

# Cognitive Dysfunction Workgroup Dinner Meeting

Co-chairs –

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## Objectives

1. Initiate Cognition Workgroup, to further advance the understanding of cognitive dysfunction in psychiatric disorders
  2. With a diverse group of stakeholders, begin work that could provide guidance on potential development pathways for future therapeutics
    - Capitalize on recent work in MDD
    - Expand to other psychiatric disorders and/or neurologic conditions
  3. Identify interested parties, necessary steps and activities
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- Introduction
  - Goals for Cognition Workshop – J. Parker
  - Cognitive Dysfunction in MDD – M. Fava
- EU Perspective – L. Pani
- Cognition across CNS indication – R. Keefe
- Measuring cognitive change – J. Jaeger
- FDA perspective – M. Mathis, T. Farchione
- Discussion
- Next steps

# Summary of Workshop

- Introduction (Parker, Fava)
  - Unmet need regarding cognition in psychiatric disease
  - Focused on cognitive dysfunction in MDD as near term need
- MATRICS learnings (Keefe)
  - Don't have to use/measure everything at all times, can tailor to what pharmacology and clinical data suggest is drug's effect
  - Function important, can be used as secondary endpoint
- Measuring change (Jaeger)
  - Changed (negative/positive) thinking is relevant and impactful to patient
  - Can't measure thinking, tests are surrogates and must be fit for purpose
- Health agency perspectives
  - EMA (Pani, Mantua): Overview of EMA activities related to cognition in three areas – CIAS, BPD and MDD
  - FDA (Mathis, Farchione): Evolving view of cognition as it relates to pseudospecificity, CD in MDD now recognized like CIAS

# Next Steps

- Strong support from members to proceed with Consensus Paper
  - View from Health Agencies –
  - EMA and FDA working on guidances in cognition
    - Both agreed input from field valuable
    - FDA agreed Consensus Paper would provide value to their ongoing work on a Guidance for CD in MDD