

Top Barriers to Participation in Clinical Trials

Why are under-enrolling clinical trials a significant problem?

The consequences of low accrual in clinical trials is significant on a number of levels, for all stakeholders – sites, sponsors, and participants. Some of the consequences include:

- ▶ Ethical implications
- ▶ Relinquish scientific validity
- ▶ Missed opportunities for participants
- ▶ Wasted time, resources, and funds

A 2021 CISC RP global study of over 11,000 participants captured the public perception of clinical research, including general perception of clinical research and possible barriers of participating or continuing on with a study.

Importance of Clinical Studies¹

Overall, 76% of survey participants felt clinical research is “very important” when discovering and developing new medicine or therapy treatments. However, there are still concerns over participating in a study. Respondents indicated the top risks included:

Suffering from a side effect



Risking overall health



Stopping current and effective treatments



Making Informed Consent Forms Understandable

A challenge for many research staff is creating an informed consent in lay terms so participants can accurately understand and interpret the information given to them. When asking study volunteers themselves²:

57%

reported it’s important to receive overall research study results presented or explained in easy-to-understand language

54%

said it’s important for research staff to give clinical trial results in simple language



To ensure consent form understanding, it’s critical for research staff to review the form with participants and ensure understanding throughout the entire document.



of participants said they reviewed with the study coordinator or research nurse



of participants said they reviewed with the principal investigator or study doctor²

Common Participation Burdens, Reasons for Drop Out

Why do participants drop out of studies?³

18%

Poor communication with the study center

18%

The study drug’s side effects

16%

Study center location

16%

Cumbersome study visit procedures

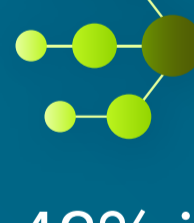
Travel is also a top participation burden³

Survey results found **25% of respondents** said they travel over an hour one way for every visit they have at a clinic.

The amount of tasks participants needed to engage in during in-person visits also became burdensome. Respondents reported the following tasks most burdensome³:



44% indicated traveling to the study clinic



42% indicated undergoing a diagnostic test



40% indicated study visit length



38% indicated getting lab work done



32% indicated completing a health questionnaire

Even though these may be burdensome reasons, there are ways to make the study less disruptive, including:

38%

participants indicated making study visits virtual

32%

participants indicated reduced travel times and distances

31%

participants indicated enabling at-home visits from a study nurse or doctor

24%

participants indicated receiving help or assistance when traveling to and from the clinic

Additionally, 27% indicated receiving a pre-paid debit card for any study-related expense incurred would make the study less disruptive. This may be due to:

Receiving compensation for their time



Receiving reimbursement via cash or check for any out-of-pocket expenses

