

Algorithms/Flags for Rating Scales used in CNS Clinical Trials

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Prior Work: Positive and Negative Syndrome Scale (PANSS)

- Flags were developed and vetted by the Workgroup
- A poster describing the results was presented at the Schizophrenia International Research Society (SIRS) meeting April 2016 Firenze Italy
- Draft MS has been reviewed by group and is under final revision for submission to Schizophrenia Research (brief report)

Current Montgomery/Asberg Depression Rating Scale MADRS

- 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?
- Could use of flags for rater feedback result in “training” raters to modify behavior?

Current Montgomery/Asberg Depression Rating Scale MADRS

- 2016 02 Working Group (WG) meeting
 - Each flag rated as
 - 0 – Should not be a flag
 - 1- possibly
 - 2- probably
 - 3- very probably
 - 27 attendees representing all ISCTM sectors
 - Rated 23 potential flags
 - Ratings were summarized and flags collated in order of probability of being a flag

Current Montgomery/Asberg Depression Rating Scale

- At the WG meeting on 9/26/2016
 - 18 attendees representing all ISCTM sectors
 - Reviewed and revised ratings of 23 flags identified before the meeting
 - Additional issues discussed
 - Same or different on-site rater between rating points
 - Central vs. on-site rater
 - Desirable to apply flags to existing study data bases
 - STEP-BD study
 - NewMeds

Future Activities

Montgomery/Asberg Depression Rating Scale

- Final definitions of flags to be circulated to meetings attendees and other Working group members
- Consider applying flags to STEP-BD and NewMeds data bases
 - Analysis would report frequency of occurrence
- Stuart Montgomery will be asked to comment for WG progress