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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Demographics (DM) dm.xpt** | |  | | Green = SDTM specific info | | Purple: Protocol Specific SDTM Implementation |  |
| **Variable** | **Label** | **Type** | **Controlled Terminology** | **Origin** | **Role** | **Comment** | **Internal Team Comment** |
| STUDYID | Study Identifier | text |  | CRF Page 7 | IDENTIFIER |  |  |
| DOMAIN | Domain Abbreviation | text |  | Assigned | IDENTIFIER |  |  |
| USUBJID | Unique Subject Identifier | text |  | Derived | IDENTIFIER | Concatenation of STUDYID, DM.SITEID and DM.SUBJID |  |
| SUBJID | Subject Identifier for the Study | text |  | CRF Page 7 | TOPIC |  |  |
| RFSTDTC | Subject Reference Start Date/Time | date | ISO8601 | Derived | RECORD QUALIFIER | Date/time of first study drug treatment derived from EX |  |
| RFENDTC | Subject Reference End Date/Time | date | ISO8601 | Derived | RECORD QUALIFIER | Date/time of last study drug treatment derived from EX |  |
| RFXSTDTC | Date/Time of First Study Treatment | datetime | ISO8601 | Derived | RECORD QUALIFIER | RFXSTDTC=RFSTDTC |  |
| RFXENDTC | Date/Time of Last Study Treatment | datetime | ISO8601 | Derived | RECORD QUALIFIER | RFXENDTC=RFENDTC |  |
| RFICDTC | Date/Time of Informed Consent | datetime | ISO8601 | Derived | RECORD QUALIFIER | Date of informed consent was not entered in database (see annotated CRF) |  |
| RFPENDTC | Date/Time of End of Participation | datetime | ISO8601 | Derived | RECORD QUALIFIER | DSSTDTC of last disposition event |  |
| DTHDTC | Date/Time of Death | datetime | ISO8601 | Derived | RECORD QUALIFIER | If DS record exists with DSDECOD="DEATH" then DTHDTC=AEENDTC. |  |
| DTHFL | Subject Death Flag | text | Y\_BLANK | Derived | RECORD QUALIFIER | If DS record exists with DSDECOD="DEATH" then DEATHFL=Y. |  |
| SITEID | Study Site Identifier | text |  | Assigned | RECORD QUALIFIER |  |  |
| AGE | Age | integer |  | Derived | RECORD QUALIFIER | Subject's Age at start of study drug (RFSTDTC). |  |
| AGEU | Age Units | text | AGEU | Assigned | VARIABLE QUALIFIER | AGEU="YEARS" |  |
| SEX | Sex | text | SEX | CRF Page 7 | RECORD QUALIFIER |  |  |
| RACE | Race | text | RACE | CRF Page 7 | RECORD QUALIFIER |  |  |
| ETHNIC | Ethnicity | text | ETHNIC | Derived | RECORD QUALIFIER | Derived from Origin entered on CRF: ETHINC="HISPANIC OR LATINO" if Origin="Hispanic". Otherwise ETHNIC="NOT HISPANIC OR LATINO" |  |
| ARMCD | Planned Arm Code | text | ARMCD | Assigned | RECORD QUALIFIER | According to randomization list | CT should have individual custom terms for ARM & ARMCD |
| ARM | Description of Planned Arm | text | ARM | Assigned | SYNONYM QUALIFIER | According to randomization list |  |
| ACTARMCD | Actual Arm Code | text | ARMCD | Derived | RECORD QUALIFIER | Derived from EX |  |
| ACTARM | Description of Actual Arm | text | ARM | Derived | SYNONYM QUALIFIER | Derived from EX |  |
| COUNTRY | Country | text | COUNTRY | Derived | RECORD QUALIFIER | Derived from site information |  |
| DMDTC | Date/Time of Collection | date | ISO8601 | CRF Page 7 | TIMING |  |  |
| DMDY | Study Day of Collection | integer |  | Derived | TIMING | See Computational Method: COMPMETHOD.STUDY\_DAY |  |

**Vital Signs (VS) vs.xpt**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Variable** | **Label** | **Type** | **Controlled Terminology** | **Origin** | **Role** | **Comment** | **Internal Team Comment** |
| STUDYID | Study Identifier | text | CRF Page 7 | IDENTIFIER |  |  |  |
| DOMAIN | Domain Abbreviation | text | Assigned | IDENTIFIER |  |  |  |
| USUBJID | Unique Subject Identifier | text | Derived | IDENTIFIER | Concatenation of STUDYID, DM.SITEID and DM.SUBJID |  |  |
| VSSEQ | Sequence Number | integer | Derived | IDENTIFIER | Sequential number identifying records within each USUBJID |  |  |
| VSTESTCD | Vital Signs Test Short Name | text | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | TOPIC |  |  |  |
| VSTEST | Vital Signs Test Name | text | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | SYNONYM QUALIFIER |  |  |  |
| VSPOS | Vital Signs Position of Subject | text | VSPOS | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | RECORD QUALIFIER |  |  |
| VSORRES | Result or Finding in Original Units | text | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | RESULT QUALIFIER |  |  |  |
| VSORRESU | Original Units | text | VSUNIT | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | VARIABLE QUALIFIER |  |  |
| VSSTRESC | Character Result/Finding in Std Format | text | Derived | RESULT QUALIFIER | VSORRES converted to standard unit |  |  |
| VSSTRESN | Numeric Result/Finding in Standard Units | integer | Derived | RESULT QUALIFIER | VSSTRESC converted to numeric |  |  |
| VSSTRESU | Standard Units | text | VSUNIT | Assigned | VARIABLE QUALIFIER | Standard unit defined per parameter for summarizing analysis |  |
| VSSTAT | Completion Status | text | ND | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | RECORD QUALIFIER |  |  |
| VSLOC | Location of Vital Signs Measurement | text | VSLOC | CRF Pages 17, 23, 30, 33, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | RECORD QUALIFIER |  |  |
| VSBLFL | Baseline Flag | text | Y\_BLANK | Derived | RECORD QUALIFIER | If VISIT="BASELINE" then VSBLFL="Y" |  |
| VISITNUM | Visit Number | float | VISITNUM | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | TIMING |  |  |
| VISIT | Visit Name | text | VISIT | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | TIMING |  |  |
| VISITDY | Planned Study Day of Visit | integer | Derived | TIMING | TV.VISITDY |  |  |
| VSDTC | Date/Time of Measurements | date | ISO8601 | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | TIMING |  |  |
| VSDY | Study Day of Vital Signs | integer | Derived | TIMING | See Computational Method: COMPMETHOD.STUDY\_DAY |  |  |
| VSTPT | Planned Time Point Name | text | VSTPT | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | TIMING |  |  |
| VSTPTNUM | Planned Time Point Number | integer | VSTPTNUM | CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | TIMING |  |  |
| VSELTM | Planned Elapsed Time from Time Point Ref | text | Derived | TIMING | VSTPT expressed in the ISO 8601 format for durations |  |  |
| VSTPTREF | Time Point Reference | text | VSTPTREF | Assigned | TIMING |  |  |

**Supplemental Qualifiers for DM (SUPPDM) suppdm.xpt**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Variable** | **Label** | **Type** | **Controlled Terminology** | **Origin** | **Role** | **Comment** | **Internal Team Comment** |
| STUDYID | Study Identifier | text | CRF Page 7 | IDENTIFIER |  |  |  |
| RDOMAIN | Related Domain Abbreviation | text | Assigned | IDENTIFIER | RDOMAIN="AE" |  |  |
| USUBJID | Unique Subject Identifier | text | Derived | IDENTIFIER | Concatenation of STUDYID, DM.SITEID and DM.SUBJID |  |  |
| IDVAR | Identifying Variable | text | Assigned | IDENTIFIER | IDVAR=" " |  |  |
| IDVARVAL | Identifying Variable Value | text | Assigned | IDENTIFIER | IDVARVAL= " " |  |  |
| QNAM | Qualifier Variable Name | text | Assigned | TOPIC |  |  |  |
| QLABEL | Qualifier Variable Label | text | Assigned | SYNONYM QUALIFIER |  |  |  |
| QVAL | Data Value | text | Derived | RESULT | see value level metadata |  |  |
| QORIG | Origin | text | Assigned | RESULT QUALIFIER |  |  |  |
| QEVAL | Evaluator | text | QEVAL | Assigned | RESULT QUALIFIER |  |  |