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| **Demographics (DM) dm.xpt (IMPUTED)** | |  | | Green = SDTM specific info | | Purple: Protocol Specific SDTM Implementation |  |
| **Variable** | **Label** | **Type** | **Controlled Terminology** | **Origin** | **Role** | **Comment** | **Internal Team Comment** |
| STUDYID | Study Identifier | xsd:string |  | Assigned / CRF Page 7 | Identifier Variable |  | sdtm:additionalMetadata cd01p:StudyIdentifier\_1 |
| DOMAIN | Domain Abbreviation | xsd:string |  | Assigned | Identifier Variable |  |  |
| USUBJID | Unique Subject Identifier | xsd:string |  | Derived | Identifier Variable | Concatenation of STUDYID, DM.SITEID and DM.SUBJID |  |
| SUBJID | Subject Identifier for the Study | xsd:string |  | Assigned / CRF Page 7 | Topic Variable |  |  |
| RFSTDTC | Subject Reference Start Date/Time | xsd:date | ISO8601 | Derived | Record Qualifier | Date/time of first study drug treatment derived from EX |  |
| RFENDTC | Subject Reference End Date/Time | xsd:date | ISO8601 | Derived | Record Qualifier | Date/time of last study drug treatment derived from EX |  |
| RFXSTDTC | Date/Time of First Study Treatment | xsd:dateTime | ISO8601 | Derived | Record Qualifier | RFXSTDTC=RFSTDTC |  |
| RFXENDTC | Date/Time of Last Study Treatment | xsd:dateTime | ISO8601 | Derived | Record Qualifier | RFXENDTC=RFENDTC |  |
| RFICDTC | Date/Time of Informed Consent | xsd:dateTime | ISO8601 | Derived | Record Qualifier | Date of informed consent was not entered in database (see annotated CRF) |  |
| RFPENDTC | Date/Time of End of Participation | xsd:dateTime | ISO8601 | Derived | Record Qualifier | DSSTDTC of last disposition event |  |
| DTHDTC | Date/Time of Death | xsd:dateTime | ISO8601 | Derived | Record Qualifier | If DS record exists with DSDECOD="DEATH" then DTHDTC=AEENDTC. |  |
| DTHFL | Subject Death Flag | xsd:string | NY | Derived | Record Qualifier | If DS record exists with DSDECOD="DEATH" then DEATHFL=Y. |  |
| SITEID | Study Site Identifier | xsd:string |  | Assigned | Record Qualifier |  |  |
| INVID | Investigator Identifier | xsd:string |  | Assigned | Record Qualifier |  |  |
| BRTHDTC | Date/Time of Birth | xsd:dateTime | ISO8601 | Collected | RecordQualifier |  |  |
| AGE | Age | xsd:integer |  | Derived | Record Qualifier | Subject's Age at start of study drug (RFSTDTC). |  |
| AGEU | Age Units | xsd:string | AGEU | Assigned | Variable Qualifier | AGEU="YEARS" |  |
| SEX | Sex | xsd:string | SEX | Collected / CRF Page 7 | Record Qualifier |  |  |
| RACE | Race | xsd:string | RACE | Collected / CRF Page 7 | Record Qualifier |  |  |
| ETHNIC | Ethnicity | xsd:string | 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 | xsd:string | ARMCD | Assigned | Record Qualifier | According to randomization list | CT should have individual custom terms for ARM & ARMCD |
| ARM | Description of Planned Arm | xsd:string | ARM | Assigned | Synonym Qualifier | According to randomization list |  |
| ACTARMCD | Actual Arm Code | xsd:string | ARMCD | Derived | Record Qualifier | Derived from EX |  |
| ACTARM | Description of Actual Arm | xsd:string | ARM | Derived | Synonym Qualifier | Derived from EX |  |
| COUNTRY | Country | xsd:string | COUNTRY | Derived | Record Qualifier | Derived from site information |  |
| DMDTC | Date/Time of Collection | xsd:date | ISO8601 | Collected / CRF Page 7 | Timing Variable |  |  |
| DMDY | Study Day of Collection | xsd:integer |  | Derived | Timing Variable | See Computational Method: COMPMETHOD.STUDY\_DAY |  |

**Vital Signs (VS) vs.xpt (IMPUTED)**

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| **Variable** | **Label** | **Type** | **Controlled Terminology** | **Origin** | | **Role** | **Comment** | **Internal Team Comment** |
| STUDYID | Study Identifier | xsd:string |  | Assigned / CRF Page 7 | | Identifier Variable |  |  |
| DOMAIN | Domain Abbreviation | xsd:string |  | Assigned | | Identifier Variable |  |  |
| USUBJID | Unique Subject Identifier | xsd:string |  | Derived | | Identifier Variable | Concatenation of STUDYID, DM.SITEID and DM.SUBJID |  |
| VSSEQ | Sequence Number | xsd:integer |  | Derived | | Identifier Variable | Sequential number identifying records within each USUBJID |  |
| VSGRPID | Group ID | xsd:string |  | Assigned | | Identifier Variable |  |  |
| VSSPID | Sponsor-Defined Identifier | xsd:string |  | Assigned | | Identifier Variable |  |  |
| VSTESTCD | Vital Signs Test Short Name | xsd:string |  | Collected /  CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | | Topic Variable |  |  |
| VSTEST | Vital Signs Test Name | xsd:string | VSTEST | Collected / CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | | Synonym Qualifier |  |  |
| VSCAT | Category for Vital Signs | xsd:string |  | Assigned | | Grouping Qualifier |  |  |
| VSSCAT | Subcategory for Vital Signs | xsd:string |  | Assigned | | Grouping Qualifier |  |  |
| VSPOS | Vital Signs Position of Subject | xsd:string | VSPOS | Assigned / 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 | xsd:string |  | Collected / 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 | xsd:string | VSUNIT | Collected / 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 | xsd:string |  | Derived | Result Qualifier | | VSORRES converted to standard unit |  |
| VSSTRESN | Numeric Result/Finding in Standard Units | xsd:integer |  | Derived | Result Qualifier | | VSSTRESC converted to numeric |  |
| VSSTRESU | Standard Units | xsd:string | VSUNIT | Derived | | Variable Qualifier | Standard unit defined per parameter for summarizing analysis |  |
| VSSTAT | Completion Status | xsd:string | ND | Derived / CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | | Record Qualifier |  |  |
| VSRSND | Reason Not Performed | xsd:string |  | Collected | | Record Qualifier |  |  |
| VSLOC | Location of Vital Signs Measurement | xsd:string | VSLOC | Assigned / CRF Pages 17, 23, 30, 33, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | | Record Qualifier |  |  |
| VSBLFL | Baseline Flag | xsd:string | NY | Derived | | Record Qualifier | If VISIT="BASELINE" then VSBLFL="Y" |  |
| VSDRVFL | Derived Flag | xsd:string | NY | Derived | | Record Qualifier |  |  |
| VISITNUM | Visit Number | xsd:float |  | Derived / CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | | Timing Variable |  |  |
| VISIT | Visit Name | xsd:string | VISIT | Assigned / CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | | Timing Variable |  |  |
| VISITDY | Planned Study Day of Visit | xsd:integer |  | Derived | | Timing Variable | TV.ISITDY |  |
| VSDTC | Date/Time of Measurements | xsd:date | ISO8601 | Collected / CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | | Timing Variable |  |  |
| VSDY | Study Day of Vital Signs | xsd:integer |  | Derived | | Timing Variable | See Computational Method: COMPMETHOD.STUDY\_DAY |  |
| VSTPT | Planned Time Point Name | xsd:string |  | Assigned / CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | | Timing Variable |  |  |
| VSTPTNUM | Planned Time Point Number | xsd:integer |  | Derived / CRF Pages 16, 17, 22, 23, 30, 33, 39, 45, 50, 55, 64, 70, 79, 85, 96, 102, 114, 135 | | Timing Variable |  |  |
| VSELTM | Planned Elapsed Time from Time Point Ref | xsd:string |  | Assigned | | Timing Variable | VSTPT expressed in the ISO 8601 format for durations |  |
| VSTPTREF | Time Point Reference | xsd:string |  | Assigned | | Timing Variable |  |  |

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