



Columbia-Suicide Severity Rating Scale Already Enrolled Subjects (C-SSRS ALREADY ENROLLED SUBJECTS)

Questionnaire Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials

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Notes to Readers

This implementation guide is intended to be used with other CDISC User Guides for specific Therapeutic/Disease Areas and follows the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical trials.

Revision History

Date	Version	Summary of Changes
2014-03-06	0.1	Columbia-Suicide Severity Rating Scale Already Enrolled Subjects (C-SSRS ALREADY ENROLLED SUBJECTS) Draft
2014-06-13	1.0	Columbia-Suicide Severity Rating Scale Already Enrolled Subjects (C-SSRS ALREADY ENROLLED SUBJECTS) Released

1 Introduction

This document describes the CDISC implementation of the Columbia-Suicide Severity Rating Scale Already Enrolled Subjects (C-SSRS ALREADY ENROLLED SUBJECTS) questionnaire, a standard questionnaire administered on a CRF that is typically used in clinical trials to identify subjects at risk for suicidal ideation and behavior.

The C-SSRS ALREADY ENROLLED SUBJECTS CRF preceded the CDISC CDASH CRF standards and based on its copyright status cannot be modified to CDASH standards.

The representation of data collected for this questionnaire is based on the Study Data Tabulation Model Implementation Guide (SDTMIG) QS domain table, which can be found at the CDISC website at: (<http://www.cdisc.org/sdtm>)

These specific implementation details for this specific questionnaire are meant to be used in conjunction with the SDTMIG. All questionnaire documentation can be found on the CDISC web site at: (<http://www.cdisc.org/content2909>)

The CDISC Intellectual Property Policy can be found on the CDISC web site at: (<http://www.cdisc.org/bylaws-and-policies>)

1.1 Representations and Warranties, Limitations of Liability, and Disclaimers

This document is a supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials and is covered under Appendix F of that document, which describes representations, warranties, limitations of liability, and disclaimers. Please see Appendix F of the SDTMIG for a complete version of this material.

2 Copyright Status

CDISC has obtained permission to include the Columbia-Suicide Severity Rating Scale Already Enrolled Subjects (C-SSRS ALREADY ENROLLED SUBJECTS) questionnaire as part of CDISC Data Standards. Hence, CDISC developed QSTESTCD and QSTEST for each question based on the actual question text on the questionnaire. There may be many versions of this questionnaire in the public domain or copyright questionnaire. CDISC has chosen to use this version as the data standard.

The CDISC documentation of this instrument consists of: (1) controlled terminology, (2) standard database structure with examples and (3) case report forms annotated with the CDISC SDTMIG submission values.

Note: CDISC controlled terminology is maintained by NCI EVS. The most recent version should be accessed through the CDISC website. (<http://www.cdisc.org/terminology>)

CDISC has developed this documentation at no cost to copyright holder or any additional cost to users of the instrument beyond the normal license fees charged by the copyright holder.

CDISC acknowledges Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Fisher, P.; Zelazny, J.; Burke, A.; Oquendo, M.; Mann, J.; copyright 2008 The Research Foundation for Mental Hygiene, Inc. for the agreement to include the Columbia-Suicide Severity Rating Scale (C-SSRS) Already Enrolled Subjects version 1/14/2009 in the CDISC data standards.

3 The QS Domain Model

3.1 Assumptions for Questionnaire Domain Model

All assumptions and business rules described in the SDTMIG QS domain are applicable to this supplement. Additional assumptions specific to the Columbia-Suicide Severity Rating Scale Already Enrolled Subjects questionnaire are listed below.

The Columbia-Suicide Severity Rating Scale Already Enrolled Subjects (C-SSRS ALREADY ENROLLED SUBJECTS) is a [suicidal ideation rating scale](#). It rates an individual's degree of suicidal ideation on a scale, ranging from "wish to be dead" to "active suicidal ideation with specific plan and intent."

1. The C-SSRS ALREADY ENROLLED SUBJECTS questionnaire is evaluated for two distinct time points, "Prior to Study Entry" and "Since Study Start". The values, "PRIOR TO STUDY ENTRY" and "SINCE STUDY START" are placed in the variable QSEVINTX, for the appropriate questions in the instrument.
2. The questionnaire evaluator is stored in QSEVAL. For C-SSRS ALREADY ENROLLED SUBJECTS, the evaluator is defined as the INVESTIGATOR. Additional identifying information to further distinguish the evaluator in QSEVAL is stored in QSEVALID. An example is the evaluator initials.
3. Terminology:
 - a. QSCAT, QSTESTCD and QSTEST are approved CDISC controlled terminology.
 - b. A full list of value sets for qualifier, timing, and result fields is provided in Section 4: SDTM Mapping Strategy.

3.2 Example for Columbia-Suicide Severity Rating Scale Already Enrolled Subjects (C-SSRS ALREADY ENROLLED SUBJECTS) QS Domain Model

The C-SSRS ALREADY ENROLLED SUBJECTS example below shows the terminology used to implement the questionnaire in the QS domain. This example shows the data for one subject collected at one visit for a C-SSRS ALREADY ENROLLED SUBJECTS questionnaire. The example uses CDISC controlled terminology for QSTESTCD, QSTEST, and QSCAT. All original results are represented with preferred terminology in QSORRES. This result is then transformed into a standard numeric score in QSSTRESN, where applicable, and a character representation of the standard numeric score in QSSTRESC. The “Prior to Study Entry” and “Since Study Start” evaluation intervals are represented in QSEVINTX.

Rows 1-62: Represent the questions from the C-SSRS ALREADY ENROLLED SUBJECTS Form.

Rows 12, 15, and 46 are included for illustrative purposes in order to display the QSTESTCD/QSTEST values for records that will not exist in the QS domain. QSORRES contains the value XXX. The actual missing record would not be created in the QS domain.

QS.XPT

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSSTRESC	QSSTRESN
1	STUDYX	QS	2324-P0001	1	CSS0501A	CSS05-Wish to be Dead-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	Yes	Y	
2	STUDYX	QS	2324-P0001	2	CSS0501B	CSS05-Wish to be Dead-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	Yes	Y	
3	STUDYX	QS	2324-P0001	3	CSS0501C	CSS05-Wish to be Dead, Describe	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	Wish dead	Wish dead	
4	STUDYX	QS	2324-P0001	4	CSS0502A	CSS05-Non-Spec Suicid Thought-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	Yes	Y	
5	STUDYX	QS	2324-P0001	5	CSS0502B	CSS05-Non-Spec Suicid Thought-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	No	N	
6	STUDYX	QS	2324-P0001	6	CSS0502C	CSS05-Non-Spec Suicid Thought, Describe	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	I have thought about killing myself	I have thought about killing myself	
7	STUDYX	QS	2324-P0001	7	CSS0503A	CSS05-Idea, No Intent, No Plan-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	Yes	Y	

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSSTRESC	QSSTRESN
8	STUDYX	QS	2324-P0001	8	CSS0503B	CSS05-Idea, No Intent, No Plan-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	No	No	
9	STUDYX	QS	2324-P0001	9	CSS0503C	CSS05-Idea, No Intent, No Plan, Describe	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	I thought about taking an overdose but I never made a specific plan	I thought about taking an overdose but I never made a specific plan	
10	STUDYX	QS	2324-P0001	10	CSS0504A	CSS05-Idea, Intent, No Plan-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	No	N	
11	STUDYX	QS	2324-P0001	11	CSS0504B	CSS05-Idea, Intent, No Plan-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	No	N	
12	STUDYX	QS	2324-P0001	12	CSS0504C	CSS05-Idea, Intent, No Plan, Describe	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	XXX		
13	STUDYX	QS	2324-P0001	13	CSS0505A	CSS05-Idea, Plan, Intent-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	No	N	
14	STUDYX	QS	2324-P0001	14	CSS0505B	CSS05-Idea, Plan, Intent-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	No	N	
15	STUDYX	QS	2324-P0001	15	CSS0505C	CSS05-Idea, Plan, Intent, Describe	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL IDEATION	XXX		
16	STUDYX	QS	2324-P0001	16	CSS0506A	CSS05-Most Severe Idea-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	3	3	3
17	STUDYX	QS	2324-P0001	17	CSS0506B	CSS05-Most Severe Idea, Desc-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Some intent to act on suicidal thoughts	Some intent to act on suicidal thoughts	
18	STUDYX	QS	2324-P0001	18	CSS0506C	CSS05-Most Severe Idea-Since	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	1	1	1
19	STUDYX	QS	2324-P0001	19	CSS0506D	CSS05-Most Severe Idea, Desc-Since	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Some intent to act on suicidal thoughts	Some intent to act on suicidal thoughts	
20	STUDYX	QS	2324-P0001	20	CSS0507A	CSS05-Most Severe Idea, Frequency-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	2-5 times in week	3	3
21	STUDYX	QS	2324-P0001	21	CSS0507B	CSS05-Most Severe Idea, Frequency-Since	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Less than once a week	1	1

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSSTRESC	QSSTRESN
22	STUDYX	QS	2324-P0001	22	CSS0508A	CSS05-Most Severe Idea, Duration-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Less than 1 hour/some of the time	2	2
23	STUDYX	QS	2324-P0001	23	CSS0508B	CSS05-Most Severe Idea, Duration-Since	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Fleeting - few seconds or minutes	1	1
24	STUDYX	QS	2324-P0001	24	CSS0509A	CSS05-Most Severe Idea, Control-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Can control thoughts with a lot of difficulty	4	4
25	STUDYX	QS	2324-P0001	25	CSS0509B	CSS05-Most Severe Idea, Control-Since	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Easily able to control thoughts	1	1
26	STUDYX	QS	2324-P0001	26	CSS0510A	CSS05-Most Severe Idea, Deterrents-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Deterrents definitely did not stop you	5	5
27	STUDYX	QS	2324-P0001	27	CSS0510B	CSS05-Most Severe Idea, Deterrents-Since	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Deterrents probably stopped you	2	2
28	STUDYX	QS	2324-P0001	28	CSS0511A	CSS05-Most Severe Idea, Reasons-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Mostly to get attention, revenge or a reaction from others	2	2
29	STUDYX	QS	2324-P0001	29	CSS0511B	CSS05-Most Severe Idea, Reasons-Since	C-SSRS ALREADY ENROLLED SUBJECTS	INTENSITY OF IDEATION	Completely to get attention, revenge or a reaction from others	1	1
30	STUDYX	QS	2324-P0001	30	CSS0512A	CSS05-Actual Attempt-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Yes	Y	
31	STUDYX	QS	2324-P0001	31	CSS0512B	CSS05-Actual Attempt-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No	N	
32	STUDYX	QS	2324-P0001	32	CSS0513A	CSS05-Number of Actual Attempts-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	2	2	2
33	STUDYX	QS	2324-P0001	33	CSS0513B	CSS05-Number of Actual Attempts-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	0	0	0
34	STUDYX	QS	2324-P0001	34	CSS0513C	CSS05-Actual Attempt, Describe	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Took pills	Took pills	
35	STUDYX	QS	2324-P0001	35	CSS0514A	CSS05-Non-suicid Self-injur Behav-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Yes	Y	
36	STUDYX	QS	2324-P0001	36	CSS0514B	CSS05-Non-suicid Self-injur Behav-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No	N	

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSSTRESC	QSSTRESN
37	STUDYX	QS	2324-P0001	37	CSS0515A	CSS05-Interrupted Attempt-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Yes	Y	
38	STUDYX	QS	2324-P0001	38	CSS0515B	CSS05-Interrupted Attempt-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No	N	
39	STUDYX	QS	2324-P0001	39	CSS0516A	CSS05-Num of Interrupted Attempts-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	2	2	2
40	STUDYX	QS	2324-P0001	40	CSS0516B	CSS05-Num of Interrupted Attempts-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	0	0	0
41	STUDYX	QS	2324-P0001	41	CSS0516C	CSS05-Interrupted Attempt, Describe	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Bought pills, threw them out	Bought pills, threw them out	
42	STUDYX	QS	2324-P0001	42	CSS0517A	CSS05-Aborted Attempt-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No	N	
43	STUDYX	QS	2324-P0001	43	CSS0517B	CSS05-Aborted Attempt-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No	N	
44	STUDYX	QS	2324-P0001	44	CSS0518A	CSS05-Number of Aborted Attempts-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	0	0	0
45	STUDYX	QS	2324-P0001	45	CSS0518B	CSS05-Number of Aborted Attempts-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	0	0	0
46	STUDYX	QS	2324-P0001	46	CSS0518C	CSS05-Aborted Attempt, Describe	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	XXX		
47	STUDYX	QS	2324-P0001	47	CSS0519A	CSS05-Preparatory Acts/Behavior-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Yes	Y	
48	STUDYX	QS	2324-P0001	48	CSS0519B	CSS05-Preparatory Acts/Behavior-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No	N	
49	STUDYX	QS	2324-P0001	49	CSS0519C	CSS05-Preparatory Acts/Behavior, Descr	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Bought Pills	Bought Pills	
50	STUDYX	QS	2324-P0001	50	CSS0520A	CSS05-Suicidal Behavior-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No	N	

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Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSSTRESC	QSSTRESN
51	STUDYX	QS	2324-P0001	51	CSS0520B	CSS05-Suicidal Behavior-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No	N	
52	STUDYX	QS	2324-P0001	52	CSS0521A	CSS05-Completed Suicide-Prior	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No	N	
53	STUDYX	QS	2324-P0001	53	CSS0521B	CSS05-Completed Suicide-Since	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No	N	
54	STUDYX	QS	2324-P0001	54	CSS0522A	CSS05-Most Recent Attempt Date	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	2010-11-09	2010-11-09	
55	STUDYX	QS	2324-P0001	55	CSS0522B	CSS05-Most Recent Attempt Damage	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Minor physical damage	1	1
56	STUDYX	QS	2324-P0001	56	CSS0522C	CSS05-Most Recent Attempt Potential	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Behavior likely to result in injury but not likely to cause death	1	1
57	STUDYX	QS	2324-P0001	57	CSS0523A	CSS05-Most Lethal Attempt Date	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	2009-03-27	2009-03-27	
58	STUDYX	QS	2324-P0001	58	CSS0523B	CSS05-Most Lethal Attempt Damage	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Severe physical damage	4	4
59	STUDYX	QS	2324-P0001	59	CSS0523C	CSS05-Most Lethal Attempt Potential	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Behavior likely to result in death despite available medical care	2	2
60	STUDYX	QS	2324-P0001	60	CSS0524A	CSS05-First Attempt Date	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	2009-02-12	2009-02-12	
61	STUDYX	QS	2324-P0001	61	CSS0524B	CSS05-First Attempt Damage	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	No physical damage or very minor physical damage	0	0
62	STUDYX	QS	2324-P0001	62	CSS0524C	CSS05-First Attempt Potential	C-SSRS ALREADY ENROLLED SUBJECTS	SUICIDAL BEHAVIOR	Behavior likely to result in injury but not likely to cause death	1	1

Row	QSBFL	QSEVAL	QSEVALID	VISITNUM	QSDTC	QSEVINTX
1 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
2 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
3 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
4 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
5 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
6 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
7 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
8 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
9 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
10 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
11 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
12 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
13 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
14 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
15 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
16 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
17 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
18 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
19 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
20 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
21 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
22 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
23 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
24 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
25 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
26 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
27 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
28 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
29 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
30 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
31 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
32 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
33 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
34 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
35 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
36 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
37 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
38 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
39 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
40 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
41 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
42 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
43 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
44 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY

Row	QSBFL	QSEVAL	QSEVALID	VISITNUM	QSDTC	QSEVINTX
45 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
46 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
47 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
48 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
49 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
50 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
51 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
52 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	PRIOR TO STUDY ENTRY
53 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	SINCE STUDY START
54 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
55 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
56 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
57 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
58 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
59 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
60 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
61 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	
62 (cont)	Y	INVESTIGATOR	DOC	1	2013-09-04	

4 SDTM Mapping Strategy

C-SSRS ALREADY ENROLLED SUBJECTS specific mapping strategy: This section is used for reference with the annotated CRF for further details on the CRF data capture and to understand the alignment of the questionnaire to the SDTM QS domain. It also provides guidance on how the result variables (QSORRES, QSSTRESC, and QSSTRESN) should be populated for each questionnaire. If a result variable is not included in the table for a questionnaire, it should not be populated.

QSSCAT	QSTESTCD
SUICIDAL IDEATION	CSS0501A – CSS0505C
INTENSITY OF IDEATION	CSS0506A – CSS0511B
SUICIDAL BEHAVIOR	CSS0512A – CSS0524C

QSTESTCD= CSS0501A	QSTEST= CSS05-Wish to be Dead-Prior
QSTESTCD= CSS0501B	QSTEST= CSS05-Wish to be Dead-Since
QSTESTCD= CSS0502A	QSTEST= CSS05-Non-Spec Suicid Thought-Prior
QSTESTCD= CSS0502B	QSTEST= CSS05-Non-Spec Suicid Thought-Since
QSTESTCD= CSS0503A	QSTEST= CSS05-Idea, No Intent, No Plan-Prior
QSTESTCD= CSS0503B	QSTEST= CSS05-Idea, No Intent, No Plan-Since
QSTESTCD= CSS0504A	QSTEST= CSS05-Idea, Intent, No Plan-Prior
QSTESTCD= CSS0504B	QSTEST= CSS05-Idea, Intent, No Plan-Since
QSTESTCD= CSS0505A	QSTEST= CSS05-Idea, Plan, Intent-Prior
QSTESTCD= CSS0505B	QSTEST= CSS05-Idea, Plan, Intent-Since

QSORRES	QSSTRESC
Yes	Y
No	N

QSTESTCD= CSS0506A	QSTEST= CSS05-Most Severe Idea-Prior
QSTESTCD= CSS0506C	QSTEST= CSS05-Most Severe Idea-Since

QSORRES	QSSTRESC	QSSTRESN
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5

QSTESTCD= CSS0507A QSTEST= CSS05-Most Severe Idea, Frequency-Prior
QSTESTCD= CSS0507B QSTEST= CSS05-Most Severe Idea, Frequency-Since

QSORRES	QSSTRESC	QSSTRESN
Less than once a week	1	1
Once a week	2	2
2-5 times in week	3	3
Daily or almost daily	4	4
Many times each day	5	5

QSTESTCD= CSS0508A QSTEST= CSS05-Most Severe Idea, Duration-Prior
QSTESTCD= CSS0508B QSTEST= CSS05-Most Severe Idea, Duration-Since

QSORRES	QSSTRESC	QSSTRESN
Fleeting – few seconds or minutes	1	1
Less than 1 hour/some of the time	2	2
1-4 hours/a lot of time	3	3
4-8 hours/most of day	4	4
More than 8 hours/persistent or continuous	5	5

QSTESTCD= CSS0509A QSTEST= CSS05-Most Severe Idea, Control-Prior
QSTESTCD= CSS0509B QSTEST= CSS05-Most Severe Idea, Control-Since

QSORRES	QSSTRESC	QSSTRESN
Easily able to control thoughts	1	1
Can control thoughts with little difficulty	2	2
Can control thoughts with some difficulty	3	3
Can control thoughts with a lot of difficulty	4	4
Unable to control thoughts	5	5
Does not attempt to control thoughts	0	0

QSTESTCD= CSS0510A QSTEST= CSS05-Most Severe Idea, Deterrents-Prior
QSTESTCD= CSS0510B QSTEST= CSS05-Most Severe Idea, Deterrents-Since

QSORRES	QSSTRESC	QSSTRESN
Deterrents definitely stopped you from attempting suicide	1	1
Deterrents probably stopped you	2	2
Uncertain that deterrents stopped you	3	3
Deterrents most likely did not stop you	4	4
Deterrents definitely did not stop you	5	5
Does not apply	0	0

QSTESTCD= CSS0511A QSTEST= CSS05-Most Severe Idea, Reasons-Prior
QSTESTCD= CSS0511B QSTEST= CSS05-Most Severe Idea, Reasons-Since

QSORRES	QSSTRESC	QSSTRESN
Completely to get attention, revenge or a reaction from others	1	1
Mostly to get attention, revenge or a reaction from others	2	2
Equally to get attention, revenge or a reaction from others and to end/stop the pain	3	3
Mostly to end or stop the pain	4	4
Completely to end or stop the pain	5	5
Dose not apply	0	0

QSTESTCD= CSS0512A QSTEST= CSS05-Actual Attempt-Prior
QSTESTCD= CSS0512B QSTEST= CSS05-Actual Attempt-Since
QSTESTCD= CSS0514A QSTEST= CSS05-Non-suicid Self-injur Behav-Prior
QSTESTCD= CSS0514B QSTEST= CSS05-Non-suicid Self-injur Behav-Since
QSTESTCD= CSS0515A QSTEST= CSS05-Interrupted Attempt-Prior
QSTESTCD= CSS0515B QSTEST= CSS05-Interrupted Attempt-Since
QSTESTCD= CSS0517A QSTEST= CSS05-Aborted Attempt-Prior
QSTESTCD= CSS0517B QSTEST= CSS05-Aborted Attempt-Since
QSTESTCD= CSS0519A QSTEST= CSS05-Preparatory Acts/Behavior-Prior
QSTESTCD= CSS0519B QSTEST= CSS05-Preparatory Acts/Behavior-Since
QSTESTCD= CSS0520A QSTEST= CSS05-Suicidal Behavior-Prior
QSTESTCD= CSS0520B QSTEST= CSS05-Suicidal Behavior-Since
QSTESTCD= CSS0521A QSTEST= CSS05-Completed Suicide-Prior
QSTESTCD= CSS0521B QSTEST= CSS05-Completed Suicide-Since

QSORRES	QSSTRESC
Yes	Y
No	N

QSTESTCD= CSS0522B QSTEST= CSS05-Most Recent Attempt Damage
QSTESTCD= CSS0523B QSTEST= CSS05-Most Lethal Attempt Damage
QSTESTCD= CSS0524B QSTEST= CSS05-First Attempt Damage

QSORRES	QSSTRESC	QSSTRESN
No physical damage or very minor physical damage	0	0
Minor physical damage	1	1
Moderate physical damage; medical attention needed	2	2
Moderately severe physical damage; medical hospitalization and likely intensive care required	3	3
Severe physical damage; medical hospitalization with intensive care required	4	4
Death	5	5

QSTESTCD= CSS0522C QSTEST= CSS05-Most Recent Attempt Potential
QSTESTCD= CSS0523C QSTEST= CSS05-Most Lethal Attempt Potential
QSTESTCD= CSS0524C QSTEST= CSS05-First Attempt Potential

QSORRES	QSSTRESC	QSSTRESN
Behavior not likely to result in injury	0	0
Behavior likely to result in injury but not likely to cause death	1	1
Behavior likely to result in death despite available medical care	2	2

End of Document