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Information Technology Evolution at Clinical Research Sites

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The end product of a clinical study is data that can be transformed into information.

Clinical research coordinators and other site personnel, such as regulatory compliance and billing specialists, spend most of their time processing (i.e., collecting, analyzing, transforming and distributing) medical, operational, regulatory and other types of information, including data. This burden on sites will likely continue to expand.

Clinical research is absurdly expensive. Information technology has streamlined some activities, but it has proliferated to such an extent that it is creating its own burden. If the clinical research enterprise is to avoid collapsing under the weight of its information technology burden, it has no choice but to slash the labor intensity of information. In other words, site personnel will have to process much more information in much less time per study.

The COVID-19 pandemic has unleashed a wave of pent-up transformational energy in the clinical research enterprise. Five years from now, we will look back at 2021 as the beginning of an informational age of enlightenment, with the emergence of "whole site" information technology at clinical research sites.

In theory, clinical research sites can operate with six generations of information technology:

First Generation. Paper and personal productivity tools like spreadsheets

Second Generation. Electronic medical records (EMR), electronic data capture (EDC), clinical research management systems (CTMS), eSource, eRegulatory, eConsent, ePatientRecruiting and other point technologies

Third Generation. Integrated solutions that combine core functions (e.g., CTMS, eRegulatory and eSource)

Fourth Generation. Whole-site solutions that enable automated and essentially paperless clinical research sites and site networks

Fifth Generation. Comprehensive, integrated analytics and visualization for site operations and transparency to study sponsors (and CROs)

Sixth Generation. Integration with sponsor-provided technologies, such as EDC, eRandomization, eSafety, eSupplyChain, eTraining, wearables and mobile apps

Third-Generation: "Best-of-Breed" Vs. "All-in-One"

Information technology has always been a battle between "best-of-breed" point solutions vs. comprehensive "all-in-one" solutions. Solution providers that optimize their product on a narrow set of functions can almost always create a better product than the corresponding functions in a best-of-breed solution. However, they can never match all-in-one" solutions for user-interface consistency or data integration. Customers are thus often forced to make difficult decisions when sourcing information technology solutions.

As the technology in an industry matures, the advantage tends to shift from best-of-breed to all-in-one solutions. In the generational scheme above, the shift begins when the third generation emerges and becomes overwhelming in the fourth generation.

Fifth-Generation: Integration and Transparency

When fully mature, information technology disappears in the sense that its use becomes natural and unobtrusive, like steering an automobile or riding in an automobile that steers itself. Fifth-generation information technology disappears into functions in the following ways:

- Information flows automatically across functions.
- Site activities are comprehensively recorded for future analysis.
- Personnel can access all information systems (subject to role-based permissions) with a single user name and password.
- When actions are required (e.g., because a timepoint has passed or a problem has been detected), the system automatically takes action or alerts the responsible person(s) with actionable information and facilitates a response.
- Managers can review intuitive visualizations of operational and financial metrics. They can drill down to investigate problems and opportunities. They can analyze situations and make plans based on comprehensive, accurate and timely information.

Clinical research is an inherently human process, so fifth-generation information technology does not replace personnel. Providing useful information is enough of a challenge for the technology.

The following are just a few potential fifth-generation opportunities:

- Most test-article reconciliation currently employs first-generation information technology: study coordinators manually record the receipt of pill bottles and manually count pills. Bar codes, QR codes or, better yet, radio frequency identification (RFID) devices can track pill bottles. Assuming the pills have a consistent weight and there are not too many of them in a bottle, a digital scale can count them and automatically enter the numbers into the site's and the sponsor's databases.
- The system can remind study participants when they need to do something and notify the study coordinator when that something does not happen on schedule. Site management and the study sponsor can monitor visualizations and dashboards for larger patterns.
- eSource data entry can detect anomalies in real-time and automatically transmit clean data to the study sponsor for same-day payment. The system can also monitor patterns of data entry to identify possible protocol deviations, training opportunities and ways to streamline visits.
- Technology providers can collect metadata across multiple sites and apply artificial intelligence to identify anomalies.

Sixth-Generation: Sponsor-Provided Information Technology

In clinical research, study sponsors choose many of the information technologies that sites use. The optimal mix of technologies can differ by therapeutic area, study phase, study design and other factors. There is no best one-size-fits-all solution and there never will be.

Because the direct customers of the solution providers are study sponsors, most of these products are optimized for study sponsors, not sites. Even if study sponsors could all get

together and choose a common set of technology solutions, it would probably violate antitrust laws to do so.

Other industries have addressed similar problems with standardization. In clinical research, the Clinical Data Interchange Standards Consortium (CDISC) develops standards for regulatory submissions to FDA. It's CDASH standards provide a common way to record data consistently across studies and sponsors.

With mature sixth-generation information technology, each site works with their preferred user interface for each function. Each user interface communicates with the study sponsor's preferred applications or databases.. A common set of application program interfaces (APIs) and common data dictionaries or data transformation facilities would be required.

A more plausible, but still difficult, option would be to expand on CDISC's approach and standardize data across all technologies that sites use. In other words, let sites use any user interface they like, provided it generates and accepts standardized data. However, this approach would also build rigidity into the system because a multitude of organizations would have to agree on and consistently implement new versions of the data standards.

Nevertheless, the flaws in the dream of technology-as-savior means that clinical research gradually becomes more and more technology-bound. A mixed solution is most likely but will yield mixed results.

Conclusion

Historically, change has come slowly and unevenly to clinical research. Recently, however, the evolution of information technology in clinical research has accelerated. This acceleration has been due, in part, to the migration of clinical research from academic medical centers and community health systems to independent sites and site networks with simpler structures and strong business orientations. The COVID-19 pandemic has driven study decentralization, which is highly dependent on information technology. Much of the information technology needed for fifth-generation clinical research sites already existed in 2020, so the pandemic has, in effect, catalyzed a phase transition from the fourth to the fifth generation.

A few solution providers, clinical research sites and site networks are leading the fifth-generation information technology wave. Study sponsors naturally gravitate to these sites because of their speed, scale, quality, reliability and transparency. Higher efficiency means lower costs, which improves site profit margins, even without value-pricing of their services.

The sixth generation, however, will require unprecedented industry leadership, collaboration and understanding that the alternative is stagnation or decline — not unlike the current challenge of climate change.

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