Alzheimer’s Disease-specific Therapeutic Area Supplement to the Study Data Tabulation Model User Guide

Prepared by the Coalition Against Major Diseases (CAMD)

Notes to Readers

This User Guide follows version 3.1.2 (V3.1.2) of the CDISC Submission Data Standards and domain models.

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Summary of Changes</th>
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<td>2010-11-30</td>
<td>1.0</td>
<td>Draft Alzheimer’s- specific TA criteria added to Safety &amp; QS domains.</td>
</tr>
<tr>
<td>2011-09-09</td>
<td>1.0</td>
<td>Alzheimer’s disease User Guide Release</td>
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Note: Please see Appendix F for Representations and Warranties, Limitations of Liability, and Disclaimers.
CDISC Alzheimer's disease SDTM User Guide (Version 1.0)

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1. Introduction

1.1 PURPOSE AND CAVEATS

This document comprises the Alzheimer’s disease-specific User Guide (SDTMUG-ALZHEIMER’S v1.0) to be used as a Therapeutic Area Supplement to the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG V3.1.2). This user guide was prepared by the Critical Path Institute’s Coalition Against Major Diseases (CAMD) with participation from volunteer members of the Submissions Data Standards (SDS) team of the Clinical Data Interchange Standards Consortium (CDISC). It is intended to guide the organization, structure, and format of standard Alzheimer’s disease and Mild cognitive impairment (MCI) clinical trial tabulation datasets submitted to a regulatory authority such as the US Food and Drug Administration (FDA).

With regards to clinical trials of Alzheimer’s disease and MCI, this guide describes the explicit implementation of a subset of the domains whose general implementation is described in the current version of the Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG v3.1.2). This document also introduces new SDTM domains, showing rules and examples on implementing these domains specifically for trials of Alzheimer’s disease or MCI.

This document does not replace, supersede, nor otherwise override any rules or requirements of the current SDTM and SDTMIG. Knowledge of this document alone is not a substitute for knowledge of SDTM nor is it sufficient to produce complete, SDTM-compliant regulatory submissions of Alzheimer’s or MCI clinical trials data. The SDTMUG-ALZHEIMER’S v1.0 should be used in close concert with the current version of the SDTMIG and the current version of the CDISC Study Data Tabulation Model (SDTM, available at http://www.cdisc.org/standards). The SDTM describes the general conceptual model for representing clinical study data that is submitted to regulatory authorities and should be read prior to reading the SDTMIG. An understanding of both of these documents is required before attempting to read and understand the SDTMUG-ALZHEIMER’S v1.0.

The standards contained in this document were developed to facilitate an integrated database of pooled retrospective and eventually prospective clinical trials for the Coalition Against Major Diseases. The standard elements and terminology contained in the subsequent sections of this guide represent the data which were prioritized for first analysis by CAMD members. Therefore, the current version of this document should not be regarded as the “complete” set of data standards required for every clinical trial of Alzheimer’s disease and MCI. The document is intended to grow in scope through iterative review and subsequent editions.

This document is intended for companies and individuals involved in the collection, preparation, and analysis of clinical data that will be submitted to regulatory authorities.

Domains for which there are no current Alzheimer’s specific rules are not included in this document. For information on these domains, refer to the current version of the SDTM/SDTMIG. Section numbers in this document are aligned to the SDTMIG to facilitate reference and are therefore not always consecutive within this document.

1.2 ORGANIZATION OF THIS DOCUMENT

Note: The section numbers in this document are not consecutive, but instead follow the corresponding section numbering in SDTMIG.

This document is organized into the following sections:

- **Section 1, Introduction**, provides an overall introduction to the V3.1.2 models and describes changes from prior versions.
• **Section 5, Models for Special-Purpose Domains**, describes special-purpose domains, including Demographics,
• **Section 6, Domain Models Based on the General Observation Classes**, provides specific metadata models based on the three general observation classes, along with assumptions and example data.
• **Appendices** provide additional background material and describe other supplemental material relevant to implementation.

### 1.3 RELATIONSHIP TO PRIOR CDISC DOCUMENTS

This document is intended as a supplement to the SDTM and SDTM IG. This document, in combination with knowledge of the SDTM/SDTMIG are required to produce CDISC SDTM-standardized dataset submissions from Alzheimer’s or MCI clinical trials to regulatory authorities.

### 1.4 HOW TO READ THIS USER GUIDE

This Alzheimer’s disease-specific SDTM Guide (SDTMUG-ALZHEIMER’S v1.0) is best read online, so the reader can benefit from the many hyperlinks included to both internal and external references. Most of the hyperlinks in this document do not work because most of the sections to which they refer have been removed. The text has been left as a reference. The following guidelines may be helpful in reading this document:

1. First, read the current version of the SDTM to gain a general understanding of SDTM concepts.
2. Next, read the current SDTMIG
   a. Read the **General Assumptions for all Domains in Section 4**.
   b. Review Section 5 and Section 6 in detail, referring back to Assumptions as directed (hyperlinks are provided). Note the implementation examples for each domain to gain an understanding of how to apply the domain models for specific types of data.
   c. Read this SDTMUG-ALZHEIMER’S v1.0 for Alzheimer’s disease and MCI Therapeutic Area standards implementation.
3. Finally, review the **Appendices** in the SDTMIG and SDTMUG-ALZHEIMER’S v1.0 (this document) as appropriate.

### 1.5 SUBMITTING COMMENTS

Comments on this document can be submitted through the [CDISC Discussion Board](#).
5. Models for Special-Purpose Domains

5.1 DEMOGRAPHICS

5.1.1 DEMOGRAPHICS — DM (ALZHEIMER’S DISEASE AND MILD COGNITIVE IMPAIRMENT)

See SDTMIG for DM domain table.

5.1.1.1 ASSUMPTIONS FOR DEMOGRAPHICS DOMAIN MODEL

All assumptions for the DM domain from the SDTMIG v3.1.2, 2008-11-12, p. 56 apply for this User Guide including those referenced in the CDISC notes. Additionally, the following assumptions apply to Alzheimer’s disease and Mild cognitive impairment (MCI):

1. For Alzheimer’s disease trials, RFSTDTC and RFENDTC values must correspond to the actual Active or Placebo study medication start and stop dates. First and last date of exposure to any protocol-specified treatment should be used to populate these fields. Any drug washout or placebo run-in dates should not be populated in RFSTDTC or RFENDTC.

   No specific Alzheimer’s/MCI example are necessary. Refer to SDTMIG v3.1.2, 2008-11-12, p. 57 for examples.
6 Domain Models Based on the General Observation Classes

6.2 EVENTS

6.2.3 MEDICAL HISTORY — MH (ALZHEIMER’S DISEASE AND MILD COGNITIVE IMPAIRMENT)

See SDTMIG for MH domain table.

6.2.3.1 ASSUMPTIONS FOR MEDICAL HISTORY DOMAIN MODEL

All assumptions for the MH domain from the SDTMIG apply for this User Guide. Refer to SDTMIG for any non-Alzheimer’s disease- and Alzheimer’s disease-and MCI- specific assumptions referenced in the table above. Additionally, the following assumptions apply to Alzheimer’s disease and mild cognitive impairment (MCI).

1. “Alzheimer’s disease”, “Mild cognitive impairment” or other terms relating to Alzheimer’s-type dementias must be in MHTERM. Coding to the preferred term with MedDRA for Alzheimer’s disease or Mild cognitive impairment to populate MHDECOD is optional. See Example 1 below for how to map the primary diagnosis.

2. MHSTDTCh is expected when MHCAT=PRIMARY DIAGNOSIS, and permissible for all other MHCAT values.

3. If general medical history information is also captured either as verbatim text or pre-specified text, it can be coded with MedDRA and reported in MHDECOD based on the sponsors coding criteria for medical history.

4. The controlled terminology for MHCAT includes “PRIMARY DIAGNOSIS and “GENERAL.”

5. Where collected, onset of symptoms for either Alzheimer’s disease or MCI should be mapped to Supplemental Qualifiers (SUPPMH). See Example 1 below for how to map onset of symptoms.
6.2.3.2 EXAMPLES FOR MEDICAL HISTORY DOMAIN MODEL

Example 1
Below are specific Alzheimer’s/MCI Medical History examples in capturing:
- General medical history either as free text or solicited events
- Primary diagnosis information

Rows 1, 4, 8: MHCAT shows the standard controlled terminology of PRIMARY DIAGNOSIS for 3 separate subjects, one with Alzheimer’s disease and two with Mild cognitive impairment. Note that in this case MHDECOD is not populated.
Rows 2-3, 5-6: Indicate general medical history with MHCAT=GENERAL

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### Onset of Symptoms

- The onset of symptoms date (QNAM=MHOSDTC) is when the symptoms of Alzheimer’s disease or mild cognitive impairment were first observed by the subject or a family member. The actual diagnosis date (MHSTDTC) is the date the subject’s physician officially diagnosed the disease. Where collected, onset of symptoms (for either Alzheimer’s or MCI) should be mapped to SUPPMH as in the following. The standard controlled terminology for QNAM is MHOSDTC and QLABEL is “Onset of Cognitive Problem”.

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6.2.6 NON-SUBJECT MEDICAL HISTORY - NSMH (ALZHEIMER’S DISEASE AND MILD COGNITIVE IMPAIRMENT)

See Non-Subject Data Supplement v1.0 to SDTMIG for NS domain tables - This domain is under review with the CDISC SDS team, following the CDISC domain development process. This section will be updated upon release of the approved domain.

The SDTMIG:NS is intended to guide the organization, structure, and format of standard data for persons who are not the subject in a clinical trial, but about whom data has been collected, when that data will be submitted to a regulatory authority such as the US Food and Drug Administration (FDA). This guide describes the implementation of any data tabulations collected about persons of interest in a clinical trial who are not the subject in the trial. These non-subject persons may or may not have a relationship to a clinical trial subject.

6.2.6.1 ASSUMPTIONS FOR NON-SUBJECT DOMAIN MODEL

All assumptions for the NSMH domain from the SDTMIG-NS Supplement apply for this User Guide. Refer to SDTMIG-NS for any non-Alzheimer’s disease- and Alzheimer’s disease- and MCI- specific assumptions referenced. Additionally, the following assumptions apply to Alzheimer’s disease and mild cognitive impairment (MCI).

1. When collecting information about Non-Subject family members, MHCAT=FAMILY HISTORY. The terms “Alzheimer’s disease” or “Mild Cognitive Impairment” or other terms relating to Alzheimer’s-type dementia need to be populated in MHTERM as is done with study subject’s Medical History Primary Diagnosis data.
2. The controlled terminology for MHRELSUB can be found in the SDTMIG-NS.

6.2.6.2 EXAMPLES FOR NON-SUBJECT MEDICAL HISTORY DOMAIN MODEL

Example 1
Below are specific Alzheimer’s/MCI Non-Subject Medical History examples in capturing:

- Family history as solicited events

Rows 1-6: MHCAT shows the standard controlled terminology of FAMILY HISTORY for 2 separate subjects with 6 Non-Subject Medical History term. The MHTERM values match the study subject’s PRIMARY DIAGNOSIS MHTERM value in MH, which are either Alzheimer’s disease or Mild cognitive impairment. Note that in this case MHDECOD is not populated.
Row 1: USUBJID=2324-P002 family history data with pre-specified questions on whether a MHPRESP term occurred or not.
Rows 2-6: USUBJID=2324-P003 family history data with pre-specified questions on whether a MHPRESP term occurred or not.

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### 6.3 FINDINGS

#### 6.3.3 LABORATORY TEST RESULTS — LB

See SDTMIG for LB domain table.

**6.3.3.1 ASSUMPTIONS FOR ALZHEIMER’S DISEASE LABORATORY TEST RESULTS DOMAIN MODEL**

All assumptions for the LB domain from the SDTMIG apply for this User Guide. Refer to SDTMIG LB domain table for any non-Alzheimer’s disease specific assumptions referenced. Additionally, the following assumptions apply to Alzheimer’s disease and Mild cognitive impairment (MCI).

1. Alzheimer’s disease biomarker lab results should be collected using controlled terminology for LBTEST, LBTESTCD as defined in NCI EVS. In addition LBCAT should have “BIOMARKER” and standard units as indicated in the example table below.

**6.3.3.2 EXAMPLES FOR LABORATORY TEST RESULTS DOMAIN MODEL**

*Example 1-Biomarker Tests:*

*Rows 1-3:* Shows how to populate three specific biomarker lab tests with the standard terminology for LBTEST, LBTESTCD, LBCAT, LBSTRESC and LBSTRESN.
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6.3.5 QUESTIONNAIRE — QS (ALZHEIMER’S DISEASE AND MILD COGNITIVE IMPAIRMENT)

See SDTMIG for QS domain table.

The following Questionnaires have been selected for standardization in Alzheimer’s disease studies. The documentation for these Questionnaires is located on the CDISC website as follows: http://www.cdisc.org/contentmgr/showdetails.php?id/2909. The QS documentation is being stored in a separate location due to many Questionnaires that are utilized across many different therapeutic areas. The CDISC Questionnaire Terminology Team is in the process of assessing copyright issues and developing controlled terminology for questionnaires. This site will be updated on a regular basis to inform you of their progress.

6.3.5.1 ASSUMPTIONS FOR QUESTIONNAIRE DOMAIN MODEL

All assumptions for the QS domain from the SDTMIG apply for this User Guide including those referenced in the CDISC notes.

- Alzheimer’s disease Assessment Scale – Cognitive (ADAS-Cog)
- Mini Mental Scale (MMSE)
- Audio Verbal Learning Test Version A (AVLTvA)
6.3.6 SUBJECT CHARACTERISTICS — SC

See SDTMIG for QS domain table.

6.3.6.1 ASSUMPTIONS FOR SUBJECT CHARACTERISTICS DOMAIN MODEL

1. If genotyping information is collected it should be stored in Subject Characteristics. The controlled terminology for these tests is shown below in the example and is maintained in NCI EVS. (add Terminology Link)

6.3.6.2 EXAMPLE FOR SUBJECT CHARACTERISTICS DOMAIN MODEL

ApoE Genotype is an important characteristic of a subject with Alzheimer’s disease or mild cognitive impairment. When collected it is stored in the SC domain. The results of the ApoE Genotype are 2, 2 or 2, 3 or 2, 4 or 3, 4 etc. We have chosen to separate the results into 2 distinct tests. The Allele values can be reported in any order. The example below shows data from two different subjects.

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## Appendices

### APPENDIX A: CAMD DATA STANDARDS WORKGROUP

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<td>Jon Neville, Co-Chair</td>
<td>Critical Path Institute</td>
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<tr>
<td>Chris Tolk</td>
<td>CDISC</td>
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<tr>
<td>Melissa Binz</td>
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<td>Shannon Labout</td>
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<td>Fred Wood</td>
<td>Octagon Research Solutions, Inc.</td>
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<td>Wayne Kubick</td>
<td>PhaseForward, Inc</td>
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<td>Roberta Rosenberg</td>
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<td>Cathy Barrows</td>
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<td>Gary Cunningham</td>
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<td>Dan Godoy</td>
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<td>Sandy Lei</td>
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<td>Suzanne Pierre</td>
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<td>Steve Wilson</td>
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<td>Marc Walton</td>
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<tr>
<td>Ana Szarfman</td>
<td>FDA Liaison</td>
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APPENDIX C5: SUPPLEMENTAL QUALIFIERS NAME CODES

The following table contains an additional standard name code for use in the Supplemental Qualifiers (SUPP--) special-purpose datasets. See SDTMIG Appendix C5 for other supplemental qualifier name codes.

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<th>Applicable Domains</th>
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<td>MHOSTDTC</td>
<td>Onset of Cognitive Problem</td>
<td>MH</td>
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APPENDIX F: REPRESENTATIONS AND WARRANTIES, LIMITATIONS OF LIABILITY, AND DISCLAIMERS

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