



International Society for CNS Clinical Trials and Methodology

Accelerating Development of Psychopathology Measures – ISCTM/ECNP Joint Working Group

Friday 13 September 2024

Chairs: Nina Schooler, Celso Arango, & Jenicka Engler

Disclosures

Nina Schooler: Grants: Co-investigator ESPRITO Learning Health System National Institute of Mental Health

Paid positions: Professor of Psychiatry and Behavioral Sciences, SUNY Downstate Health Services Center; Senior Research Scientist, Vanguard, Northwell Health System

Advisory Boards: Alkermes, Boehringer- Ingelheim, Otsuka, Lundbeck

Celso Arango: Consultant: Acadia, AMGEN, Angelini, AstraZeneca, Bristol-Myers Squibb, Fundación Alicia Koplowitz, Geodon Richter, Instituto de Salud Carlos III, Spanish Ministry of Economy and Competitiveness, Janssen-Cilag, Lundbeck, Otsuka, Roche, Sage, Servier, Schering-Plough, Shire, Spanish Ministry of Education, Stanley Foundation, Sumitomo Dainippon Pharma, Sunovion, Takeda.

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Speaker Bureau: AMGEN, AstraZeneca, Bristol-Myers Squibb, Exeltis, Janssen-Cilag, Lundbeck, Otsuka, Roche, Sanofi, Sumitomo Dainippon Pharma, Takeda

Jenicka Engler: Employee of Cronos Clinical Consulting Services, Inc an IQVIA Business; Scale assessment royalties from EBAD and AIRS

History 101: Are our clinician-rated psychopathology measures fit for purpose decades later?

- 2023: Symposium at ISCTM/ECNP joint meeting in Barcelona
 - Chairs: Celso Arango, Stephen Marder, Nina Schooler
 - Focused on currently used scales for three indications
 - PANSS - schizophrenia/psychosis Arango
 - HDRS and MADRS – depression Demyttenaere
 - YMRS – bipolar disorder mania Vieta
 - Reviewed characteristics of successful program for new scales Marder
 - Addressed strategies/methodologies for developing improved scales
 - Digital technologies /Ecological momentary assessment Cohen
 - Computerized adaptive testing Schooler

History 201: Accelerating Development of Psychopathology Measures

- 2023: Established a working group supported by ECNP and ISCTM
 - Group met immediately after the session
 - Identified co-chairs from ECNP and ISCTM
 - Robust discussion indicated support for going forward with scale development
 - Many creative ideas of how to proceed
 - Challenges include process, addressing heterogeneity , meeting regulatory standard
 - Broke into three subgroups based on indication – following the symposium model
 - Schizophrenia
 - Depression
 - Bipolar

History 202: It's all about the subgroups Schizophrenia

- 2023
 - Affirmed the need for a new assessment tool/rating scale
 - First step: develop MS that supports that claim
 - Subgroup chairs Anzalee Khan, Armida Mucci, Simon Desjardins
- 2024
 - DC ISCTM meeting
 - Discussed MS
 - Interim Zoom meeting defined the MS sections
 - MS draft 1 completed
- Today's agenda
 - discuss MS draft & timeline for publication
 - Identify next steps

History 202: It's all about the subgroups

Schizophrenia

- 2023
 - Affirmed the need for a new assessment tool/rating scale
 - First step: develop MS that supports that claim describing the limitations and weaknesses in key domains of scale development, psychometric assessment, clinical utility, and research utility
 - Subgroup chairs Anzalee Khan, Armida Mucci, Simon Desjardins
- 2024
 - DC ISCTM meeting
 - Discussed MS
 - Interim Zoom meeting defined the MS sections
 - Draft MS completed
- Today's agenda: discuss MS

History 202: It's all about the subgroups Depression

History 202: It's all about the subgroups

Bipolar Disorder

- 2023
 - Discussion of advantages (e.g. legacy) and limitations (e.g. susceptibility to context of assessment, items weighted differently) of the Young Mania Rating Scale, in collaboration with EU
- 2024
 - Met with Bob Young to provide historical context and to develop a framework for revising the instructions for the YMRS to ensure improved reliability
 - Initiated assessment of any licensing considerations and collaborations (Gary Sachs) on improving administration of YMRS through clarifying instructions (Guide to the YMRS)
 - Approached FDA about item analyses of registration data; will work on item-level post hoc analyses from any datasets that can be acquired
 - Planning to draft manuscript to motivate rationale to iterate on mania severity endpoint