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Leveraging EHRs and Community Practices to Accelerate Patient-Focused Decentralized Clinical Trials

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Supporting a learning health system by leveraging data from healthcare can accelerate the way we conduct research and inform clinical decisions for patients. While it has been widely agreed for years that clinical research needs to increase diversity, Dr. Janet Woodcock, Acting FDA Commissioner, succinctly states, "We need to move clinical research out into the community, and we need to support this if we are going to be successful in enrolling populations who reflect this country."

One key goal to accomplish this is to increase the number of patients and physicians who participate in clinical research. The percentage of patients who participate in research today is very low — a tiny fraction of the eligible population. The pandemic validated the widespread feasibility of decentralized clinical trials (DCTs); but COVID-19 left no other choice besides halting research altogether.

According to John Kerins and David W. Johnson (from the Cain Brothers and 4SightHealth, respectively), "Decentralized and virtual trials offer compelling alternatives to clinic-based trials. Under the right conditions, they could rapidly supplant traditional in-person approaches, and dramatically enhance the scale, data collection, geographic range, cost-effectiveness, and speed of clinical trials. The FDA has issued guidance that supports virtual visits during and potentially beyond the pandemic." In fact, the FDA had spoken out in favor of DCTs well in advance of the pandemic.

Key means of accelerating clinical trials include a) standards-based data flow from source to submission; b) rapid access to data for management and analysis; and c) timely enrollment and high retention of patients. The standards-based data flow can accelerate study startup by an estimated 70%-90% and having rapid access to data for management and analyses allows database lock within hours of last patient out.

The timely enrollment and high retention of patients is often elusive for many trial protocols, and this critical component can override the acceleration from data-related processes. More than 97% of physicians and patients do not participate in clinical trials. Most patients are never approached about participating in a clinical

trial and their physicians do not engage in research. These are key reasons to engage the practices of community physicians in research. Doing so can also help address the lack of diversity in trial participants and increase the number of patients who contribute their data to research.

Currently, healthcare and research largely remain separate even though there are clear opportunities to bridge the divide between them. The pandemic has increased awareness about the importance of clinical research, and we hope to take advantage of this.

So, how can we address the challenges of patient enrollment to accelerate research?

Efficiently locating and enrolling patients is mandatory to shorten trial timelines. In a traditional enrollment process, sites begin enrolling patients at different times and do so at different rates, thus extending the overall duration of the enrollment process significantly. Through the use of real-world data within the community practices, patients in community-based practices can be identified in advance, while the trial master files are being checked, the site personnel are being trained, and the database is being developed. Patient outreach and recruitment can begin right away at all sites and all of the trial patients can then be enrolled in less time overall.

Utilizing an expanded healthcare network among community practices also provides scale, expanding the resource pool beyond academic institutions and dedicated trial sites; this brings a wealth of opportunities to increase patient resources and physician participation. The number of recruitable subjects who have already participated in studies via professional research sites is much smaller than the database of eligible participants available through a community of primary care physicians and their electronic health records (EHRs).

Access to these EHRs provides an abundance of healthcare data. Patient identification per protocol can be done in advance to encourage more rapid enrollment. If patients do not exist and cannot be found to meet the protocol inclusion and exclusion requirements, appropriate protocol amendments can be completed before the trial starts. Patient diversity also increases as the potential patient pool is drawn from the large population across many physicians' practices.

When working with community practices, one key concern is the desire to have the patient remain under the care of their trusted physician. First, the physician should learn about research well in advance — especially if this is a new area for them. They will want to understand the opportunity and what clinical research will entail. Partnering with the physician means identifying what type of support they need to conduct research. Earning physician trust is important so they can do effective outreach to their patients. Ongoing communication with the physician and the patients during the trial reinforces their relationship and helps with retention and compliance.

For physicians who are not investigators, support may include help with identifying patients who may be eligible for research, providing Good Clinical Practice (GCP) training, establishing a central electronic repository for master files, assisting with study manager tasks, and possibly even having a central principal investigator (PI). In this situation, the physician might be a sub-investigator, ensuring they have ample time to attend to the needs of patients while the PI handles the bulk of the trial-related administration and medical monitoring.

Leveraging the abundance of EHR data across community physicians can be challenging, especially considering the number of different EHRs; however, the opportunities are profound. Aggregating EHR data into a data repository with a standard data format is helpful; with such a repository, data registries can be created so patients with specific diagnoses can be contacted when recruitment for a relevant study begins. Once these patients have been identified, their physicians are notified, and they can begin doing outreach.

Technology plays a very important role in making DCTs and hybrid trials successful, including the connections between the EHR data and the research data. This requires adherence to regulations and guidance documents, such as those relevant to eSource data and the use of EHRs for clinical research in addition to 21CFR11. It is also clearly important to preserve patient privacy and data security, which is a good reason for the physician or study manager at the site to perform the patient outreach.

Communication is important for many reasons, especially in the area of patient retention. Innovative technology that leverages artificial intelligence (AI) to assist with communication has been shown to keep patients engaged. Implementing data standards to facilitate the technical flow of data from eSource to submission is important because it not only enables a more rapid study startup, but it also prevents having to reenter data and eliminates transcription, which reduces time and resource requirements while increasing the quality of the data. Collecting "true eSource" data entered directly by study managers or other site personnel is preferred to eSource tools that are controlled by a CRO or vendor when meeting regulatory requirements.

DCTs and hybrid trials are here to stay. Having a model that leverages the community and healthcare data has the potential to vastly increase the number of patients and physicians who participate in clinical research. Retaining the patient-physician partnership and adding support as needed makes it easier for patients and physicians to participate in research. Rapid access to extremely large repositories of healthcare data from engaged physicians enables identification of eligible patients at the start of the study, which accelerates enrollment. Technology and standards streamline data flow and improve data quality and compliance. By bridging research and healthcare through data, patients everywhere benefit.

For more insights on how to leverage EHRs and community practices to accelerate patient-focused decentralized clinical trials or hybrid trials, contact us at elligohealthresearch.com.

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