Improving Site Relationships through EDC

Modern clinical research studies are impacted by powerful technologies and often conflicting social factors. This combination can result in strained relationships among clinical trial personnel and site participants. This paper looks at how thoughtful selection and use of one of the core clinical trial software technologies, electronic data capture (EDC), combined with deliberate communications best practices, can actually increase study efficiencies while strengthening critical relationships with study sites.

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Poor Communication = Strained Relationships

Productive communication can either make or break a relationship in clinical research. From the sponsor and contract research organization (CRO) perspective, trials are teeming with challenges, topmost being study delays caused by under-performing sites. From the site's perspective, overly complex protocols, tough deadlines, payment issues, and enrollment pressures are caused, in part, by the sponsor or CRO. It is easy to see how each group perceives the other. With increasing complexity of trial designs, there is enormous demand for clarity, to listen and learn from one another, and to build relationships essential for success.

Twenty years ago, site-sponsor relationships seemed to be more friendly and cooperative. Since then, as pharmaceutical companies have swallowed each other up, many internal processes have become centralized in an organizational attempt to become more efficient. A negative side effect of this is that sponsors are becoming increasingly distanced from the study sites, and the human interaction has become less important.

As Ron Montgomery, an experienced former CRA and consultant, aptly observes:

> *Developing long-term relationships has become secondary to getting the job done for the least amount of money and grief. They talk about developing relationships but in fact do the hard line, confrontational, 'business-like' thing more often. Time is money, and 'what have you done for me today?' applies.[1]*

Sponsor Perceptions

Poor Recruitment
Protocol Deviations
Poor Scheduling Adherence
Resistance to Technology
Form Inaccuracies
Learning Retention
Poor Drug Supply Mgmt.
No Active Communication

Site Perceptions

Recruiting Pressures
Overly Complex Protocols
Scheduling Deadlines
Too Much New Technology
Overly Complex Forms
Not Enough Training
Payment Issues
No Active Communication

Managing Effective Site Relationships

Sites under-enrolling and inaccurately recording trial data can actually be catalysts for new sponsor-driven efficiencies centered on deliberately enhancing relationships between the sponsor and site. Referred to as Site Relationship Management (SRM) in the clinical trials industry, this involves focused efforts by sponsors to intentionally improve relationships with sites for mutual gain. By more closely analyzing and addressing the individual site needs and building mechanisms for recognition, appreciation, setting realistic goals, clearly defined payment schedules and more fluid communication, a sponsor can affect site performance and predictability. A natural bi-product of this "nurtured" site is the opportunity for increased regulatory compliance and trial repeatability.

Relationship Ambassadors

Trials generally have a built-in channel for nurturing site relationships—CRAs, who liaise between the sponsors and the sites. With the evolution of a pedagogical CRA role in favor of one more focused on relationship management, the hope is to engage and nurture sites in a more mutually beneficial way. Over time, forward-thinking sponsors and CROs currently rolling out relationship-building initiatives will be in a position to measure the outcomes of these efforts. Producing significant results will encourage other sponsors and CROs to begin viewing their sites as valued partners and realize the full potential of genuinely mutual relationship.

Beth Harper on how soft skills add value:

> *Success in delivering clinical trial results depends on the extent to which the investigator and site personnel are committed to the sponsor's trial, which is often a direct reflection of the strength and quality of the relationship they have with the study team. In the end, clinical research is a people business, and recognizing that factor makes the work more meaningful and effective.[2]*

Relationship skills are becoming an increasingly important trait for people working at the intersection of sponsor/CRO and site interactions. This is evidenced by the marketplace for careers in clinical research. Most job listings for CRC, CRA or PI positions have SRM or some form of relationship management requirements, accompanied by a long list of technology skills. This demonstrates that today's successful clinical research professional must be not only adept in human relations but proficient in technology.

EDC and Relationship Building

It is widely known that electronic data capture (EDC) is a cornerstone technology most clinical research professionals use to obtain greater speed, flexibility, quality, and usability around collecting and managing their research data. Used sub-optimally, EDC can inadvertently create barriers to productive long-term relationships by removing the human element. However, implementing EDC in concert with a well-devised socio-technical strategy can help align mutual interests and produce stronger relationships.

Mutual Interests

Dimension	Sponsor	Site
Trial Speed	✓	✓
Minimal Platforms	✓	✓
Data Quality and Access	✓	✓
Flexiblity	✓	✓
Useability	✓	✓
Regulatory Compliance	✓	✓

Trial Speed

Trial speed is an aspect of clinical trials where the interests of sponsors and sites are naturally aligned. First and foremost, sponsors and CROs are focused on the velocity of trials to quickly gain approval for medications, devices, and procedures. In a similar vein, sites value speed when entering and reporting data, receiving quick payments and successfully completing a study. Meeting the mutual 'need for speed' can be achieved by the effective use of web-based electronic data capture, minimizing the frustration levels in both groups.

Minimizing Platforms

There are many choices for EDC technology, and most products are complicated, difficult-to-use proprietary tools. In addition, each product has inherent idiosyncrasies. To realize the full benefits of EDC, organizations should seek to minimize their number of platforms. Fewer software products to learn and support mitigate the time-consuming and redundant efforts of training, building studies, developing electronic case report forms (eCRFs), creating custom rules and analyzing and reporting data. By adhering to a one or two EDC platform strategy, you also mitigate data manager frustration and decrease the learning curve for CROs, CRAs, CRCs and site personnel.

Data Quality and Access

EDC is known for increasing the quality of your clinical research data. With fully-automated edit checks and powerful rules, research teams can reduce errors during data entry and decrease delays caused by queries, saving the site and the sponsors valuable time, money and major frustration. The ability for EDC to minimize data entry errors not only improves, but elevates performance and confidence in the overall quality of the data, which ultimately impacts the entire study ecosystem.

In addition to clean data, sponsors require access to interim data. EDC technologies provide faster access to "real time" data, and a sufficiently agile EDC platform can give CROs, CRAs, PIs, and other stakeholders what they need, when they need it.

Top Three Reasons for EDC
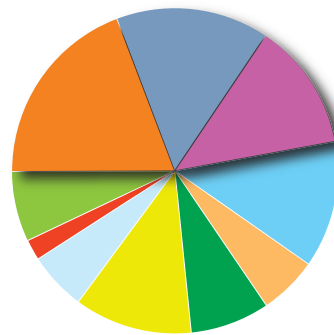
- **Immediate Feedback**
- **More Accessible Data**
- **Higher Data Quality**
- Easy to Use
- Higher Patient Compliance
- Evidence of Patient Compliance
- Faster Trials
- Less Expensive
- Patient Preference
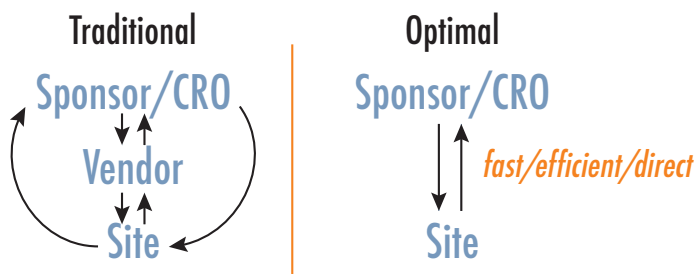- Regulatory Authorities Accept EDC

In 2011, ARITHMOS, conducted a global survey on the use of EDC. The survey gathered responses from multiple roles in clinical trials from over 20 countries. Respondents listed their top three reasons above for using EDC.

The faster the data can be processed and reported, the faster the drug gets to market, and the faster the pharmaceutical company reaps the profits from the sale of the drug. One disadvantage that I see with other EDC systems is the lack of flexibility and processes. Many EDC vendors force you to utilize their standards of practice and install massive software solutions on your systems. Many also require high-speed internet connections, which are not always accessible in global trials, where sites only have dial-up. EDC systems need to be flexible, easy-to-use and intuitive.[3]

Flexibility

Many EDC systems are structured (and priced) to only cater to certain types and sizes of trials, and thus lack the flexibility (both functional and economic) to be used as a standardized tool across a range of studies. A general factor to consider is the flexibility of the study build process itself. Does the EDC platform allow the data manager to build the study? Or, does it necessitate that the vendor or a third party build it? Will the vendor provide direct support to the sites or to the data manager? Innovative EDC models, such as those enabled by open source, can provide flexibility in these areas that can be used to your advantage when it comes to site relations. Having the ability to remove middlemen between you and the site enables both faster and higher quality communication between parties, helping to strengthen your site relationships.

Balanced Usability

As with any software, the usability of a given EDC application has an enormous effect on adoption and user success. It is important to include stakeholders from the sponsor or CRO and site when determining usability. From building the study, to data entry and reporting/analysis, assess how intuitive and flexible the platform is.

Questions to ask when assessing EDC usability:
- Can I customize and configure my study or do I need to rely on a vendor?
- How quickly can the vendor handle change orders?
- Can my site enter data and report results with minimal training?
- Is there ample training and technical support?

The best way to determine overall EDC usability is to see a demonstration or gain practical insight by testing an actual instance of the software. To further increase the adoption rate and improve relationships, consider including one or two willing sites in the testing of the EDC platform.

Summary

In today's technology-laden clinical research ecosystem, building strong relationships with sites is vital to maximizing study results. By supporting these integral relationships with well-vetted and thoughtfully implemented EDC software, benefits include higher caliber and repeatable sites that produce quality data, increased efficiencies and shorter study life-cycles.

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Communication Models

Traditional

Sponsor/CRO

Vendor

Site

Optimal

Sponsor/CRO

fast/efficient/direct

Site

[1] University of Michigan, "Informed Consent," http://www .med.umich. edu/irbmed/InformationalDocuments/consent/consenttoc.html; and University of Southern California, "IRB Forms," http://ccnt.hsc.usc.edu/ irb/docs/instruction.htm

[2] Beth Harper, "Engage Sites and Build Study Visibility Through Good Effective Communication Practices," http://www.ngpharma.com/article/ Engage-Sites-and-Build-Study-Visiblity-Through-Good-Effective-Communication-Practices/

[3] Moving on from paper-based trials, http://www.ngpharma.com/article/ Moving-on-frpm-paper-based-trials/

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