	WIKI	CDISC Wiki	Spaces	People	Polls C	alendars	Create □					
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		SDTMIG v3.3 Metadata Check for Domain Specification Table 1.2.2  Metadata check macro is applied and detected issue(s). Please address finding(s) listed below the specification table. An FAQ is available to aid troubleshooting. Release Notes										
		Variable Name	Variable Label	Туре	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core				
		STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req				
		DOMAIN	Domain Abbreviation	Char	EG	Identifier	Two-character abbreviation for the domain.	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				
		SPDEVID	Sponsor Device Identifier	Char		Identifier	Sponsor-defined identifier for a device.	Perm				
		EGSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req				
		EGGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm				
		EGREFID	ECG Reference ID	Char		Identifier	Internal or external ECG identifier. Example: "UUID".	Perm				
		EGSPID	Sponsor- Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the ECG page.	Perm				
□ <b>▼</b>		EGTESTCD	ECG Test or Examination Short Name	Char	(EGTESTCD) (HETESTCD)	Topic	Short name of the measurement, test, or examination described in EGTEST. It can be used as a column name when converting a dataset from a vertical to a	Req				
		1										

	Result/Finding in Std Format		(HESTRESC)	Qualifier	findings, copied or derived from EGORRES in a standard format or standard units. EGSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in EGSTRESN. For example, if a test has results of "NONE", "NEG", and "NEGATIVE" in EGORRES and these results effectively have the same meaning, they could be represented in standard format in EGSTRESC as "NEGATIVE". For other examples, see general assumptions. Additional examples of result data: SINUS BRADYCARDIA, ATRIAL FLUTTER, ATRIAL FLUTTER, ATRIAL FIBRILLATION.  Test results are in two separate codelists, one for tests based on regular 10-second ECGs (EGSTRESC) and one for tests	
					based on Holter monitoring (HESTRESC).	
EGSTRESN	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 EGSTRESC. EGSTRESN should store all numeric test results or findings.	Perm
EGSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized units used for EGSTRESC and EGSTRESN.	Perm
EGSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate an ECG was not done, or an ECG measurement was not taken. Should be null if a result exists in EGORRES.	Perm
EGREASND	Reason ECG Not Done	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: "BROKEN EQUIPMENT" or "SUBJECT REFUSED". Used in conjunction with EGSTAT when value is "NOT DONE".	Perm
EGXFN	ECG External File Path	Char		Record Qualifier	File name and path for the external ECG waveform file.	Perm
EGNAM	Vendor Name	Char		Record Qualifier	Name or identifier of the laboratory or vendor who provided the test results.	Perm
EGMETI	Method of Test or Examination	Char	(EGMETHOD)	Record Qualifier	Method of the ECG test. Examples: 12 LEAD STANDARD.	Perm
EGLEAD	Lead Location	Char	(EGLEAD)	Record	The lead used for the	Perm

	Used for Measurement			Qualifier	measurement. Examples: "LEAD 1", "LEAD 2", "LEAD 3", "LEAD rV2", "LEAD V1".	
EGLOBXFL	Last Observation Before Exposure Flag	Char	(NY)	Record Qualifier	Operationally-derived indicator used to identify the last non-missing value prior to RFXSTDTC. The value should be "Y" or null.	Exp
EGBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. Should be "Y" or null. Note that EGBLFL is retained for backward compatibility. The authoritative baseline for statistical analysis is in an ADaM dataset.	Perm
EGDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record. The value should be "Y" or null. Records which represent the average of other records, or that do not come from the CRF, or are not as originally collected or received are examples of records that would be derived for the submission datasets. If EGDRVFL = "Y", then EGORRES could be null, with EGSTRESC, and EGSTRESN (if the result is numeric) having the derived value.	Perm
EGEVAL	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). Should be null for records that contain collected or derived data. Examples: "INVESTIGATOR", "ADJUDICATION COMMITTEE", "VENDOR".	Perm
EGEVALID	Evaluator Identifier	Char	(MEDEVAL)	Variable Qualifier	Used to distinguish multiple evaluators with the same role recorded in EGEVAL. Examples: "RADIOLOGIST 1" or "RADIOLOGIST 2".	Perm
EGREPNUM	Repetition Number	Num		Record Qualifier	The incidence number of a test that is repeated within a given timeframe for the same test. The level of granularity can vary, e.g., within a time point or within a visit. For example, multiple measurements of blood pressure or multiple analyses of a sample.	Perm
VISITNUM	Visit Number	Num		Timing	Clinical encounter number. 2.     Numeric version of VISIT, used for sorting	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of	Perm

					clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
TAETORD	Planned Order of Element within Arm	Num		Timing	Number that gives the planned order of the Element within the Arm for the element in which the assessment was made.	Perm
EPOCH	Epoch	Char	(EPOCH)	Timing	Epoch associated with the date/time at which the assessment was made.	Perm
EGDTC	Date/Time of ECG	Char	ISO 8601	Timing	Date/Time of ECG.	Exp
EGDY	Study Day of ECG	Num		Timing	1. Study day of the ECG, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
EGTPT	Planned Time Point Name	Char		Timing	1. Text Description of time when measurement should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See EGTPTNUM and EGTPTREF. Examples: "Start", "5 min post".	Perm
EGTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of EGTPT to aid in sorting.	Perm
EGELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a fixed time point reference (EGTPTREF). Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by EGTPTREF, or "PT8H" to represent the period of 8 hours after the reference point indicated by EGTPTREF.	Perm
EGTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by EGELTM, EGTPTNUM, and EGTPT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".	Perm
EGRFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time for a fixed reference time point defined by EGTPTREF.	Perm

Metadata Checks FindingsSDTMIG v3.3 Metadata Check User Macros FAQ

- Structure: Mismatch column 4 label: Controlled Terms, Codelist or Format (seen) vs. Controlled Terms, Codelist or Format1 (expected)
- Notice: Checks for table content are suspended due to structrual issues reported above.
   Content checks will resume after all structural issues are resolved

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