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NEXT GEN EDC

Making EDC Integration Work

By **David Stein & Solomon Shacter**

Should all clinical technology systems be linked? Or can they stand apart? That is a fundamental question facing those who select and implement clinical trial technology systems in the coming era of eclinical trials.

Over time, vendors like ourselves have created specific applications that power niche areas of a clinical project. These applications are driven by the needs of specific users. So far, so good.

Key Linkages

But a great deal of overlap often exists in the data required by each program. Yes, some overlap between applications is natural and inevitable. But usually such overlap will not lead to the outright elimination of applications. Instead, the importance of each application creates another need—for combining or integrating data.

It is with integration, we believe, that the full promise of electronic data capture can be realized. Without integration, clinical trial software may simply introduce new silos of information, even new sources of inefficiency. Clinical trial technology integration is not for beginners.

The Challenge

Integration, fortunately, is already yielding early benefits. These can include the elimination of redundant data entry and associated discrepancies between databases; the immediate availability of data in multiple applications; and faster decision-making and database lock. The ultimate value of a successful integration strategy is realized when it enables interoperability.

Interoperability, quite simply, is the ability of two or more systems or components to exchange and use the same information. Interoperability may include just one sign-on to all systems, advanced searches and reporting across all data points. It may encompass a full audit trail of all data exchanges. An integrated electronic data capture (EDC) system may exchange information with many data streams including labs, electronic patient reported outcomes (ePRO), interactive voice response systems (IVRS), drug safety, dictionary coding, clinical trial management systems—and more.

Patient randomization is a good illustration. Many EDC systems can perform simple randomizations. However, such systems do not address management of the drug supply chain on the project, or patient dosing at follow-up visits.

A Case History

More importantly, many sites do not have a web-connected PC in the same area where patient visits occur. So the IVRS remains the most common method of randomizing and dosing patients.

The benefits of integration are well-documented. But there are few publications that address the challenges of integration and how these can be overcome. In fact, a number of clinical trial technology vendors have stated that “integration is easy.” Really?

In one case we’re familiar with, an EDC vendor was sending automated messages to an IVR vendor whenever a patient withdrawal was logged into an electronic case report form (eCRF). This ensured that the IVR system would stop allocating drugs for patients who were no longer in the trial.

What could go wrong? Plenty. The EDC vendor had a software upgrade. It was tested rigorously and switched on. But the EDC vendor did not include any integration projects in their upgrade testing and failed to notice that the upgraded EDC system

stopped sending withdrawal messages to the IVR. Since withdrawals do not occur every day, some time passed before this oversight was noticed. The trial, needless to say, was delayed.

Having A Plan

While integration may appear to be easy to set up to IT personnel, it requires high rigor in planning, maintenance and support. All integrations must be considered an integral part of the systems they touch and should be included in plans for upgrades, hot fixes and other changes.

When multiple in-house teams or external vendors are involved, more issues are raised. Organizations linking their applications should have technical plans and documents, as well as best practices for building, maintaining and supporting integration projects.

The Clinical Hub

One common approach to these information exchanges is a point-to-point manner. The EDC system connected might have five separate connectors to other systems that must be built and maintained. What are the implications of this model?

Each and every connector must be tested every time one element is updated. This represents significant time and effort. It could discourage building such integrations in the first place. Is there a way to gain efficiencies? The answer lies in a concept used in other industries for the past two to three decades.

“Middleware,” essentially, is software that sits in the middle of two or more applications and facilitates all interactions between these systems, including, but not limited to, data exchanges and mapping.

Meeting Industry Standards

Each application that connects to the middleware hub has only one connector. Thus, if one application is upgraded or replaced, which happens frequently during the course of a trial, only one connector is affected. So long as the new system exchanges the same messages, the single connector need not be changed.

While commercially available middleware products exist, they are prohibitively expensive and serve a broad IT market, not having been customized for the life sciences. They tend to be general tools to connect systems but lack HIPAA, HL7, and 21 CFR Part 11 compliance and do not follow any clinical industry standards such as CDISC, SDTM or DICOM.

A Better Way

When discussing clinical middleware, we like the term Clinical Technology Interchange Platform (CTIP). A CTIP has the advantage of existing connectors that can serve as templates for future integrations. The CTIP offers a simpler approach that is easier to update and troubleshoot. It will pay off over time, as trials become more complex.

As clinical technologies continue to gain adoption and scale up, integrations will continue to proliferate. We doubt it will be practical for organizations running and managing trials to support individual point-to-point solutions. Little by little, CTIP will take over and be the preferred way to enable an eclinical strategy.

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