

## More than Data Integration: A Vision for “eClinical”

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Last month, I considered clinical trial technologies that are core to every clinical trial (see, “Implementing Core Clinical Trial Technologies”). Now we’ll consider the vision for future integration of these solutions.

The aim of integration of technologies is certainly the sharing of common data to ensure that all systems have the most up to date information, data don’t need to be re-keyed, and discrepancies are reconciled between applications. For example, a CTMS application receiving live feeds of study recruitment and patient progress data from EDC and RTSM will ensure that the CTMS can be confidently consulted by senior management to provide an accurate picture of progress across the portfolio.

However, integrating common data between systems does not resolve all the areas that an eClinical solution should aim to address. Data integration, for example, does not prevent sites from having to log in and out of different systems to achieve their workflow. For example, entering screening data in EDC, logging out, logging into the web interface of the RTSM solution (IWR), randomizing a subject, returning to EDC to update the subject status and continue entering data. Multiply this by the number of technologies a site must use in a particular study, and the number of studies they are running—many using different vendor solutions—and this becomes inefficient and difficult for busy site personnel.

By further defining eClinical to represent combining technologies in such a way

as to provide process-driven solutions tailored to the way clinical trials are operated by each key user type, we can begin to construct an enhanced vision for how solutions should work together. Think first about other industries: single handheld devices now contain a collection of applications: mobile phone, MP3 player, camera, email system, electronic organizer etc., all once deployed independently, but now through a single interface. Isn’t this the vision of how we’d like to see our technologies working together in the clinical trials arena—to declutter and enhance the way our sites and sponsors work with multiple solutions to manage their studies?

This future vision, then, could be expressed by meeting a number of objectives in addition to simply integrating common data between systems:

**Objective 1. Convergence of Technologies.** Convergence is the blurring of boundaries between once independent applications to create a seamless and highly optimized user experience. Consider Microsoft Office. This suite of products has some elements of convergence built in. Create a chart in Excel, using the graphing module – and the exact same functionality can be accessed within PowerPoint and Word. Expanding this concept to the core clinical trial technologies, if a site is using an EDC application to perform their patient-level activities around data management—it would be optimal for them to be able to perform other patient-level activities through this same system without exiting and entering another application. Making activities such as

randomization and medication dispensing accessible through the EDC interface is an example of this. This doesn’t mean building EDC systems to contain all that functionality, but enabling them to access and utilize that functionality through integration with an RTSM system. Making this happen, however, isn’t as simple as enabling a web-service connection between EDC and RTSM. Other considerations need to be addressed:

- How is this functionality accessed through the EDC interface in a way that’s straightforward and logical for the user?
- Are special forms required within EDC to manage the new processes?
- How are errors and unexpected feedback from the RTSM system reported through the EDC interface?
- What happens if the user performs the RTSM action via IVR or another interface independent of the EDC application?
- What tools within the EDC study designer application need to be created to ensure the integration is configured correctly and data points are mapped correctly between systems?

For a study manager the CTMS application may ideally be their primary interface. Creating and activating user accounts for EDC and RTSM based on CTMS data by triggering actions within the CTMS application, might be an efficient way for them to triage access to study technologies.

None of these examples of convergence can be achieved easily without modifying individual applications to make the integration work effectively, but the objective is to blur the boundaries between applications in

important areas where this blurring can make the use of combined technologies simpler for the user.

**Objective 2.** Data Consolidation for Effective Decision Making. Consider a study manager wishing to assess the performance of their study. They may be required to access independent reports within different internal and external systems. RTSM may give real-time study progress data and information on the status of the supply chain; EDC on data management, query resolution and Source Data Verification progress; CTMS on progress against planned study milestone dates and budgeting; and so on. Piecing together the full picture of study performance is time consuming if it depends upon collation of data and metrics from multiple sources. An eClinical objective is to devise a way to draw data from across many systems and present in a consolidated way through a single interface. A further advantage of this is the ability to enable users who do not have access to some of the source sys-

tems to have access to their data through the common interface. Providing data in the most beneficial way will also mean deriving key performance indicators and metrics of value to the different user types and perspectives involved in measuring study performance and progress, in addition to provision of detailed data for those more intimately involved in aspects of the study.

**Objective 3.** A Common Technology Suite. Microsoft Office became the leading provider for word-processing and spreadsheet software by combining these independent applications as components of a suite. The common look and feel, navigational structure and menus across the suite applications mean that users familiar with one product find the others relatively intuitive. In the eClinical vision, we see sites and sponsors overcoming the issues of having to learn and operate many different applications within and across their studies by utilizing applications that follow a common approach to their use and navigation.

Like convergence, this leads to the apparent feel of working within a single product, particularly if the user is not required to re-authenticate when navigating between individual applications within the suite.

**Objective 4.** Integrated Service Delivery. So far we've focused on the products themselves, but a successful eClinical suite solution must also provide integrated service delivery. The specification, configuration and development of each component application must be delivered in a coordinated manner, to ensure all pieces and the underlying integration can be delivered on time and fully end-to-end tested. This requires oversight by a single project manager. Once live, users should be able to receive support from a single help desk independent of the technology solution they are experiencing difficulty with. Combined with the technology vision of convergence, data convergence and the product suite concept, integrated support and service is the final component of this eClinical vision.