Patient Engagement Guide for Sponsors and CROs

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Introduction

Current State of Patient Engagement

Now, more than ever, sponsors and CROs need to prioritize including patient engagement in their study builds from the ground-up. This involves defining processes to remove barriers for access, increasing awareness and education for clinical trials, and creating effective exchanges between patients and their clinicians.

Experts continue to find that patient-centric trials recruit eligible participants in half the time of traditional trials and are 20% more likely to go to launch.[1] But effective, sustainable patient engagement goes beyond single-focused solutions for recruitment and retention. Sponsors and CROs must put themselves into the mindsets of their patients and find ways to incorporate their needs into the entire clinical trial lifecycle.

Benefits and Costs of Investing in Patient Engagement

A 2018 study tasked with thematically analyzing over 91 publications on patient engagement found 18 benefits and five costs to sponsors and CROs investing in patient engagement.[2] The most pressing of those include:

Benefits of investing in patient engagement

- Identify research topics and priorities that more closely match patients' needs
- More accurate (and less wasteful) resource allocation based on patients' needs
- Research questions, interventions, and technologies that are more relevant and usable for patients
- More inclusive and sensitive research design and workflows
- Higher-quality, more accurate data that adds value
- Quicker approvals by regulators and governing bodies
- Improved readability, accessibility, and comprehension of research materials
- More relevant and usable research endpoints and outcomes
- Improved recruitment rates and reduction in drop-out rates
- Improved trial satisfaction
- Better adherence to study protocols
- Increased fundability - and credibility - of research proposals

Costs associated with investing in patient engagement

- Increased personnel and resources dedicated to patient engagement
- Greater upfront cost of investing in engagement research and development

Patient engagement is an upfront investment for sponsors and CROs but can yield powerful ROI when implemented properly.

In fact, a 2017 study quantified the impact of investing in patient engagement and found that a $100,000 investment from sponsors and CROs could produce gains of more than 500X the initial investment.[3]

Involving the patient perspective on study protocol also benefits the participant experience. "How often do we actually start a clinical trial only to find that they cannot enroll the target patient group?" shared Kevin Kwok, a Parkinson's patient advocate. "Patient and caregiver input might identify barriers that actually impact accrual or prevent dropout. We're often told that we don't have time to do these types of patient engagement assessments. It actually ends up costing developers more time at the end." [4]

Considering the Patient Perspective

The reason many clinical trials fail to meet patient expectations and continue to struggle with recruitment and retention are because a disconnect exists between what patients actually want and what researchers *think* they want.

Results from three surveys conducted by the Medical Device Innovation Consortium highlights the unique contrast between industry and patient expectations in clinical research. Ninety-two percent of industry respondents rated physician recommendation as a key driver for a patient's decision to participate in a trial. In contrast, only 32% of trial participants indicated they had heard about a study from their healthcare provider. And only 9% of participants noted "doctor recommendation" as the deciding factor to participate in clinical research.[5]

Similarly, nearly three in four patients indicated that knowing the types of medical procedures required in a trial was "important" or "very important" to their decision.[5] Yet, research finds that clinicians only spend an average of six minutes training patients on the use of a medication.[6]

Disconnects like these can persist throughout the entire patient journey and cause unnecessary, avoidable patient burden. To understand patient burden, sponsors and CROs must consider the patient perspective. And, in order to do that, they should look to engage patients along each stage of trial development.

Yet, less than half of trial operators seek out patient input before finalizing their study protocol. And once protocols are finalized, less than 20% of trials seek out patient input on operational study design.[6]

Sponsors and CROs need to remember that although we are the ones designing the study protocol, patients are the ones expected to adhere

to those designs. Considering the patient perspective is crucial because the needs patients want addressed may not be obvious to physicians or study managers.

Instead, many trials continue to apply single-focused solutions—such as electronic health records or wearables—that attempt to change the dynamic between clinical research and patients. But these attempts are largely unsuccessful because they are being approached from the perspective of the trial operators.

Understanding the patient perspective means developing a deep understanding of the characteristics, needs, and perceived values of your unique patient groups and aligning your study protocol to those needs.

As Dr. Anthony Yanni, Senior VP and Global Head of Patient Centricity at Astellas Pharma, weighed in, "At the end of the day we know that development processes have to be much more focused on the right patient, the right disease with the right characteristics so that we deliver outcomes that are connected to the patient, the provider, and the caregiver. We know that delivering good science without a connection to patient need is not a satisfactory process." [7]

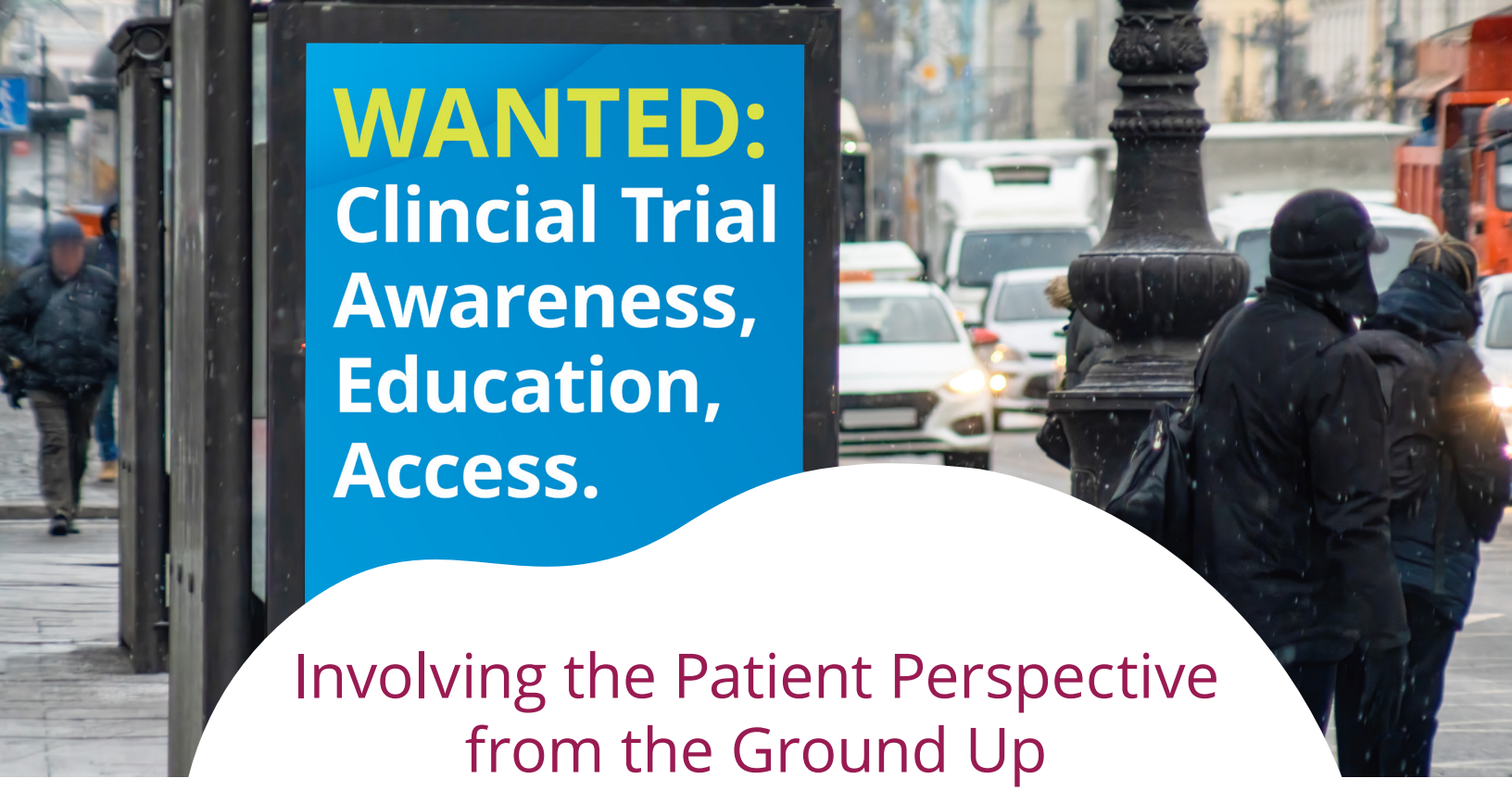
Patient-centric tools may ease trial-related burden; but technology still requires a human-touch to both empower and engage patients, as well as inform and aid clinicians.

Sponsors and CROs need to think about the patient experience as a tool for driving compliance and strengthening adherence. This can be achieved by asking questions and approaching situations from the perspective of your patients. It's important to consider:

- What motivates patients to register for trial and take on the foreseen and unforeseen burdens?
- What financial and physical burdens will the patient be expected to take on and how has that been shared with them?
- Are the consent forms clear and easily digestible?
- What data collection is necessary from the patient and what will motivate them to continue providing that data throughout the course of the study?
- How will the patient be expected to remember everything required of them in the trial?

The goal of these questions - and of patient engagement in general - is to view patients as partners in the clinical trial process.

Patients have a deep and personal understanding of living with their unique disease or situation and their needs may not be obvious or addressed by study managers. By creating meaningful relationships with patient groups, sponsors and CROs can enable their research teams to align study protocol to the unique needs, characteristics, and perceived value of their various patient groups.



Involving the Patient Perspective from the Ground Up

Public Awareness, Education, and Access for Clinical Trials

Market research found that the average patient recruitment spend for trials in 2019 was $3.2 million.[8] Larger portions of sponsors' study budgets are getting sunken into recruitment efforts, yet recruitment continues to suffer. By looking at the three biggest barriers to patient entry in clinical research, sponsors and CROs can better understand where to target and reallocate recruitment resources:

Lack of Awareness—Half of the general population claim they are unaware of clinical trials available to them and even worse, 57% do not recall ever seeing advertising for clinical trials.[9] Although more money is being sunk into recruitment efforts, patients still don't know where to find pertinent information.

Lack of Education—Patients are struggling to find answers to their questions and one in three American adults are estimated to have below-average health literacy.[10] Applying principles of health literacy to clinical research communications can help patients make well informed decisions with their health information.

Lack of Access—Only one-fifth of Americans live within ten miles of any hospital - let alone a top-tier research facility.[11] Geographic and financial constraints continue to plague participants, and disproportionately impact those in underserved communities.

In short, patients are telling us that they lack information about how to access a trial, what that trial will involve, and how the trial will affect their well-being. Patients lack this information on such a mass scale that less than one in three individuals claimed they felt "confident" or "very confident" that they could find or even identify a clinical trial if they wanted to participate.[12]

For years, clinical trials relied on traditional methods of recruitment, such as physician recommendations. But nearly half of millennials don't have a regular primary care doctor.[13] Additionally, although a majority of the public have indicated they'd be willing to participate in clinical research, only 38% claim they have actually been asked to participate.[12]

Patient needs are changing. Sponsors and CROs will have to adjust their approach to recruitment and allocate resources to align with new patient expectations.

To better align with changing patient needs, consider implementing the following tactics at the beginning of your trial kick-off:

Get to Know Your Patients Again:

- Patient needs are constantly evolving. Before kicking off any study, make a point to conduct research and understand the unique pain points of your patient population.
- Re-engage with your patient community by facilitating community-based participatory research (CBPR).[14]

Strengthen Channels with Healthcare Professionals:

- Train healthcare workers on upcoming clinical trials to raise awareness and knowledge.
- Create communication channels with healthcare professionals in a way that is clear, accurate, and jargon-free so they can pass that onward to their patients.

Create Health Literacy for Patients:

- Use plain language in clinical trial content and literature so patients understand it.
- Leverage eConsent forms that can be enriched with media, including videos and quizzes to ensure comprehension.

Refresh Awareness Campaigns:

- Consider digital advertising to appeal to potential patients that are more tech-savvy or don't have primary care doctors.
- Eighty percent of internet users search for health information online so it's critical that trial information be online and available where patients are searching for it.[15]

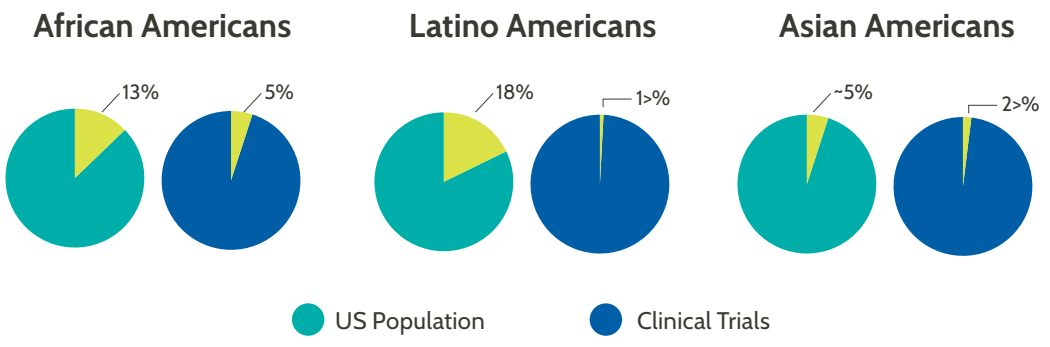
Understand - and Support - Trial Burden Upfront:

- Prior to a study, start by conducting research to recognize and address the possible burdens for patients, sites, and clinicians.
- Help patients plan for unavoidable burden by providing them with clear information and directing them to supportive resources like financial counseling.
- Invest in decentralized technologies that remove standard financial and geographic barriers.

In addition, restructuring recruitment efforts gives sponsors and CROs a chance to expand their participant pools. The growing number of remote monitoring solutions, patient-centric mobile apps, and media-rich communication tools are making it easier for trials to engage with a wider audience by overcoming common barriers associated with lower income or minority populations.

Clinical trials need to reflect the make-up of their local population. Only then can we ensure drugs and treatments are safe for people across a range characteristics, backgrounds, and lifestyles. Research repeatedly shows that African, Latino, and Asian Americans are often underrepresented in clinical trials - while these ethnicities comprise about 36% of the total US population, together they only represent about 8% of clinical trial participants.

Sponsors and CROs can start by engaging with minority communities and bringing clinical trial knowledge into the places minorities are seeking care. Pairing that with decentralized technologies can help ensure better access to participants across geography, sex, race, age, and socioeconomic background. Involving diverse patient groups in your feedback means researchers can collect better data necessary to understanding efficacy, dosing, and safety across a broad range of patients.



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Involving Patients and Advocacy Groups in Study Design Early

Patients may not be medical experts, but they can provide powerful insight on study design, identify potential barriers to research participation, and help develop appropriate solutions. Involving patients in study design early can bridge the disconnect between gathering patient input and applying it towards an intended outcome. It is also crucial for identifying the questions to ask and the outcomes to assess in a study.

There are three types of ideal patients that sponsors and CROs can aim to engage with:

1. **Experiential Patients**—They offer feedback on elements of the trial process, such as travel and logistics, that they have experienced first-hand and have a direct impact on their lives.
2. **Pro Patients**—These patients know the wider patient community and can anticipate other patients' needs and share from theirs and others' experiences.
3. **Expert Patients**—These individuals engage with multiple patient communities, are aware of issues affecting the healthcare system, and can offer advice on the entire journey.

To engage with these patients throughout their journey, sponsors and CROs should create more formal, patient-led roles within their clinical teams. These roles will be responsible for creating a plan to collect and translate patient feedback into trial endpoints. In order to create this robust plan, the patient engagement lead should consider all internal SOPs and legal guidance, consider the budgetary needs, timelines, and resource allocations, as well as include IRB/ethical considerations.

This may sound like a lot of steps to build into a study, but patients can be instrumental in providing input on designs and trial protocol that strengthen adherence and reduce drop-out rates.

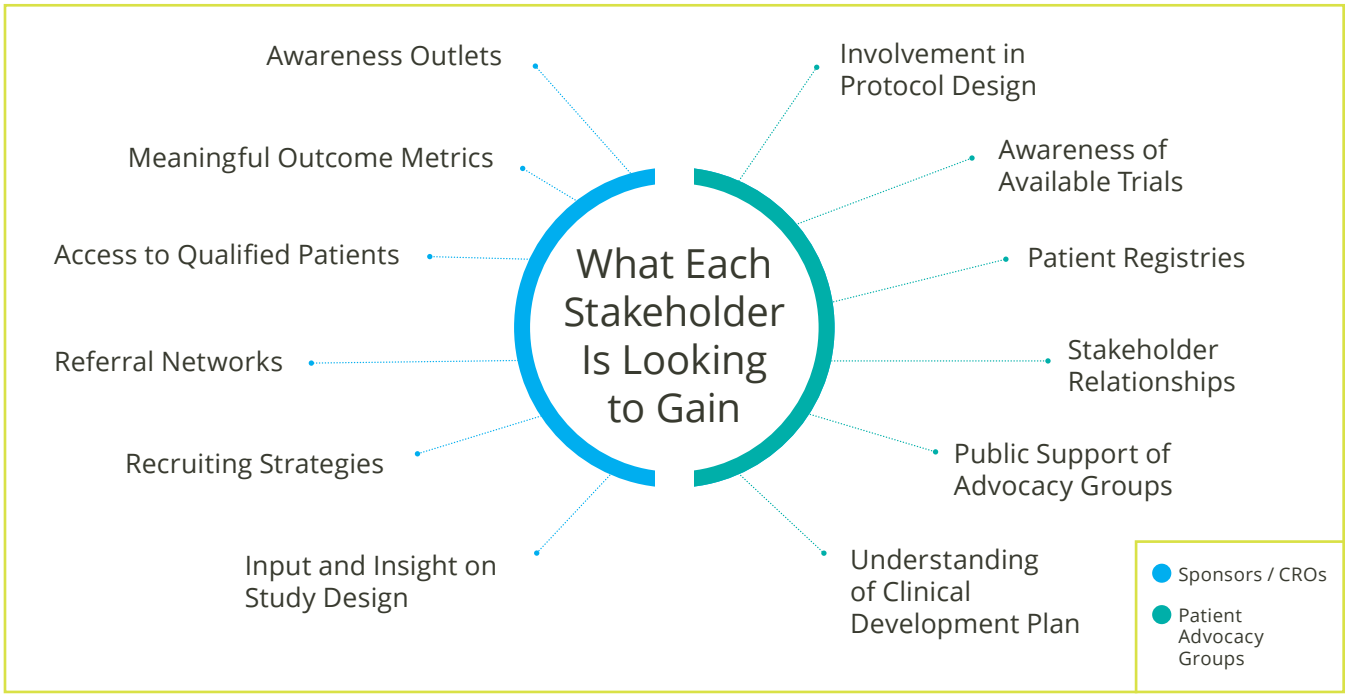
To collect this feedback organically from your participant pools, sponsors and CROs can look to engage patients in the following ways:

- Establishing healthy two-way communication between patients and clinical team
- Engaging via patient platforms or networks
- Hosting patient focus groups
- Conducting one-on-one interviews
- Encouraging former study participants to share their experience via social media, study forums, and word of mouth
- Working directly with a patient advisory board or advocacy groups.

The method of engagement will depend on your study needs, but sponsors and CROs shouldn't underestimate the power of leveraging patient advocacy groups. Not only do they provide an informed and fairly representative embodiment of the patient population, they can be gatekeepers and funnels for recruiting pre-screened patients into research. Engaging early with advocacy organizations is beneficial because they have a deep understanding of the challenges faced by patients and unmet needs of current research.

Patient advocacy groups regularly support and engage in clinical research, but are largely underutilized as partners in the process. Sponsors and CROs should nurture relationships with local advocacy groups but be mindful to ensure the relationship is mutually beneficial. Sponsors and CROs are looking to gain meaningful input on their outcome metrics, recruiting strategies, and overall study messaging. They also benefit from access to qualified patients who pre-identify as interested in clinical research trials.

On the inverse, advocacy groups want more input on study design so they can better connect their patient registries to trials that meet their needs. By strengthening relationships with trial operators, they can get clarifications on trial regulations and requirements, while giving sponsors a better understanding of how advocacy groups can support their recruitment strategies.



Listening to - and Acting on - Patient Feedback

In order to involve patient perspective in your study builds, sponsors and CROs need a concrete plan for collecting feedback from patients and putting that feedback into practice. Creating feedback loops wherein patients can provide ongoing input is essential for identifying and resolving burdens that wouldn't otherwise be obvious to clinicians.

For example, 75% of diabetes patients would prefer that clinical trials include endpoints that measure the impact of the disease on their quality of life - including the onset of kidney failure and dialysis.[17] Creating healthy channels for two-way clinician-patient communication not only establishes trust in the relationship, it can also help clinicians go from focusing on survival-based study endpoints to patient-experience endpoints.

Healthy feedback loops can also help prevent costly delays before they happen. Patient input on eligibility criteria could improve recruitment efforts, make screenings less arduous, and modify the schedule to make it more manageable for patients.

Recruitment takes up to 40% of an average research budget, totaling over $1.89 billion per year. Yet, approximately 80% of clinical trials are delayed or closed because of problems with recruitment and these delays could end up costing sponsors between $600,000 - $8 million a day.[18]

Assume a patient protocol review results in the avoidance of one Phase 2 amendment and improvement to the patient experience. The combined impact to your study is estimated to result in a 9-month-earlier launch and a $500,000 trial cost reduction.

Almost any changes made to eligibility criteria or design implemented after protocol submission will require an amendment. On average, a single amendment to a Phase 2 trial adds 90 days to the development timeline and costs sponsors $141,000.[3]

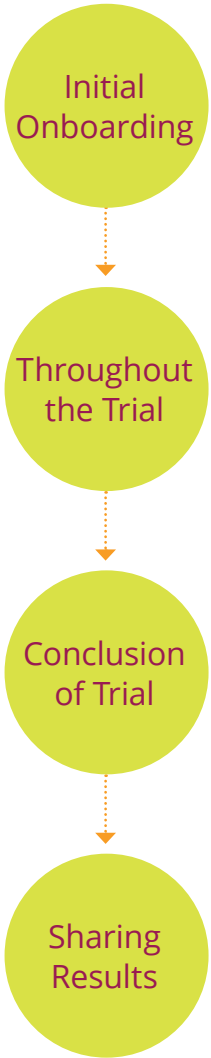
Creating pre-trial and ongoing feedback loops not only increases protocol adherence and reduces patient drop-out, it also benefits a sponsors' bottom line.

Ways sponsors and CROs can create a robust patient-clinician feedback loop:

- Modify trial design elements to ensure patients find value in the study.
- Enhance enrollment by using patient feedback to develop key messages and outreach materials.
- Develop logistic support to overcome barriers such as study format, location, scheduling, length, and timing of assessments.
- Design patient-friendly communication that is free of confusing medical jargon.
- Identify condition-specific responses to trial protocol design.

Patient feedback can be collected through a number of avenues including focus groups, interviews, patient surveys, UX testing, advisory panels, embedded patient advisors, and formal steering committees.

The key times in the patient journey where communication matters most:



Use this as a time to clearly, concisely, and directly explain the patient expectations in the trial, answer any specific questions they have, and introduce them to new processes or decentralized technologies.

Build a process to check in with patients at regular intervals and offer a space for questions, explicitly enquire about any issues, and make them aware of additional support.

It's crucial to show appreciation to the role patients play in the success of the study. Throughout the trial - but especially at the end - acknowledge the role patients played in your trial, thank them for it, and do your best to make sure they feel appreciated.

Patients who complete a trial are investors in its success. Keep participants updated on the outcome of the study so that they can see the difference they have made (and may be more inclined to participate in research again).

Implementation of a Patient-Centric Strategy

Achieving Informed Consent

Confusion around processes, protocols, and expectations is another leading reason patients drop out of studies. Poor communication or confusing consent forms can cost sponsors and CROs in lost time and revenue, as well as jeopardize trust between clinicians and patients. Involving the patient perspective on study forms and patient-facing documents can help make sure patients digest and comprehend what's expected of them.

Astellas Pharma embarked on re-evaluating its consent form with a patient-centric approach and were surprised with what they found. "We did some assessments on the complexity and really had some surprising learnings around what we had previously considered patient-friendly language," said Marie Rosenfeld, VP, Head of Clinical Science, "We worked to completely restructure it to ensure that the content was appropriate at a reader useability level."

Challenges in achieving informed consent can range from poor communication, lack of time dedicated to building the consent process, inability to detect lack of patient comprehension, and the list goes on. In order for patients to overcome any anxieties, unanswered questions, or lack of comprehension, sponsors and CROs should focus on making consent forms as brief, direct, and digestible as possible.

Sponsors and CROs can involve patients in the following ways to strengthen adherence:

- Don't make them feel like outsiders. Use plain language and avoid heavy medical jargon so patients can understand what is being asked of them.
- Offer extended discussions with patients to address fears and anxieties they're facing before providing informed consent documentation.
- Offer translation in local languages (and ensure the translated information is still easily digestible).
- Don't assume lack of questions means patients understand the consent forms. Actively check on their comprehension throughout the consent process.
- Enrich eConsent forms with engaging media such as video and audio that are more friendly ways of communicating with a lower health literacy population.
- Consider adding advanced digital features like quizzes or gamification that participants can interact with without sacrificing compliance.
- Provide supplemental information to the consent form that patients can review for additional information. This could be in the form of educational videos or informational pamphlets.

As simple as it might sound to translate your medical guidelines into "plain English", this is something researchers still struggle with.

Experts suggest writing guidelines using high behavioral specificity in conjunction with "plain English" study guidelines. This simple, yet effective method has been shown to result in stronger patient adherence, more positive attitudes in patients, and better perceived control over following the guidelines.[22]

Reducing Patient Burden

Once feedback loops are effectively created, sponsors and CROs can better identify and ease trial-related burden for patients and sites. Feedback loops go beyond a clinicians' outcome-driven perspective and address unique fears, anxieties, and unforeseen burdens experienced first-hand by patients. Sponsors and CROs need to fully put themselves into the mindset of their patients and ask themselves:

- What keeps patients showing up to site visits or logging into virtual appointments?
- What makes patients comfortable sharing their personal and medical information?
- What motivates patients to continue logging their entries?

To help answer these questions, it's crucial that study managers take time to understand the barriers and burdens faced by patients that make it hard for them to complete the trial.

The top barriers for patients in clinical trials continues to be:

- Inconvenience (schedule conflicts, travel requirements, time commitments)
- Ineffective communication and documentation
- Feeling underappreciated
- Financial constraints (traveling, time off work)
- Lack of knowledge/understanding (not understanding medical jargon, not grasping what's expected of them, uncertainty about side effects)

To understand and detail the patient burden upfront, sponsors and CROs should develop a robust plan for conducting research prior to the study. The aim of this research - which can be done alongside patient groups or advocates - is to identify all potential trial-related burdens. Once identified, study managers can help patients plan for unavoidable burden by providing them with clear information, offering support resources, or directing them to financial or personal counseling.

For site-based or even hybrid studies, a heavy burden is placed on sites to conduct recruitment and engage with the patient. Identifying these factors early can also help sponsors and CROs identify if decentralized technology is needed to help ease heavy onsite burden.

If a trial has been identified as lengthy or potentially strenuous, sponsors and CROs should consider the following approaches:

Automate communication where you can - Although sites will need to reserve some conversations for phone or email, where possible, sponsors should look to streamline visit or dosing reminders using an automated SMS system.

Consider logistical support - Currently 44% of research sites offer transportation assistance for patients.[20] Although it may be a bigger upfront cost, taking on some burden for patients could save money in the long run by preventing costly withdrawals or underpowered studies.

Be flexible - Many trial participants are living with conditions, some of which are chronic or have invisible symptoms. Consider how symptoms of a condition may impact day-to-day trial experience and try to create flexible workflows to accommodate this.

Decentralize - ePRO/eCOA, eConsent, telehealth, and other decentralized technologies can help lesson trial burden while improving compliance, producing better data accuracy, and expanding recruitment potential with remote patient access.

Creative health literacy - Deliver information to patients with lower health literacy using easy-to-understand videos and gamification tactics. [20]

Removing Obstacles in Data Collection

As clinical trials grow in complexity, so do the types and amounts of data endpoints. The average number of data endpoints has increased 86% and the number of eligibility criteria increased 50% in the past 20 years.[21] Data complexity impacts patience adherence and increases the clinician, site, and patient burden due to the need for more visits, procedures, and data collection.

Engaging patients in data management protocol build-out can help minimize the number of endpoints and focus on producing data that is more relevant to patients' needs.

Patient input can help determine:

- How or when to collect data
- Data selection or assessment protocol
- When to reorder, shorten, or add data points
- Specific aspects of analytic approach (ex: suggest covariates)
- Interpretation of results
- Inform real-world use of results
- Ensure measures align with participants' culture
- Enhance participant experience (lower burden, greater emphasis on patient-centric data collection)

The goal of involving patient input in your data collection protocol is to increase efficacy while streamlining trial operations. The key to finding success is to rethink your data collection and adopt a "less-is-more" approach. Applying the patient-perspective can help sponsors and CROs restructure trials to collect only the most important data in order to simplify the process for patients, save time, and reduce costs.

Lotus Mallbris, VP, Chief Development Officer, Global Clinical Development, Immunology Therapeutic Area at Eli Lilly said, "Historically, we have collected as much [data] as possible, but now it's about reducing the burden, not just for the patient but for the doctor as well. More often than not clinical trials are demanding data that doesn't have any purpose for that study." [7]

Streamlining Patient Reported Outcomes

Similarly, the patient perspective must be applied to restructuring how studies manage, collect, and analyze patient reported outcomes. For many years, the process was manual, cumbersome, and produced unreliable data as patients forgot to log their entries or missed critical site visits.

Sponsors and CROs must identify what keeps patients entering and providing accurate data throughout the course of the study. By involving patient input on this element of study design, trials can improve the quality, accuracy, and effectiveness of your patient-reported outcomes.

Largely, the industry has found that replacing paper with ePRO solutions can improve patient adherence up to 60 - 80% and even reduce ER visits in patients by 7%.[23] In addition, electronic Patient Reported Outcome (ePRO) solutions help patients feel more engaged in the process.

They can leverage their own mobile device, receive reminders when it's time to enter data, and feel safe knowing their clinicians have real-time access to the information they report.

Engaging patients in the build out of your PRO design can further strengthen the results. Patients can help identify flexible workflows that help clinicians gain insight they otherwise wouldn't have. A study of 766 oncology PRO patients found that systemic web-based collection of information on symptoms led to improved health-related quality of life, survival and quality-adjusted survival, and fewer visits to the ER.[24] By contrast, without PRO solutions, symptoms in oncology patients are only detected by doctors half of the time.[24]

When patient reported outcomes produce reliable, accurate data, they can also benefit studies in the following ways:

- Inform regulatory approvals and drug labeling
- Provide new information on the burden of a disease or condition
- Provide real-world evidence of treatment safety and effectiveness
- Monitor the live status of patients
- Provide timely care tailored to a patient's unique needs

The Impact of Decentralized Trials

Leveraging Technology That Empowers Patients and Informs Sponsors

As sponsors and CROs look to engage patients along every stage of their trial development process, it's important to leverage technology that supports these workflows. As a result of COVID-19, many trials adopted technologies to help them streamline operations. But not all trial technology is created equal. As more complex studies call for additional endpoints, sponsors and CROs may find themselves overwhelmed by disparate systems.

Patient-centric trials require a solution that both empowers and engages patients, while also providing real-time visibility and accurate data to study managers. Full-service, fully-integrated eClinical solutions are proving to be the most reliable, and efficient form of managing in-clinic, hybrid, and remote studies.

This trend towards integrated solutions has grown in recent years with 99% of CROs reporting the need to unify clinical applications. And 90% of studies without unified solutions noted they have or plan to have an initiative in place to do so.[25]

COVID-19's Impact on Patient Engagement: How to Sustain This Momentum

COVID-19 turned the clinical trial industry on its head with over 1,200 studies being halted or interrupted worldwide.[26] As a result, adoption of patient-centric technologies, remote monitoring solutions, and adaptive workflows were accelerated by the industry.

As sponsors and CROs look to re-engage with their patients and foster stronger relationships, they should look to continue some of the trends that COVID-19 introduced.

Lowering Data Burden

COVID-19 had the industry rethinking trial requirements and conducting thorough reviews of their study protocols. Moving forward, the industry should still be thinking about which data is crucial for patient safety/adherence/efficacy and which can be eliminated.

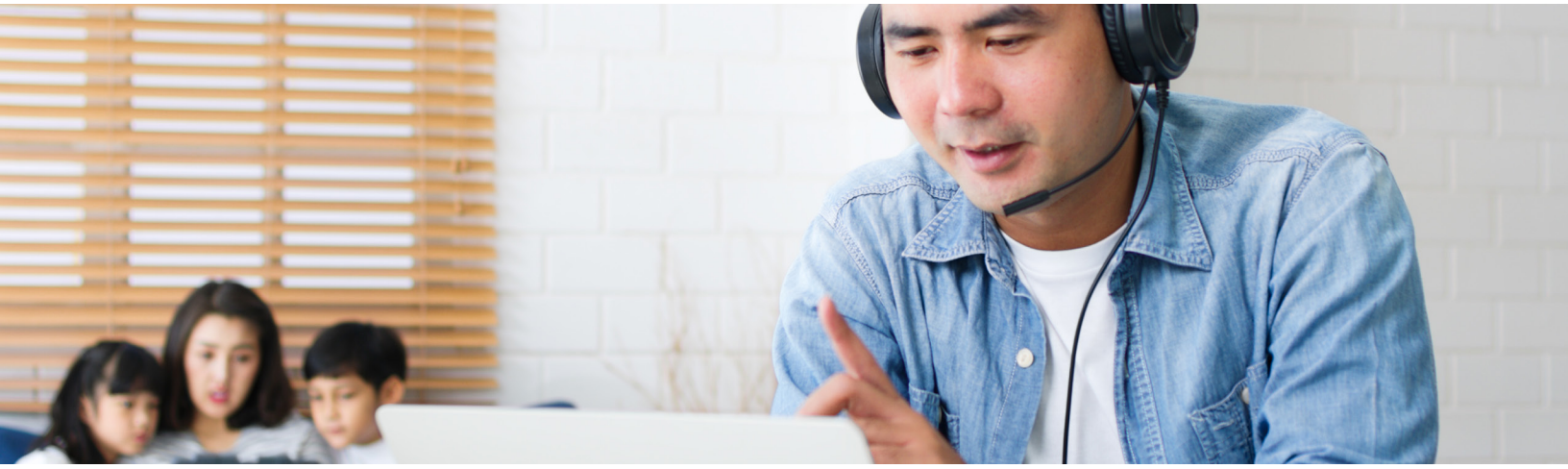
Supporting Sites with Decentralized Solutions

We are heading towards an expected site shortage with the number of clinical trials rising faster than sites can keep up with.[27] Decentralized solutions are helping sponsors and CROs remove heavy burdens from their sites by reducing visit frequency, streamlining recruitment, and ensuring patient adherence.

Adopting Flexible Workflows

Approaches like those taken during a recent Lily-sponsored COVID-19 trial show the power of flexible workflows.[7] Across the U.S., Europe, and Asia, a flexible approach was adopted with sites being chosen according to where the highest rates of the virus were at any given moment. Eligibility criteria changed as the disease evolved and sites where the disease was brought under control were closed. This not only helped Lily lower cost and eliminate waste, it also allowed them to respond to their patient needs in real-time to make the greatest impact possible.

Patient engagement can no longer be seen as simply a “buzzword” in the clinical trial industry. COVID-19 put clinical research in the public eye and patients are waiting to see how the industry responds. Sponsors and CROs have an obligation to aid in creating patient-centric workflows that involve the participant perspective from the ground up. Only then can we bridge the gap between clinical research and the patient experience.



About the Author

Melissa Newara is an experienced clinical trial technology professional with over 16 years in the clinical research space. Serving as Medrio's eSource Subject Matter Expert, she supports customers in understanding industry trends and regulations and helps to identify ways to optimize data collection by focusing on the patient and site experience.

Melissa's deep-rooted understanding of patient engagement and eSource collection stems from her extensive background working within clinical research in neuro-oncology, multiple sclerosis, behavioral health and gastroenterology. Most recently, she focused her work in eCOA as a clinical solutions specialist and a proposal operations manager. Melissa received her Master's in Psychology from Drexel University in 2007.

About Medrio

At Medrio, we know that it takes a global village to achieve a healthier world. Our leading eClinical data solutions have helped sponsors, CROs, and sites from all trial phases and therapeutic areas secure over 375 regulatory approvals. Whether conducting traditional, hybrid, or fully-virtual trials—our adaptive platform of EDC, DDC, eConsent, RTSM, and ePRO/eCOA help streamline your studies, without compromising data quality. And our experts are on-call 24/7 to help you solve your most pressing needs. Discover the Medrio difference and learn more at medrio.com.

References

1 Patient-Centric Trials Summary

2 Vat, L. E., Finlay, T., Jan Schuitmaker-Warnaar, T., Fahy, N., Robinson, P., Boudes, M., Diaz, A., Ferrer, E., Hivert, V., Purman, G., Kürzinger, M. L., Kroes, R. A., Hey, C., & Broerse, J. (2020). Evaluating the "return on patient engagement initiatives" in medicines research and development: A literature review. Health expectations : an international journal of public participation in health care and health policy

3 Bennett Levitan, Kenneth Getz, Eric L. Eisensten, Michelle Goldberg, Matthew Harker, Sharon Hesterlee, Bray Patrick-Lake, Jamie N. Roberts, Joseph DiMasi (2017). Assessing the Financial Value of patient Engagement: A Quantitative Approach from CTTI's patient Groups and Clinical Trials Process

4 FDA-medtech consortium offers strategy to boost patient engagement in clinical trials

5 Medical Device Innovation Consortium (2021). Maximizing Patient Input in the Design and Development of Medical Device Clinical Trials

6 How to Strengthen Trial Retention Through Patient Education

7 Lowering the patient burden in clinical trials

8 5 ways to lower clinical trial patient recruitment costs

9 SubjectWell (2020). Survey of Clinical Trial Awareness and Attitudes

10 Improving Health Literacy in Clinical Trials

11 How far Americans live from the closest hospital differs by community type

12 The Center for Information and Study on Clinical Research Participation (2019). Deciding to Participate: 2019 Perceptions and Insights Study

13 How Decentralized Trials Strengthen Your Participation Pools

14 Chhatre, S., Jefferson, A., Cook, R. et al (2018). Patient-centered recruitment and retention for a randomized controlled study. Trials 19, 205

15 25+ useful clinical trial retention statistics for better results

16 Diversity in Clinical Trials: Path to Achieving Health Equity

17 Sacristán JA, Aguarón A, Avendaño-Solá C, et al. Patient involvement in clinical research: why, when, and how. Patient Prefer Adherence. 2016;10:631-640. Published 2016 Apr 27. doi:10.2147/PPA.S104259

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22 Words matter: increasing the implementation of clinical guidelines

23 Implementing Patient-Reported Outcomes Systems Improves Overall Survival, Quality of Life

24 Basch E, Deal AM, Dueck AC, et al. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. JAMA. 2017;318(2):197–198. doi:10.1001/jama.2017.7156

25 CRO Report Notes Issues with Clinical Applications

26 COVID-19 pandemic disrupted more than 1,200 clinical trials: GlobalData

27 Overwhelmed by Cost and Complexity, Need Sponsors Help to Bear the Burden

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