

## Electronic Source Record: Fulfilling the Promise of EDC

*“This is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning.”* Winston Churchill

The much-heralded EDC revolution has reached a decisive point, to use an equally heralded term, a ‘tipping’ point. 58% of clinical trials started last year employed EDC systems. Sponsors have implemented EDC systems in trials ranging from Phase I to Phase IV and are beginning to reap the benefits of their multi-year deployment efforts. Current EDC systems have come a long way from the first generation remote data entry systems (RDE) and have overcome many of the limitations of the second generation, laptop based, study specific systems.

However, tipping points are tricky and sometimes it is difficult to determine the direction of the tip. While sponsors are generally satisfied with EDC, research sites appear to be increasingly dissatisfied. The very systems that streamline data processing for the sponsor impose significant burdens on the research sites. EDC systems were designed with the requirements of the sponsor, who after all pays for them, firmly in mind. Discussions of EDC are almost always focused on sponsor-side issues; rarely are Investigators, not to mention coordinators, given the opportunity to discuss the impact of EDC on their work. And yet over 50% of Investigators fail to complete more than one trial. Considering the resources expended on recruiting Investigators and the shockingly low retention rate, clearly more needs to be done to make participating in clinical research more attractive to physicians.

Perhaps the tipping point will prove to be that Investigators simply cannot accept more EDC trials until new systems are designed that better address the needs of the research sites as well as those of the sponsors. To do so, these next generation systems must overcome the inherent limitations of both EDC and paper source documents. What is called for is an Electronic Source Record (ESR). To fulfill the promise of EDC, ESR must accomplish four key objectives:

1. Electronic capture of initial source documents/data
2. Site-centric user interface that facilitates patient interactions
3. Remote viewing of source documents – not just the data
4. Integration of patient clinical and medical information.

### Electronic Capture of Source Documents – not CRFs

First, data capture must be extended all the way to the beginning of the data stream and include source documents. Current EDC tools reflect the limitations of their origins in RDE systems; they are electronic versions of an old, inefficient paper process that required both source documents and case report forms (CRF). ESR tools will eliminate not just the paper case report form but the case report form altogether by initially capturing the source data electronically (eSource) and then transmitting downstream only

that data required by the sponsor. The benefits of eliminating the CRF (paper or electronic) step are numerous and compelling.

Using eSource allows data to be entered only once, greatly reducing the burden on the research site. No longer will coordinators or dedicated data entry personnel spend hours transcribing data from paper source to eCRF screens long after the visit. Point of capture edit checks greatly reduce data entry errors and clarifications requiring the subject's input are completed while they are still onsite. Sponsors get clean data in real time. Since the source document is electronic, a robust audit trail is possible. All data entries are attributable, reducing the likelihood of fraud. The majority of queries are also avoided with the elimination of eCRFs because there is no difference between the source document and the source data. Finally, eSource documents can be stored and retrieved far more securely and cheaply than paper source documents.

#### Site-centric Software Design

Second, ESR systems must do a better job addressing the workflow needs of the research sites. Fundamentally, people are accustomed to working with documents – not data entry screens/forms. A simple, elegant user interface that reflects a document-based site workflow is needed. Current EDC applications are far too often described as cumbersome due to the focus on data entry. Consequently, rather than enhancing the work of site staff, they become the source of frustration; rather than decreasing the burden and expense of collecting data, they increase it. While the usability of some EDC systems has improved somewhat, new systems require even more intuitive interfaces that allow data to be captured with a minimum of intrusion, confusion and training. Ideally, these new tools will fade into the background of the coordinator / patient interaction as much as possible.

Clinical research also requires mobile data capture, regardless of connectivity. While the web is a great place to host software that aggregates and displays data, capturing that data requires an application that is mobile and works whether or not it's connected to the web. Current web-based EDC systems feature zero footprint deployment but require a constant connection to work at all. Coordinators interview subjects in various locations, from down the hall to across town, and their data capture system must be able to accommodate this mobility. ESR systems will be hybrids that take advantage of the strengths of both approaches, using mobile devices for the initial capture of data and web based components to review and share the data.

#### Remote Monitoring

Third, an ESR should allow CRA's, data managers and others with proper authority to view source data and documents remotely. Simply being able to review *data* is not enough; the *documents* themselves must be available for remote review. Having secure, remote access to source documents provides the full context of the study information rather than only the subset of data that is currently reentered into EDC screens and passed downstream. Remote viewing of eSource allows clarifications to be made without having to travel to the site.

Overcoming the source document / data divide also makes faster and more complete reporting of safety concerns possible. Safety teams have immediate access to both the

data and the documents that provide the essential context. Furthermore, since there is only one data set, source data verification—an artifact of the limitations inherent in paper data collection—is completely eliminated. Security measures need to safeguard the data and to ensure that only authorized research site personnel can create or modify source data. While eSource security requires careful attention, the reality of paper source documents is that they are highly insecure and open to manipulation, loss or destruction. Ultimately, ESR systems have the potential to integrate subject visit information with consent and regulatory information in one seamless interface.

### Clinical Data Integration

Fourth, and finally, an ESR must provide a means by which patient data can be shared with site electronic medical records (EMR). While the challenges to data integration are generally acknowledged, many within the industry naively believe that EMRs will displace systems designed specifically to collect clinical data. The principal integration challenge is the handling of the discrete data elements within separate systems designed for distinct purposes.

To be sure, at a technical level the data “could” be exchanged but at this point there are far too many unknowns to expect widespread integration for many years – we need only look at the EMRs that have been in place in the United Kingdom over the last 15 years to realize that the dream of seamless integration of clinical and medical data is years away. Eventually, data standards may evolve to the point where selective patient information could prepopulate the clinical system used to capture specific trial-related information, medical history and concomitant medications, for example; however, the unique requirements of each study will make it extremely difficult for EMR applications to serve effectively as a clinical research platform.

Nonetheless, the opportunity to share research information from an electronic source record as a document image is much closer. An ESR application has the advantage of capturing information as a document – the document image can then be shared with the EMR system thus eliminating the redundant data entry necessary to record the research visit as part of the patient’s medical record. This accomplishes the goal of making the clinical research information an integral part of the patient record without the necessity of solving the complex data integration problems at each site.

eClinical technologies, particularly EDC, have made remarkable progress in a few short years. However, the promise of reducing clinical trial costs remains elusive. As Churchill suggests, perhaps we are nearing the end of the beginning. The success and limitations of current EDC tools calls for renewed effort to focus on technologies that address the core problems. ESR systems offer benefits to sites and sponsors in ways that directly eliminate cost and time, fulfilling the original promise of EDC.

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