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5 things to consider before starting your psychiatric clinical trial

A practical planning guide for reducing variability
and building confidence in your data



Psychiatric trials are difficult to interpret because subjective endpoints, rater variability, placebo response, safety risks and operational complexity can impact confidence in the results.

Increasingly, sponsors are incorporating objective and predictive data strategies to improve signal detection and reduce trial risk.

Use these five planning questions before study start to help strengthen endpoint reliability and reduce avoidable trial risk.



01 Are your endpoints designed to support confident decision-making?

Psychiatric endpoints should do more than assess symptoms. They should support clear scientific, clinical and regulatory decisions.

② | Ask before study start:

- Are we measuring outcomes that will clearly detect meaningful patient benefit?
- Are objective digital, imaging, speech or physiological measures needed to add supportive context?

Planning tip



Plan not only what you will measure, but how each endpoint is collected, reviewed, and protected throughout the study. Administration quality, timing, rater consistency, and data review all influence the reliability of your results.

02 What is your strategy for controlling variability?

In psychiatric studies, small differences in rater performance and scoring can obscure the detection of a meaningful signal within unwanted noise.

② | Ask before study start:

- How will raters be trained, qualified and monitored for consistency across all sites?
- Can centralized review support retraining or early intervention when underperformance is detected?

Planning tip



Build rater oversight into the full study lifecycle, from qualification and training through ongoing monitoring. If variability goes undetected early in development, it can weaken long-term data and adversely impact confidence in results.

03 What is your placebo response plan?

Placebo response can reduce drug-placebo separation, making it difficult to determine whether a treatment is truly effective. In some psychiatric indications, it may completely obscure drug efficacy.

🔍 | Ask before study start:

- Are participant and site expectations being managed consistently across the study?
- How will you identify and respond to unexpected placebo-driven patterns in the data?

Planning tip



Prevent significant placebo response before the study begins, not after it appears in the data. Success requires thoughtful study design, site and rater training, participant communication, and ongoing data monitoring.

04 Is your safety strategy aligned to participant and regulatory risk?

Psychiatric studies often involve vulnerable populations and complex safety needs, including suicidality, cognition, sedation, behavior change and cardiovascular effects.

🔍 | Ask before study start:

- Which risks are most relevant to the therapy, population and mechanism of action?
- Are psychiatric, cognitive, behavioral, physiological and cardiac risks captured where relevant?

Planning tip



Match safety monitoring to the drug's mechanism or class-specific risk profile. Connected oversight can help teams identify emerging risks earlier and interpret safety data in context.

05 How will you use objective and predictive measures to strengthen signal detection?

Digital assessments, speech biomarkers, neuroimaging, cardiac monitoring, video review and AI-supported analytics can all add important context but only when they answer a clear question.

Ask before study start:

- What will each measure help explain?
- Will it improve interpretation without adding unnecessary complexity, participant or site burden?

Planning tip

Use objective measures only when they answer a clear scientific or operational question. The goal is not more data but meaningful data that helps explain treatment effect, patient impact or study risk.



Quick-start planning checklist

Planning area	Ask this first
Endpoints	Are we measuring what matters most?
Raters	Can we detect variability early?
Placebo response	Is there a proactive mitigation plan?
Safety	Are key psychiatric and physiological risks covered?
Objective measures	Does each measure answer a clear question?

How Clario can help

Psychiatric trials require more than endpoint technology. They require scientific guidance, consistent execution and active oversight that help reduce variability and improve confidence in results.

Clario supports psychiatric studies with integrated expertise across eCOA, medical imaging, cardiac safety, centralized review, data monitoring and digital endpoint capabilities, including:

- Science-led endpoint strategy and protocol consultation
- Rater training, qualification, independent review and independent rating
- Centralized oversight across sites, raters, participants and assessments
- Real-time analytics, dashboards and AI-enhanced monitoring to detect emerging quality risks

Talk with a psychiatric trial expert about planning your next study.

To learn more, please visit
clario.com or email
info@clario.com.



About Clario

Clario is a leading provider of endpoint data solutions to the clinical trials industry, generating high-quality clinical evidence for life sciences companies. We offer comprehensive evidence-generation solutions that combine medical imaging, eCOA, precision motion, cardiac and respiratory endpoints.

For more than 50 years, Clario has delivered deep scientific expertise and broad endpoint technologies to help transform lives around the world. Our endpoint data solutions have been deployed over 30,000 times to support clinical trials in more than 100 countries. Our global team of science, technology, and operational experts have supported over 70% of all FDA drug approvals since 2015.



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