

## Full Service EDC: Blending Technology with Clinical Expertise

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### Data, Data, Data

The sole product of the drug development enterprise is the creation of information. Given this pre-eminent role of data, it is remarkable that every serious drug development enterprise does not utilize the most advanced methods for data collection, cataloging, distribution and analysis for every clinical trial. This is especially baffling as these technologies are robust, cost effective and are really the only way to deal efficiently with the growing quantity of data needed to support a drug marketing application.

Despite earlier reluctance, it is evident that the adoption of these technologies is now accelerating. A recent study found that 83 percent of clinical trial sponsors reported using EDC as part of their research efforts. That same study also found that over 50 percent of clinical trials professionals find EDC more attractive as an outsourced service. Pharmaceutical companies of all sizes seek EDC vendors that can tackle the whole spectrum of the data collection needs with both clinical experience and technological expertise. These findings and respective rationales support the requisite bottom line: the demand for trials that are efficient in cost and performance, ensuring quick study preparation and close-out as well as subject safety through enhanced reporting and risk management safety.

### What About the Little and the Not-So-Little-But-Still-Little-By-Comparison Guys?

EDC use for small-to-mid size companies has commonly been perceived as a potentially risky proposition. Resource-challenged clinical groups of less than 100 employees often do not have the internal support, funds or infrastructure to support a large investment in EDC technology. Issues surrounding hardware installation, IT support, system validation, ongoing training and high recurring costs have, at one time or another, been claimed as reasons why EDC is not for them. The cost and time associated with training is often more than a typical small-to-mid size drug developer can absorb, especially since the software requires customization for each trial. These companies simply don't run enough trials to rack up the necessary experience to become fluent in the process. Adding sophisticated tools and integration requirements can worsen the chances for success instead of improving the results.

### Is a CRO the Answer?

Some drug developers turn to their CRO as a resource for both EDC and data management. Many CROs looking to expand their product list and increase revenues are eager to offer data management as a line item. However, in many instances their attempts at combining eClinical with outsourced data management do not achieve expectations. If the CRO has not embraced fully electronic processes they may not be capable of utilizing the chosen technology to its maximum. Also, since these groups often actually just lease the EDC services for the study, they are largely stuck with whatever cost and delay the CRO dictates is necessary to make it work. They have no real control.

Many CROs still prefer paper-based studies and will only perform EDC studies if a sponsor insists. A CRO's EDC experience is often spread across various technologies and vendors. Combined with staff turnover and availability, their learning curve on these technologies may start closer to the bottom than sponsors would like to believe.

## **The Full Arsenal**

There is a better approach. The solution is not just to outsource EDC, but to couple EDC with electronic data management as an integrated offering, supported by experienced staff. It's not just the EDC technology that needs outside expertise – it's the clinical data management experience, too. This is especially valuable when trying to extract the most from these powerful data capture, data visualization, and data analysis technologies.

Combining EDC with electronic data management yields faster start-up time with more comprehensive edit checks, better compliance to the data management specifications, real-time access to high quality data and the ability to change the study as a result of emerging information (i.e., adaptive trials). With all of the pressures on pharmaceutical companies from regulators, investors, patients, and the public at large, the more efficient, transparent, and integrated the clinical data management process is, the faster the data can be put into use.

For small-to-mid size pharmaceutical companies, devoting an entire infrastructure to manage and master eClinical technologies can be a distraction, and even an impediment, to extracting the lifeblood data. By outsourcing for the full range of EDC services to a single, capable vendor, they acquire an arsenal of technology and clinical expertise and can focus on what they do best: getting drugs to market in the quickest, safest, most cost-effective manner possible.

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