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Reach for the Sky

Cloud-based software is now blowing firmly into pharma and biotech companies. Despite initial slow adoption, clinical operations teams are realising its business benefits, particularly for trial master files

Jen Goldsmith at Veeva Systems

It is hard to believe that, in a world where we can instantly send a video from a laptop in a rural US town all the way to a smartphone on a South Pacific beach, many pharma companies still share clinical documentation via email, or worse. Trial managers sometimes fly halfway around the world to view a study's documentation, just to demonstrate they are meeting regulations and prepare for inspection. These inefficiencies are adding tremendous costs, especially to Phase 3 trials, which could easily entail more than 150 sites across 25 countries.

However, the take-up of cloud technologies is bringing a welcome change to clinical operations. Many pharma chief information officers and IT professionals are excited about its promise. Concerns about the open nature of the cloud initially slowed adoption, but the benefits are now being fully recognised by pharma and biotech companies.

In fact, the cloud has become the preferred software platform for life sciences sales and marketing departments,

and is growing rapidly throughout the clinical sphere (1). Medidata Solutions, a leading global provider of cloud-based solutions for clinical research, continues to enjoy year-over-year increases in adoption of its cloud-based platform (2).

Business Benefits

The cloud provides many business benefits that should be considered by clinical operations or document management teams – especially given the complexity of today's trials and the steady increase in partnering with contract research organisations (CROs). GBI Research estimates that the global R&D outsourcing market is expected to reach 37.1 per cent of the total R&D expenditure by 2018 (3). With so many players in different locations worldwide – all under the watchful eye of health authorities – the need for systems that are cost-efficient, highly accessible and easily configurable (characteristics that are innately 'cloud') is acute.

"Cloud is a consistent trend that is making an impact on both the data collection side of trials and the accompanying ecosystem of tools. It will become the most prominent software deployment strategy in all enterprises, including life sciences," says Rick Morrison, head of Comprehend Systems. "The companies in the cloud can take advantage of significant economies of scale, including security and redundancy. Cloud networks typically require no upfront capital expense, which allows sponsors to simply pay for what they use – nothing more, nothing less" (4).

One of the areas where clinical operations teams have the most to gain from moving to the cloud is the management of the trial master file (TMF). With all of the content it must capture from disparate sources, a cloud-based electronic TMF system (eTMF) gives clinical operations managers potentially trial-changing benefits such as streamlined processes for faster start-up and time to market, increased trial oversight and control, and improved collaboration for better quality documentation and milestone adherence.

Centralised Documentation

In all trial phases, clinical studies require focused collaboration among the sponsoring company, CROs, investigators, ethics committees, and many other contributors. Trials need to meet the requirements for regulatory oversight and documentation every step of the way, often for multiple regions. Thousands of documents are required just to launch a new study, and the time required to keep it all straight creates considerable administrative overhead and costs.

In response, we are experiencing an industry shift toward systems that support an eTMF. In fact, 2012 survey data from the DIA TMF Reference Model group showed a 12 per cent increase in the number of respondents planning, building or evaluating an eTMF. Furthermore, a cloud-based eTMF provides superior accessibility and availability over traditional eTMF solutions that are managed internally by sponsors or CROs.

Can the cloud bring sunshine?

The key advantages of a multitenant, cloud-based eTMF system:

- Scales up and down: cloud eTMFs can scale as big or small as needed. Small, pre-commercial sponsors can access the same high-quality software as the largest global pharma companies. Companies of any size can easily start with a single trial or an eTMF archive
- Improves compliance and quality: when the cloud-based eTMF becomes part of the normal workflow, content gets added in real time. This means status reporting is more accurate and the entire team is able to make better decisions. Overall compliance and documentation quality improves
- Enables seamless collaboration: eTMF provides a single, secure place in the cloud for all clinical players to share their documentation in a standardised and fully reportable system

Cloud technology – where software is web-based, rather than installed on individual hard drives or in a sponsor or CRO's data centre – enables document exchange on demand, wherever permissioned users can connect to the internet. Cloud-based eTMF systems provide a centralised, secure place for all clinical players to share their documentation in a standardised and fully reportable system. It can be quickly accessed from any device, anywhere in the world. Necessary changes can be made at any point in the process, and saved back to the cloud repository.

Collaborative Workflow

This is quite different from traditional systems, where lack of access forces each party to maintain their own copies of the documents. The manual hand-offs (email, courier and so on) of these documents can create information overload and propensity for error. Inaccessibility also means that simple questions like "What documents are missing?" and "Has the contract for the site been signed?" take far too long to answer.

The cloud, on the other hand, allows collaborative workflow between sponsors, CROs and investigators, while maintaining a single, consistent audit trail of activities and updates. Everyone works 'on the same page', with complete visibility on all aspects of the study process. This empowers everyone involved in the trial, by giving them direct and real-time access to the information they need in order to understand core metrics and milestones such as site status or inspection readiness.

System Efficiencies

Workflow efficiencies are paramount in clinical trials. Ultimately, these workflows help sponsors meet governance, risk and compliance obligations, too. Cloud-based eTMFs that are accessible by all parties naturally incorporate

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participants into a single workflow structure. The software then automates the flow of documents and tasks between participants to help ensure trial documentation processes are followed to completion. Traditional systems where workflows and TMF documents are tracked manually, in contrast, can lead to inaccuracies, missing information and an overall lack of document control.

"Now, with a bird's eye view of all trial participants and processes, management has a greater opportunity to identify bottlenecks or inefficiencies, so they can improve the clinical process," comments Marcus Thornton of Medidata Solutions.

More important today than ever, the global accessibility of the cloud helps sponsors overcome the difficulties of coordinating trial materials across worldwide locations. A cloud eTMF system is structurally designed to make it easy to provision new users when site locations are added, and to automatically include them in the workflows for that trial.

Faster Start-Up

Implementation of cloud-based eTMF systems can take as little as four weeks. Because the system infrastructure and software is maintained by the vendor, there is nothing to install. In addition, site personnel can be added to the system in minutes, rather than days or weeks.

Cloud applications can be tailored to each individual sponsor without customised code, enabling sponsors to easily configure the out-of-the-box application to reflect their company's standard operating procedures and study protocols. Combined, these features dramatically speed study start-up. "This allows for reduced IT burden and greater accessibility for the clinical team, thereby reducing costs and driving further operational efficiencies," adds Marcus Thornton.

Throughout the clinical trial, sponsors can respond to changes much more quickly when the eTMF system is in the cloud. Most features are configurable by business administrators within the clinical operations team. So, for example, when there is a change in protocol or a need to add new pick-list items, the changes can be made simply.

Bright Future

Worldwide, regulators are recognising that there is a future for life sciences in the cloud, and they are increasingly focused on how to adapt their oversight practices to address the industry shift. This is a necessary step toward more clearly defined rules for use of cloud-based systems in the clinical development process.

The 2011 update of the European Union Guidance on Computerised Systems (EU Annex 11) has provided clarity to both sponsors and vendors on the validation requirements for cloud-based systems, and is influencing the US Food and Drug Administration. As many companies adopt cloud-based eTMF systems, their successful use is helping to dispel any concerns about compliance or security.

Can the life sciences industry embrace the cloud and take advantage of the efficiencies provided by this technology? The answer is yes – and it must. Paper files and locally installed software tools are no longer manageable under today's cost pressures and the urgency to complete worldwide studies successfully. The cloud is key to truly achieving scalability and efficiencies across clinical trials.

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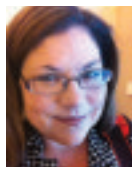
About the author



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