



Clinical Trials and the Power of the Cloud

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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 the 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

Industry analysts estimate that the data generated by the pharmaceutical industry doubles every six months and recently published research indicates that by 2020 approximately 70% of clinical trials will be outsourced to CROs. How will on-premise or custom-built applications handle these scale and business operational challenges – simply put they won't.

Cloud computing is attractive because its inherent scalability, availability and flexibility offer the potential to streamline the clinical development process, accelerate timelines, and cut information technology costs. Additionally, the cloud can add a layer of security and control that is simply not possible with paper-based processes. Introducing these important efficiencies into routine clinical processes helps companies adhere to increasingly aggressive timelines, and comply with the changing nature of global regulations in a timely manner.

And while the pharmaceutical industry might not be the vanguard of innovative cloud technology adoption, one thing remains clear – the cloud will continue to revolutionize the healthcare industry by enabling pharmaceutical companies to bring their drugs to patients faster at a lower cost.



Craig Morgan is a technology and life sciences management professional with more than 15 years experience in the application of informatics and bioinformatics to drug discovery. He currently heads up the marketing and brand development functions at goBalto, working with sponsors, CROs and sites to reduce cycle times and improve collaboration and oversight in clinical trials.