Survey of Sponsor Practices in Conducting Prospective Assessments of

1. What is your training? [Select all that apply.]

- [ ] Clinical pharmacologist
- [ ] Internist
- [ ] Neurologist
- [ ] Nurse/nurse practitioner
- [ ] Physician, other specialty
- [ ] Psychiatrist
- [ ] Psychologist
- [ ] Other (please describe)

2. Please indicate the type of company you work for.

- ◯ Large pharmaceutical company
- ◯ Mid-size pharmaceutical company
- ◯ Small pharmaceutical company
- ◯ Biotech

3. How many years of industry experience do you have?

- ◯ <5
- ◯ 6-10
- ◯ 11-15
- ◯ >15

Survey of Sponsor Practices in Conducting Prospective Assessments of

4. What area do you work in at your company? [Select all that apply.]

- [ ] Clinical development
- [ ] Medical affairs
- [ ] Therapeutic area or disease specialist
- [ ] Study management
- [ ] Development operations or project management
- [ ] Outcomes research
- [ ] Clinical safety
- [ ] Regulatory

Other (please describe)

5. Are you involved in any way with the implementation of prospective Suicidal Ideation and Behavior (SIB) assessments in clinical trials at your company?

- ◯ Yes
- ◯ No

If yes, please describe your role/s and your experiences with prospective implementation of SIB assessments in clinical trials at your company.

Survey of Sponsor Practices in Conducting Prospective Assessments of

6. Generally within your company what factors are considered in deciding whether a study should include prospective Suicidal Ideation and Behavior (SIB) assessments? [Select all that apply.]

- [ ] Psychiatric or neurologic drug product
- [ ] Disease under study
- [ ] Patient population
- [ ] Capacity of patient population to understand the wording and give meaningful responses to SIB assessments (eg, autism, dementia, retardation)
- [ ] Background rates of SIB
- [ ] CNS effects in Phase 1 trials
- [ ] Regulatory announcements and policies
- [ ] Micro vs macro dosing study
- [ ] Evidence of SIB for other drugs of the same class
- [ ] Adverse events indicative of SIB
- [ ] CNS active compound
- [ ] CNS behavioral effects in animal studies
- [ ] Potential for indirect CNS effects
- [ ] Type of study (eg, Phase 1 PK or single dose study)

Other (please describe)

Survey of Sponsor Practices in Conducting Prospective Assessments of

7. Please indicate for which of the following CNS indications your company has included prospective SIB assessments in clinical trials. [Select all that apply.]

- [ ] Depression
- [ ] Anxiety
- [ ] Schizophrenia
- [ ] Bipolar disorder
- [ ] ADHD
- [ ] Autism
- [ ] Mild Cognitive Impairment
- [ ] Alzheimer's disease or other dementia
- [ ] Pain
- [ ] Alcoholism
- [ ] PTSD
- [ ] Opioid dependence
- [ ] Substance abuse
- [ ] Traumatic Brain Injury
- [ ] Parkinson's Disease
- [ ] Epilepsy
- [ ] Stroke
- [ ] Multiple Sclerosis
- [ ] Amyotrophic Lateral Sclerosis
- [ ] Suicidal ideation and behavior

Other psychiatric or neurologic disorder (please specify)

Survey of Sponsor Practices in Conducting Prospective Assessments of

8. Please indicate for which of the following non-CNS indications your company has included prospective SIB assessments in clinical trials. [Select all that apply.]

- [ ] Obesity
- [ ] Smoking cessation
- [ ] Respiratory allergy/sinusitis
- [ ] Fibromyalgia
- [ ] Insomnia, other sleep disorders
- [ ] HIV
- [ ] Diabetes

Other (please describe)

9. For studies at your company which include prospective SIB assessments, are assessments done at the Screening Visit?

- ◯ Yes
- ◯ No

10. What specific past time period(s) has your company used at the Screening Visit for assessment of SIB? [Select all that apply.]

	Suicidal Ideation	Suicidal Behavior
Lifetime	☐	☐
10 years	☐	☐
5 years	☐	☐
1 year	☐	☐
6 months	☐	☐
1 month	☐	☐
2 weeks	☐	☐
1 week	☐	☐

Other (please specify)

11. In the previous question did you indicate multiple past time periods for either Suicidal Ideation or Suicidal Behavior at the Screening Visit?

- ◯ Yes
- ◯ No

Survey of Sponsor Practices in Conducting Prospective Assessments of

12. What factors determine the use of different time periods for Screening assessments of Suicidal Ideation and Behavior?

13. For studies at your company which include prospective SIB assessments, are assessments done at the Baseline Visit?

- ◯ Yes
- ◯ No

14. What specific past time period(s) has your company used at the Baseline Visit for assessment of SIB? [Select all that apply.]

	Suicidal Ideation	Suicidal Behavior
Lifetime	☐	☐
10 years	☐	☐
5 years	☐	☐
1 year	☐	☐
6 months	☐	☐
1 month	☐	☐
2 weeks	☐	☐
1 week	☐	☐

Other (please specify)

15. In the previous question did you indicate multiple past time periods for either Suicidal Ideation or Suicidal Behavior at the Baseline Visit?

- ◯ Yes
- ◯ No

16. What factors determine the use of different time periods for Baseline assessments of Suicidal Ideation and Behavior?

17. What specific past time period(s) for SIB has your company used at the Screening Visit to determine if the subject is at risk of suicide and should be excluded from the study? [Select all that apply.]

	Suicidal Ideation	Suicidal Behavior
Lifetime	☐	☐
10 years	☐	☐
5 years	☐	☐
1 year	☐	☐
6 months	☐	☐
1 month	☐	☐
2 weeks	☐	☐
1 week	☐	☐

Other (please specify)

Survey of Sponsor Practices in Conducting Prospective Assessments of

18. Please indicate which SIB instruments you are aware that your company has employed for screening assessments, baseline assessments, and tracking SIB in clinical trials. [Select all that apply.]

	Screening	Baseline	Tracking
Columbia Suicide Severity Rating Scale (C-SSRS)	☐	☐	☐
IVR version of C-SSRS (eC-SSRS)	☐	☐	☐
Sheehan Suicide Tracking Scale (S-STS)	☐	☐	☐
Suicidality module of the Mini Neuropsychiatric Interview	☐	☐	☐
Concise Health Risk Tracking – Clinician Rating	☐	☐	☐
Concise Health Risk Tracking – Self Rating	☐	☐	☐
InterSept Scale for Suicide Thinking (ISST)	☐	☐	☐
InterSept Scale for Suicide Thinking – Plus (ISST-Plus)	☐	☐	☐
Beck Scale for Suicide Ideation	☐	☐	☐
Suicide Behaviors Questionnaire	☐	☐	☐
Paykel Suicide Scale	☐	☐	☐
Suicide item of the HAM-D	☐	☐	☐
Suicide item of the MADRS	☐	☐	☐
Suicide item of the PHQ-9	☐	☐	☐
Suicide item of the IDS/QIDS	☐	☐	☐
Suicide item of the CDRS	☐	☐	☐
Don't Know	☐	☐	☐

Other (please specify)

19. Does your company conduct post-hoc analyses of potential suicide related adverse events (e.g., by using computerized search of verbatim adverse event reports and submission of narratives for external adjudication) in addition to the prospective assessment of SIB in clinical studies?

◯ Yes

◯ No

Survey of Sponsor Practices in Conducting Prospective Assessments of

20. In your experience in clinical trials at your company, which of the following responses best characterizes your company's management of subjects who report active suicidal ideation or behavior? [Active suicidal ideation is defined as specific suicidal thoughts including either method, plan, or intent to do so. Suicidal behavior includes preparatory acts towards imminent suicide, actual attempts, interrupted attempts, and aborted attempts.]

- ◯ Discontinued from the study without requiring specific referral of the subject for further evaluation
- ◯ Discontinued from the study and required to be referred for evaluation by a mental health professional
- ◯ Risk assessment is performed by a mental health professional to determine if it is appropriate for the subject to continue in the study
- ◯ Continue subject in the study without additional risk assessment

Other (please describe)

21. In your experience in clinical trials at your company, which of the following responses best characterizes how study level SIB assessment data are summarized by your company?

- ◯ Combined summary of suicidal ideation and behavior data
- ◯ Separate summaries each of suicidal ideation and suicidal behavior
- ◯ Summary of suicidal ideation data only
- ◯ Summary of suicidal behavior data only
- ◯ No standard approach used

Other (please describe)

Survey of Sponsor Practices in Conducting Prospective Assessments of

22. What challenges has your company encountered in implementing prospective SIB assessments in clinical trials? [select all that apply.]

- [ ] Investigator/rater discomfort with asking about suicidal ideation and behavior
- [ ] Investigator/rater discomfort with managing suicidal ideation and behavior
- [ ] Patient resistance to responding to questions about SIB
- [ ] Site difficulty in obtaining adequate baseline history
- [ ] Site not prepared to handle suicidal patients
- [ ] Inadequate training of raters to administer SIB ratings
- [ ] Site difficulties with referring patients who report SIB for mental health evaluations
- [ ] Failure of sites to respond to positive reports of SIB by study subjects (ie continuing subject in study when should have been excluded)
- [ ] Cross-cultural differences in acceptance of SIB assessments
- [ ] Having to exclude or discontinue people when they report SIB
- [ ] Translations of SIB rating instruments into relevant language
- [ ] SIB assessment instrument version control

23. Has your company conducted SIB assessments in children <12 years of age?

- ◯ Yes
- ◯ No

24. What instrument(s) does your company use for SIB assessments in children aged <12 years of age? [Select all that apply.]

- [ ] Columbia-Suicide Severity Rating Scale
- [ ] Pediatric version of the Columbia-Suicide Severity Rating Scale
- [ ] Sheehan Suicide Tracking Scale
- [ ] Pediatric Version of the Sheehan Suicide Tracking Scale
- [ ] Suicidality module of the Mini Kid
- [ ] Suicide Behaviors Questionnaire
- [ ] Suicidal ideation item of the Children's Depression Rating Scale-Revised

Other (please describe)

Survey of Sponsor Practices in Conducting Prospective Assessments of

25. Has your company conducted SIB assessment in adolescents 12-17 years of age?

- ◯ Yes
- ◯ No

26. What instrument(s) does your company use to perform SIB assessments in adolescents aged 12-17 years of age?

- ☐ Columbia-Suicide Severity Rating Scale
- ☐ Pediatric version of the Columbia-Suicide Severity Rating Scale
- ☐ IVR version of the C-SSRS (eC-SSRS)
- ☐ Sheehan Suicide Tracking Scale
- ☐ Pediatric Version of the Sheehan Suicide Tracking Scale
- ☐ Suicidality module of the Mini International Neuropsychiatric Interview (Adult version)
- ☐ Suicidality module of the Mini Kid DEL **Concise Health Risk Tracking – Clinician Rating**
- ☐ **Concise Health Risk Tracking – Self Rating**
- ☐ **InterSePT Scale for Suicide Thinking (ISST)**
- ☐ **InterSePT Scale for Suicide Thinking-Plus (ISST-Plus)**
- ☐ **Beck Scale for Suicide Ideation**
- ☐ **Suicide Behaviors Questionnaire**
- ☐ **Paykel Suicide Scale**
- ☐ **Suicide item of PHQ-9**
- ☐ **Suicide item of IDS/QIDS**
- ☐ **Suicide item of the HAM-D**
- ☐ **Suicide item of the MADRS**
- ☐ **Suicidal ideation item of the CDRS**

Other (please describe)

Survey of Sponsor Practices in Conducting Prospective Assessments of

27. Has your company conducted studies in which SIB assessments were performed in patients with cognitive impairment (ie, patients with autism, mental retardation, Mild Cognitive Impairment or dementia)?

- ◯ Yes
- ◯ No

28. What instrument(s) does your company use to perform SIB assessments in patients with cognitive impairment? [Select all that apply.]

- ☐ Columbia-Suicide Severity Rating Scale
- ☐ Pediatric version of the Columbia-Suicide Severity Rating Scale
- ☐ IVR version of the C-SSRS (eC-SSRS)
- ☐ Sheehan Suicide Tracking Scale
- ☐ Pediatric Version of the Sheehan Suicide Tracking Scale
- ☐ Suicidality module of the Mini International Neuropsychiatric Interview (Adult version)
- ☐ Suicidality module of the Mini Kid DEL Concise Health Risk Tracking – Clinician Rating
- ☐ Concise Health Risk Tracking – Self Rating
- ☐ InterSePT Scale for Suicide Thinking (ISST)
- ☐ InterSePT Scale for Suicide Thinking-Plus (ISST-Plus)
- ☐ Beck Scale for Suicide Ideation
- ☐ Suicide Behaviors Questionnaire
- ☐ Paykel Suicide Scale
- ☐ Suicide item of PHQ-9
- ☐ Suicide item of IDS/QIDS
- ☐ Suicide item of the HAM-D
- ☐ Suicide item of the MADRS
- ☐ Suicidal ideation item of the CDRS

Other (please describe)

Survey of Sponsor Practices in Conducting Prospective Assessments of

29. Aside from interviews of the patient, what other sources of data are used in assessing the suicidal risk of patients in clinical trials conducted by your company? [Select all that apply.]

- [ ] Medical/psychiatric/coroner records
- [ ] Information provided by the referring physician or medical provider
- [ ] Information from family (partner/spouse, parent, other relative)
- [ ] Information from assisted living or nursing home staff
- [ ] Other informants (such as friend or neighbor)
- [ ] None

Other (please specify)

30. Please add any additional comments you have on the issue of assessing suicidal ideation and behavior in clinical trials (250 characters or less):

Thank you for taking the time to complete the survey.