses in some of our SLAs," declared the President of Company D, (personal communication, June 26, 2012).

Cloud Vendor Lock-in. Another major concern from a majority of organizations cited was their perceived inability to move to another cloud offering or to another CSP. Few organizations had undergone significant moves therefore much of this fear was speculation. However, in order to alleviate this issue, most organizations view data portability as a crucial aspect when choosing CSPs. Deployments that utilized different cloud provider solutions, e.g. for disaster recovery or global presence, were considered the best solutions in terms of portability and risk management.

Lack of IS Control. A majority of participants in this study indicated they believe their organizations lack complete control over their data, which is an ongoing issue. Although most CSPs used by participant organizations deploy fully automated management platforms that maintained IT control and transparency, they could not provide specific instances where lack of control resulted in negative outcomes since cloud adoption. Several participants did describe experiences prior to cloud adoption when their in-house controls failed, mainly due to their small staffs and inadequate support. "After being burned using our own equipment, and getting over the mental hurdle that we must relinquish some control to the cloud vendor, we haven't yet looked back." declared the Associate Director of QC & Analytical Development from Company A. (personal communication, June 13, 2012)

Case Studies

Orlikowski and Baroudi (1991) and Alavi and Carlson (1992) maintained that case study research is the most common qualitative method used in information systems. Case studies used in this research provided empirical evidence and phenomenon within real-life context.

As small life science organizations search for novel methods to meet their business needs, CSPs are responding and helping them with innovative ways to meet those challenges. Ten oncologists at South Florida Radiation Oncology (SFRO) used CareCloud's SaaS to scale quickly their business processes while providing better integration (McGee, 2011). Another small team of doctors at California Pacific Medical Center found hard-to-find kidneys for patients using a cloud-based software program (McGee, 2011). Software giant Oracle recently released cloud-based applications for clinical trials recruitment that make it easier for small pharmaceutical companies to find qualified subjects for clinical studies (McBride, 2012a). Google has been attracting many small biotech companies like Numerate, who integrated their drug discovery technology with Google's Compute Engine, allowing them to collaborate easily with larger companies like Merck (McBride, 2012c). At DIA Conference in 2012, life science industry veterans discussed how cloud computing and mobile technologies have definite benefits in clinical trials, such as monitoring patients' conditions outside of traditional hospitals and clinics (McBride, 2012b).

Evidence has shown that cloud computing is dramatically helping SMB life science companies rapidly scale and grow at lower cost. Chidambaram (2011, pp. 1) suggested, ". . . while large enterprises are still weighing the pros and cons of cloud business models, it is the SMBs that are out there taking daring steps and reaping all the benefits." Chidambaram's study illustrated how a

small life sciences company can effectively manage their collaborations and document sharing, CRM, and ERP all in the cloud. According to Barbadora (2012), an increasing number of SMB life sciences companies are choosing cloud-based CRMs that give them enterprise-class performance within a reasonably priced model. These systems historically are cost-prohibitive for most small life sciences companies because traditional in-house CRM applications, ongoing maintenance, and upgrade costs are normally beyond their budgets. Barbadora (2012) also suggested cloud computing enables growing life sciences companies the ability to quickly and efficiently scale up or down in order to meet their CRM demands. Heritage (2012) argued small pharma and biotech companies, that do not have the resources to support a large informatics infrastructure, could use SaaS based informatics that save time, costs, and are more effective with better collaborative workflows. BT in England recently partnered with Accelrys to create a life sciences research and development cloud, or On Demand Compute service, that helps scientists working in the pharmaceutical and biotech industries reduce the costs associated with R&D when bringing new drugs to market (Nguyen, 2012). As emerging biotech and pharmaceutical companies achieve real value using cloud computing, their need for fast, nimble, and cost-effective cloud-based solutions seem likely to grow.

In the future, these and other cloud adoption trends are expected to increase. According to Gardner Research, by 2016 at least 50 percent of enterprise email users will rely primarily on a web browser, mobile tablet or mobile device instead of a desktop client. Gardner Research also predicted by 2017 more than 50 percent of Global 1000 companies will store customer-sensitive data in the public cloud (Savitz, 2012). Mullin (2009) argued as drug companies realize what can be accomplished in cloud computing, CSPs are "amassing a distributed computer utility infrastructure to accommodate booming demand." Mullin (2009) also suggested drug companies like Pfizer, Eli Lilly & Co., Johnson & Johnson, and Genentech that have adopted cloud computing found benefits with large amounts data storage, lower costs, and faster data processing. The researcher of this study also found a majority of organizations studied indicate they plan to continue using various types of cloud computing. "We are proceeding cautiously and always feasibility testing, and based on our experiences we believe our cloud adoption will accelerate," maintained the Director of Chemistry, Manufacturing and Quality Control of Company D, (personal communication, June 26, 2012).

CONCLUSIONS

Interpretations from this research indicated that small biotech and pharmaceutical companies found cloud computing very attractive with some relatively minor drawbacks, which can be mitigated with adequate planning and proper implementation. In forming conclusions, the major and minor themes were developed from the researcher's use of action research, first-hand observations, interviews, surveys, and case studies. The advantages of cloud computing in the emerging biotech and pharmaceutical organizations studied were identified as: reduced cost and greater R&D speed, improved efficiency, enhanced agility, superior storage and data analysis, improved change management, superior collaboration and connectivity, enhanced security, faster drug discovery, better performance, appreciable regulatory proficiency, and much greater scalability and flexibility of IT resources. Further, the researcher concluded the following are disadvantages of cloud computing in the emerging biotech and pharmaceutical organizations

studied: concerns about security, confidentiality of corporate data, legal ramifications, cloud vendor lock-in, and lack of information systems control.

Security concerns and regulatory issues in cloud computing were the predominant negative issues in this research. In spite of those issues, with limited budgets and few, if any, onsite security professionals, SMB life science organizations in this study considered overall security and controls in place from CSPs as superior and more comprehensive than could be produced by their limited in-house staff, at far greater efficiency and reduced cost. However, as cloud computing grows, CSPs must maintain the highest levels of security in order to retain this advantage and true business value for these emerging life science organizations. CSPs helped the organizations studied satisfy their regulatory challenges. A lack of clear-cut regulations regarding cloud computing from the overseeing regulatory agencies, remain a disincentive to further cloud adoption.

Small life science organizations in this study initially lacked the adequate computational infrastructure to meet their future needs. In order to gain such abilities they often partnered with larger academic institutions, biotech, or pharmaceutical companies. The participants and life science organizations in this study seem to be ideal candidates for larger-scale participation in cloud computing. Those organizations that have embraced cloud computing were able to efficiently grow and more quickly build competitive advantages, while simultaneously reducing IT expenditures – no longer having to procure, maintain, and update systems or support all end-users.

Smaller organizations that lacked adequate computational or data management infrastructure were ideally poised to take advantage of cloud computing's pay-as-you-grow structure. The organizations in this study found cloud computing met their needs for voluminous internal computer power without additional IT overhead. The researcher found that a major business advantage of cloud computing, with its faster, cheaper, more scalable model, is with SMB life science companies, by helping them create a competitive parity with much larger organizations and at least a competitive advantage over their peers.

Implications

Throughout the lifespan of biotech and pharmaceutical organizations, from start-up to R&D, from the pre-clinical phase to clinical trial work, and drug approval to market, etc., the massive volumes of data being generated must be analyzed and securely stored in accordance with regulatory agencies and corporate directives, all while improving cost and time efficiencies. Cloud computing, when properly implemented, can add multiple security layers and controls that small biotech and pharmaceutical organizations often cannot accomplish on their own. Organizations can first introduce cloud computing into routine processes, without large capital expenditures, and increase usage as necessary. Life science companies, in particular, can adhere to increasingly aggressive development timelines and comply with their changing global regulations in a timely manner.

Limitations

Cloud security and privacy in life science organizations are complex, considering their use of public, private, and hybrid models and the overall lack of data control due to the varied physical locations of off-site infrastructure. These limitations can be significantly reduced by proper planning and evaluating CSPs along with these key elements: application security, including strong encryption and authentication controls; data security, including best practice cryptography and exhaustive security checks that prevent breaches and are auditable; infrastructure security, including redundancy of infrastructure and uninterruptible service; process security, including industry's best practices managed by certified security professionals; personnel security, including background checks and strong confidentiality agreements with all personnel exposed to data; and product development security, including secure development lifecycle processes that protect applications in production and in development.

FUTURE WORK

This research could be expanded into a larger study involving significantly more participants and organizations, helping to determine additional opportunities or threats cloud computing would pose to those organizations and their business processes. This research could also be extended to develop a cloud taxonomy or cloud enterprise architecture that is suitable for life science research and their organizations.

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APPENDIX

Survey Questions and Interview Protocol

1. What is your strategic role within your organization?
2. What are the reasons behind your organization's use of Cloud Computing?
3. Which service model does your organization currently utilize, based on this Cloud Computing taxonomy
4. Which deployment model does your organization currently utilize, based on this Cloud Computing taxonomy?
5. Who currently hosts and manages your cloud-computing environment?
6. Which IT services or applications, that support your business processes, have/would you migrate to Cloud Computing?
7. Are you or would you be willing to outsource to multiple cloud computing providers?
8. In your assessment of the feasibility and profitability of your cloud computing environment what are the biggest advantages
9. In your assessment of the feasibility and profitability of your cloud computing environment what are the biggest disadvantages
10. What are your main concerns regarding your organization's approach to Cloud Computing?

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