



6 Minute Walk Test (SIX MINUTE WALK)

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
2014-04-28	1.0	6 Minute Walk Test (SIX MINUTE WALK) Draft
2014-05-21	1.0	6 Minute Walk Test (SIX MINUTE WALK)

1 Introduction

This document describes the CDISC implementation of the 6 Minute Walk Test (SIX MINUTE WALK) functional test, an objective evaluation of functional exercise capacity. For the SIX MINUTE WALK, a subject is asked to walk as far as possible and as fast as possible for 6 minutes. The result of the test is the total distance walked.

The SIX MINUTE WALK functional test 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 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 in the public domain. CDISC has included the 6 Minute Walk Test (SIX MINUTE WALK) as part of CDISC Data Standards. Hence, CDISC developed FTTESTCD and FTTEST for each task and question based on the actual text on the functional test. There may be many versions of this functional test, in the public domain or copyrighted. 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>)

Details about the SIX MINUTE WALK can be found in the following reference:

Goldman MD, Marrie RA, Cohen JA. Evaluation of the six-minute walk in multiple sclerosis subjects and healthy controls. *Multiple Sclerosis* 2008; 14: 383-390.

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 6 Minute Walk Test functional test are listed below.

6 Minute Walk Test (SIX MINUTE WALK): The SIX MINUTE WALK is a quantitative measure of functional capacity. The test measures the distance that a subject can quickly walk on a flat, hard surface in a period of 6 minutes. Subjects are allowed to use their typical assistive devices when performing this task.

1. The numerical value for the total distance a subject walked, measured at each minute (FTTESTCD=SIXMW101 - SIXMW106), is represented in FTORRES. The units, typically meters, are represented in FTORRESU.
2. Terminology:
 - a. FTTCAT, FTTESTCD and FTTEST are approved CDISC controlled terminology.
 - b. A full list of value sets for qualifier, result and unit fields is provided in Section 4: SDTM Mapping Strategy.

3.2 Example for 6 Minute Walk Test (SIX MINUTE WALK) FT Domain Model

The SIX MINUTE WALK example below shows the terminology used to implement the functional test in the FT domain. This example shows the data for one subject collected at one visit for a SIX MINUTE WALK 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 in FTORRES. This result is then transformed into a standard numeric score in FTSTRESN and a character representation of the standard numeric score in FTSTRESU.

Rows 1-6: Show the distance (in meters) that USUBJID=MS01-01 walked at each minute of the 6 Minute Walk Test. The assistive device the subject used during the test is represented in the SUPPFT dataset.

ft.xpt

Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTGRPID	FTTESTCD	FTTEST	FTCAT	FTORRES	FTORRESU	FTSTRESC	FTSTRESN
1	STUDYX	FT	MS01-01	1	1	SIXMW101	SIXMW1-Distance at 1 Minute	SIX MINUTE WALK	101	m	101	101
2	STUDYX	FT	MS01-01	2	1	SIXMW102	SIXMW1-Distance at 2 Minutes	SIX MINUTE WALK	201	m	201	201
3	STUDYX	FT	MS01-01	3	1	SIXMW103	SIXMW1-Distance at 3 Minutes	SIX MINUTE WALK	299	m	299	299
4	STUDYX	FT	MS01-01	4	1	SIXMW104	SIXMW1-Distance at 4 Minutes	SIX MINUTE WALK	396	m	396	396
5	STUDYX	FT	MS01-01	5	1	SIXMW105	SIXMW1-Distance at 5 Minutes	SIX MINUTE WALK	493	m	493	493
6	STUDYX	FT	MS01-01	6	1	SIXMW106	SIXMW1-Distance at 6 Minutes	SIX MINUTE WALK	597	m	597	597

ft.xpt (cont)

Row	FTSTRESU	FTBLFL	VISITNUM	FTDTC
1 (cont)	m	Y	1	2014-03-10
2 (cont)	m	Y	1	2014-03-10
3 (cont)	m	Y	1	2014-03-10
4 (cont)	m	Y	1	2014-03-10
5 (cont)	m	Y	1	2014-03-10
6 (cont)	m	Y	1	2014-03-10

The standard terminology for QNAM and QLABEL are listed below.

Row 1: Shows that USUBJID=MS01-01 used a cane while performing the 6 Minute Walk Test. In this example, FTGRPID is used to link this SUPPFT record to the 6 result records in FT. FTGRPID groups the FT records together by FTCAT and VISITNUM for an USUBJID.

suppft.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	STUDYX	FT	MS01-01	FTGRPID	1	FTASSTDV	Assistance Device	CANE	CRF	INVESTIGATOR

4 SDTM Mapping Strategy

SIX MINUTE WALK 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 functional test to the SDTM FT domain. The units in FTORRESU and FTSTRESU may vary by site, but should use CDISC controlled terminology.

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
FTASSTDV	Assistance Device	FT

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