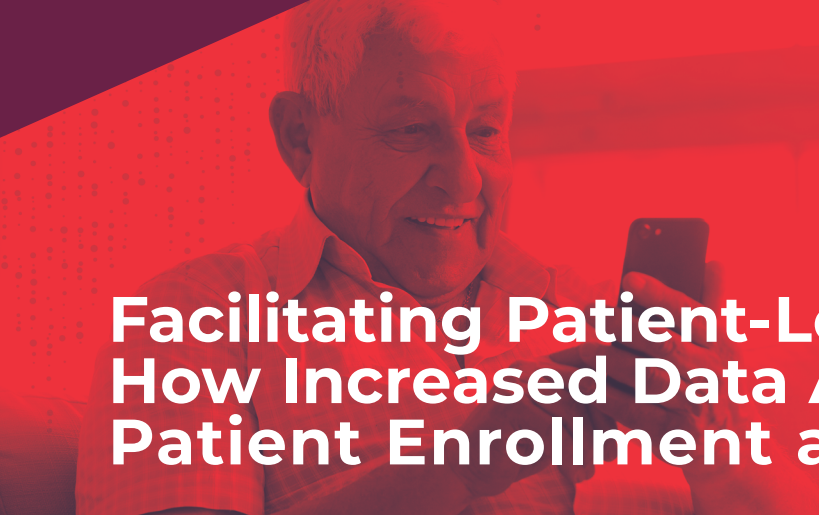

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Facilitating Patient-Led Research: How Increased Data Access Can Increase Patient Enrollment and Engagement

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If identifying and including patients is one of the biggest hurdles of a clinical trial, how does access to 100 million patients sound?

Although it's not the panacea for all patient recruitment challenges, having access to millions of patients offers an opportunity to provide study designers the ability to transform clinical trials. After all, ready access to such an enormous and diverse patient population should facilitate enrollment in an unprecedented way, while enhancing and supporting patient engagement like never before. This paper shares how a robust patient database is one critical key that impacts multiple facets of a trial, leading to more successful outcomes that put patients at the center of research.

Building truly patient-centric protocols

Leading with patients in mind creates a holistic trial design system in which patients aren't viewed as "subjects," but rather as informed collaborators. This active, engaged participation increases the overall success of trials and enables patients to play a more central role in their own healthcare using technology, communication, and continued education and engagement.

Real-world-compatible trial design

With access to a vast patient pool increasing opportunities for enrollment and engagement, study designers can focus more on building patient-friendly protocols, investing time in understanding the lifestyle of the patient population, and building designs accordingly for flexibility, comfort, and patient needs.[i]

Further, patients have become increasingly proactive in self-education about clinical research prior to enrollment. After educating themselves on the disease, mechanisms for cure or treatment, similar trial results, and more, these digitally savvy patients are proactive about conversations with physicians regarding the possibility of clinical trials as a care option. Engaging them allows for faster testing of inclusion/exclusion criteria and allows sponsors to prescreen patients and refer them to sites.[ii]

Empowering a more diverse patient population

Increasing diversity in clinical research has become imperative.[iii] Racial, gender, and age disparities are not fully represented in

research, creating health equity gaps and treatment opportunities that must be addressed. With increased access to a much larger patient population, rather than opening up sites that provide access to diverse populations and waiting years to enroll, patients can be identified in advance and site locations opened to accommodate the patients' convenience and proximity. Identifying and accessing community physicians to facilitate patient enrollment and increasing patient trust and confidence are critical parts in achieving diversity organically.[iv]

Broader inclusion for greater patient impact

By accessing a much larger patient population, studies have the potential to expand inclusion criteria, creating opportunities that provide for a greater impact on patient quality of life. With the patient-first approach that this broadened inclusion allows, protocols that previously would be pulled because of strict inclusion/exclusion criteria can expand their threshold of inclusion — change the severity threshold, for example. This allows for patient enrollment that can vastly improve the quality of life for a patient whom might not otherwise meet criteria for inclusion.

Promoting physician/patient relationship

The range of identified potential trial participants allows the researchers to engage the physician to initiate an authentic interaction with the patient about clinical trial enrollment, coming from a position of trust to broach the topic. Being patient-centric is being physician-centric. As custodians of the patient's medical records, physicians are authentically connecting with patients from a position of trust and play a critical role in clinical trial recruitment.[v]

Locating difficult-to-reach patients

A larger patient population data pool allows location and identification of patients who are otherwise "invisible" to the opportunity for enrollment, because of their geographic location or a rare disease diagnosis, for example. This opens an opportunity to them that they might not otherwise have or even be aware of as an option, putting individuals, rather than sites, at the center of the research process.[vi]

Benefits to the research community

Patient centricity begins with the research community. Increased access to patient populations allows researchers to focus on priorities that will enhance the patient experience and trial outcomes, creating more successful trials that, in turn, will further help more patients as therapies move to market faster.

Streamlining inclusion/exclusion

When designing protocols, inclusion/exclusion criteria often narrow study protocols to a point where an artificial sample has been created that is no longer relevant to the studied indication, at which point the trial's recruitment and feasibility is directly impacted. Further, with stricter regulatory requirements, inclusion/exclusion criteria become even more stringent. Simply put, the more participants, the higher chance of obtaining significant results, so access to more patients provides increased opportunity for feasibility.[vii]

Expedited timelines

With a vast scope of data available, researchers can more rapidly assess feasibility and enrollment. Because of segmented markets and regulatory pressures, the sheer scope of data scales up the opportunities to rapidly assess even the strictest protocols for viability, ultimately saving time and preventing under-enrollment or failed trials.

Forging valued connections between researchers and physicians

As researchers have access to a larger patient population and are able to connect with the patient's trusted physician to facilitate enrollment, a stronger relationship between researchers and physicians will be forged. This not only leads to future trial success and enhanced patient care, but the closer research is to healthcare, the more relevant protocols will become — and the more informed the healthcare system will be as physicians will be thinking proactively about research as a care option. Further, advising patients about clinical research participation can be incorporated into the medical education process, further enhancing and solidifying a successful relationship.[viii]

By creating a holistic ecosystem between physicians, researchers, and patients, the patient is no longer at the end of a linear ecosystem; instead, they are at the very center, and all research circles around them. Access to a vast patient data resource affords all stakeholders the opportunity to be fully supported and enhances and streamlines the entire clinical research process, leading to results that ultimately benefit more patients with successful outcomes.

[i] Patient centric approach for clinical trials: Current trend and new opportunities https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4504054

[ii] Capsey L, Butlin R. In the Patients Shoes from Protocol to Publication-How to Achieve a Patient-Centric Approach to Clinical Trial Design.

[iii] Increasing Diversity in Clinical Trials: Overcoming Critical Barriers https://www.sciencedirect.com/science/article/pii/S0146280618301889?via%3Dihub

[iv] Building trust and diversity in patient-centered oncology trials: An integrated model https://journals.sagepub.com/doi/abs/10.1177/1740774516688860

[v] Physician-Related Factors Involved in Patient Decisions to Enroll Into Cancer Clinical Trials https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2790653/

[vi] The Remote Patient-Centered Study Approach in Clinical Research https://www.appliedclinicaltrialsonline.com/view/remote-patient-centered-study-approach-clinical-research

[vii] Designing Inclusion and Exclusion Criteria, UPenn https://repository.upenn.edu/cgi/viewcontent.cgi?article=1000&context=crp

[viii] Clinical research and the physician-patient relationship https://pubmed.ncbi.nlm.nih.gov/12693890/

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