

Beyond traditional assessments

4 emerging approaches to improving psychiatric trial outcomes

Psychiatric drug development is entering a period of renewed innovation, with novel mechanisms, rising neuroscience investment and growing interest in precision psychiatry creating new opportunities across depression, schizophrenia, anxiety disorders, PTSD and related conditions.

Despite this growing interest, familiar challenges remain. Assessment variability, placebo response, subjective endpoints and inconsistent execution can make treatment effects difficult to distinguish.

As studies become more complex, sponsors are exploring new methods to strengthen endpoint reliability, improve confidence in study outcomes and generate more objective evidence.

Why psychiatric trials require a different approach

Psychiatric trials rely heavily on clinician-rated assessments, patient-reported outcomes, behavioral observations, and complex symptom measures, making treatment effects more difficult to interpret than in many other therapeutic areas.

Variability can appear through assessment administration, rater differences, site inconsistencies, placebo response, and disjointed endpoint workflows, obscuring the ability to detect meaningful treatment effects and reducing confidence in development decisions.

As a result, sponsors are exploring approaches that improve consistency while also creating a more complete picture of treatment response.

This guide introduces four emerging approaches shaping psychiatric clinical research.

01 Structured endpoint strategies

02 Placebo-response mitigation

03 Objective digital and behavioral biomarkers

04 Multimodal endpoint approaches

01 Structured endpoint strategies

The approach

Psychiatric endpoint quality is shaped long before data are analyzed. A more structured strategy connects endpoint selection, assessment administration, rater oversight, quality monitoring and risk management from protocol design through study closeout.

Why it matters

Variability often begins before participants enter the study. Decisions about endpoint selection, training, administration, oversight and risk monitoring can significantly influence data consistency later in development.

Potential benefit

A structured endpoint strategy can improve consistency, strengthen oversight, reduce operational fragmentation and identify emerging risks earlier.

🔍 | Questions for your next study

- Are endpoint decisions aligned to study objectives and milestones?
- Do teams have visibility into endpoint data quality throughout the study?
- Are risk mitigation strategies established to reduce occurrence of data variability?

02 Placebo-response mitigation

The approach

Placebo response cannot be eliminated, but it can be anticipated and managed. Sponsors are proactively including enhanced placebo-response mitigation training for participant and raters, centralized monitoring, independent review and earlier identification of scoring inconsistencies to minimize this risk.

Why it matters

Placebo response remains one of the most persistent challenges in psychiatric research. Even effective therapies may struggle to demonstrate meaningful treatment-placebo separation when placebo response is substantial.

Potential benefit

When implemented appropriately, these approaches can strengthen assessment consistency, improve differentiation to detect treatment effects and increase confidence in efficacy evaluations.

🔍 | Questions for your next study

- How impactful is placebo response in the indication you're studying?
- What means are being deployed to reduce this potential risk?
- How quickly can emerging data quality concerns be identified and addressed?

03 Objective digital and behavioral biomarkers

The approach

Traditional psychiatric assessments remain essential, but they may not capture every dimension of how symptoms change over time. Objective digital and behavioral biomarkers can add complementary measures, using tools such as speech analysis, video assessment, digital activity monitoring and AI-supported analytics to evaluate cognition, mood, behavior or function.

These measures are intended to complement, not replace, other validated psychiatric assessments.

Why it matters

Traditional psychiatric assessments remain critical, but sponsors are increasingly evaluating ways to supplement subjective measures with more objective behavioral data. Objective digital and behavioral measures can provide additional evidence to help sponsors develop a more complete understanding of treatment response.

Potential benefit

Sponsors are evaluating behavioral biomarkers to add objective evidence, enhance endpoint sensitivity, enrich study populations, support patient stratification and strengthen interpretation of treatment response.

🔍 | Questions for your next study

- Where could innovative objective behavioral measures complement subjective assessments?
- Could behavioral biomarkers improve confidence in treatment response?
- Which studies and indications are best suited for applying digital behavioral endpoints?

04 Multimodal endpoint approaches

The approach

Psychiatric disorders rarely present through a single symptom, signal or measure. Multimodal endpoint approaches bring together complementary evidence, including clinical outcome assessments, behavioral biomarkers, digital assessments, neuroimaging, cardiac safety data and independent review, to create a more complete view of efficacy, safety, function and treatment response.

Why it matters

No single measure may capture the full complexity of a psychiatric disorder or treatment response. Bringing together complementary sources of evidence can provide a more comprehensive view of efficacy, safety, behavior and function.

Potential benefit

Multimodal approaches can strengthen evidence generation, improve confidence in key milestone decisions and better support regulatory and stakeholder discussions.

🔍 | Questions for your next study

- Does your current endpoint strategy capture the full patient experience?
- Are important dimensions of treatment response missing from your endpoint strategy?
- Could integrated evidence provide greater confidence in outcomes?

Key takeaways

Psychiatric trials continue to face challenges related to assessment variability, placebo response and endpoint sensitivity. In response, sponsors are increasingly adopting structured endpoint strategies, placebo-response mitigation, objective digital and behavioral biomarkers and multimodal evidence to improve study quality and confidence in treatment outcomes.

Although every study requires a tailored approach, these emerging trends reflect a broader shift toward more holistic and informative psychiatric trial endpoint strategy.

How Clario supports modern psychiatric endpoint strategies

By integrating scientific expertise, operational oversight and a holistic approach to endpoint solutions, Clario helps sponsors implement more comprehensive psychiatric endpoint strategies through a single, coordinated partner.

Together, these capabilities help sponsors reduce variability, strengthen endpoint reliability and improve confidence in psychiatric trial outcomes.



Connect with a Clario psychiatric endpoint expert to discuss your upcoming development program. To learn more, go to clario.com/therapeutic-areas/neuroscience/psychiatric-disorders or email info@clario.com.

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.