



Columbia-Suicide Severity Rating Scale Baseline (C-SSRS BASELINE)

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

Prepared by
CDISC and Analgesic Clinical Trial Translations, Innovations, Opportunities, and
Networks (ACTION)

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
2012-03-03	0.1	Columbia-Suicide Severity Rating Scale Baseline (C-SSRS BASELINE) Draft
2012-08-07	1.0	Columbia-Suicide Severity Rating Scale Baseline (C-SSRS BASELINE) Released
2013-02-06	1.1	Columbia-Suicide Severity Rating Scale Baseline (C-SSRS BASELINE) Revised: <ul style="list-style-type: none">• QSSCAT added to be compatible with all CSSR-S questionnaires• QSTPT replaced with QNAM=EVLINTTX to be compatible with all CSSR-S questionnaires using evaluation intervals• Corrected “Dose not apply”, associated with the Most Severe Ideation,

		Reasons on page 9 to “Does not apply”. <ul style="list-style-type: none">Added QS terminology reference
2014-09-03	1.2	Columbia-Suicide Severity Rating Scale Baseline (C-SSRS BASELINE) Revised: <ul style="list-style-type: none">Updated references to QSCAT and questionnaire name throughout the document.Section 3.1: Assumption # 2 – Evaluation Interval mapped to QSEVINTX (from EVLINTTX).Section 3.2: Updated text above example table. Example table updated to include QSEVINTX in the QS table. Removed the SUPPQS.xpt table.Section 4: (SDTM Mapping Strategy) for QSTESTCD=CSS0111. Old value: Completely to end or stop pain New value: Completely to end or stop the pain

1 Introduction

This document describes the CDISC implementation of the Columbia-Suicide Severity Rating Scale Baseline (C-SSRS BASELINE) 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 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, but are recorded separately since this questionnaire may be used in many different therapeutic area implementations. 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 Baseline (C-SSRS BASELINE) questionnaire as part of CDISC Data Standards. This means that CDISC developed QSTESTCD and QSTEST for each question based on the actual question text on the questionnaire. The instrument itself was not changed.

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 licenses 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-Suicidality Severity Rating Scale (C-SSRS) Baseline version 2009-01-14 scale in the CDISC data standards.

3 The QS Domain Model

3.1 Assumptions for Questionnaire Domain Model

All assumptions for the QS domain from the SDTMIG apply for this supplemental implementation guide including those referenced in the CDISC notes. Additional, assumptions specific to the Columbia-Suicide Severity Rating Scale Baseline questionnaire are listed below.

1. Columbia-Suicide Severity Rating Scale Baseline: (C-SSRS BASELINE) 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."
2. The C-SSRS BASELINE questionnaire is evaluated for a single time point, "Lifetime". The value, "LIFETIME" is recorded in the variable QSEVINTX.
3. The evaluator of the questionnaire is stored in QSEVAL and for the C-SSRS BASELINE form the INVESTIGATOR provides the evaluation.
4. 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: Mapping Strategy.

3.2 Example for Columbia-Suicide Severity Rating Scale Baseline (C-SSRS Baseline) QS Domain Model

The C-SSRS BASELINE example below shows the terminology used to implement the questionnaire in the QS domain.

This example shows data from one subject collected at one visit for a C-SSRS BASELINE questionnaire. The example uses controlled terminology for QSTESTCD, QSTEST, and QSCAT. The evaluation interval for this questionnaire is over the lifetime of the subject and is represented in QSEVINTX as “LIFETIME”.

Rows 1-39: Represent the questions from the C-SSRS BASELINE Form. All original results are represented with preferred terminology in QSORRES. This result is then transformed into a standard numeric score in QSSTRESN and a character representation of the standard numeric score in QSSTRESC.

Rows 8, 10 and 27 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 records 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	CSS0101	CSS01-Wish to be Dead	C-SSRS BASELINE	SUICIDAL IDEATION	Yes	Y	
2	STUDYX	QS	2324-P0001	2	CSS0101A	CSS01-Wish to be Dead, Describe	C-SSRS BASELINE	SUICIDAL IDEATION	Wish dead	Wish dead	
3	STUDYX	QS	2324-P0001	3	CSS0102	CSS01-Non-Specific Suicidal Thought	C-SSRS BASELINE	SUICIDAL IDEATION	Yes	Y	
4	STUDYX	QS	2324-P0001	4	CSS0102A	CSS01-Non-Specific Suicid Thought, Descr	C-SSRS BASELINE	SUICIDAL IDEATION	I have thought about killing myself	I have thought about killing myself	
5	STUDYX	QS	2324-P0001	5	CSS0103	CSS01-Suicidal Ideation-No Intent	C-SSRS BASELINE	SUICIDAL IDEATION	Yes	Y	
6	STUDYX	QS	2324-P0001	6	CSS0103A	CSS01-Suicidal Ideation-No Intent, Descr	C-SSRS BASELINE	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	
7	STUDYX	QS	2324-P0001	7	CSS0104	CSS01-Ideation With Intent, No Plan	C-SSRS BASELINE	SUICIDAL IDEATION	No	N	

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSSTRESC	QSSTRESN
8	STUDYX	QS	2324-P0001	8	CSS0104A	CSS01-Ideation With Intent No Plan Descr	C-SSRS BASELINE	SUICIDAL IDEATION	XXX		
9	STUDYX	QS	2324-P0001	9	CSS0105	CSS01-Ideation With Plan/Intent	C-SSRS BASELINE	SUICIDAL IDEATION	No	N	
10	STUDYX	QS	2324-P0001	10	CSS0105A	CSS01-Ideation With Plan/Intent, Descr	C-SSRS BASELINE	SUICIDAL IDEATION	XXX		
11	STUDYX	QS	2324-P0001	11	CSS0106	CSS01-Most Severe Ideation	C-SSRS BASELINE	INTENSITY OF IDEATION	2	2	2
12	STUDYX	QS	2324-P0001	12	CSS0106A	CSS01-Most Severe Ideation, Description	C-SSRS BASELINE	INTENSITY OF IDEATION	Some intent to act on suicidal thoughts	Some intent to act on suicidal thoughts	
13	STUDYX	QS	2324-P0001	13	CSS0107	CSS01-Most Severe Ideation, Frequency	C-SSRS BASELINE	INTENSITY OF IDEATION	2-5 times in week	3	3
14	STUDYX	QS	2324-P0001	14	CSS0108	CSS01-Most Severe Ideation, Duration	C-SSRS BASELINE	INTENSITY OF IDEATION	Less than 1 hour/some of the time	2	2
15	STUDYX	QS	2324-P0001	15	CSS0109	CSS01-Most Severe Ideation, Control	C-SSRS BASELINE	INTENSITY OF IDEATION	Can control thoughts with a lot of difficulty	4	4
16	STUDYX	QS	2324-P0001	16	CSS0110	CSS01-Most Severe Ideation, Deterrents	C-SSRS BASELINE	INTENSITY OF IDEATION	Deterrents definitely did not stop you	5	5
17	STUDYX	QS	2324-P0001	17	CSS0111	CSS01-Most Severe Ideation, Reasons	C-SSRS BASELINE	INTENSITY OF IDEATION	Mostly to get attention, revenge or a reaction from others	2	2
18	STUDYX	QS	2324-P0001	18	CSS0112	CSS01-Actual Attempt	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Yes	Y	
19	STUDYX	QS	2324-P0001	19	CSS0113	CSS01-Number of Actual Attempts	C-SSRS BASELINE	SUICIDAL BEHAVIOR	2	2	2
20	STUDYX	QS	2324-P0001	20	CSS0113A	CSS01-Actual Attempt, Describe	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Try to get injured to get attention	Try to get injured to get attention	
21	STUDYX	QS	2324-P0001	21	CSS0114	CSS01-Non-suicidal Self-injurious Behav	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Yes	Y	
22	STUDYX	QS	2324-P0001	22	CSS0115	CSS01-Interrupted Attempt	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Yes	Y	
23	STUDYX	QS	2324-P0001	23	CSS0116	CSS01-Number of Interrupted Attempts	C-SSRS BASELINE	SUICIDAL BEHAVIOR	1	1	1
24	STUDYX	QS	2324-P0001	24	CSS0116A	CSS01-Interrupted Attempt, Describe	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Stopped from overdose	Stopped from overdose	
25	STUDYX	QS	2324-P0001	25	CSS0117	CSS01-Aborted Attempt	C-SSRS BASELINE	SUICIDAL BEHAVIOR	No	N	

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSSTRESC	QSSTRESN
26	STUDYX	QS	2324-P0001	26	CSS0118	CSS01-Number of Aborted Attempts	C-SSRS BASELINE	SUICIDAL BEHAVIOR	0	0	0
27	STUDYX	QS	2324-P0001	27	CSS0118A	CSS01-Aborted Attempt, Describe	C-SSRS BASELINE	SUICIDAL BEHAVIOR	XXX		
28	STUDYX	QS	2324-P0001	28	CSS0119	CSS01-Preparatory Acts/Behavior	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Yes	Y	
29	STUDYX	QS	2324-P0001	29	CSS0119A	CSS01-Preparatory Acts/Behavior, Descr	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Buying pills	Buying pills	
30	STUDYX	QS	2324-P0001	30	CSS0120	CSS01-Suicidal Behavior	C-SSRS BASELINE	SUICIDAL BEHAVIOR	No	N	
31	STUDYX	QS	2324-P0001	31	CSS0121A	CSS01-Most Recent Attempt Date	C-SSRS BASELINE	SUICIDAL BEHAVIOR	2010-11-09	2010-11-09	
32	STUDYX	QS	2324-P0001	32	CSS0121B	CSS01-Most Recent Attempt Damage	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Minor physical damage	1	1
33	STUDYX	QS	2324-P0001	33	CSS0121C	CSS01-Most Recent Attempt Potential	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Behavior likely to result in injury but not likely to cause death	1	1
34	STUDYX	QS	2324-P0001	34	CSS0122A	CSS01-Most Lethal Attempt Date	C-SSRS BASELINE	SUICIDAL BEHAVIOR	2009-03-27	2009-03-27	
35	STUDYX	QS	2324-P0001	35	CSS0122B	CSS01-Most Lethal Attempt Damage	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Severe physical damage	4	4
36	STUDYX	QS	2324-P0001	36	CSS0122C	CSS01-Most Lethal Attempt Potential	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Behavior likely to result in death despite available medical care	2	2
37	STUDYX	QS	2324-P0001	37	CSS0123A	CSS01-First Attempt Date	C-SSRS BASELINE	SUICIDAL BEHAVIOR	2009-02-12	2009-02-12	
38	STUDYX	QS	2324-P0001	38	CSS0123B	CSS01-First Attempt Damage	C-SSRS BASELINE	SUICIDAL BEHAVIOR	No physical damage or very minor physical damage	0	0
39	STUDYX	QS	2324-P0001	39	CSS0123C	CSS01-First Attempt Potential	C-SSRS BASELINE	SUICIDAL BEHAVIOR	Behavior likely to result in injury but not likely to cause death	1	1

Row	QSBFL	QSEVAL	VISITNUM	QSEVINTX
1 (cont)	1	INVESTIGATOR	1	LIFETIME
2 (cont)	1	INVESTIGATOR	1	LIFETIME
3 (cont)	1	INVESTIGATOR	1	LIFETIME
4 (cont)	1	INVESTIGATOR	1	LIFETIME
5 (cont)	1	INVESTIGATOR	1	LIFETIME
6 (cont)	1	INVESTIGATOR	1	LIFETIME

Row	QSBFL	QSEVAL	VISITNUM	QSEVINTX
7 (cont)	1	INVESTIGATOR	1	LIFETIME
8 (cont)	1	INVESTIGATOR	1	LIFETIME
9 (cont)	1	INVESTIGATOR	1	LIFETIME
10 (cont)	1	INVESTIGATOR	1	LIFETIME
11 (cont)	1	INVESTIGATOR	1	LIFETIME
12 (cont)	1	INVESTIGATOR	1	LIFETIME
13 (cont)	1	INVESTIGATOR	1	LIFETIME
14 (cont)	1	INVESTIGATOR	1	LIFETIME
15 (cont)	1	INVESTIGATOR	1	LIFETIME
16 (cont)	1	INVESTIGATOR	1	LIFETIME
17 (cont)	1	INVESTIGATOR	1	LIFETIME
18 (cont)	1	INVESTIGATOR	1	LIFETIME
19 (cont)	1	INVESTIGATOR	1	LIFETIME
20 (cont)	1	INVESTIGATOR	1	LIFETIME
21 (cont)	1	INVESTIGATOR	1	LIFETIME
22 (cont)	1	INVESTIGATOR	1	LIFETIME
23 (cont)	1	INVESTIGATOR	1	LIFETIME
24 (cont)	1	INVESTIGATOR	1	LIFETIME
25 (cont)	1	INVESTIGATOR	1	LIFETIME
26 (cont)	1	INVESTIGATOR	1	LIFETIME
27 (cont)	1	INVESTIGATOR	1	LIFETIME
28 (cont)	1	INVESTIGATOR	1	LIFETIME
29 (cont)	1	INVESTIGATOR	1	LIFETIME
30 (cont)	1	INVESTIGATOR	1	LIFETIME
31 (cont)	1	INVESTIGATOR	1	LIFETIME
32 (cont)	1	INVESTIGATOR	1	LIFETIME
33 (cont)	1	INVESTIGATOR	1	LIFETIME
34 (cont)	1	INVESTIGATOR	1	LIFETIME
35 (cont)	1	INVESTIGATOR	1	LIFETIME
36 (cont)	1	INVESTIGATOR	1	LIFETIME
37 (cont)	1	INVESTIGATOR	1	LIFETIME
38 (cont)	1	INVESTIGATOR	1	LIFETIME
39 (cont)	1	INVESTIGATOR	1	LIFETIME

4 SDTM Mapping Strategy

C-SSRS BASELINE 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, QSORRESU, QSSTRESC, QSSTRESN, and QSSTRESU) 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	CSS0101 – CSS0105A
INTENSITY OF IDEATION	CSS0106 – CSS0111
SUICIDAL BEHAVIOR	CSS0112 – CSS0123C

QSTESTCD= CSS0101... CSS0105
Ideation With Plan/Intent

QSTEST= CSS01-Wish to be Dead... CSS01-

QSORRES	QSSTRESC
Yes	Y
No	N

QSTESTCD= CSS0106 QSTEST= CSS01-Most Severe Ideation

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

QSTESTCD= CSS0107 QSTEST= CSS01-Most Severe Ideation, Frequency

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= CSS0108 QSTEST= CSS01-Most Severe Ideation, Duration

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= CSS0109 QSTEST= CSS01-Most Severe Ideation, Control

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= CSS0110 QSTEST= CSS01-Most Severe Ideation, Deterrents

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= CSS0111 QSTEST= CSS01-Most Severe Ideation, Reasons

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
Does not apply	0	0

QSTESTCD= CSS0112... CSS0120
Suicidal Behavior

QSTEST= CSS01-Actual Attempt... CSS01-

QSORRES	QSSTRESC
Yes	Y
No	N

QSTESTCD= CSS0121B QSTEST= CSS01-Most Recent 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= CSS0121C QSTEST= CSS01-Most Recent 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

QSTESTCD= CSS0122B QSTEST= CSS01-Most Lethal 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= CSS0122C QSTEST= CSS01-Most Lethal 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

QSORRES	QSSTRESC	QSSTRESN
Behavior likely to result in death despite available medical care	2	2

QSTESTCD= CSS0123B QSTEST= CSS01-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= CSS0123C QSTEST= CSS01-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