

Barriers to Participation in Clinical Trials

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BACKGROUND

Clinical trials are essential for improving the lives of patients, especially those with rare, complex and life-limiting diseases. Barriers exist that stop enrolment or continuation on trials.¹ Recognising and addressing these barriers enhances trial recruitment and retention. The aim of the research was to understand the needs and challenges of participants on clinical trial studies to enable better patient support.

METHOD

The study used a qualitative case review of recurring issues communicated by patients across 10 clinical trial studies throughout 20 countries and highlighted consistent issues across countries, disease groups and different studies.

RESULTS

Several themes were identified that appeared consistently throughout the review. These were separated into three main categories.

FINANCIAL



Upfront costs

- Inability to pay for upfront costs incurred on study visits
- Wait for reimbursement can leave participants out of pocket

Loss of earnings

- Time off work required for attendance
- Finding new employment if relocated and visa restrictions
- Travelling long distances to site and need for recovery time can result in extended absence from work
- Most travel and reimbursement policies do not cover loss of earnings

TREATMENT



Concerns

- Making decisions for paediatric patients undertaking unknown, experimental treatments
- Worries of treatment failing and subsequent emotional burden
- Unable to progress with trial due to preliminary screen failure

Understanding

- Scientific language not accessible to all
- Process of clinical trial may be unfamiliar
- International patients may have additional language barriers

PRACTICAL



Travelling

- Long journeys challenging for affected children
- Decision between long days travelling or staying overnight
- Anxiety of using public transport and facilities
- Tiredness after treatment

Childcare

- Struggle to find childcare for siblings
- Affected siblings may need specialised care – more expensive and harder to source
- Employment affected if parent must stay home for childcare, also less support for patient and pressure on lone caregiver
- Challenge to balance needs of trial, patient and siblings

CONCLUSION

Our research highlighted the many challenges and concerns faced by participants and families on clinical trials that may not be covered solely by travel and reimbursement policies. To help families with these challenges, trial sponsors may wish to consider:

- Alleviating financial outlay by offering alternative payment options such as prepayment or prepaid cards
- How emotional support can be provided and assessed
- The additional support needs of international patients
- Ways to ease the travel burden with innovative trial design and decentralisation
- Out of policy requests



REFERENCES

1. Gray S. Reducing barriers to participation in clinical trials for rare disease. *Clinical Researcher*. 2021 August 16:35(6).

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