White Paper

QCentrix®

Navigating the clinical research process:

Experiences and opportunities

One North Franklin, Suite 1800 | Chicago, IL 60606
q-centrix.com

Introduction

Clinical research plays a vital role in advancing medical knowledge, improving patient outcomes, and driving innovation in healthcare. Through clinical trials, healthcare facilities can identify new treatment options that improve patient outcomes.

However, some challenges pose barriers to participation. Hospitals and health systems may struggle to identify and enroll enough patients that meet study criteria, searching through disparate information systems to find relevant patient data can be time-intensive, and clinical staff may lack the time to devote to facilitating research when patient care is their top priority. Further, many racial and ethnic groups are underrepresented in clinical research, highlighting a need to recruit a more diverse group of clinical trial participants.[1]

This white paper shares experiences and insights about the clinical research process, drawing from discussions Q-Centrix held with an associate director of clinical research operations and a research nurse coordinator, who both facilitate research at a multistate health system based in Pennsylvania; and a chief scientist at Burkhart Research Institute for Orthopaedics (BRIO), an academic research center and clinical research site based in San Antonio. This white paper also discusses the benefits and challenges associated with clinical research and shares recommendations for how hospitals and health systems can facilitate meaningful clinical research most effectively.

[1] Ashwarya Sharma and Latha Palniappan. "Improving diversity in medical research." *Nature Reviews Disease Primers* 7, no. 74 (October 14, 2021). https://www.nature.com/articles/s41572-021-00316-8.

Benefits of conducting clinical research

- **Early access to new and promising treatments.** Facilitating clinical trials allows hospitals and health systems to offer patients access to cutting-edge treatments, devices, and techniques that may not be available through standard care. This provides patients with additional treatment options and potentially improves their health outcomes.
- **Better patient outcomes.** Studies have found that hospitals with more research publications have higher patient ratings, lower patient mortality rates, and improved care quality.[2, 3]
- **Financial benefits.** Sponsoring organizations typically provide funding for research activities, covering expenses such as patient recruitment, research staff salaries, and administrative costs.
- **Reputation and prestige.** Facilities that actively engage in clinical research can enhance their reputation as centers of excellence and leaders in healthcare. Participation in clinical trials demonstrates a commitment to advancing medicine and attracts patients seeking access to innovative treatments.
- **Contribute to life-saving research.** Leading clinical research studies gives hospitals and health systems the opportunity to advance the medical field and make a lasting impact.

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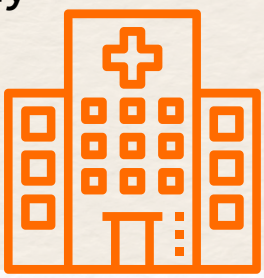

[2] Michael Morrison. "Do hospitals that conduct research provide better care for patients?" Massachusetts General Hospital (February 28, 2022). https://www.massgeneral.org/news/press-release/do-research-hospitals-provide-better-care-for-patients.

[3] Leon Jonker, Stacey Jayne Fisher, and Dave Dagnan. "Patients admitted to more research-active hospitals have more confidence in staff and are better informed about their condition and medication: Results from a retrospective cross-sectional study." *Journal of Evaluation in Clinical Practice* 26, no. 1 (February 19, 2019): 203-208. https://onlinelibrary.wiley.com/doi/10.1111/jep.13118.

›› Challenges

Identifying patients who meet the study criteria.

Finding and enrolling patients has long been cited as a major challenge in conducting clinical trials.[4] "You can get a protocol that's 200 pages long and has 26 inclusion and 36 exclusion criteria," said an associate director of clinical research operations at a multistate health system. "How do you pinpoint what is the most important to start with when you're looking at an EMR?"

Relying on EMRs and disparate data sources.

Sifting through data in electronic medical records (EMRs) and other information systems to search for patients who meet study criteria can be time-consuming, particularly when these systems are usually not suited for this work. "A lot of times, the information that's being requested of us is not living in one system; it's living across multiple different independent systems," said Dr. Mike Proffitt, chief scientist at BRIO. As searching for information within a single EMR can pose difficulties—an associate director of clinical research operations noted that patient details relevant to a study are often stored in different sections of the EMR, and even a single record may have conflicting information—these challenges can multiply when searching across several systems.

Enrolling patients.

This process may involve cold calling patients who could be reluctant to participate, especially if they have no existing relationship with the research nurse coordinator. "Typically, we're enrolling patients that have a known heart condition, [and] they usually have a standing relationship with their cardiologist," said a research nurse coordinator who works on cardiology studies at a multistate health system. "They want to hear from their cardiologist. They don't really want to hear from me because they don't know me. And so we get a lot of nos right off the bat because of that barrier."

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[4] Rachana Pradhan. "The business of clinical trials is booming. Private equity has taken notice." KFF Health News (December 2, 2022). https://kffhealthnews.org/news/article/business-clinical-trials-private-equity/.

Lack of diversity among participants.

People of color are vastly underrepresented in clinical research, representing 2 to 16 percent of trial patients despite forming 39 percent of the U.S. population.[5] While healthcare organizations are taking steps to address this—for example, the FDA has issued draft guidance for increasing diversity in clinical trials—diversity continues to be an ongoing challenge in medical research.[6] Until trial participants are fully representative of the U.S. population, uncertainties may remain about how treatments impact different racial and ethnic groups.

Data quality concerns.

"When you have humans entering data into EMRs, and humans entering information into inventory systems . . . inevitably you run into and encounter errors," said Dr. Proffitt. "That's another big part there—doing that quality control piece and looking at data quality to make sure that what you're getting actually makes sense and is consistent."

Competing priorities for clinical staff.

Because patient care is the top priority for clinical staff, they may not be able to dedicate sufficient time to research when patient care needs arise. "Clinical folks—or people who have to wear two different hats, the clinical side of things and the research side of things—will always have to make clinical a priority because patient care and safety is the priority," said a research nurse coordinator. "Therefore, research will always be on the back burner."

"When you have humans entering data into EMRs, and humans entering information into inventory systems . . . inevitably you run into and encounter errors."

[5] Victor Wang. "Clinical Research News: The hospital's evolving role in complementing clinical trials." Clinical Research News (September 12, 2022). https://www.q-centrix.com/news/clinical-research-news-the-hospitals-evolving-role-in-complementing-clinical-trials/.

[6] U.S. Food and Drug Administration (FDA). "FDA takes important steps to increase racial and ethnic diversity in clinical trials" (November 4, 2022). https://www.fda.gov/consumers/minority-health-and-health-equity-resources/clinical-trial-diversity.

Clinical research in action

To learn more about the intricacies of conducting clinical research, Q-Centrix spoke with two research facilitators at a Pennsylvania-based health system and a chief scientist at BRIO. These include a research nurse coordinator who coordinates cardiology clinical trials at a hospital-based clinic; an associate director of clinical research operations who hires, manages, and standardizes her facility's centralized clinical trials unit (which conducts research in cardiology as well as other areas such as neurology and oncology); and Dr. Mike Proffitt, chief scientist at BRIO, who manages a mix of investigator-led research as well as sponsored clinical trials. Together, their perspectives provide a detailed picture of the considerations and complexities that clinical research involves.

Determining a study's feasibility involves many considerations. Research teams must consider whether the study is relevant to the facility's priorities and whether the facility can meet the needs of the trial. This includes having sufficient staff to take on the study and having a patient population that matches the trial's needs.

Enrollment varies widely from study to study. An associate director of clinical research operations shared that she starts with a goal of recruiting one to two patients per month, then adjusts this number depending on the study and other factors. Minimal-risk studies with short interventions are much easier to enroll patients in than higher-risk interventional studies. Depending on the study, recruitment volumes may range anywhere from recruiting 20 patients over five years to recruiting more than 1,000 patients over two years.

Data savviness is a valuable skill for navigating data-related roadblocks. Given the challenges of relying on disparate data sources, data management skills are essential for research coordinators or other staff tasked with pulling the data required for research needs. "Having some data savviness definitely helps smooth things along," Dr. Proffitt explained. "I think the things you can accomplish by being a little bit data savvy can really have huge gains, as opposed to doing individual chart chasing." Dr. Proffitt said that being able to write custom queries and pull data through their EMR's backend enables his team to obtain data much more efficiently than through manual searches.

> "Having some data savviness definitely helps smooth things along."

In a typical year, research teams may work on a dozen or more clinical trials. The research facilitators Q-Centrix spoke with noted that their teams work on anywhere from 12 to 25 clinical trials per year. As a research nurse coordinator stated, these are typically a mix of different types of studies at different phases in the study life cycle: "For us to support the staff that we have, we should typically be actively enrolling in about five trials. We should be having about five trials that are maybe closed to enrollment but still have patients in follow-up. And then we should have about five that are on the horizon that we're considering or being considered for."

Study timelines can be impacted by a variety of different factors. These include sponsor cooperation, the contracting process, a research coordinator's level of availability, screening difficulties for complex protocols, patient interest in the study, and the perceived benefits of participation. "Make sure you understand that it can take half a year just to get [the study] on board," said an associate director of clinical research operations. To that end, Dr. Proffitt advised that realistic timelines are key. "Have realistic benchmarks and timelines for getting contracts turned around and getting them executed," he said.

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›› Opportunities and recommendations

Participate in a research network.

Research networks help organizations conduct research effectively by connecting hospitals and health systems to industry-sponsored research opportunities and providing tools and services that help research teams facilitate clinical research. By joining a research network, healthcare facilities can connect with industry-sponsored prospective clinical trials matched to their needs, gain access to a broader pool of deidentified patient data, receive funded services for patient screening, use tools to assess study feasibility and identify relevant patients in real-time, rely on qualified data experts who can curate clinical data and complete data quality checks, and more. Additionally, the utilization of registry data within research networks can be advantageous, as it often overlaps up to 80% with primary data sets used in clinical trials, thereby significantly reducing resource burdens. This holistic approach to data integration and collaboration is precisely why Q-Centrix has launched a research network dedicated to providing healthcare organizations with these comprehensive services and opportunities.

Plan for a rotation of trials in different phases.

Maintaining a varied roster of trials six to twelve months in advance enables research teams to accommodate the different levels of time and effort these studies require and ensure a consistent and feasible stream of work. The research facilitators Q-Centrix spoke with simultaneously work on a variety of clinical trials at different stages of development, including enrollment, follow-up, and studies they are evaluating for participation.

Work closely with providers to get buy-in and assistance with patient enrollment.

This may involve participating in providers' rounds, having monthly meetings about trials, and communicating with them in the way that is most convenient. One research nurse coordinator Q-Centrix spoke with uses her health system EMR's secure chat function to communicate with providers about patients, as it is very accessible to providers and places less demand on their busy schedules than other forms of communication.

Make it as easy as possible for clinical staff to participate.

A research nurse coordinator mentioned that her department has a daily 15-minute meeting each morning to discuss clinical information, staffing, and research needs, providing an ongoing opportunity for research and clinical teams to keep one another informed about research efforts. Similarly, Dr. Proffitt shared that being cognizant of others' clinical duties can help clinical staff maintain a balanced workload. "I try to be mindful of what's going on with the research coordinator's clinical load," he said.

Develop a workflow.

Establishing a system for where to begin when identifying patients for a study can help streamline the process. Rather than relying solely on the protocol to understand the study specifications, an associate director of clinical research operations uses the protocol to inform conversations with study sponsors and investigators. "If you talk to the people who wrote the protocol, they will tell you where to begin," she said. She shared that she typically begins by reviewing the protocol, then speaking with the principal investigator, and then speaking with the sponsor.

Foster a culture that centers on communication.

Facilitating clinical trials is a complex process, and questions are likely to arise on the job. Research teams should foster an environment that emphasizes communication and transparency. "Part of that culture is having mutual trust and respect, having regular touchpoints, and having transparency with what's going on," said Dr. Proffitt. An associate director of clinical research operations also emphasized the need for effective communication: "Having that open, honest communication is huge," she said.

Research networks help organizations conduct research effectively by connecting hospitals and health systems to industry-sponsored research opportunities and providing tools and services that help research teams facilitate clinical research.

Conclusion

Clinical trials are instrumental in shaping the future of medicine, leading to exciting developments that continue to transform patient care and treatment outcomes.[7] The ever-growing number of registered studies—which increased by 67 percent in the last five years—suggests that many more innovations are on the way.[8] Moreover, the FDA's recent draft guidance on good clinical practices hints at forthcoming changes to modernize trial design and help researchers conduct clinical trials more effectively.[9]

In the meantime, hospitals and health systems can act now to further their involvement in clinical research. Partnering with research networks, planning strategically, and prioritizing collaboration and communication are key to overcoming common barriers and facilitating research successfully. By taking these steps, healthcare facilities can drive innovation, improve patient care, and make a meaningful contribution to the broader medical community.

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[7] Carrie Arnold and Paul Webster. "11 clinical trials that will shape medicine in 2023." *Nature Medicine* 28 (December 23, 2022): 2444-2448. https://www.nature.com/articles/s41591-022-02132-3.
[8] ClinicalTrials.gov. "Trends, charts, and maps" (September 11, 2023). https://classic.clinicaltrials.gov/ct2/resources/trends.
[9] Food and Drug Administration (FDA). "FDA announces additional steps to modernize clinical trials" (June 6, 2023). https://www.fda.gov/news-events/press-announcements/fda-announces-additional-steps-modernize-clinical-trials.

About Q-Centrix

Q-Centrix believes there is nothing more valuable than clinical data—it is critical in delivering safer, consistent, quality healthcare for all. Providing the industry's first Enterprise Clinical Data Management (eCDM™) approach, Q-Centrix utilizes its market-leading software, the largest and broadest team of clinical data experts, analytics and reporting data structure, and the best practices from more than its 1,200 hospital partners to curate meaningful, high-fidelity, complete, and secure clinical data. Its solutions address a variety of clinical data needs, including regulatory, cardiology, oncology, trauma, research and more. For more information about Q-Centrix, visit www.q-centrix.com.

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