



Towards Precision Medicine in CNS Disorders: Progress and Challenges

Chairs:

Larry Alphas, MD, PhD

Ole Andreassen, MD

Disclosures

- **Past Affiliations**

- University of Maryland; Case Western Reserve University; Wayne State University
- VA (Perry Point/Baltimore, Cleveland, Detroit)
- Sandoz; Novartis; Knoll Pharmaceuticals (Abbvie); Pfizer; Johnson & Johnson; Newron Pharmaceuticals; Denovo Biopharma

- **Consultancies**

- Johnson & Johnson
- SIGNANT
- Denovo Biopharma
- NetraMark
- Neumarker



Speakers

Joseph Geraci, PhD

Hakon Heimer, MS

Wen Luo, PhD

Tineke Mollema

Abhishek Pratap, PhD

Sue-Jane Wang, PhD

Ole Andreassen, MD

Larry Alphas, MD, PhD

CNS Medicine Challenges

- **Poor animal models for CNS diseases**
- **Disease nomenclature is imprecise**
 - Heterogeneous subtypes of depression, schizophrenia, dementia, etc. respond differently to treatment
- **Understanding of treatment response remains limited**
 - Mediators and modulators of CNS disorders are inadequately understood
 - Disease progression not well understood
 - Medications sometimes lose effectiveness over time
 - Finding the most effective treatment for patients is by trial and error
- **Large placebo effects**
- **Side effects of treatments unacceptable for some patients**

Rationale for AI/ML Session

- **Rapid development of field**

- Enormous resources are being poured into the pursuit of artificial intelligence
- Development of AI coming from many sectors
- “The singularity,” the moment when AI is no longer under human control, is less than a decade away

BUT

- Can take 20+ years to translate medical insights into clinical practice
- AI innovation presents challenges
 - Regulatory science challenges
 - Effective communication of medical knowledge
 - Potential for misuse

Agenda

Introduction: The Vision for Precision Psychiatry and Goals of this Session

Larry Alphs

CNS Precision Medicine: from Research to Real-World Impact

Ole Andreassen

Discussion

Biomarker identification for Patient Enrichment Strategies in CNS Clinical Trials: Alternative Approaches and Challenges

Joseph Geraci

Discussion

Discovery and Validation of a Genetic Biomarker for a Triple Reuptake Inhibitor (Liafensine) in TRDPrecision Psychiatry in Psychotic Disorders

Wen Luo

Discussion

Industry Perspectives on Precision Medicine

Abhishek Pratap

Discussion

Nordic Initiatives in Precision Medicine: Stakeholders, Strategies, and Scary Stories about Data

Hakon Heimer

User Perspectives on Precision Psychiatry

Tineke Mollema,
GAMIAN-Europe, Belgium

Statistical Expectations for Precision Medicine in Psychiatry and Neurology: A Regulatory Perspective

Sue Jane Wang, FDA

Discussion

Goals of Session

- Provide greater insights into evolving innovations and how they might be used in clinical trials and clinical practice
- Identify challenges and hurdles to implementing these innovations in CNS disorders

Innovations in CNS Medicine to Change Clinical Trials and Practice

- Development of large health databases that include key parameters from broad segments of clinical populations
- Machine learning capabilities that can better organize and better interpret the multimodal data
- Identification of subpopulations of disease entities using phenotypic data already available and emerging biomarker data
 - Better interpret EEG and imaging data
 - Identification of genetic biomarkers
 - Digital tools for new biomarker identification