Timed 25-Foot Walk (T25FW)

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
2014-03-07	1.0	Timed 25-Foot Walk (T25FW) Draft
2014-03-26	1.0	Timed 25-Foot Walk (T25FW)

1 Introduction

This document describes the CDISC implementation of the Timed 25-Foot Walk (T25FW) functional test, a quantitative measure of lower extremity function. It is the first component of the Multiple Sclerosis Functional Composite (MSFC) administered at each visit. For the T25FW, a subject is timed while walking 25 feet as quickly as possible, but safely.

The T25FW functional test preceded the CDISC CDASH CRF standards and, based on its copyrighted 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 copyright approved. CDISC has included the Timed 25-Foot Walk (T25FW) 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)

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.

CDISC acknowledges the National Multiple Sclerosis Society for the agreement to include the Timed 25-Foot Walk (T25FW) in the CDISC data standards.

Details about the T25FW can be found in the following reference:

- Fischer JS, Jak AJ, Kniker JE, Rudick RA, Cutter G, National Multiple Sclerosis Society Outcome Assessment Task Force. Administration and Scoring Manual for the Multiple Sclerosis Functional Composite. Demos Publications, New York. In press 1999.

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 Timed 25-Foot Walk functional test are listed below.

Timed 25-Foot Walk (T25FW): The T25FW is a quantitative mobility and leg function performance test based on the time it takes a subject to walk 25 feet as quickly, but safely, as possible. The T25FW typically consists of two trials, where the task is immediately administered again by having the subject walk back the same distance. Subjects are allowed to use assistive devices when performing this task.

1. The numerical value for the time it takes to walk 25 feet (FTTESTCD=T25FW101) is recorded in FTORRES, FTSTRESC, and FTSTRESN. The units, typically seconds, are recorded in FTORRESU and FTSTRESU. Record any circumstances that affected the subject's performance in SUPPFT where QNAM=FTAFFPER, using FTSEQ to link this SUPPFT record to the affected performance time record in FT.
2. If one of the "trial was not completed" options was checked, this is recorded as FTSTAT = "NOT DONE" with FTREASND = "PHYSICAL LIMITATIONS" or "OTHER", depending on which option was selected. The "specify" text is recorded in SUPPFT where QNAM=FTREASDL, using FTSEQ to link this SUPPFT record to the "NOT DONE" record in FT.
3. The response to the "more than two attempts" question (FTTESTCD=T25FW102) is recorded in FTORRES as "Yes" or "No" and in FTSTRESC as "Y" or "N". If the response was yes, record the reason(s) in SUPPFT where QNAM=FTREASM2, using FTSEQ to link this SUPPFT record to the "more than two attempts" record in FT.
4. The functional test evaluator is stored in FTEVAL. For T25FW, the evaluator is usually defined as the INVESTIGATOR. Additional identifying information to further distinguish the rater in FTEVAL should be stored in FTEVALID. An example is rater initials, which are sometimes captured electronically and not on the CRF.
5. Terminology:
   a. FTCAT, 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 Timed 25-Foot Walk (T25FW) FT Domain Model

The T25FW example below shows the terminology used to implement the functional test in the FT domain. This example shows the data for two subjects collected at one visit for a T25FW 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. When applicable, 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 times (in seconds) that it took for USUBJID=MS01-01 to complete Trials 1 and 2. The trial number is indicated by FTREPNUM. The testing condition as well as the circumstances that affected the subject's performance for the two trials can be found in Rows 1 – 6 of the SUPPFT dataset.

Row 3: Shows that it took USUBJID=MS01-01 more than two attempts to get two successful trials. The reason for more than two attempts can be found in Row 7 of the SUPPFT dataset.

Row 4: Shows the time (in seconds) that it took for USUBJID=MS01-02 to complete Trial 1. The trial number is indicated by FTREPNUM. The testing condition as well as the circumstances that affected the subject's performance for the trial can be found in Rows 8 – 12 of the SUPPFT dataset.

Row 5: Shows that USUBJID=MS01-02 was unable to complete Trial 2 due to physical limitations. FTSTAT is populated with NOT DONE and FTREASND is populated with PHYSICAL LIMITATIONS. Further information about the reason not done is stored in Row 13 of the SUPPFT dataset. Because the trial was not completed, data regarding circumstances that affected performance was not collected and thus is not represented in the below table.

ft.xpt

Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTGRPID	FTTESTCD	FTTEST	FTCAT	FTORRES	FTORRESU	FTSTRESC	FTSTRESN
1	STUDYX	FT	MS01-01	1	1	T25FW101	T25FW1-Time to Complete 25-Foot Walk	T25FW	32.4	sec	32.4	32.4
2	STUDYX	FT	MS01-01	2	1	T25FW101	T25FW1-Time to Complete 25-Foot Walk	T25FW	47.9	sec	47.9	47.9
3	STUDYX	FT	MS01-01	3	1	T25FW102	T25FW1-More Than Two Attempts	T25FW	Yes		Y	
4	STUDYX	FT	MS01-02	1	1	T25FW101	T25FW1-Time to Complete 25-Foot Walk	T25FW	151.3	sec	151.3	151.3
5	STUDYX	FT	MS01-02	2	1	T25FW101	T25FW1-Time to Complete 25-Foot Walk	T25FW				

ft.xpt (cont)

Row	FTSTRESU	FTSTAT	FTREASND	FTBLFL	FTEVAL	FTEVALID	VISITNUM	FTDTC	FTREPNUM
1 (cont)	sec			Y	INVESTIGATOR	ELH	1	2013-08-16	1
2 (cont)	sec			Y	INVESTIGATOR	ELH	1	2013-08-16	2
3 (cont)				Y	INVESTIGATOR	ELH	1	2013-08-16	
4 (cont)	sec			Y	INVESTIGATOR	ELH	1	2013-08-16	1
5 (cont)		NOT DONE	PHYSICAL LIMITATIONS	Y	INVESTIGATOR	ELH	1	2013-08-16	2

The standard terminology for QNAM and QLABEL are listed below.

Rows 1-4: Show information about the testing conditions for USUBJID=MS01-01. Because these conditions are applicable to both trials of the task, the information is connected to the parent domain via FTGRPID.

Row 5: Shows that no circumstances affected the performance of USUBJID=MS01-01 for Trial 1. This record is created because, in this example, the investigator actually recorded the value "none" on the CRF. If the "circumstances" field had been left blank, then this record would not be created.

Row 6: Shows the circumstances that affected the performance of USUBJID=MS01-01 for Trial 2.

Row 7: Shows the reason USUBJID=MS01-01 had more than two attempts was that the examiner forgot to reset the stopwatch in between the trials.

Rows 8-11: Show information about the testing conditions for USUBJID=MS01-02. Because these conditions are applicable to both trials of the task, the information is connected to the parent domain via FTGRPID.

Row 12: Shows the circumstance that affected the performance of USUBJID=MS01-02 for Trial 1.

Row 13: Shows that USUBJID=MS01-02 did not complete Trial 2 due to fatigue.

suppft.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	STUDYX	FT	MS01-01	FTGRPID	1	FTPTAFO	Patient Wore Ankle-foot Orthosis	Y
2	STUDYX	FT	MS01-01	FTGRPID	1	FTASSTUD	Was Assistive Device Used	Y
3	STUDYX	FT	MS01-01	FTGRPID	1	FTASSTTY	Assistance Type	UNILATERAL ASSISTANCE
4	STUDYX	FT	MS01-01	FTGRPID	1	FTASSTDV	Assistance Device	CANE
5	STUDYX	FT	MS01-01	FTSEQ	1	FTAFFPER	Circumstance Affected Performance	NONE
6	STUDYX	FT	MS01-01	FTSEQ	2	FTAFFPER	Circumstance Affected Performance	SUBJECT TRIPPED BUT DID NOT FALL
7	STUDYX	FT	MS01-01	FTSEQ	3	FTREASM2	Reason More Than Two Attempted Trials	EXAMINER FORGOT TO RESET STOPWATCH IN BETWEEN TRIALS
8	STUDYX	FT	MS01-02	FTGRPID	1	FTPTAFO	Patient Wore Ankle-foot Orthosis	N
9	STUDYX	FT	MS01-02	FTGRPID	1	FTASSTUD	Was Assistive Device Used	Y
10	STUDYX	FT	MS01-02	FTGRPID	1	FTASSTTY	Assistance Type	BILATERAL ASSISTANCE
11	STUDYX	FT	MS01-02	FTGRPID	1	FTASSTDV	Assistance Device	WALKER/ROLLATOR
12	STUDYX	FT	MS01-02	FTSEQ	1	FTAFFPER	Circumstance Affected Performance	SUBJECT PAUSED TO REST HALFWAY THROUGH TRIAL
13	STUDYX	FT	MS01-02	FTSEQ	2	FTREASDL	Reason Not Done Details	SUBJECT TOO FATIGUED TO COMPLETE ANOTHER TRIAL

4 SDTM Mapping Strategy

T25FW 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. It also provides guidance on how the result variables (FTORRES, FTSTRESC, and FTSTRESN) should be populated for the functional test.

FTCAT
T25FW

FTTESTCD=T25FW102 FTTEST=T25FW1-More Than Two Attempts

FTORRES	FTSTRESC
Yes	Y
No	N

Note: For FTTESTCD=T25FW102, FTSTRESN is not populated.

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
FTPTAFO	Patient Wore Ankle-foot Orthosis	FT
FTASSTUD	Was Assistive Device Used	FT
FTASSTTY	Assistance Type	FT
FTASSTDV	Assistance Device	FT
FTAFFPER	Circumstance Affected Performance	FT
FTREASM2	Reason More Than Two Attempted Trials	FT
FTREASDL	Reason Not Done Details	FT

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