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Feature

4 Ways You Can Overcome Roadblocks To Technology Adoption In Clinical Trials

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Technology continues to advance at almost breakneck speeds. Not only are these advancements surpassing anything we could have imagined just 10 or 20 years ago, they are touching every professional field, including Life Sciences. More advanced computers, displays, and software programs are replacing paper, cards, files, and binders in libraries, banks, and professional offices around the world. Yet despite a clear need and desire to move in a paperless direction, clinical trials still lag far behind other highly regulated industries.

For most tasks, there is no question the electronic method of input is preferred over paper. This doesn't apply to just casual interactions on social media, like reconnecting with old friends via Facebook or viewing photos of far-flung grandchildren on Pinterest or Instagram. We do our banking online. We shop online. And we transmit highly private and sensitive data over the internet all the time. If visiting a doctor's office or applying for a job, would you prefer they hand you a stack of forms to fill out, or sit you in front of a terminal where you can electronically enter the information?

You would think this ease and comfort with technology in our private lives would seamlessly transfer over to the professional space. Unfortunately, it doesn't. Some have argued there are multiple factors at play here: processes mired in multi-vendor complications, employee comfort with new technologies, a lack of understanding (or interpretation) when it comes to regulation and guidelines, and of course the dreaded specter of cost. Fortunately, it doesn't have to be this way, especially with respect to Study Start Up and Trial Master File storage.

With this in mind, let's look at why companies resist the move to a paperless environment, and why these roadblocks should be eliminated as quickly as possible so as to decrease cost and increase efficiency across all of your clinical trials.

1. One of the most common reasons companies do not move toward an electronic environment stems from our multi-vendor clinical trial structure. Generally, each vendor will have a system they prefer using. This often results in translating too many passwords and wasted time on training and retraining staff on multiple systems (It has been noted that even with only one system to learn and implement, users may experience difficulty). Fortunately, a single-system submission, with a review and approval interface during study start up, can save companies time on training and allow investigative sites to focus on patient safety. Furthermore, familiarity with a single system yields increased user compliance and allows for higher data quality.

2. Employee unfamiliarity with technology, or employee aversions to using new technologies, is also cited as a factor that leads to hesitancy in adopting new solutions. However, according to SoCRAs 2010 survey[1] of employed Clinical Research Coordinators, the majority of coordinators are aged 45 and above. Recent research[2] into the comfort level of technology users by age determined that only 9% of respondents aged 45+ classify themselves as "Somewhat Uncomfortable" and "Very Uncomfortable" with technology. More than 50% deem themselves "Comfortable" while 36% classify themselves as "Very Proficient." Combine that with the fact that men and women aged 55-64 are the fastest growing demographic using social media[3], and you have a strong argument against these folks having a lack of comfort with technology. It's possible that some workers will be afraid of any change and the unknown aspects of it, even when they are comfortable with the technology. This fear can be overcome with proper education and training.

3. If employees are comfortable with technology, why are a majority of companies in the industry still apprehensive about moving towards an electronic environment? Some will cite concerns over regulatory oversight. But what exactly does the FDA have to say about paperless clinical trials, and what are the current rules we need to follow? Luckily for us, the FDA and EMA have both acknowledged the paperless direction in which the industry is headed. In early 2013, the EMA published[4] a reflection paper on GCP compliance in relation to trial master files (paper and/or electronic) for management, audit, and inspection of clinical trials. Specifically, the paper discussed guidelines for audit and inspection. Similarly, in September 2013, the FDA released guidance[5] on the Electronic Source Data in Clinical Investigations. In this guidance, the FDA went a step further by releasing confirmation that they now accept digital and electronic signatures in place of wet signatures[6].

4. As with many things in life, the decision over whether or not to go paperless may simply come down to cost. There always

seems to be an underlying belief that the decision to go electronic (paperless) will involve additional costs. Some of these concerns are valid – certainly computers will need to be updated and Internet access will have to be installed at those clinical sites that don't have it. In addition to the cost, there are also problems of perception. The public generally believes any new technology will be expensive. In the case of electronic trials, this is simply not the case. When you take into consideration the resulting cost savings from going paperless, the cost can be minimal. In fact, the opportunity cost of NOT going paperless (lost hours of staff productivity spent digging through binders full of paper to file or retrieve a document) makes the actual costs seem trivial.

If you're still not convinced, consider one additional benefit. At the investigative site level, we often see sites leaving the global clinical trial space after one or two studies, simply due to cost inefficiencies[7]. With paperless studies, the decreased time spent collecting and mailing documents also contributes to greater efficiency and lower costs. This efficiency, as well as the more organized nature of the eTMF structure, allows sites to participate in more global trials, and subsequently increase the site's revenue.

A 2013 TMF Reference Model survey determined that 37% of respondents currently use an eTMF with 14% building/implementing one and 20% in the process of evaluating systems. Although these numbers are promising, 30% of industry vendors are not advancing their use of technology. There will always be reasons not to embrace a new way of doing something. Our industry's ultimate objective is to push for needed advancements, to research, test, and discover new and better ways to treat patients, and to improve quality of life. Change in the clinical space is progress, and I would argue that embracing the electronic and paperless clinical trial will help us reach our goals faster and more efficiently.

1. http://www.socra.org/pdf/Salary_Survey/SoCRA_Salary_Survey2010.pdf
2. http://waves.wavgroup.com/wp-content/uploads/2011/12/MLS-Tech-Survey-Age-TechComfort-Performance.pdf
3. http://www.fastcompany.com/3021749/work-smart/10-surprising-social-media-statistics-that-will-make-you-rethink-your-social-stra
4. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/02/WC500138893.pdf
5. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf
6. http://www.fda.gov/forindustry/electronicsubmissionsgateway/ucm113223.htm
7. http://www.softconference.com/DIA/sessionDetail.asp?SID=336022