

Objective: Generate a Consensus Document Addressing Contemporary Issues on the Topic

Considerations:

Broad or specific focus?

Focus on methodology or on cultural issues?

Perhaps US-centric view is limiting (e.g., is “harmonization” a disguised form of cultural hegemony)

Variability in outcomes internationally is not limited to CNS and is hard to explain (e.g., hard outcomes in cardiology are variable across regions)

Note: many successful global trials have been conducted in CNS and analyses are underway to address these questions

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## Sources of challenge in international trials:

- regional differences in signal detection
- linguistic (with patients and investigators)
- cultural acceptability (e.g., sexual symptoms)
- cultural values (e.g., speed of cognition)
- regulatory (e.g., definitions of partial responder in MDD in US vs EU)
- nosologic (relevance of DSM to non-Western cultures)
- young vs mature science of measurement (cognition, functional outcomes vs psychosis)
- payer concerns and standards

- **Outcome for Workshop**

Analysis of key challenges in international trials, with a focus on real-world, practical concerns

- Manuscript detailing challenges with examples from different areas of research (e.g., a single therapeutic or measurement area)
- Focus on possible solutions

- **Next Steps**

Send workshop summary to group

- Work virtually to identify challenges to be addressed in manuscript
  - Enlist outside experts (regulatory, methodology, cultural issues) in project
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