



UNDERSTANDING CLINICAL TRIAL PATIENT ATTRITION: Causes & Impact on Research Success

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From adverse events and voluntary withdrawal to lack of compliance and other factors outside of patient or researcher control, there are many factors that contribute to patient attrition—or the loss of participants over the course of a clinical trial. 15 to 40%¹ of patients drop out of clinical trials before they're completed. In addition to the average initial recruitment cost of \$6,500 per patient, the average cost to replace a patient who drops out is about \$19,500².

Patient attrition is not only costly, but also a significant obstacle to the success and validity of a trial. Therefore, it's critical to minimize patient attrition through strategies like improving patient engagement, addressing barriers to participation, and ensuring that study visits are as convenient as possible for participants. This article presents an exploration of patient attrition in clinical trials, its underlying causes, and the profound impact it can have on the success of medical research.

Factors That Contribute to Patient Attrition

Understanding the reasons patients may choose to drop out can help sponsors and researchers create a comprehensive strategy to keep them engaged. *Factors that create barriers to patient participation can include:*

Participant Characteristics: Age, sex, gender³, race, and education are just a few known factors that impact patients' willingness to participate in and complete a study.

Socioeconomic & Cultural Factors: Lack of understanding of research as a viable care option can lead to low engagement and visit compliance.

Informed Consent Process: Simplicity in the informed consent process and participant comprehension of the study requirements are critical to confidence in the trial process. If any aspect of the study design or assessments are unclear or if the patient doesn't understand what is required of them, they may lose confidence and choose to quit the study.

Study Protocol: A complicated or overly demanding study protocol can cause patients to feel overwhelmed and drop out of the study.

Treatment Side Effects: Treatment-related side effects can negatively impact both physical and emotional health. Patients may not see the benefits to continued participation, leading to their withdrawal.

Lack of Transparent Outcomes: If patients feel disconnected or uninvolved in the study's progress, they may withdraw. Communicating milestones and keeping patients involved in the progress of their treatment promotes collaboration and a sense of being part of the larger patient and research community.

Patient Attrition's Impact on Clinical Trial Success

Beyond simply delaying trial completion, patient attrition can have a significant impact on the data gathered over the life of the trial.

Statistical Power: If a significant number of participants drop out, it may become more difficult to detect a difference between treatment and control groups.

Bias: If the patients who drop out are systematically different from those who stay (for example, if they experience more severe side effects), then the results of the study may be skewed.

Generalizability: If the people who stay in the study are not representative of the broader population, it becomes more difficult to apply the results to the wider community.

Economic Impact: As attrition rates rise, additional resources may be required to recruit and retain replacement participants. This could lead to increased costs for drug developers, which may be passed on to consumers.

Regulatory Approval: Regulatory agencies may question the validity of the results if a significant proportion of participants drop out.

High attrition rates can also make future study recruitment more difficult. Firstly, high attrition can create a negative perception of the study, and word-of-mouth from previous participants who dropped out can discourage others from participating. Secondly, attrition reduces the available pool of eligible participants, making it more challenging to find suitable candidates. Finally, abnormally high attrition rates can raise ethical considerations, causing potential participants to question the benefits and risks associated with enrollment. To address these challenges, it's crucial to understand the reasons behind patient attrition and implement strategies to manage it.

Managing Patient Attrition in Clinical Trials

It's important to understand that clinical trials involve patients who are, first and foremost, people navigating a diverse range of personal experience, circumstances, and obligations. Patient attrition is not entirely unavoidable, but it can be managed and minimized with the appropriate strategies in place. Researchers should identify the factors contributing to high attrition rates early and make adaptations to mitigate them where possible. For sites and studies where resources and staff availability are at a premium, this could look like partnering with a third-party provider like Scout to address patients' logistical and financial needs.

In addition to overcoming the challenges of standard participants, these clinical trial patient services are designed to expand access to a broader patient population. By accommodating the unique circumstances of patients from various backgrounds and life situations, we can increase trial adherence for

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patients of all ages, races, ethnicities, and socioeconomic statuses. Ensuring that more patients have the opportunity to participate in, and benefit from, clinical research enhances the overall validity and applicability of research findings.

Conclusion

Patient attrition presents a significant challenge in clinical trials by potentially compromising the validity of study results and escalating both costs and timelines. However, with a better understanding of the underlying issues that contribute to high attrition rates, researchers can create strategies to prevent more dropouts from occurring. It's vital to maintain a people-first approach that acknowledges trial participants as individuals with unique needs and circumstances.

Managing patient attrition is a complex, ongoing process of enhancing patient engagement and addressing barriers to participation. Working with a partner like Scout is a key component of a successful strategy. Our Scout Clinical services provide a whole-person approach on a global scale to make participation easier and help patients stick with it. Visit scoutclinical.com or contact hello@scoutclinical.com to explore specialized solutions for your next study's success.

1. OpenClinica. (2023, April 17). "Patient-centered clinical trials improve recruitment and retention." BioPharma Dive. <https://www.biopharmadive.com/spons/patient-centered-clinical-trials-improve-recruitment-and-retention/647481/>

2. James, Ben. (2023, April 28) "Engaging Patients with Behavioral Science and Patient-Centered Technology." Applied Clinical Trials Online. <https://www.appliedclinicaltrialsonline.com/view/engaging-patients-with-behavioral-science-and-patient-centered-technology>.

3. Weiland, N. (2022, July 26). "Working towards a more inclusive environment: Transgender & Non-Binary participants in Clinical Research." Center for Information & Study on Clinical Research Participation. <https://www.ciscrp.org/working-towards-a-more-inclusive-environment-transgender-non-binary-participants-in-clinical-research/>