Suicidal Ideation and Behavior: Methodological and Technical Challenges

Chairs:
Adam Butler
Michelle Stewart, PhD
Roger Meyer, MD
Guidance for Industry
Suicidality: Prospective Assessment of Occurrence in Clinical Trials
2007
Columbia Classification Algorithm of Suicide Assessment (C-CASA), Posner et al, 2007
2007
Columbia Classification Algorithm of Suicide Assessment (C-CASA), Posner et al, 2007

2009
Introduction of mandatory SIB assessments
2007
Columbia Classification Algorithm of Suicide Assessment (C-CASA), Posner et al, 2007

2009
Introduction of mandatory SIB assessments

2010
FDA Draft Guidance (version 1)
2007
*Columbia Classification Algorithm of Suicide Assessment (C-CASA)*, Posner et al, 2007

2009
Introduction of mandatory SIB assessments

2010
*FDA Draft Guidance (version 1)*

2012
*FDA Draft Guidance (revision)*
A Critical Issue

Sponsors and investigators have struggled to implement these measures consistently.
A Critical Issue

The emergence of new measures meant to satisfy the requirements of the guidance has introduced many methodology questions.
C-SSRS

- Posner, K.; Brent, D.; Lucas, C.; Gould, M; Stanley, B; Brown, G.; Zelazny, J.; Fisher, P.; Burke, A; Oquendo, M.; Mann, J.
- Developed by leading experts/evidence-based
- Feasible, low-burden – short administration time
- Assesses both behavior and ideation: uniquely addressing the need for a summary measure of suicidality
- Comprehensive measure that includes only the most necessary suicidality characteristics (low-burden), i.e., the most essential, evidence-based items needed in a thorough assessment
ISST-Plus Overview

- A modified version of the ISST (1997), was developed by Alphs and Lindenmayer in 2009.
- Components
  - Part I: Suicidal Ideation—13 items (Time: Last 7 Days)
  - Part II: Suicidal Behavior (Time: Since last visit)
  - Part III: Global Suicidal ideation and behavior (Time: Now)
    - Severity
    - Status if subject misses assessment
  - Suicide Narrative (optional) (Time: Since last visit)
- If the subject reports suicidal behavior (e.g., preparation, injuries, accidents, passive or active attempt) in Part II, or if the subject completes suicide (documented in Part III), all available information will be reported in the Suicide Attempt Narrative section.
- The ISST-Plus takes 15-20 minutes to complete.
Sheehan-STS

- Assesses and tracks treatment emergent suicidal ideation and behaviors
- Evolved from the Suicidality Module of the Mini International Neuropsychiatric Interview (MINI), a structured diagnostic interview for DSM IV
- 11 item scale (+ 2 + 5)
- Scored on a 5 point Likert scale
- Maps to C-CASA 2010 and 2012
- Clinician and patient rated
- 3 pediatric versions (6-8, 9-12, 13-17 yr olds)
- Computerized mapping calculations and scoring
- Linguistically validated versions from MAPI
The goal of the symposium is to expand awareness of real challenges to these assessments, and present the most recent evidence that will guide design and decision-making moving forward.