6 Domain Models Based on the General Observation Classes

Note: This copy of the OE domain model is identical to the one that was made available for public review as part of Batch 2 for SDTMIG v3.3.

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, Codelist 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
FOCID	Focus of Study-Specific Interest	Char	(OEFOCUS)	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. 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

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
OEGRPID	Group ID	Char		Identifier	Optional group identifier, used to link together a block of related records within a subject in a domain.	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 OELINKID 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: *NUMLCOR*.	Req
OETEST	Name of Measurement, Test or Examination	Char	(OETEST)	Synonym Qualifier of OETESTCD	Long name for test. Example: *Number of Letters Correct* for OETESTCD=*NUMLCOR*.	Req
OETSTDTL	Measurement, Test or Examination Detail	Char	*	Variable Qualifier of OETESTCD and OETEST	Further description of OETESTCD and OETEST. Example: "*Chart Distance 3.2m"* when OETESTCD = *NUMLCOR*.	Perm
OECAT	Category	Char	*	Grouping Qualifier	Used to define a category of Topic-variable values. Examples: VISUAL ACUITY, CONTRAST SENSITIVIY, OCULAR COMFORT. Not to be used as a test differentiator, just as a grouping variable.	Perm
OESCAT	Subcategory	Char	*	Grouping Qualifier	Used to define a further categorization of OECAT values. Example: HIGH CONTRAST and LOW CONTRAST when OECAT is VISUAL ACUITY. Not to be used as a test differentiator, just as a sub-grouping variable.	Perm
OEORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: 120, <1, NORMAL, RED SPOT VISIBLE ON CONJUNCTIVA.	Exp
OEORRESU	Original Units	Char	(UNIT)	Variable Qualifier of OEORRES	Unit for OEORRES. Examples: IN, mm, um.	Exp
OEORNRLO	Normal Range Lower Limit-Original Units	Char		Variable Qualifier of OEORRES	Lower end of normal range or reference range for results stored in OEORRES.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
OEORNRHI	Normal Range Upper Limit-Original Units	Char		Variable Qualifier of OEORRES	Upper end of normal range or reference range for results stored in OEORRES.	Perm
OESTRESC	Result or Finding in Standard Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from OEORRES in a standard format or in standard units. OESTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in OESTRESN. For example, if various tests have results “NONE”, “NEG”, and “NEGATIVE” in OEORRES and these results effectively have the same meaning, they could be represented in standard format in OESTRESC as "NEGATIVE". If OEORRES is numeric, OESTRESC is a copy of OEORRES.	Exp
OESTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from OESTRESC. OESTRESN should store all numeric test results or findings.	Exp
OESTRESU	Standard Units	Char	(UNIT)	Variable Qualifier of OESTRESC and OESTRESN	Standardized units used for OESTRESC and OESTRESN. Example: mol/L.	Exp
OESTNRLO	Normal Range Lower Limit-Standard Units	Num		Variable Qualifier of OESTRESC and OESTRESN	Lower end of normal range or reference range for standardized results (e.g., OESTRESC, OESTRESN) represented in standardized units (OESTRESU).	Perm
OESTNRHI	Normal Range Upper Limit-Standard Units	Num		Variable Qualifier of OESTRESC and OESTRESN	Upper end of normal range or reference range for standardized results (e.g., OESTRESC, OESTRESN) represented in standardized units (OESTRESU).	Perm
OESTNRC	Normal Range for Character Results	Char		Variable Qualifier of OESTRESC	Normal range or reference range for results stored in OESTRESC that are character in ordinal or categorical scale. Example: Negative to Trace.	Perm
OENRIND	Normal/Reference Range Indicator	Char	(NRIND)	Variable Qualifier of OEORRES	Used to indicate the value is outside the normal range or reference range. May be defined by OEORNRLO and OEORNRHI or other objective criteria. Examples: Y, N; HIGH, LOW; NORMAL; ABNORMAL.	Perm
OERESCAT	Result Category	Char		Variable Qualifier of OEORRES	Used to categorize the result of a finding or medical status per interpretation of test results. Example: “POSITIVE”, “NEGATIVE. The variable OERESCAT is not meant to replace the use of OENRIND for cases where normal ranges are provided.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
OESTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a question was not asked or a test was not done, or a test was attempted but did not generate a result. Should be null or have a value of NOT DONE.	Perm
OEREASND	Reason Not Done	Char		Record Qualifier	Reason not done. Used in conjunction with OESTAT when value is NOT DONE.	Perm
OEXFN	External File Path	Char		Record Qualifier	Filename for an external file, such as one for a retinal OCT image.	Perm
OELOC	Location Used for the Measurement	Char	(LOC)	Record Qualifier	Anatomical location of the subject relevant to the collection of the measurement. Examples: EYE for a finding record relative to the complete eye, RETINA for a measurement or assessment of only the RETINA. See SDTMIG *Section 4.1.5.1.2 Tests Not Done* and associated example included in the attachment for an example on when LOC=*EYE* may be applicable. The variable should be populated at a minimum when the test refers to a part of the eye and the information is collected.	Perm
OELAT	Laterality	Char	(LAT)	Variable Qualifier of OELOC	Qualifier for anatomical location or specimen further detailing laterality. Examples: RIGHT, LEFT, BILATERAL The variable should be populated at a minimum when the test refers to a part of the eye and the information is collected.	Perm
OEDIR	Directionality	Char	(DIR)	Variable Qualifier of OELOC	Qualifier for anatomical location or specimen further detailing directionality. Examples: ANTERIOR, LOWER, PROXIMAL. The variable should be populated as needed, at a minimum when the test refers to a part of the eye and the information is collected.	Perm
OEPORTOT	Portion or Totality	Char	(PORTOT)	Variable Qualifier of OELOC	Qualifier for anatomical location or specimen further detailing the distribution, which means arrangement of, apportioning of. . Examples: ENTIRE, SINGLE, SEGMENT, MANY. The variable should be populated as needed, at a minimum when the test refers to a part of the eye and the information is collected.	Perm
OEMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples: *ETDRS* for OETESTCD=*NUMLCOR*; *CIRRUS OCT*, *STRATUS OCT*, *SPECTRAL DOMAIN OCT* for Optical Coherence Tomography (OCT) methods. The different methods may offer different functionality or granularity, affecting the set of results and associated meaning.	Exp

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
OEBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. Should be Y or null.	
OEDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be Y or null.	Perm
OEEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Examples: ADJUDICATION COMMITTEE, INDEPENDENT ASSESSOR, RADIOLOGIST.	Exp
OEEVALID	Evaluator Identifier	Char		Variable Qualifier of OEEVAL	Used to distinguish multiple evaluators with the same role recorded in OEEVAL. Examples: RADIOLOGIST1 or RADIOLOGIST2	Perm
OEACPTFL	Accepted Record Flag	Char		Record Qualifier	In cases where more than one assessor provides an evaluation of a result or response, this flag identifies the record that is considered, by an independent assessor, to be the accepted evaluation. Expected to be Y or null.	Perm
VISITNUM	Visit Number	Num		Timing	Clinical encounter number. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	Protocol-defined description of a clinical encounter.	Exp
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of VISIT. Should be an integer.	Perm
EPOCH	Epoch	Char		Timing	Epoch associated with the start date/time of the observation, or the date/time of collection if start date/time is not collected.	Perm
OEDTC	Date/Time of Collection	Char	IS0 8601	Timing	Collection date and time of an observation represented in IS0 8601 character format.	Exp
OETPT	Planned Time Point Name	Char		Timing	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See OETPTNUM and OETPTREF.	Perm
OETPTNUM	Planned Time Point Number	Num		Timing	Numeric version of planned time point used in sorting.	Perm
OETPTREF	Time Point Reference	Char		Timing	Description of the fixed reference point referred to by OEELTM, OETPTNUM, and OETPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
OEREPNUM	Repetition Number	Num		Timing	Used to indicate the chronological order of repeated tests. The level of granularity can vary, for example within a time point or within a visit. Used for cases where date/time in conjunction with time points or visits alone cannot distinguish between repetitions of a test.	Perm

** Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)*

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OE – Assumptions for Ophthalmic Examinations Domain Model

Since there are no separate guidelines to cover specific Ophthalmology Therapeutic Area needs at the time the OE Domain is released, a few guidelines included in this document are intended to cover some of those cross-domain needs, such as, the use of --CAT/--SCAT and the recommended use of other SDTM Domains as in the examples provided (e.g., PR, DI, AE, RELREC).

1. This 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. The *OE* Domain should not include morphological ophthalmic examinations, which should be included in the *MO* domain. In general, the *OE* Domain should not be a domain to place all ophthalmic related data. Rather, data that appropriately should be modeled in other established domains should be continued to be placed in those domains, with *OE* being reserved for the physiological ophthalmic examinations only. However, those guidelines and assumptions that refer to all ophthalmic examinations may need to be taking into account when modeling ophthalmic examinations in other Findings domains.

    b. Regardless of the SDTM domain that the ophthalmic examinations data are stored (MO, OE, and others), it should be possible to create a combined, cohesive view (*OE Single Virtual View*) of all ophthalmic examinations. 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 combined in a single virtual view of all ophthalmic findings, all detailed metadata must be consistent.

        i. The *OE Single Virtual View* can be thought of a "data listing" dataset created by combining all ophthalmic records stored in any Finding domains. In case of a submission, this data listing could be saved in the eCTD folder reserved for data listings, for instance, with a name of *oesvw* with the appropriate extension (currently *.xpt*, in the future *.xml*) and a dataset listing description "Virtual View of Ophthalmic Examinations".

2. The variable FOCID (Focus of Study-Specific Interest), introduced in SDTM v1.5, is allowed in all subject-level general-observation-class domains. In ophthalmic studies, FOCID is used to represent the terms OD, OS, OU as an identifier to group ophthalmic data. These terms are the exclusively preferred terms used by the ophthalmology community as abbreviations for the expanded Latin terms listed below. The meaning for each term is included in parenthesis.

    OD: Oculus Dexter (Right Eye)
    OS: Oculus Sinister (Left Eye)
    OU: Oculus Uterque (Both Eyes)

    a. The use of these controlled FOCID terms for all ophthalmic data will facilitate creating the cohesive *OE Single Virtual View* containing all the records from OE joined with ophthalmic records from MO and any other Findings domains.

    b. Ophthalmic records in any subject-level domain are identified with 1) location values referencing the eye or parts of the eye, when location variables are populated or 2) having the variable --FOCID populated with one of the three terms listed above.

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3. The variables --LOC, --LAT, --DIR, and --PORTOT are permissible for other uses, in particular the ability of specifying detailed locations and performing queries at an aggregate level.
    a. Note the potential duplication of information between FOCID and --LOC/--LAT; however, the variables --LOC and --LAT are recommended to be populated in all cases for ophthalmic findings since the benefits of facilitating grouping and data aggregation for other needs are recognized.
4. The variables OETEST, OETSTDTL and OEMETHOD are expected to uniquely identify an ophthalmic test.
    a. Result and other variables' 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.

5. The approach followed in the use of --CAT and --SCAT variables for ophthalmic examinations is described below. Most values are reflected in the examples provided for OE and MO.
    a. For functional examinations, use --CAT to indicate the function that correspond to the object of the test and --SCAT as a further sub-classification when needed. The following would be suggested --CAT values:
        i. Visual Acuity
            1. High Contrast
            2. Low Contrast
        ii. Contrast Sensitivity
        iii. Color Vision
        iv. Visual Field
        v. Ocular Comfort
        vi. [Other functional groups]

        Functional exams may also occur to follow the sequence in the process of examination; however, those will be differentiated from the morphological examinations in that generally functional exams involve subjects answering questions [and evaluator providing observations].
    b. For morphological examinations, use --CAT to indicate the segment of the eye that is being examined and --SCAT as a further sub-classification when needed. For the most part, it would coincide with the way CRFs are normally designed to follow the sequence in the process of examination. The following would be suggested --CAT/--SCAT values (displayed in title case in this document for readability):
        i. Anterior Segment Examination
            1. External
            2. Anterior Chamber
            3. Posterior Chamber
        ii. Posterior Segment Examination

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c. For evaluations that may result from the combined assessments of results from other ophthalmic examinations, use --CAT to indicate that it is an overall evaluation and --SCAT as a further sub-classification when needed. The following would be suggested --CAT values:

    i. Overall Evaluation

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6. As illustrated in the examples, when procedures are performed on the eye:
    a. The OE domain is expected to contain the test results for physiological assessments associated to those procedures.
        i. For instance, the OE domain would contain the results of the Visual Acuity assessments. Refer to the Visual Acuity examples shown in Section *OE – Examples for Ophthalmic Examinations Domain Model* (*Example 6* and *Example 7* in the *OE* tab*)*. In these examples, the information of the procedure is sufficient with the data included since no other separate information was collected.
    b. The PR (Procedures) domain can be used to include the information on the procedure performed when the Findings data is not sufficient to describe the conduct of a procedure and details of the procedure are collected. In particular the complete start and end dates and times of the procedure (e.g., Visual field computerized procedures, OCT, MRI, Fundus Photography), the occurrence or not for pre-specified procedures and reason a procedure does not occur; plus the device ID when device information is collected.
        i. When information on devices used in the study is collected:
            1. The DI (Study Device Identifiers) domain is expected to contain device identification information.
            2. The DU (Device In-Use) domain is expected to contain information on device settings used in a given procedure, when settings used are collected and the device has setting options available. The DO (Device Properties) domain may be added to include the different properties and device settings available.
                a. Note that many devices come with options to adjust settings for a particular property at time of use (i.e., adjust the field strength when performing an MRI procedure on a subject at a given date and time). In this case, the field strength corresponding to an image produced by the device on the corresponding procedure, for a given subject, would be naturally captured in the DU domain as opposed to a Supplemental Qualifier variable for the OE or MO domains.
                b. When DO is included and there are no optional settings or when individual settings are specified by protocol to be the same for each use of the device, there is no need to capture individual device use since the date of the procedure is expected to be in PR.
        ii. As a general example, in Visual Field computerized assessments the OE domain would contain the results of the Visual Test assessments and the PR and DI/DU/DO domains would contain procedural and device related information if collected.
    c. For illustration on how to use the –LNKID variable in cases where PR, DI and RELREC domains are used, since a detailed OE example for this use case is not included at the present time for OE, refer to the OCT examples shown in Section *OE – Examples for Ophthalmic Examinations Domain Model (Example 4 and Example 7* in the *MO* tab plus *PR* and *DI* tabs).

7. This domain should not include eye examinations when those occur as part of a standard general physical examination and no specialized ophthalmic exams are performed in the trial. The Physical Examination (PE) domain may be used in those cases to report abnormalities or normal condition.

8. The following Qualifiers would not generally be used in OE: --MODIFY, --POS, -BODSYS, --LOINC, --SPEC, --ANTREG, --SPCCND, --SPCUFL, -LEAD, --CSTATE, --FAST, --TOX, --TOXGR, --DTHREL, --LLOQ, --ULOQ, --EXCLFL, --REASEX, --DETECT.

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OE – Examples for Ophthalmic Examinations Domain Model

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

1. From the "View" menu select "Navigation Panes" and then select "Attachments", or click here.
   - The "View" menu options may vary with newer versions of Acrobat Reader. For instance, with Adobe Reader XI, from the "View" menu select "Show/Hide", then "Navigation Panes" and then select "Attachments".

2. The "Attachments Panel" will open and you will be able to select and open the attached spreadsheet.

Spreadsheets Included

#	Name	Description
1	ReadMe	Summary explanation of the content of the spreadsheet and purpose of inclusion in this set of examples.
2	OE(SingleVirtualView)	Contain examples of ophthalmic findings when looked as a combined/joined single virtual view of all physiological, morphological and other types of ophthalmic findings data.
3	OE	Contain examples of physiological ophthalmic findings and corresponding supplemental qualifier variables.
4	SUPPOE	
5	MO	Contain examples of morphological ophthalmic findings and corresponding supplemental qualifier variables.
6	SUPPMO	
7	PR	Contains examples of PR data for any procedures performed associated to the ophthalmic examinations, for which a link has been provided in the corresponding finding observation. It also illustrates the use of the variable FOCID (newly introduced in SDTM v1.5)
8	DI	Contains examples of DI data for any devices associated to procedures performed associated to the ophthalmic examinations, for which a reference has been provided in the corresponding procedure observation.
9	AE	Contains examples of AE data displaying one ophthalmic observation illustrating the use of the variable FOCID (newly introduced in SDTM v1.5)
10	RELREC	Contains an example of the RELREC dataset representing the relationship between ophthalmic examinations domain(s) and any other domain included in the examples.

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