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Get a Handle on Your Research Site's Technology

By Norman M. Goldfarb

Technology is pervasive in clinical research. A modern research site might employ a clinical trial management system (CTMS), an electronic medical records system (EMR), an electronic data capture system (EDC), an electronic source data capture system (eSource), an electronic regulatory document management system (eRegBinder), an electronic informed consent system (eConsent), a patient recruitment and engagement system, and more. Some of these systems are in-house, and some might be provided by study sponsors…in multiple versions.

Research sites also employ technology to manage broader business functions, such as schedules/calendars, billing, payroll and accounting. And let's not forget about personal productivity and communication systems like spreadsheets, word processors, email, and Internet browsers.

Some technology, such as EKG machines and other medical equipment, might stand alone, but other systems should communicate amongst themselves and with the general technology infrastructure.

Technology employed by study participants, such as electronic clinical outcome assessments (eCOA), patient-reported outcomes (ePRO), and mobile health (mHealth), further complicate the picture.

Even creating the list of technology *categories* is time-consuming, much less understanding the properties of all the systems. Who uses the technologies? Who maintains and supports them? Who provides the training? What are the security requirements and processes?

Now think about the implications of working with multiple sponsors and CROs, each with its own unique configuration of technologies and processes. Now think about the trend of consolidation in the industry, with sites coalescing into multi-site organizations or networks. Now think about increasing customer demands for productivity, quality and timeliness. Now think about increasing competitive pressures. Now think about fundamental shifts in clinical research brought on by precision medicine, immunotherapy, etc.

Now imagine you want to upgrade or replace one of these technologies. Who needs to be involved in making and implementing the decision? What other systems will be affected? Will those systems need to change and, if so, will that affect yet other systems?

It does make one's head spin. If it doesn't, you're not paying attention. Given all these considerations, its amazing technology works at all, but work it must. The clinical research enterprise is gradually— or, perhaps, not so gradually — migrating to a paperless environment. Research sites that intend to survive the transition must accept that technology is an inevitable part of their lives, and they will have to grapple with it, like it or not.

So, Where Do We Start?

Before we can go anywhere, we need to know where we are. That means we need to identify the technologies we already have and determine their purposes, characteristics, interactions, etc. We can also characterize technologies that we are considering for adoption and integration into our technology infrastructure.

Start by using MAGI's "Site Technology Inventory Form" to capture this information. The form is available at www.magiworld.org/Standards. (Suggestions for improving the form are welcome.) By inventorying the elements of your technology infrastructure, you will probably confirm or discover gaps and trouble spots that require immediate attention. You can then set priorities and make a coherent plan to efficiently strengthen your systems. The future of your research site depends on it.

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Author

Norman M. Goldfarb is Editor of the Journal of Clinical Research Best Practices. Contact him at 1.650.465.0119 or ngoldfarb@magiworld.org.

