

> Integrating Electronic Systems
in the Clinical Trial Process

+ *As the use of electronic data collection systems continues to proliferate in clinical trials, the demand for integrated systems is, likewise, growing. However, while the somewhat generic concept of ‘integrated systems’ for the clinical trial process is well recognized, often discussed, and quite interesting, only the pioneers have embraced it. Basic stand-alone EDC was in a similar lifecycle stage roughly ten years ago. At that time, there was an understanding that the technology would be a mainstay in the future, but it had a limited number of early adopters. And indeed, the growth of electronic data capture for clinical trials can be represented by a gradual upward slope. The demand for integrated systems appears to be on a similar path. But there are signs that integrated systems will play an increasingly important role in the management of information for clinical trials and for the drug development process in general.*

The signs can be seen in collaboration and consolidation among front-end and back-end systems, increased activity of standards committees, and the emergence of technologies, such as portals, which provide a view of several different data sources.

Defining Integrated Systems

What exactly is an integrated electronic system for clinical trials? Though the term means different things to different people, there are some basic similarities on which the industry can agree. Broadly defined in non-technical terms, it is a system that presents as a single interface into a variety of applications typically used in the clinical trial process; or it may be a system that gathers, consolidates, and presents information from disparate sources. In a perfect world, an integrated system for clinical trials would have a single point of entry into all related applications or modules and utilize data consolidated within a single database.

This may be best explained through the following scenarios. It is possible to construct a portal or ‘dashboard’ that would enable a user to log in once and have access to various tools. The tools may include a data entry system (EDC) for a study, perhaps a reporting center, and a site management component that houses site and site user information. However, this information is not necessarily derived from single source. That is, site data may have been collected separately and stored in a separate database from the EDC data. And it is possible that certain reports are created from data entered into a database that is also different from the EDC database.

While this may be relatively invisible to the end user, this could not be considered a truly integrated system, though it will certainly meet the requirements of many users. It is

also possible to construct a system that would gather data from various sources and consolidate in a single database, making the consolidated data available to the end user through a single access point.

For example, data may be derived from electronic patient diaries and from EDC tools and from central laboratories, and then consolidated in a single database, permitting the end user to access this multisource data together.

In this example, the components may or may not be accessed through a portal but the data is truly integrated. To take this a step further, some methods of data integration are more proactive than others. A seamless integration whereby data from points A, B, and C all mingle at point D automatically with little or no user intervention is far more desirable than a manual transfer of data from points A, B, or C into point D. Most useful would be a system tightly integrated both at the user interface level and the underlying architecture level. In combining the best features of the two examples given above, a well organized and integrated electronic system would allow the user to enter through a single access point – a ‘portal’. Based upon the user’s role and privileges (profile), he or she would be granted or denied access to the various components of the system.

Within a portal, a user might place a request for additional clinical supplies, then click another tab to enter data into an eCRF, and then click on the reporting center to check

enrollment status. But in this scenario, upon checking the eCRF the user would see the date the clinical supplies were requested. In the reporting center the user would see the enrollment status that has just been updated based on the work done within the eCRF.

Moving on to a grants management tab, the user would see a payment request generated based on the procedures just completed within the eCRF.

What Is Included in Integrated Systems

The preceding examples are not intended to imply that there is a right way and a wrong way to define an integrated system. On the contrary, they should show that 'integration', in our industry, can be interpreted differently, and that what may be acceptable to one buyer is unacceptable to another. However, it is also important to understand that a truly integrated approach is usually preferred over systems that require data to be pushed and pulled and manipulated between its point of origination and its end point, simply from a manageability and integrity perspective. Is an integrated system for clinical trials also defined by inclusion or exclusion of specific components?

No, an integrated system may blend any number of components – there is nothing specific that must be included. Rather, it is up to the Sponsor to determine what data elements are most beneficial. Modules or components that comprise an integrated system for clinical trials are any technologies that are routinely, or even rarely, used in the clinical trial process. This includes, but is not limited to:

- Electronic data capture
- Clinical database management system (CDMS)
- Clinical trials management system (CTMS)
- IVRS
- Electronic Patient Diary
- Site Management system
- Reporting system
- Cardiovascular devices—EKG, blood pressure, pulse, etc.
- Respiratory devices – peak flow, etc.
- Devices that capture physiologic
- Central laboratory
- Grants management (may be part of CTMS)
- Scheduling (may be part of CTMS or Site Management)
- Clinical supply
- Electronic submission system
- Printing system (for CRFs, workbooks, audit trails, etc.)
- Document Management system
- Patient recruitment system

- Investigator recruitment / Investigator database
- Protocol simulation
- Statistical / Analytical tools
- Warehousing and mining
- And others

The growing requests for integrated systems make sense and should be expected. As the technologies continue to improve and address specific needs within the trial process, and as buyers become more savvy technology users, one would expect the requirements to increase. As these users become more comfortable embedding the technologies within their everyday workflow, they'll seek ways to increase efficiencies further and build in more convenience for themselves and the organization. This is where the integrated, single-stop shop has so much appeal. When the user must log in and log out of multiple disconnected systems, it is inconvenient. Where a user, or IT department, must be concerned that data from a variety of sources is accurately brought together, there is fear and trepidation. An integrated system, both in underlying architecture and end user interface, quells these problems and fears.

The Future of Data Integration

While it is true that offering a large number of tools through an integrated platform is valuable, it may also be unnecessary for many users and buyers in the near future. The value of integration will grow over time, as companies realize the efficiencies and advantages to storing and viewing data in one format. As it was with EDC, it is expected that the competitive advantage of integrating various data sources will be available first to those companies who are nimble enough to undertake the transformation without massive internal reorganizations and the displacing of huge legacy systems.

For many small to mid-sized life science companies, while there is limited resource to research numerous technologies, there is less internal resistance to change. For these companies, the benefit of being able to see data catalogued across a number of studies and across a number of data sources is significant. It provides a view and a level of analysis that was previously difficult at best, impossible at worst. When seeking an integrated electronic system for clinical trials, the buyer must have a clear plan for current and future requirements. What does the organization want to accomplish now? What available technologies meet those requirements? What does the organization want to accomplish in 2 years? 5 years? Do any technologies meet those requirements today? If yes, is

there a trade-off between quality of the components and the fact that the system is integrated? If no, is there technology available that, by virtue of architecture and design, can be developed into the broad platform that the organization desires? Many technologies used within clinical development have experienced a slow but steady adoption. It is likely that integrated systems for clinical trials will likewise witness a slow but consistent growth. Buyers of such systems should carefully plan their implementation path and consider the expansion potential of an integrated platform that can grow with their needs.

About Merge Healthcare

Merge Healthcare is the leading provider of enterprise imaging and interoperability solutions. Merge solutions facilitate the sharing of images to create a more effective and efficient electronic healthcare experience for patients and physicians. Merge provides enterprise imaging solutions for radiology, cardiology and orthopaedics; a suite of products for clinical trials; software for financial and pre-surgical management, and applications that fuel the largest modality vendors in the world. Merge's products have been used by healthcare providers, vendors and researchers worldwide to improve patient care for more than 20 years. Additional information can be found at www.merge.com.

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