Data Dictionary for CF Studies

# AE

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| AEACN | Action Taken with Study Treatment | Char | Describes changes to the study treatment as a result of the event. AEACN is specifically for the relationship to study treatment. AEACNOTH is for actions unrelated to dose adjustments of study treatment. Examples of AEACN values include ICH E2B values: "DRUG WITHDRAWN", "DOSE REDUCED", "DOSE INCREASED", "DOSE NOT CHANGED", "UNKNOWN" and "NOT APPLICABLE" | BPCFRD, STRONG |
| AEACNDEV | Action Taken with Device | Char | An action taken with a device as the result of the event. The device may or may not be a device under study | BPCFRD, STRONG |
| AEACNOTH | Other Action Taken | Char | Describes other actions taken as a result of the event that are unrelated to dose adjustments of study treatment. Usually reported as free text. Example: "TREATMENT UNBLINDED. PRIMARY CARE PHYSICIAN NOTIFIED". | BPCFRD, STRONG |
| AEBDSYCD | Body System or Organ Class Code | Char | Dictionary derived. Code for the body system or organ class used by the sponsor. When using a multiaxial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables, which may not necessarily be the primary SOC. | BPCFRD, STRONG |
| AEBODSYS | Body System or Organ Class | Char | Dictionary derived. Body system or organ class used by the sponsor from the coding dictionary (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables, which may not necessarily be the primary SOC. | BPCFRD, STRONG |
| AECAT | Category for Adverse Event | Char | Used to define a category of related records across subjects. | BPCFRD, STRONG |
| AECONTRT | Concomitant or Additional Trtmnt Given | Char | Was another treatment given because of the occurrence of the event? | BPCFRD, STRONG |
| AEDECOD | Dictionary-Derived Term | Char | Dictionary-derived text description of AETERM or AEMODIFY. Equivalent to the Preferred Term (PT in MedDRA). The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the external codelist element in the Define-XML document. | BPCFRD, STRONG |
| AEDUR | Duration of Adverse Event | Char | Collected duration and unit of an adverse event. Used only if collected on the CRF and not derived from start and end date/times | BPCFRD, STRONG |
| AEENDTC | End Date/Time of Adverse Event | Char | End date/time of the adverse event | BPCFRD, STRONG |
| AEENRF | End Relative to Reference Period | Char | Describes the end of the event relative to the sponsor-defined reference period. | BPCFRD |
| AEENTPT | End Reference Time Point | Char | Description of date/time in ISO 8601 character format of the reference point referred to by AEENRTPT. Examples: "2003-12-25", "VISIT 2". | BPCFRD, STRONG |
| AEGRPID | Group ID | Char | Used to tie together a block of related records in a single domain for a subject. | BPCFRD, STRONG |
| AEHLGT | High Level Group Term | Char | Dictionary-derived text description of the high level group term for the primary SOC. | BPCFRD, STRONG |
| AEHLGTCD | High Level Group Term Code | Char | Dictionary-derived code for the high level group term for the primary SOC. | BPCFRD, STRONG |
| AEHLT | High Level Term | Char | Dictionary-derived text description of the high level term for the primary system organ class (SOC). | BPCFRD, STRONG |
| AEHLTCD | igh Level Term Code | Char | Dictionary-derived code for the high level term for the primary SOC. | BPCFRD, STRONG |
| AELIFE | Is Life Threatening | Char | Was the serious event life-threatening? | BPCFRD |
| AELLT | Lowest Level Term | Char | Dictionary-derived text description of the lowest level term. | BPCFRD, STRONG |
| AELLTCD | Lowest Level Term Code | Char | Dictionary-derived code for the lowest level term. | BPCFRD, STRONG |
| AELOC | Location of Event | Char | Describes anatomical location relevant for the event (e.g., "ARM" for skin rash). | BPCFRD, STRONG |
| AEOUT | Outcome of Adverse Event | Char | Description of the outcome of an event. | BPCFRD, STRONG |
| AEPATT | Pattern of Adverse Event | Char | Used to indicate the pattern of the event over time. Examples: "INTERMITTENT", "CONTINUOUS", "SINGLE EVENT". | BPCFRD, STRONG |
| AEPRESP | AE Pre-Specified | Char | A value of "Y" indicates that this adverse event was prespecified on the CRF. Values are null for spontaneously reported events | BPCFRD, STRONG |
| AEPTCD | Preferred Term Code | Char | Dictionary-derived code for the preferred term. | BPCFRD, STRONG |
| AEREL | Causality | Char | Records the investigator's opinion as to the causality of the event to the treatment. ICH does not establish any required or recommended terms for non-device relatedness. ICH E2A and E2B examples include (up-cased here for alignment to SDTM conventions) terms such as "NOT RELATED", "UNLIKELY RELATED", "POSSIBLY RELATED", "RELATED", but these example terms do not establish any conventions or expectations. | BPCFRD, STRONG |
| AERELDS | Description if possibly related to study drug/Device/intervention or procedure | char | Assess the relationship of the adverse event to study drug, study device, other study intervention (e.g., laser, surgical procedure), or study procedure. | BPCFRD, STRONG |
| AERELNST | Relationship to NonStudy Treatment | Char | Records the investigator's opinion as to whether the event may have been due to a treatment other than study drug. May be reported as free text. Example: "MORE LIKELY RELATED TO ASPIRIN USE". | BPCFRD, STRONG |
| AERLDEV | Relationship of Event to Device | Char | A judgment as to the likelihood that the device caused the adverse event. The relationship is to a device identified in the data (i.e., has an SPDEVID). The device may be ancillary or under study. Terminology: • In the EU, follow the European Commission Guidelines on Medical Devices, Clinical Investigations: SAE Reporting (MEDDEV 2.7/3) (e.g., Not Related, Unlikely, Possible, Probable, Causal Relationship), with device-specific definitions. • No required Controlled Terminology in US. | BPCFRD, STRONG |
| AESCAT | Subcategory for Adverse Event | Char | Used to define a subcategory of related records across subjects. | BPCFRD, STRONG |
| AESCONG | Congenital Anomaly or Birth Defect | Char | as the serious event associated with congenital anomaly or birth defect? | BPCFRD |
| AESDISAB | Persist or Significant Disability/Incapacity | Char | Did the serious event result in persistent or significant disability/incapacity? | BPCFRD |
| AESDTH | Results in Death | Char | Cause of death | BPCFRD, STRONG |
| AESDTHDT | Death Date | Char | Death Date | BPCFRD, STRONG |
| AESEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| AESER | Serious Event | Char | Is this a serious event? Valid values are "Y" and "N". | BPCFRD, STRONG |
| AESEV | Severity/Intensity | Char | The severity or intensity of the event. Examples: "MILD", "MODERATE", "SEVERE". | BPCFRD, STRONG |
| AESHOSP | Requires or Prolongs Hospitalization | Char | Did the serious event require or prolong hospitalization? | BPCFRD, STRONG |
| AESINTV | Needs Intervention to Prevent Impairment | Char | Records whether medical or surgical intervention was necessary to preclude permanent impairment of a body function, or to prevent permanent damage to a body structure, with either situation suspected to be due to the use of a medical product. This variable is used in conjunction with the other "seriousness" variables (e.g., fatal, life-threatening). | BPCFRD |
| AESMIE | Other Medically Important Serious Event | Char | Do additional categories for seriousness apply? | BPCFRD |
| AESOC | Primary System Organ Class | Char | Dictionary-derived text description of the primary SOC. Will be the same as AEBODSYS if the primary SOC was used for analysis. | BPCFRD, STRONG |
| AESOCCD | Primary System Organ Class Code | Char | Dictionary-derived code for the primary SOC. Will be the same as AEBDSYCD if the primary SOC was used for analysis. | BPCFRD, STRONG |
| AESTDTC | Start Date/Time ofAdverse Event | Char | Start date/time of the adverse event | BPCFRD, STRONG |
| AESURGERY | Type of surgery/procedure | char | If Adverse Event resulted in surgery, Type of surgery/procedure | BPCFRD, STRONG |
| AETOXGR | Standard Toxicity Grade | Char | Level of Severity (based on National Cancer Institute) | BPCFRD, STRONG |
| AEUNANT | Unanticipated Adverse Device Effect | Char | Any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. | BPCFRD, STRONG |
| AEWORSEN | Is the adverse event a worsening of a pre-existing condition present prior to study entry | Char | Is the adverse event a worsening of a pre-existing condition present prior to study entry | BPCFRD, STRONG |
| AGSTAT | Completion Status | Char | Used to indicate that a question about a prespecified agent was not answered. Should be null or have a value of "NOT DONE". | BPCFRD, STRONG |
| AGTERM | Reported Term for the Adverse Event | Char | Verbatim name of the event. | BPCFRD, STRONG |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# AG

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| AGCAT | Category for Agent | Char | Used to define a category of related records across subjects. | BPCFRD, STRONG |
| AGFAST | Fasting Status | Char | Valid values include "Y", "N", "U", or null if not relevant. | BPCFRD, STRONG |
| AGPRESP | AG Pre-Specified | Char | sed to indicate whether ("Y"/null) information about the use of a specific agent was solicited on the CRF. | BPCFRD, STRONG |
| AGSCAT | Subcategory for Agent | Char | Used to define a subcategory of related records across subjects. | BPCFRD, STRONG |
| AGSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| AGSTAT | Completion Status | Char | Used to indicate that a question about a prespecified agent was not answered. Should be null or have a value of "NOT DONE". | BPCFRD, STRONG |
| AGSTDTC | Date/Time of SStart Date/Time of Agent | Char | The date/time when administration of the treatment indicated by AGTRT and the dosing variables began. | BPCFRD, STRONG |
| AGTPT | Planned Time Point Name | Char | The description of the time when a protocol-defined activity is planned to occur, used for study data tabulation. | BPCFRD, STRONG |
| AGTRT | Reported Agent Name | Char | Verbatim medication name that is either preprinted or collected on a CRF. | BPCFRD, STRONG |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| FNGLUCTM | How long did it take for the participant to finish the glucose | num | How long in minutes | BPCFRD, STRONG |
| FNGLUCTMU | Original Units | char | Unit for FNGLUCTM. | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# CE

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| APPROXDT | Date of Event is approximate | Char | Date of Event is approximate | BPCFRD |
| APROXAGE | Approximate age at time of fracture | Char | Approximate age at time of fracture | BPCFRD, STRONG |
| AUTODEL | Was the participant wearing an automated insulin delivery system at time of event | Char | Was the participant wearing an automated insulin delivery system at time of event | BPCFRD |
| CECAT | Category for Clinical Event | Char | Used to define a category of related records. Examples: "CARDIAC", "GENERAL". | BPCFRD, STRONG |
| CEDECOD | Dictionary-Derived Term | Char | Controlled terminology for the name of the clinical event. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the external codelist element in the DefineXML document. | BPCFRD, STRONG |
| CEDTC | nan | nan | nan | BPCFRD, STRONG |
| CEEVLINT | Evaluation Interval | char | Duration of interval associated with an observation | BPCFRD, STRONG |
| CEGRPID | Group ID | Char | Used to tie together a block of related records in a single domain for a subject. | BPCFRD, STRONG |
| CELOC | Location | char | Location of fracture | BPCFRD, STRONG |
| CEOCCUR | Clinical Event Occurrence | Char | Used when the occurrence of specific events is solicited, to indicate whether or not a clinical event occurred. Values are null for spontaneously reported events. | BPCFRD, STRONG |
| CEREFID | Reference ID | Char | Internal or external medical history identifier., Reference Identifier | BPCFRD, STRONG |
| CESCAT | Subcategory for Clinical Event | Char | A further categorization of the condition or event. | BPCFRD, STRONG |
| CESEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| CESPID | Sponsor-Defined Identifier | Char | Sponsor-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a Clinical Events CRF page. | BPCFRD, STRONG |
| CESTDTC | Start Date/Time of Clinical Event | Char | Start date/time of the clinical event represented in ISO 8601 character format. | BPCFRD, STRONG |
| CETERM | Reported Term for the Clinical Event | Char | Verbatim or preprinted CRF term for the medical condition or event. | BPCFRD, STRONG |
| CGMWEAR | Was the participant wearing a CGM sensor during event | Char | Was the participant wearing a CGM sensor during event | BPCFRD |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| FACTORS | Were there any factors that may have contributed to the occurrence of event | Char | Were there any factors that may have contributed to the occurrence of event | BPCFRD |
| FRACHOSP | Did the fracture lead to hospitalization | Char | Did the fracture lead to hospitalization | BPCFRD, STRONG |
| FRACTRAU | Was the fracture traumatic (ie: fall from greater than standing height, playing sports, car accident, fight, etc.) | Char | Was the fracture traumatic (ie: fall from greater than standing height, playing sports, car accident, fight, etc.) | BPCFRD, STRONG |
| REQSURG | Did the Fracture require surgery | Char | Did the Fracture require surgery | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| UKDT | Date of Event is Unknown | Char | Date of Event is Unknown | BPCFRD |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# CM

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| CMADVEVNT | What is the adverse event(s) for which the medication was taken | Char | What is the adverse event(s) for which the medication was taken | BPCFRD, STRONG |
| CMAPPROX | Date or time approximate | Char | Date or time approximate | BPCFRD |
| CMAPPRXDOSE | Dose is approximate | Char | Dose is approximate | BPCFRD |
| CMCAT | Category for Medication | Char | Used to define a category of medications/treatment. Examples: "PRIOR", "CONCOMITANT", "ANTICANCER MEDICATION", "GENERAL CONMED". | BPCFRD, STRONG |
| CMDECOD | Standardized Medication Name | Char | Standardized or dictionary-derived text description of CMTRT or CMMODIFY. Equivalent to the generic drug name in WHO Drug. The sponsor is expected to provide the dictionary name and version used to mapthe terms utilizing the external codelist element in the Define-XML document. If an intervention term does not have a decode value in the dictionary, then CMDECOD will be left blank. | BPCFRD, STRONG |
| CMDOSE | Dose per Administration | Char | Amount of CMTRT given | BPCFRD, STRONG |
| CMDOSEU | Dose Units | Char | Units for dose given | BPCFRD, STRONG |
| CMDOSFRQ | Dosing Frequency per Interval | Char | Usually expressed as the number of repeated administrations of CMDOSE within a specific time period. | BPCFRD, STRONG |
| CMDOSRGM | Intended Dose Regimen | Char | Text description of the (intended) schedule or regimen for the Intervention | BPCFRD |
| CMENDTC | End Date/Time of Medication | Char | End date/time of the medication administration | BPCFRD, STRONG |
| CMENRF | End Relative to Reference Period | Char | End Relative to Reference Period | BPCFRD, STRONG |
| CMGRPID | Group ID | Char | Used to facilitate identification of relationships between records. | BPCFRD, STRONG |
| CMINDC | Indication | Char | Denotes why a medication was taken or administered. | BPCFRD, STRONG |
| CMMEDCOND | What is the medical history event(s) for which the medication was taken | Char | What is the medical history event(s) for which the medication was taken | BPCFRD, STRONG |
| CMOCCUR | CM Occurrence | Char | When the use of a specific medication is solicited. CMOCCUR is used to indicate whether ("Y"/"N") use of the medication occurred. Values are null for medications not specifically solicited. | BPCFRD, STRONG |
| CMPREMEDCOND | What is the pre existing medical history event(s) for which the medication was taken | Char | What is the pre existing medical history event(s) for which the medication was taken | BPCFRD, STRONG |
| CMPRESP | CM Pre-specified | Char | Used to indicate whether ("Y"/null) information about the use of a specific medication was solicited on the CRF. | BPCFRD, STRONG |
| CMREASND | Reason Medication Not Collected | Char | Reason not done. Used in conjunction with CMSTAT when value is "NOT DONE". | BPCFRD, STRONG |
| CMROUTE | Route of Administration | Char | Route of Administration | BPCFRD, STRONG |
| CMSCAT | Subcategory for Medication | Char | A further categorization of medications/treatment | BPCFRD, STRONG |
| CMSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| CMSTAT | Completion Status | Char | Used to indicate that a question about the occurrence of a prespecified intervention was not answered. Should be null or have a value of "NOT DONE". | BPCFRD, STRONG |
| CMSTDTC | Start Date/Time of Medication | Char | Start date/time of the medication administration | BPCFRD, STRONG |
| CMSTRF | Start Relative to Reference Period | Char | Start Relative to Reference Period | BPCFRD, STRONG |
| CMTRT | Reported Name of Procedure | Char | Verbatim medication name that is either preprinted or collected on a CRF. | BPCFRD, STRONG |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# DE

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DEACNDEV | Action Taken with Device | Char | Describes Action Taken with respect to the device. Action Taken may include removal, calibration, reprogramming, and so on. | BPCFRD |
| DEAE | Did AE occur as a result | Char | Did an adverse event or adverse device effect that requires reporting according to the protocol occur in association with this device deficiency | BPCFRD |
| DEAEPOS | reasonable likelihood that the device deficiency could have led to a SAE | Char | If not associated with a reportable adverse event or adverse device effect, is there a reasonable likelihood that the device deficiency could have led to a serious adverse device effect | BPCFRD |
| DEAEPOS.1 | what adverse device effect could have occurred | Char | what adverse device effect could have occurred | BPCFRD |
| DECAT | Category for Device Events | Char | Used to categorize observations across subject | BPCFRD |
| DEDECOD | Device Events Dictionary-Derived Term | Char | Dictionary-derived form of the event described in DETERM. Dictionary-derived text description of DETERM or DEMODIFY. | BPCFRD |
| DEDEVICE | Identified device with event | char | Device with issue | BPCFRD |
| DEDTC | Date of Device Event Data Collection | Char | Date the device event information was collected. | BPCFRD |
| DEEFFECT | Effect on study device | Char | Effect on study device | BPCFRD |
| DEENDTC | End Date/Time of Device Event | char | End date/time of the device event. End date/time of the device event. If an event lasted over a period of time, DEENDTC can be used to capture the end date/time. | BPCFRD |
| DEFREQ | Frequency | Char | Frequency | BPCFRD |
| DEISSUEDS | Description of device deficiency | nan | Description of device deficiency | BPCFRD |
| DEMODIFY | Modified Device Event Name | Char | he modified text for DETERM. If DETERM is modified, then the modified text is placed here. | BPCFRD |
| DEOCCUR | Device Event Occurrence | Char | When information about specific events is solicited, DEOCCUR is used to indicate whether or not (Y/N) a particular pre-specified event occurred. | BPCFRD |
| DEPRESP | Pre-Specified Device Event | Char | Used to indicate whether (Y/null) information about a specific event was solicited on the CRF. | BPCFRD |
| DEREASND | Reason Device Event Not Collected | Char | Reason DESTAT was "NOT DONE". | BPCFRD |
| DEREPLACE | Date Device Replaced | Char | Date device replaced or modified and first used by participant | BPCFRD |
| DESCAT | Subcategory for Device Events | Char | A further categorization. | BPCFRD |
| DESEQ | Sequence Number | Char | Sequence number to ensure uniqueness of records within a dataset for a subject. May be any valid number (including decimals) and does not have to start at 1. | BPCFRD |
| DESEV | Device Event Severity | Char | Describes the severity of the event, | BPCFRD |
| DESPID | Sponsor-Defined Identifier | Char | ponsor-defined reference number. | BPCFRD |
| DESTAT | Device Event Collection Status | Char | he status indicates that the pre-specified question was not answered. For example, if equipment operation requires checking, such as checking an event log to detect events. | BPCFRD |
| DESTDTC | Start Date/Time of Device Event | Char | tart date/time of the device event. If the event happened at a single point in time, DESTDTC is used | BPCFRD |
| DETERM | Reported Term for Device Event | Char | Verbatim name of the observed event. | BPCFRD |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD |
| VISITNUM | Visit Number | Num | Clinical encounter number. Numeric version of VISIT, used for sorting. | BPCFRD |

# DM

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| AGE | AGE | Num | Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns). | BPCFRD, STRONG |
| AGEU | Age Units | Char | Units associated with AGE. | BPCFRD, STRONG |
| COUNTRY | Country | Char | Country of the investigational site in which the subject participated in the trial. Generally represented using ISO 3166-1 Alpha-3. Note that regulatory agency specific requirements (e.g., US FDA) may require other terminologies; in such cases, follow regulatory requirements. | BPCFRD, STRONG |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| DTHDTC | Date/Time of Death | Char | Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database. | BPCFRD, STRONG |
| DTHFL | Subject Death Flag | Char | ndicates the subject died. Should be "Y" or null. Should be populated even when the death date is unknown. | BPCFRD, STRONG |
| ETHNIC | Ethnicity | Char | The ethnicity of the subject. Sponsors should refer to the FDA guidance regarding the collection of ethnicity. | BPCFRD, STRONG |
| RACE | Race | Char | Race of the subject. Sponsors should refer to the FDA guidance regarding the collection of race. | BPCFRD, STRONG |
| RFENDTC | Subject Reference End Date/Time | Char | Reference end date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects. | BPCFRD, STRONG |
| RFICDTC | Date/Time of Informed Consent | Char | Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent. | BPCFRD, STRONG |
| RFPENDTC | Date/Time of End of Participation | Char | Date/time when subject ended participation or follow-up in a trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last known date of contact. Examples include completion date, withdrawal date, last follow-up, date recorded for lost to follow up, and death date. | BPCFRD, STRONG |
| RFSTDTC | Subject Reference Start Date/Time | Char | Reference start date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. | BPCFRD, STRONG |
| RFXENDTC | Date/Time of Last Study Treatment | Char | Last date/time of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing). | BPCFRD, STRONG |
| RFXSTDTC | Date/Time of First Study Treatment | Char | First date/time of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC. | BPCFRD, STRONG |
| SEX | Sex | Char | Sex of Subject | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# DX

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD |
| DXCAT | Category for Device Exposure | Char | Used to define a category of device exposures. | BPCFRD |
| DXDOSE | exposure per Administration | Char | Amount administered/delivered per administration. Dose if captured as a numeric value. | BPCFRD |
| DXDOSFRQ | Device Exposure Frequency per Interval | Char | Exposure frequency per interval. Usually expressed as the number of repeated administrations of DXDOSE within a specific time period. | BPCFRD |
| DXDOSTOT | Total Daily Device Exposure | Char | Total daily exposure of DXTRT using the units in DXDOSU. Total exposure over a period other than day could be recorded in a separate Supplemental Qualifier variable. | BPCFRD |
| DXDOSTXT | Device Exposure Description | Char | Exposure amount or a range of exposure information collected in text form. | BPCFRD |
| DXDOSU | Device Exposure Units | Char | Units | BPCFRD |
| DXDTC | Date Information obtained | Char | Visit Date | BPCFRD |
| DXENRTPT | End Relative to Reference Time Point | Char | End Relative to Reference Time Point | BPCFRD |
| DXEVINTX | Evaluation Interval Text | Char | Evaluation interval where interval is not able to be represented in ISO 8601. examples: LIFETIME, LAST NIGHT, RECENTLY, OVER THE LAST FEW WEEKS | BPCFRD |
| DXMANF | Device Manufaturer | char | Device Manufaturer | BPCFRD |
| DXPRESP | DX Pre-specified | Char | Indicate whether information about the use of a specific device was solicited | BPCFRD |
| DXROUTE | Route of Administration | char | Route of Administration | BPCFRD |
| DXSCAT | Subcategory for Device Exposure | Char | A further categorization of device exposures. | BPCFRD |
| DXSEQ | Sequence Number | Num | Sequence Number given to ensure uniqueness of device | BPCFRD |
| DXSTAT | Completion Status | Char | Used to indicate that a question about the occurrence of a prespecified intervention was not answered. Should be null or have a value of "NOT DONE". | BPCFRD |
| DXSTRTPT | Start Relative to Reference Time Point | Char | Start Relative to Reference Time Point | BPCFRD |
| DXTRT | Name of Device Exposure or Output | Char | Name of the device or the exposure outputs | BPCFRD |
| SPDEVID | Sponsor Device Identifier | Char | Sponsor-defined identifier for the device. | BPCFRD |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject | BPCFRD |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD |

# FT

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| FTCAT | Category | Char | Used to define a further categorization of FTCAT values. | BPCFRD, STRONG |
| FTDTC | Date/Time of Test | Char | Collection date and time of functional test. | BPCFRD, STRONG |
| FTENDTC | End Date/Time of Test | Char | End date/time of the test represented in ISO 8601 character format. | BPCFRD, STRONG |
| FTORRES | Result or Finding in Original Units | Char | Result of the measurement or finding as originally received or collected. | BPCFRD, STRONG |
| FTREASND | Reason Medication Not Collected | Char | Reason not done. Used in conjunction with FTSTAT when value is "NOT DONE". | BPCFRD, STRONG |
| FTSCAT | Subcategory | Char | Used to define a further categorization of FTCAT values. | BPCFRD, STRONG |
| FTSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| FTSTAT | Completion Status | Char | Used to indicate that a question about the occurrence of a prespecified intervention was not answered. Should be null or have a value of "NOT DONE". | BPCFRD, STRONG |
| FTTEST | Name of Test | Char | Verbatim name of the question used to obtain the finding. The value in FTTEST cannot be longer than 40 characters. | BPCFRD, STRONG |
| FTTESTCD | Short Name of Test | Char | Short character value for FTTEST, which can be used as a column name when converting a dataset from a vertical format to a horizontal format. The value cannot be longer than 8 characters, nor can it start with a number | BPCFRD, STRONG |
| FTTPTREF | Time Point Reference | Char | Description of fixed reference point | BPCFRD, STRONG |
| STOPNUM | Number of stops | Num | Number of stops during functional test | BPCFRD, STRONG |
| STPREASN | Reason for stops | char | Reason for stops during the 6 minute walk | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISABLELIMIT | Visible Limitations | char | Limitations to completing test | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# FA

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| CMCAT | Category for Medication | Char | Used to define a category of medications/treatment. Examples: "PRIOR", "CONCOMITANT", "ANTICANCER MEDICATION", "GENERAL CONMED". | STRONG |
| CMDECOD | Standardized Medication Name | Char | Standardized or dictionary-derived text description of CMTRT or CMMODIFY. Equivalent to the generic drug name in WHO Drug. The sponsor is expected to provide the dictionary name and version used to mapthe terms utilizing the external codelist element in the Define-XML document. If an intervention term does not have a decode value in the dictionary, then CMDECOD will be left blank. | STRONG |
| CMOCCUR | CM Occurrence | Char | When the use of a specific medication is solicited. CMOCCUR is used to indicate whether ("Y"/"N") use of the medication occurred. Values are null for medications not specifically solicited. | STRONG |
| CMPRESP | CM Pre-specified | Char | Used to indicate whether ("Y"/null) information about the use of a specific medication was solicited on the CRF. | STRONG |
| CMREASND | Reason Medication Not Collected | Char | Reason not done. Used in conjunction with CMSTAT when value is "NOT DONE". | STRONG |
| CMSTAT | Completion Status | Char | Used to indicate that a question about the occurrence of a prespecified intervention was not answered. Should be null or have a value of "NOT DONE". | STRONG |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| FACAT | Category for Findings About | Char | Used to define a category of related records. | BPCFRD |
| FAOBJ | Object of the Observation | Char | Used to describe the object or focal point of the findings observation that is represented by --TEST. Examples: the term (e.g., "Acne") describing a clinical sign or symptom that is being measured by a severity test; an event | BPCFRD |
| FAORRES | Result or Finding in Original Units | Char | Result of the test as originally received or collected. | BPCFRD |
| FAORRESU | Original Units | Char | Original units in which the data were collected. | BPCFRD |
| FAREASND | Reason Not Performed | Char | Describes why a question was not answered. Example: "Subject refused". Used in conjunction with FASTAT when value is "NOT DONE" | BPCFRD |
| FASCAT | Subcategory for Findings About | Char | A further categorization of FACAT. | BPCFRD |
| FASEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| FASTAT | Completion Status | Char | Used to indicate that the measurement was not done. Should be null if a result exists in FAORRES. | BPCFRD |
| FASTRESC | Character Result/Finding in Std Format | Char | Contains the result value for all findings, copied or derived from FAORRES in a standard format or standard units. FASTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in FASTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in FAORRES, and these results effectively have the same meaning; they could be represented in standard format in FASTRESC as "NEGATIVE". | BPCFRD |
| FATEST | Reported Name of Procedure | Char | Verbatim name of the test or examination used to obtain the measurement or finding. , Verbatim name of the test or examination used to obtain the measurement or finding. The value in FATEST cannot be longer than 40 characters. Examples: "Severity/Intensity", "Occurrence". Note that controlled terminology is in a FATEST general codelist and in several therapeutic area-specific codelists. | BPCFRD, STRONG |
| FATESTCD | Findings About Test Short Name | Char | hort name of the measurement, test, or examination described in FATEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in FATESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). FATESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "SEV", "OCCUR". Note that controlled terminology is in a FATESTCD general codelist and in several therapeutic area-specific codelists. , short name of the measurement, test, or examination described in FATEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD |

# GF

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| GFAPPRDT | Date is an approximation | Char | Date is an approximation | BPCFRD |
| GFDTC | Date/Time of Specimen Collection | Char | Date and time of specimen collection. | BPCFRD, STRONG |
| GFORRES | Result or Finding in Original Units | Char | Result of the measurement or finding as originally received or collected. | BPCFRD, STRONG |
| GFREFID | Reference ID | Char | A unique identifier for the assayed genetic specimen. | BPCFRD, STRONG |
| GFSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| GFSTAT | Completion Status | Char | Used to indicate that a question was not asked or a test was not done, or a test was attempted but did not generate a result. Should be null or have a value of "NOT DONE". | BPCFRD, STRONG |
| GFTEST | Name of Genomic Measurement | Char | ong name for GFTESTCD. The value in GFTEST cannot be longer than 40 characters. | BPCFRD, STRONG |
| GFTESTCD | Short Name of Genomic Measurement | Char | Short name of the measurement, test, or examination described in GFTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in GFTESTCD cannot be longer than 8 characters, nor can it start with a number | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# HE

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD |
| HEAPPROXDT | Date is Approximate | char | Date is Approximate | BPCFRD |
| HEAPPROXTM | Time is Approximate | char | Time is Approximate | BPCFRD |
| HEAUTOINS | Participant using an automated insulin delivery system | char | Was the participant using an automated insulin delivery system that was automating insulin delivery at the time of the Hypoglycemic Event | BPCFRD |
| HEBOLTMAP | bolus prior to the Hypoglycemic Event time approximate | char | bolus prior to the Hypoglycemic Event time approximate | BPCFRD |
| HEBOLUS | Most recent manual insulin bolus prior to the Hypoglycemic Event | char | Most recent manual insulin bolus prior to the Hypoglycemic Event | BPCFRD |
| HECAT | Category for Clinical Event | Char | Used to define a category of related records. Examples: "CARDIAC", "GENERAL". | BPCFRD |
| HEDECOD | Dictionary-Derived Term | Char | Controlled terminology for the name of the clinical event. The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the external codelist element in the DefineXML document. | BPCFRD |
| HEDTC | nan | nan | nan | BPCFRD |
| HEEVLINT | Evaluation Interval | char | Duration of interval associated with an observation | BPCFRD |
| HEGLUC | Was glucagon used to treat | char | Was glucagon used to treat | BPCFRD |
| HEGRPID | Group ID | Char | Used to tie together a block of related records in a single domain for a subject. | BPCFRD |
| HELASTML | Information on the last meal and/or snacks consumed prior to the Hypoglycemic Event | char | Information on the last meal and/or snacks consumed prior to the Hypoglycemic Event | BPCFRD |
| HELOC | Location | char | Location of fracture | BPCFRD |
| HEOCCUR | Clinical Event Occurrence | Char | Used when the occurrence of specific events is solicited, to indicate whether or not a clinical event occurred. Values are null for spontaneously reported events. | BPCFRD |
| HEOTCAUSE | Other factors that may have contributed to the occurrence of the Hypoglycemic Event | char | Other factors that may have contributed to the occurrence of the Hypoglycemic Event | BPCFRD |
| HEPHYS | Hypoglycemic Event occur during or following physical activity | char | Hypoglycemic Event occur during or following physical activity | BPCFRD |
| HEREFID | Reference ID | Char | Reference Identifier | BPCFRD |
| HERESOF | Result of Hypo Even | char | All of the following that apply for this Hypoglycemic Event | BPCFRD |
| HESCAT | Subcategory for Clinical Event | Char | A further categorization of the condition or event. | BPCFRD |
| HESEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD |
| HESLEEP | Event occur while asleep | char | Did the Hypoglycemic Event occur while the participant was asleep | BPCFRD |
| HESPID | Sponsor-Defined Identifier | Char | Sponsor-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a Clinical Events CRF page. | BPCFRD |
| HESTDTC | Start Date/Time of Clinical Event | Char | Start date/time of the clinical event represented in ISO 8601 character format. | BPCFRD |
| HETERM | Reported Term for the Clinical Event | Char | Verbatim or preprinted CRF term for the medical condition or event. | BPCFRD |
| HEUNKDT | Date is Unknown | char | Date is Unknown | BPCFRD |
| HEUNKTM | Date is Unknown | char | Time is Unknown | BPCFRD |
| HEWAKE | Event wake the participant | char | Did the Hypoglycemic Event wake the participant | BPCFRD |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD |

# HO

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| CMPRESP | CM Pre-specified | Char | Used to indicate whether ("Y"/null) information about the use of a specific medication was solicited on the CRF. | STRONG |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| HOCAT | Category for Healthcare Encounter | Char | Used to define a category of topic-related values., sed to define a category of topic-related values. | BPCFRD, STRONG |
| HODECOD | Dictionary-Derived Term | Char | Dictionary or sponsor-defined derived text description of HOTERM or the modified topic variable (HOMODIFY). | BPCFRD, STRONG |
| HODUR | Duration of Healthcare Encounter | Char | Duration of Healthcare Encounter | BPCFRD |
| HOENDTC | End Date/Time of Healthcare Encounter | Char | End date/time of the healthcare encounter | BPCFRD, STRONG |
| HOOCCUR | Healthcare Encounter Occurrence | Char | Used when the occurrence of specific healthcare encounters is solicited, to indicate whether an encounter occurred., When the use of a specific medication is solicited. HOOCCUR is used to indicate whether ("Y"/"N") use of the medication occurred. Values are null for medications not specifically solicited. | BPCFRD, STRONG |
| HOPRESP | Pre-Specified Healthcare Encounter | Char | A value of "Y" indicates that this healthcare encounter event was prespecified on the CRF. Values are null for spontaneously reported events. | BPCFRD, STRONG |
| HOREASND | Reason Healthcare Encounter Not Collected | Char | Reason not done. Used in conjunction with HOSTAT when value is "NOT DONE". | BPCFRD, STRONG |
| HOSCAT | Subcategory for Healthcare Encounter | Char | A further categorization of HOCAT values. | BPCFRD, STRONG |
| HOSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| HOSTAT | Completion Status | Char | Used to indicate that a question about the occurrence of a prespecified intervention was not answered. Should be null or have a value of "NOT DONE". | BPCFRD, STRONG |
| HOSTDTC | Start Date/Time of Healthcare Encounter | Char | Start date/time of the healthcare encounter | BPCFRD, STRONG |
| HOTERM | Healthcare Encounter Term | Char | Verbatim or preprinted CRF term for the healthcare encounter. | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# LB

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| LBANMETH | Analysis Method | Char | Analysis method applied to obtain a summarized result. Analysis method describes the method of secondary processing applied to a complex observation result (e.g., a calculation used to measure eGFR). | BPCFRD, STRONG |
| LBAPPROXDT | Date is approximate | Char | Date is approximate | BPCFRD |
| LBCAT | Category for Lab test | Char | Used to define a category of related records across subjects. | BPCFRD, STRONG |
| LBDTC | Date/Time of Specimen Collection | Char | Date/time of specimen collection represented in ISO 8601 character format. | BPCFRD, STRONG |
| LBELTM | Planned Elapsed Time from Time Point Ref | Char | Planned elapsed time (in ISO 8601) relative to a planned fixed reference (LBTPTREF). This variable is useful where there are repetitive measures. Not a clock time or a date/time variable. Examples: "-PT15M" to represent the period of 15 minutes prior to the reference point indicated by LBTPTREF, "PT8H" to represent the period of 8 hours after the reference point indicated by LBTPTREF. | BPCFRD, STRONG |
| LBFAST | Fasting Status | Char | Indicator used to identify fasting status. Examples: "Y", "N". | BPCFRD, STRONG |
| LBLLOD | Lower Limit of Detection | Char | The lowest threshold (as originally received or collected) for reliably detecting the presence or absence of substance measured by a specific test. The value for the field will be as described in documentation from the instrument or lab vendor. | BPCFRD, STRONG |
| LBLOINC | LOINC Code | Char | Code for the lab test from the LOINC code system. | BPCFRD, STRONG |
| LBMETHOD | Method of Test or Examination | Char | Method of the test or examination. Examples: "EIA" (enzyme immunoassay), "ELECTROPHORESIS", "DIPSTICK". | BPCFRD, STRONG |
| LBORNRHI | Reference Range Upper Limit in Orig Unit | Char | Upper end of reference range for continuous measurement in original units. Should be populated only for continuous results. | BPCFRD, STRONG |
| LBORNRLO | Reference Range Lower Limit in Orig Unit | Char | Lower end of reference range for continuous measurement in original units. Should be populated only for continuous results. | BPCFRD, STRONG |
| LBORRES | Result or Finding in Original Units | Char | Result of the measurement or finding as originally received or collected. | BPCFRD, STRONG |
| LBORRESU | Original Units | Char | Original units in which the data were collected. | BPCFRD, STRONG |
| LBREASND | Reason Test Not Done | Char | Describes why a measurement or test was not performed. | BPCFRD, STRONG |
| LBREFID | Reference ID | Char | Reference Identifier | BPCFRD |
| LBRESSCL | Result Scale | Char | Classifies the scale of the original result value; for example, whether the result is ordinal, nominal, quantitative, or narrative. | BPCFRD, STRONG |
| LBRESTYP | Result Type | Char | Classifies the kind of result (i.e., property type) originally reported for the test. Examples include substance concentration, proportion, mass rate, and arbitrary concentration. | BPCFRD, STRONG |
| LBRFTDTC | Date/Time of Reference Time Point | Char | Date/time of the reference time point, LBTPTREF. | BPCFRD, STRONG |
| [LBSCAT](#_LBSCAT) | Subcategory for Lab test | Char | Used to define a subcategory of related records across subjects. | BPCFRD, STRONG |
| LBSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| LBSPCCND | Specimen Condition | Char | The physical state or quality of a sample for an assessment. Examples: "HEMOLYZED", "ICTERIC", "LIPEMIC". | BPCFRD, STRONG |
| LBSPCUFL | Specimen Usability for the Test | Char | Describes the usability of the specimen for the test. The value will be "N" if the specimen is not usable, and null if the specimen is usable. | BPCFRD, STRONG |
| LBSPEC | Specimen Type | Char | Defines the type of specimen used for a measurement. Examples: "SERUM", "PLASMA", "URINE". | BPCFRD, STRONG |
| LBSTAT | Completion Status | Char | Used to indicate exam not done. Should be null if a result exists in LBORRES. | BPCFRD, STRONG |
| LBTEST | Lab Test or Examination Name | Char | Verbatim name of the test or examination used to obtain the measurement or finding. Note: Any test normally performed by a clinical laboratory is considered a lab test. The value in LBTEST cannot be longer than 40 characters. | BPCFRD, STRONG |
| LBTESTCD | Lab Test or Examination Short Name | Char | Short name of the measurement, test, or examination described in LBTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in LBTESTCD cannot be longer than 8 characters, nor can it start with a number | BPCFRD, STRONG |
| LBTMTHSN | Test Method Sensitivity | Char | The sensitivity of the test methodology with respect to observation, detection, or quantification. (HIGH SENSITIVITY, LOW SENSITIVITY, ULTRA-HIGH SENSITIVITY) | BPCFRD, STRONG |
| LBTPT | Planned Time Point Name | Char | Text description of time when specimen should be taken. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See LBTPTNUM and LBTPTREF. Examples: "Start", "5 min post". | BPCFRD, STRONG |
| LBTPTREF | Time Point Reference | Char | Name of the fixed reference point referred to by LBELTM, LBTPTNUM, and LBTPT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL". | BPCFRD, STRONG |
| LBUNKDT | Date Unknown | Char | use to indicate the date of last CT Scan was unkonwn | BPCFRD, STRONG |
| MODTHRPY | Was participant on modulator therapy at the time of the test | char | used to capture if participant was on modulator therapy at time of test | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# MH

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| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| APROXAGE | Approximate age at time of fracture | Char | Approximate age at time of fracture | BPCFRD, STRONG |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| FRACHOSP | Did the fracture lead to hospitalization | Char | Did the fracture lead to hospitalization | BPCFRD, STRONG |
| FRACTRAU | Was the fracture traumatic (ie: fall from greater than standing height, playing sports, car accident, fight, etc.) | Char | Was the fracture traumatic (ie: fall from greater than standing height, playing sports, car accident, fight, etc.) | BPCFRD, STRONG |
| MHAPPRDT | Date is an approximation | Char | Date is an approximation | BPCFRD, STRONG |
| MHBODSYS | Body System or Organ Class | Char | Body system or organ class that is involved in an event or measurement from a standard hierarchy (e.g., MedDRA). | BPCFRD, STRONG |
| MHCAT | Category for Medical History | Char | Used to define a category of related records. Examples: "CARDIAC", "GENERAL". | BPCFRD, STRONG |
| MHDECOD | Dictionary-Derived Term | Char | Dictionary-derived text description of MHTERM or MHMODIFY. Equivalent to the Preferred Term (PT in MedDRA). The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the external codelist element in the Define-XML document. | BPCFRD, STRONG |
| MHENDTC | End Date/Time of Medical History Event | Char | End date/time of the medical history event represented in ISO 8601 character format. | BPCFRD |
| MHENRTPT | End Relative to Reference Time Point | char | End Relative to Reference Time Point | BPCFRD |
| MHENTPT | Reference Time Point | char | Reference Time Point | BPCFRD |
| MHEVDTYP | Medical History Event Date Type | Char | Specifies the aspect of the medical condition or event by which MHSTDTC and/or the MHENDTC is defined. | BPCFRD, STRONG |
| MHEVLINT | Evaluation Interval | char | Duration of interval associated with an observation | BPCFRD, STRONG |
| MHEXISTDUR | Approximate duration prior to asking/enroll | char | Approximate duration prior to asking/enroll | BPCFRD |
| MHGRPID | Group ID | Char | Used to tie together a block of related records in a single domain for a subject. | BPCFRD, STRONG |
| MHLEGACH | Have you had any pain, aching or stiffness in either of your legs/feet in the past 7 days | Char | Have you had any pain, aching or stiffness in either of your legs/feet in the past 7 days | BPCFRD, STRONG |
| MHLOC | Location | char | Location of fracture | BPCFRD, STRONG |
| MHLOCPRF | where was Chest CT scan performed | Char | used to capture where the Chest CT scan was performed | BPCFRD, STRONG |
| MHMODIFY | Modified Reported Term | Char | If MHTERM is modified to facilitate coding, then MHMODIFY will contain the modified text. | BPCFRD, STRONG |
| MHOCCUR | Medical History Occurrence | Char | Used when the occurrence of specific medical history conditions is solicited, to indicate whether ("Y"/"N") a medical condition (MHTERM) had ever occurred. Values are null for spontaneously reported events. | BPCFRD, STRONG |
| MHREFID | Reference ID | Char | Internal or external medical history identifier. | BPCFRD, STRONG |
| MHSCAT | Subcategory for Medical History | Char | A further categorization of the condition or event. | BPCFRD, STRONG |
| MHSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| MHSPID | Sponsor-Defined Identifier | Char | Sponsor-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a Medical History CRF page. | BPCFRD, STRONG |
| MHSTAT | Completion Status | Char | The status indicates that the prespecified question was not asked/answered. | BPCFRD, STRONG |
| MHSTDTC | Start Date/Time of Medical History Event | Char | Start date/time of the medical history event represented in ISO 8601 character format. | BPCFRD, STRONG |
| MHSURLOC | Which leg/foot was the surgery on | Char | Which leg/foot was the surgery on | BPCFRD, STRONG |
| MHTERM | Reported Term for the Medical History | Char | Verbatim or preprinted CRF term for the medical condition or event. | BPCFRD, STRONG |
| MHUNKDT | Date Unknown | Char | use to indicate the date of last CT Scan was unkonwn | BPCFRD, STRONG |
| PULMEVNT | Number of pulmonary exacerbation events in the prior period | num | used to capture how many pulmonayr exacerbations event occurred in the time period specified | BPCFRD, STRONG |
| REQSURG | Did the Fracture require surgery | Char | Did the Fracture require surgery | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# MK

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| HANDACH | Have you had any pain, aching or stiffness in either of your hands in the past 7 days | char | Have you had any pain, aching or stiffness in either of your hands in the past 7 days | BPCFRD, STRONG |
| HANDLIMIT | Visible Limitations for Handgrip strength test | char | Visible Limitations for Handgrip strength test | BPCFRD, STRONG |
| MKCAT | Category for Musculoskeletal Test | Char | Used to define a category of topic-variable values. | BPCFRD, STRONG |
| MKDTC | Date/Time of Collection | char | Start date/time of the collection represented in ISO 8601 character form | BPCFRD, STRONG |
| MKEVALID | Study staff performing measurements | char | Study staff performing measurements | BPCFRD, STRONG |
| MKLAT | Laterality | Char | Qualifier for anatomical location or specimen further detailing laterality. | BPCFRD, STRONG |
| MKLNKID | Link ID | Char | Used to facilitate identification of relationships between records. | BPCFRD, STRONG |
| MKLOC | Location Used for the Measurement | Char | Anatomical location of the subject relevant to the collection of the measurement. | BPCFRD, STRONG |
| MKMESDAT | Date of Measurements | char | Date of Measurements represented in ISO 8601 character form | BPCFRD, STRONG |
| MKMETHOD | Method of Test or Examination | Char | Method of the test or examination. | BPCFRD, STRONG |
| MKORRES | Result or Finding in Original Units | Char | Result of the measurement or finding as originally received or collected. | BPCFRD, STRONG |
| MKORRESU | Original Units | char | Unit for MKORRES. | BPCFRD, STRONG |
| MKREASND | Reason Not Done | Char | Reason not done. Used in conjunction with MKSTAT when value is "NOT DONE". | BPCFRD, STRONG |
| MKSCAT | Subcategory for Musculoskeletal Test | Char | Used to define a further categorization of MKCAT values. | BPCFRD, STRONG |
| MKSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| MKSTAT | Completion Status | Char | Used to indicate that a test was not done or a measurement was not taken. Should be null if a result exists in MKSTDTC. | BPCFRD, STRONG |
| MKTEST | Name of Musculoskeletal Test | Char | Long name For MKTESTCD. | BPCFRD, STRONG |
| MKTESTCD | Short Name of Musculoskeletal Test | Char | Short character value for MKTEST used as a column name when converting a dataset from a vertical format to a horizontal format. The value in MKTESTCD cannot be longer than 8 characters, nor can it start with a number. MKTESTCD cannot contain characters other than letters, numbers, or underscores. | BPCFRD, STRONG |
| MKUSPEID | Ultrasound done by | char | Study staff performing ultrasound | BPCFRD, STRONG |
| NOGRIPTS | In this test we will be asking you to squeeze this instrument as hard as you can. Do you know of any reason why you should not do the test | char | In this test we will be asking you to squeeze this instrument as hard as you can. Do you know of any reason why you should not do the test | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |
| VISITNUM | Visit Number | Num | Clinical encounter number. Numeric version of VISIT, used for sorting. | BPCFRD, STRONG |

# ML

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| MLDTC | Date/Time of Collection | char | Date/time of meal. | BPCFRD, STRONG |
| MLENDTC | End Date/Time of Meal | char | End date/time of the meal | BPCFRD, STRONG |
| MLENDTCUK | End Date/Time of Meal Unknown | char | End date/time of the meal unknown | BPCFRD, STRONG |
| MLFAST | Was participant fasted for at least 10 hrs | char | Was participant fasted for at least 10 hrs | BPCFRD, STRONG |
| MLREASND | eason Meal Not Collected | char | Describes the reason a response to a question about the occurrence of a meal was not collected. | BPCFRD, STRONG |
| MLSEQ | Sequence Number | Char | Sequence number to ensure uniqueness of records within a dataset for a subject. May be any valid number (including decimals) and does not have to start at 1. | BPCFRD, STRONG |
| MLSTDTC | Start Date/Time of Meal | char | Start date/time of the meal | BPCFRD, STRONG |
| MLTRT | Name Of Meal | Char | Verbatim food product name that is either preprinted or collected on a CRF. | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |
| VISITNUM | Visit Number | Num | Clinical encounter number. Numeric version of VISIT, used for sorting. | BPCFRD, STRONG |

# PR

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| PRBIACAL | Was BIA machine calibrated | char | Was BIA machine calibrated | BPCFRD, STRONG |
| PRLIVDON | Was the organ from a live donor | char | Was the organ from a live donor | BPCFRD, STRONG |
| PRLNKID | Link ID | Char | Used to facilitate identification of relationships between records. | BPCFRD, STRONG |
| PROCCUR | Occurrence | char | Used to record whether a prespecified procedure occurred when information about the occurrence of a specific procedure is solicited. | BPCFRD, STRONG |
| PRPCMAKR | Does participant have a pacemaker or other implantable electronic device | char | does participant have any devices | BPCFRD, STRONG |
| PRREASND | Reason Not Done | Char | Describes why a measurement or test was not performed. Examples: "BROKEN EQUIPMENT", "SUBJECT REFUSED". Used in conjunction with PRSTAT when value is "NOT DONE". | BPCFRD, STRONG |
| PRRMAPDT | Date is approximate | char | Date is approximate | BPCFRD, STRONG |
| PRRMOVDT | If the participant was removed from the transplant list, what was the date of removal | char | If the participant was removed from the transplant list, what was the date of removal | BPCFRD, STRONG |
| PRSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| PRSTAT | Completion Status | Char | Used to indicate that a test was not done or a measurement was not taken. Should be null if a result exists in PRSTDTC. | BPCFRD, STRONG |
| PRSTDTC | Start Date/Time of Procedure | char | Start date/time of the procedure represented in ISO 8601 character form | BPCFRD, STRONG |
| PRTRT | Reported Name of Procedure | Char | Name of procedure performed, either preprinted or collected on a CRF. | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |
| VISITNUM | Visit Number | Num | Clinical encounter number. Numeric version of VISIT, used for sorting. | BPCFRD, STRONG |

# QS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| [QSCAT](#_QSCAT) | Category of Question | Char | Used to specify the questionnaire in | BPCFRD, STRONG |
| QSDTC | Date/Time of Finding | Char | Date of questionnaire. | BPCFRD, STRONG |
| QSEVLINT | Evaluation Interval | Char | Evaluation Interval associated with a QSTEST question represented in ISO 8601 character format. | BPCFRD, STRONG |
| QSGRPID | Group ID | Char | Used to tie together a block of related records in a single domain for a subject. | BPCFRD, STRONG |
| QSORRES | Finding in Original Units | Char | Finding as originally received or collected | BPCFRD, STRONG |
| QSORRESU | Original Units | Char | Original units in which the data were collected. T | BPCFRD, STRONG |
| QSSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness | BPCFRD, STRONG |
| QSSTRESC | Character Result/Finding in Std Format | Char | Contains the finding for all questions or sub-scores | BPCFRD, STRONG |
| QSSTRESN | Numeric Finding in Standard Units | Num | Used for continuous or numeric findings in standard format | BPCFRD, STRONG |
| QSSTRESU | Standard Units | Char | Standardized unit used for QSSTRESC or QSSTRESN. | BPCFRD, STRONG |
| QSTEST | Question Name | Char | Verbatim name of the question | BPCFRD, STRONG |
| QSTESTCD | Question Short Name | Char | Topic variable for QS. Short name for the value in QSTEST | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |
| VISITNUM | Visit Number | Num | Clinical encounter number. Numeric version of VISIT, used for sorting. | BPCFRD, STRONG |

# RE

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| RECAT | Category for Respiratory Test | Char | Used to categorize observations across subject | BPCFRD |
| REDTC | Date/Time of Collection | char | Date/time of procedure or test. | BPCFRD, STRONG |
| REORRES | Result or Finding in Original Units | Char | Result of the procedure measurement or finding as originally received or collected. | BPCFRD, STRONG |
| REORRESU | Original Units | Char | Original units in which the data were collected. The unit for REORRES and REORREF. | BPCFRD, STRONG |
| REREASND | Reason Not Done | Char | Describes why a measurement or test was not performed. Examples: "BROKEN EQUIPMENT", "SUBJECT REFUSED". Used in conjunction with RESTAT when value is "NOT DONE". | BPCFRD, STRONG |
| REREFID | Reference ID | Char | Optional internal or external procedure identifier. | BPCFRD, STRONG |
| RESCAT | Subcategory for Respiratory Test | Char | A further categorization. | BPCFRD |
| RESEQ | Sequence Number | Char | Sequence number to ensure uniqueness of records within a dataset for a subject. May be any valid number (including decimals) and does not have to start at 1. | BPCFRD, STRONG |
| RESTAT | Completion Status | Char | Used to indicate that a test was not done or a measurement was not taken. Should be null if a result exists in REORRES. | BPCFRD, STRONG |
| RETEST | Name of Respiratory Test | Char | Verbatim name of the test or examination used to obtain the measurement or finding. The value in RETEST cannot be longer than 40 characters. Examples: "Forced Expiratory Volume in 1 Second", "Forced Vital Capacity". | BPCFRD, STRONG |
| RETESTCD | Short Name of Respiratory Test | Char | Short name of the measurement, test, or examination. It can be used as a column name when converting a dataset from a vertical format to a horizontal format. The value in RETESTCD cannot belonger than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). RETESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "FEV1", "FVC". | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |
| VISITNUM | Visit Number | Num | Clinical encounter number. Numeric version of VISIT, used for sorting. | BPCFRD, STRONG |

# TI

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD |
| IECAT | Inclusion/Exclusion Category | Char | Used for categorization of the inclusion or exclusion criteria. | BPCFRD |
| IESCAT | Inclusion/Exclusion Subcategory | Char | A further categorization of the exception criterion. Can be used to distinguish criteria for a sub-study or to categorize as major or minor exceptions. | BPCFRD |
| IETEST | Inclusion/ExclusionCriterion | Char | Full text of the inclusion or exclusion criterion. | BPCFRD |
| IETESTCD | Incl/Excl Criterion Short Name | Char | Short name IETEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. | BPCFRD |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD |
| TIDTC | Date/Time of Finding | Char | Date entered. | BPCFRD |
| TIORRES | Result | Char | Finding as originally received or collected | BPCFRD |
| TIREASND | Reason Not Done | Char | Describes why a criteria was not performed. Examples: "BROKEN EQUIPMENT", "SUBJECT REFUSED". Used in conjunction with TISTAT when value is "NOT DONE". | BPCFRD |
| TIRL | Inclusion/Exclusion Criterion Rule | Char | Programing guide | BPCFRD |
| TISEQ | Sequence Number | Char | Sequence number to ensure uniqueness of records within a dataset for a subject. May be any valid number (including decimals) and does not have to start at 1. | BPCFRD |
| TISTAT | Completion Status | Char | Used to indicate that a test was not done or a measurement was not taken. Should be null if a result exists in TIORRES. | BPCFRD |
| TIVERS | Protocol CriteriaVersions | Char | The number of this version of the Inclusion/Exclusion criteria. May be omitted if there is only 1 version. | BPCFRD |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD |
| VISITNUM | Visit Number | Num | Clinical encounter number. Numeric version of VISIT, used for sorting. | BPCFRD |

# RP

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| PORRESU | Original Units | Char | Unit for RPORRES. | BPCFRD |
| PRCLSET | Setting where findings were confirmed | Char | Setting where findings were confirmed | BPCFRD |
| RPCAT | Category for Reproductive Test | Char | Used to define a category of topic-variable values | BPCFRD |
| RPCHGSTDTRT | Change In Study Treatment as Result | Char | Change In Study Treatment as Result | BPCFRD |
| RPDTC | Date/Time of Collection | Char | Collection date and time of an observation. | BPCFRD, STRONG |
| RPDUEDTC | Date/Time of Due Date of pregnancy | Char | Date/Time of Due Date of pregnancy | BPCFRD |
| RPORRES | Result or Finding in Original Units | Char | Result of the measurement or finding as originally received or collected. | BPCFRD, STRONG |
| RPREASND | Reason Not Done | Char | Reason not done. Used in conjunction with RPSTAT when value is "NOT DONE". | BPCFRD |
| RPREFID | Reference ID | Char | A unique identifier for the assayed genetic specimen. | BPCFRD, STRONG |
| RPRFTDTC | Date/Time of Reference Time Point | Char | Date/time for a fixed reference time point defined by RPTPTREF | BPCFRD |
| RPSCAT | Subcategory for Reproductive Test | Char | Used to define a further categorization of RPCAT values | BPCFRD |
| RPSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| RPSTAT | Completion Status | Char | Used to indicate that a question was not asked or a test was not done, or a test was attempted but did not generate a result. Should be null or have a value of "NOT DONE". | BPCFRD |
| RPTEST | Name of Reproductive Test | Char | Long name For RPTESTCD. Examples: "Childbearing Potential", "Birth Control Method", "Menarche Age". | BPCFRD, STRONG |
| RPTESTCD | Short Name of Reproductive Test | Char | Short character value for RPTEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: "CHILDPOT", "BCMETHOD", "MENARAGE". | BPCFRD, STRONG |
| RPTPTREF | Time Point Reference | nan | Description of the fixed reference point. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL". | BPCFRD |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# SC

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| SCDTC | Date/Time of Collection | Char | Collection date and time of the subject characteristic | BPCFRD, STRONG |
| SCORRES | Result or Finding in Original Units | Char | Result of the subject characteristic as originally received or collected. | BPCFRD, STRONG |
| SCSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. of subject records within a domain. | BPCFRD, STRONG |
| SCSTRESC | Character Result/Finding in Std Format | Char | Contains the result value for all findings, copied or derived from SCORRES in a standard format or standard units. | BPCFRD, STRONG |
| SCTEST | Subject Characteristic | Char | Verbatim name of the test or examination | BPCFRD, STRONG |
| SCTESTCD | Subject Characteristic Short Name | Char | Short name of the measurement, test, or examination described in SCTEST | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across all studies. across all studies | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |

# VS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable | Label | Type | Comment | Study |
| DOMAIN | Domain Abbreviation | Char | Two-character abbreviation for the domain. | BPCFRD, STRONG |
| STUDYID | Study Identifier | Char | Unique identifier for a study. | BPCFRD, STRONG |
| SUBJID | Subject Identifier for the study | Char | Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF. | BPCFRD, STRONG |
| USUBJID | Unique Subject Identifier | Char | Identifier used to uniquely identify a subject across | BPCFRD, STRONG |
| VISIT | Visit record was collected | Char | Visit record was collected | BPCFRD, STRONG |
| VISITNUM | Visit Number | Num | Clinical encounter number. Numeric version of VISIT, used for sorting. | BPCFRD, STRONG |
| VSCAT | Category for Vital Signs | Char | Used to define a category of related records. | BPCFRD, STRONG |
| VSDTC | Date/Time of Measurements | Char | Date and time of the vital signs assessment represented in ISO 8601 character format. | BPCFRD, STRONG |
| VSGRPID | Group ID | Char | sed to tie together a block of related records in a single domain for a subject. | BPCFRD, STRONG |
| VSO2 | Date/Time of Measurements | Char | Date and time of the vital signs assessment represented in ISO 8601 character format. | STRONG |
| VSORRES | Subcategory for Vital Signs | Char | Result of the vital signs measurement as originally received or collected. | BPCFRD, STRONG |
| VSORRESU | Original Units | Char | Original units in which the data were collected. The unit for VSORRES. Examples: "in", "LB", "beats/min". | BPCFRD, STRONG |
| VSREASND | nan | nan | nan | BPCFRD, STRONG |
| VSSCAT | Subcategory for Vital Signs | Char | A further categorization of a measurement or examination. | BPCFRD, STRONG |
| VSSEQ | Sequence Number | Num | Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number. | BPCFRD, STRONG |
| VSSPID | Sponsor-Defined Identifier | Char | Sponsor-defined reference number. May be preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. | BPCFRD, STRONG |
| VSSTAT | Completion Status | Char | Used to indicate that a vital sign measurement was not done. Should be null if a result exists in VSORRES. | BPCFRD, STRONG |
| [VSTEST](#_VSTEST) | Vital Signs Test Name | Char | Verbatim name of the test or examination used to obtain the measurement or finding. The value in VSTEST cannot be longer than 40 characters. | BPCFRD, STRONG |
| VSTESTCD | Vital Signs Test Short Name | Char | Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). VSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "SYSBP", "DIABP", "BMI". | BPCFRD, STRONG |
| VSTPT | Planned Time Point Name | Char | Text description of time when measurement should be taken. This may be represented as an elapsed time relative to a fixed reference point (e.g., time of last dose). | BPCFRD |

# LBSCAT

|  |  |
| --- | --- |
| Subvariable | Study |
| CBC with Differential | STRONG |
| DKA EVENT BLOOD GLUCOSE | BPCFRD |
| HCO3 (or CO2) | BPCFRD |
| HYPO EVENT BLOOD GLUCOSE | BPCFRD |
| HbA1c | STRONG |
| Iron Panel | STRONG |
| KETONES | BPCFRD |
| PREGNANCY TEST | STRONG |
| SWEAT CHLORIDE TEST | BPCFRD, STRONG |
| Serum Chemistry | STRONG |
| pH | BPCFRD |

# QSCAT

|  |  |
| --- | --- |
| Subvariable | Study |
| AHQ | STRONG |
| BENEFITS AND BURDENS USER EXPECTATION SURVEY HYBRID CLOSED LOOP - BASELINE | BPCFRD |
| BESSA | STRONG |
| BREIF-ADULT | BPCFRD |
| BRISTOL | STRONG |
| CFF | STRONG |
| CRISS | STRONG |
| DIABETES DISTRESS SCALE (DDS-17) | BPCFRD |
| DIABETES MANAGEMENT QUESTIONNAIRE (DMQ) | BPCFRD |
| EUROPEAN QUALITY OF LIFE FIVE DIMENSION FIVE LEVEL SCALE QUESTIONNAIRE | BPCFRD |
| EUROPEAN QUALITY OF LIFE FIVE DIMENSION FIVE LEVEL SCALE QUESTIONNAIRE - CHILD | BPCFRD |
| FEAR OF HYPOGLYCEMIA SURVEY - ADULT | BPCFRD |
| FEAR OF HYPOGLYCEMIA SURVEY - CHILD | BPCFRD |
| FEAR OF HYPOGLYCEMIA SURVEY - PARENT | BPCFRD |
| FOODINS | STRONG |
| GAD-7 | STRONG |
| HYPOGLYCEMIA CONFIDENCE | BPCFRD |
| IDENTIFYING PROBLEM AREAS IN DIABETES – PARENTS OF TEENS (P - PAID-T) | BPCFRD |
| IDENTIFYING YOUR PROBLEM AREAS IN DIABETES – TEEN VERSION (PAID-T) | BPCFRD |
| INSPIRE FOR PARENTS OF YOUTH WITH DIABETES - BASELINE | BPCFRD |
| INSPIRE FOR PARENTS OF YOUTH WITH DIABETES - POST INTERVIEW | BPCFRD |
| INSPIRE FOR YOUTH WITH DIABETES - BASELINE | BPCFRD |
| INSPIRE FOR YOUTH WITH DIABETES - POST INTERVIEW | BPCFRD |
| INSPIRE QUESTIONNAIRE FOR ADULTS WITH DIABETES - BASELINE | BPCFRD |
| INSPIRE QUESTIONNAIRE FOR ADULTS WITH DIABETES - POST INTERVIEW | BPCFRD |
| PAC-SYM | STRONG |
| PAGI-SYM | STRONG |
| PATIENT ASSESSMENT OF CONSTIPATION - SYM | BPCFRD |
| PATIENT ASSESSMENT OF CONSTIPATION QUALITY OF LIFE (PAC-QOL) | BPCFRD |
| PATIENT ASSESSMENT OF GASTROINTESTINAL DISORDERS SYMPTOM SEVERITY INDEX (PAGI-SYM) | BPCFRD |
| PG-SGA | STRONG |
| PHQ-8 | STRONG |
| TSRQ | STRONG |
| TSRQ-Nutrition | STRONG |

# VSTEST

|  |  |
| --- | --- |
| Subvariable | Study |
| Abdominal Skinfold Thickness | STRONG |
| DIABP | BPCFRD, STRONG |
| HEIGHT | BPCFRD, STRONG |
| HR | BPCFRD, STRONG |
| Hip Circumference | STRONG |
| Mid-arm muscle Circumference | STRONG |
| Mid-thigh Circumference | STRONG |
| OXYSAT | STRONG |
| RESP | STRONG |
| SYSBP | BPCFRD, STRONG |
| Suprailiac Skinfold Thickness | STRONG |
| TEMP | BPCFRD, STRONG |
| Thigh Skinfold Thickness | STRONG |
| Triceps Skinfold Thickness | STRONG |
| Umbilicus Circumference | STRONG |
| WEIGHT | BPCFRD, STRONG |
| Waist Circumference | STRONG |