



Paced Auditory Serial Addition Test (PASAT)

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	Paced Auditory Serial Addition Test (PASAT) Draft
2014-04-09	1.0	Paced Auditory Serial Addition Test (PASAT)

1 Introduction

This document describes the CDISC implementation of the Paced Auditory Serial Addition Test (PASAT) functional test, a measure of cognitive function that specifically assesses auditory information processing speed and flexibility, as well as calculation ability. It is the third and last component of the Multiple Sclerosis Functional Composite (MSFC) administered at each visit.

The PASAT 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 Paced Auditory Serial Addition Test (PASAT) 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 Paced Auditory Serial Addition Test (PASAT) in the CDISC data standards.

Details about the PASAT 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 Paced Auditory Serial Addition Test functional test are listed below.

Paced Auditory Serial Addition Test (PASAT): The PASAT is a measure of cognitive function that specifically assesses auditory information processing speed and flexibility, as well as calculation ability. Single digits are presented using an audiocassette tape or compact disc to control the rate of stimulus presentation, such as every 3 seconds, every 2 seconds, etc. The subject must add each new digit to the one immediately prior to it. The PASAT generally has alternate testing forms and the order of these should be counterbalanced across testing sessions to minimize familiarity with the stimulus items.

1. The rate of stimulus presentation is recorded in FTSCAT as “3 SECONDS”, “2 SECONDS”, etc. When a study uses alternate testing forms across testing sessions, the information about the specific form used during a session (e.g., “FORM A” or “FORM B”) is recorded in SUPPFT where QNAM=FTFORM, using FTGRPID to link this SUPPFT record to the result records in FT.
2. The minimum and maximum number of correct sums that the subject can give are recorded in SUPPFT where QNAM=RNGVALLO and RNGVALHI, using FTTESTCD to link this SUPPFT record to the result records in FT.
3. The number of correct answers (FTTESTCD=PASAT101), the percentage of correct answers (FTTESTCD=PASAT102), and the supplemental scores (FTTESTCD=PASAT104 – PASAT107) for a test are recorded in FTORRES, FTSTRESC, and FTSTRESN. Record any circumstances that affected the subject’s performance in SUPPFT where QNAM=FTAFFPER, using FTGRPID to link this SUPPFT record to the result records in FT.
4. If one of the “PASAT 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.
5. The response to the “more than one attempt” question (FTTESTCD=PASAT103) 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=FTREASM1, using FTSEQ to link this SUPPFT record to the “more than one attempt” record in FT.
6. The functional test evaluator is stored in FTEVAL. For PASAT, 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.
7. 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 Paced Auditory Serial Addition Test (PASAT) FT Domain Model

The PASAT example below shows the terminology used to implement the functional test in the FT domain. This example shows the data for two subjects collected during two visits for a PASAT functional test. The example uses CDISC controlled terminology for FTTESTCD, FTTEST, and FTCAT. FTBLFL is Y when 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 1-6:** Show the results for USUBJID=MS01-01 for the Form A version of the PASAT 3” test taken at the baseline visit. The circumstances that affected the subject’s performance for the test can be found in Row 5 of the SUPPFT dataset, linked via FTGRPID.
- Rows 7-12:** Show the results for USUBJID=MS01-01 for the Form A version of the PASAT 2” test taken at the baseline visit. The circumstances that affected the subject’s performance for the test can be found in Row 6 of the SUPPFT dataset, linked via FTGRPID.
- Row 13:** Shows that it did not take USUBJID=MS01-01 more than one attempt to get one successful trial for the PASAT test taken at the baseline visit. FTGRPID is not populated because the “Circumstance Affected Performance” SUPPFT records should not be linked to this record.
- Row 14:** Shows that USUBJID=MS01-02 was unable to complete the PASAT test at the baseline visit due to physical limitations. Further information about the reason not done can be found in Row 7 of the SUPPFT dataset, linked via FTSEQ.
- Rows 15-20:** Show the results for USUBJID=MS01-01 for the Form B version of the PASAT 3” test taken at visit 2. The circumstances that affected the subject’s performance for the test can be found in Row 10 of the SUPPFT dataset, linked via FTGRPID.
- Row 21:** Shows that USUBJID=MS01-01 did not complete the Form B version of the PASAT 2” test at visit 2. Further information about the reason not done can be found in Row 11 of the SUPPFT dataset, linked via FTSEQ. Because the PASAT 2” test was not completed, data regarding circumstances that affected performance was not collected.
- Row 22:** Shows that it took USUBJID=MS01-01 more than one attempt to get one successful trial for the PASAT test taken at visit 2. The reason for more than one attempt can be found in Row 12 of the SUPPFT dataset, linked via FTSEQ. FTGRPID is not populated because the “Circumstance Affected Performance” SUPPFT records should not be linked to this record.

ft.xpt

Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTGRPID	FTTESTCD	FTTEST	FTCAT	FTSCAT	FTORRES	FTSTRESC	FTSTRESN
1	STUDYX	FT	MS01-01	1	1	PASAT101	PASAT1-Total Correct	PASAT	3 SECONDS	43	43	43
2	STUDYX	FT	MS01-01	2	1	PASAT102	PASAT1-Percent Correct	PASAT	3 SECONDS	71.7	71.7	71.7
3	STUDYX	FT	MS01-01	3	1	PASAT104	PASAT1-Total Correct in First Half	PASAT	3 SECONDS	24	24	24
4	STUDYX	FT	MS01-01	4	1	PASAT105	PASAT1-Total Correct in Second Half	PASAT	3 SECONDS	19	19	19
5	STUDYX	FT	MS01-01	5	1	PASAT106	PASAT1-Total Commission Errors	PASAT	3 SECONDS	7	7	7
6	STUDYX	FT	MS01-01	6	1	PASAT107	PASAT1-Total Omission Errors	PASAT	3 SECONDS	10	10	10
7	STUDYX	FT	MS01-01	7	2	PASAT101	PASAT1-Total Correct	PASAT	2 SECONDS	29	29	29
8	STUDYX	FT	MS01-01	8	2	PASAT102	PASAT1-Percent Correct	PASAT	2 SECONDS	48.3	48.3	48.3
9	STUDYX	FT	MS01-01	9	2	PASAT104	PASAT1-Total Correct in First Half	PASAT	2 SECONDS	16	16	16
10	STUDYX	FT	MS01-01	10	2	PASAT105	PASAT1-Total Correct in Second Half	PASAT	2 SECONDS	13	13	13
11	STUDYX	FT	MS01-01	11	2	PASAT106	PASAT1-Total Commission Errors	PASAT	2 SECONDS	6	6	6

Row	STUDYID	DOMAIN	USUBJID	FTSEQ	FTGRPID	FTTESTCD	FTTEST	FTCAT	FTSCAT	FTORRES	FTSTRESC	FTSTRESN
12	STUDYX	FT	MS01-01	12	2	PASAT107	PASAT1-Total Omission Errors	PASAT	2 SECONDS	25	25	25
13	STUDYX	FT	MS01-01	13		PASAT103	PASAT1-More Than One Attempt	PASAT		No	N	
14	STUDYX	FT	MS01-02	1	1	FTALL	Functional Test	PASAT				
15	STUDYX	FT	MS01-01	14	3	PASAT101	PASAT1-Total Correct	PASAT	3 SECONDS	36	36	36
16	STUDYX	FT	MS01-01	15	3	PASAT102	PASAT1-Percent Correct	PASAT	3 SECONDS	60.0	60.0	60.0
17	STUDYX	FT	MS01-01	16	3	PASAT104	PASAT1-Total Correct in First Half	PASAT	3 SECONDS	19	19	19
18	STUDYX	FT	MS01-01	17	3	PASAT105	PASAT1-Total Correct in Second Half	PASAT	3 SECONDS	17	17	17
19	STUDYX	FT	MS01-01	18	3	PASAT106	PASAT1-Total Commission Errors	PASAT	3 SECONDS	8	8	8
20	STUDYX	FT	MS01-01	19	3	PASAT107	PASAT1-Total Omission Errors	PASAT	3 SECONDS	16	16	16
21	STUDYX	FT	MS01-01	20	4	PASAT101	PASAT1-Total Correct	PASAT	2 SECONDS			
22	STUDYX	FT	MS01-01	21		PASAT103	PASAT1-More Than One Attempt	PASAT		Yes	Y	

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Row	FTSTAT	FTREASND	FTBLFL	FTEVAL	FTEVALID	VISITNUM	FTDTC
1 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
2 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
3 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
4 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
5 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
6 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
7 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
8 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
9 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
10 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
11 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
12 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
13 (cont)			Y	INVESTIGATOR	NRH	1	2013-08-16
14 (cont)	NOT DONE	PHYSICAL LIMITATIONS	Y	INVESTIGATOR	NRH	1	2013-08-16
15 (cont)				INVESTIGATOR	NRH	2	2013-11-15
16 (cont)				INVESTIGATOR	NRH	2	2013-11-15
17 (cont)				INVESTIGATOR	NRH	2	2013-11-15
18 (cont)				INVESTIGATOR	NRH	2	2013-11-15
19 (cont)				INVESTIGATOR	NRH	2	2013-11-15
20 (cont)				INVESTIGATOR	NRH	2	2013-11-15
21 (cont)	NOT DONE	OTHER		INVESTIGATOR	NRH	2	2013-11-15
22 (cont)				INVESTIGATOR	NRH	2	2013-11-15

The standard terminology for QNAM and QLABEL are listed below.

- Rows 1-2:** Show the range of possible values for the total correct result of the PASAT tests for USUBJID=MS01-01.
- Rows 3-4:** Show that USUBJID=MS01-01 took the Form A version of the PASAT 3” and PASAT 2” tests at visit 1.
- Rows 5-6:** Show the circumstances that affected the performance of USUBJID=MS01-01 for the PASAT tests taken at the baseline visit. Record 5 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.
- Rows 7:** Shows that USUBJID=MS01-02 did not complete the PASAT test at the baseline visit because the subject did not get at least 2 answers correct on any of the 3 practice sequences.
- Rows 8-9:** Show that USUBJID=MS01-01 took the Form B version of the PASAT 3” and PASAT 2” tests at visit 2.
- Rows 10:** Shows the circumstances that affected the performance of USUBJID=MS01-01 for the PASAT 3” test taken at visit 2.
- Rows 11:** Shows that USUBJID=MS01-01 did not complete the PASAT 2” test at visit 2 because the subject refused to complete the test.
- Row 12:** Shows the reason USUBJID=MS01-01 had more than one attempt to complete the PASAT 3” test was that the test was interrupted by someone walking into the testing room.

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Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	STUDYX	FT	MS01-01	FTTESTCD	PASAT101	RNGVALLO	Range Value Low	0
2	STUDYX	FT	MS01-01	FTTESTCD	PASAT101	RNGVALHI	Range Value High	60
3	STUDYX	FT	MS01-01	FTGRPID	1	FTFORM	FT Form	FORM A
4	STUDYX	FT	MS01-01	FTGRPID	2	FTFORM	FT Form	FORM A
5	STUDYX	FT	MS01-01	FTGRPID	1	FTAFFPER	Circumstance Affected Performance	NONE
6	STUDYX	FT	MS01-01	FTGRPID	2	FTAFFPER	Circumstance Affected Performance	SUBJECT REPORTS FRUSTRATION
7	STUDYX	FT	MS01-02	FTSEQ	1	FTREASDL	Reason Not Done Details	SUBJECT DID NOT GET AT LEAST 2 ANSWERS CORRECT ON ANY OF THE 3 PRACTICE SEQUENCES
8	STUDYX	FT	MS01-01	FTGRPID	3	FTFORM	FT Form	FORM B
9	STUDYX	FT	MS01-01	FTGRPID	4	FTFORM	FT Form	FORM B
10	STUDYX	FT	MS01-01	FTGRPID	3	FTAFFPER	Circumstance Affected Performance	SUBTLE NOISES OUTSIDE OF THE TESTING ROOM
11	STUDYX	FT	MS01-01	FTSEQ	8	FTREASDL	Reason Not Done Details	SUBJECT REFUSED TO COMPLETE TEST DUE TO FRUSTRATION WITH NOISES OUTSIDE OF THE TESTING ROOM
12	STUDYX	FT	MS01-01	FTSEQ	9	FTREASM1	Reason More Than One Attempted Trial	TEST INTERRUPTED BY SOMEONE WALKING INTO THE ROOM

4 SDTM Mapping Strategy

PASAT 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
PASAT

FTSCAT
3 SECONDS
2 SECONDS

FTTESTCD=PASAT103

FTTEST=PASAT1-More Than One Attempt

FTORRES	FTSTRESC
Yes	Y
No	N

Note: For FTTESTCD=PASAT103, 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
RNGVALLO	Range Value Low	FT, QS
RNGVALHI	Range Value High	FT, QS
FTFORM	FT Form	FT
FTAFFPER	Circumstance Affected Performance	FT
FTREASM1	Reason More Than One Attempted Trial	FT
FTREASDL	Reason Not Done Details	FT

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