

# Consolidated Database in Otolaryngology

## Standard Variable Library

The Consolidated Database in Otolaryngology (CDO) is organized in the CDISC format. CDISC is a global organization that supports data standards to enable information to be used across multiple systems. The CDISC standard has been implemented by the FDA. More information is available at [www.cdisc.org](http://www.cdisc.org).

CDISC organizes information across different domains using common variable names. The attached variable library represents the domains and variables currently in use in the CDO.



### Overview of Available Domains

Domain	Domain Label	Class	Structure	Domain Sort Keys	Repeating
AE	Adverse Event	Events	One record per event per subject	STUDYID, USUBJID, AESEQ	Yes
CM	Concomitant Medication	Interventions	One record per medication intervention per subject	STUDYID, USUBJID, CMSEQ	Yes
DM	Demographics	Special-Purpose Domain	One record per subject	STUDYID, USUBJID	No
LB	Laboratory	Findings	One record per lab value per visit per subject	STUDYID, USUBJID, LBSEQ	Yes
MH	Medical History	Events	One record per medical history event per subject	STUDYID, USUBJID, MHSEQ	Yes
PR	Procedures	Interventions	One record per procedure per subject	STUDYID, USUBJID, PRSEQ	Yes
QS	Questionnaires	Findings	One record per question per visit per subject	STUDYID, USUBJID, QSSEQ	Yes
SC	Subject Characteristics	Findings	One record per characteristic per subject	STUDYID, USUBJID, SCSEQ	Yes
SU	Substance Use	Trial Design	One record per substance per subject	STUDYID, USUBJID, SUSEQ	Yes
SV	Subject Visits	Trial Design	One record per visit per subject	STUDYID, USUBJID, SVSEQ	Yes
VS	Vital Signs	Findings	One record per vital sign per visit per subject	STUDYID, USUBJID, VSSEQ	Yes

### AE Domain

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
AESEQ	Sequence Number	Numeric	
AETERM	Reported Term for the Adverse Event	Character	200
AEMODIFY	Short form of AETERM for searching	Character	10
AEDECOD	Dictionary-Derived Term	Character	50
AESEV	Severity/Intensity	Character	50
AESER	Serious Event	Character	50
AEACN	Action Taken	Character	50
AEACNOTH	Other Action Taken	Character	200
AEOUT	Outcome of Adverse Event	Character	50
AECAT	Category of Adverse Event	Character	200
AESCAT	Subcategory of Adverse Event	Character	200
VISITDY	CRF Day of Collection of Adverse Event	Numeric	
AEDY	Study Day of Adverse Event	Numeric	

### CM Domain

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
CMSEQ	Sequence Number	Numeric	
CMRESP	Medication Pre-Specified	Character	50
CMMODIFY	Modified Term for the Medication	Character	8
CMTERM	Reported Term for the Medication	Character	200
CMCAT	Medication Category	Character	200
CMSCAT	Medication Subcategory	Character	200
CMOCCUR	Medication Occurrence	Character	50
CMUNIT	Range of valid units (responses) for CMOCCUR	Character	200
VISITDY	CRF Day of Collection of Medication	Numeric	
CMDY	Study Day of Medication Collection	Numeric	

### DM Domain

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
SUBJID	Subject Identifier for the Study	Character	8
RFSTDY	Subject Reference Start Day	Numeric	
RFXSTDY	Time to First Study Treatment (Days)	Numeric	
DTHDY	Time to Death (Days)	Numeric	
DTHFL	Subject Death Flag	Character	1
SITEID	Study Site Identifier	Character	50
INVID	Investigator Identifier	Character	200
AGE	Age	Character	20
AGEU	Age Units	Character	5
SEX	Sex	Character	2
RACE	Race	Character	45
ETHNIC	Ethnicity	Character	40
ARMCD	Planned Arm Code	Character	8
ARM	Description of Planned Arm	Character	200
ACTARMCD	Actual Arm Code	Character	8
ACTARM	Description of Actual Arm	Character	200
COUNTRY	Country	Character	3
STATE	US State, When Applicable	Character	2

### LB Domain

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
LBSEQ	Sequence Number	Numeric	
LBTESTCD	Lab Test or Examination Short Name	Character	8
LBTEST	Lab Test or Examination Name	Character	200
LBCAT	Category for Lab Test	Character	200
LBSCAT	Subcategory for Lab Test	Character	200
LBORRES	Result or Finding in Original Units	Character	50
LBORRESN	Result or Finding in Original Units - Numeric	Numeric	
LBORRESU	Original Units	Character	200
LBORNRL0	Reference Range Lower Limit	Character	50
LBORNRLHI	Reference Range Upper Limit	Character	50
LBSPEC	Specimen Type	Character	50
VISITDY	CRF Day of Collection of Lab	Numeric	
LBDY	Study Day of Lab	Numeric	

### **MH Domain**

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
MHSEQ	Sequence Number	Numeric	
MHPRESP	Medical History Event Pre-Specified	Character	1
MHMODIFY	Modified Term for the Medical History	Character	8
MHTERM	Reported Term for the Medical History	Character	200
MHCAT	Medical History Event Category	Character	200
MHSCAT	Medical History Event Subcategory	Character	200
MHOCCUR	Medical History Occurrence	Character	1
MHUNIT	Medical History Unit	Character	200
VISITDY	CRF Day of History Collection	Numeric	
MHDY	Study Day of History Collection	Numeric	

**PR Domain**

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
PRSEQ	Sequence Number	Numeric	
PRINDC	Indication for the procedure	Character	50
PRTRT	Reported Term for the procedure	Character	200
PRCAT	Procedure category	Character	200
PRSCAT	Procedure subcategory	Numeric	200
PROCCUR	Procedure occurred	Character	50
PRUNIT	Unit	Character	200
PRDOSE	Dose (if applicable)	Character	50
PRDY	Study Day of procedure	Numeric	



### QS Domain

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
QSSEQ	Sequence Number	Numeric	
QSTESTCD	Question Short Name	Character	8
QSTEST	Question Name	Character	200
QSCAT	Question Category	Character	200
QSSCAT	Question Subcategory	Character	200
QSORRES	Result or Finding	Character	50
QSORRESU	Unit for Result or Finding	Character	200
QSREAS	Reason (if any) for Result or Finding	Character	200
QSEVAL	Evaluator	Character	50
QSDY	Study Day of Finding	Numeric	
QSTPT	Planned Time Point for Questionnaire Collection	Character	50
QSSURG	Surgeon Name (For surgical questionnaires)	Character	50

### SC Domain

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
SCSEQ	Sequence Number	Numeric	
SCTESTCD	Subject Characteristic Short Name	Character	8
SCTEST	Subject Characteristic	Character	200
SCCAT	Category for Subject Characteristic	Character	200
SCSCAT	Subcategory for Subject Characteristic	Character	200
SCORRES	Result or Finding	Character	50
SCORRESU	Range of valid units (responses) for SCORRES	Character	200
SCDY	Study Day of Collection	Numeric	

### SU Domain

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
SUSEQ	Sequence Number	Numeric	
SUTRT	Reported Name of Substance	Character	200
SUCAT	Category for Substance Use	Character	200
SUDOSTXT	Substance Use Consumption Text	Character	50
SUDOSU	Substance Use Consumption Unit	Character	200

### SV Domain

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
VISITNUM	Visit Number	Numeric	
VISIT	Visit Name	Character	200
VISITDY	Planned Study Day of Visit	Numeric	
SVSTDY	Study Day of Start of Visit	Numeric	
SVENDY	Study Day of End of Visit	Numeric	
SVUPDES	Description of Unplanned Visit	Character	200

### VS Domain

<b>Variable Name</b>	<b>Variable Label (describes the data captured)</b>	<b>Character or Numeric</b>	<b>Length of Variable</b>
STUDYID	Study Identifier	Character	20
DOMAIN	Domain Abbreviation	Character	2
USUBJID	Unique Subject Identifier	Character	50
VSSEQ	Sequence Number	Numeric	
VSTESTCD	Vital Signs Test Short Name	Character	8
VSTEST	Vital Signs Test Name	Character	200
VSCAT	Vital Signs Category	Character	200
VSSCAT	Vital Signs Subcategory	Character	200
VSORRES	Result or Finding in Original Units	Character	50
VSORRESN	Numeric Result or Finding in Original Units	Numeric	
VSORRESU	Original Units	Character	200
VSLOC	Location of Vital Sign	Character	50
VISIT	Visit Name	Character	50
VISITDY	CRF Day of Measurement	Numeric	
VSDY	Study Day of Measurement	Numeric	