disruptive views

THE CLOUD: speeding drug delivery

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Clinical trials play an essential role in the drug development process by effectively demonstrating the efficacy and safety of a pharmaceutical compound. Current estimates show, however, that only about 1 out of every 10 drugs that actually start the clinical trials process are eventually approved by the FDA to go to market. In addition, according to PhRMA, the U.S. pharmaceutical industry's advocacy group, it costs $1.3 billion (the cost of clinical trials being the bulk of this cost) to bring a new drug to market with time invested into a single project totalling up to 12 years. The traditional drug discovery process is incredibly inefficient, complex, bureaucratic and, above all else, expensive. Inefficiencies stem from a variety of issues, including overly complicated protocols, globalization, and old-school paper-based processes. Mounting stakeholder frustration (companies seeking to develop new treatments, insurers formulating policy, providers, and patients) is driving pressures to expedite the time-to-market for new drugs and to make the approval process simpler. In response, the market has been embracing cloud-based solutions such as clinical trial management systems (CTMS), electronic data capture (EDC), electronic trial master file (eTMF), and study startup (SSU), collectively referred to as the eClinical stack, which offer the potential for quantum leaps in cost reductions and accelerated timelines for clinical trials.

Why the cloud?

Cloud computing continues to be a disruptive force in IT with no signs of slowing down. According to the Synergy Research Group, the worldwide cloud computing market grew 28% to $110B in revenues in 2015, and forecasts from the International Data Corporation (IDC) indicate worldwide spending on public cloud services will grow at a 19.4% compound annual growth rate (CAGR) – almost six times the rate of overall IT spending growth – from nearly $70 billion in 2015 to more than $141 billion in 2019. "Cloud computing provides a dramatic opportunity across all industries," according to Randy Bias, Director, OpenStack Foundation, and author of Grasping the Cloud Is Essential to Business Efficiency. "Old businesses are leveraging cloud to disrupt the existing incumbents. Cloud computing is profoundly disruptive in a way few can truly understand."

By playing a critical role in enabling digital transformation, cloud computing lowers typical IT barriers of slow time to value, risky implementations, limited resources, heavy maintenance, and incompatible systems. Allowing cloud computing to free up resources to run the business enables organizations to focus their time and energy on the pursuit of innovation and growth.

Some of the key reasons driving cloud-based adoption are:

- Ease of deployment and management
- Greater flexibility in supporting evolving business needs from both a technical and business perspective
- Lower cost of operations
- Easier way to scale and ensure availability and performance
- Overall ease of use
- According to Nan Bulger, Executive Director of SCIP, the Strategic & Competitive Intelligence Professionals society, and author of The New Decision Influencer, “In profit and nonprofit based businesses alike, the future of anything rests in the ability to influence the bottom line through operational efficiency and effectiveness, customer revenue generation and social impact.”

The need for more efficient clinical trials is driving greater use of cloud-based solutions in the pharmaceutical industry – historically slow in adopting new technologies – especially with the rise in outsourcing and globalization. The “cloud” gives the ability to access value-added services from anywhere at anytime with a level of simplicity, flexibility, and cost-efficiency never seen before.

Leveraging the cloud for speed

The public’s growing dissatisfaction with the clinical trial process is evident in the press with the recent push for expedited programs, such as the 21st Century Cures Act, compassionate use and the “Right to Try” laws leading the vanguard of change to an industry which has been historically mired in regulation and slow to adopt new innovative technologies, technologies which have the ability to significantly reduce cycle times and get much-needed therapies to those in need faster.

Significant financial losses bolster the insistent calls for change. Data from the Tufts Center for the Study of Drug Development indicate that mean clinical development time is 6.7 years, and daily revenue lost because a drug is not yet on the market has been estimated in the range of $1 million – $8 million. To confront these issues of cost and time, the industry has been evolving from its slow paper-based methods toward cloud-based systems. With the flurry of attention focused on the issue of speeding clinical trials, the need for collaborative, cloud-based solutions has never been greater. In the cloud, data is available in real-time from anywhere in the world, and the rapid elasticity afforded to cloud-based hosting solutions can offer virtually infinite scalability – a proposition that is attractive for large Pharma and Contract Research Organizations (CROs). Cloud-based technologies also allow results to be analyzed more quickly and facilitate communication amongst clinical research teams across the globe.

The introduction, and growing adoption, of cloud technologies for clinical trials will lower of cost of technology and thus the barrier to entry, making the cloud attractive for small-to-mid sized biotech, medical device companies and universities. For small companies, cloud computing services can provide a fast way to launch a new product, while keeping the focus on developing product features instead of fine-tuning office servers.

Improving Study Startup with Cloud-Based Services

While companies have often focused on improving study conduct in order to make gains in clinical trial efficiency, stakeholders are becoming increasingly aware that better Study Startup (SSU) processes – a perpetual bottleneck – are linked to shorter clinical timelines, and the emphasis is slowly shifting in that direction. SSU includes activities such as country selection, pre-study visits, site selection and initiation, regulatory document submission, contract and budget execution, and enrolling the first patient.

Research indicates that lengthy start-up times are problematic for many stakeholders: companies seeking to develop new treatments, insurers formulating policy, providers, and patients. Addressing this issue is a challenge because too often, information needed to launch clinical trials still resides in multiple databases, leaving SSU activities to be performed using Excel spreadsheets, e-mail, and shared file drives. Consequently, too much time is spent on non-productive activities, such as status meetings, because the desired information is housed in various locations and is not readily available.

These inefficiencies can be minimized using a purpose-built SaaS SSU solution. With this type of solution, real-time viewing of data and smart workflows that standardize processes become possible. Some key advantages of the solution are: it functions as a single repository for study documents; information only needs to be entered once; and documents from the study database can be accessed using a single logon. Overall, the technology is designed to provide better collaboration with sites, improve business processes, identify bottlenecks, and avoid redundant processes. Using cloud-based technology, a better SSU methodology aligns with the goal of faster development by significantly impacting cycle times. This approach leads to greater cost savings and faster market entry, making valuable therapies available to patients sooner.

Conclusion

Recently published research indicates that by 2020, approximately 70% of clinical trials will be outsourced to CROs. Additionally, industry analysts state that the amount of data produced by the pharmaceutical industry continues to double every six months, leaving little doubt that these trends will present serious operational and scalability challenges to Pharma companies that continue to rely on custom-built or on-premise applications[i].

Fortunately, the cloud's inherent scalability, availability and flexibility offer a natural solution to these challenges. No longer bound by the need to buy, build and maintain IT infrastructure associated with SSU, Pharma and CROs can plug in and collaborate using shared infrastructure. This offers the ability to scale globally as the workflows demand it. And by enabling access to real-time study data and statuses, global study teams can eliminate data silos, make decisions faster, and ultimately speed the pace of clinical trials.

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