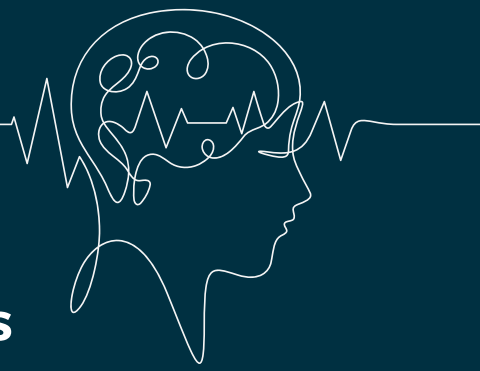
Worldwide Clinical Trials



Checklist

Preventing & Reducing Participant Dropout in Schizophrenia Clinical Trials

Schizophrenia clinical trials face unique challenges in participant retention due to the nature of the disorder and the characteristics of the patient population. As a complex and chronic mental health condition, conducting trials in this space requires careful attention to trial design and participant management to reduce dropout.

Below, we present design and participant management considerations for your schizophrenia clinical trials.

- [ ] **In-Patient Studies**

  Whenever possible, conduct in-patient studies to reduce dropout. Participants stay onsite for an extended period, facilitating continued engagement. Eliminating day passes from the facility can further improve retention; otherwise, patients may leave for extended periods, increasing dropout rates.

- [ ] **Participant, Family, & Caregiver Engagement**

  Adequate communication with caregivers about the trial and potential benefits will help to overcome some of the psychosocial and environmental barriers, including the associated stigma of mental health conditions. Provide transportation, meals, and missed wage stipends for caregivers.

- [ ] **Flexible Trial Design**

  Building flexibility into the protocol for visit schedules and allowing digital data collection whenever possible will make participation easier by reducing participant burden, partially due to the impaired motor and sedation that participants sometimes present.

- [ ] **Support Services**

  Ensure additional support; providing transportation and mental health resources lowers the barrier to participants' continued engagement.

- [ ] **Protocol Compliance Reminders**

  Cognitive and motivational deficits lead to protocol compliance issues, and when coupled with anosognosia, participants are more likely to forget or refuse to continue the study. Consider positive multimedia reminders for participants (e.g., emails, phone calls, and text messages).

- [ ] **Specific Screening Requirements**

  Establish participant screening based on symptom severity and current medications. Include eligibility criteria that focus on prospective participants' stable living environment (e.g., living in a group home or with a caregiver) — many participants experience episodes of homelessness or incarceration, which interfere with participation.

- [ ] **Tamper-Proof IP & Placebo**

  Paranoia and unblinding can lead to participant dropout; participants may attempt to unblind or otherwise manipulate the IP, believing it harmful. Thus, avoid capsules and other easily manipulated treatment mediums when possible.

- [ ] **Home-Based Follow-Ups**

  Check-ins with the participant at home between site visits builds rapport and trust to encourage ongoing participation.

While patient dropout is challenging in clinical trials, particularly for schizophrenia, careful designs and close participant management can significantly increase retention.

For a more detailed conversation about your schizophrenia trial strategy, contact us →