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Why the cloud is pivotal to speeding clinical trials

By Craig Morgan

Clinical trials are growing in complexity, complicated further by the convolution of demand, outsourcing and globalization. According to a recent study by KPMG, within the pharmaceutical industry the return on R&D expenditure has fallen from an industry average of approximately 20% in the late 1990s to just 10% today, while the average cost of developing a drug has risen during that period at a rate of 7.4% higher than inflation, due largely to the cost of conducting clinical trials. The drug discovery process is incredibly inefficient, complex, bureaucratic and, above all else, expensive—with only one out of every 10 drugs that start trials being approved by the FDA.

Inefficiencies stem from a variety of issues, including poor site selection, complicated protocols, country-specific regulatory requirements and old-school paper-based processes. Mounting stakeholder frustration calling for greater transparency and changes to expedite the time-to-market for new therapies is adding pressure to automate and speed the adoption of technology, which can elevate these bottlenecks. In response, sponsors and CROs have 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), which offer the potential for quantum leaps in cost reductions and accelerated timelines.

Why is the cloud seen as pivotal to these efforts? Cloud computing lowers typical IT barriers of slow time-to-value, risky implementations, limited resources, heavy maintenance and incompatible systems. This allows organizations to focus their time and efforts on the pursuit of innovation and growth.

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

- Ease of deployment and management
- Greater flexibility in supporting evolving business needs
- Lower cost of operations
- Easier way to scale, ensuring availability and performance
- Overall ease of use

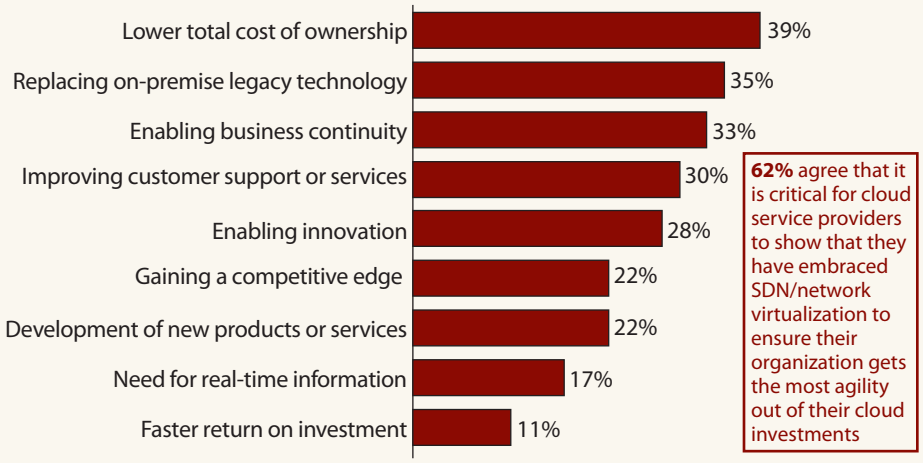
Study conduct has often been the focus of efforts to improve clinical trial efficiency, but as stakeholders become increasingly aware that better SSU processes are linked to shorter timelines, the emphasis has been shifting in that direction. SSU includes activities such as country selection, pre-study visits, site selection and initiation, contract and budget execution and enrolling the first patient.

Research indicates that lengthy start-up times are costly and problematic. SSU presents a challenge because, too often, information needed to start a trial resides in multiple databases, leaving SSU activities to be performed using Excel spreadsheets, email and shared file drives. Clinical operations teams are often dispersed across time zones, further complicating communications and fueling inefficiencies as information is not readily accessible and status updates are not in real-time.

These inefficiencies can be minimized using a purpose-built software as a service (SaaS) SSU solution, allowing real-time status updates, combined with workflows that standardize regulatory/SOP processes. Overall, the technology provides improved collaboration, adherence with business

Speed and low costs amplify cloud investments

What business goals or objectives are driving investments for cloud initiatives at your organization?



Source: 2014 IDG Enterprise Cloud Computing Study

processes and bottleneck identification, and eliminates redundant processes.

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 organizations that continue to rely on custom-built or on-premise applications.

Fortunately, the cloud's inherent scalability, availability and flexibility offer a natural solution to these challenges, eliminating the need to buy, build and maintain IT infrastructure associated with SSU. A shared, globally accessible platform affords study teams the opportunity to eliminate data silos and share institutional knowledge, speeding decisions and ultimately the pace of trials.

Using cloud-based technology, a better SSU methodology aligns with the goal of faster development by significantly impacting cycle times, which haven't budged in over two decades, while providing a flexible infrastructure that can be scaled globally "as needed" to accommodate studies. This approach leads to greater cost savings and faster market entry, allowing valuable therapies to get to patients sooner.

Craig Morgan is a technology and life sciences management professional with more than 15 years experience in the application of informatics to drug discovery. He leads the marketing and brand development functions at goBalto, working with sponsors, CROs and sites to reduce cycle times, improve collaboration and oversight in clinical trials. Email cmorgan@gobalto.com or tweet @goBalto.