What Clinical Technology Can Learn from Electronic Health Records

A Conversation with Mike Nolte

The future of clinical technology encompasses both better adoption of simple solutions and a slower evolution toward new technologies with the focus on the patient at the center.

Mike Nolte
CEO, Signant Health

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Early in the adoption of electronic health records (EHRs), some technology leaders recognized the potential of those solutions to change the way healthcare was delivered. Years later, there is no doubting the impact that EHRs have on healthcare, but there is still discussion about whether that impact has always been positive. As EHRs were adopted, there were significant challenges that the industry overcame — and some it didn't — which present learning opportunities for the adoption of electronic solutions within clinical research. There also remains an enormous opportunity to move the practice of research toward a more impactful, more progressive, and simpler use of digital solutions.

The Bigger Picture

Mike Nolte, CEO of Signant Health, says "real" EHR adoption never really started until there was significant government intervention." Before that, even with technology advancing in many other industries, clinicians were quite comfortable with paper records. In fact, in the United States, EHR adoption was limited to places where physician champions and budget capacity came together with innovative thinking, largely in academic environments. The situation in clinical research has many similarities.

"There's a burden of risk in clinical research, which is understandably associated with the potential of any change in practice to introduce variability into data," Nolte continues. "Study teams that are comfortable with paper solutions view technology as introducing new risk. eCOA, patient engagement tools, and many other solutions have the potential to make an enormous, positive impact on clinical research, but it takes commitment, collaboration, and patience to work through the necessary process and cultural changes and see the longer term benefit. Ultimately, the industry must demonstrate that the quality, consistency, and efficiency benefits outweigh the risk of change, and without direct government intervention, it's more difficult to get technology to a steady state of adoption."

In the United States, government intervention in EHRs came in the late 2000s with the American Recovery and Reinvestment Act (ARRA) as more than $40 billion was allocated for EHR adoption, However, that investment was, in many ways, less efficient than it might have been. "The ARRA focused on a template for what constituted an acceptable EHR," Nolte says. This initially led to a proliferation — more than 200 at one point — of vendors and little real differentiation or innovation. A better approach, he says, would have been the creation of two standards. First, a national patient identifier would have allowed much simpler portability of medical information. Second, more aggressive data standards could have ensured sharing of patient information across competing platforms was simple and consistent. With that backbone in place, better, more creative solutions could have emerged with less urgency to scale and more urgency to innovate.

"In the evolution of clinical technology for research, this approach could work in a similar way," he says. "For example, a challenge that clinical sites face is the complexity of multiple third-party vendors, all of which operate independently. There are certainly data standards for data submission, but if regulatory bodies or an industry consortium were to mandate how data moves between applications, we would see more interesting ways to build connections to clinical data outside of traditional clinical research, simpler site solutions, and more patient-focused innovation."

Applying Lessons Learned

In addition to understanding the impact of government influence, Nolte offers four other lessons from the adoption of U.S. EHRs in the 2009-2011 timeframe.

- **Keep it simple.** Clinical researchers are highly comfortable with complexity, but they're

often less comfortable with how software can facilitate simplification, data quality, and reliability. Anything that interrupts their work, creates a barrier for them to be successful, or introduces — real versus perceived — new risks isn't likely to be adopted rapidly. With EHRs, physicians were — initially and to some extent are still — resistant to anything that would make their day harder or result in them spending less time with patients. Building workflows and solutions that simplify the customer experience creates greater potential for success over the long term.

- **Start with the patient first.** This is an opportunity to rethink the way software tools and solutions are designed, how they're integrated, and how they're deployed throughout the clinical trial process. With EHRs, the burden of a device — PC, laptop, tablet — to enter data created a new barrier between patients and clinicians that, for the most part, has never really been addressed. In part, this is because the solutions were built around the clinicians' experience, not around the patient. In fact, EHR vendors are already rethinking how data, voice, and video can improve that patient experience. Addressing this earlier in the adoption cycle within clinical research creates the potential to arrive at more effective solutions more quickly.

- **Accept common practices.** Early EHR adoption largely ignored modern software architecture, such as SAAS, cloud, etc., because of concerns about local control of patient data. Early commitments to outdated databases, deployment, and development models continue to tax the pace of innovation. In research, there's an opportunity to accelerate innovation by adopting relatively current technologies in different ways. For example, expecting patients to use a secondary, provisioned device versus their own smartphone for a patient diary has clear benefits in terms of scale consistency and technology reliability. There are also other social and technology hurdles that limit adoption of research-focused applications on personal devices. However, it's likely that these issues are not permanent barriers and in reality, it simply takes persistence — or perhaps a government mandate — to address these issues with creativity and innovation. That, incidentally, is without recognizing the potential of devices, video communication, and other telehealth platforms to permanently change the practice of research.

- **Insight from start to finish.** There's power in having a complete view of the workflows associated with delivering clinical care. Enabling data availability that follows the patient's journey through a health system and developing workflows that are simpler across different environments makes it easier for clinicians to derive real insight in both diagnosis and treatment. In the early days of EHR adoption in the U.S., many clinicians actually used two EHRs. One was used in their, usually independent, practice and the other was a completely different EHR used within the hospital. As the EHR industry has consolidated and as physician practices have, more commonly, become part of large health systems, this is less typical and common workflows have allowed clinicians to follow the complete patient "journey" more easily. In research, seeking end-to-end solutions has similar potential to move the industry from a focus on direct data, to adding focus on derivative data that informs how to run more effective research in the first place.

"There is no doubt that there are essential differences between traditional HCIT and clinical research," Nolte says. "At the same time, we believe that focusing on patients is consistent with the mission of drug development; creates more effective engagement with sites; eliminates unnecessary time, frustration, and confusion; and helps drive better access for patients who wish to participate in clinical trials."

A Vision for the Future

There are several approaches and technologies with the potential to help bridge data gaps within clinical research and streamline the patient journey. One development, Nolte says, is using data, devices, and patient platforms to address previously difficult to measure endpoints.

"Neuroscience is a great example of a therapeutic area with the potential to reshape data collection," he says. "Today, neuroscience trials are highly dependent on scales that introduce the possibility of bias, inconsistency of use and other variability. Technology introduces opportunities to potentially measure more objective data, including facial expressions, physical movements, etc. Everything from gait — how and how quickly a person walks — to physical signs of neurological conditions, for example tremor, can be signals of changes in a neurological disease."

Nolte says it's also important to think about ways to create and adopt solutions that eliminate the need for the number of patient visits required in typical trials. "Truly virtual trials are difficult as an initial step, but there are ways to simplify and enrich patient interactions to accelerate and simplify trials beyond medication and visit reminders," he says. "Making participation more engaging and personal will both drive efficiency for sites and improve the experience for patients. It's compelling to see technology at the center of coordinating the necessary activities and aligning the services to make this happen. If we can reduce the time patients spend doing something associated with a clinical trial by 40% to 50%, this creates a time benefit for them, efficiency for the sites that they work with, and allows our customers to invest research dollars more effectively."

Another important consideration for Signant Health is around data and analytics and rethinking the insights that can be gained from understanding the breadth of the trial itself from an operational perspective.

"We already do significant work in data quality and managing site risks," Nolte says. "There is real power in clinical expertise combined with technology. What patient population is available for a given protocol? Which geographies matter? Which are the best sites to select? How are those same sites performing? We want to take the noise out of the conduct of the trial so that the actual effectiveness or lack of the effectiveness of the drug or the treatment can be measured."

As for potentially game-changing technologies, such as artificial intelligence, Nolte says while these hold enormous potential, the industry would benefit more by adopting some very simple solutions first, such as well-understood workflows, software algorithms, and basic analytics. "At the same time, we are looking at some interesting opportunities, such as using AI as a way to understand variability in speech patterns, or using avatars to demonstrate the impact of disease progression" he says.

Nolte sees the future of clinical technology as encompassing both better adoption of simple solutions and a slower evolution toward new technologies, but his focus remains on the patient at the center. "Our work is deeply personal, because its impact isn't abstract. Our customers develop life-changing therapies that matter to our communities, to our families and, potentially, to us personally." ■