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Early Chart Reviews Can Provide Steady Flow of Potential Study Subjects, Experts Say.

By Conor Hale

Beginning chart reviews before initiating a site can generate a list of prequalified candidates for outreach — and give sponsors the chance to examine the study's inclusion and exclusion criteria, and their potential to cause enrollment issues, according to experts during two WCG webinars on acceptable methods for sites and sponsors, and best recruitment practices.

Reviewing patient charts and both paper and electronic medical records through an end-to-end, systematic process can help identify patients within each site that may be eligible for the protocol, said Amanda Plucinak, program manager at ThreeWire.

"We have access to these patients' charts, we know their medical history and these patients are already familiar with each site," Plucinak said. "The nice thing about an electronic medical record review is that you could run a report that has the top criteria for where patients are going to be disqualified — for example, by a diagnosis or an age range."

"That's easily going to get rid of a number of charts that you don't have to review," she said. "You can really hone in on these chart review efforts by specifically looking at patients who are the most eligible."

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Institutional review boards get a lot of questions about the use of electronic health records as a vehicle for identifying potential subjects, and what is acceptable and not acceptable when it comes to recruitment, said David Borasky, WCG's VP of quality management.

In theory, IRBs shouldn't have any issue using EHRs for recruiting and finding patients, Borasky said.

"It happens all the time," he added. "Obviously things like HIPAA may come into play, depending on whether or not the entity involved is a covered entity," and sponsors should examine any permission or privacy standards that may already be in place at an institution or site.

Many of the questions stem from the lack of updated federal guidance on patient recruitment, Borasky said. FDA information sheets on recruiting study subjects and screening tests prior to enrollment have not been updated since 1998.

While sponsors and investigators may use several patient recruitment tactics, they still need to optimize their efforts to get the best returns. And with most clinical trials chronically lagging behind schedule — dovetailing with expensive delays in patient enrollment and the costs of increasing the number of sites — sponsors need to understand the importance of implementing robust recruitment plans from the beginning of a study, Plucinak said.

"Oftentimes, sponsors will opt to add more sites in response to underenrollment," Plucinak said. "However, the more sites required to meet the enrollment goals, the more sponsors will pay for startup, monitoring and study management."

Instead, effective, one-on-one interactions with potential patients — and even early confirmation of informed consent — can be pursued in the community, through booths at health fairs, advocacy group events or even farmers' markets, she said. The goal of a study's outreach programs should be to build and maintain relationships with candidate patients, and to educate them about clinical research in general.

But effective community engagement can be time consuming and require dedicated attention from staff, said Fabian Sandoval, CEO of Emerson Clinical Research Institute. One of the reasons that all sponsors and sites don't reach out to community events or health fairs is simply because they don't know where to go.

"You have to have a lot of planning. You can't just show up and put down your table and start setting up," Sandoval said. In addition to finding the proper event, you have to have the right materials to attract potential patients.

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"The worst thing to do at these community events is to be that boring table, right?" he said. "We actually do screenings at health fairs — we do our own kind of glucose test or blood pressure screenings."

Having staff dedicated to patient recruitment, even a single person, can make a dramatic impact in the workflow of a study by eliminating bottlenecks, said Kari Lotsberg, manager of site services at ThreeWire.

The time needed to conduct prescreening phone interviews, for example, can add up quickly, Lotsberg said. Even at an average of 10 minutes per conversation with a potential patient, the total process to equal one enrollment can equal 8 hours.

And with patient recruitment delays reaching several months on average, having dedicated staff can alleviate burdens on study coordinators, Sandoval said, allowing them to focus more on handling site visits and keeping patients flowing through the study.

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