Need for Equivalent In-Person and Remote-Based Cognitive Assessments:
A Perspective from Pharma

Maura Furey, PhD

Executive Director, Clinical Development, Psychiatry

Neurocrine Biosciences, San Diego CA

Disclaimer

This presentation reflects the views of the speaker and may not be understood or quoted as being made on behalf or reflecting the position of the agencies or organizations with which the speaker was/is affiliated.

Currently, the speaker is an employee of Neurocrine Biosciences, Inc., San Diego, CA.

Current Status Of Cognitive Assessments in Clinical Trials
A Pharma Perspective

Assessment of Cognition within Clinical Trials is Burdensome

- *There are multiple cognitive domains to be assessed*
  - *e.g. processing speed, attention/vigilance, working memory, verbal learning, visual learning, reasoning/problem solving, social cognition*
- *To assess all cognitive domains is time consuming*
- *The time and personnel required results in site burden*
- *Time commitment is difficult for patients*

Covid-19 Pandemic

- *Sudden shutdown highlights need for preparedness*
- *Persistent impact creates new challenges*

Status quo not working

Implementation of Cognitive Assessments in Clinical Trials
A recent example

- **Initiated large multi-center, multi-regional study with on-site cognitive assessments**

- **Rater Training assigned (not only for cognitive assessments)**
  - *Completion was slow (delayed site activation)*
  - *Required frequent follow up reminders*
  - *Required **at least** 2 cognitive raters per site (cognitive function vs cognitive performance)*

- **Patient recruitment quite slow- *collected site feedback***
  - *the study is too burdensome*
  - *Studies with cognitive assessments are more time consuming*
  - *Additional burden due to extensive cognitive battery (covering all cognitive domains per regulatory requirements)*
  - *Covid has exaggerated these challenges*
    - Rebound in number of clinical trials – increased study competition at site level
    - Sites and patients 'select' other studies based on perceived burden
    - Patients decline participation due to time commitment

Key Questions:

- **Is it feasible to deploy remote cognitive assessments within clinical trials?**

- **Can remote cognitive assessments be used successfully in cognitive clinical trials?**

- **Can remote cognitive assessments address the current key challenges in cognitive clinical trials?**

Is it feasible to deploy remote cognitive testing within clinical trials?

Are patients able to respond to this new structure?

- *Will this differ by patient population?*

What infrastructure (e.g. hardware; internet access) is required to support at home assessments?

- *Will access to infrastructure be limiting?*
- *Will limitations differ by patient population or by study region?*

How can technical difficulties be addressed to avoid loss of assessments/data?

Can remote cognitive assessments be used successfully in cognitive clinical trials?

- **Does remote testing produce comparable results to in-person testing?**
- **Do remote and in-person cognitive assessments correlate?**
- **How would remote cognitive assessments affect variability in measures?**
- **Are all cognitive domains amenable to remote assessments?**
- **Can remote assessments be self-administered?**
  - *Role of informant or study partner*
  - *Disease severity*
  - *Environment*
- **What existing limitations in current applications will need to be addressed?**

Can remote cognitive assessments address the current key challenges in cognitive clinical trials?

- *Burden for sites to conduct cognitive trials*

- *Burden for patients to participate in cognitive trials*

Study Success Requires Site Partnership
Cognitive studies and site burden

"**Cognitive studies are burdensome**"

- *Required staff training*
- *Administration of cognitive assessments*
- *Overall duration of site visits*

Question:

Can use of remote cognitive assessments reduce site burden?

Sites Require Trained Staff to Conduct Assessments
Retaining staff is difficult

Staffing to Support Cognitive Clinical Trials

- *Broad staffing difficulties (Covid-19)*
- *Limited staff experience in cognitive assessments*
- *Studies require 2 or more trained and experienced staff*
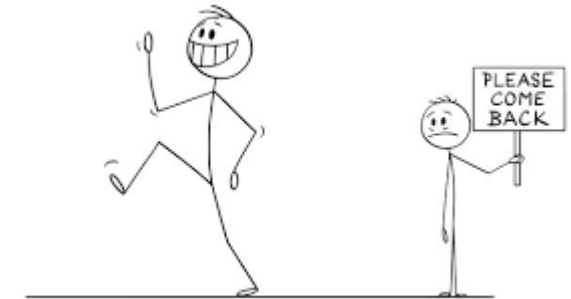
Questions:

- *Are there creative solutions that utilize remote assessments to address this problem?*

Study Success Requires Patient Commitment
Cognitive studies and patient burden

Cognitive assessments are time consuming/tiring for patients

- *Site visits take too long (time burden)*
- *Patients are tired after visits*
- *Caregiver support can be difficult*
- *Patients decline participation due to visit length*

Questions:

Can use of remote cognitive assessments reduce burden for patients? Or would this preferentially impact site burden?

Is there a solution to reduce patient burden while obtaining all necessary assessments through remote testing?

Study Success Requires Patient Commitment:
Self-administered vs remote rater assessments
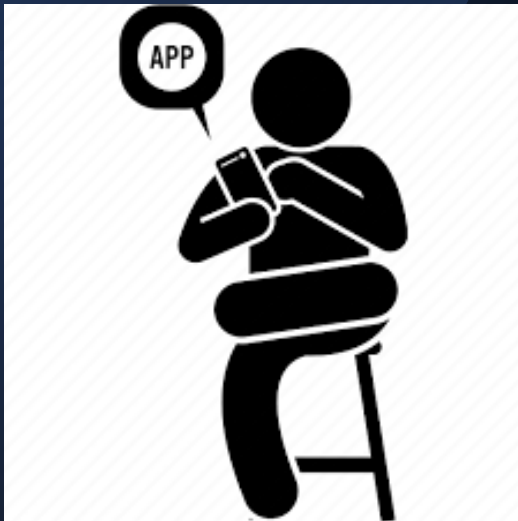
- **Can cognitive assessments be self-administered?**

- **Is this a solution to address patient burden?**

- **How would the flexibility offered by self-administration impact study data**
  - *time of day (same time of day?)*
  - *testing at multiple times across day*

- **Can self-administered cognitive assessments address current challenges?**

- **Regulatory acceptance of such changes?**

Cognitive Assessments in Pharmaceutical Development
Summary – Are remote assessments the answer

- Cognitive dysregulation is **critical** in many brain-based illnesses

- Cognitive studies have **unique challenges** driven by increased study burden for sites and patients

- Remote assessments- **Is this the solution?**

Pharma will need confidence that:

| Remote assessments measure the same cognitive constructs/domains as in-person assessments | Remote and in-person assessments produce comparable results/findings | Using remote assessments will address the current barriers to conducting cognitive clinical trials |