

From Insight → Implementation

Embedding Mental Health Support in Clinical Trials



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Executive
Follow-up to
the White
Paper
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Why Mental Health Support in Trials Matters

This executive follow-up translates the insights of the white paper into practical implementation guidance for sponsors, CROs and clinical trial designers. Clinical trial participation is not only a medical experience. It's also an emotional and practical journey for both patients and caregivers.

The White Paper “Moving Beyond the Participant Role – Mental Health Support in Trials” highlighted that across both physical and psychological trials, participants frequently experience significant emotional strain, uncertainty, and practical burden during the trial process. Despite this, mental health support is rarely embedded structurally in clinical trial design. Support often depends on individual site staff or informal solutions, leading to inconsistent participant experiences.

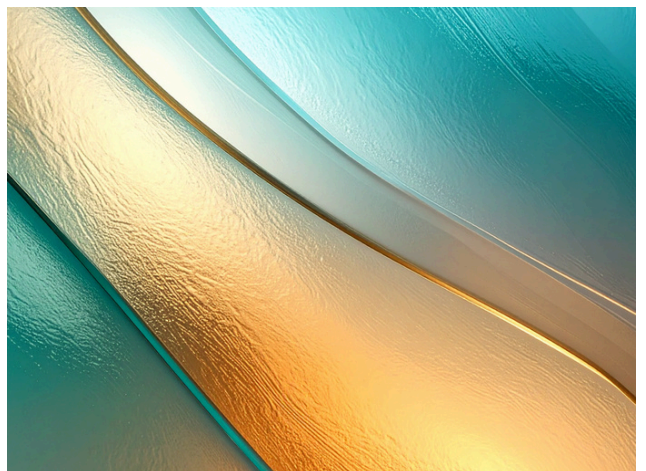
Patients and caregivers consistently reported:

- High levels of stress and anxiety related to participation
- Lack of continuity and human contact throughout the trial
- Feeling “dropped” once the study ends
- Limited inclusion of caregivers, despite their central role
- A strong need to be recognised as whole people, not just participants

A clear message emerged from participants:

Mental health support does not need to be extensive – but it must be meaningful, timely, and built into the system.

This executive follow-up translates patient insights into practical priorities for sponsors, CROs, and clinical trial designers.



Key Structural Shifts

Moving from insight to implementation requires five structural changes.

Mental health must be designed in – not added on

Mental health support should be addressed already at the protocol design stage, including:

- psychological safety considerations
- defined support functions throughout the trial
- planned post-trial follow-up



Embedding these elements early ensures consistency across trial sites. **Support must follow the full trial journey.** Participants' mental health needs evolve across the trial process. Support should therefore be structured across three phases:

Before the trial

- preparation and expectation alignment
- emotional readiness
- clear explanation of trial logistics and processes

During the trial

- consistent contact points
- clear communication about side effects and results
- small but meaningful check-ins

After the trial

- explanation of results
- guidance on next treatment options
- structured follow-up and transition support

Psychological and physical trials require different support models.

The nature of support needs differs depending on the type of study.

Psychological trials

- Participation itself may carry stigma or emotional vulnerability. Support should focus on:
 - normalization of participation
 - stigma-sensitive communication
 - preparation before participation
 - structured support after the intervention ends

Physical health trials

- Support should focus on:
 - side-effect management
 - logistics and treatment phases
 - communication of results and next steps.

Implementation Priorities

Moving from insight to implementation requires five structural changes

1. Clear communication and contact structures

Participants should always know:

- who to contact
- how to contact them
- when to expect responses

Key measures include:

- one clearly named contact person per participant
- defined communication channels and response times
- plain-language communication focused on understanding

Human connection is often more valuable to participants than additional information alone.

2. Structured peer-to-peer support

Peer support can significantly reduce anxiety and strengthen trust in trials. However, to avoid potential bias, peer support should follow clear principles:

- peer roles are non-clinical
- peer interaction is separated from intervention and data collection
- moderated or facilitated formats may be used
- distinct peer spaces may be provided for patients and caregivers

When structured appropriately, peer support enhances engagement without affecting scientific integrity.

3. Inclusion of caregivers as partners

Caregivers often carry significant emotional and logistical responsibility during trial participation, yet they are rarely formally included. With appropriate consent, trials should:

- include caregivers in communication
- provide caregiver-specific information
- offer peer or support pathways for relatives

Supporting caregivers directly contributes to participant wellbeing and adherence.

Implementation Priorities

The following implementation priorities can be integrated into trial design without compromising scientific rigor.

4. Tailored support based on trial context

Support models should reflect the context of each trial, including:

- disease characteristics
- expected side effects
- study duration
- participant demographics

A flexible, whole-person approach ensures that support remains relevant and meaningful.

A Combined Approach to Implementation

Effective implementation requires collaboration between different stakeholders.

Patient-led organisations contribute:

- lived experience insight
- co-design approaches
- ethical patient engagement frameworks

Implementation partners can provide:

- patient-friendly trial information
- navigation and concierge-style support
- improved trial visibility and accessibility

Together, this enables mental health support to move from recommendation to operational reality.

Outcomes of Implementation

Embedding mental health support in clinical trials can deliver measurable benefits:

- improved participant and caregiver wellbeing
- increased retention and reduced drop-out
- stronger trust between participants, sites, and sponsors
- higher ethical and operational quality
- more sustainable and people-centred research

Conclusion

Clinical trials rely on the willingness of patients and caregivers to participate under conditions of uncertainty and vulnerability. Treating mental health support as optional is no longer compatible with ethical, effective, and sustainable research.

Moving from insight to implementation means recognising participants as whole people — and designing clinical trials that reflect that reality. Sponsors, CROs, and research teams now have the opportunity to translate these insights into practical trial design.

Reference

Snedde L.O. et al.

Moving Beyond the Participant Role – Mental Health Support in Trials.

PiCC United White Paper, 2026.



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