Sheehan-Suicidality Tracking Scale (S-STS)

General Directions & Scoring Instructions for the standard and CMCM versions

- Use data from all sources.
- The S-STS can be a) patient rated and/or b) clinician administered and then c) any differences reconciled (reconciliation version), if they are blindly done to each other (patient rating first).
- Consider severity, frequency and time frame in your responses.
- Different timeframes may be used with this scale (e.g. “in the past week”, “in the past month”, “since the last visit", or “ever”). See the discussion of timeframes on page 4 below.

All clinicians using this scale in clinical trials should receive instruction using approved training materials for S-STS. This is to ensure consistency in the understanding and application of definitions for each scale item and each C-CASA item coded.

At Screening (for past 13-month timeframe), exclude anyone with a score of:
(A 13-month timeframe used to capture anniversary reactions.)

- 3 or 4 on Question 2 or 13.

- 2 or higher on any Question 1a (only if 1b is coded YES), 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 14.

During the study call the medical monitor:

- if the score is 3 or 4 on Question 2 or 13.
- if the score is 2 or higher on any Question 1a (only if 1b is coded YES), 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 20 or if suicide results in death (question 17 is Yes).
- on items of concern in your clinical judgment, clarify and ask for examples from patient.

During any study exclude anyone:

- if the score is 3 or 4 on Question 2, 3, 4, 5, 6, 7, 8 or 13.

- if the score is 2 or higher on any Question 1a (only if 1b is coded YES), 9, 10, 11, 12, (on the highest score of 14 or 15), 20 or if suicide results in death (Question 17 is Yes).

- more conservative thresholds should be set by the study sponsor or the FDA if they judge this necessary in the interest of safety. The above levels are set at a high threshold and reflect a significant level of concern about the wisdom of continuing such a subject in a research study.

Suicidality studies:
In studies designed for the study of suicide, the above recommendations need to be altered to meet the needs of the protocol under investigation.

Tracking Log:
In tracking suicidality over time, use the 2 "Tracking Logs". The first log tracks item scores and the 2nd log tracks total and factor scores. This permits quick comparisons and visual tracking over time.

Scoring S-STS

12 scores are derived from the S-STS in addition to individual item scores:

1) Total S-STS Score

Sum the scores (0-4) for each of the following:
Questions 1a (only if 1b is coded YES), 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, (highest of 12 or any row of 16), (highest of 14 or any row of 15), 17 and 20.

2) Suicidal Ideation/Intent Factor Score

Sum the scores (0-4) for each of the following:
Questions 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11.

3) Suicidal Planning Factor Score

Sum the scores (0-4) for each of the following:
Questions 5, 6, 7, 8 and 11.

4) Suicidal Behavior Factor Score

Sum the scores (0-4) for each of the following:
Questions 1a (only if 1b is coded YES), (highest of 12 or any row of 16), (highest of 14 or any row of 15),
17 and 20. Note question 13 is not a suicidal behavior.

5) Non-Suicidal Self Injury Score

From Question 13.

6) Total Number of Suicidal Ideation Events

From Questions 2 plus 3.

7) Total Number of Events of Preparatory Acts Toward Suicidal Behaviors (the preparatory acts not immediately connected with a suicide attempt)

From Question 16.

8) Total Number of Suicide Attempt Events

From Question 15.

9) Total Number of Non-Suicidal Self Injury Events

From Question 13.

10) Usual Time Spent Per Day with Suicidal Impulses, Ideations, or Behaviors

From bottom of page 2.

11) Least Amount of Time Spent Per Day with Suicidal Impulses, Ideations, or Behaviors
From bottom of page 2.

12) Most Amount of Time Spent Per Day with Suicidal Impulses, Ideations, or Behaviors
From bottom of page 2.

Additional Scores from the S-STS Clinically Meaningful Change Measure (CMCM) version

Total Risk / Protective Factor Score =
Add up all the scores on pages 4 and 5 by applying the following scoring system:
Does Not Apply = 0
Lessens Suicidality A lot = 1
Lessens Suicidality Moderately = 2
Lessens Suicidality A little = 3
No Impact on Suicidality = 4
Increases Suicidality A little = 5
Increases Suicidality Moderately = 6
Increases Suicidality A lot = 7

On the Adolescent S-STS CMCM the corresponding scores range from 0 through 4

The clinician should not rely exclusively on the numeric value of the total score in assessing this total score, without assessing the relative importance of the trade-offs between the risk and protective factors in each individual.

Total Risk Factor Score = Add up all the "Increasing Suicidality" scores

Total Protective Factor Score = Add up all the "Lessens Suicidality" scores and multiply by 2.

Total Clinically Meaningful Impairment Score

Add up all the 15 individual domain score on pages 6 through 9 (do not include in the calculation the days lost or days underproductive on page 8). The maximum score here is 150.

Functional Impairment from Suicidality Scores (from page 8)
Work Impairment
Social Life / Leisure Activities Impairment
Family Life / Home Responsibilities Impairment
Total Functional Impairment = Total of the above 3 scores

Patient Rated Unpredictability of Suicidality Score & Checkbox (from page 9)

Patient Rated Likelihood of a Suicide Attempt Score (from page 10)

Patient Rated Treatment Needed Score (from page 10)

Clinician Rated Global Severity of Suicidal Impulses, Thoughts, and Behaviors (score from page 11)

Clinician Judgment of Suicide Risk *at This Time* and Level of Management Needed for Suicidality (score from page 12)

Clinician Judgment of Patient's Likelihood of Making a Suicide Attempt or of Dying by Suicide *in the Next 7 Days* (score from page 12)

There are no numeric scores assigned for responses to questions 1 or 1b in the calculation of the S-STS Total Score, the Suicidal Ideation score or the Suicidal Behavior score.

Cross-walking the S-STS and the S-STS CMCM with other classification systems / definitions.

If information from the S-STS needs to be coded as an adverse event in a research study, classify the adverse event by the C-CASA or FDA-CASA 2012 category number and C-CASA or FDA-CASA 2012 category name when naming the adverse event (see S-STS to C-CASA and FDA-CASA 2012 mapping Tables). *Mapping tables* are available for the S-STS to both the 2010 (C-CASA and 2012 FDA-CASA Draft Guidance Documents.

Interrupted attempts and aborted attempts are NOT classified as suicide attempts, but should be scored under suicide preparatory behaviors (Question 12) and classified accordingly in the "Level" column of Question 16.

S-STS accommodates the same *definitions* for suicide assessment as outlined in:

1. Guidance for Industry Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials. August 2012. Revision 1. U.S Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Silver Spring, MD 20992-0002. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/ Direct download from www.fda.gov/downloads/Drugs/Guidances/UCM225130.pdf
   The S-STS to FDA-CASA 2012 categories mapping table is available at: http://harmresearch.org/index.php/product/sheehan-suicidality-tracking-scale-s-sts-fda-2012-mapping-tables/
   The S-STS to FDA-CASA 2012 categories mapping table scoring form is available at: http://harmresearch.org/index.php/product/sheehan-suicidality-tracking-scale-s-sts-fda-2012-scoring-forms/
2. Food and Drug Administration, U.S. Department of Health and Human Services. *Suicidality: Prospective Assessment of Occurrence in Clinical Trials, Draft Guidance,* issued in September 2010.
   The S-STS to FDA-CASA 2010 categories *mapping table* is available at: http://harmresearch.org/index.php/product/sheehan-suicidality-tracking-scale-s-sts-fda-2010-mapping-tables/
   The S-STS to FDA-CASA 2010 categories *mapping table scoring form* is available at: http://harmresearch.org/index.php/product/sheehan-suicidality-tracking-scale-s-sts-fda-2010-scoring-form/
3. Posner K, Oquendo MA et al. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric

Suicidal Risk Analysis of Antidepressants. C-CASA Definitions in Table 2, page 1037. Am J Psychiatry 2007; 164:1035-1043.
The *mapping table* for the S-STS to C-CASA 2010 categories, as defined in the FDA Draft Guidance document for Suicidality Assessment, is available at: http://harmresearch.org/index.php/product/sheehan-suicidality-tracking-scale-s-sts-fda-2010-mapping-tables/
The *mapping table scoring form* for the S-STS to C-CASA 2010 categories, as defined in the FDA Draft Guidance Document for Suicidality Assessment is available at: http://harmresearch.org/index.php/product/sheehan-suicidality-tracking-scale-s-sts-fda-2010-scoring-form/

4. Sheehan & Giddens definitions of suicidality phenomena in: Sheehan DV, Giddens JM. (2016). *Suicidality Assessment and Documentation for Healthcare Providers: A Brief, Practical Guide.* (1st ed.). Tampa, FL: Harm Research Press. April 2016. (Available from: http://HarmResearch.org)
The *mapping table* / *scoring form* for the S-STS to the Sheehan & Giddens suicidality phenomena definitions, is available at: http://harmresearch.org/index.php/product/sheehan-suicidality-tracking-scale-s-sts-sheehan-giddens-definitions-mapping-tables-scoring-forms/

In *research studies*, I recommend using all 3 pages of S-STS to be in compliance with FDA expectations outlined in the following 3 documents:

- The FDA Guidance Document on Suicidality Assessment. (Guidance for Industry. Suicidality: Prospective Assessment of Occurrence in Clinical Trials. Draft Guidance. September 2010. U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research [CDER]).
- The FDA Guidance for Industry Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials Draft Guidance August 2012 Revision 1 [10302 dft.doc 08/06/12].
- The definitions for the 5 levels of suicidal behavior adopted by the Centers for Disease Control and Prevention [Crosby, Ortega, et al 2011].

In *treatment outcome studies* where the S-STS CMCM version is used as an efficacy measure, the items on page 4 through 10 of S-STS CMCM should also be included.

In *clinical settings* not involved in research, where the goal is to assess and monitor suicidality in a simple, thorough, yet efficient manner, use Page 1 in addition to asking about time spent (bottom of page 2) at the very least.

Print Page 1 of the S-STS and pages 1, 4 and 5 of the S-STS CMCM version in color.

Timeframe Choices for S-STS and for the S-STS CMCM versions

The following look-back timeframes may be used with the S-STS depending on the clinical or research needs or questions of interest:

1. Over the past (timeframe)
    - In your lifetime ("Ever")
    - In the past year
    - In the past 13 months (to accommodate anniversary reactions)
    - In the past 3 months (12 weeks)
    - In the past month
    - In the past week or in the past 7 days
    - Since your last visit
    - Since your last evaluation
2. During the most recent suicidal event (for use during or immediately after a crisis or in an emergency room)
    - "Concerning your most recent attempt or suicidal event:"
3. Look-forward timeframe assessments (e.g. 1- 3 months) may be valuable in future planning. These highlight the suicidal phenomena or risk / protective factors the patient expects to experience. Clinicians can then formulate a plan with the patient to cope with these expected issues. For example, the timeframe question prefacing questions on page 1 could read: "Over the next (timeframe), how serious do you expect the following to be:". Anyone wishing this forward-looking version of the S-STS or the S-STS CMCM should contact the author for these versions.

Because of problems of recall, the optimal time frames to balance reliability and clinical value in making clinical decisions for suicidal impulses, ideation, preparatory behaviors and attempts are as follows:

- Each study should adopt a consistent timeframe throughout the study if the scale is to be used as an outcome measure. The next 3 bullet points below may serve as a guide to the user in choosing the appropriate time frame to use based on the focus and needs of each study or each clinical setting.
- Ideation, impulses, command hallucinations or dreams – "in the past month" or "in the past week" or "during your most recent or current suicidal event",
- Preparatory behaviors – "In the past 13 months" – to accommodate anniversary reactions
- Attempts – "In your lifetime".
- For Screening Visit assessments in research studies a variant of the S-STS using all 3 of the above as indicated within the same S-STS may provide the most accurate data.

- The “In the past 7 days” timeframe yields the most reliable and accurate data.
- Be careful using the “Since your last visit” version in research studies if the interval between all the visits is not constant. If the S-STS is used as a safety data capture system only, then “since the last visit” is the most appropriate
- On the “Likelihood of a suicide attempt” domain in the S-STS CMCM version, use the same timeframe in looking forward as used in the look-back for the other domain assessments. This will vary by study or by clinical setting, based on the goals. There may be circumstances when these 2 timeframes may need to be different.

Optimal Timeframe choices in treatment outcome studies

The optimal choices for timeframes in treatment outcome studies are the following:

At **screening** visit: a lifetime look-back – “Over the course of your lifetime:”.

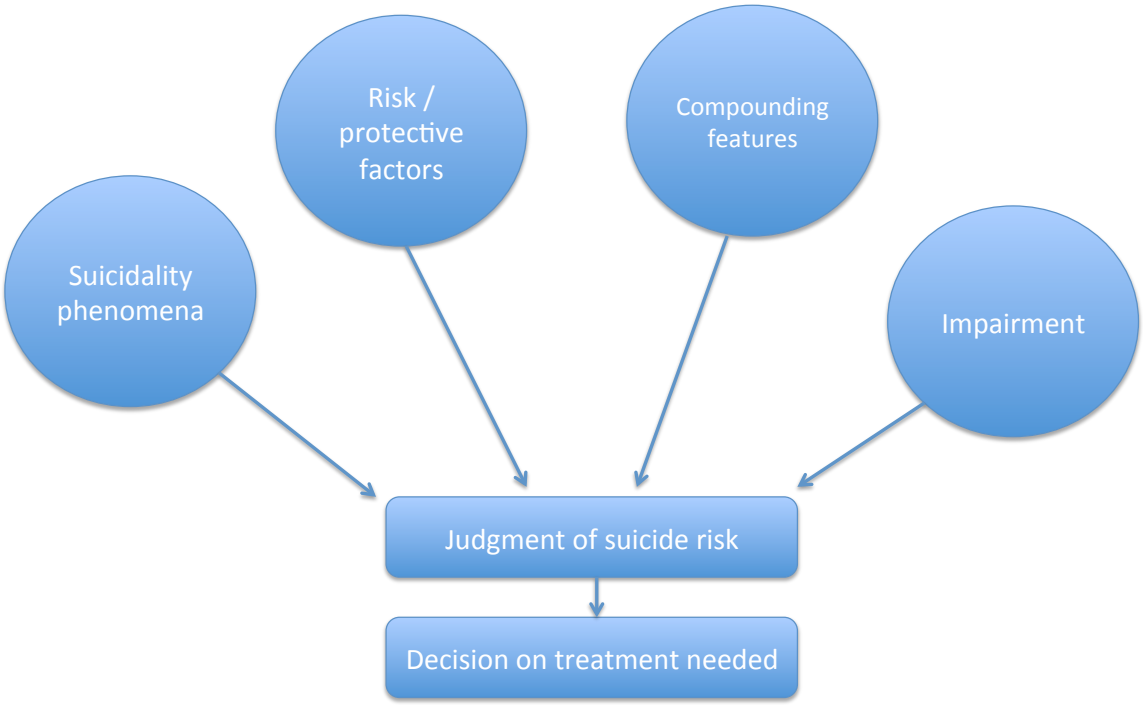
At **baseline** visit: a look-back timeframe that equals the full length of the acute phase of the clinical study (e.g. 8, 10 or 12 weeks) AND in addition a look-back timeframe of to correspond to the interval between visits and suicidality assessments during the clinical study (e.g. 1 week). A treatment emergent suicidal phenomenon will be defined as “treatment emergent” during the study only if it exceeds the seriousness score for that item at the baseline assessment timeframe that is equivalent to the duration of the acute phase of the study. In some studies, (e.g. on Seasonal Affective Disorder) variants on this recommendation may be appropriate.

Sheehan-Suicidality Tracking Scale (S-STS CMCM)

(**C**linically **M**eaningful **C**hange **V**ersion)

The logic and structure behind the S-STS CMCM version mirrors the suicide assessment protocol used by psychiatrists for decades. It is captured in the Figure below.

Judging risk and treatment needed in clinical practice



The **S-STS CMCM version** assesses the following domains:

1. Suicidality **phenomena**
    - passive suicidal ideation (5)
    - active suicidal ideation
    - impulsive suicidality
    - suicidal hallucinations
    - suicidal delusions
    - suicidal dreams
    - suicide plan - method (how)
    - suicide plan - means (with what)
    - suicide plan - date (when)

- suicide plan - place (where)
- suicide plan - thinking about any task you want to complete before killing yourself
- intent to act in any suicidal way,
- intent to die by suicide
- preparatory suicidal behaviors (aborted = halted by self)
- preparatory suicidal behaviors (interrupted = halted by another person or event)
- preparatory suicidal behaviors (neither aborted nor interrupted)
- suicide attempts (halted by self)
- suicide attempts (halted by another person or event)
- suicide attempts (completed as intended)
- accidents involving any suicidal accident
- death from suicide

Other phenomena needing assessment to enhance accuracy of suicidality data collection

- non-suicidal self harm behaviors
- death from other causes

2. Suicide **risk / protective factors**

3. **Compounding** features
   - hopelessness
   - ability & willingness to cope and to stay safe from suicidality
   - quality of life related to suicidality & overall quality of life
   - deliberate suicidality
   - desire to recover from suicidality
   - unpredictability of suicidality
   - likelihood of a suicide attempt (patient's judgment)
   - global severity of suicidality (clinician's and patient's judgment)

4. **Functional impairment** from suicidality
   - Work / school
   - Social life / leisure activities / personal relationships
   - Family life / home responsibilities

5. **Clinician judgment of suicide risk** and **need for treatment**
   - patient's judgment of needed disposition / treatment
   - clinician's judgment of suicide risk *at this time* with clinician's judgment of management needed for suicidality *at this time*

- clinician's judgment of patient's suicide risk *in the next 7 days*

At the end of the assessment, it is useful to ask the patient if there is **anything else** they didn't share about their suicidality, that they are now willing to share.

The S-STS (in contrast to the S-STS CMCM version) assesses all the suicidal phenomena in item 1 above only.

Judging Clinically Meaningful Change Using the S-STS CMCM as a Treatment Outcome Measure in Research Studies

On the "Clinically Meaningful Change Anchors for Suicide Outcomes Assessment" on Page 12 of the CMCM version, a clinically meaningful change for each investigational treatment group in a sample, should meet or exceed all of the following thresholds:

- a score of 3.0 or less in >33% of patients and
- a mean reduction for the entire sample by >2.0 points and
- a statistically significant difference between the drug and the placebo at endpoint.

For an individual patient, a clinically meaningful change is deemed to be:

- a score of 3 or less and
- a reduction by >2 points

Scoring S-STS CMCM

Additional Scores to extract from the S-STS CMCM version

In addition to the scoring instructions listed above for the standard version of S-STS the following additional scores may be extracted from the S-STS CMCM version:

1. Clinician's judgment of suicide risk *at this time* with clinician's judgment of management needed for suicidality at this time (score from page 12)
2. Clinician's judgment of patient's suicide risk *in the next 7 days* (score from page 12)
3. Clinician's judgment of patient's future suicide risk *in their lifetime* (score from page 12)
4. Patient rated likelihood of a suicide attempt (page 10)
5. Patient's judgment of needed disposition / treatment (score from page 10)
6. Risk/protective factors for suicide score (score from pages 4 + 5). Add all the scores from pages 4 & 5 as follows: does not apply = 0; lessens a lot = 1; lessens moderately = 2; lessens a little = 3; no impact = 4; increases a little = 5; increases moderately = 6; increases a lot = 7. These scores can change from visit to visit even on the factor item. A risk factor at one point or for one patient may be a protective factor at another point or for another patient and vice versa. Some studies may wish to further subdivide and analyze these factors into their 4 subcategories + a total risk / protective factor score (suicidality phenomena factors; family / social factors; personal history factors; health factors).
   On the Adolescent S-STS CMCM the corresponding scores range from 0 through 4 rather than from 0 through 7
7. Functional impairment and quality of life impairment from suicidality
   a. Work impairment (score from page 8)
   b. Social life & personal relationships & leisure activities impairment (score from page 8)
   c. Family life & home responsibilities impairment (score from page 8)
   d. Total impairment (sum of scores of 5a + 5b + 5c above)
   e. Quality of life impairment related to suicidality (score from page 9)
8. Days lost from work / school due to suicidality (score from page 8)
9. Days underproductive at work / school due to suicidality (score from page 8)
10. Hopelessness (score from page 6)
11. Ability & willingness to cope and to stay safe (4 scores from pages 6 & 7)
12. Deliberate suicidality (from page 7)
13. Impulsive suicidality ("impulse to act in any suicidal way" from page 7)
14. Desire to recover from suicidality (page 9)
15. Overall quality of life (page 7) and quality of life disruption (scores from page 9)

16. Global severity of suicidal impulses, thoughts and behavior (score from page 9)
17. Unpredictability of suicidality (page 9).

If an anti-suicidal treatment impacts all or a meaningful number of the above domains to a meaningful degree (especially reflected on the "Clinician's judgment of suicide risk score" on page 12 and the "Patient Rated Treatment Needed Score on page 10 of the S-STS CMCM version, then it may reasonably be assumed that it is having a clinically meaningful effect above and beyond a statistically significant effect on suicidality scale scores.