



# Symbol Digit Modalities Test (SDMT)

## Functional Test 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
2014-09-12	1.0	Symbol Digit Modalities Test (SDMT) Draft
2014-10-01	1.0	Symbol Digit Modalities Test (SDMT)
2014-11-19	1.1	Symbol Digit Modalities Test (SDMT) Revised <ul style="list-style-type: none"><li>Moved the subject response format out of FTMETHOD and into SUPPFT. Added Section 5 and modified the example and Assumption 2, accordingly.</li></ul>

## 1 Introduction

This document describes the CDISC implementation of the Symbol Digit Modalities Test (SDMT) functional test, which detects cognitive impairment and has demonstrated sensitivity in detecting not only the presence of brain damage, but also changes in cognitive functioning over time.

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

These specific implementation details for this functional test are meant to be used in conjunction with the SDTMIG. All functional test 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 copyrighted and CDISC was unable to obtain copyright approval to include an annotated CRF in this package. Therefore, CDISC has created controlled terminology (FTCAT, FTTESTCD, and FTTEST) for only the total score of the Symbol Digit Modalities Test (SDMT).

The CDISC documentation of this instrument consists of: (1) controlled terminology and (2) standard database structure with examples.

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 the copyright holder or any additional cost to users of the instrument beyond the normal licenses fees charged by the copyright holder.

Copyright for the Symbol Digit Modalities Test (SDMT) is held by Dr. Aaron Smith and the Western Psychological Services.

Details about the SDMT can be found in the following reference:

Smith A. (1982). Symbol digit modalities test: Manual. Los Angeles: Western Psychological Services.

## 3 The FT Domain Model

### 3.1 Assumptions for Functional Test Domain Model

All assumptions and business rules described in the SDTMIG FT domain are applicable to this supplement. Additional assumptions specific to the Symbol Digit Modalities Test functional test are listed below.

Symbol Digit Modalities Test (SDMT): The SDMT is an assessment of concentration and decision making. It consists of a simple substitution task where, using a reference key, the examinee has 90 seconds to pair specific numbers with given geometric figures. Examinees can give either written or spoken responses.

1. For SDMT, the numerical value for the total score is recorded in FTORRES, FTSTRESC, and FTSTRESN where FTTESTCD=SDMT0101.
2. For SDMT, the examinee can give either written or spoken responses. Record the response format in SUPPFT where QNAM=RESPMOD, using FTSEQ to link this SUPPFT record to the total score record in FT. If the responses were written, QVAL=WRITTEN. If the responses were spoken, QVAL=SPOKEN.
3. Terminology:
  - a. FTCAT, FTTESTCD and FTTEST are approved CDISC controlled terminology.

### 3.2 Example for Symbol Digit Modalities Test (SDMT) FT Domain Model

The SDMT example below shows the terminology used to implement the functional test in the FT domain. This example shows the data for four subjects collected at one visit for a SDMT functional test. The example uses CDISC controlled terminology for FTTESTCD, FTTEST, and FTCAT. FTBLFL is Y based on VISITNUM=1. All original results are represented with preferred terminology in FTORRES. This result is then transformed into a standard numeric score in FTSTRESN and a character representation of the standard numeric score in FTSTRESC.

**Rows 1-2:** Show the total scores for two subjects who gave written responses.

**Rows 3-4:** Show the total scores for two subjects who gave spoken responses.

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Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTTESTCD	FTTEST	FTCAT	FTORRES	FTSTRESC	FTSTRESN	FTBLFL	VISITNUM	FTDTC
1	STUDYX	FT	MS01-01	1	SDMT0101	SDMT01-Total Score	SDMT	97	97	97	Y	1	2013-08-16
2	STUDYX	FT	MS01-02	1	SDMT0101	SDMT01-Total Score	SDMT	33	33	33	Y	1	2013-08-16
3	STUDYX	FT	MS01-03	1	SDMT0101	SDMT01-Total Score	SDMT	78	78	78	Y	1	2013-08-16
4	STUDYX	FT	MS01-04	1	SDMT0101	SDMT01-Total Score	SDMT	56	56	56	Y	1	2013-08-16

The standard terminology for QNAM and QLABEL are listed below.

**Rows 1-4:** Show that subjects MS01-01 and MS01-02 gave written responses while subjects MS01-03 and MS01-04 gave spoken responses.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	STUDYX	FT	MS01-01	FTSEQ	1	RESPMOD	Response Modality	WRITTEN	CRF
2	STUDYX	FT	MS01-02	FTSEQ	1	RESPMOD	Response Modality	WRITTEN	CRF
3	STUDYX	FT	MS01-03	FTSEQ	1	RESPMOD	Response Modality	SPOKEN	CRF
4	STUDYX	FT	MS01-04	FTSEQ	1	RESPMOD	Response Modality	SPOKEN	CRF

## 4 SDTM Mapping Strategy

SDMT specific mapping strategy: This section is not applicable to the SDMT because it is not copyright approved and there is no an annotated CRF to reference. The SDMT total score terminology is not tied to any specifics of this instrument.

## 5 Supplemental Qualifier Name Codes

The following table contains additional standard name codes for use in the Supplemental Qualifiers for Functional Tests (SUPPFT) special-purpose dataset.

QNAM	QLABEL	Applicable Domains
RESPMOD	Response Modality	FT

**End of Document**