



Hauser Ambulation Index

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
2014-04-21	1.0	Hauser Ambulation Index Draft
2014-04-23	1.0	Hauser Ambulation Index

1 Introduction

This document describes the CDISC implementation of the Hauser Ambulation Index functional test, a rating scale developed by Hauser et al. (1983) to assess mobility by evaluating the time and degree of assistance required to walk 25 feet.

The Hauser Ambulation Index 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 Hauser Ambulation Index 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 Stephen L. Hauser for the agreement to include the Hauser Ambulation Index in the CDISC data standards.

The reference for this functional test is:

- Hauser SL, Dawson DM, Leirich JR, Beal MF, Kevy SV, Propper RD, Mills JA, Weiner HL. Intensive immunosuppression in progressive multiple sclerosis. A randomized, three-arm study of high-dose intravenous cyclophosphamide, plasma exchange, and ACTH. N Engl J Med. 1983 Jan 27;308(4):173-80.

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 Hauser Ambulation Index functional test are listed below.

Hauser Ambulation Index: It is a rating scale used to assess mobility by evaluating the time and degree of assistance required to walk 25 feet. Scores range from 0 (asymptomatic and fully active) to 9 (restricted to wheelchair). The patient is asked to walk a marked 25-foot course as quickly and safely as possible. The examiner then scores the patient according to the time and type of assistance (e.g., cane, walker, crutches) needed. Total administration time should be approximately 1 – 5 minutes, depending on the ability of the patient.

1. The scale points include a rating (e.g. “8”) and a definition of what is represented by the rating (e.g. “Restricted to wheelchair; able to transfer self independently”). For the Hauser Ambulation Index, FTORRES is populated with the rating definition. FTSTRESC and FTSTRESN are populated with the numerical rating only.
2. The functional test evaluator is stored in FTEVAL. For the Hauser Ambulation Index, 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.
3. Terminology:
 - a. FTCAT, FTTESTCD and FTTEST are approved CDISC controlled terminology.
 - b. A full list of value sets for qualifier and result fields is provided in Section 4: SDTM Mapping Strategy.

3.2 Example for Hauser Ambulation Index FT Domain Model

The Hauser Ambulation Index example below shows the terminology used to implement the functional test in the FT domain. This example shows the data for ten subjects collected at one visit for a Hauser Ambulation Index functional test. The example uses CDISC controlled terminology for FTTESTCD, FTTEST, and FTCAT. FTBLFL is NULL based on VISITNUM=2. 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 1-10: Show the question from the Hauser Ambulation Index form. An example of each possible answer is shown.

ft.xpt

Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTTESTCD	FTTEST	FTCAT	FTORRES	FTSTRESC
1	STUDYX	FT	P0001	1	HAI0101	HAI01-Ambulation Index	HAUSER AMBULATION INDEX	Asymptomatic; fully active.	0
2	STUDYX	FT	P0002	1	HAI0101	HAI01-Ambulation Index	HAUSER AMBULATION INDEX	Walks normally, but reports fatigue that interferes with athletic or other demanding activities.	1
3	STUDYX	FT	P0003	1	HAI0101	HAI01-Ambulation Index	HAUSER AMBULATION INDEX	Abnormal gait or episodic imbalance; gait disorder is noticed by family and friends; able to walk 25 feet (8 meters) in 10 seconds or less.	2
4	STUDYX	FT	P0004	1	HAI0101	HAI01-Ambulation Index	HAUSER AMBULATION INDEX	Walks independently; able to walk 25 feet in 20 seconds or less.	3
5	STUDYX	FT	P0005	1	HAI0101	HAI01-Ambulation Index	HAUSER AMBULATION INDEX	Requires unilateral support (cane or single crutch) to walk; walks 25 feet in 20 seconds or less.	4
6	STUDYX	FT	P0006	1	HAI0101	HAI01-Ambulation Index	HAUSER AMBULATION INDEX	Requires bilateral support (canes, crutches, or walker) and walks 25 feet in 20 seconds or less; or requires unilateral support but needs more than 20 seconds to walk 25 feet.	5
7	STUDYX	FT	P0007	1	HAI0101	HAI01-Ambulation Index	HAUSER AMBULATION INDEX	Requires bilateral support and more than 20 seconds to walk 25 feet; may use wheelchair on occasion.	6
8	STUDYX	FT	P0008	1	HAI0101	HAI01-Ambulation Index	HAUSER AMBULATION INDEX	Walking limited to several steps with bilateral support; unable to walk 25 feet; may use wheelchair for most activities.	7
9	STUDYX	FT	P0009	1	HAI0101	HAI01-Ambulation Index	HAUSER AMBULATION INDEX	Restricted to wheelchair; able to transfer self independently.	8
10	STUDYX	FT	P0010	1	HAI0101	HAI01-Ambulation Index	HAUSER AMBULATION INDEX	Restricted to wheelchair; unable to transfer self independently.	9

ft.xpt (cont)

Row	FTSTRESN	FTBLFL	FTEVAL	VISITNUM	FTDTC
1 (cont)	0		INVESTIGATOR	2	2013-11-16
2 (cont)	1		INVESTIGATOR	2	2013-11-16
3 (cont)	2		INVESTIGATOR	2	2013-11-16
4 (cont)	3		INVESTIGATOR	2	2013-11-16
5 (cont)	4		INVESTIGATOR	2	2013-11-16
6 (cont)	5		INVESTIGATOR	2	2013-11-16
7 (cont)	6		INVESTIGATOR	2	2013-11-16
8 (cont)	7		INVESTIGATOR	2	2013-11-16
9 (cont)	8		INVESTIGATOR	2	2013-11-16
10 (cont)	9		INVESTIGATOR	2	2013-11-16

4 SDTM Mapping Strategy

Hauser Ambulation Index 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.

FTTESTCD=HAI0101

FTTEST=HAI01-Ambulation Index

FTORRES	FTSTRESC	FTSTRESN
Asymptomatic; fully active.	0	0
Walks normally, but reports fatigue that interferes with athletic or other demanding activities.	1	1
Abnormal gait or episodic imbalance; gait disorder is noticed by family and friends; able to walk 25 feet (8 meters) in 10 seconds or less.	2	2
Walks independently; able to walk 25 feet in 20 seconds or less.	3	3
Requires unilateral support (cane or single crutch) to walk; walks 25 feet in 20 seconds or less.	4	4
Requires bilateral support (canes, crutches, or walker) and walks 25 feet in 20 seconds or less; or requires unilateral support but needs more than 20 seconds to walk 25 feet.	5	5
Requires bilateral support and more than 20 seconds to walk 25 feet; may use wheelchair on occasion.	6	6
Walking limited to several steps with bilateral support; unable to walk 25 feet; may use wheelchair for most activities.	7	7
Restricted to wheelchair; able to transfer self independently.	8	8
Restricted to wheelchair; unable to transfer self independently.	9	9

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