

# Algorithms/Flags for Rating Scales used in CNS Clinical Trials

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# **Prior Work: Positive and Negative Syndrome Scale (PANSS)**

- Flags have been developed and vetted by the Workgroup
- A draft manuscript will be circulated in March
- A poster describing the results will be presented at the Schizophrenia International Research Society (SIRS) meeting April 2016 Firenze Italy

## Current

# Montgomery/Asberg Depression Rating Scale

- Prior to Working Group (WG) meeting
  - MADRS agreed to as next scale to review
  - Work endorsed by Stuart Montgomery
  - Additional members recruited to add depression rating scale and clinical expertise
  - Flags developed and circulated to the group
  - Decision to rate each flag as
    - 0 – Should not be a flag
    - 1- possibly
    - 2- probably
    - 3- very probably

# Current Montgomery/Asberg Depression Rating Scale

- At the WG meeting on 2/16/2016
  - 27 attendees representing all ISCTM sectors
  - Reviewed and rated 23 flags identified before the meeting
  - Detailed minutes to the WG provide details of review
  - General issues discussed
    - See next slide
  - Decided to apply flags to
    - STEP-BD study
    - NewMeds

## Current

# Montgomery/Asberg Depression Rating Scale

- General principles and concerns
  - Use of flags for rater feedback could result in “training” raters to modify behavior to avoid being caught and affect validity of ratings
  - Flags are designed for ratings 1 or more weeks apart
  - Flags describing complete remission between consecutive visits may not be valid for novel short acting treatments
  - Are some combinations of flag occurrence better measures than frequency of individual flags

# Future Activities

## Montgomery/Asberg Depression Rating Scale

- Ratings made at the meeting will be integrated with those provided by others both before and after the meeting
- Flags will be applied to STEP-BD and NewMeds data bases for frequency
- Analysis will report frequency of occurrence in relation to expert confidence in flag validity
  - Address the question do these flags matter?
- Stuart Montgomery will be asked to comment further on WG progress