

Cognition as an Under- Explored Aspect of Multiple Disorders

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Potential Financial Conflicts of Interest

Consulting/Advisory Board: Abbott, Acadia, Astra-Zeneca, BiolineRx, Bristol Myers Squibb, Cephalon, Dainippon Sumitomo, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Lundbeck, Memory, Merck, Orexigen, Otsuka, Pfizer, Sanofi/Aventis, Wyeth, Xenoport.

Royalties: Brief Assessment of Cognition in Schizophrenia (BACS), MATRICS Consensus Cognitive Battery

Founder and CEO of NeuroCog Trials, Inc., which provides rater training, data quality assurance and consultation to several pharmaceutical companies and other consortia

Overview

- The purpose of this session will be to discuss, in the context of clinical trial design, the methodology of assessing cognition in psychiatry and neurology
- The focus of this session will be on disorders where cognitive dysfunction has not traditionally been viewed as a primary manifestation or target outcome in the context of clinical trials
 - Multiple sclerosis, epilepsy and bipolar disorder as examples
- We will focus on several issues on cognition in clinical trials for each disorder, and concluding with an extended interactive discussion period involving the chairs, panelists, and audience

- Michael Green
 - Cognitive Assessment in Schizophrenia Clinical Trials: MATRICS and Beyond
- Ralph Benedict
 - Psychometric considerations and consensus standards for cognitive testing in MS
- David Loring
 - Cognitive and behavioral endpoints as primary outcome variables in epilepsy clinical trials
- Kate Burdick
 - Application of Cognitive Assessment Methods for Bipolar Disorder Clinical Trials
- Panelists: Tom Laughren, Rusty Katz, Gretchen Tucker

- The current perspective regarding the role of cognition in the disorder
 - Profile of cognitive impairments
 - Clinical perspective regarding the role of cognition in the disorder
 - The role of cognitive deficits in contributing to decrements in functional ability and quality of life in the illness
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- Types of assessments that should be completed to assess the relevant cognitive impairments in the disorder
 - How does a typical assessment battery overlap with that from other disorders?
 - Is a MATRICS-like initiative is needed?
 - Is the work initiated by MATRICS for identifying cognitive domains applicable?
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- Challenges and proposed solutions for assessing cognition accurately in clinical trials
- Existing trial designs
- Disease-specific regulatory hurdles to getting indications for treatment of cognition
- Identification of any particular areas that need development
- Other log jams or logical inconsistencies that need to be addressed