Solving Patient Identification and Enrollment Challenges in Clinical Trials

How a Patient-Centric Approach Combined with Novel Technology Results in More Qualified, Engaged Patients
In an effort to control escalating costs and avoid expensive study delays, clinical trial stakeholders are looking at novel approaches to attracting and retaining larger pools of qualified trial participants. In addition to implementing innovative technologies to improve the identification of potential participants, sponsors and clinicians are seeking ways to better address the needs of patients, such as making trials more accessible and convenient to larger segments of the population.

A patient-centric approach can control study costs, as well as create greater participant diversity and make trials more readily available to certain patients who previously had limited opportunities to participate in life-enhancing and potentially life-saving clinical trials.

What follows are several approaches that sponsors and contract research organizations (CROs) should consider to make clinical trials more patient-centric, including involving community physicians; making trials more accessible to more patients (including targeting previously underrepresented patients); and making trial participation more convenient.
Involving the doctor

Leveraging the physician-patient relationship makes for a more patient-centric and positive experience that leaves the patient feeling that he or she is surrounded by a team of caring and motivated providers. Patients are grateful when their community physician proactively brings trial opportunities to them and helps them through the process, since their doctor is familiar with the patient’s disease state/s and medical history. Not surprisingly, nearly three-quarters (72 percent) of Americans say it’s likely they would participate in a clinical trial if recommended by their doctor.

Physician-referred patients are also more likely to remain in a trial for the duration and to be adherent with the study protocols. Traditionally, about one-third of patients drop out of studies before completion. When community physicians are involved in the process, they have the opportunity to fully review patients’ medical records in advance to determine the likelihood of meeting study inclusion and exclusion criteria. Physician-referred patients also are more likely to remain engaged in the trial process because they continue to see the physician for their routine healthcare needs during their clinical trial participation.

THE ePATIENTFINDER MODEL: PROVIDER PARTICIPATION IS KEY

The ePatientFinder® model for clinical trial identification and enrollment is based on the assumption that patients are more likely to participate in clinical trials if their physicians are involved in the process. This approach includes automated outreach to referring physicians when relevant trials become available in their area, or when a newly diagnosed patient appears well-qualified for an existing trial. Alternatively, referring physicians have the option to run a pre-configured query of their own electronic health record (EHR) databases to find qualified candidates.

Participating physicians provide the ePatientFinder program with secure, compliant access to their EHR databases. Databases are accessed regularly to identify qualified patients and their treating providers. This visibility also provides researchers with critical insights into how to attract a larger percentage of qualified participants, such as optimizing protocol designs or establishing study sites in a specific geographic area.

Meanwhile, the ePatientFinder model compensates physicians for their participation and pays them at a rate comparable to what they would receive for regular patient care. CROs and sponsors benefit from the ability to tap into an greatly expanded population of qualified patients that have never before participated in trials.
Making trials accessible to all patients

A patient-centered approach helps make clinical research trials more accessible to a larger cross-section of patients. Unfortunately, community physicians—and their patients—are typically less involved in the clinical trial process than those at large academic medical centers because they have less visibility to active studies. This means a large segment of the population never has the opportunity to gain early access to the advanced therapies offered in clinical trials. However, the widespread adoption of EHRs and the use of sophisticated analytics is making it possible for physician sites to identify all potentially eligible patients. For example, because EHRs typically contain codified fields that match various study inclusion and exclusion criteria, practices can easily pinpoint those patients that may be protocol-eligible.

A patient-centric model can also improve the diversity of study participants. According to the Food and Drug Administration (FDA), minority patients—along with elderly patients and women—have historically been underrepresented in clinical trials. African-American patients, for example, comprise 13.2 percent of the population, but only 5 percent of clinical trial participants, while Hispanic patients represent 16 percent of the population, but just 1 percent of participants. Meanwhile, Caucasian patients account for 67 percent of the population and 83 percent of research participants.

Ethnic diversity is critical in the trial process because different ethnicities respond differently to the same disease and to different therapies. Consider the blood thinner clopidogrel, or Plavix, which FDA approved in 1997. Today we realize that about 50 percent of Asian patients and 75 percent of Pacific Islanders lack the enzymes required to activate the drug. Similarly, certain classes of hypertension drugs have recently been found to be less effective in African-American patients, while African-Americans with a certain common genetic variation require lower doses of the blood thinner warfarin compared with Caucasian patients.

Traditionally low clinical trial participation rates among minorities have been fueled by feelings of mistrust among potential participants, as well as an overall lack of awareness of potential trials. Language barriers can also create an obstacle. Researchers who adopt a patient-centric approach to trial enrollment—especially by working directly with the patients’ physicians—are more likely to work to increase overall patient trial awareness, as well as address potential misgivings on the part of patients.

THE TUSKEGEE SYPHILIS STUDY

Past mistakes on the part of the government have contributed to feelings of mistrust among clinical trial potential participants, especially among the African-American community. Perhaps the most famous and well-documented example of unethical clinical research involved the U.S. Public Health Service and its Public Health Service’s Tuskegee syphilis study.

The study induced 600 African-American men to participate in various experiments over a 40-year period. Participants who were diagnosed with syphilis were never informed of their condition, nor were they offered treatment. Many died of the disease, infected their wives, and/or passed congenital syphilis to their children. As a result, residual mistrust of clinical trials remains today among many members of the African-American community.
Target groups of patients

In order to manage study costs and increase efficiencies, researchers prefer to locate studies in areas where there are large concentrations of potentially protocol-eligible study participants. However, researchers have traditionally had difficulty identifying how many patients with specific medical conditions reside in specific areas. As organizations seek to make studies more patient-centric and accessible to larger numbers of potentially qualified patients, innovative heat-mapping tools that leverage EHR data are making the identification process easier.  

Heat-mapping helps researchers identify areas where clusters of potentially eligible patients exist. With the integration of powerful analytics, heat-map data can be made actionable and individual patients identified. Study organizers can then reach out to patients on an individual basis to advance the trial enrollment process.

Make participation convenient

Researchers must work to ensure that trial participation is as convenient as possible for participants. Participants are more likely to remain engaged in the process if participation is convenient, which means organizers may need to make accommodations to minimize certain practical burdens.

To increase accessibility, study organizations may opt to provide special assistance when a patient has difficulty making appointments because he or she is responsible for dependent children or has other responsibilities that could limit participation. Researchers also may want to offer evening or weekend appointments for participants who are unable to make appointments during regular work hours. If transportation is an issue, study coordinators or organizations that support them may opt to coordinate a car or medical van. For example, ePatientFinder works with a company, Circulation, that arranges transportation via Uber for patients who need transportation to trial sites during the identification and enrollment process.
Embracing change

In order to minimize trial costs and avoid study delays, clinical trial stakeholders must consider new approaches for identifying and enrolling qualified trial participants. By leveraging new technologies, study sponsors can improve the identification of potential participants, as well as make trials more accessible and convenient to a larger segment of the population. Making trials more readily available to previously underrepresented patient populations also leads to greater participant diversity.

One novel, patient-centric approach to consider includes working directly with the community physicians who treat protocol-eligible patients. Referring physicians and trial sponsors/CROs can be connected via EHRs and other health IT partnerships, providing access to millions of patient lives. This method also reduces study costs and minimizes delays because physician-referred patients are typically better qualified than self-referred patients and remain more engaged in the trial process.

KEY BENEFITS OF THE EPATIENTFINDER APPROACH OVER TRADITIONAL PATIENT RECRUITMENT METHODS:

- Patients who learn about a clinical trial from their doctors are more likely to participate. In fact, nearly three-quarters (72 percent) of Americans say it’s likely they would participate in a clinical trial if recommended by their doctor.¹

- Referred patients are thoroughly pre-screened, and as a result, are far more likely to be accepted into a trial. In fact, in a recent chronic conditions trial, 78 percent of patients referred by ePatientFinder were accepted for study participation, compared to 3 percent of patients referred by traditional, direct-to-patient recruitment methods.⁹

- Patients are more likely to remain in a trial for the duration and to be adherent with the study protocols. Traditionally, about one-third of patients drop out of studies before completion.² With the ePatientFinder model, patients continue to see their referring physician for routine medical care, which adds another layer of accountability and engagement.

EPATIENTFINDER®: OFFERING A NEW APPROACH TO PATIENT RECRUITMENT

ePatientFinder®’s approach to identifying and enrolling clinical trial participants is patient-centric and involves working directly with the doctors who are treating protocol-eligible patients. Using the innovative Clinical Trial Exchange™ platform, physicians are able to easily identify, thoroughly screen, and refer patients to clinical trials in their community.¹⁰

The Clinical Trial Exchange connects life-science companies—including numerous “top 10” pharmaceutical, medical device and CRO clients—with a robust network of referring physicians. The exchange is deployed through numerous top-tier EHR and health IT partnerships that provide access to more than 100 million patient lives across the United States.

Contact sales@epatientfinder.com for more information.
Sources


