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THE MYTHS AND REALITIES ABOUT EDC IN TODAY'S CLINICAL RESEARCH

In nearly every aspect of today's society, we enjoy the benefits and the efficiencies of technology's impact. We buy theater and plane tickets online, travel with directions from global positioning satellites, and accomplish everything from paying bills to making dinner reservations and then instant messaging the details. With a laptop and a cell phone we could be anywhere.

But where are we in the world of clinical research? In this field, we have celebrated fantastic advances in medical breakthroughs and in the delivery methods of them. Who would have thought that laser-eye surgery would become as commonplace as it is today? Birth control via a patch? The list of accomplishments and advances is staggering ... and the outlook is that this process will accelerate in the short term. Yet these manufacturers will often tell stories of the long road and tedious process required to get approval and to realize the end of the journey from idea to in-house labs to pharmacy shelves.

Contract research organizations endeavor to make sure that new pharmaceuticals are thoroughly tested and made compliant with the given FDA regulations in the shortest and most efficient way possible. Before they enter the marketplace, pharma developers have to make certain about the purported benefits of their product, and they must do so without sacrificing the quality of the research or the integrity of the data involved. Through the use of technology, CROs can enhance the ability of a pharma developer to smooth through the process of FDA approval by providing client data in real time, so that for instance, dosage and composition questions do not bring down the integrity (and ultimate viability) of the macro study. These changes are possible in real time.

So one would think that an industry such as this would embrace the future, and not hold on to archaic methods of collecting data. Why is there still resistance, when it is apparent that technology in this field has the potential to have massive beneficial impacts?

The answer may lie in the myths that surround electronic data capture (EDC). When examined closely, however, many of these fall away when contrasted with today's reality because they have to deal with a client's potential objections on a day-to-day basis. Here are some of the major obstacles encountered when talking to contacts out in the field, so without further ado, a drum roll please for the top five reasons why EDC is not more universally embraced today:

MYTH NO. 1: EDC is less secure.

REALITY: The truth is that with encryption, multiple levels of password security, etc., transactions are much safer online than at the corner grocery. By an overwhelming margin, this is the No. 1 myth, not necessarily surprising, because it does reflect a general security concern expressed by online bankers, shoppers, etc. when doing transactions.

Remember Y2K? Under most normal circumstances, the fact that the preponderance of feared glitches and problems did not materialize would have been a reason for IT departments at pharmaceutical firms to emerge smugly and advocate a greater reliance upon EDC methodology. And in fact, this did occur — but at a very slow pace when compared with other fields, for example financial services.

It has been postulated that the inherent conservative nature of pharmaceutical companies is a big reason, yet why the pharma industry and not banking, for instance? Government regulators are not an adequate explanatory factor — not in this age of online tax filings. Of course, the U.S. FDA has accepted and approved EDC-gathered data for quite some time.

In truth, all of these factors are partial explanations, and they add up to a general climate of resistance to change. Yet not even the most conservative people in the pharmaceutical industry deny that the day is coming when EDC will be the norm; the only disagreement is the pace at which this transition occurs.

The real truth is that nothing is perfectly secure. We all know paper can be lost, stolen, or destroyed. The track record of EDC in pharmaceutical trials compares very favorably with other industries and against other modes of data collection. Procedures can be followed to minimize all security risks. All files, including data and programming, can be backed-up daily and sent to secure storage off site for disaster recovery. Only authorized personnel have access to databases. In addition, a controlled procedure can be used to archive two sets of data containing all pertinent system files employed for each project, for example, software, data sets, screen modules, programming, and listing files.

Now, imagine asking a basic paper-diary shop to make back-up copies and warehouse them off-premise. Assuming they could find the labor pool to do such a tedious task, just imagine what that would do to a project's budget and cost-structure. This leads to Myth No. 2.

MYTH NO. 2: EDC is more expensive.

REALITY: You do get what you pay for, but not necessarily what you ask for.

When a pharmaceutical company budgets for research and testing, EDC is certainly contemplated. But, EDC often is viewed as an additional line item, which would in many instances add to the overall testing budget by 40% to 50% or more. This is one of the most-often cited myths about EDC — that it is a high-tech add-on that might yield some long-term efficiencies and speed, but in the short term the associated costs are highly prohibitive to con-

template. What these budgeters do not realize, or acknowledge, is the immediate savings that a switch to EDC might engender.

This is in the face of some fine studies in the industry that have shown in detail that whether Phase I, II, III or IIIb trials are analyzed, the absolute worst-case scenario is that the costs associated with EDC versus paper are a statistical dead-heat. In most cases, however, the savings that could be realized by using EDC are so substantial as to make any bean counter blink with surprise and perhaps dance with glee.

By far the biggest savings are realized by the lower reliance on field-audits and monitoring that yield on-site queries, and the associated general administration and management fees. Many times a study can be held up while a field monitor awaits a query response. The study's progress grinds to a halt; but the costs continue.

Some CROs are often their own worst enemy. CROs with large labor pools are primarily composed of field monitors and related personnel. Of course, the trick is to keep them active and productive. Firms with the largest employee count are going to be least likely to recommend EDC in its most favorable — efficient — light. Even if it is a viable weapon in the arsenal, many companies will position EDC as an expensive addition, so as not to compromise the integrity of their labor force.

In contrast, data that come to an EDC-based CRO are analyzed and queried in real-time, and most general queries are handled before the field monitors have a chance to encounter them, thus their field visits are fewer in number. Those that do occur are more often than not shorter, more efficient, and productive because the monitors are primarily concentrating on their necessary audit functions. Remember, no one in the industry disputes that the future belongs to EDC; however, it is the lean and mighty companies that will rule the day when competitive markets are employed.

An associated sub-myth, regarding the cost component is that to transition to EDC, it will be necessary to lease or purchase a wide variety of specialty hardware, software, and other associated gizmos to make it happen. If that were the case, no CRO would ever get its foot in the door. The major hardware modes of EDC-oriented firms are the touch-tone telephone, fax machine, and the Internet. If you are reading this, chances are you have all three at your disposal.

MYTH NO. 3: Pharma clients will have to adapt to an unfamiliar, inflexible system of data capture. Clients will need to further absorb the greater costs and efforts to support a specific technology.

REALITY: In other words, the process of conversion to a Web-based system of data capture is the demon here. Not so. As noted above, data capturing can be done through fax forms, the telephone, and even paper that is scanned in addition to being Web-based. The associated myth that major technical support is going to increase the burden on pharma companies also is mostly untrue. The simple fact is that if a pharma firm is still left with these impressions, it is probably because the selling research organization did not do a thorough enough job of acquainting the prospect with all the options available and/or they had some favorite "sacred cow" mode of technology it was enamored with at the time. Similarly, the support of a given system is usually the province of the technology vendor. While there may in fact be a cost component here, in most cases the client will see little (if any) increase in cost to them. The CRO is the system owner, and the client usually leases the package with support as part of the initial price.

MYTH NO. 4: All the options for data capture will lead to difficulties in aggregating data from various source material.

REALITY: This is a dragon that has been slain for a long time.

The use of technology such as Cardiff's .pdf+Forms and Criterium's Study Control system has enabled research studies to accept and summarize data from a variety of source material.

MYTH NO.5: The use of EDC monitoring will compromise the "human touch" in interpreting data.

REALITY: EDC systems are about speed, efficiency, and increased accuracy.

This is one of the longest-standing myth's — one that of course supercedes pharmaceutical research and gets to the heart of technology in society. The fact that a field monitor spends less time at the beginning of a study correcting picky errors and queries and applies his or her time to productively concentrate on the specific functions that they do, makes the process no less human. And in fact, the systems that look for response deviations that are outside the expected norm usually prompt an actual human being in the home office for more immediate and timely follow-up.

LOOKING AHEAD

While there are still some predominating myths remaining in the marketplace that appear to be forestalling wholesale application and acceptance of EDC, no one in the pharmaceutical industry expects that a regression to the tedious processes of yesteryear is in the offing. That the FDA has accepted EDC data for sometime is further evidence of its viability. Those who resist the marketplace's transition to leaner, more efficient, and more thorough modes of delivering pharmaceutical advances to market appear to be as futile as King Canute commanding the oceans to stop making waves. Yet before CROs celebrate impending victory as a foregone conclusion, they must first make a concerted effort to educate the fearful and the resistant, and while in advocating a certain course of action, they should be resolute in informing potential clients about the variety of options, as well as the costs associated with them. The major conclusion that should be derived from thorough consultations with clients, if they are educated thoroughly, is that the change to EDC is something that should be cause for their celebration, especially for their bottom lines.

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