ADVERTORIAL

Clinical Trials' Renaissance: Real-time Harmonization of Composite Clinical Trials

By MaxisIT, Inc

Intense financial pressure and competitive forces are making it increasingly difficult to stay focused on the core mission of doing research and continuously maintaining innovative edge in order to compete in today's global market place.

Downward trends on drug prices challenge both R&D investments and net productivity. Uncertain outcomes of a clinical trial, even in Phase III, raise major concerns over the ability to predict safety and efficacy or the drugs – Thus, the industry demands better methods that are more intelligent, which indicates an urgency of reshaping R&D operations.

Traditional solutions, outsourcing partners and legacy systems don't allow the desired efficiency, scalability and quality with the flexibility to adapt. Many organizations depend on expensive eClinical solutions that are error-prone, replete with workarounds across the clinical development landscape without any long term business-technology alignment. Ultimately, the result is a conglomerate collection of heterogeneous technology, a poor user landscape that requires huge support costs and increased setup times for new studies. Moreover, partnering strategies are not supported by any collaborative platform that can span across the geographically distributed

partners (CROs, sites and labs). In short, the strategy lacks a desired level of process transparency, data security, compliance and control.

Despite technology and standards, clinical trials continue to be labor intensive, as well as expensive. And despite various applications that perform many tasks, *such as source data capture and even the creation of the submission oriented Case Report Tabulation – Data Definition document (CRT-DD), known as define-xml, there is de facto disconnect* that often compounds the ambitious goal of a timely submission to the FDA – to site an example. Even with the advent of CDISC standards, which many pharmaceutical companies are now actively embracing, clinical studies are often jeopardized by a fragmented infrastructure such that project managers contend with overwhelming situations where nobody seems to know either *what needs to be done* or *what has been done*.

Part of the problem has been the existence of sovereign departments that do not integrate well with respect to processes, as well as the overall objective, that is, to produce the deliverables for a submission to the FDA. Indeed these departments resemble more a collection of silos.

The world of clinical trials needs a fresh-thought, revitalization in their current processes – an innovative approach or technology that can bring renaissance.

Traditionally, the evolution of processes involving clinical trials might include:

- Electronic or Paper Based Data Collection and Manual Analysis
- Computer Processing Using Data Files and Application Software (e.g. Using various software for Statistical Analysis)
- Proprietary Standards for Processes and Data (e.g., SOP's, Metadata)
- Standardized Data (CDISC, HL7)
- Data Exchange via FTP or Application Integration (XML)

Although technological innovations have afforded better tools, there has been a lack of real integration and true interoperability with respect to processes. Thus, we consider two more steps:

- Interoperability via Process Integration
- Web-based Environment (Global Access)

Nonetheless, the proposed system is *still* not quite complete. Thus, we consider a more holistic platform, as follows:

- Single Source of Process Initiation
- Completely metadata driven, configurable environment
- Standardized, Non-redundant Data Sources
- Full Interoperability Across Processes
- Web-based and Collaborative Environment

The proposed computing platform affords end-to-end processing in a seamless Web-based environment such that professional teams would be able to access one of many studies in order to perform a specific task, accordingly. In fact, a team consisting of professionals located in various parts of the world could function as if everyone were in the same room.

Having an ***integrated and affordable solution*** that can support desired end-to-end clinical development activities under one umbrella was almost impossible, until now. Life sciences organizations are more focused on innovation and managing their core research; they do have neither the time nor the resources to manage multiple software vendors or even multiple service providers. In fact – their limited time and funding must be targeted to end product, not the overall infrastructure. That is the reason why CTRenaissance® is gaining the attention from many industry leaders who are moving toward the next generation of clinical trials' infrastructure that is completely web-based and on-demand – a faster and more affordable alternative. To further extend these benefits to you, MaxisIT, a pioneer in eClinical integration, offering a On-demand Clinical Development Platform for the pharmaceutical and life sciences industry; that is, to apply the power of CTRenaissance® for energizing your innovations.

CTRenaissance® is a configurable, homogenous computing platform that allows options to leverage existing investments in existing infrastructure by integrating and exchanging data in multiple standards such as CDISC, HL7 and even proprietary standards. CTRenaissance® enables the protocol driven execution of clinical development activities from designing monitoring, analyzing, reporting, and including submission so that the majority of the more mundane tasks and manual interventions are automated, thereby allowing end-users to conduct the trial unencumbered. CTRenaissance® provides data and process driven standardization building a layer of abstraction on an existing fragmented landscape and siloed functional views. Its unique approach allows multiple partners and stake holders to collaborate and innovate under one unified and regulatory compliant platform.

CTRenaissance® On-Demand is an integrated and affordable clinical development solutions' suite built from the ground up to meet with the immediate and long-term evolving needs of life sciences organizations with productivity and compliance at its core. It offers a unified view of clinical development operations across the development processes enabling the cross-functional and interdependent stakeholders to make timelier and informed decisions. Simple to use, yet very powerful, CTRenaissance® On-Demand empowers business users with the critical timelines to make the right decisions with confidence.

"CTRenaissance® On-Demand empowers small to large businesses with a web-based and collaborative environment to design, monitor, analyze and submit clinical trials on-demand."

Summary

The fundamental business problem facing pharmaceutical companies doing drug development is to increase the speed of development while reducing the cost. Certainly, the solution is not a collection of standalone applications that were not designed to share information, especially across systems. Instead, the use of industry standards such as CDISC, along with an integrated platform having a true interoperable architecture, offers the best alternative. On such a platform, information would be entered only once and used appropriately at predetermined points; processes would be performed, in some cases automatically, at the appropriate point in the end-to-end process; project management would become more proactive rather than reactive; monitoring of progress would be performed using real-time metrics; and most importantly, the integrity of the deliverables would be unsurpassed.

The proposed platform exemplifies the emergence of Software as a Service (known as SaaS); whereupon, users will access enterprise applications via a Web browser on and as required basis. This value-added service will eliminate the expense and frustration of installing, configuring, and maintaining applications software. The initiative at MaxisIT, Inc. continues to promote industry-wide standards and true interoperability by expanding its own enterprise solution for clinical trials, known as the CTRenaissance® platform.

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