



Disability Rating Scale (DRS)

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

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Notes to Readers

This supplement 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
2014-03-10	1.0	Disability Rating Scale (DRS) Draft
2014-03-21	1.0	Disability Rating Scale (DRS)

1 Introduction

This document describes the CDISC implementation of the Disability Rating Scale (DRS) questionnaire, an ordinal clinical rating scale developed to accurately measure general functional changes over the course of recovery from a traumatic brain injury.

The Disability Rating Scale (DRS) questionnaire preceded the CDISC CDASH CRF standards and based on its public domain 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 model, 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 Disability Rating Scale (DRS) 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. 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>)

The two references for this questionnaire are:

- Disability Rating Scale (DRS) (Rappaport et al. (1982) Disability Rating Scale for Severe Head Trauma Patients: Coma to Community. Archives of Physical Medicine and Rehabilitation, 63:118-123).
- Wright, J. (2000). The Disability Rating Scale. The Center for Outcome Measurement in Brain Injury. <http://www.tbims.org/combi/drs> (accessed January 9, 2014).*

*Note: This citation is for the COMBI web material. Mr. Wright is not the scale author for the DRS.

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 Disability Rating Scale (DRS) questionnaire are listed below.

Disability Rating Scale (DRS) is an ordinal clinical rating scale developed for Traumatic Brain Injury to measure general functional changes over the course of recovery. There are 8 individual questions each with specific text and matching numeric answers. The DRS Score is derived in the ADaM dataset.

1. The scale points include a rating (e.g. “Spontaneous”) and a definition of what is represented by the rating (e.g. “eyes open with sleep/wake rhythms indicating active arousal mechanisms, does not assume awareness.”). For Disability Rating Scale (DRS), QSORRES is populated with the rating only. The rating definition is considered as a reference for the investigator to use in selecting a rating and is not submitted in SDTM. The numeric values are populated in QSSTRESC and QSSTRESN.
 - a. Use of .5 ratings: In 1994, the Traumatic Brain Injury Model Systems (TBIMS) National Database adopted a 0.5 rating option for the last 5 items of the DRS. Although raters found the half point discrimination useful, no validation study was ever completed on the use of the 0.5 rating option. In 2010, the TBIMS National Database members voted to omit the 0.5 rating option. Use of the 0.5 rating option after April 1, 2010 is not recommended.
2. Terminology:
 - a. QSCAT, QSTESTCD and QSTEST are approved CDISC controlled terminology.
 - b. A full list of value sets for qualifier and result fields is provided in Section 4: SDTM Mapping Strategy.

3.2 Example for Disability Rating Scale (DRS) QS Domain Model

The Disability Rating Scale (DRS) example below shows the terminology used to implement the questionnaire in the QS domain. This example shows the data for a subject collected at the baseline visit for a Disability Rating Scale (DRS) questionnaire. The example uses CDISC controlled terminology for QSTESTCD, QSTEST, and QSCAT. QSBLFL is Y based on VISITNUM=1. 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 1-8: Shows the questions from the Disability Rating Scale (DRS) for one subject.

qs.xpt

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES	QSSTRESC	QSSTRESN
1	STUDYX	QS	P0001	1	DRS0101	DRS01-Eye Opening	DRS	Spontaneous	0	0
2	STUDYX	QS	P0001	2	DRS0102	DRS01-Communication Ability	DRS	Confused	1	1
3	STUDYX	QS	P0001	3	DRS0103	DRS01-Motor Response	DRS	Withdrawing	2	2
4	STUDYX	QS	P0001	4	DRS0104	DRS01-Feeding	DRS	None	3.0	3.0
5	STUDYX	QS	P0001	5	DRS0105	DRS01-Toileting	DRS	None	3.0	3.0
6	STUDYX	QS	P0001	6	DRS0106	DRS01-Grooming	DRS	None	3.0	3.0
7	STUDYX	QS	P0001	7	DRS0107	DRS01-Level of Functioning	DRS	Markedly Dependent- assist all major activities, all times	4.0	4.0
8	STUDYX	QS	P0001	8	DRS0108	DRS01-Employability	DRS	Sheltered workshop, Non-competitive	2.0	2.0

Row	QSBLFL	VISITNUM	QSDTC
1 (cont)	Y	1	2012-11-16
2 (cont)	Y	1	2012-11-16
3 (cont)	Y	1	2012-11-16
4 (cont)	Y	1	2012-11-16
5 (cont)	Y	1	2012-11-16
6 (cont)	Y	1	2012-11-16
7 (cont)	Y	1	2012-11-16
8 (cont)	Y	1	2012-11-16

4 SDTM Mapping Strategy

Disability Rating Scale (DRS) 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=DRS0101

QSTEST=DRS01-Eye Opening

QSORRES	QSSTRESC	QSSTRESN
Spontaneous	0	0
To Speech	1	1
To Pain	2	2
None	3	3

QSTESTCD=DRS0102

QSTEST= DRS01-Communication Ability

QSORRES	QSSTRESC	QSSTRESN
Oriented	0	0
Confused	1	1
Inappropriate	2	2
Incomprehensible	3	3
None	4	4

QSTESTCD=DRS0103

QSTEST= DRS01-Motor Response

QSORRES	QSSTRESC	QSSTRESN
Obedying	0	0
Localizing	1	1
Withdrawing	2	2
Flexing	3	3
Extending	4	4
None	5	5

QSTESTCD=DRS0104**QSTEST= DRS01-Feeding****QSTESTCD=DRS0105****QSTEST= DRS01-Toileting****QSTESTCD=DRS0106****QSTEST= DRS01-Grooming**

QSORRES	QSSTRESC	QSSTRESN
Complete	0.0	0.0
Partial	1.0	1.0
Minimal	2.0	2.0
None	3.0	3.0

QSTESTCD=DRS0107**QSTEST= DRS01-Level of Functioning**

QSORRES	QSSTRESC	QSSTRESN
Completely Independent	0.0	0.0
Independent in special environment	1.0	1.0
Mildly Dependent-Limited assistance (non-resid - helper)	2.0	2.0
Moderately Dependent-moderate assist (person in home)	3.0	3.0
Markedly Dependent-assist all major activities, all times	4.0	4.0
Totally Dependent-24 hour nursing care.	5.0	5.0

QSTESTCD=DRS0108**QSTEST= DRS01-Employability**

QSORRES	QSSTRESC	QSSTRESN
Not Restricted	0.0	0.0
Selected jobs, competitive	1.0	1.0
Sheltered workshop, Non-competitive	2.0	2.0
Not Employable	3.0	3.0

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