

# Suicide Ideation and Behavior Assessment Tool (SIBAT): A Novel Measure of Suicidal Ideation and Behavior and Perceived Suicide Risk

Larry Alphas,<sup>1</sup> Carla Canuso,<sup>2</sup> David Williamson,<sup>1</sup> and the SIBAT Consortium

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## INTRODUCTION

- Accurately assessing risk of suicide in patients with suicidal ideation and behavior (SIB) is essential for clinicians who must make critical management decisions regarding appropriate interventions based on their judgment of this risk
- Current tools and assessment instruments for SIB, such as the International Suicide Prevention Trial (InterSePT) Scale for Suicidal Thinking (ISST), the Clinical Global Impression of Severity of Suicidality (CGI-SS) scale, the ISST-Plus, and the Columbia-Suicide Severity Rating Scale (C-SSRS), have several limitations<sup>1-3</sup>:
  - They fail to provide a specific clinician-based suicide assessment of suicide risk and management
  - They omit some risk factors that are important for clinician-based suicide risk assessment
  - They conflate measures of suicide risk that are likely to change (ie, current suicidal ideation) with those that are not (ie, past suicidal behavior)
  - They are unable to reliably capture changes in SIB over short intervals (eg, within hours)
- The SIBAT is a new instrument being developed to address these unmet needs and to support the clinical development program of a therapy for the treatment of symptoms of major depressive disorder, including suicidal ideation, in patients who are assessed to be at imminent risk for suicide

## GOALS OF THE SIBAT

- Include both patient- and clinician-reported information relevant to suicide risk assessment
- Separate the measurement of constructs prone to rapid change (eg, suicidal ideation) from those that are not (eg, history of suicidal behavior)
  - SIBAT permits quantification of dynamic constructs
  - SIBAT decreases patient burden because assessment of stable constructs is not needlessly repeated
- Capture the clinician's assessment of imminent and long-term suicide risk and his or her plan for management of the patient under real-world treatment conditions
- Meet regulatory standards for use in clinical trials and be useful for both efficacy and safety assessments
- Incorporate patient feedback early in the instrument development process

## SIBAT STRUCTURE

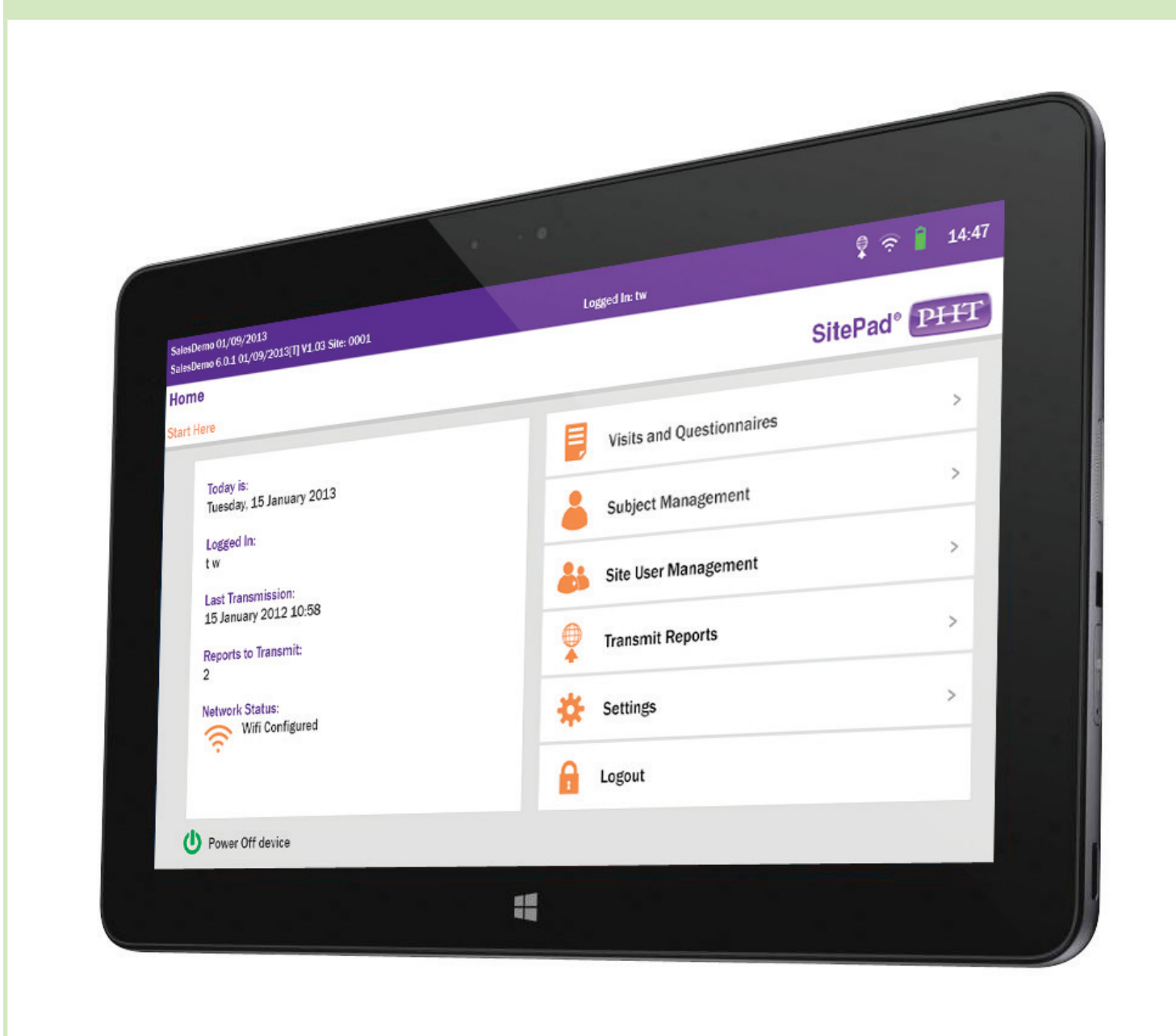
- SIBAT includes 10 modules that capture information on demographics, known suicide risk factors, history of suicidal behavior, and severity of suicide ideation
  - Modules are organized into separate units according to category and susceptibility to change
  - The modular format allows different question sets to be administered independently with different frequencies
  - Compared to most scales, the SIBAT assesses a broader range of severity for each item, allowing it to be more sensitive to change
  - Items and wording of items were reviewed by patients with histories of suicide
  - During revisions of the provisional versions of the SIBAT scale, modules were added and item wordings refined
  - Each of these modules is scored from 0 (no risk) to 6 (extreme risk)
- Patient-reported modules are completed as assigned (Modules 1–5) for a given rating session

- Module 6 is a brief computer-based task for which patients categorize stimuli (words and images) into one of two groups using two different keys on a standard keyboard
- Clinician-reported modules: the clinician reviews Modules 1–5
  - Following the review, the clinician conducts a brief, semistructured interview of the patient (Module 7)
  - The clinician's review and interview provide the basis for completing the Clinical Global Judgment of Imminent Suicide Risk (CGJSR-I) and the Clinical Global Judgment of Long-Term Suicide Risk (CGJSR-LT) (Modules 8 and 9) and for making decisions about optimal clinical management (Module 10)
  - Changes in suicidal ideation, behavior, and static and dynamic risk factors captured in Modules 1–5 and Module 7 will inform on clinically meaningful changes in the CGJSR-I and the CGJSR-LT

## ADMINISTRATION AND SCORING

- To facilitate efficient, secure data collection, we will collect data electronically. Our initial implementation will use an electronic device called SitePad® (PHT Corp., Boston, MA) (Figure 1)
  - Module 1 will be performed only at the baseline visit
  - Modules 2, 4, 6, and 9 will be performed as specified in study protocols to meet study-specific requirements
  - Modules 3, 5, 7, 8, and 10 are to be performed at each study visit
- Individual scores are obtained from patient self-reporting (Modules 1–6) and from a semistructured interview by an experienced, well-trained clinician (Module 7)
  - The median total time for a patient to complete all of the patient-associated modules is 23.65 minutes
  - The median time to complete the patient-reported modules that are recommended to be repeated on each occasion (Modules 3 and 5) is less than 5 minutes
- Scoring of Modules 8 and 9 is based on the judgment of an experienced, well-trained clinician using his or her knowledge of suicide risk factors and information from the patient
  - Conservatively, a 1-point change in Module 8 or 9 will be considered clinically meaningful. Future empirical work will examine this assumption more closely
- Scoring of Module 10 will be performed by an experienced clinician

Figure 1. SitePad®.

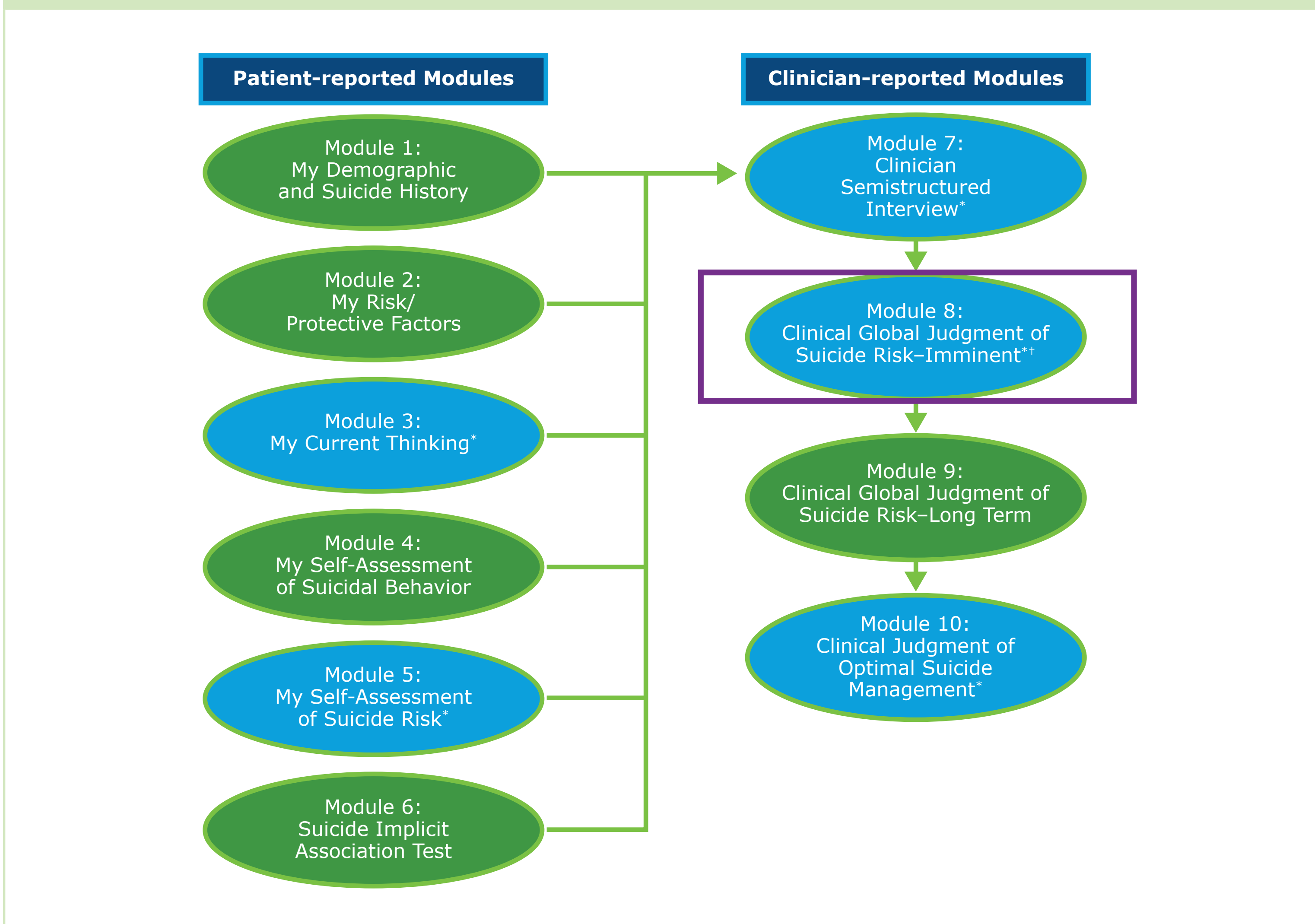


## SIBAT DEVELOPMENT

- The SIBAT Consortium (see Acknowledgments for a complete list of members), a group of clinical trial and academic experts in scale development, suicidality, and clinical management of suicidal patients, met regularly over 18 months and developed a modular instrument based on consensus, a review of the suicide literature, and the ISST-Plus
- The SIBAT Consortium agreed on a draft version of the SIBAT, which was reviewed by 14 patients from a psychiatric clinical research setting and by 686 members of Patients Like Me (<http://www.patientslikeme.com>), an online patient community. All patients had a history of suicidal ideation and/or behavior
- Throughout the development process, patients evaluated SIBAT items in patient-reported modules in terms of semantic clarity, relevance, and adequacy of response and provided their feedback
  - Patient feedback was incorporated and SIBAT revisions were approved by the SIBAT Consortium

## Overview

Figure 2. The 10 modules of the SIBAT are divided into two major sections: a patient-reported section (Modules 1–6) and a clinician-reported section (Modules 7–10).



\*Modules 3, 5, 7, 8, and 10 are repeated at every assessment.  
†Module 8 will be qualified as a regulatory end point.

## VALIDATION

- Types of validation performed for the SIBAT and the corresponding validation studies are shown in Table 1
- A validation trial is planned to examine reliability, factor structure, and item-response characteristics

Table 1. Measurement Properties Considered in the Review of Patient-Reported Outcome Instruments Used in Clinical Trials

Measurement Property	Corresponding Validation Study
Intra-rater reliability	Psychometric validation study (SIBAT-03)
Internal consistency	Psychometric validation study (SIBAT-03)
Inter-rater reliability	Psychometric validation study (SIBAT-03)
Cross-diagnostic appropriateness	Online cognitive interviews (SIBAT-02)
Comprehensibility	• Face-to-face cognitive interviews in adult patients (SIBAT-01) • Translatability review • Online cognitive interviews (SIBAT-02) • Geriatric and adolescent expert reviews • Reading-level assessment
Patient-perceived relevance	• Face-to-face cognitive interviews in adult patients (SIBAT-01) • Online cognitive interviews (SIBAT-02)
Cultural appropriateness (language/religion/ethnicity); cross-cultural validity (language/religion/ethnicity)	• Online cognitive interviews (SIBAT-02) • Translatability review
Comprehensiveness; choice of vocabulary	• Online cognitive interviews (SIBAT-02) • Translatability review • Geriatric and adolescent expert reviews
Age-appropriate contextual validity	Geriatric and adolescent expert reviews
Content validity	• Initial development by SIBAT Consortium • Face-to-face cognitive interviews in adults (SIBAT-01) • Face-to-face cognitive interviews, adolescent cohort • Online cognitive interviews
Construct validity	Psychometric validation study (SIBAT-03)
Convergent validity	Psychometric validation study (SIBAT-03)
Clinical meaningfulness	Final review by SIBAT Consortium
Discriminant validity	Psychometric validation study (SIBAT-03)
Sensitivity to change	Clinical study (ESKETINSUI2001)

## DEVELOPMENTAL MILESTONES

- Major steps in the ongoing development of the SIBAT are summarized by study in Table 2

Table 2. Overview of the Development and Validation of the SIBAT by Study

Study Description	Population Studied	Types of Validation	Status
ISST-Plus*	N/A	N/A	N/A
Modification of ISST-Plus by the SIBAT Consortium	N/A	N/A	Version β-1
Face-to-face cognitive interviews (SIBAT-01)	Adults with history of suicidal ideation (no specific diagnosis required); two consecutive phases (N = 7 each)	• Patient-perceived relevance • Comprehensibility	Completed: incorporated into versions β-2 and β-3
Online cognitive interviews (SIBAT-02)	Adult and elderly PLM members who have reported relevant mood/mental health conditions and a history of suicidal ideation in the past 12 months (N ≤ 686)	• Patient-perceived relevance • Comprehensibility • Comprehensiveness • Choice of vocabulary • Cultural appropriateness • Cross-cultural validity • Diagnostic condition	Completed: incorporated into version β-4
Translatability assessments	Review by experts in translation to multiple languages <sup>b</sup>	• Comprehensibility • Comprehensiveness • Choice of vocabulary • Cultural appropriateness • Cross-cultural validity	Completed: incorporated into version β-4
Geriatric and adolescent expert reviews	Review by different external experts in treating geriatric or adolescent patients with a history of suicidal ideation	• Comprehensibility • Comprehensiveness • Choice of vocabulary • Age-appropriate contextual validity	Completed: incorporated into version β-4
Reading-level assessments using the Flesch-Kincaid grade-level formula	Computerized review	Readability of the patient-reported modules (Modules 1–6)	Completed: incorporated into version β-4
Psychometric validation study (SIBAT-03)	Cross-sectional study of subjects with various levels of suicidality (including those with accidental injury and no suicidal ideation) admitted to acute care settings (no specific diagnosis required) (N = 120) (10–20 adolescent patients and 10–20 patients aged >65 years)	• Inter-rater reliability • Construct validity • Exploratory factor analysis • IRT analysis • Mapping to the C-CASA • Clinical meaningfulness of CGJSR-I and CGJSR-LT (Modules 8 and 9)	Planned completion date: 2016
Phase 2 study (ESKETINSUI2001)	Patients with MDD and assessed to be at imminent risk for suicide (N = 70)	Sensitivity to change and clinical meaningfulness of CGJSR (β-2 Module 8) <sup>c</sup> for MDD patients	Planned completion date: 2016
Final review by SIBAT Consortium	N/A	Clinician validation	Planned completion date: 2016 <sup>d</sup>

C-CASA, Columbia Classification Algorithm of Suicide Assessment; IRT, item-response theory; MDD, major depressive disorder; N/A, not applicable; PLM, Patients Like Me; SIBAT, Suicide Ideation and Behavior Assessment Tool.  
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<sup>b</sup>Languages included Mandarin, Japanese, Ukrainian, French, German, Spanish, and Swedish.  
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<sup>d</sup>Interim review is to be conducted upon completion of the SIBAT-03 Study (December 2015); final review is to be conducted upon completion of the phase 2 study.

## DISCUSSION

- The proposed validation plan supports the use of the SIBAT as an efficacy and safety instrument to measure patient- and clinician-based assessment of imminent suicide risk in adolescents and adults
- Once the SIBAT has been validated, it is expected that change from baseline in suicide risk from the CGJSR-I (ie, Module 8) will be an appropriate key outcome for demonstrating a change in clinician-assessed imminent suicide risk (including changes within hours) in patients with major depressive disorder at risk for suicide
- We anticipate that the SIBAT will be a valuable tool for assessing change—particularly rapid change—in suicide risk in patients at risk for suicide

## REFERENCES

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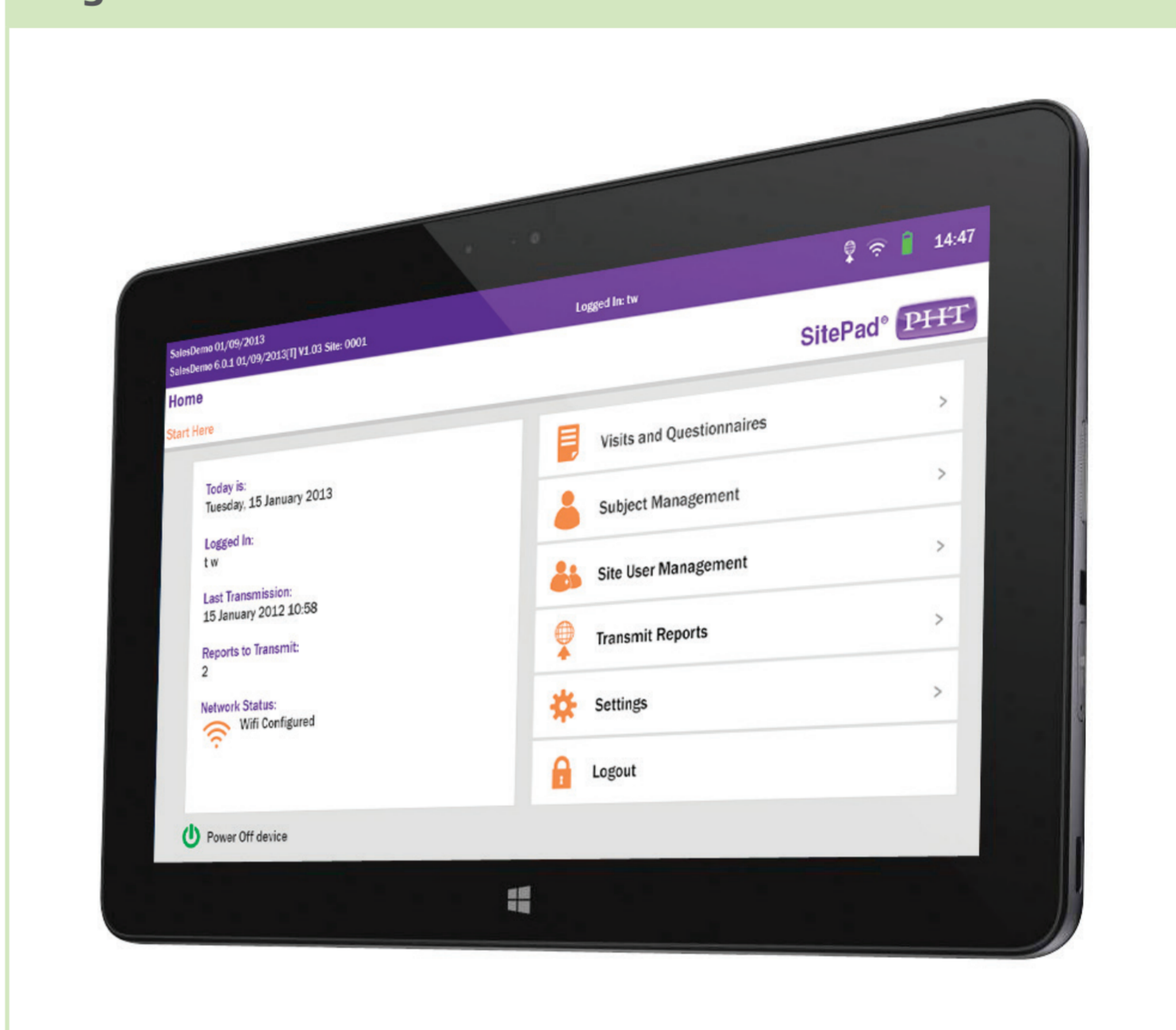
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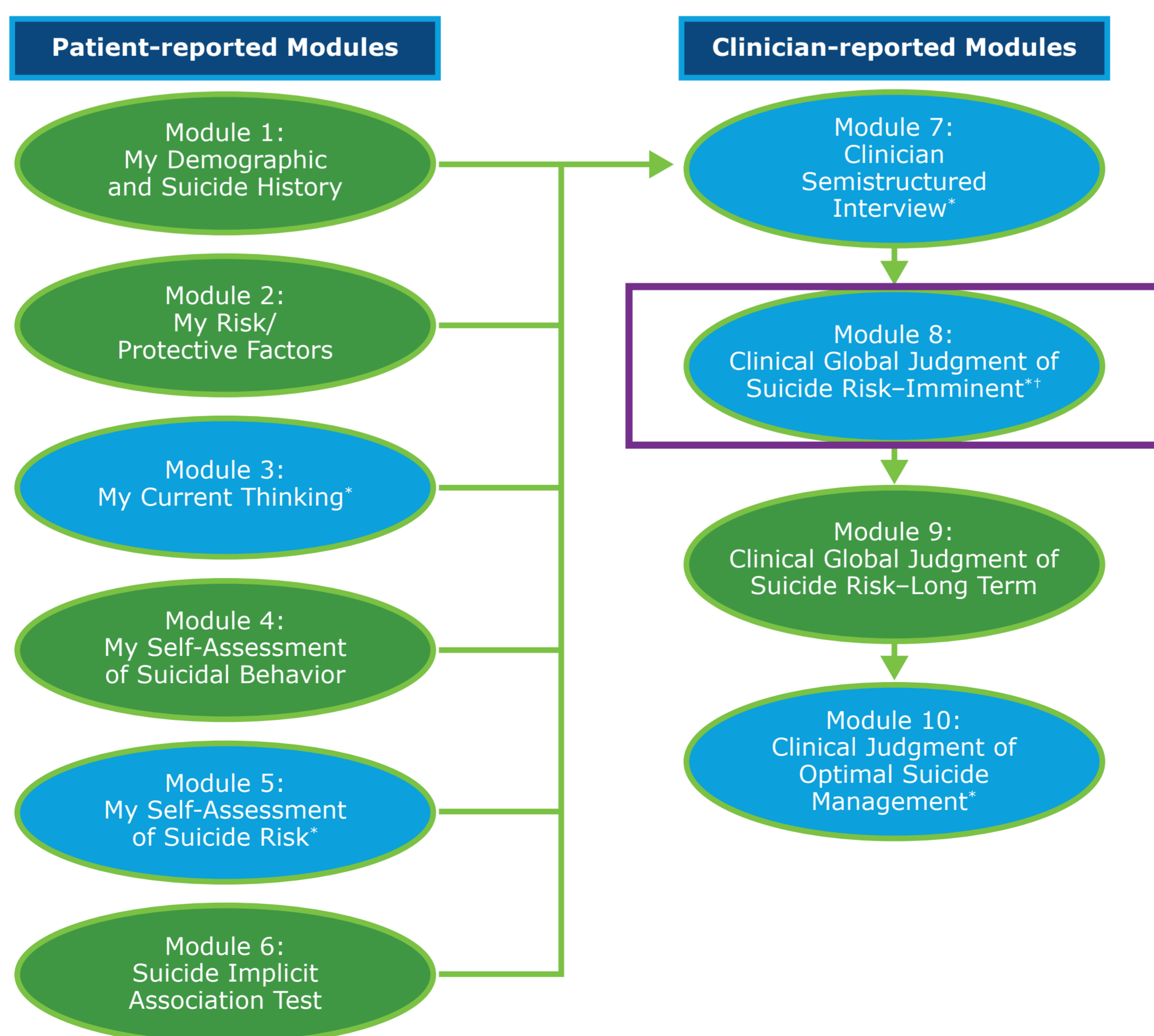


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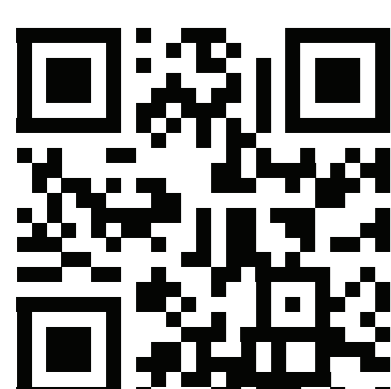
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# VALIDATION

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Internal consistency	Psychometric validation study (SIBAT-03)
Inter-rater reliability	Psychometric validation study (SIBAT-03)
Cross-diagnostic appropriateness	Online cognitive interviews (SIBAT-02)
Comprehensibility	<ul style="list-style-type: none"> <li>Face-to-face cognitive interviews in adult patients (SIBAT-01)</li> <li>Translatability review</li> <li>Online cognitive interviews (SIBAT-02)</li> <li>Geriatric and adolescent expert reviews</li> <li>Reading-level assessment</li> </ul>
Patient-perceived relevance	<ul style="list-style-type: none"> <li>Face-to-face cognitive interviews in adult patients (SIBAT-01)</li> <li>Online cognitive interviews (SIBAT-02)</li> </ul>
Cultural appropriateness (language/religion/ethnicity); cross-cultural validity (language/religion/ethnicity)	<ul style="list-style-type: none"> <li>Online cognitive interviews (SIBAT-02)</li> <li>Translatability review</li> </ul>
Comprehensiveness; choice of vocabulary	<ul style="list-style-type: none"> <li>Online cognitive interviews (SIBAT-02)</li> <li>Translatability review</li> <li>Geriatric and adolescent expert reviews</li> </ul>
Age-appropriate contextual validity	Geriatric and adolescent expert reviews
Content validity	<ul style="list-style-type: none"> <li>Initial development by SIBAT Consortium</li> <li>Face-to-face cognitive interviews in adults (SIBAT-01)</li> <li>Face-to-face cognitive interviews, adolescent cohort</li> <li>Online cognitive interviews</li> </ul>
Construct validity	Psychometric validation study (SIBAT-03)
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Clinical meaningfulness	Final review by SIBAT Consortium
Discriminant validity	Psychometric validation study (SIBAT-03)
Sensitivity to change	Clinical study (ESKETINSUI2001)

# DEVELOPMENTAL MILESTONES

- Major steps in the ongoing development of the SIBAT are summarized by study in **Table 2**

**Table 2. Overview of the Development and Validation of the SIBAT by Study**

Study Description	Population Studied	Types of Validation	Status
ISST-Plus <sup>a</sup>	N/A	N/A	N/A
Modification of ISST-Plus by the SIBAT Consortium	N/A	N/A	Version $\beta$ -1
Face-to-face cognitive interviews (SIBAT-01)	Adults with history of suicidal ideation (no specific diagnosis required); two consecutive phases (N = 7 each)	<ul style="list-style-type: none"> <li>Patient-perceived relevance</li> <li>Comprehensibility</li> </ul>	Completed: incorporated into versions $\beta$ -2 and $\beta$ -3
Online cognitive interviews (SIBAT-02)	Adult and elderly PLM members who have reported relevant mood/mental health conditions and a history of suicidal ideation in the past 12 months (N $\leq$ 686)	<ul style="list-style-type: none"> <li>Patient-perceived relevance</li> <li>Comprehensibility</li> <li>Comprehensiveness</li> <li>Choice of vocabulary</li> <li>Cultural appropriateness</li> <li>Cross-cultural validity</li> <li>Diagnostic condition</li> </ul>	Completed: incorporated into version $\beta$ -4
Translatability assessments	Review by experts in translation to multiple languages <sup>b</sup>	<ul style="list-style-type: none"> <li>Comprehensibility</li> <li>Comprehensiveness</li> <li>Choice of vocabulary</li> <li>Cultural appropriateness</li> <li>Cross-cultural validity</li> </ul>	Completed: incorporated into version $\beta$ -4
Geriatric and adolescent expert reviews	Review by different external experts in treating geriatric or adolescent patients with a history of suicidal ideation	<ul style="list-style-type: none"> <li>Comprehensibility</li> <li>Comprehensiveness</li> <li>Choice of vocabulary</li> <li>Age-appropriate contextual validity</li> </ul>	Completed: incorporated into version $\beta$ -4
Reading-level assessments using the Flesch-Kincaid grade-level formula	Computerized review	Readability of the patient-reported modules (Modules 1-6)	Completed: incorporated into version $\beta$ -4
Psychometric validation study (SIBAT-03)	Cross-sectional study of subjects with various levels of suicidality (including those with accidental injury and no suicidal ideation) admitted to acute care settings (no specific diagnosis required) (N = 120) (10–20 adolescent patients and 10–20 patients aged >65 years)	<ul style="list-style-type: none"> <li>Inter-rater reliability</li> <li>Construct validity</li> <li>Exploratory factor analysis</li> <li>IRT analysis</li> <li>Mapping to the C-CASA</li> <li>Clinical meaningfulness of CGJSR-I and CGJSR-LT (Modules 8 and 9)</li> </ul>	Planned completion date: 2016
Phase 2 study (ESKETINSUI2001)	Patients with MDD and assessed to be at imminent risk for suicide (N = 70)	Sensitivity to change and clinical meaningfulness of CGJSR ( $\beta$ -2 Module 8) <sup>c</sup> for MDD patients	Planned completion date: 2016
Final review by SIBAT Consortium	N/A	Clinician validation	Planned completion date: 2016 <sup>d</sup>

C-CASA, Columbia Classification Algorithm of Suicide Assessment; IRT, item-response theory; MDD, major depressive disorder; N/A, not applicable; PLM, Patients Like Me; SIBAT, Suicide Ideation and Behavior Assessment Tool.

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# DISCUSSION

- The proposed validation plan supports the use of the SIBAT as an efficacy and safety instrument to measure patient- and clinician-based assessment of imminent suicide risk in adolescents and adults
- Once the SIBAT has been validated, it is expected that change from baseline in suicide risk from the CGJSR-I (ie, Module 8) will be an appropriate key outcome for demonstrating a change in clinician-assessed imminent suicide risk (including changes within hours) in patients with major depressive disorder at risk for suicide
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