



# **Brief Psychiatric Rating Scale-Anchored (BPRS-A)**

## **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
2012-12-12	0.1	Brief Psychiatric Rating Scale (BPRS-A) Draft
2013-01-18	1.0	Brief Psychiatric Rating Scale (BPRS-A)
2013-05-22	1.1	Changed response of "CANNOT BE ASSESSED ADEQUATELY..." from QSTAT = "NOT DONE" to a non-missing response.
2014-07-28	1.2	Removed text above example describing "Row 5" per the Version 1.1 change.

## 1 Introduction

This document describes the CDISC implementation of the Brief Psychiatric Rating Scale-Anchored (BPRS-Anchored or BPRS-A) questionnaire, a standard questionnaire that is typically used in clinical trials to provide an assessment of psychopathology.

The BPRS-A questionnaire preceded the CDISC CDASH CRF standards and based on its public domain status, cannot be modified to CDASH standards. The annotated CRF that accompanies this implementation guide was transcribed from the BPRS-A reference article, although some header information has been omitted (i.e. Pt. Name and Rater) and form completion instructions have been added (i.e. INSTRUCTIONS: Indicate the appropriate scale point for each item by marking X in the appropriate numbered box. Do not leave any items blank.). The annotated CRF is supplied only to illustrate how the questionnaire items map to SDTM and is not intended to serve as the data collection instrument for sponsors.

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 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

This instrument is in the public domain. CDISC has included the Brief Psychiatric Rating Scale-Anchored (BPRS-A) 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. There may be many versions of this questionnaire in the public domain. 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.

CDISC has developed this documentation at no cost to users of the instrument.

## 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. Additionally, the following assumptions apply to the Brief Psychiatric Rating Scale-Anchored form:

1. Brief Psychiatric Rating Scale-Anchored (BPRS-A): BPRS-A is a multiple choice questionnaire that clinicians may use to provide an assessment of psychopathology. It consists of 18 items, each rated on a 7-point scale. Ratings are made during a brief (15-20 min), semi-structured interview with the subject.
2. The scale points include a rating (e.g. “Mild”) and a definition of what is represented by the rating (e.g. “occasionally feels moderately depressed, or often feels somewhat depressed”). For BPRS-A, QSORRES is populated with the rating only. The rating definition is considered as just a reference for the evaluator to use in assigning a rating and is not submitted in SDTM.
3. For some items, the BPRS-A questionnaire has a choice of “9 = Cannot be assessed adequately because of severe formal thought disorder, uncooperativeness, or marked evasiveness/guardedness; or Not assessed”. The result of “9” is included in QSSTRESC and QSSTRESN; however, the sponsor’s analysis plan should determine whether or not this value is considered a score for purposes of summary statistic calculations.
4. The time period of evaluation for the BPRS-A is populated in the QSEVLINT field in ISO 8601 format when the evaluation interval can be precisely described as duration. Typically, the evaluation interval for BPRS-A is the past week.
5. The questionnaire rater’s role should be stored in QSEVAL. For BPRS-A, the rater is usually defined as INVESTIGATOR. Additional identifying information to further distinguish the rater in QSEVAL should be stored in QSEVALID. An example is rater initials.
6. Terminology:
  - a. QSCAT, QSTESTCD and QSTEST are approved CDISC controlled terminology.
  - b. A full list of value sets for QSORRES, QSSTRESC and QSSTRESN fields is provided in Section 4: SDTM Mapping Strategy.

### **3.2 Example for Brief Psychiatric Rating Scale-Anchored QS Domain Model**

The BPRS-A example below shows the terminology for QSCAT, QSTEST, QSTESTCD and QSORRES that should be utilized for this scale. A full list of value sets for QSORRES, QSSTRESC and QSSTRESN fields are listed in Section 4: SDTM Mapping Strategy.

**Example: Brief Psychiatric Rating Scale-Anchored (BPRS-A)**

This example shows data from one subject collected at one visit for a BPRS-A questionnaire. The example uses standard controlled terminology for QSTESTCD, QSTEST, and QSCAT. This example is based on a questionnaire with an evaluation interval of the past week.

**Rows 1-18:** Represent the questions from the BPRS-A 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.

## QS.XPT

Row	STUDYID	DOMAIN	USUBJID	QSESEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN
1	STUDYX	QS	P0001	1	BPR0101	BPR01-Somatic Concern	BPRS-A	Very Mild	2	2
2	STUDYX	QS	P0001	2	BPR0102	BPR01-Anxiety	BPRS-A	Mild	3	3
3	STUDYX	QS	P0001	3	BPR0103	BPR01-Emotional Withdrawal	BPRS-A	Very Mild	2	2
4	STUDYX	QS	P0001	4	BPR0104	BPR01-Conceptual Disorganization	BPRS-A	Not observed	1	1
5	STUDYX	QS	P0001	5	BPR0105	BPR01-Guilt Feelings	BPRS-A	Cannot be assessed adequately because of severe formal thought disorder, uncooperativeness, or marked evasiveness/guardedness; or Not assessed	9	9
6	STUDYX	QS	P0001	6	BPR0106	BPR01-Tension	BPRS-A	Mild	3	3
7	STUDYX	QS	P0001	7	BPR0107	BPR01-Mannerisms and Posturing	BPRS-A	Severe	6	6
8	STUDYX	QS	P0001	8	BPR0108	BPR01-Grandiosity	BPRS-A	Very Mild	2	2
9	STUDYX	QS	P0001	9	BPR0109	BPR01-Depressive Mood	BPRS-A	Mild	3	3
10	STUDYX	QS	P0001	10	BPR0110	BPR01-Hostility	BPRS-A	Not reported	1	1
11	STUDYX	QS	P0001	11	BPR0111	BPR01-Suspiciousness	BPRS-A	Very Mild	2	2
12	STUDYX	QS	P0001	12	BPR0112	BPR01-Hallucinatory Behavior	BPRS-A	Very Mild	2	2

13	STUDYX	QS	P0001	13	BPR0113	BPR01-Motor Retardation	BPRS-A	Moderate	4	4
14	STUDYX	QS	P0001	14	BPR0114	BPR01-Uncooperativeness	BPRS-A	Not observed	1	1
15	STUDYX	QS	P0001	15	BPR0115	BPR01-Unusual Thought Content	BPRS-A	Mild	3	3
16	STUDYX	QS	P0001	16	BPR0116	BPR01-Blunted Affect	BPRS-A	Moderate	4	4
17	STUDYX	QS	P0001	17	BPR0117	BPR01-Excitement	BPRS-A	Moderate	4	4
18	STUDYX	QS	P0001	18	BPR0118	BPR01-Disorientation	BPRS-A	Very Severe	7	7

Row	QSSTAT	QSBLFL	QSEVAL	QSEVALID	VISITNUM	QSDTC	QSEVLINT
1 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
2 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
3 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
4 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
5 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
6 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
7 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
8 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
9 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
10 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
11 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
12 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
13 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
14 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
15 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
16 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
17 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W
18 (cont)			INVESTIGATOR	GEC	2	2012-11-16	-P1W

## 4 SDTM Mapping Strategy

BPRS-A 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 the questionnaire.

**QSTESTCD=BPRS0101 QSTEST= BPR01-Somatic Concern**  
**QSTESTCD=BPRS0102 QSTEST= BPR01-Anxiety**  
**QSTESTCD=BPRS0105 QSTEST= BPR01-Guilt Feelings**  
**QSTESTCD=BPRS0108 QSTEST= BPR01-Grandiosity**  
**QSTESTCD=BPRS0109 QSTEST= BPR01-Depressive Mood**  
**QSTESTCD=BPRS0110 QSTEST= BPR01-Hostility**  
**QSTESTCD=BPRS0111 QSTEST= BPR01-Suspiciousness**  
**QSTESTCD=BPRS0112 QSTEST= BPR01-Hallucinatory Behavior**  
**QSTESTCD=BPRS0115 QSTEST= BPR01-Unusual Thought Content**

QSORRES	QSSTRESC	QSSTRESN
Not reported	1	1
Very Mild	2	2
Mild	3	3
Moderate	4	4
Moderately Severe	5	5
Severe	6	6
Very Severe	7	7
Cannot be assessed adequately because of severe formal thought disorder, uncooperativeness, or marked evasiveness/guardedness; or Not assessed	9	9

**QSTESTCD=BPRS0103 QSTEST= BPR01-Emotional Withdrawal**  
**QSTESTCD=BPRS0104 QSTEST= BPR01-Conceptual Disorganization**  
**QSTESTCD=BPRS0106 QSTEST= BPR01-Tension**  
**QSTESTCD=BPRS0107 QSTEST= BPR01-Mannerisms and Posturing**  
**QSTESTCD=BPRS0113 QSTEST= BPR01-Motor Retardation**  
**QSTESTCD=BPRS0114 QSTEST= BPR01-Uncooperativeness**  
**QSTESTCD=BPRS0116 QSTEST= BPR01-Blunted Affect**  
**QSTESTCD=BPRS0117 QSTEST= BPR01-Excitement**

<b>QSORRES</b>	<b>QSSTRESC</b>	<b>QSSTRESN</b>
Not observed	1	1
Very Mild	2	2
Mild	3	3
Moderate	4	4
Moderately Severe	5	5
Severe	6	6
Very Severe	7	7

**QSTESTCD=BPRS0118 QSTEST= BPR01-Disorientation**

<b>QSORRES</b>	<b>QSSTRESC</b>	<b>QSSTRESN</b>
Not observed	1	1
Very Mild	2	2
Mild	3	3
Moderate	4	4
Moderately Severe	5	5
Severe	6	6
Very Severe	7	7
Cannot be assessed adequately because of severe formal thought disorder, uncooperativeness, or marked evasiveness/guardedness; or Not assessed	9	9

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