Implementing Interactive Response Technology IN A SOFTWARE-AS-A-SERVICE MODEL

Historically, the software used in clinical trials has taken the form of either a fully installed customized solution, or a hybrid customized and configurable solution. The implementation of such systems has been time-consuming with costly infrastructure, and because minimizing IT delivery times remains crucial for clinical trials, CROs and research Sponsors have the opportunity to embrace new SaaS approaches. This is especially true for interactive response technology (IRT), which is often used to manage randomization, supply of investigational product, patient visit scheduling, and other data collection for clinical studies.

SaaS is Shifting the Landscape

The application of SaaS has shifted the location of the infrastructure from a company server to the cloud. As a result, the time to deliver a fully formed project-specific solution has been reduced from a typical 8-12 weeks to just 4 weeks with platforms such as endpoint Pulse and Medidata Balance. There are additional benefits to implementing IRT via SaaS in terms of cost, scalability, and overall control.

THE SOFTWARE-AS-A-SERVICE MARKET IS EXPECTED TO BE VALUED AT $87 BILLION BY 2015; GROWTH DRIVEN BY THE PHARMACEUTICAL RESEARCH SECTOR.

One clear advantage of using a SaaS IRT solution is reduced burden from related IT costs. There would be no need for dedicated servers, and other than the license fees, no software to purchase, install, and qualify. Consequently, CROs and sponsors would not be required to take on the costs associated with the validation and verification of installation, operation, and performance of the hardware (IQ/OQ/PQ). Once up and running, there is no price to pay for backup of applications, data, and databases. And since maintenance generally takes up over two-thirds of IT budgets, the use of SaaS agreements would provide welcome resource relief.

Another benefit of using IRT in a SaaS arrangement is scalability, as the CRO or sponsor can elect to "insource" as much or as little of the process as their budget and training will allow. This could be especially appealing to a biotech or pharmaceutical company that has a dedicated IRT group or data management staff that are able to easily adapt to different system development life cycles. All of this flexibility allows the organization to maintain greater control over milestones and timelines for system deliveries because there would be no competition for resources after decisions are reached regarding which programs and protocols will take priority.

For companies considering increased utilization of SaaS IRT, there would be new considerations that will need to be addressed. Specifically, there are training and travel costs that need mitigation. And the idea of cloud-based computing raises valid concerns regarding security and reliability.

The added training costs emerge in many areas: IRT project management, IRT system design management, IRT testing and validation, and IRT programming (for items that require customization, and the generation of new databases tables and fields). There are costs associated with travel too, as staff members would go to the vendor's location for training, and the vendor would need to make appearances at the company offices. To allay these costs, IRT subject matter experts could be hired as consultants to bridge the gap until internal employees are fully trained.

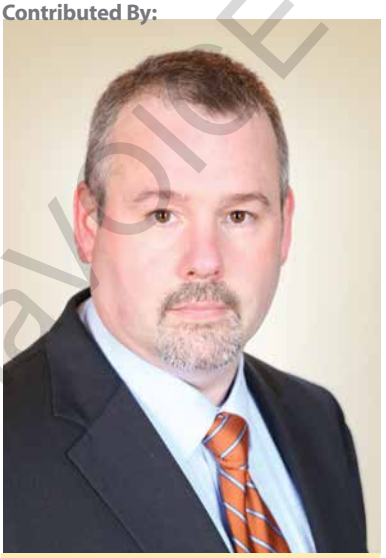
Protection and Privacy Are Paramount

Since the protection and privacy of both the systems and the data is paramount in clinical research, regulators require assurance that using the cloud for trials would be safe. As a response to this concern, an additional layer of protection could be added by supplementing the vendor's software development life cycle (SDLC) procedures with the subscriber company's standard operating procedure.

To address outages outside the control of the vendor, a vendor management program could be instituted. And to ensure compliance on all levels and in all processes, the vendor would be audited on a regular schedule.

Interestingly, when the IBM Center for Applied Insights conducted a study in order to ascertain the trends in SaaS by industry, the pharmaceutical sector stood out because it was discovered that business and IT leaders in pharmaceutical companies collaborate more closely than in other field when choosing and implementing SaaS solutions. Therefore IRT in a SaaS environment appears to make sense as both a business decision and an eclinical delivery decision. PV

Contributed By:



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