Remote Cognitive Testing: an Exploration of Methodological Considerations in Designing Clinical Trials

Chairs:

Phil Harvey, PhD
Raeanne Moore, PhD

Speakers

Phil Harvey, PhD
Dwight Dickinson, PhD, JD
Maura Furey, PhD
Raeanne Moore, PhD
Luca Pani, MD

Remote Cognitive Assessment in Clinical Trials

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MILLER SCHOOL
of MEDICINE

Philip D. Harvey, PhD
Leonard M. Miller Professor
University of Miami Miller School of Medicine

Pharvey@Miami.edu

Disclosure Information

- Dr. Harvey has served as a consultant in the past year to:
  - Alkermes; Boehringer-Ingelheim; EMA Wellness; Karuna Pharma, Minerva Pharma, Sunovion Pharmaceuticals; Takeda; Teva
  - CSO i-Function

Cognition in Clinical Trials

- Several conditions where cognition is a central focus
  - Schizophrenia
  - Dementia Related Conditions
  - Major Depression
  - ADHD
- Measurement of side effects can involve cognitive assessments

Challenges with in Person Assessment

- During Normal Times
  - Logistics
    - Getting there
  - Micro Adherence
    - Assessments at the Same Time seem important
  - By definition they are dispersed assessments and do not capture full streams of momentary experience

Alternatives

- Perform Assessments remotely across schedules
  - Monthly, every 6 weeks, etc.
- Perform assessments on a momentary basis using smart devices
- Perform assessments on a targeted basis
  - “I feel… sedated, sleepy, sad, nervous

Challenges

- Several studies have shown that some tests are hard to do remotely and even harder to do remotely without an examiner
- If the hard-to-perform tests are seen to be critical to existing composite scores, what do you do?

Content for Today

- Can you shorten current batteries or substitute alternatives and “get the same answer” on a remote basis
- What are the current challenges in cognitive enhancement trials that need to be addressed with remote assessment?
- Are fully remote assessments valid, feasible, and equivalent, and what else can you get besides cognition?
- Finally, how is this approached from a regulatory perspective?