



International Society for CNS Clinical Trials and Methodology

**Suicidality: What have we learned after a decade of research? What challenges remain?**

# Disclosures

- **SVP CNS Development, Denovo Biopharma, LLC**
- **RSUs Denovo Biopharma, LLC**
- **Stock J&J**

# Consensus Meeting on Methodological Considerations for Suicide Assessment and Clinical Trial Design

17 – 18 November, 2015 // Arlington, VA

## Working Groups

- [Nomenclature & Classification](#)  
[Instrumentation & Special Populations](#)  
[Analysis of SIB Data](#)  
[Design and Methodology for SIB Treatment Studies](#)  
[Developing Policy and Education on SIB Assessment](#)

# Statements Voted on at F2F Meeting on Nov 18

Statement	n	Yes	No
When selecting an instrument and method of administration for a study, one should consider the research settings (e.g., academic, hospital, CRU), study teams (e.g., psychiatric vs. nonpsychiatric, level of experience) and patient populations (e.g., youth, elderly, cognitively impaired, acutely ill).	79	94%	4%
Evidence of validity must be provided for formal use of an instrument in clinical trials. Reliability and validity of an SIB instrument must be demonstrated for the population to be studied, taking into account vulnerable populations and cultural relevance. (This does not apply to experimental measures, which may be included	83	77%	18%
When assessing outcome for treatment of SIB, two or more perspectives for assessing SIB can provide more comprehensive and clinically meaningful information than a single instrument. Perspectives may include different methods of assessment, instruments and/or sources of information.	83	71%	23%
One perspective may be sufficient for determining eligibility to participate in a clinical trial	74	93%	7%
One perspective may be sufficient for determining treatment emergent events	80	76%	14%
Assessment tools for suicidal ideation and behavior must be translated taking cultural factors into account and ideally have demonstrated reliability and validity for use wi	73	90%	10%

# Consensus Meeting on Methodological Considerations for Suicide Assessment and Clinical Trial Design

## Publications

- [Study Site Experiences and Attitudes Toward Prospective Assessments of Suicidal Ideation and Behavior in Clinical Trials: Results of an Internet-based Survey](#); **M Stewart**, A Butler, L Alphas, P Chappell, D Feltner, W Lenderking, A Mahableshwarkar, C Makumi, S DuBrava, ISCTM Suicidal Ideation and Behavior Assessment Working Group; *Innovations in Clinical Neuroscience: May-June 2013 (ISCTM Supplement #1)*
- [Assessment of Suicidal Ideation and Behavior: Report of the International Society for CNS Clinical Trials and Methodology Consensus Meeting](#); **Phillip Chappell, MD, MBA**, Michelle Stewart, PhD; Larry Alphas, MD, PhD; Franco DiCesare, MD; Sarah DuBrava, MS; Jill Harkavy-Friedman, PhD; Pilar Lim, PhD; Sian Ratcliffe, PhD; Morton M. Silverman, MD; Steven D. Targum, MD; and Stephen R. Marder, MD *J Clin Psychiatry 2017;78(6):e638–e647 (Open Access)*
- [Prospective Assessment of Suicidal Ideation and Behavior: An Internet Survey of Pharmaceutical Sponsor Practices](#); **ISCTM Suicidal Ideation and Behavior Working Group**, Phillip B. Chappell, MD; Atul R. Mahableshwarkar, MD; Larry D. Alphas, MD, PhD; Mark E. Bangs, MD; Adam Butler, BA; Sarah J. Dubrava, MS; John H. Greist, MD; William R. Lenderking, PhD; James C. Mundt, PhD; and Michelle Stewart, PhD, *Innovations in Clinical Neuroscience Vol11, 9-10*

Statistic	2015	2020
Cause of death	12 <sup>th</sup>	Top 10
Suicide deaths	44,193	45,979
Suicide attempts	1.4 M	1.2 M
Deaths by Firearms	22,018	23,941 (>50% of total)
Deaths by Suffocation	11,185	13,563
Deaths by Poisoning	6,816	6,125

# **2022 Autumn Conference**

8-9 September 2022

Boston, MA

**Suicidality: What have we learned after a decade of research? What challenges remain?**

# 2022 Autumn Conference

8-9 September 2022

Boston, MA

<b>1:25pm</b>	<b>Real world assessments of suicide ideation and behavior. Challenges and next steps.</b>	<b>Eric Chan</b>
<b>1:45pm</b>	<b>Discussion</b>	
<b>1:50pm</b>	<b>Veteran suicide surveillance and development and evaluation of the REACH VET clinical program</b>	<b>John McCarthy</b>
<b>2:10pm</b>	<b>Discussion</b>	
<b>2:15pm</b>	<b>Suicide prevention research: What we have learned and what we haven't</b>	<b>Jill Harkavy-Friedman</b>
<b>2:35pm</b>	<b>Discussion</b>	
<b>2:40pm</b>	<b>Insights into study design and methodology for assessing suicidality and behavior in clinical trials for safety and efficacy: Hurdles and advances</b>	<b>David Sheehan</b>
<b>3:00pm</b>	<b>Discussion</b>	
<b>3:05pm</b>	<b>Statistical challenges and potential solutions for assessing suicide ideation and behavior endpoints</b>	<b>Kari Nations</b>
<b>3:25pm</b>	<b>Discussion</b>	
<b>3:30pm</b>	<b>Panel Discussion</b>	<b>Sheehan/Nations/Friedman /Chan/McCarthy</b>
<b>3:45pm</b>	<b>Summary</b>	<b>Larry Alphas</b>



