



Timed Up and Go (TUG)

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	Timed Up and Go (TUG) Draft
2014-05-21	1.0	Timed Up and Go (TUG)

1 Introduction

This document describes the CDISC implementation of the Timed Up and Go (TUG) functional test, a quantitative measure of functional mobility, balance, walking ability, and fall risk.

The TUG 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 Timed Up and Go (TUG) 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 TUG test can be found in the following reference:

Podsiadlo D, Richardson S. The Timed “Up & Go”: a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc.* 1991; 39:142–148.

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 Up and Go functional test are listed below.

Timed Up and Go (TUG): The TUG is a quantitative measure of functional mobility based on the time it takes an individual to stand up from a standard arm chair, walk a distance of 3 meters, turn, walk back to the chair, and sit down again. The subject wears his regular footwear and uses his customary walking aid while performing the test.

1. The numerical value for the total time a subject takes to perform the TUG test (FTTESTCD=TUG0101) is represented in FTORRES. The units, typically seconds, are represented in FTORRESU. The date the test was performed on is recorded in FTDTTC.
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 Timed Up and Go (TUG) FT Domain Model

The TUG 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 two separate visits for a TUG functional test. The example uses CDISC controlled terminology for FTTESTCD, FTTEST, and FTCAT. FTBLFL is Y when 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 FTSTRESC.

Rows 1-2: Show the result times (in seconds) that it took for USUBJID=MS01-01 to complete the TUG test at visits 1 and 2, respectively.

Rows 3-4: Show the result times (in seconds) that it took for USUBJID=MS01-02 to complete the TUG test at visits 1 and 2, respectively.

ft.xpt

Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTTESTCD	FTTEST	FTCAT	FTORRES	FTORRESU	FTSTRESC	FTSTRESN	FTSTRESU
1	STUDYX	FT	MS01-01	1	TUG0101	TUG01-Time to Complete TUG Test	TUG	8.9	sec	8.9	8.9	sec
2	STUDYX	FT	MS01-01	2	TUG0101	TUG01-Time to Complete TUG Test	TUG	9.2	sec	9.2	9.2	sec
3	STUDYX	FT	MS01-02	1	TUG0101	TUG01-Time to Complete TUG Test	TUG	95.1	sec	95.1	95.1	sec
4	STUDYX	FT	MS01-02	2	TUG0101	TUG01-Time to Complete TUG Test	TUG	98.7	sec	98.7	98.7	sec

ft.xpt (cont)

Row	FTBLFL	VISITNUM	FTDTC
1 (cont)	Y	1	2013-08-16
2 (cont)		2	2014-02-21
3 (cont)	Y	1	2013-08-16
4 (cont)		2	2014-02-21

4 SDTM Mapping Strategy

TUG 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 unit variables (FTORRESU and FTSTRESU) should be populated for the functional test.

FTTESTCD=TUG0101 FTTEST=TUG01-Time to Complete TUG Test

FTORRESU	FTSTRESU
sec	sec

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