Clinical Research Information Technology: The Future is Here

By Norman M. Goldfarb

The recent CHI Summit for Clinical Ops Executives (SCOPE) conference in Orlando gave almost 900 attendees from phamas, biotechs, CROs and other service providers exposure to exciting developments in information technology that will revolutionize the practice of clinical research.

“The future is already here — it's just not very evenly distributed.”

— William Gibson

This article discusses clinical research technology in the future tense, but most, if not all, of the following significant, but not exhaustive, trends are already underway.

**eEverything**

eTMF, eSource, ePRO, eRegulatory, ePayments, eMonitoring, eConsent, eLabs, eSupply, eContracts, etc., are all contributing to a paperless eClinical environment. To take just one example, do we really need eMonitoring in the form of a tool that site monitors can use when they physically visit research sites? What's wrong with Word or Acrobat forms? Well, imagine a software application that walks the site monitor through the visit, adapting to any discrepancies found, detecting problematic trends, monitoring the monitor’s work, and alerting the medical monitor or data manager for follow-up during the visit.

**More listening**

Patient-centricity requires listening to patients. The same can be said about site-centricity — study sponsors need to listen to sites when developing protocols that sites can actually conduct.

Social listening, i.e., monitoring what is being said on social media about studies, investigators and other clinical research topics, is a hot new trend. Unfortunately, there are three major obstacles to engaging in social media dialogues: First, there is the “big brother” issue — it creeps people out when big companies listen to their conversations. Second, polite explanations can easily generate hostile “flames,” just making things worse. Third, IRBs are not currently set up to give real-time blessings on public statements (but, could this change?). Nevertheless, public discussions can be very useful when designing protocols, recruiting study participants, and formulating outbound messages.

**Devolution**

Technology will push responsibilities down from the sponsor to the site and from the site to the patient.

“OpenStudy” apps (a la OpenTable) will empower patients to find the best clinical trial for them, not just the one their physician happens to offer. It will become easier for appealing studies to recruit patients and harder for those that are unappealing. Patient advocacy groups, patient recruiting firms, current study participants, and every Tom, Dick and Harry will publish reviews about enrolling studies for potential participants to peruse.
Similarly, as more and more information about studies becomes available publicly (or just to preferred sites), investigators might be able to choose the studies that interest them and apply for admission, rather than wait for an invitation from the sponsor.

Wearable devices and “study buddy” apps will enable participants to collect data, adhere to study requirements, report adverse events, schedule study visits, etc.

**Bigger, faster data**

Sponsors, CROs and sites will collect more real-time data about supplier processes and their own processes, as well as continuous data about study participants. Multiple internal and external sources of data will be integrated. Unstructured EMR, social media, and study documentation data will be analyzed with natural language technologies. Everything will be instrumented, so the amount of data collected will explode. Old data will become valuable for trend analysis.

Data will flow upstream in real-time to feed pervasive analytics and pattern recognition engines. Data-driven decision-making, often automatic or semi-automatic, will permeate clinical research organizations. For example, real-time data feeds from site CTMS systems will advise study managers when a site should get a higher — or lower — screen failure limit.

Expanding databases will make it easier and easier for sponsors to determine which sites are suitable for particular studies (and which should be avoided at all costs). However, site networks, site management organizations (SMOs), and various consultants will continue to play an important role in site selection, since the databases will not capture “soft” information about sites...or will they?

**Analyze this**

Analytics will become part of everyone’s job as data-driven decision making becomes pervasive. Intelligent “dashboards” in CTMS, risk-based monitoring (RBM), and other systems will reconcile the disconnect between human and computer information capacities by constantly weighing the importance of a vast library of metrics, presenting only those that are most important and actionable.

Organizational structures will evolve to favor those who control the data (e.g., data management) and those who secure the expertise and tools to leverage it.

**Confidential, really?**

Traditional methods of ensuring confidentiality, privacy and security for business and personal data will become somewhat obsolete, as the walls around pockets of data become less relevant. The interesting constraints — if possible at all — will be on synthesizing data from multiple sources.

**Small is enough**

Phase III studies will become smaller as electronic medical records (EMR) and big data improve post-marketing safety surveillance and epidemiology. The European Medicines Agency (EMA) and then other regulatory authorities will adopt “adaptive licensing,” initially approving the use of promising drugs by the most desperate patients and then using the resulting data to decide whether to expand the approval to broader populations.
What Won’t Change Any Time Soon

Technology providers understand that their products are useful only if people actually implement and use them. However, the struggle between features and usability will continue. As organizations become more technology-intensive, it can become even harder to integrate yet another new technology. Software providers will do more to integrate their applications with other applications. However, there are no signs of emerging “platforms” that host multiple applications. (A widely used system is not a “platform” just because it is widely used.) In other words, the challenge of adopting technology is not going away any time soon.

Computers can treat people like bags of data, but they also enable “high touch” personalization. There is no substitute for the personal interaction between study coordinator and study participant or study coordinator and site monitor. The medical judgment of investigators and medical monitors cannot be replaced. We will always need institutional review boards (IRBs) to make subtle judgments for the protection of study participants. And, of course, we’re stuck with study participants for the foreseeable future, although perhaps a lot fewer of them with precision medicine. In other words, there will always be humans in clinical research, so technology’s primary role is to empower them. The important questions, as usual, are who, what, where, why and how.

Conclusion

There is no shortage of technology. Over time, clinical research organizations will employ more and more of it. The issue is not the technology, but the interest and ability of organizations to evolve their current processes. The check a company writes to a technology supplier can be dwarfed by the cost of implementation, to say nothing of the inertia that needs to be overcome. Most clinical research professionals are already pressed to the limit, so it’s not easy to generate enthusiasm for the guarantee of more work today that might eventually generate a payoff down the road.

Nevertheless, the clinical research industry is far too inefficient to survive in its current form. Technology is a big part of the cure, even if it means swallowing some very big pills. Some organizations will thrive because they are better at adopting new technology.

A thousand technology suppliers will bloom, but winners will emerge to play dominant roles in the industry, and not necessarily because their technology is “better.” TransCelerate will expand its role in choosing winners (or creating standards) for technologies where study sponsors benefit from shared systems.

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