A Patient-Centered Approach in Clinical Trials: Impact on Patient Retention and Costs
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Abstract

This white paper reviews patient-centered strategies for clinical trials and treatments, including their impact in reducing clinical trial dropouts and total costs. In particular, we analyze how adopting a patient-centered approach in clinical trial recruitment offers greater potential for cost savings through patient education and engagement in research functions and retention of chronically ill patients. In an era of value-driven healthcare and personalized medicine, the pharmaceutical industry is increasingly focusing on diversity in patient recruitment strategies. However, there is little discussion on maximizing patient retention in clinical research studies. Key obstacles to retention include functional limitations, limited access to care, lack of education and awareness regarding clinical trials, and lack of ongoing support. Patient-centered interventions, including increasing access to transportation, utilizing health information technology (HIT), and increasing stakeholder engagement, can drive efficiency and cost-containment initiatives. Informed and empowered stakeholders can be pivotal in maximizing enrollment of diverse patients in clinical trials and reducing study lengths and costs.
Introduction

Clinical Trial Costs and Patient Retention

Clinical trial costs continue to rise and recent estimates put direct costs for Phase 1-3 development between $50-$100 million.\(^1\) While some estimates of total costs that incorporate previous R&D costs, development failures, and estimates of opportunity costs to bring a therapeutic to market are as high as $2.6 billion, a recent Journal of the American Medical Association analysis of the average costs for cancer drug development was much lower, approximately $641 million.\(^2\)\(^3\)\(^4\) Regardless of the methodology used to estimate these costs, clinical trial costs are widely regarded as an inflection point for cost reduction initiatives and economic innovation. In particular, patient retention strategies to keep patients in trials has shown much promise for reducing avoidable costs to the clinical trial system.

High clinical trials costs negatively affect the entire healthcare ecosystem. Pharmaceutical Research and Manufacturers of America (PhRMA) suggests that rising clinical development costs are a major contributor to escalating drug costs.\(^5\) While the extent to which clinical trial costs affect drug prices is currently debated, as noted previously, it is inarguable that the costs incurred during development are passed on to drug pricing. The relationship between access, cost, and quality of care demands a deeper understanding of the effect of high costs clinical trials on patients' access to novel treatments, affordable prescription drugs, and ultimately better clinical outcomes for patients. For these reasons, identifying inefficiencies within the drug development process, and especially clinical trials, is especially pertinent to the current discussion to reduce costs and increase quality of healthcare in the United States.

Although bringing novel drugs to market are a high priority, the pharmaceutical industry is faced with a number of barriers in conducting clinical trials to completion. These include complex research protocols, increased regulations and requests for safety data, and lengthy timelines. These additional requests require increased financial capital, lost opportunity costs, and increased demand for patient enrollment. This increased need for larger patient cohorts is concerning due to previous issues with patient recruitment and retention.

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“A Patient-Centered Approach in Clinical Trials: Impact on Patient Retention and Costs

“Pharmaceutical Research and Manufacturers of America (PhRMA) suggests that rising clinical development costs are a major contributor to escalating drug costs.”
The Department of Health and Human Services (HHS) defines patient retention simply as the "amount paid to the patient for study participation, which might include financial compensation, reimbursement for travel, meals, etc." Further, the HHS estimates $6,145 for all patient retention expenses in a Phase I trial. By definition, this estimate fails to take into consideration delayed or failed trials, lost time, or the costs necessary to re-establish trials. Taking a more holistic approach to estimating patient costs within trials, PhRMA estimates the costs to enroll and retain a patient in any phase trial at approximately $36,000 per patient. In particular, it is estimated that the per patient costs for Phase III and IV trials account for a disproportionately large fraction of this estimate: 74% of the total patient costs due mostly to the larger cohort of enrolled patients. These figures are expected to continue rising with the increased need for clinical trial participants, resulting in increased trial costs. In addition to the patient recruitment problem, increasing clinical trial costs are also attributed to patient retention challenges. Recent reports revealed a 30% dropout rate across all clinical trials. Furthermore, of those randomized into a clinical trial, 18% dropped out before trial completion. As a result, only 15% of all clinical trials are able to retain enough patients to completion. This presents a large opportunity for the pharmaceutical industry to implement patient-centered recruitment and enrollment approaches as a cost saving initiative. For example, recruiting a new patient into a clinical trial when another drops out of the trial or is lost to follow-up poses a significant financial burden. In addition, the failure of clinical trials to recruit and retain an adequate number of patients can result in lost time and effort, lost financial resources, missing data that can skew the results of the clinical trial, increased time and length of the approval process, or even a cancellation of the study.

Patient Centered Care

The New England Journal of Medicine (NEJM) defines patient-centered care (PCC) as a system that “encourages the active collaboration and shared decision-making between patients, families, and providers to design and manage a customized and comprehensive care plan.” The Picker Institute derived eight patient-centered care metrics designed to serve as a foundation for creating patient-centered focus: (i) respect of
patient’s preferences, (ii) coordination and integration of care, (iii) information and education, (iv) physical comfort, (v) emotional support, (vi) involvement of family of friends, (vii) continuity and transition, and (viii) access to care. PCC initiatives have shown success as a satisfying patient experience improves outcomes, increases compliance with treatment, and reduces unhealthy behaviors and trips to the Emergency Department. We believe that focusing on these PCC metrics, creating benchmarks, and establishing goals based on their guidelines can offer an avenue for reducing patient dropouts in clinical trials and therefore reduce costs of the trials.

Patient Retention and Clinical Trial Success

Patient retention in clinical trials is crucial for the success of a study. Nonetheless, it is a patient’s right to drop out of a clinical trial. While there are various reasons why a patient may decide to drop out, some of the contributing factors can be addressed. Forte Research, an organizational research firm, aggregated a database of contributing factors to why patients miss appointments or drop out of trials entirely. Among the reasons are inconvenient locations, schedule conflicts, forgetting visits, fear and anxiety, financial constraints, family matters, side effects, and failure for condition to improve. Many of these reasons for withdrawal can be consolidated under inadequate patient education of their medical care, poor planning, and indifference to family or social concerns. For example, a common reason patients drop out of clinical trials is inconvenience. Many patients live far from their sites or have difficulty accessing them. Implementing a patient-centered approach would focus on understanding the needs of the patients and ensuring access to the trial location through travel reimbursement, assistance in travel booking, use of low-cost facilities such as local clinics or at-home testing, and creating a comforting environment. Utilizing such alternate approaches may allow companies to follow-up beyond the initial trial period and assist in conducting time studies. Through such patient retention strategies, companies decrease their overhead, total costs, and can utilize the additional data in studies against competitors.

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Current patient retention strategies focus on the following: (i) patient understanding, (ii) incentives and reimbursement, (iii) and counseling sessions. However, there is no evidence as to whether these strategies are guided by patient-centered care principles or whether these strategies are disseminated throughout clinics or Contract Research Organizations (CROs) in the United States. In order to improve retention rates, we propose the use of patient retention strategies grounded in the ability of clinical researchers, providers, nurses, and CROs involved in clinical studies to adopt a patient-centered attitude. A patient-centered approach is rooted in better communication between provider and patient and built to accommodate patient preferences to help engage patients and encourage compliance throughout the length of the clinical study. We fundamentally believe incorporating these approaches will help retain patients in their respective trials, increase trial success rates, and reduce the cost burden of trial costs on the healthcare system.

“A patient-centered approach is rooted in better communication between provider and patient and built to accommodate patient preferences to help engage patients and encourage compliance throughout the length of the clinical study.”
Strategies to Improve Patient-Centeredness in Clinical Trials

We believe three specific PCC approaches can benefit patient retention and reduce dropout rates. These approaches include emphasis on patient education, respecting patients’ preferences, and enabling the involvement of family and friends.

(i) Information and Education

Lack of knowledge about the clinical trial process creates barriers including, (i) patient’s fear of a reduced quality of life, (ii) uncertainty regarding the drug or placebo and the potential side effects, (iii) potential side effects, (iv) concern that the experimental drug might not be the best option, and (v) misunderstood expectations. Thus, clinicians and providers should assume that patients have limited knowledge and familiarity with clinical trials. Clinicians should educate the participants regarding trial process, expectations, and address any concerns in an approachable manner. Patient-centered retention tactics that target these barriers will help educate the patient and ensure their understanding of the clinical trial process.
Currently, clinicians typically begin to educate patients during the recruitment phase. As early as trial design, patient education can be emphasized by forming education plans and identifying potential educational hurdles that may arise. These plans would be designed to mitigate any informational issues that arise and can be built around the best ways to educate patients. Studies suggest that patients drop out overwhelmingly due to the five factors listed above. Thus, educational material or programs should be designed and developed in the trial design phase aimed at mitigating these obstacles. Also, discuss incorporating patient, advocate, physicians, research staff, etc. in this initial stage so that all concerns are heard and incorporated. Similar to an advisory panel – incorporating patients at each stage will ensure success. A patient-centered strategy could be implemented to determine the most effective form of communication with each patient or population. Communication and education strategies could be built around e-mail, telephone, in-person conversations, focus groups, and informational dissemination would include presentations, literature, or physician consultations. Patient-centered strategies acknowledge that each patient is unique in their ability to learn and understand clinical trial design and expectations. Thus, it is important to begin early in the trial design process to develop strategies that mitigate potential shortcomings in patient education that arise during patient recruitment and inevitably persist through enrollment. While this is primarily a patient recruitment strategy, it has a direct effect on patient retention ensuring that those patients that are recruited are educated about the trial in its early stages.

Throughout each clinical phase, education remains critically important. It is imperative that patients have the ability to ask questions and remain engaged with trial sponsors or clinicians. If patients feel their questions are going unanswered, or they do not fully understand their current status within the trial, they are generally more likely to drop out of a trial. Several strategies can be implemented such as dissemination of health information technology (HIT). Electronic devices such as tablets can be distributed to patients that are pre-loaded with literature on clinical trial background or information about their particular treatment or disease. These tablets could also interface directly with a provider at the sponsor hospital that can respond to questions that may arise. Separate from

“It is important to begin early in the trial design process to develop strategies that mitigate potential shortcomings in patient education that arise during patient recruitment and inevitably persist through enrollment.”
technological interventions, there are social solutions such as in-person group meetings for patients in the trial. This serves an educational purpose that patients can correspond with each other on how they feel day-to-day and potentially answer each other’s questions. This also serves to enhance comradery within the trial that enhances their motivation to complete the study. These are relatively simple patient-centered solutions that can be implemented to ensure patients are educated and remain engaged within a trial.

(ii) Respect the Patient’s Values, Culture, Preferences, and Needs

Patients from various backgrounds, ethnicities, and socio-economic statuses participate in clinical trials. At all stages of the clinical trial process, it is important that patients feel that their values and preferences are being respected. Additionally, it is important for providers and other clinical stakeholders to be culturally competent and ensure they are aware of differences between patients. Patients with functional limitations, such as those with chronic diseases, should also be recognized and extra attention should be given to ensure they are enabled to participate in clinical trials.

A proactive patient-centered strategy would initiate focus groups during the design phase to gather information on patients’ motivations and restrictions in terms of their values or preferences. This gives the patients the opportunity to express themselves and is insightful to clinical researchers who can use this information to design a clinical study that is tailored to the patients. We also propose the frequent use of surveys to understand patient perceptions of study burden, and other patient concerns. Surveys should be conducted upon initial enrollment and throughout the course of the study to ensure patients feel valued and engaged throughout the trial. During the study design, researchers must account for cultural and functional limitations, such as feasibility and implications to the patient’s life. Factors such as the frequency of study visits, the nature of patient responsibilities, and site convenience should be addressed during enrollment phases.

“It is important for providers and other clinical stakeholders to be culturally competent and ensure they are aware of differences between patients.”
Respecting patient preferences and values is equally important in the patient consent phase and the patient participation phase. During the patient consent phase, patients are committing to participation in the clinical trial assuming that all terms and conditions of the study align with their values and preferences. At time of consent, some patients may decide to withdraw because of concerns relating to personal preferences, financial obstacles, or other barriers. This is an opportunity to use patient retention strategies that will clear any misconceptions or alleviate possible patient burden associated with the study, which have already been designed to meet the cultural needs of the patient. We recommend frequent consultations with providers and clinical stakeholders to reassure patients that their values and preferences are taken into account.

Most at risk of dropout are those patients with functional limitations which can create higher barriers to clinical access. It is important for providers and stakeholders to be especially cognizant of the needs and limitations of these patients. In the likely case that it is difficult for these patients to transport themselves to appointments, sponsor hospitals can arrange or provide transportation for these individuals. Several health centers across the country, such as Oak Street Health in Chicago, are implementing transportation initiatives to ensure lower-mobility patients have access to care. It is important to take into consideration all patients’ values and preferences and also to be aware of their needs and limitations when developing clinical protocols.

(iii) Involvement of Family and Friends

Engaging family and friends sits at the core of patient-centeredness. When patients complete treatment, family and friends take over provider responsibilities and take an active role in care and surveillance. Properly educated family and friends can answer patient questions, keep them motivated, and keep them compliant in the trial protocol. Further, patients’ families and friends can give different perspectives and provide information based on personal knowledge of the patient’s circumstances to providers and clinical stakeholders. When patients and their support
network of families or friends are active participants in their care, we expect a better experience during clinical studies.

The most important strategy for providers and other clinical stakeholders is to ensure family and friends are included in the two previous patient-centered strategies: education and respecting patient preferences. Providers should encourage friends and family to be involved in surveillance away from the hospital. Family and friends can help watch for adverse effects such as changes in mood, excessive fatigue, fever, and other easily identifiable symptoms that providers would otherwise not be able to monitor. Family and friends can then disseminate this information back to providers and not be biased as a patient potentially would. Family and friends that are knowledgeable about the trial can also motivate the patient to stay in the protocol and mitigate negative emotions or depression. Patients with functional limitations or debilitating conditions are especially reliant on family and friends for transportation, so it is important for providers to engage them and ensure they know the critical importance of making appointments. Overall, engaging family and friends is important for reiterating and reinforcing patient education and respecting patient preferences.

“Engaging family and friends is important for reiterating and reinforcing patient education and respecting patient preferences.”
Conclusions

Patient retention is a critical metric of clinical trial success. Studies that experience significant patient dropout generally take longer and are much costlier. Thus, patient retention strategies are of critical importance. Here, we have discussed the importance of patient-centered strategies to enhance patient retention and identified three patient-centered care metrics that could be particularly effective: patient education, respecting patient preferences and values, and engagement of family and friends. Taken together, these strategies describe an effort to change the paradigm of clinical trials to become more patient-centered, acknowledge that patients are unique and will require different interventions, and that focus on patient needs will make trials more successful.
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Key Contacts

Authors:

Mr. Joseph Gaspero  
Chief Executive Officer & Co-Founder  
Center for Healthcare Innovation

Mr. Ryan Haake, MS  
Research Associate  
Center for Healthcare Innovation

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Key Contacts:

Mr. Joseph Gaspero  
Chief Executive Officer & Co-Founder  
Center for Healthcare Innovation  
706 S. Ada St.  
Chicago, IL 60607  
P: +1.773.330.2416  
www.chisite.org  
joseph@chisite.org

Dr. James Gillespie, PhD, JD, MPA  
President  
Center for Healthcare Innovation  
706 S. Ada St.  
Chicago, IL 60607  
www.chisite.org  
james@chisite.org
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CHI Memberships provide members with comprehensive access to research and education throughout the year. Together, CHI and members aim to:

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- Create dialogue among organizational leaders and professionals, CHI Board of Directors, and CHI staff on some of the most pressing healthcare issues and challenges

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<td>Opportunity to serve as distinguished panelist(s) at CHI’s educational events (Based on representative’s area of expertise &amp; current role)</td>
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<td>Guest blogging &amp; other thought-leadership opportunities</td>
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<td>Get exclusive early access (30 days earlier) to CHI’s research reports</td>
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<td>Organizational logo &amp; branding opportunities on CHI’s research reports</td>
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<td>Opportunity to make Opening Remarks at CHI’s Board of Directors Strategic Retreat (June)</td>
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<td>Receive special briefing from Chairman &amp; Vice Chairman of the Board on CHI’s annual report</td>
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<td>Sponsor research reports &amp; white papers (assist in shaping topic or become a collaborator)</td>
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8th Annual Diversity, Inclusion, & Health Equity Symposium
Wednesday, 6/27/2018 | Chicago, IL, USA

The 8th annual Diversity, Inclusion, & Health Equity Symposium is a leading annual, collaborative event focusing on health equity and health disparities in the U.S. The symposium brings together leading healthcare professionals, executives, physicians, patient groups, patients, researchers, academics, clinical trial professionals, and diversity and inclusion advocates to discuss health equity in the life sciences and the health sectors. The symposium focuses on the latest trends, challenges, opportunities in both the marketplace and workplace, with a specific focus on how to best serve an increasingly diverse patient base. We also aim to address the broader health disparity challenges in the U.S., and the symposium equips attendees with the latest insights and ideas. Attendees will learn practical solutions, share perspectives, and meet new industry and marketplace colleagues.


This white paper, A Collaborative Health System: A Guide to Actionable Measures for Successful Community Engagement, is based on CHI's Healthcare Executive Roundtable held on October 12, 2017, in New York City. The white paper is meant to help operationalize the insights discussed at the roundtable, with a specific focus on providing actionable and implementable steps that healthcare organizations and individuals can take to build a more collaborative healthcare system that successfully engages patients in the 21st century. Special thanks to all for attending the roundtable. We hope the white paper can be a resource for you and your organization as we think about how to successfully build a value-based, collaborative healthcare ecosystem for all.

Breakthroughs in Healthcare Equity Action Plan

This Action Plan is based on CHI’s second annual Breakthroughs in Healthcare Equity Symposium, a leading annual, collaborative symposium for patients, patient groups, clinicians, researchers, technologists, healthcare and life science executives, and diversity and inclusion advocates to discuss equity in healthcare. The second annual symposium brought these groups together in a collaborative forum to create networks, discuss best practices, and exchange new ideas related to making healthcare more equitable, with a specific focus on understanding how to serve underserved patient groups, including racial and ethnic minorities, women, and the LGBT community. The symposium also focused on helping provider, pharma, and other organizations who serve patients with the latest ideas and insights on how these organizations can better understand the unique and diverse needs of the patients they serve. Attendees exchanged the newest insights and ideas, discussed practical solutions, and met industry and marketplace colleagues.
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Dr. James Su, PhD, Chief Science Officer, Lap IQ

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Dr. James Gillespie, PhD, JD, MPA, President, Center for Healthcare Innovation

Dr. Tina Shah, MD, MPH, Ambassador, CHI; White House Fellow, U.S. Department. of Veteran Affairs

Mr. Tolga Babur, Research Associate, CHI; MHA Student, Johns Hopkins

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Ms. Ritu Kamal, Ambassador, CHI; Global Project Manager, Bodesign Program, Stanford University

Mr. Joshua Limp, Senior Project Manager, Center for Healthcare Innovation

Mr. Brian Sandoval, MPH, MBA, Advisor, CHI, Co-Founder, Binary Health
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