

Study Name	CDISC01_1
Study Description	CDISC Test Study Modified to illustrate Define-XML 2.1 features
Protocol Name	CDISC01-1
Metadata Name	Study CDISC01_1, Data Definitions V-1
Metadata Description	Data Definitions for CDISC01-01 SDTM datasets. This metadata version contains only a subset of datasets compa version. The metadata provided is only intended to illustrate most Define-XML 2.1 new features and not meant to comprehensive example of all metadata expected to be defined to fully describe an SDTM dataset package. Notes Supplemental documents released in prior Define-XML versions were not updated to reflect changes to the metac example is prepared for a context other than submission; however, still using the approach of non-standard varia supplemental qualifiers datasets.

Standards for Study CDISC01\_1

Standard	Type	Status	Documentation
SDTMIG 3.1.2	IG	Final	The CDISC01 study was modeled on a very old SDTMIG and no attempt was done yet to upversion it to a newer
SDTMIG 3.2	IG	Final	As an example, the CDISC01 study was adjusted to include a new Domain available in SDTM IG 3.2
SDTMIG-MD 1.0	IG	Final	As an example, the CDISC01 study was adjusted to include a new Domain available in SDTMIG-MD 1.0. The XS expected to reference the device used with variable SPDEVID.
CDISC/NCI SDTM 2011-12-09	CT	Final	Assuming the CT was not upversioned for this study
CDISC/NCI SDTM 2015-12-18	CT	Final	The CT version applicable for the new Domain is the 2015-12-18 version

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation
TS [SDTMIG 3.1.2]	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	
DI [SDTMIG-MD 1.0]	Device Identifiers	SPECIAL PURPOSE	One record per device identifier per device	Tabulation	STUDYID, SPDEVID, DIPARMCD	The DI domain is included to illustrate the use of a separate complementary SDTMIG. In this example, the device ID is referenced from a Findings Doma (XS).
DM [SDTMIG 3.1.2]	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	See Reviewer's Guide, Section 2.: Demographics Reviewers Guide [section2.1 (csdrg.pdf#section2.1).]
EC [SDTMIG 3.2]	Exposure as Collected	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, ECSTDTC, ECENDTC, ECTRT, ECDOSE	
EX [SDTMIG 3.1.2]	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXSTDTC, EXENDTC, EXTRT, EXDOSE	
LB [SDTMIG 3.1.2]	Laboratory Tests Results	FINDINGS	One record per analyte per visit per subject	Tabulation	STUDYID, USUBJID, LBCAT, LBMETHOD, LBTESTCD, LBDTC, VISITNUM, LBNAM	
VS [SDTMIG 3.1.2]	Vital Signs	FINDINGS	One record per vital sign measurement per visit per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VSDTC, VISITNUM, VSPOS	
XS [Non Standard]	S Findings	FINDINGS	One record per finding per visit	Tabulation	STUDYID, USUBJID,	

			per subject		XSTESTCD, XSDTC, VISITNUM	
XX [Non Standard] [No Data]	X Findings	FINDINGS	One record per finding per visit per subject	Tabulation	STUDYID, USUBJID, XSTESTCD, XXDTC, VISITNUM	Special domain contingent on ran conditions observed.
SUPPDM [SDTMIG 3.1.2]	Supplemental Qualifiers for DM (Demographics)	RELATIONSHIP	One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	
SUPPVS [SDTMIG 3.1.2] [No Data]	Supplemental Qualifiers for VS (Vital Signs)	RELATIONSHIP	One record per IDVAR, IDVARVAL, and QNAM value per subject	Tabulation	STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM	

TS (Trial Summary) - [SDTMIG 3.1.2]

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Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN		Domain Abbreviation	text	2	Domain Abbreviation (TS) • "TS" = "Trial Summary"	Assigned (Source: Sponsor)
TSSEQ		Sequence Number	integer	1		Derived (Source: Sponsor) Sequential number identifier within each TSPARM instance
TSPARMCD		Trial Summary Parameter Short Name	text	8	Trial Summary Parameter Test Code [24 Terms]	Assigned (Source: Sponsor)
TSPARM		Trial Summary Parameter	text	36	Trial Summary Parameter Test Name [24 Terms]	Assigned (Source: Sponsor)
TSVAL <a href="#">VLM</a>		Parameter Value	text	100		Protocol (Source: Sponsor)
	TSPARMCD = "AGEMAX" (Planned Maximum Age of Subjects)	Planned Maximum Age of Subjects	integer	2		Protocol (Source: Sponsor)
	TSPARMCD = "AGEMIN" (Planned Minimum Age of Subjects)	Planned Minimum Age of Subjects	integer	2		Protocol (Source: Sponsor)
	TSPARMCD = "AGEU" (Age Unit)	Age Unit	text	5	Age Unit • "YEARS"	Protocol (Source: Sponsor)
	TSPARMCD = "DOSE" (Dose per Administration)	Dose per Administration	integer	2		Protocol (Source: Sponsor)
	TSPARMCD = "FCNTRY" (Planned Country of Investigational Sites)	Planned Country of Investigational Sites	text	3	Study Planned Countries • "USA" = "United States of America (the)" • "CAN" = "Canada" • "MEX" = "Mexico"	Protocol (Source: Sponsor)
	TSPARMCD = "PLANSUB" (Planned Number of Subjects)	Planned Number of Subjects	integer	2		Protocol (Source: Sponsor)

DI (Device Identifiers) - [SDTMIG-MD 1.0]

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Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (DI) • "DI" = "Device Identifiers"	Assigned (Source: Sponsor)
SPDEVID	Sponsor Device Identifier	text	30		Collected (Source: Vendor)

DISEQ	Sequence Number	integer	3		Derived (Source: Sponsor) Sequential number identifying records within ea domain.
DIPARMCD	Device Identifier Element Short Name	text	20		Assigned (Source: Vendor)
DIPARM	Device Identifier Element Name	text	100		Assigned (Source: Vendor)
DIVAL	Device Identifier Element Value	text	200		Collected (Source: Vendor)

**DM (Demographics) - [SDTMIG 3.1.2]**

Location:

Related Supplemental Qualifiers Dataset: SUPPDM (Supplemental Qualifiers for DM)					
Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (DM) • "DM" = "Demographics"	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
SUBJID	Subject Identifier for the Study	text	6		Collected (Source: Investigator) Annotated CRF [3_(acrf.pdf#page=3).]
RFSTDTC	Subject Reference Start Date/Time	date		ISO 8601	Derived (Source: Sponsor) RFSTDTC = first date/time of study drug, for safety subject. Null for screen failures.
RFENDTC	Subject Reference End Date/Time	date		ISO 8601	Derived (Source: Sponsor) RFENDTC = termination date, for safety subjects. Null for screen failures.
SITEID	Study Site Identifier	text	3		Collected (Source: Investigator) Annotated CRF [3_(acrf.pdf#page=3).]
BRTHDTC	Date/Time of Birth	date		ISO 8601	Collected (Source: Investigator) Annotated CRF [6_(acrf.pdf#page=6).]
AGE	Age	integer	2		Derived (Source: Sponsor) Age at Screening Date (Screening Date - Birth date).  For the complete algorithm see the referenced external docume Complex Algorithms [DM_(complexalgorithms.pdf#DM).]
AGEU	Age Units	text	5		Assigned (Source: Sponsor) Defaulted to YEARS
SEX	Sex	text	16	Sex • "F" = "Female" • "M" = "Male" • "U" = "Unknown" • "UNDIFFERENTIATED" = "Undifferentiated"	Collected (Source: Investigator) Annotated CRF [6_(acrf.pdf#page=6).]
RACE	Race	text	41	Race • "WHITE" • "AMERICAN INDIAN OR ALASKA NATIVE" • "BLACK OR AFRICAN AMERICAN" • "ASIAN" • "NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER"	Collected (Source: Investigator) Annotated CRF [6_(acrf.pdf#page=6).] Selected value converted to upper case to match CT. Note that the study protocol has been amended to not allow the other race per current regulatory requirements. Refer to FDA G PMDA Guidance P-XYZ.
ETHNIC	Ethnicity	text	22	Ethnic Group • "HISPANIC OR LATINO" • "NOT HISPANIC OR LATINO"	Collected (Source: Investigator) Annotated CRF [6_(acrf.pdf#page=6).]
ARMCD	Planned Arm Code	text	8	Planned Arm Code	Assigned (Source: Sponsor) Assigned based on Randomization Number. See Note 2.1

				<ul style="list-style-type: none"> <li>"WONDER10" = "Miracle Drug 10 mg"</li> <li>"WONDER20" = "Miracle Drug 20 mg"</li> <li>"PLACEBO" = "Placebo"</li> <li>"SCRNFAIL" = "Screen Failure"</li> </ul>	Reviewers Guide ( <a href="#">csdrg.pdf</a> )
ARM	Description of Planned Arm	text	20	Description of Planned Arm <ul style="list-style-type: none"> <li>"Miracle Drug 10 mg"</li> <li>"Miracle Drug 20 mg"</li> <li>"Placebo"</li> <li>"Screen Failure"</li> </ul>	Assigned (Source: Sponsor) Assigned from TA.ARM based on ARMCD.
COUNTRY	Country	text	3	Country Codes ISO-3166 (Country Codes) 2013-11-15	Assigned (Source: Sponsor)

**EC (Exposure as Collected) - [SDTMIG 3.2]**

Location

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (EC) <ul style="list-style-type: none"> <li>"EC" = "Exposure as Collected"</li> </ul>	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
ECSEQ	Sequence Number	integer	1		Derived (Source: Sponsor) Sequential number identifying records within each domain.
ECTRT	Name of Actual Treatment	text	20	Treatment <ul style="list-style-type: none"> <li>"Miracle Drug"</li> <li>"Placebo"</li> </ul>	Derived (Source: Sponsor) Derived from ARM, ARMCD
ECDOSE	Dose per Administration	integer	2		Derived (Source: Sponsor)
ECDOSU	Dose Units	text	2		Derived (Source: Sponsor)
ECDOSFRM	Dose Form	text	7	Pharmaceutical Dosage Form <ul style="list-style-type: none"> <li>"TABLET" = "tab"</li> </ul>	Collected (Source: Investigator) Annotated CRF [20_( <a href="#">acrf.pdf#page=20</a> )]
ECSTDTC	Start Date/Time of Treatment	date		ISO 8601	Collected (Source: Investigator) Annotated CRF [20_( <a href="#">acrf.pdf#page=20</a> )]
ECENDTC	End Date/Time of Treatment	date		ISO 8601	Collected (Source: Investigator) Annotated CRF [20_( <a href="#">acrf.pdf#page=20</a> )]
ECSTDY	Study Day of Start of Treatment	integer	2		Derived (Source: Sponsor) EXSTDY = EXSTDTC - RFSTDTC+1 if EXSTDTC is on RFSTDTC. EXSTDTC - RFSTDTC if EXSTDTC precedes RFSTDTC
ECENDY	Study Day of End of Treatment	integer	2		Derived (Source: Sponsor) ECENDY = ECENDTC-RFSTDTC+1 if ECENDTC is on RFSTDTC. ECENDTC - RFSTDTC if ECENDTC precedes RFSTDTC

**EX (Exposure) - [SDTMIG 3.1.2]**

Location

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (EX) <ul style="list-style-type: none"> <li>"EX" = "Exposure"</li> </ul>	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID

EXSEQ	Sequence Number	integer	1		Derived (Source: Sponsor) Sequential number identifying records within each USUBJID
EXTRT	Name of Actual Treatment	text	20	Treatment • "Miracle Drug" • "Placebo"	Derived (Source: Sponsor) Derived from ARM, ARMCD
EXDOSE	Dose per Administration	integer	2		Derived (Source: Sponsor) If ARMCD=WONDER10 then EXDOSE = Number of Tablets where QNAM=SMNO) * 10. If ARMCD=WONDER20 then EXDOSE = Number of Tablets where QNAM=SMNO) * 20. If ARMCD=PLACEBO then EXDOSE = 0.
EXDOSU	Dose Units	text	2		Derived (Source: Sponsor) Derived from ARM, ARMCD - equal to mg
EXDOSFRM	Dose Form	text	7	Pharmaceutical Dosage Form • "TABLET" = "tab"	Predecessor (Source: Sponsor) EC.ECDOSFRM Annotated CRF [20_(acrf.pdf#page=20).]
EXSTDTC	Start Date/Time of Treatment	date		ISO 8601	Predecessor (Source: Sponsor) EC.ECSTDTC Annotated CRF [20_(acrf.pdf#page=20).]
EXENDTC	End Date/Time of Treatment	date		ISO 8601	Predecessor (Source: Sponsor) EC.ECENDTC Annotated CRF [20_(acrf.pdf#page=20).]
EXSTDY	Study Day of Start of Treatment	integer	2		Derived (Source: Sponsor) EXSTDY = EXSTDTC - RFSTDTC+1 if EXSTDTC is on or after EXSTDTC - RFSTDTC if EXSTDTC precedes RFSTDTC.
EXENDY	Study Day of End of Treatment	integer	2		Derived (Source: Sponsor) EXENDY = EXENDTC-RFSTDTC+1 if EXENDTC is on or after EXENDTC - RFSTDTC if EXENDTC precedes RFSTDTC.

**LB (Laboratory Tests Results) - [SDTMIG 3.1.2]**

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Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN		Domain Abbreviation	text	2	Domain Abbreviation (LB) • "LB" = "Laboratory Data"	Assigned (Source: Sponsor)
USUBJID		Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
LBSEQ		Sequence Number	integer	2		Derived (Source: Sponsor) Sequential number identifying records within the domain.
LBREFID		Specimen ID	text	7		Collected (Source: Vendor) Accession number
LBTESTCD		Lab Test or Examination Short Name	text	7	Laboratory Test Code [10 Terms]	Assigned (Source: Sponsor)
LBTEST		Lab Test or Examination Name	text	22	Laboratory Test Name [10 Terms]	Collected (Source: Vendor)
LBCAT		Category for Lab Test	text	10		Collected (Source: Vendor)
LBORRES <a href="#">VLM</a>		Result or Finding in Original Units	text	8		Origin specified at Value Level Metadata
	LBTESTCD IN ( "BILI" (Bilirubin), "GLUC" (Glucose) ) and LBSPEC = "BLOOD"	Result or Finding in Orig Units - Set 1	float	3		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB"
	LBTESTCD IN ( "BUN" (Blood Urea	Result or Finding in Orig Units - Set 2	float	4		Collected (Source: Vendor)

	Nitrogen), "HGB" (Hemoglobin), "LYM" (Lymphocytes) ) and LBSPEC = "BLOOD"					From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD IN ( "GLUC" (Glucose), "OCCBLD" (Occult Blood) ) and LBSPEC = "URINE"	Result or Finding in Orig Units Set 3	text	8		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD = "HCT" (Hematocrit) and LBSPEC = "BLOOD" and LBNAM = "LOCAL LAB"	Hematocrit	float	4		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD = "HCT" (Hematocrit) and LBSPEC = "BLOOD" and LBNAM = "LOCAL LAB"	Hematocrit	float	4		Collected (Source: Investigator) From Local lab (LB.LBNAM="LOCAL LAB"). No page reference is given only for illustration purpose. sample acrf.pdf does not include the local lab Annotated CRF [1_(acrf.pdf#page=1)].
	LBTESTCD = "PH" (pH) and LBSPEC = "URINE"	pH	float	3		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD = "VITB12" (Vitamin B12) and LBSPEC = "SERUM"	Vitamin B12	integer	3		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD = "VITB9" (Vitamin B9) and LBSPEC = "BLOOD"	Vitamin B9	float	5		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
LBORRESU		Original Units	text	7	Unit (LBRESU) [6 Terms]	Collected (Source: Vendor) Note this example does not include VLM for t it is just an example and the way to specify \ for LBORRESU.
LBORNRO		Reference Range Lower Limit in Orig Unit	float	6.1		Collected (Source: Vendor)
LBORNRI		Reference Range Upper Limit in Orig Unit	float	6.1		Collected (Source: Vendor)
LBSTRESC		Character Result/Finding in Std Format	text	8		Collected (Source: Vendor) Note this example does not include VLM for t it is just an example and the way to specify \ for LBORRESU.
LBSTRESN		Numeric Result/Finding in Standard Units	float	5.2		Collected (Source: Vendor)
LBSTRESU		Standard Units	text	7		Collected (Source: Vendor) Note this example does not include VLM for t it is just an example and the way to specify \ for LBORRESU.
LBSTNRLO		Reference Range Lower Limit-Std Units	float	4.2		Collected (Source: Vendor)
LBSTNRHI		Reference Range Upper Limit-Std Units	float	4.2		Collected (Source: Vendor)
LBSTNRC		Reference Range for Character Result-Std Units	text	19		Collected (Source: Vendor)
LBNRIND		Reference Range Indicator	text	20	Reference Range Indicator • "ABNORMAL" • "HIGH" • "LOW" • "NORMAL"	Assigned (Source: Vendor) Reference Range Indicator based upon standard ranges. Assuming the LBNRIND is derived by the vendor
LBNAM		Vendor Name	text	20		Collected (Source: Vendor)
LBSPEC		Specimen Type	text	5	Specimen Type	Collected (Source: Vendor)

					<ul style="list-style-type: none"> <li>• "BLOOD"</li> <li>• "SERUM"</li> <li>• "URINE"</li> </ul>	
LBMETHOD		Method of Test or Examination	text	8	Method <ul style="list-style-type: none"> <li>• "DIPSTICK"</li> <li>• "QUANT"</li> </ul>	Collected (Source: Vendor)
LBBLFL		Baseline Flag	text	1	No Yes Response Subset <ul style="list-style-type: none"> <li>• "Y" = "Yes"</li> <li>• "N" = "No"</li> <li>• "U" = "Unknown"</li> </ul>	Derived (Source: Sponsor) Safety subjects only: LBBLFL = "Y" for last re LBORRES on or before the first dose date (RF Null otherwise.
LBFAST		Fasting Status	text	1	No Yes Response Subset <ul style="list-style-type: none"> <li>• "Y" = "Yes"</li> <li>• "N" = "No"</li> <li>• "U" = "Unknown"</li> </ul>	Collected (Source: Vendor)
VISITNUM		Visit Number	integer	2		Assigned (Source: Sponsor)
VISIT		Visit Name	text	7		Collected (Source: Vendor)
VISITDY		Planned Study Day of Visit	integer	3		Protocol (Source: Sponsor)
LBDTC		Date/Time of Specimen Collection	datetime		ISO 8601	Collected (Source: Vendor)
LBDY		Study Day of Specimen Collection	integer	3		Derived (Source: Sponsor) LBDY = LBDTC-RFSTDTC+1 if LBDTC is on or LBDTC - RFSTDTC if LBDTC precedes RFSTDTC

**VS (Vital Signs) - [SDTMIG 3.1.2]**

Location

Related Supplemental Qualifiers Dataset: SUPPVS (Supplemental Qualifiers for VS)						
Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN		Domain Abbreviation	text	2	Domain Abbreviation (VS) <ul style="list-style-type: none"> <li>• "VS" = "Vital Signs"</li> </ul>	Assigned (Source: Sponsor)
USUBJID		Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
VSSEQ		Sequence Number	integer	2		Derived (Source: Sponsor) Sequential number identifying records within each USL domain.
VSTESTCD		Vital Signs Test Short Name	text	20	Vital Signs Test Code [7 Terms]	Assigned (Source: Sponsor)
VSTEST		Vital Signs Test Name	text	24	Vital Signs Test Name [7 Terms]	Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]
VSPOS		Vital Signs Position of Subject	text	7		Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]
VSORRES <a href="#">VLM</a>		Result or Finding in Original Units	text	30		Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]
	VSTESTCD = "DIABP" (Diastolic Blood Pressure)	Diastolic Blood Pressure in Orig U	integer	2		Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]
	VSTESTCD = "FRMSIZE" (Body Frame Size)	Body Frame Size - Orig	text	6	Size <ul style="list-style-type: none"> <li>• "SMALL"</li> <li>• "MEDIUM"</li> <li>• "LARGE"</li> </ul>	Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]

	VSTESTCD = "HEIGHT" (Height)	Height in Orig U	float	5.1		Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]
	VSTESTCD = "PULSE" (Pulse Rate)	Pulse Rate in Orig U	integer	2		Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]
	VSTESTCD = "SYSBP" (Systolic Blood Pressure)	Systolic Blood Pressure in Orig U	integer	3		Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]
	VSTESTCD = "WEIGHT" (Weight)	Weight in Orig U	float	5.1		Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]
VSORRESU <a href="#">VLM</a>		Original Units	text	20		Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]
	VSTESTCD = "HEIGHT" (Height) and COUNTRY IN ( "CAN", "MEX" )	Height: Original Units MC	text	5	Unit (UH_MC) • "cm" = "Centimeter"	Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]  The data submitted only includes subjects in the USA s did not enroll any subjects.  Join any Subject Level dataset with the Demographics [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, as 'IG.datasetname' is the OID of the ItemGroupDef that subject-level dataset to be joined with the Demograph
	VSTESTCD = "HEIGHT" and COUNTRY = "USA"	Height: Original Units NMC	text	5	Unit (UH_NMC) • "IN" = "Inch"	Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]  Join any Subject Level dataset with the Demographics [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, as 'IG.datasetname' is the OID of the ItemGroupDef that subject-level dataset to be joined with the Demograph
	VSTESTCD = "WEIGHT" (Weight) and COUNTRY IN ( "CAN", "MEX" )	Weight: Original Units MC	text	4	Unit (UW_MC) • "kg" = "Kilogram"	Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]  The data submitted only includes subjects in the USA s did not enroll any subjects.  Join any Subject Level dataset with the Demographics [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, as 'IG.datasetname' is the OID of the ItemGroupDef that subject-level dataset to be joined with the Demograph
	VSTESTCD = "WEIGHT" (Weight) and COUNTRY = "USA"	Weight: Original Units NMC	text	4	Unit (UW_NMC) • "LB" = "Pound"	Collected (Source: Investigator) Annotated CRF [11_(acrf.pdf#page=11).]  Join any Subject Level dataset with the Demographics [IG.datasetname]IT.USUBJID = [IG.DM]IT.USUBJID, as 'IG.datasetname' is the OID of the ItemGroupDef that subject-level dataset to be joined with the Demograph
VSSTRESC <a href="#">VLM</a>		Character Result/Finding in Std Format	text	6		Derived (Source: Sponsor) EDC System  Data collected in non-standard units (i.e. lbs, inches) i standard conversion factors to standard units (kg, cm) Testing a comment in addition to a method: BMI is der specific method is provided at VLM
	VSTESTCD = "DIABP" (Diastolic Blood Pressure)	Diastolic Blood Pressure Char in Std U	integer	2		
	VSTESTCD = "FRMSIZE" (Body Frame Size)	Body Frame Size - Std	text	6	Size • "SMALL" • "MEDIUM" • "LARGE"	
	VSTESTCD = "HEIGHT" (Height)	Height Char in Std U	float	5.1		
	VSTESTCD = "PULSE" (Pulse Rate)	Pulse Rate Char in Std U	integer	2		
	VSTESTCD = "SYSBP" (Systolic Blood Pressure)	Systolic Blood Pressure Char in Std U	integer	3		
	VSTESTCD = "WEIGHT" (Weight)	Weight Char in Std U	float	5.1		



	VSTESTCD = "BMI" (Body Mass Index)	BMI (Std U)	float	5.1		character value of VSSTRESN Formal Expression
VSSTRESN <a href="#">VLM</a>		Numeric Result/Finding in Standard Units	float	6.2		Derived (Source: Sponsor) VSSTRESN = numeric value of VSSTRESC, when VSST numeric data. Testing a comment in addition to a method: BMI is ope and the specific method is provided at VLM
	VSTESTCD = "DIABP" (Diastolic Blood Pressure)	Diastolic Blood Pressure Num in Std U	integer	2		
	VSTESTCD = "HEIGHT" (Height)	Height Num in Std U	float	5.1		
	VSTESTCD = "PULSE" (Pulse Rate)	Pulse Rate Num in Std U	integer	2		
	VSTESTCD = "SYSBP" (Systolic Blood Pressure)	Systolic Blood Pressure Num in Std U	integer	3		
	VSTESTCD = "WEIGHT" (Weight)	Weight Num in Std U	float	5.1		
	VSTESTCD = "BMI" (Body Mass Index)	BMI Num in Std U	float	6.2		Derived (Source: Sponsor) EDC System Annotated CRF [11_( <a href="#">acrf.pdf#page=11</a> )] round((VSSTRESN for weight/ (VSSTRESN for height / Note: height and weight at the closest visit collected. <sup>f</sup>
VSSTRESU		Standard Units	text	9	Units for Vital Signs Orig Results • "Beats per Minute" = "Beats per Minute" • "cm" = "Centimeter" • "kg" = "Kilogram" • "mmHg" = "Millimeter of Mercury" • "kg/m2" = "Kilogram per Square Meter"	Assigned (Source: Sponsor) Standard units consistent with CDISC controlled termin
VSBLFL		Baseline Flag	text	1	No Yes Response Subset • "Y" = "Yes" • "N" = "No" • "U" = "Unknown"	Derived (Source: Sponsor) Safety subjects only: VSBLFL = "Y" for last record with VSORRES on or before the first dose date (RFSTDTC). Null otherwise.
VISITNUM		Visit Number	integer	Z2.		Assigned (Source: Sponsor) Assigned from the TV domain based on the VISIT
VISIT		Visit Name	text	8		Assigned (Source: Sponsor)
VISITDY		Planned Study Day of Visit	integer	3		Protocol (Source: Sponsor)
VSDTC		Date/Time of Measurements	date		ISO 8601	Collected (Source: Investigator) Annotated CRF [11_( <a href="#">acrf.pdf#page=11</a> )]
VSDY		Study Day of Vital Signs	integer	3		Derived (Source: Sponsor) VSDY = VSDTC-RFSTDTC+1 if VSDTC is on or after RFSTDTC if VSDTC precedes RFSTDTC.

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (VS) • "VS" = "Vital Signs"	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
SPDEVID	Sponsor Device Identifier	text	30		Collected (Source: Vendor)
XSSEQ	Sequence Number	integer	2		Derived (Source: Sponsor) Sequential number identifying records within each U domain.
XSTESTCD	S Findings Test Short Name	text	20	S Findings Test Code • "TEST1" = "Test 1" • "TEST2" = "Test 2" • "TEST3" = "Test 3"	Assigned (Source: Sponsor)
XSTEST	S Findings Test Name	text	24	S Findings Test Name • "Test 1" • "Test 2" • "Test 3"	Collected (Source: Vendor)
XSORRES	Result or Finding in Original Units	text	30		Collected (Source: Vendor)
XSORRESU [No Data]	Original Units	text	20	Units for S Findings Results • "g/dL" = "g/dL" • "mg/dL" = "mg/dL"	Collected (Source: Vendor) Planned Numeric tests were not performed.
XSSTRESC	Character Result/Finding in Std Format	text	30		Derived (Source: Sponsor) EDC System Data collected in non-standard units (i.e. lbs, inches using standard conversion factors to standard units  BMI is calculated by the EDC system (operationally c follows: round((XSSTRESN for weight/ (XSSTRESN for height  Note: If height is not collected at a visit, use the he screening.
XSSTRESN	Numeric Result/Finding in Standard Units	float	5.1		Derived (Source: Sponsor) XSSTRESN = numeric value of XSSTRESC, when XSSTRESU is numeric data.
XSSTRESU [No Data]	Standard Units	text	9	Units for S Findings Results • "g/dL" = "g/dL" • "mg/dL" = "mg/dL"	Assigned (Source: Sponsor) Planned Numeric tests were not performed.
XSBLFL	Baseline Flag	text	1	No Yes Response Subset • "Y" = "Yes" • "N" = "No" • "U" = "Unknown"	Derived (Source: Sponsor) Safety subjects only: XSBLFL = "Y" for last record w XSORRES on or before the first dose date (RFSTDTC Null otherwise.
VISITNUM	Visit Number	integer	Z2.		Assigned (Source: Sponsor)
VISIT	Visit Name	text	8		Assigned (Source: Sponsor)
VISITDY	Planned Study Day of Visit	integer	3		Protocol (Source: Sponsor)
XSDTC	Date/Time of Measurements	date		ISO 8601	Collected (Source: Vendor)
XSDY	Study Day of Vital Signs	integer	3		Derived (Source: Sponsor) XSDY = XSDTC-RFSTDTC+1 if XSDTC is on or after RFSTDTC if XSDTC precedes RFSTDTC.

**XX (X Findings) - [Non Standard] [No Data]**

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (VS) • "VS" = "Vital Signs"	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
XXSEQ	Sequence Number	integer	2		Derived (Source: Sponsor) Sequential number identifying records within each USUBJID i
XXTESTCD	X FindingsTest Short Name	text	20	X Findings Test Code • "TEST11" = "Test 11" • "TEST12" = "Test 12" • "TEST13" = "Test 13"	Assigned (Source: Sponsor)
XXTEST	X Findings Test Name	text	24	X Findings Test Name • "Test 11" • "Test 12" • "Test 13"	Collected (Source: Vendor)
XXORRES	Result or Finding in Original Units	text	30		Collected (Source: Vendor)
XXORRESU	Original Units	text	20	Units for X Findings Results • "g/dL" = "g/dL" • "mg/dL" = "mg/dL" • "%" = "%"	Collected (Source: Vendor) Planned Numeric tests were not performed.
XXSTRESC	Character Result/Finding in Std Format	text	30		Derived (Source: Sponsor) EDC System Data collected in non-standard units (i.e. lbs, inches) is conv standard conversion factors to standard units (kg, cm).  BMI is calculated by the EDC system (operationally derived) : round((XXSTRESN for weight/ (XXSTRESN for height / 100)  Note: If height is not collected at a visit, use the height colle
XXSTRESN	Numeric Result/Finding in Standard Units	float	5.1		Derived (Source: Sponsor) XXSTRESN = numeric value of XXSTRESC, when XXSTRESC i data.
XXSTRESU	Standard Units	text	9	Units for X Findings Results • "g/dL" = "g/dL" • "mg/dL" = "mg/dL" • "%" = "%"	Assigned (Source: Sponsor) Planned Numeric tests were not performed.
XXBLFL	Baseline Flag	text	1	No Yes Response Subset • "Y" = "Yes" • "N" = "No" • "U" = "Unknown"	Derived (Source: Sponsor) Safety subjects only: XXBLFL = "Y" for last record with non N or before the first dose date (RFSTDTC). Null otherwise.
VISITNUM	Visit Number	integer	22.		Assigned (Source: Sponsor)
VISIT	Visit Name	text	8		Assigned (Source: Sponsor)
VISITDY	Planned Study Day of Visit	integer	3		Protocol (Source: Sponsor)
XXDTC	Date/Time of Measurements	date		ISO 8601	Collected (Source: Vendor)
XXDY	Study Day of Vital Signs	integer	3		Derived (Source: Sponsor) XXDY = XXDTC-RFSTDTC+1 if XXDTC is on or after RFSTDTC RFSTDTC if XXDTC precedes RFSTDTC.

SUPPDM (Supplemental Qualifiers for DM, Demographics) - [SDTMIG 3.1.2]Location: suppdm.2

Related Parent Dataset: DM (Demographics)						
Variable	Label / Description	Type	Role	Length or	Controlled Terms or ISO Format	Origin / Source / Method / Comm

				Display Format		
STUDYID	Study Identifier	text		7		Protocol (Source: Sponsor)
RDOMAIN	Related Domain Abbreviation	text		2		Derived (Source: Sponsor) Domain abbreviation from where data ori
USUBJID	Unique Subject Identifier	text		14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
IDVAR	Identifying Variable	text		1		Assigned (Source: Sponsor) Name of the variables for the related rec
IDVARVAL	Identifying Variable Value	text		1		Assigned (Source: Sponsor) Value of identifying variable described in
QNAM	Qualifier Variable Name	text		8		Assigned (Source: Sponsor)
QLABEL	Qualifier Variable Label	text		26		Assigned (Source: Sponsor)
QVAL <a href="#">VLM</a>	Data Value	text		200		
► QNAM = "RACE1"	Race 1	text	Record Qualifier	41	Race • "WHITE" • "AMERICAN INDIAN OR ALASKA NATIVE" • "BLACK OR AFRICAN AMERICAN" • "ASIAN" • "NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER"	Collected (Source: Investigator) Annotated CRF [ <a href="#">6_(acrf.pdf#page=6)_</a> ] Selected value converted to upper case t
► QNAM = "RACE2"	Race 2	text	Record Qualifier	41	Race • "WHITE" • "AMERICAN INDIAN OR ALASKA NATIVE" • "BLACK OR AFRICAN AMERICAN" • "ASIAN" • "NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER"	Collected (Source: Investigator) Annotated CRF [ <a href="#">6_(acrf.pdf#page=6)_</a> ] Selected value converted to upper case t
► QNAM = "RACE3"	Race 3	text	Record Qualifier	41	Race • "WHITE" • "AMERICAN INDIAN OR ALASKA NATIVE" • "BLACK OR AFRICAN AMERICAN" • "ASIAN" • "NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER"	Collected (Source: Investigator) Annotated CRF [ <a href="#">6_(acrf.pdf#page=6)_</a> ] Selected value converted to upper case t
► QNAM = "RAND"	Randomized Population Flag	text	Record Qualifier	1	No Yes Response Subset • "Y" = "Yes" • "N" = "No" • "U" = "Unknown"	Collected (Source: Investigator) Annotated CRF [ <a href="#">16_(acrf.pdf#page=16)_</a> ]
► QNAM = "RANDNO"	Randomization Number	text	Record Qualifier	4		Collected (Source: Investigator) Annotated CRF [ <a href="#">16_(acrf.pdf#page=16)_</a> ]
► QNAM = "SAFETY"	Safety Population Flag	text	Record Qualifier	1	No Yes Response Subset • "Y" = "Yes" • "N" = "No" • "U" = "Unknown"	Derived (Source: Sponsor) SAFETY = "Y" for randomized subjects w one dose study medication. Null otherwis
QORIG	Origin	text		11		Assigned (Source: Sponsor)
QEVAL	Evaluator	text		30		Assigned (Source: Sponsor)

**SUPPVS (Supplemental Qualifiers for VS, Vital Signs) - [SDTMIG 3.1.2] [No Data]**

Related Parent Dataset: VS (Vital Signs)						
Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text		7		Protocol (Source: Sponsor)
RDOMAIN	Related Domain Abbreviation	text		2		Derived (Source: Sponsor) Domain abbreviation from where data originated.
USUBJID	Unique Subject Identifier	text		14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
IDVAR	Identifying Variable	text		5		Assigned (Source: Sponsor) Name of the variables for the related records.
IDVARVAL	Identifying Variable Value	text		2		Assigned (Source: Sponsor) Value of identifying variable described in IDVAR.
QNAM	Qualifier Variable Name	text		7		Assigned (Source: Sponsor)
QLABEL	Qualifier Variable Label	text		36		Assigned (Source: Sponsor)
QVAL <a href="#">VLM</a>	Data Value	text		2		
► QNAM = "VSCLSIG"	Clinically Significant	text	Record Qualifier	1	No Yes Response Subset • "Y" = "Yes" • "N" = "No" • "U" = "Unknown"	Derived (Source: Sponsor) Only created if value qualifies as potentially clinically low based on the high and low ranges specified in the Analysis Plan.
QORIG	Origin	text		7		Assigned (Source: Sponsor)
QEVAL	Evaluator	text		30		Assigned (Source: Sponsor)

CodeLists

Age Unit [C66781] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
YEARS [C29848]

Description of Planned Arm [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
Miracle Drug 10 mg
Miracle Drug 20 mg
Placebo
Screen Failure

Planned Arm Code [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
WONDER10	Miracle Drug 10 mg
WONDER20	Miracle Drug 20 mg
PLACEBO	Placebo
SCRNFAIL	Screen Failure

Study Planned Countries [CDISC/NCI SDTM 2011-12-09]

This is a subset of the ISO-3166 (Country Codes) codelist

Permitted Value (Code)	Display Value (Decode)
USA	United States of America (the)
CAN	Canada
MEX	Mexico

Domain Abbreviation (DI) [C66734] [CDISC/NCI SDTM 2015-12-18]

Permitted Value (Code)	Display Value (Decode)

DI [C102618]	Device Identifiers
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Domain Abbreviation (DM) [C66734] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
DM [C49572]	Demographics

Domain Abbreviation (EC) [C66734] [CDISC/NCI SDTM 2015-12-18]

The Domain codelist was updated when SDTMIG 3.2 became production. Referencing a newer CT version that includes the revised codelist

Permitted Value (Code)	Display Value (Decode)
EC [C49587]	Exposure as Collected

Ethnic Group [C66790] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
HISPANIC OR LATINO [C17459]
NOT HISPANIC OR LATINO [C41222]

Domain Abbreviation (EX) [C66734] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
EX [C49587]	Exposure

Treatment [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
Miracle Drug
Placebo

Pharmaceutical Dosage Form [C66726] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
TABLET [C42998]	tab

Domain Abbreviation (LB) [C66734] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
LB [C49592]	Laboratory Data

Unit (LBRESU) [C71620] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
% [C25613]	Percentage
X10^9/L [*]	X10^9/L
g/dL [C64783]	Gram per Deciliter
mg/dL [C67015]	Milligram per Deciliter
ng/dL [C67326]	Nanogram per Deciliter
pg/mL [*]	pg/mL

\* Extended Value

Laboratory Test Name [C67154] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
Bilirubin [C38037]
Blood Urea Nitrogen [C61019]
Glucose [C41376]
Hematocrit [C64796]
Hemoglobin [C64848]
Lymphocytes [C51949]
Occult Blood [C74686]
Vitamin B12 [C64817]
Vitamin B9 [C74676]

pH [C45997]
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Laboratory Test Code [C65047] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
BILI [C38037]	Bilirubin
BUN [C61019]	Blood Urea Nitrogen
GLUC [C41376]	Glucose
HCT [C64796]	Hematocrit
HGB [C64848]	Hemoglobin
LYM [C51949]	Lymphocytes
OCCBLD [C74686]	Occult Blood
PH [C45997]	pH
VITB12 [C64817]	Vitamin B12
VITB9 [C74676]	Vitamin B9

Method [C85492] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
DIPSTICK [*]
QUANT [*]

\* Extended Value

Reference Range Indicator [C78736] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
ABNORMAL [C78802]
HIGH [C78800]
LOW [C78801]
NORMAL [C78727]

No Yes Response Subset [C66742] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
Y [C49488]	Yes
N [C49487]	No
U [C17998]	Unknown

Race [C74457] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
WHITE [C41261]
AMERICAN INDIAN OR ALASKA NATIVE [C41259]
BLACK OR AFRICAN AMERICAN [C16352]
ASIAN [C41260]
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER [C41219]

Sex [C66731] [CDISC/NCI SDTM 2015-12-18]

The term "UN" was changed to "UNDIFFERENTIATED" for codelist "SEX" on the 2014-03-28 CT release. Referencing the codelist from a newer release since th other codelists used in the study.

Permitted Value (Code)	Display Value (Decode)
F [C16576]	Female
M [C20197]	Male
U [C17998]	Unknown
UNDIFFERENTIATED [C17998]	Undifferentiated

Size [C66733] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Rank
SMALL [C25376]	1
MEDIUM [C49507]	2

LARGE [C49508]	3
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Specimen Type [C78734] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
BLOOD [C12434]
SERUM [C13325]
URINE [C13283]

Domain Abbreviation (TS) [C66734] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
TS [C53483]	Trial Summary

Trial Summary Parameter Test Name [C67152] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
Added on to Existing Treatments [C49703]
Age Span [C20587]
Age Unit [*]
Clinical Study Sponsor [C70793]
Control Type [C49647]
Dose Units [C73558]
Dose per Administration [C25488]
Dosing Frequency [C89081]
Investigational Therapy or Treatment [C41161]
Planned Country of Investigational Sites [C98770]
Planned Maximum Age of Subjects [C49694]
Planned Minimum Age of Subjects [C49693]
Planned Number of Subjects [C49692]
Route of Administration [C38114]
Sex of Participants [C49696]
Trial Blinding Schema [C49658]
Trial Indication Type [C49652]
Trial Length [C49697]
Trial Phase Classification [C48281]
Trial Primary Objective [C85826]
Trial Secondary Objective [C85827]
Trial Title [C49802]
Trial Type [C49660]
Trial is Randomized [C25196]

\* Extended Value

Trial Summary Parameter Test Code [C66738] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
ADDON [C49703]	Added on to Existing Treatments
AGEMAX [C49694]	Planned Maximum Age of Subjects
AGEMIN [C49693]	Planned Minimum Age of Subjects
AGESPAN [C20587]	Age Span
AGEU [*]	Age Unit
DOSE [C25488]	Dose per Administration
DOSFRQ [C89081]	Dosing Frequency
DOSU [C73558]	Dose Units
FCNTRY [C98770]	Planned Country of Investigational Sites
LENGTH [C49697]	Trial Length
OBJPRIM [C85826]	Trial Primary Objective



OBJSEC [C85827]	Trial Secondary Objective
PLANSUB [C49692]	Planned Number of Subjects
RANDOM [C25196]	Trial is Randomized
ROUTE [C38114]	Route of Administration
SEXPOP [C49696]	Sex of Participants
SPONSOR [C70793]	Clinical Study Sponsor
TBLIND [C49658]	Trial Blinding Schema
TCNTRL [C49647]	Control Type
TINDTP [C49652]	Trial Indication Type
TITLE [C49802]	Trial Title
TPHASE [C48281]	Trial Phase Classification
TRT [C41161]	Investigational Therapy or Treatment
TTYPE [C49660]	Trial Type

\* Extended Value

Unit (UH\_MC) [C71620] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
cm [C49668]	Centimeter

Unit (UH\_NMC) [C71620] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
IN [C48500]	Inch

Unit (UW\_MC) [C71620] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
kg [C28252]	Kilogram

Unit (UW\_NMC) [C71620] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
LB [C48531]	Pound

Domain Abbreviation (VS) [C66734] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
VS [C49622]	Vital Signs

Units for Vital Signs Orig Results [C66770] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
Beats per Minute [C49673]	Beats per Minute
cm [C49668]	Centimeter
kg [C28252]	Kilogram
mmHg [C49670]	Millimeter of Mercury
kg/m2 [C49671]	Kilogram per Square Meter

Vital Signs Test Name [C67153] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
Body Mass Index [C16358]
Body Frame Size [C49680]
Diastolic Blood Pressure [C25299]
Height [C25347]
Pulse Rate [C49676]
Systolic Blood Pressure [C25298]
Weight [C25208]

Vital Signs Test Code [C66741] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
BMI [C16358]	Body Mass Index
DIABP [C25299]	Diastolic Blood Pressure
FRMSIZE [C49680]	Body Frame Size
HEIGHT [C25347]	Height
PULSE [C49676]	Pulse Rate
SYSBP [C25298]	Systolic Blood Pressure
WEIGHT [C25208]	Weight

Units for S Findings Results [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
g/dL [C64783]	g/dL
mg/dL [C67015]	mg/dL

S Findings Test Name [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
Test 1
Test 2
Test 3

S Findings Test Code [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
TEST1	Test 1
TEST2	Test 2
TEST3	Test 3

Units for X Findings Results [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
g/dL [C64783]	g/dL
mg/dL [C67015]	mg/dL
% [C25613]	%

X Findings Test Name [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)
Test 11
Test 12
Test 13

X Findings Test Code [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
TEST11	Test 11
TEST12	Test 12
TEST13	Test 13

External Dictionaries

Reference Name	External Dictionary	Diction
Country Codes The code values used are the Alpha-3 codes	ISO-3166 (Country Codes)( <a href="https://www.iso.org/iso-3166-country-codes.html">https://www.iso.org/iso-3166-country-codes.html</a> )	2013-1

Methods

Method	Type	Description
Algorithm to derive AGE	Computation	Age at Screening Date (Screening Date - Birth date).  For the complete algorithm see the referenced external document.

		Complex Algorithms [DM_(complexalgorithms.pdf#DM).]
Algorithm to derive BMISC	Computation	<p>character value of VSSTRESN</p> <p><b>Formal Expression</b> [ SAS 9.0 or later as a macro call. Macro developed as a standard macro that returns a value to be assigned to a variable in a data set. Notes: 1) need to be able to specify more information about the context of the macro call and corresponding input parameters. For ODMv1.3.2 / Define-XML 2.1 free-text. 2) As an example, included a version of the macro name as it can be defined by the user somewhere in the metadata definition for the method to be used. ]:</p> <pre>%convert_to_character_versionx(numeric_value=bmi_numeric_value,length=bmi_defined_length)</pre> <p><b>Formal Expression</b> [SAS 9.0 or later using a SAS Base function, assuming no restriction on length and decimal places ]:</p> <pre>putc(bmi_numeric_value,best.)</pre> <p><b>Formal Expression</b> [R version xyz, using a generic method assuming no restriction on length and decimal places ]:</p> <pre>toString(bmi_numeric_value, width=NULL)</pre>
Algorithm to derive BMISN	Computation	<p>round((VSSTRESN for weight/ (VSSTRESN for height / 100)^2), .01).</p> <p>Note: height and weight at the closest visit collected.</p> <p><b>Formal Expression</b> [ SAS 9.0 or later as a macro call. Macro developed as a standard macro that returns a value to be assigned to a variable in a data set. Notes: 1) need to be able to specify more information about the context of the macro call and corresponding input parameters. For ODMv1.3.2 / Define-XML 2.1 free-text. 2) As an example, included a version of the macro name as it can be defined by the user somewhere in the metadata definition for the method to be used. ]:</p> <pre>%bmiscn_versionx(weight=retrieved_weight_closest_visit,height=retrieved_height_closest_visit)</pre> <p><b>Formal Expression</b> [ SAS 9.0 or later as a macro call. Macro developed as a standard macro that returns a value to be assigned to a variable in a data set. Notes: 1) need to be able to specify more information about the context of the macro call and corresponding input parameters. For ODMv1.3.2 / Define-XML 2.1 free-text. 2) As an example, included a version of the macro name as it can be defined by the user somewhere in the metadata definition for the method to be used. ]:</p> <pre>%bmiscn_versiony(weight=retrieved_weight_closest_visit,height=retrieved_height_closest_visit)</pre>
Algorithm to derive CLSIG	Computation	Only created if value qualifies as potentially clinically significant high or low based on the high and low ranges specified in the SDTMIG 3.1.2.
Algorithm to derive ECENDY	Computation	<p>ECENDY = ECENDTC-RFSTDTC+1 if ECENDTC is on or after RFSTDTC.</p> <p>ECENDTC - RFSTDTC if ECENDTC precedes RFSTDTC.</p>
Algorithm to derive EXDOSE	Computation	<p>If ARMCD=WONDER10 then EXDOSE = Number of Tablets per Day (QVAL where QNAM=SMNO) * 10.</p> <p>If ARMCD=WONDER20 then EXDOSE = Number of Tablets per Day (QVAL where QNAM=SMNO) * 20.</p> <p>If ARMCD=PLACEBO then EXDOSE = 0.</p>
Algorithm to derive EXDOSU	Computation	Derived from ARM, ARMCD - equal to mg
Algorithm to derive EXENDY	Computation	<p>EXENDY = EXENDTC-RFSTDTC+1 if EXENDTC is on or after RFSTDTC.</p> <p>EXENDTC - RFSTDTC if EXENDTC precedes RFSTDTC.</p>
Algorithm to derive EXSTDY	Computation	<p>EXSTDY = EXSTDTC - RFSTDTC+1 if EXSTDTC is on or after RFSTDTC.</p> <p>EXSTDTC - RFSTDTC if EXSTDTC precedes RFSTDTC.</p>
Algorithm to derive EXTRT	Computation	Derived from ARM, ARMCD
Algorithm to derive LBBFL	Computation	Safety subjects only: LBBFL = "Y" for last record with non Null LBBORRES on or before the first dose date (RFSTDTC). Null otherwise.
Algorithm to derive LBDY	Computation	LBDY = LBDTC-RFSTDTC+1 if LBDTC is on or after RFSTDTC. LBDTC - RFSTDTC if LBDTC precedes RFSTDTC.
Algorithm to derive LBNRIND	Computation	Reference Range Indicator based upon standard results and ranges.
Algorithm to assign RACE	Computation	Selected value converted to upper case to match CT.
Algorithm to derive RDOMAIN	Computation	Domain abbreviation from where data originated.

Algorithm to derive RFENDTC	Computation	RFENDTC = termination date, for safety subjects. Null for screen failures.
Algorithm to derive RFSTDTC	Computation	RFSTDTC = first date/time of study drug, for safety subject. Null for screen failures.
Algorithm to derive the SAFETY population flag	Computation	SAFETY = "Y" for randomized subjects who took at least one dose study medication. Null otherwise.
Algorithm to derive SEQ	Computation	Sequential number identifying records within each USUBJID in the domain.
Algorithm to derive TSSEQ	Computation	Sequential number identifying records within each TSPARM in the domain.
Algorithm to derive USUBJID	Computation	Concatenation of STUDYID and SUBJID
Algorithm to derive VSBLFL	Computation	Safety subjects only: VSBLFL = "Y" for last record with non Null VSORRES on or before the first dose date (RFSTDTC). Null otherwise.
Algorithm to derive VSDY	Computation	VSDY = VSDTC-RFSTDTC+1 if VSDTC is on or after RFSTDTC. VSDTC - RFSTDTC if VSDTC precedes RFSTDTC.
Algorithm to derive VSSTRESC	Computation	Data collected in non-standard units (i.e. lbs, inches) is converted using standard conversion factors to standard units (kg, cm).
Algorithm to derive VSSTRESN	Computation	VSSTRESN = numeric value of VSSTRESC, when VSSTRESC contains numeric data.
Algorithm to derive XSBFLFL	Computation	Safety subjects only: XSBFLFL = "Y" for last record with non Null XSORRES on or before the first dose date (RFSTDTC). Null otherwise.
Algorithm to derive XSDY	Computation	XSDY = XSDTC-RFSTDTC+1 if XSDTC is on or after RFSTDTC. XSDTC - RFSTDTC if XSDTC precedes RFSTDTC.
Algorithm to derive XSSTRESC	Computation	Data collected in non-standard units (i.e. lbs, inches) is converted using standard conversion factors to standard units (kg, cm).  BMI is calculated by the EDC system (operationally derived) as follows: round((XSSTRESN for weight/ (XSSTRESN for height / 100)^2), .01).  Note: If height is not collected at a visit, use the height collected at screening.
Algorithm to derive XSSTRESN	Computation	XSSTRESN = numeric value of XSSTRESC, when XSSTRESC contains numeric data.
Algorithm to derive XXBFLFL	Computation	Safety subjects only: XXBFLFL = "Y" for last record with non Null XXORRES on or before the first dose date (RFSTDTC). Null otherwise.
Algorithm to derive XXDY	Computation	XXDY = XXDTC-RFSTDTC+1 if XXDTC is on or after RFSTDTC. XXDTC - RFSTDTC if XXDTC precedes RFSTDTC.
Algorithm to derive XXSTRESC	Computation	Data collected in non-standard units (i.e. lbs, inches) is converted using standard conversion factors to standard units (kg, cm).  BMI is calculated by the EDC system (operationally derived) as follows: round((XXSTRESN for weight/ (XXSTRESN for height / 100)^2), .01).  Note: If height is not collected at a visit, use the height collected at screening.
Algorithm to derive XXSTRESN	Computation	XXSTRESN = numeric value of XXSTRESC, when XXSTRESC contains numeric data.