

ISCTM Innovative Technologies for CNS Clinical Trials Working Group

Chairs: Rich Keefe, PhD
Mike Davis, MD, PhD

Agenda

- 4:40 - 4:50pm – Chairs review objectives
- 4:50 - 6:00pm
 - Review plans after last meeting
 - Brief overview of emerging manuscript
 - Open discussion of manuscript goals and structure
- 6:00 - 6:15 – Wrap-up, discuss logistics for next steps

Plan following last WG meeting

- Instead of creating three separate manuscripts, create one integrated manuscript
- Start with text from three writing groups:
 - Recruitment and retention (Lutz, Shaheen Lakhan)
 - Placebo response (Horan, Anderson)
 - Clinical meaningfulness (Marder)
- Create a structure to minimize redundancy across sections
- Get text on paper!
- Explore potential journals for this type of article

Integration process

- Jacqueline & Bill attempted to pull the three sections together in one document
- Seemed necessary to provide some type of brief overview, early in the manuscript, of the types of technology that will be considered – need to avoid redundancy
 - Added a section to provide a brief overview of relevant technologies
- Key issue: how to handle “clinical meaningfulness” section
 - Should this be a standalone section?
 - May have been some drift in this section over time
 - Challenging issue even with long-used measures in clinical trials - how would we demonstrate this for digital tools?
 - Have we strayed from the original idea?
 - I.e., can digital tools provide more clinically meaningful ways of assessing real-world *functioning* than existing measures?
 - Decision: not included as a standalone section
 - Shift to include in final section (scientific and regulatory considerations)

Innovative Technologies to Address Key Challenges in CNS Clinical Trials: Promises, Pitfalls, and Pathways Forward

In the past decade, rapid technological advances have substantially influenced how CNS clinical trials are conducted. Further technological innovations may help to directly address several of the most persistent and vexing challenges in CNS trials. In this article, we critically review the potential of technological innovations to address two such challenges: (1) problems in the recruitment and retention of appropriate participants, and (2) elevated placebo response rates. We begin by briefly surveying the array of technological solutions that may help address these challenges. We then consider the potential promises and pitfalls of these technologies for addressing the patient recruitment/retention and placebo response challenges. We conclude by looking forward to key operational, scientific, and regulatory issues that will need to be carefully considered and addressed for technical innovations be implemented in CNS trials. Rigorous empirical evaluations will be critical for translating rapidly emerging new technologies into strategies that can truly address old clinical trial challenges.

Goals

- Provide a critical review of technological innovations that may help address recruitment/retention & placebo response challenges in CNS trials
- Describe key scientific and regulatory issues that need to be considered and addressed to move productively forward

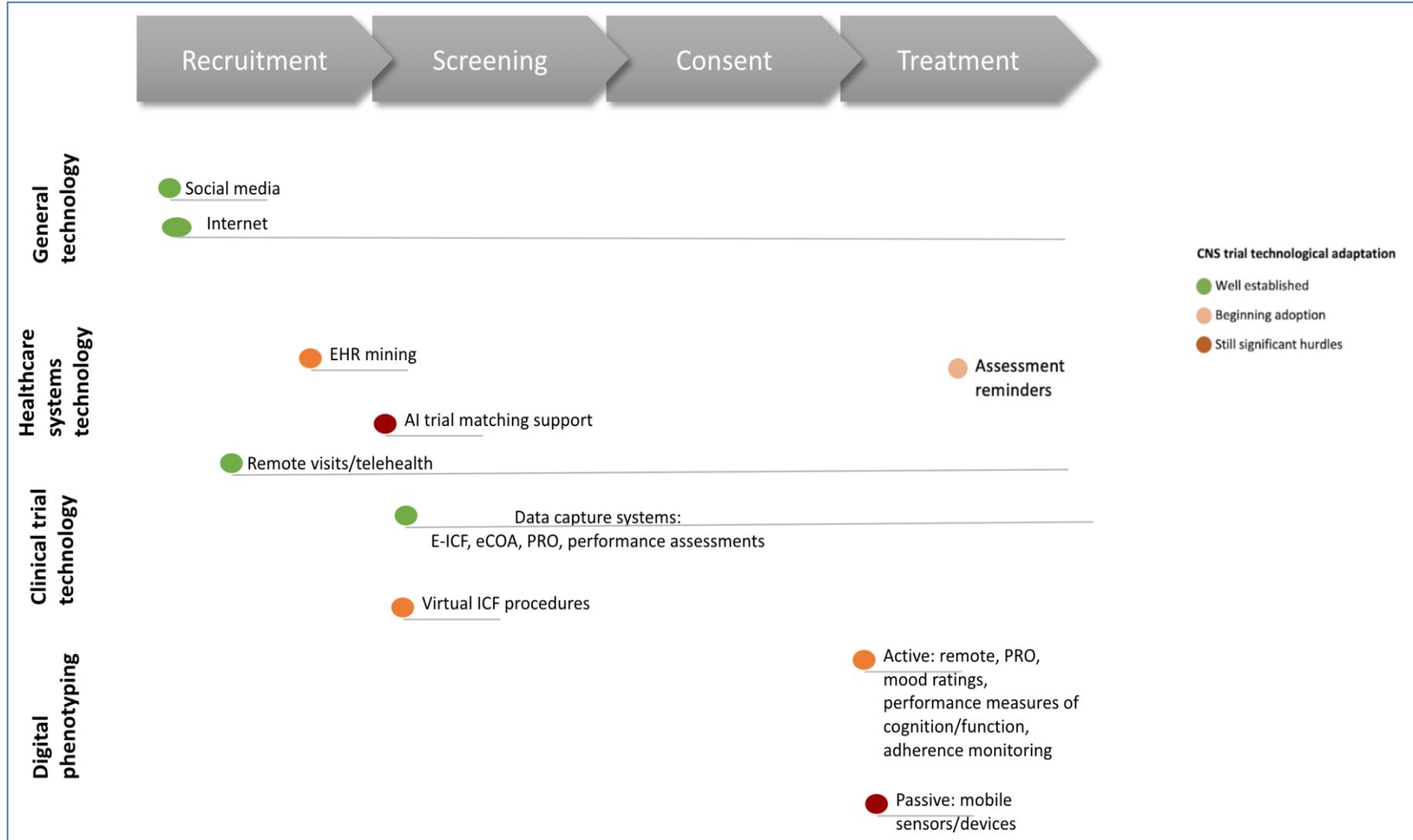
Outline

1. **Introduction**
 - Brief background
 - Describe goals of article
2. **Brief overview of relevant technologies**
3. **Patient recruitment & retention** (reorganization of existing subgroup text)
 - Brief background on the challenges
 - Promises of relevant technologies
 - Potential pitfalls
4. **Placebo response mitigation** (reorganization of existing subgroup text)
 - Brief background on the challenge
 - Promises of relevant technologies
 - Potential pitfalls
5. **Moving forward progress**
 - Scientific considerations
 - Clinical meaningfulness (**should this be a standalone section?)
 - Regulatory (and payer?) considerations
6. **Brief conclusion**

Some questions for discussion...

- Should we include a section that provides a brief overview of relevant technologies - or is that too broad for this article?
- Should “clinical meaningfulness” be a standalone section? Go under FDA considerations?
- Should the two main sections, recruitment/retention & placebo, be restructured?
- What content to cover in the final section on scientific and regulatory considerations?

2. OVERVIEW OF TECHNOLOGIES APPLICABLE TO CNS TRIALS



4. ADDRESSING THE PLACEBO RESPONSE

