

## METHODOLOGICAL QUESTION

The rapidly expanding field of digital health programs seeks to introduce increasingly affordable and global mobile digital technologies including smartphones, digital apps and wearable devices to enhance psychiatric care and for passive data collection. Smartphone technologies may be able to assist with the monitoring, and treatment of schizophrenia, providing novel and cost-effective interventions with potentially real-time reach. While evidence supports the feasibility of using digital mobile tools in mental health, most studies to date have not reported accessibility, scalability, replicability, User Experience (UX) testing, or subject engagement. Additionally, little is known about the clinical and research reliability of digital health technologies in the care of patients with schizophrenia.

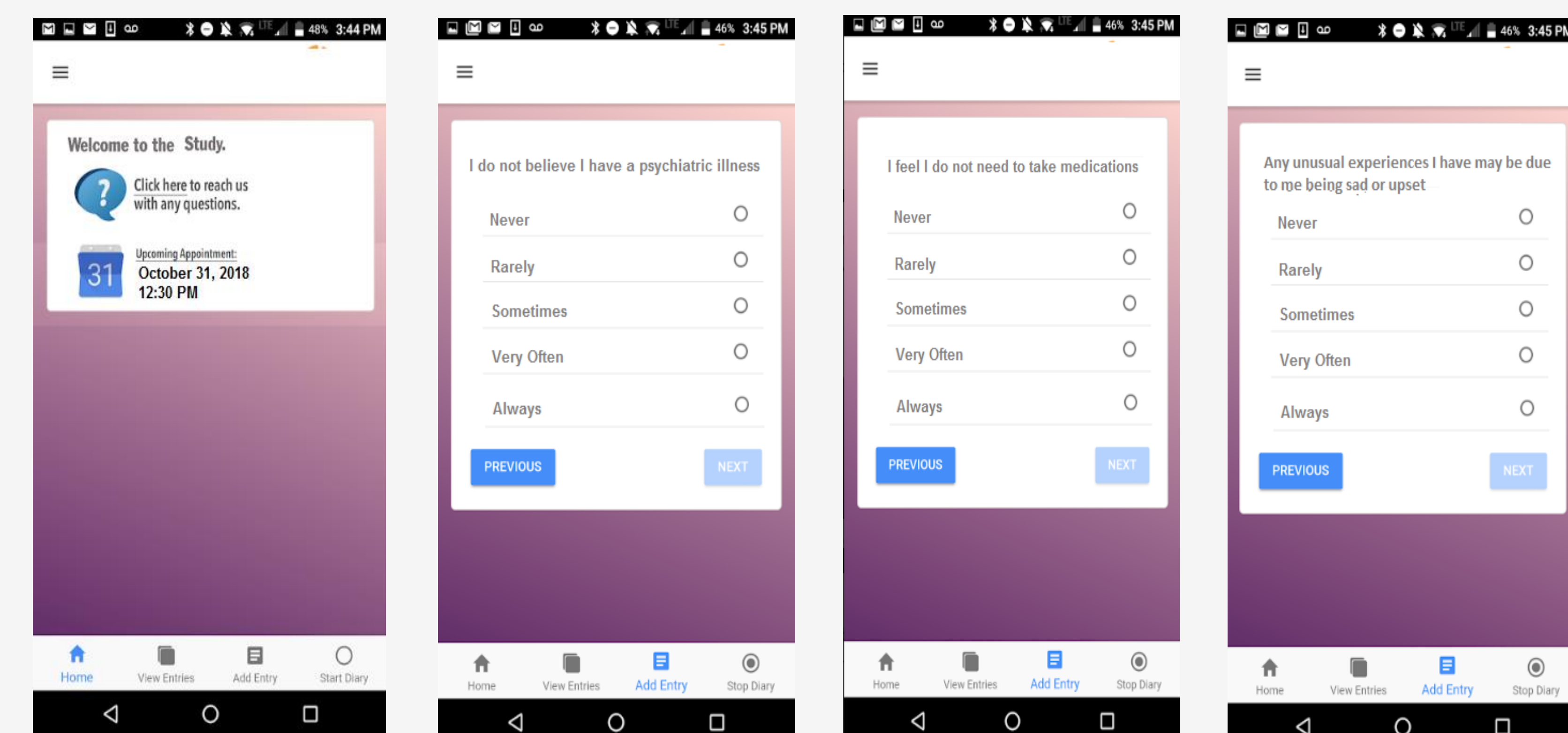
## AIMS

To evaluate the methodological strengths and weaknesses of implementation of digital health modalities (smartphones for passive data monitoring and ePROs) for schizophrenia.

## DIGITAL HEALTH PLATFORMS

### Digital Health Platforms

- **Digital Phenotyping App (Discovery by Mindstrong Health):** The Discovery app incorporates passive data defined by collected patterns of use without any obligatory participation from the user (barren of content), from the subject's mobile device with digital phenotyping, defined as device usage patterns to identify behavior patterns that may be associated with mental health conditions, functioning, relapse and behaviors, where the technology analyzes factors associated with cell phone usage (passive data).
- **ePRO Awareness of Illness Scale:** A new scale with 8 items incorporating David's (1990) dimensions of insight was developed consisting of: (1) awareness of having a mental illness, 2) relate unusual mental events as pathological, and 3) adherence to treatment. The scale was presented as an app that was installed on each patient's smartphone for 6 months via a parent study assessing passive digital biomarkers of psychiatric morbidity (Mindstrong Health). The ePRO was designed with push messages suggesting patients complete the scale once per week.

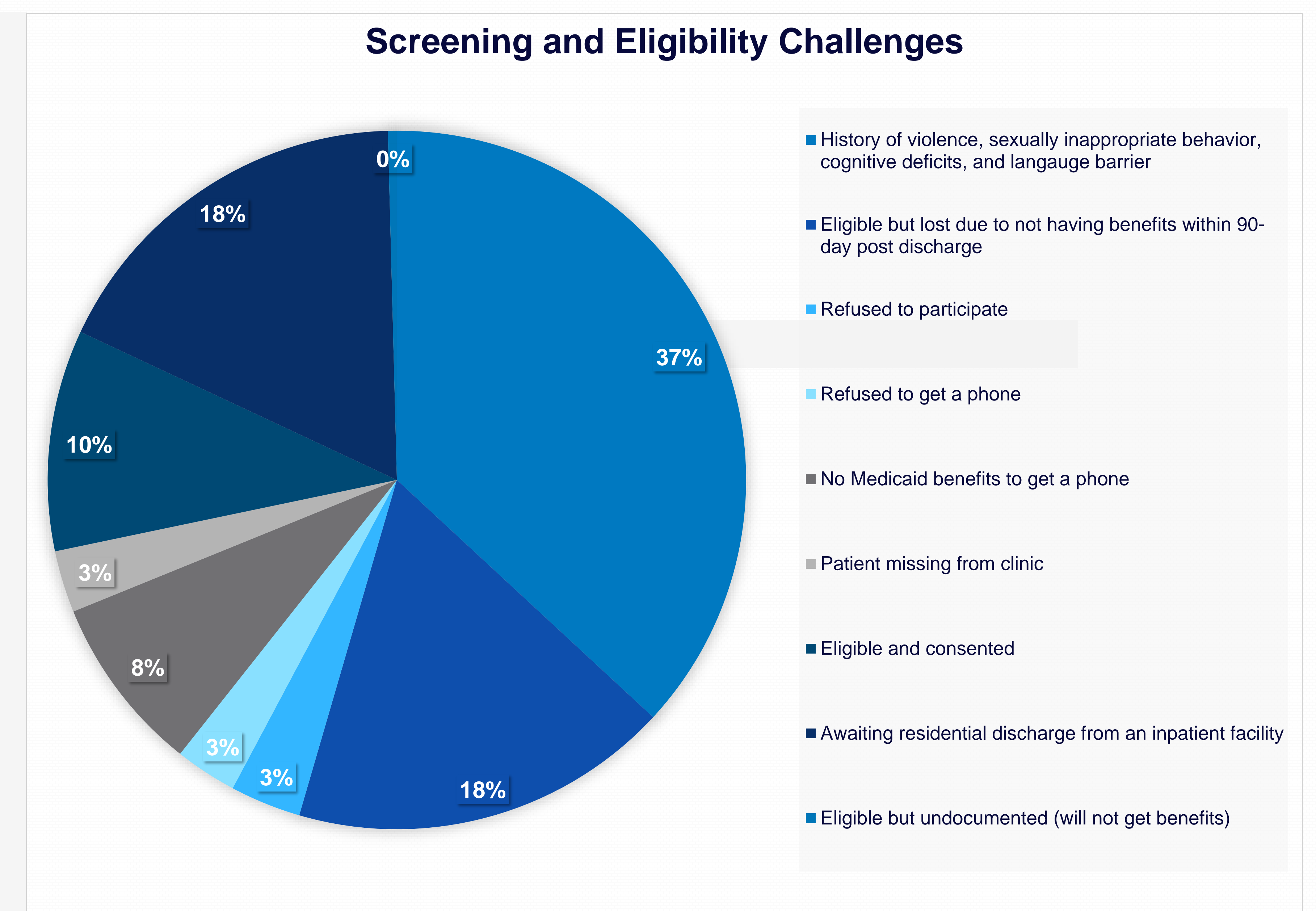


## METHODS

- Data includes 244 subjects who were eligible for enrollment in a study assessing relapse, using passive digital phenotyping and completion of electronic Patient Report Outcome (ePRO) via an Android app.
- Feasibility was assessed following review of characteristics related to participants' phone usage prior to study start, symptomatology, compliance rate with ePRO, engagement with digital health app, social support, phone quality, and enrollment rate in relation to eligibility.
- Subjects were enrolled from Manhattan and Bronx Psychiatric Center outpatient clinics in New York, NY who were recently discharged (< 90 days) from an inpatient hospitalization.

## RESULTS: ENROLLMENT CHALLENGES

- Eligible subjects had > 2 inpatient hospitalizations with a mean age of 41.22 (SD = 4.56) years.
- Barriers to enrollment included not having a cell phone prior to or at the time of discharge (26.23%), not receiving Medicaid benefits within 90 days post discharge, thereby not being able to acquire a government provided phone (17.62%), refusal to participate and to get a smartphone due to suspiciousness/persecutory delusions regarding tracking activities via smartphone (6.15%).
- Compliance rate with ePRO assessing awareness of illness (AIS) was 68.75% in completing all weekly assessments since enrollment with an average of 3.66 minutes to complete.
- Of the enrolled subjects, Interviewers/Clinicians reported having to help 90.9% of subject with phone related technical issues and engagement (ranging from showing them to use the phone, to using apps, to reinstalling apps, making calls, replacing lost phones).
- Interviewers/Clinicians also reported the quality of the phones provided resulted in delays in data uploads and data collection for 86.36% of subjects.



## RESULTS: IN-STUDY CHALLENGES

- Subjects would lose their phones or get them stolen. Replacement phones take an average of 1-2 weeks to arrive.
- 75% of patients were not actively using the phone or were not physically active (not moving around, not making many calls).
- Subjects would not turn their phones on.
- Most subjects (55%) have not used a smartphone before and needed assistance at the early phases of the study (e.g. going on the internet, texting, etc.).



## CONCLUSIONS

- Although the current literature on the role of digital health technologies in schizophrenia suggests high feasibility and acceptability, implementation of and engagement with digital devices in individuals with chronic schizophrenia in low-income populations is challenging.
- It is important for sponsors and investigators be aware of potential challenges that may cause a delay in recruitment and affect study endpoints.
- With further research and clinical innovation, digital health technologies have the potential to become an important tool that mental health professionals can employ in the clinical care and research of psychotic disorders, specific procedures and methods need to be in place to overcome barriers in the implementation process.