

New Domain Specification for SDTM 3.3

FT – Functional Tests

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FT – Functional Tests

- ✓ Includes named, stand-alone task-based evaluations
- ✓ To provide an assessment of mobility, dexterity, and/or cognitive ability
- ✓ Objective measurement of the performance of the task by the subject
- ✓ Functional Tests have documented methods for administration and analysis and require a subject to perform specific activities
- ✓ Most often, functional tests are direct quantitative measurements

FT – Functional Tests

- ✓ Examples of Functional Tests:
 - Timed 25-Foot Walk
 - 9-Hole Peg Test
 - Paced Auditory Serial Addition Test
- ✓ The following tests do not belong to FT:
 - Vision Tests
 - Hearing Tests
 - Pulmonary Function Tests

FT – Functional Tests

- ✓ Findings Domain
- ✓ Testing conditions should be submitted in SUPPFT
- ✓ The name of the functional test is recorded in FTCAT and values of FTTESTCD/FTTEST are unique within FTCAT.
Naming rules for FTCAT, FTTESTCD and FTTEST are available at www.cdisc.org/{to be created}
- ✓ For list of functional tests that have controlled terminology defined, access www.cdisc.org/terminology

FT – Functional Tests

- ✓ New variable:

FTREPNUM (Repetition Number) – Timing (perm)

Used to indicate the chronological order of repeated tests. Enables the reuse of FTTESTCD and FTTEST values when tests are repeated

- ✓ The following Qualifiers would not generally be used in FT:

--BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI,
--STNRC, --NRIND, --XFN, --LOINC, --SPEC, --SPCCND,
--FAST, --TOX, --TOXGR, --SEV

FT – Functional Tests

- ✓ A functional test is either in the public domain or has copyright requirements
- ✓ A copyrighted functional test requires that CDISC obtain permission from the copyright holder before implementing them in a published CDISC FT data standard
- ✓ That permissions only relates to creation of the CDISC FT data standard, not the use of the functional test in clinical studies

FT – Examples

Example 1: Shows the data from the Timed 25-Foot Walk test from one subject at one visit. The result of the test is the amount of time measured in seconds.

ft.xpt

Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTGRPID	FTTESTCD	FTTEST	FTCAT	FTORRES	FTORRESU
1	STUDYX	FT	MS01-01	1	1	T25FW101	T25FW1-Time to Complete 25-Foot Walk	T25FW	150.3	sec
2	STUDYX	FT	MS01-01	2	1	T25FW101	T25FW1-Time to Complete 25-Foot Walk	T25FW	170.1	sec
3	STUDYX	FT	MS01-01	3	1	T25FW102	T25FW1-More Than Two Attempts	T25FW	Yes	

Row	FTSTRESC	FTSTRESN	FTSTRESU	FTDTC	FTREPNUM
1 (cont)	150.3	150.3	sec	2011-03-20	1
2 (cont)	170.1	170.1	sec	2011-03-20	2
3 (cont)	Y			2011-03-20	

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
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	LEG PAIN
7	STUDYX	FT	MS01-01	FTSEQ	3	FTREASM2	Reason More Than Two Attempted Trials	EXAMINER FORGOT TO RESET STOPWATCH IN BETWEEN TRIALS

FT – Examples

Example 2: Shows the data from the 9-Hole Peg Test (9-HPT) from one subject at one visit. The result of the test is the amount of time measured in seconds.

ft.xpt

Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTTESTCD	FTTEST	FTCAT	FTSCAT	FTORRES
1	STUDYX	FT	MS01-01	1	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	DOMINANT HAND	50.7
2	STUDYX	FT	MS01-01	2	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	DOMINANT HAND	65.4
3	STUDYX	FT	MS01-01	3	NHPT0102	NHPT01-More Than Two Attempts	NHPT	DOMINANT HAND	Yes
4	STUDYX	FT	MS01-01	4	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	NON-DOMINANT HAND	75.1
5	STUDYX	FT	MS01-01	5	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	NON-DOMINANT HAND	

Row	FTORRESU	FTSTRESC	FTSTRESN	FTSTRESU	FTSTAT	FTREASND	VISITNUM	FTDIC	FTREPNUM
1 (cont)	sec	50.7	50.7	sec			1	2011-03-20	1
2 (cont)	sec	65.4	65.4	sec			1	2011-03-20	2
3 (cont)		Y					1	2011-03-20	
4 (cont)	sec	75.1	75.1	sec			1	2011-03-20	1
5 (cont)					NOT DONE	PHYSICAL LIMITATIONS	1	2011-03-20	2

suppft.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	STUDYX	FT	MS01-01	FTSEQ	1	FTAFFPER	Circumstance Affected Performance	NONE
2	STUDYX	FT	MS01-01	FTSEQ	2	FTAFFPER	Circumstance Affected Performance	SUBJECT TIRED
3	STUDYX	FT	MS01-01	FTSEQ	3	FTREASM2	Reason More Than Two Attempted Trials	HAND PAIN
4	STUDYX	FT	MS01-01	FTSEQ	4	FTAFFPER	Circumstance Affected Performance	SUBJECT TIRED
5	STUDYX	FT	MS01-01	FTSEQ	5	FTREASDL	Reason Not Done Details	FATIGUE

sc.xpt

Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCTESTCD	SCTEST	SCORRES	SCDTC
1	STUDYX	SC	MS01-01	1	DOMHAND	Dominant Hand	RIGHT	2011-03-20

Questions?



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