



# Nine-Hole Peg Test (NHPT)

## Functional Test Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials

Prepared by  
Multiple Sclerosis Outcomes Assessment Consortium  
and the CDISC Functional Test Sub-team

---

### 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	Nine-Hole Peg Test (NHPT) Draft
2014-04-02	1.0	Nine-Hole Peg Test (NHPT)

## 1 Introduction

This document describes the CDISC implementation of the Nine-Hole Peg Test (NHPT) functional test, a quantitative measure of upper extremity (arm and hand) function. It is the second component of the Multiple Sclerosis Functional Composite (MSFC) administered at each visit.

The NHPT 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 Nine-Hole Peg Test (NHPT) 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 Nine-Hole Peg Test (NHPT) in the CDISC data standards.

Details about the NHPT 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 Nine-Hole Peg Test functional test are listed below.

Nine-Hole Peg Test (NHPT): The NHPT is a brief, standardized, quantitative test of upper extremity function based on the time it takes a subject to pick up nine pegs one at a time as quickly as possible, put them in the nine holes on a board, and, once they are in the holes, remove them again as quickly as possible one at a time. The NHPT typically consists of two trials per hand, two consecutive trials of the dominant hand followed immediately by two consecutive trials of the non-dominant hand.

1. The hand that was used during a trial is recorded in FTSCAT as “DOMINANT HAND” or “NON-DOMINANT HAND”. The information about which hand is dominant is recorded in the Subject Characteristics (SC) domain, where SCTESTCD=DOMHAND, SCTEST = “Dominant Hand”, and SCORRES = “RIGHT” or “LEFT”.
2. The numerical value for the time to complete a trial for one hand (FTTESTCD=NHPT0101) 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.
3. 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.
4. The response to the “more than two attempts” question (FTTESTCD=NHPT0102) 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.
5. The functional test evaluator is stored in FTEVAL. For NHPT, 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.
6. Terminology:
  - a. FTSCAT, 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 Nine-Hole Peg Test (NHPT) FT Domain Model

The NHPT example below shows the terminology used to implement the functional test in the FT domain. This example shows the data for two subjects (one left-handed subject and one right-handed subject) collected at one visit for a NHPT 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 using the dominant hand. The trial number is indicated by FTREPNUM. The circumstances that affected the subject's performance for the two trials can be found in Rows 1 – 2 of the SUPPFT dataset.
- Row 3:** Shows that it did not take USUBJID=MS01-01 more than two attempts to get two successful trials using the dominant hand.
- Rows 4-5:** Show the times (in seconds) that it took for USUBJID=MS01-01 to complete Trials 1 and 2 using the non-dominant hand. The trial number is indicated by FTREPNUM. The circumstances that affected the subject's performance for the two trials can be found in Rows 3 – 4 of the SUPPFT dataset.
- Row 6:** Shows that it took USUBJID=MS01-01 more than two attempts to get two successful trials using the non-dominant hand. The reason for more than two attempts can be found in Row 5 of the SUPPFT dataset.
- Rows 7-8:** Show the times (in seconds) that it took for USUBJID=MS01-02 to complete Trials 1 and 2 using the dominant hand. The trial number is indicated by FTREPNUM. The circumstances that affected the subject's performance for the two trials can be found in Rows 6 – 7 of the SUPPFT dataset.
- Row 9:** Shows that it took USUBJID=MS01-02 more than two attempts to get two successful trials using the dominant hand. The reason for more than two attempts can be found in Row 8 of the SUPPFT dataset.
- Row 10:** Shows the time (in seconds) that it took for USUBJID=MS01-02 to complete Trial 1 using the non-dominant hand. The trial number is indicated by FTREPNUM. The circumstances that affected the subject's performance for the trial can be found in Row 9 of the SUPPFT dataset.
- Row 11:** Shows that USUBJID=MS01-02 was unable to complete Trial 2 using the non-dominant hand 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 10 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	FTTESTCD	FTTEST	FTCAT	FTSCAT	FTORRES	FTORRESU	FTSTRESC
1	STUDYX	FT	MS01-01	1	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	DOMINANT HAND	113.6	sec	113.6
2	STUDYX	FT	MS01-01	2	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	DOMINANT HAND	109.7	sec	109.7
3	STUDYX	FT	MS01-01	3	NHPT0102	NHPT01-More Than Two Attempts	NHPT	DOMINANT HAND	No		N
4	STUDYX	FT	MS01-01	4	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	NON-DOMINANT HAND	148.2	sec	148.2
5	STUDYX	FT	MS01-01	5	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	NON-DOMINANT HAND	121.3	sec	121.3
6	STUDYX	FT	MS01-01	6	NHPT0102	NHPT01-More Than Two Attempts	NHPT	NON-DOMINANT HAND	Yes		Y

Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTTESTCD	FTTEST	FTCAT	FTSCAT	FTORRES	FTORRESU	FTSTRESC
7	STUDYX	FT	MS01-02	1	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	DOMINANT HAND	256.3	sec	256.3
8	STUDYX	FT	MS01-02	2	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	DOMINANT HAND	282.1	sec	282.1
9	STUDYX	FT	MS01-02	3	NHPT0102	NHPT01-More Than Two Attempts	NHPT	DOMINANT HAND	Yes		Y
10	STUDYX	FT	MS01-02	4	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	NON-DOMINANT HAND	288.9	sec	288.9
11	STUDYX	FT	MS01-02	5	NHPT0101	NHPT01-Time to Complete 9-Hole Peg Test	NHPT	NON-DOMINANT HAND			

*ft.xpt (cont)*

Row	FTSTRESN	FTSTRESU	FTSTAT	FTREASND	FTBLFL	FTEVAL	FTEVALID	VISITNUM	FTDTC	FTREPNUM
1 (cont)	113.6	sec			Y	INVESTIGATOR	LDH	1	2013-08-16	1
2 (cont)	109.7	sec			Y	INVESTIGATOR	LDH	1	2013-08-16	2
3 (cont)					Y	INVESTIGATOR	LDH	1	2013-08-16	
4 (cont)	148.2	sec			Y	INVESTIGATOR	LDH	1	2013-08-16	1
5 (cont)	121.3	sec			Y	INVESTIGATOR	LDH	1	2013-08-16	2
6 (cont)					Y	INVESTIGATOR	LDH	1	2013-08-16	
7 (cont)	256.3	sec			Y	INVESTIGATOR	LDH	1	2013-08-16	1
8 (cont)	282.1	sec			Y	INVESTIGATOR	LDH	1	2013-08-16	2
9 (cont)					Y	INVESTIGATOR	LDH	1	2013-08-16	
10 (cont)	288.9	sec			Y	INVESTIGATOR	LDH	1	2013-08-16	1
11 (cont)			NOT DONE	PHYSICAL LIMITATIONS	Y	INVESTIGATOR	LDH	1	2013-08-16	2

The standard terminology for QNAM and QLABEL are listed below.

- Rows 1-2:** Show the circumstances that affected the performance of USUBJID=MS01-01 for Trials 1 and 2, respectively, using the dominant hand. These records are created because, in this example, the investigator actually recorded the value “none” on the CRF. If the “circumstances” fields had been left blank, then these records would not be created.
- Rows 3-4:** Show the circumstances that affected the performance of USUBJID=MS01-01 for Trials 1 and 2, respectively, using the non-dominant hand. Record 4 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 5:** Shows the reason USUBJID=MS01-01 had more than two attempts using the non-dominant hand was that the examiner forgot to reset the stopwatch in between the trials.
- Rows 6-7:** Show the circumstances that affected the performance of USUBJID=MS01-02 for Trials 1 and 2, respectively, using the dominant hand.
- Row 8:** Shows the reason USUBJID=MS01-02 had more than two attempts using the dominant hand was that the subject knocked the entire apparatus on the floor.
- Row 9:** Shows the circumstance that affected the performance of USUBJID=MS01-02 for Trial 1 using the non-dominant hand.

**Row 10:** Shows that USUBJID=MS01-02 did not complete Trial 2 using the non-dominant hand because the subject could not complete the trial within the time limit.

*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	NONE
3	STUDYX	FT	MS01-01	FTSEQ	4	FTAFFPER	Circumstance Affected Performance	SUBJECT TALKED DURING THE TASK
4	STUDYX	FT	MS01-01	FTSEQ	5	FTAFFPER	Circumstance Affected Performance	NONE
5	STUDYX	FT	MS01-01	FTSEQ	6	FTREASM2	Reason More Than Two Attempted Trials	EXAMINER FORGOT TO RESET STOPWATCH IN BETWEEN TRIALS
6	STUDYX	FT	MS01-02	FTSEQ	1	FTAFFPER	Circumstance Affected Performance	SUBJECT DROPPED A PEG
7	STUDYX	FT	MS01-02	FTSEQ	2	FTAFFPER	Circumstance Affected Performance	SUBJECT KNOCKED A PEG OUT OF A HOLE WHILE PLACING ANOTHER PEG
8	STUDYX	FT	MS01-02	FTSEQ	3	FTREASM2	Reason More Than Two Attempted Trials	SUBJECT KNOCKED ENTIRE APPARATUS ON THE FLOOR
9	STUDYX	FT	MS01-02	FTSEQ	4	FTAFFPER	Circumstance Affected Performance	SUBJECT DROPPED SEVERAL PEGS
10	STUDYX	FT	MS01-02	FTSEQ	5	FTREASDL	Reason Not Done Details	SUBJECT COULD NOT COMPLETE TRIAL WITHIN TIME LIMIT

The information about which hand is the subject's dominant hand is stored in the Subject Characteristics Domain.

**Row 1:** Shows that the left hand of USUBJID=MS01-01 is the dominant hand.

**Row 2:** Shows that the right hand of USUBJID=MS01-02 is the dominant hand.

*sc.xpt*

Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCTESTCD	SCTEST	SCORRES	SCSTRESC	SCDTC
1	STUDYX	SC	MS01-01	1	DOMHAND	Dominant Hand	LEFT	LEFT	2013-08-16
2	STUDYX	SC	MS01-02	1	DOMHAND	Dominant Hand	RIGHT	RIGHT	2013-08-16

## 4 SDTM Mapping Strategy

NHPT 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 and SC domains. It also provides guidance on how the result variables (FTORRES, FTSTRESC, FTSTRESN, SCORRES, and SCSTRESC) should be populated for the functional test.

FTCAT
NHPT

FTSCAT
DOMINANT HAND
NON-DOMINANT HAND

**FTTESTCD=NHPT0102      FTTEST=NHPT01-More Than Two Attempts**

FTORRES	FTSTRESC
Yes	Y
No	N

*Note: For FTTESTCD=NHPT0102, FTSTRESN is not populated.*

**SCTESTCD=DOMHAND      SCTestest=Dominant Hand**

SCORRES	SCSTRESC
LEFT	LEFT
RIGHT	RIGHT



## 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.

<b>QNAM</b>	<b>QLABEL</b>	<b>Applicable Domains</b>
FTAFFPER	Circumstance Affected Performance	FT
FTREASM2	Reason More Than Two Attempted Trials	FT
FTREASDL	Reason Not Done Details	FT

**End of Document**