



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

Ophthalmic Examinations (OE) Domain Overview and Status

Marcelina Hungria, Sub-team Lead
on behalf of the
[SDS Ophthalmology Sub-team](#)

*The CDISC Vision is to Inform Patient Care & Safety
Through Higher Quality Medical Research*

A decorative graphic consisting of several overlapping wavy lines in dark blue, light blue, and green, extending horizontally across the page.

Preparing for Public Review

Strength *through Collaboration*

OE Domain - Agenda

- Project Background
- OE Domain
 - Description/Overview
 - Structure / Variables Table
 - Assumptions
 - Examples
- CT Requests, status
- Others
 - Dependency considerations with TAUG-MS
 - Validation Rules and Define-XML, metadata needs / suggestions
- Timelines
- Q&A

OE Domain - Project Background

- Started as an attempt to develop the standard to report findings for ophthalmic examinations (EYE examinations) in clinical trials
 - Specialized domain, NOT a general Physical Exam
- Team organized during 3Q2013
- Work started in 4Q2013

OE Domain - Project Background

(cont.)

- Thought of as a “simple, easy, project” at the beginning
 - Faced major questions and debate that needed decisions from the SDSLT^{1&2}
 - Resolution provided after Internal Review

Notes:

1. Place to hold terms “OD”, “OS” and “OU”
2. Pros and Cons of *One versus Multiple Findings domains for ophthalmic data* evaluated and presented to the SDSLT.

OE Domain - document layout

- Based on SDTMIG 3.3 Template
- Examples in Excel file
 - As an attachment
 - Presentation similar to Oncology Domains

OE Domain - document layout

Section 6.3 - OE Domain v0.27(draftforPR).pdf - Adobe Reader

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Bookmarks

- 6 Domain Models Based on the General Observation Classes
 - 6.3 Findings
 - Ophthalmic Examinations (OE)
 - OE – Description/Overview for Ophthalmic Examinations Domain Model
 - OE – Specification for Ophthalmic Examinations Domain Model
 - OE – Assumptions for Ophthalmic Examinations Domain Model
 - OE – Examples for Ophthalmic Examinations Domain Model

CDISC SDTM Implementation Guide (Version 3.3)

6 Domain Models Based on the General Observation Classes

6.3 Findings

Ophthalmic Examinations (OE)

OE – Description/Overview for Ophthalmic Examinations Domain Model

The OE domain is for findings related to tests that measure a person's ocular health and visual status, to detect abnormalities in the components of the visual system, and to determine how well the person can see.

OE – Specification for Ophthalmic Examinations Domain Model

oe.xpt, Ophthalmic Examinations — Findings, Version 3.3. One record per ophthalmic finding per method per location, per time point per visit per subject. Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Code list or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	OE	Identifier	Two-character abbreviation for the domain most relevant to the observation. The Domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req

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OE Domain - document layout

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Variable Name	Variable Label	Type	Controlled Terms, Code list or Format	Role	CDISC Notes	Core
FOCID	Focus of Study-specific Interest	Char	(FOCID)	Identifier	Identification of a focus of study-specific interest on or within a subject or specimen as called out in the protocol for which a measurement, test, or examination was performed. In the case of the OE domain, the variable is used as a key identifying variable to store the terms "OD", "OS" and "OU". Refer to Assumption 2.	Exp
OESEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness of records within a dataset for a subject. May be any valid number (including decimals) and does not have to start at 1.	Req
OEGRPID	Group ID	Char		Identifier	Optional group identifier, used to link together a block of related records within a subject in a domain (Section 3.4).	Perm
OELNKID	Link ID	Char		Identifier	Identifier used to link related records across domains. This may be a one-to-one or a one-to-many relationship. For Example, A single location and its qualifiers may have multiple measurements/assessments based on a procedure performed at a study visit and OELNKID used to link to the specific procedure performed.	Perm
OETESTCD	Short Name of Measurement, Test or Examination	Char	(OETESTCD)	Topic	Short character value for OETEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: <i>NUMLCOR</i> .	Req

OE Domain - document layout

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Variable Name	Variable Label	Type	Controlled Terms, Code list or Format	Role	CDISC Notes	Core
OETEST	Name of Measurement, Test or Examination	Char	(OETEST)	Synonym Qualifier of OETEST CD	Long name for test. Example: <i>Number of Letters Correct</i> for OETESTCD=NUMLCOR. The following rules must be considered when requesting additional terms for tests: - OETESTCD and OETEST must have a 1:1 relationship. - OETEST, OETSTDTL and OEMETHOD are expected to uniquely differentiate a test. - Result and other variable's values may have a different meaning depending on values of each unique test. It means that more granular Value Level Metadata (VLM) may need to be defined for appropriate interpretation of findings.	Req
OETSTDTL	Measurement, Test or Examination Detail	Char	*	Variable Qualifier of OETEST CD and OETEST	Further description of OETESTCD and OETEST. Example: <i>"Chart Distance 3.2m"</i> when OETESTCD = NUMLCOR. See Notes for OETEST.	Perm
OECAT	Category	Char	*	Grouping Qualifier	Used to define a category of topic-variable values. Examples: VISUAL ACUITY, CONTRAST SENSITIVITY, OCULAR COMFORT.	Perm

OE Domain - document layout

OE – Assumptions for Ophthalmic Examinations Domain Model

1. This specialized domain includes findings for all physiological ophthalmic examinations, regardless of its origin; i.e., collected on a CRF, received from a central provider or vendor, or assessed by other means.
 - a. All morphological ophthalmic examinations are expected to be included in the MO domain. However, the guidelines and assumptions applicable to the OE domain are to be applicable to the ophthalmic examinations included in the MO or other Findings domains as well.
 - b. Regardless of the SDTM domain the ophthalmic examinations data is stored (MO, OE and others), it should be possible to create a combined logical view (OE Single Virtual View) of all ophthalmic examinations without conflict on the use of the variables included with respect to any guidelines on variable requirements or CT. It means that all detailed metadata items applicable to each SDTMIG domain holding ophthalmic findings, including key structure and CT applicable to variables of each domain, should have the same definition. When data is integrated in a single virtual view of all ophthalmic findings, all detailed metadata must be consistent regardless of the finding to be considered a morphological or physiological finding.
 - i. The OE Single Virtual View should pass the validation rules defined for the OE Domain.

OE Domain - document layout, cont.

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CDISC SDTM Implementation Guide (Version 3.3)

OE – Examples for Ophthalmic Examinations Domain Model

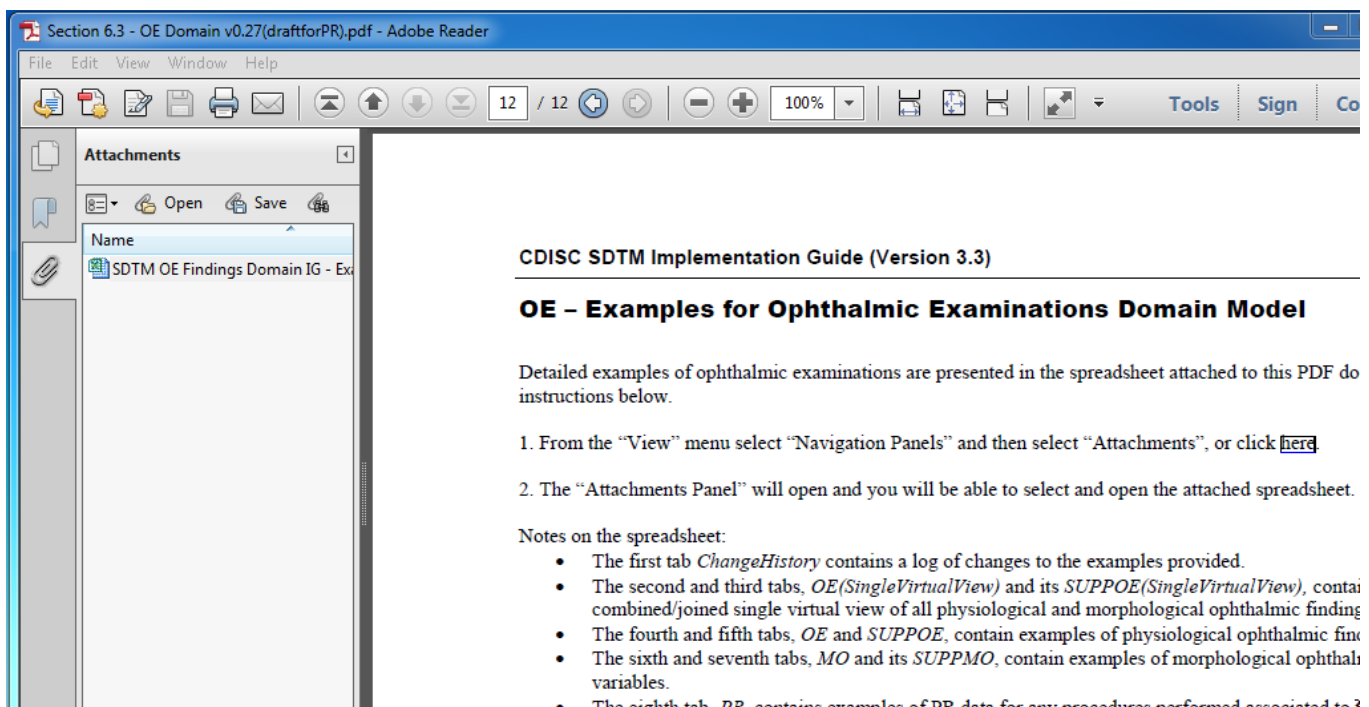
Detailed examples of ophthalmic examinations are presented in the spreadsheet attached to this PDF document. To access the example spreadsheet, follow the instructions below.

1. From the "View" menu select "Navigation Panels" and then select "Attachments", or click here.
2. The "Attachments Panel" will open and you will be able to select and open the attached spreadsheet.

Notes on the spreadsheet:

- The first tab *ChangeHistory* contains a log of changes to the examples provided.
- The second and third tabs, *OE(SingleVirtualView)* and its *SUPPOE(SingleVirtualView)*, contain examples of ophthalmic findings when looked as a combined/joined single virtual view of all physiological and morphological ophthalmic findings data.
- The fourth and fifth tabs, *OE* and *SUPPOE*, contain examples of physiological ophthalmic findings and corresponding supplemental qualifier variables.
- The sixth and seventh tabs, *MO* and its *SUPPMO*, contain examples of morphological ophthalmic findings and corresponding supplemental qualifier variables.
- The eighth tab, *PR*, contains examples of PR data for any procedures performed associated to the ophthalmic examinations.
- The ninth tab, *DI*, contains examples of DI data for any devices associated to procedures performed associated to the ophthalmic examinations.
- The tenth tab, *DU*, contains examples of DU data for any device settings associated to procedures performed associated to the ophthalmic examinations.
- The eleventh tab, *RELREC*, contains an example of the RELREC dataset representing the relationship between ophthalmic examinations: domain(s) and any other domain included in the examples
- Each of the <Domain> data tabs include any supplemental qualifier variables needed, listed as QNAM.[Variable name (Variable label)] to facilitate visualization.

OE Domain - document layout, cont.



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Attachments

Name

SDTM OE Findings Domain IG - Ex

CDISC SDTM Implementation Guide (Version 3.3)

OE – Examples for Ophthalmic Examinations Domain Model

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- The fourth and fifth tabs, *OE* and *SUPPOE*, contain examples of physiological ophthalmic fin
- The sixth and seventh tabs, *MO* and its *SUPPMO*, contain examples of morphological ophthal variables.
- The eighth tab, *PR*, contains examples of PR data for any procedures performed associated to 3

OE Domain - Examples layout

SDTM OE Findings Domain IG - Examples - V0_26(draftforPR).xlsx - Microsoft Excel

File Home Insert Page Layout Formulas Data Review View Acrobat QuickBooks SAS

Clipboard Font Alignment Number Styles Cells Editing

B3 For purposes of facilitating a global view of ophthalmic examinations, this set of OE examples is combined with the MO examples as a logical view (single virtual view) of all ophthalmic examinations and presented as an aggregated domain in tab OE(SingleVirtualView). The

	A	B	C	D	E	F	G	H	I	J	K
1	oe.xpt	Legend columns headings: <i>Italics - Key variable, Color (beige) - CT</i>									
2	Row	STUDYID	DOMAIN	USUBIID	FOCID	OESEQ	OEGRPID	OELNKID	OETESTCD	OETEST	OETSTDTL
3		For purposes of facilitating a global view of ophthalmic examinations, this set of OE examples is combined with the MO examples as a logical view (single virtual view) of all ophthalmic examinations and presented as an aggregated domain in tab OE(SingleVirtualView). The modelling of ophthalmic examination in Finding domains is expected to follow the same structure and CT guidelines regardless of the individual domains chosen. Note: There are many grey areas and some disadvantages that the Ophthalmology team has encountered while reviewing the use cases. Therefore, the team felt it was necessary to illustrate some of those cases. Notes highlighted in blue illustrate specific cases of disadvantages or issues faced when trying to model ophthalmic examinations in separate domains. The summary of pros and cons of using one domain versus multiple domains prepared by the Ophthalmology subteam is presented in the last spreadsheet "OneVsMultipleDomainsDecision" in this workbook.									
4		Example 2: This example illustrates the case when all tests scheduled were not done for a visit. Note that in this case variable FOCID is not populated. This case also illustrates one of the practical inconveniences of having to split ophthalmic examinations in separate Findings domains. A similar NOT DONE record will have to be included in the MO domain.									
5	1	XXX	OE	XXX-450-110		1			OEALL	Ophthalmic Examinations	
6		Example 6: This example illustrate the measurement of intraocular pressure on both eyes at one visit. Note: This is a 'grey-area' case. It is hard to determine whether it is morphology (MO) or functional (OE). We don't have a clear CAT value for it yet.									
7	1	XYZ	OE	XYZ-100-001	OD	1			IOP	Intraocular Pressure	
8	2	XYZ	OE	XYZ-100-001	OS	2			IOP	Intraocular Pressure	
		Example 7: This example demonstrates IOP measurements for an IOP-lowering study. The study protocol requires IOP to be measured at least two times per eye per visit per timepoint. If any of the two measurements is higher than the predetermined normal range (18 to 22 mmHg), then take the third measurement. Rows 1 to 3: At Visit 1									

ChangeHistory OE(SingleVirtualView) SUPPOE(SingleVirtualView) OE SUPPOE MO SUPPMO PR DI DU

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OE Domain – New Variable Requested

- New variable requested to store widely known ophthalmology terms OD/OS/OU
 - New *Identifier* variable to be part of SDTM in version 1.5, available in all Domain Classes was approved:
 - FOCID (Focus of Study-specific Interest):
- Continue on next page

OE Domain – New Variable Requested

- FOCID versus --LOC/--LAT/--DIR/--PORTOT
 - **FOCID**: Identifier variable with **Core="Exp" in OE** and Core="Perm" in other domains that hold ophthalmic data, where --LOC is allowed
 - **--LOC and --LAT/--DIR/--PORTOT**, Record Qualifier variable and its variable qualifiers with **Core="Perm"**
 - This is the SDS recommended way to provide location information
 - A bit of redundancy is acknowledged with the terms in FOCID versus the --LAT terms plus --LOC term when --LOC="EYE"; however, NOT when location refers to a part of the eye

OE Domain – Other Guidelines

- General guidelines for –TEST/--TSTDTL / METHOD in Findings domains, ophthalmic data
 - All with CT

A few Ophthalmic TA like guidelines¹:

- Guidelines for CATs/SCATs for ALL ophthalmic findings
- Guidelines for linking to other standard Domains
 - i.e, PR

1. Not covered elsewhere at the present time

OE Domain – CT Requests, Status

- FOCID, new extensible codelist with terms “OD”, “OS” and “OU” for ophthalmic data – for public review 12Sep2014, production release expected 19Dic2014

CT for ophthalmic tests and methods is extensive, currently only addressing terms included in examples

- OETESTCD/OETEST, new extensible codelist with a few terms – in progress to submit¹
- MOTESTCD/MOTEST, new terms – in progress to submit¹
- METHOD, new terms - in progress to submit¹
- LOC, new terms for parts of the eye not yet in CT – pending

→Feedback on next package(s) of CT for public review appreciated

1. CDISC Notes may include “only applicable when FOCID=“OD”|“OS”|“OU”

OE Domain – Dependency with TAUG-MS

- TAUG-MS released with a *Provisional* status
 - It included the draft OE Domain used for Internal Review
 - To be updated once OE Domain is final (OE expected to be released with the SDTMIG 3.3)

OE Domain – Validation Rules

- TBD – will require meeting with SDTM Validation Rules Team
- Note:
 - Cross-Domain Validation Rules need more attention that originally envisioned due to the split of ophthalmic findings in different SDTM domains
- To be incorporated in SHARE at a later date

OE Domain – Define-XML considerations

- Need appropriate Value Level Metadata definition to help check consistency in usage
 - CT subsets; i.e., Valid --TESTCD/--TEST / --TSTDTL / METHOD for each Findings domain holding ophthalmic data (OE, MO, NV, etc.)
 - Basic Where Clause: FOCID in *FOCID* codelist subset applicable to ophthalmic data
 - i.e, FOCID in (“OD”, ”OS” and ”OU”)
 - More complex Where Clauses may be needed:

OE Domain – Define-XML considerations

Working on a Define-XML 2.0 basic example for an ophthalmic study.

- VLM for MO.MOORRES, MO.MOORRESU & MO.MOSTRESU with WCs similar to the ones illustrated for VSORRES and VSORRESU below:
 - Plus: FOCID IN ("OD", "OS", "OU")

The screenshot displays a software interface for defining XML metadata. On the left, a table titled 'Value Level Metadata - VS [VSORRES]' lists variables, their types, lengths, and origins. Below it, another table titled 'Value Level Metadata - VS [VSORRESU]' lists variables, their types, lengths, and origins. On the right, a code editor shows XML code for defining a 'WhereClauseDef' with a 'def:WhereClauseDef' element and a 'def:ItemOID' element. The code includes checks for 'WC.MO.MOORRESU.THICK' and 'WC.MO.MOORRESU.FOCID'.

Variable	Where	Type	Length / Display Format	Controlled Terminology	Origin		
VSORRES	VSTESTCD	EQ	DIABP (Diastolic Blood Pressure)	integer	2	CRF Page 11	IT
VSORRES	VSTESTCD	EQ	FRMSIZE (Body Frame Size)	text	6	CRF Page 11	C
VSORRES	VSTESTCD	EQ	HEIGHT (Height)	float	5.1	CRF Page 11	f
VSORRES	VSTESTCD	EQ	PULSE (Pulse Rate)	integer	2	CRF Page 11	EN
VSORRES	VSTESTCD	EQ	SBP (Systolic Blood Pressure)	integer	3	CRF Page 11	EN
VSORRES	VSTESTCD	EQ	WEIGHT (Weight)	float	5.1	CRF Page 11	EN

Variable	Where	Type	Length / Display Format	Controlled Terminology	Origin		
VSORRESU	VSTESTCD	EQ	HEIGHT (Height) AND COUNTRY IN ("CAN", "MEX")	text	5	CRF Page 11	DL

```
<def:WhereClauseDef OID="WC.MO.MOORRESU.THICK">
  <RangeCheck SoftHard="Soft" def:ItemOID="IT.MO.MOORRESU.THICK" Comparator="EQ">
    <CheckValue>THICK</CheckValue>
  </RangeCheck>
  <RangeCheck SoftHard="Soft" def:ItemOID="IT.MO.MOORRESU.FOCID" Comparator="IN">
    <CheckValue>OD</CheckValue>
    <CheckValue>OS</CheckValue>
    <CheckValue>OU</CheckValue>
  </RangeCheck>
  <RangeCheck SoftHard="Soft" def:ItemOID="IT.MO.MOORRESU.COUNTRY" Comparator="EQ">
    <CheckValue>XYZ</CheckValue>
  </RangeCheck>
</def:WhereClauseDef>
```

OE Domain – Tentative Timeline

- Draft for Public Review
 - Scheduled to be included in Batch 2 for public review of the SDTMIG 3.3
- SDTM 1.5 and SDTMIG 3.3 Production Release
 - TBD: still during 2014 as per current understanding

OE Domain – Examples

- Brief look at one the Examples

Thank you!

Questions?



SDS Ophthalmology Sub-team



- [Marcelina Hungria](#) (Sub-team Lead), Dcore Group, LLC
 - Shannon Labout, (co-Lead, not active), CDISC
 - Anthony Chow, CDISC
 - Bess LeRoy, Critical Path Institute
 - Donna Bezner, QCP Support
 - Jon Neville, Critical Path Institute
 - Joyce Hernandez, Consultant
 - Kim Truett, KCT Data Inc.
 - Melanie Fuellbeck (not currently), Bayer Health Care
 - Susan Potts, SDC
-
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-
- **Thanks in advance to any future reviewers – we look forward to your feedback during the public review period!**