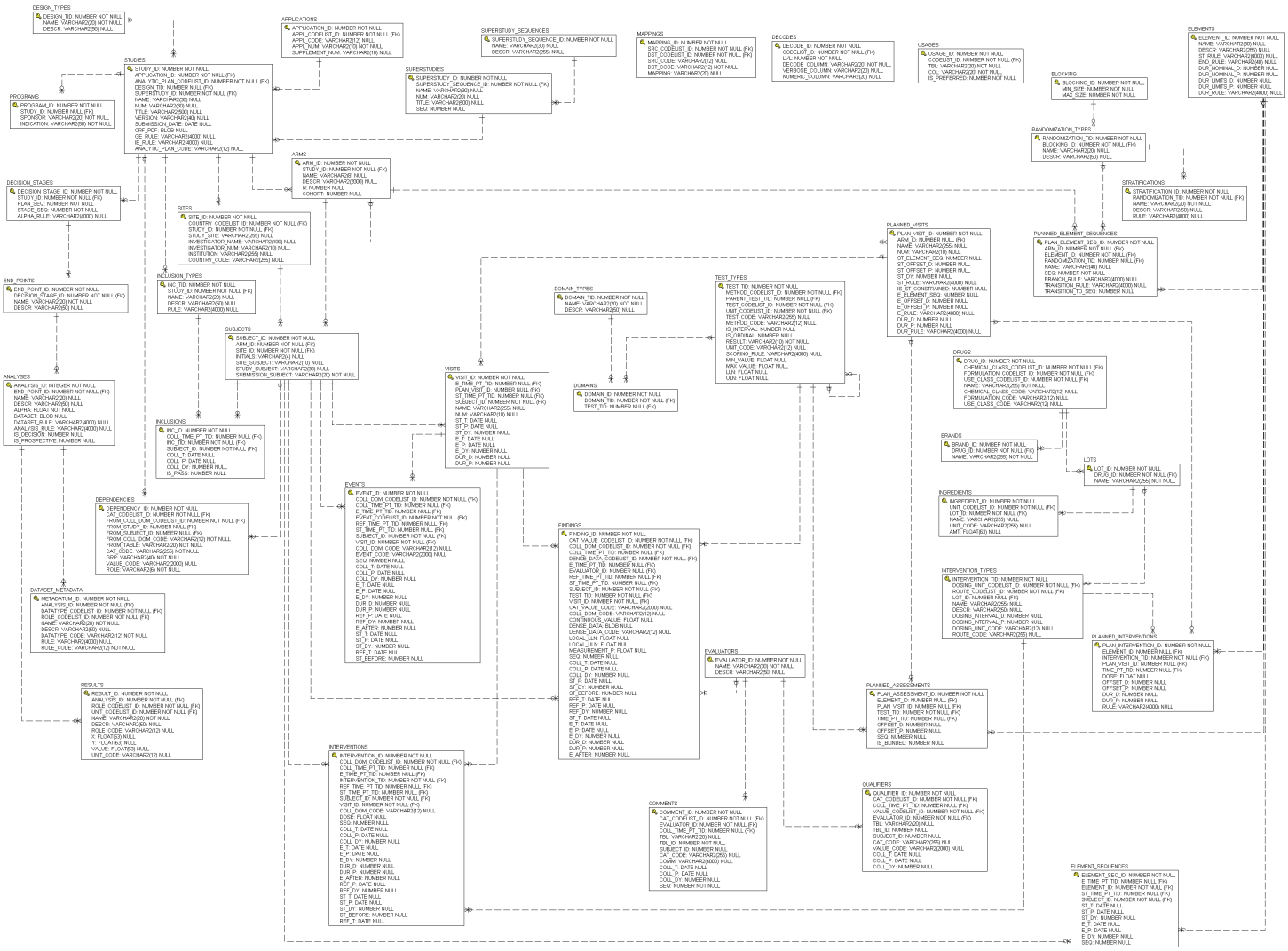
Janus Base Model Report

zMainDiagram/Display1



Table

Table	
Name	**Comment**
ANALYSES	Statistical analysis of end points for a defined population. Use associated Comment for ADaM "Reason" and "Documentation"
APPLICATIONS	INDs and NDAs comprising a development program.
ARMS	A study arm corresponds to a prespecified treatment strategy, and may consist of multiple elements and treatments. Branching and crossover designs must be converted to a fully parallel representation.
BLOCKING	Block sizes for randomization within a site
BRANDS	Brand names associated with a drug.
CODELISTS	Controlled vocabularies
COMMENTS	Free-text comments associated with records in other tables.
DATASET_METADATA	Description of analysis dataset columns ala ADaM.
DECISION_STAGES	Hierarchy for the analysis plan
DECODES	Ways to use Codelists
DEPENDENCIES	Relationships among Findings, Events, & Interventions
DESIGN_TYPES	Generic descriptions of types of studies.
DOMAIN_TYPES	Categories of tests (assays and assessments.
DOMAINS	Assignments of tests to Domain_Types
DRUGS	Generic information about drugs that may be used in interventions.
ELEMENT_SEQUENCES	Actual order of execution of elements or steps within an arm by subject
ELEMENTS	One of a set of contiguous periods comprising a treatment arm, during which conditions are stable.
END_POINTS	Planned bases for evaluating studies.
EVALUATORS	Entities asserting attribution of events to treatments; e.g., 'Sponsor', 'Investigator', 'DSMB'
EVENTS	Association of Event_Types with Subjects. Events prior to enrollment represent medical history.
FINDINGS	Values of assessments made on subjects based on planned assessments that are part of the study protocol.
INCLUSION_TYPES	This table contains names and descriptions of inclusion criteria. (Exclusions should have their logic inverted.)
INCLUSIONS	Evaluations of the protocol-specified inclusion criteria.
INGREDIENTS	Components of a formulated drug product
INTERVENTION_TYPES	Generic information which identifies or classifies a treatment.
INTERVENTIONS	Actual treatments given. These can be investigational or theraputic treatments or surgical procedures.
LOTS	Batches of study drug
MAPPINGS	Correspondence or relationships among Codelists for the same usage.
PLANNED_ASSESSMENTS	Schedule of measurements. Timing can be relative either to the start or end of a planned visit, a planned element, a planned intervention or a subject's reference timepoint.
PLANNED_ELEMENT_SEQUENCES	Temporal ordering of Elements within Arms
PLANNED_INTERVENTIONS	Timing and nature of the treatments that are scheduled during an element.
PLANNED_VISITS	Protocol-specified encounters with subjects.
PROGRAMS	Development programs are comprised of the studies that support an indication.
QUALIFIERS	Categorical information about an observation in another table. Subjective information is associated with the particular observer (Evaluators).
RANDOMIZATION_TYPES	Generic information on procedures used to assign subjects to Arms.
RESULTS	Output from Analyses
SITES	Institutions and investigators performing a study
STRATIFICATIONS	Subgroups for randomization
STUDIES	Information about trials, their conduct and results.
SUBJECTS	Individuals participating in a study at a site.
SUPERSTUDIES	Collections of studies performed simultaneously on the same subjects
SUPERSTUDY_SEQUENCES	Ordered grouping for follow-on studies
TEST_TYPES	Hierarchical features of all tests
TIME_PT_TYPES	Named reference time points in a study.
USAGES	Where Codelists are referenced in Janus.
VISITS	Actual subject visits

Column(s) of "ANALYSES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
ANALYSIS_ID	INTEGER	System-generated to identify uniquely an Analysis.	Yes	No	0	NOT NULL	No
END_POINT_ID	NUMBER	System-generated to identify uniquely an End_Point.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2(20)	Statistical analysis name. Should tie back to analysis documentation.	No	No	20	NULL	No
DESCR	VARCHAR2(50)	Description of the analysis and its proposed population.	No	No	50	NULL	No
ALPHA	FLOAT	Criterion by which p-value should be judged significant	No	No		NOT NULL	No
DATASET	BLOB	If no Dataset_Rule, then the actual dataset is here.	No	No	0	NULL	No
DATASET_RULE	VARCHAR2 (4000)	Procedure for constructing analysis dataset view	No	No	4000	NULL	No
ANALYSIS_RULE	VARCHAR2 (4000)	Procedure for using the analysis dataset to produce analysis results	No	No	4000	NULL	No
IS_DECISION	NUMBER	TRUE if analysis is part of the decision-making rule	No	No	0	NULL	No
IS_PROSPECTIVE	NUMBER	TRUE if analysis was specified before study was unblinded.	No	No	0	NULL	No

Is In Index(s) of "ANALYSIS_ID" Column		
Name	**Type**	**Unique**
PK_ANALYSES	PK	Yes

Is In Index(s) of "END_POINT_ID" Column		
Name	**Type**	**Unique**
IDX_ANALYSES2	IF1	No

Column(s) of "APPLICATIONS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
APPLICATION_ID	NUMBER	System-generated to identify uniquely an Application.	Yes	No	0	NOT NULL	No
APPL_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
APPL_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
APPL_NUM	VARCHAR2(10)	Administratively assigned application number.	No	No	10	NOT NULL	No
SUPPLEMENT_NUM	VARCHAR2(10)	Identifies a program from a sponsor's perspective	No	No	10	NULL	No

Is In Index(s) of "APPLICATION_ID" Column		
Name	**Type**	**Unique**
PK_APPLICATIONS	PK	Yes

Is In Index(s) of "APPL_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_APPLICATIONS2	IF1	No

Column(s) of "ARMS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
ARM_ID	NUMBER	System-generated to identify uniquely an Arm.	Yes	No	0	NOT NULL	No
STUDY_ID	NUMBER	System-generated to identify uniquely a Study.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2(8)	SDTM-DEM. TRTCD The name given the arm of the study, e.g. "Active", "Control", etc.	No	No	8	NULL	No
DESCR	VARCHAR2 (2000)	SDTM-DEM. TRTGRP A textual description of the study arm	No	No	2000	NULL	No
N	NUMBER	Planned enrollment	No	No	0	NULL	No
COHORT	NUMBER	Ordering for sequential study designs	No	No	0	NULL	No

Is In Index(s) of "ARM_ID" Column		
Name	**Type**	**Unique**
PK_ARMS	PK	Yes

Is In Index(s) of "STUDY_ID" Column		
Name	**Type**	**Unique**
IDX_ARMS3	AK1	Yes
IDX_ARMS2	IF1	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_ARMS3	AK1	Yes

Column(s) of "BLOCKING" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
BLOCKING_ID	NUMBER	System-generated to identify uniquely a Blocking.	Yes	No	0	NOT NULL	No
MIN_SIZE	NUMBER	Smallest block size	No	No	0	NOT NULL	No
MAX_SIZE	NUMBER	Largest block size	No	No	0	NOT NULL	No

Is In Index(s) of "BLOCKING_ID" Column		
Name	**Type**	**Unique**
PK_BLOCKING	PK	Yes

Column(s) of "BRANDS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
BRAND_ID	NUMBER	System-generated to identify uniquely a Brand.	Yes	No	0	NOT NULL	No

DRUG_ID	NUMBER	System-generated to identify uniquely	No	Yes	0	NOT NULL	No
NAME	VARCHAR2 (255)	The brand name of a drug.	No	No	255	NOT NULL	No

Is In Index(s) of "BRAND_ID" Column		
Name	**Type**	**Unique**
PK_BRANDS	PK	Yes

Is In Index(s) of "DRUG_ID" Column		
Name	**Type**	**Unique**
IDX_BRANDS3	AK1	Yes
IDX_BRANDS2	IF1	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_BRANDS3	AK1	Yes

Column(s) of "CODELISTS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	Yes	No	0	NOT NULL	No
NAME	VARCHAR2(20)	Name of a controlled vocabulary	No	No	20	NOT NULL	No
DESCR	VARCHAR2(50)	Description of a controlled vocabulary	No	No	50	NULL	No
DATABASE	VARCHAR2(20)	Location of named code list	No	No	20	NULL	No
TBL	VARCHAR2(20)	Name of code list table in Database	No	No	20	NULL	No
VERSION	VARCHAR2(20)	Version of controlled vocabulary	No	No	20	NULL	No
SOURCE	VARCHAR2 (100)	Party or site responsible for list.	No	No	100	NULL	No
CODE_COLUMN	VARCHAR2(20)	Name of column within Table containing coded values	No	No	20	NULL	No
VALUELIST_COLUMN	VARCHAR2(20)	Column name in Table containing value code list parameters	No	No	20	NULL	No
VALUELIST_LEVEL_COLUMN	VARCHAR2(20)	Indicates which hierarchy level to use with ValueList_Column	No	No	20	NULL	No

Is In Index(s) of "CODELIST_ID" Column		
Name	**Type**	**Unique**
PK_CODELISTS	PK	Yes

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_CODELISTS3	AK1	Yes

Is In Index(s) of "TBL" Column		
Name	**Type**	**Unique**

IDX_CODELISTS2	IE1	No

Is In Index(s) of "CODE_COLUMN" Column		
Name	**Type**	**Unique**
IDX_CODELISTS2	IE1	No

Column(s) of "COMMENTS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
COMMENT_ID	NUMBER	System-generated to identify uniquely a Comment.	Yes	No	0	NOT NULL	No
CAT_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
EVALUATOR_ID	NUMBER	System-generated to identify uniquely an Evaluator.	No	Yes	0	NOT NULL	No
COLL_TIME_PT_TID	NUMBER	System-generated to identify uniquely a time point.	No	Yes	0	NULL	No
TBL	VARCHAR2(20)	Table (Events, Findings or Interventsions) with which comment is associated	No	No	20	NULL	No
TBL_ID	NUMBER	Identifies the related observation in Findings, Interventions, Events, or some other Tbl.	No	No	0	NOT NULL	No
SUBJECT_ID	NUMBER	Not for JOINs! Provided to support partitioning	No	No	0	NULL	No
CAT_CODE	VARCHAR2 (255)	Key to specified code list	No	No	255	NULL	No
COMM	VARCHAR2 (4000)	Actual comment text.	No	No	4000	NULL	No
COLL_T	DATE	Nominal date/time to nearest second; can be implemented as long integer offset in seconds from midnight 1/1/-1960.	No	No		NULL	No
COLL_P	DATE	Precision of X_T; can be implemented as long integer (seconds).	No	No		NULL	No
COLL_DY	NUMBER	Sponsor-assigned "study day"	No	No	0	NULL	No
SEQ	NUMBER		No	No	0	NOT NULL	No

Is In Index(s) of "COMMENT_ID" Column		
Name	**Type**	**Unique**
PK_COMMENTS	PK	Yes

Is In Index(s) of "CAT_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_COMMENTS3	IF1	No

Is In Index(s) of "EVALUATOR_ID" Column		
Name	**Type**	**Unique**
IDX_COMMENTS4	IF2	No

Is In Index(s) of "COLL_TIME_PT_TID" Column		
Name	**Type**	**Unique**
IDX_COMMENTS5	IF3	No

Is In Index(s) of "TBL" Column		
Name	**Type**	**Unique**
IDX_COMMENTS7	AK1	Yes
IDX_COMMENTS6	IE2	No

Is In Index(s) of "TBL_ID" Column		
Name	**Type**	**Unique**
IDX_COMMENTS7	AK1	Yes
IDX_COMMENTS6	IE2	No

Is In Index(s) of "SUBJECT_ID" Column		
Name	**Type**	**Unique**
IDX_COMMENTS7	AK1	Yes
IDX_COMMENTS2	IE1	No

Is In Index(s) of "CAT_CODE" Column		
Name	**Type**	**Unique**
IDX_COMMENTS7	AK1	Yes

Is In Index(s) of "SEQ" Column		
Name	**Type**	**Unique**
IDX_COMMENTS7	AK1	Yes

Column(s) of "DATASET_METADATA" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
METADATUM_ID	NUMBER	System-generated to identify uniquely an Analysis Metadatum.	Yes	No	0	NOT NULL	No
ANALYSIS_ID	NUMBER	System-generated to identify uniquely an Analysis.	No	Yes	0	NOT NULL	No
DATATYPE_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
ROLE_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2(20)	Variable name in the analysis dataset.	No	No	20	NOT NULL	No
DESCR	VARCHAR2(50)	Corresponds to variable label in the analysis dataset.	No	No	50	NULL	No
DATATYPE_CODE	VARCHAR2(12)		No	No	12	NOT NULL	No
RULE	VARCHAR2 (4000)	Corresponds to Origin in ADaM.	No	No	4000	NULL	No
ROLE_CODE	VARCHAR2(12)	Corresponds to Role in ADaM.	No	No	12	NOT NULL	No

Is In Index(s) of "METADATUM_ID" Column		
Name	**Type**	**Unique**
PK_DATASET_METADATA	PK	Yes

Is In Index(s) of "ANALYSIS_ID" Column		
Name	**Type**	**Unique**
IDX_DATASET_METADATA1	IF1	No

Is In Index(s) of "DATATYPE_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_DATASET_METADATA2	IF2	No

Is In Index(s) of "ROLE_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_DATASET_METADATA3	IF3	No

Column(s) of "DECISION_STAGES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
DECISION_-STAGE_ID	NUMBER	System-generated to identify uniquely a Decision_Stage.	Yes	No	0	NOT NULL	No
STUDY_ID	NUMBER	System-generated to identify uniquely a Study.	No	Yes	0	NOT NULL	No
PLAN_SEQ	NUMBER	Identifies distinct analysis plans within a study	No	No	0	NOT NULL	No
STAGE_SEQ	NUMBER	Order of stages in a sequential analysis plan	No	No	0	NOT NULL	No
ALPHA_RULE	VARCHAR2 (4000)	How total stage alpha depends on component analyses	No	No	4000	NULL	No

Is In Index(s) of "DECISION_STAGE_ID" Column		
Name	**Type**	**Unique**
PK_DECISION_STAGES	PK	Yes

Is In Index(s) of "STUDY_ID" Column		
Name	**Type**	**Unique**
IDX_DECISION_STAGES2	IF1	No

Column(s) of "DECODES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
DECODE_ID	NUMBER	System-generated to identify uniquely a Decode.	Yes	No	0	NOT NULL	No
CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
LVL	NUMBER	Indicates the hierarchy within the decoding schemes	No	No	0	NOT NULL	No
DECODE_C-OLUMN	VARCHAR2(20)	Column in Codelists.Table column containing the decoded values	No	No	20	NOT NULL	No
VERBOSE_-COLUMN	VARCHAR2(20)	Column in Codelists.Table column which describes values	No	No	20	NULL	No
NUMERIC_-COLUMN	VARCHAR2(20)	Column in Codelists.Table column containing rank values	No	No	20	NULL	No

Is In Index(s) of "DECODE_ID" Column		
Name	**Type**	**Unique**
PK_DECODES	PK	Yes

Is In Index(s) of "CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_DECODES2	IF1	No

Column(s) of "DEPENDENCIES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
DEPENDENCY_ID	NUMBER	System-generated to identify uniquely a Dependency.	Yes	No	0	NOT NULL	No
CAT_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
FROM_COLL_DOM_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
FROM_STUDY_ID	NUMBER	System-generated to identify uniquely a Study.	No	Yes	0	NULL	No
FROM_SUBJECT_ID	NUMBER	If NULL, applies to all records with matching Qualifiers	No	Yes	0	NULL	No
FROM_COLL_DOM_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NOT NULL	No
FROM_TABLE	VARCHAR2(20)	One of {Events, Findings, Interventions}	No	No	20	NOT NULL	No
CAT_CODE	VARCHAR2 (255)	Key to specified code list	No	No	255	NOT NULL	No
GRP	VARCHAR2(40)	Ties together the set of Dependency records in a relationship.	No	No	40	NOT NULL	No
VALUE_CODE	VARCHAR2 (2000)	Dependency Grouping; must match Qualifiers. Value_CD for the same Cat_CD.	No	No	2000	NULL	No
ROLE	VARCHAR2(6)	Role in Relationship	No	No	6	NOT NULL	No

Is In Index(s) of "DEPENDENCY_ID" Column		
Name	**Type**	**Unique**
PK_DEPENDENCIES	PK	Yes

Is In Index(s) of "CAT_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_DEPENDENCIES2	IF1	No

Is In Index(s) of "FROM_COLL_DOM_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_DEPENDENCIES3	IF2	No

Is In Index(s) of "FROM_STUDY_ID" Column		
Name	**Type**	**Unique**
IDX_DEPENDENCIES6	AK1	Yes
IDX_DEPENDENCIES5	IF4	No

Is In Index(s) of "FROM_SUBJECT_ID" Column		
Name	**Type**	**Unique**
IDX_DEPENDENCIES6	AK1	Yes
IDX_DEPENDENCIES4	IF3	No

Is In Index(s) of "CAT_CODE" Column		
Name	**Type**	**Unique**
IDX_DEPENDENCIES6	AK1	Yes

Is In Index(s) of "GRP" Column		
Name	**Type**	**Unique**
IDX_DEPENDENCIES6	AK1	Yes

Is In Index(s) of "VALUE_CODE" Column		
Name	**Type**	**Unique**
IDX_DEPENDENCIES6	AK1	Yes

Column(s) of "DESIGN_TYPES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
DESIGN_TID	NUMBER	System-generated to identify uniquely a Design Type.	Yes	No	0	NOT NULL	No
NAME	VARCHAR2(20)	A term for the type of design. Examples: Crossover, double blind.	No	No	20	NOT NULL	No
DESCR	VARCHAR2(50)	A description of the design type.	No	No	50	NULL	No

Is In Index(s) of "DESIGN_TID" Column		
Name	**Type**	**Unique**
PK_DESIGN_TYPES	PK	Yes

Column(s) of "DOMAIN_TYPES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
DOMAIN_TID	NUMBER	System-generated to identify uniquely a Domain Type.	Yes	No	0	NOT NULL	No
NAME	VARCHAR2(20)	Name of the domain.	No	No	20	NOT NULL	No
DESCR	VARCHAR2(50)		No	No	50	NULL	No

Is In Index(s) of "DOMAIN_TID" Column		
Name	**Type**	**Unique**
PK_DOMAIN_TYPES	PK	Yes

Column(s) of "DOMAINS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
DOMAIN_ID	NUMBER	System-generated to identify uniquely a Domain.	Yes	No	0	NOT NULL	No
DOMAIN_TID	NUMBER	System-generated to identify uniquely a Domain Type.	No	Yes	0	NOT NULL	No
TEST_TID	NUMBER	System-generated to identify uniquely a Test Type.	No	Yes	0	NULL	No

Is In Index(s) of "DOMAIN_ID" Column		
Name	**Type**	**Unique**
PK_DOMAINS	PK	Yes

Is In Index(s) of "DOMAIN_TID" Column		
Name	**Type**	**Unique**
IDX_DOMAINS2	IF1	No

Is In Index(s) of "TEST_TID" Column		
Name	**Type**	**Unique**

IDX_DOMAINS3	IF2	No

Column(s) of "DRUGS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
DRUG_ID	NUMBER	System-generated to identify uniquely a Drug.	Yes	No	0	NOT NULL	No
CHEMICAL-_CLASS_CO-DELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
FORMULAT-ION_CODEL-IST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
USE_CLASS-_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2 (255)	The generic name of the drug.	No	No	255	NOT NULL	No
CHEMICAL-_CLASS_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
FORMULAT-ION_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
USE_CLASS-_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No

Is In Index(s) of "DRUG_ID" Column		
Name	**Type**	**Unique**
PK_DRUGS	PK	Yes

Is In Index(s) of "CHEMICAL_CLASS_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_DRUGS2	IF1	No

Is In Index(s) of "FORMULATION_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_DRUGS3	IF2	No

Is In Index(s) of "USE_CLASS_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_DRUGS4	IF3	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_DRUGS5	AK1	Yes

Column(s) of "ELEMENT_SEQUENCES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
ELEMENT_-SEQ_ID	NUMBER	System-generated to identify uniquely an Element_Sequence	Yes	No	0	NOT NULL	No
E_TIME_PT-_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
ELEMENT_ID	NUMBER	System-generated to identify uniquely an Element.	No	Yes	0	NOT NULL	No
ST_TIME_P-T_TID	NUMBER	System-generated to ifdentify uniquely a Time Point	No	Yes	0	NULL	No

SUBJECT_ID	NUMBER	System-generated to identify uniquely a Subject.	No	Yes	0	NOT NULL	No
ST_T	DATE	Nominal date/time to nearest second; can be implemented as long integer offset in seconds from midnight 1/1/-1960.	No	No		NULL	No
ST_P	DATE	Precision of X_T; can be implemented as long integer (seconds)	No	No		NULL	No
ST_DY	NUMBER	Sponsor-assigned "study day"	No	No	0	NULL	No
E_T	DATE	Nominal date/time to nearest second; can be implemented as long integer offset in seconds from midnight 1/1/-1960.	No	No		NULL	No
E_P	DATE	Precision of X_T; can be implemented as long integer (seconds).	No	No		NULL	No
E_DY	NUMBER	Sponsor-assigned "study day"	No	No	0	NULL	No
SEQ	NUMBER		No	No	0	NULL	No

Is In Index(s) of "ELEMENT_SEQ_ID" Column

Name	Type	Unique
PK_ELEMENT_SEQUENCES	PK	Yes

Is In Index(s) of "E_TIME_PT_TID" Column

Name	Type	Unique
IDX_ELEMENT_SEQUENCES4	IF3	No

Is In Index(s) of "ELEMENT_ID" Column

Name	Type	Unique
IDX_ELEMENT_SEQUENCES2	IF1	No

Is In Index(s) of "ST_TIME_PT_TID" Column

Name	Type	Unique
IDX_ELEMENT_SEQUENCES5	IF4	No

Is In Index(s) of "SUBJECT_ID" Column

Name	Type	Unique
IDX_ELEMENT_SEQUENCES6	AK1	Yes
IDX_ELEMENT_SEQUENCES3	IF2	No

Is In Index(s) of "SEQ" Column

Name	Type	Unique
IDX_ELEMENT_SEQUENCES6	AK1	Yes

Column(s) of "ELEMENTS" Table

Name	Datatype	Comment	Is PK	Is FK	Average Width	Null Option	Physical Only
ELEMENT_ID	NUMBER	System-generated to identify uniquely an Element.	Yes	No	0	NOT NULL	No
NAME	VARCHAR2(80)	Single word name of the Element.	No	No	80	NULL	No
DESCR	VARCHAR2 (255)	Description of Element	No	No	255	NULL	No

ST_RULE	VARCHAR2 (4000)	Rule describing entry criteria for Element	No	No	4000	NULL	No
END_RULE	VARCHAR2(40)	Rule describing exit criteria for Element	No	No	40	NULL	No
DUR_NOMI-NAL_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
DUR_NOMI-NAL_P	NUMBER	Precision of X_D (seconds).	No	No	0	NULL	No
DUR_LIMIT-S_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
DUR_LIMITS_P	NUMBER	Precision of X_D (seconds).	No	No	0	NULL	No
DUR_RULE	VARCHAR2 (4000)	Rule governing duration of Element	No	No	4000	NULL	No

Is In Index(s) of "ELEMENT_ID" Column		
Name	**Type**	**Unique**
PK_ELEMENTS	PK	Yes

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_ELEMENTS2	AK1	Yes

Is In Index(s) of "DESCR" Column		
Name	**Type**	**Unique**
IDX_ELEMENTS2	AK1	Yes

Is In Index(s) of "ST_RULE" Column		
Name	**Type**	**Unique**
IDX_ELEMENTS2	AK1	Yes

Column(s) of "END_POINTS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
END_POINT_ID	NUMBER	System-gener-ated to identify uniquely an End_Point.	Yes	No	0	NOT NULL	No
DECISION_-STAGE_ID	NUMBER	System-gener-ated to identify uniquely a Decision_Stage	No	Yes	0	NOT NULL	No
NAME	VARCHAR2(20)	Short name for end point	No	No	20	NOT NULL	No
DESCR	VARCHAR2(50)	Description of end point	No	No	50	NULL	No

Is In Index(s) of "END_POINT_ID" Column		
Name	**Type**	**Unique**
PK_END_POINTS	PK	Yes

Is In Index(s) of "DECISION_STAGE_ID" Column		
Name	**Type**	**Unique**
IDX_END_POINTS2	IF1	No

Column(s) of "EVALUATORS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
EVALUATO-R_ID	NUMBER	System-gener-ated to identify uniquely an Evaluator.	Yes	No	0	NOT NULL	No

NAME	VARCHAR2(30)	Identity of individual making comment or qualifier observation.	No	No	30	NOT NULL	No
DESCR	VARCHAR2(50)	Role of evaluator within the study	No	No	50	NULL	No

Is In Index(s) of "EVALUATOR_ID" Column		
Name	**Type**	**Unique**
PK_EVALUATORS	PK	Yes

Column(s) of "EVENTS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
EVENT_ID	NUMBER	System-generated to identify uniquely an Event.	Yes	No	0	NOT NULL	No
COLL_DOM-_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
COLL_TIME-_PT_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
E_TIME_PT-_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
EVENT_CO-DELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
REF_TIME_-PT_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
ST_TIME_P-T_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
SUBJECT_ID	NUMBER	System-generated to identify uniquely a Subject.	No	Yes	0	NOT NULL	No
VISIT_ID	NUMBER	System-generated to identify uniquely a Visit.	No	Yes	0	NOT NULL	No
COLL_DOM-_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
EVENT_CODE	VARCHAR2 (2000)	Key to specified code list	No	No	2000	NULL	No
SEQ	NUMBER	Connection for related Events, Findings, & Interventions at the record level.	No	No	0	NULL	No
COLL_T	DATE	Nominal date/ time to nearest second.	No	No		NULL	No
COLL_P	DATE	Precision of Coll_T.	No	No		NULL	No
COLL_DY	NUMBER	Sponsor-assigned "study day"	No	No	0	NULL	No

E_T	DATE	Nominal date/ time of End.	No	No		NULL	No
E_P	DATE	Precision of E_T.	No	No		NULL	No
E_DY	NUMBER	Sponsor-assigned "study day".	No	No	0	NULL	No
DUR_D	NUMBER	Nominal value of duration (seconds).	No	No	0	NULL	No
DUR_P	NUMBER	Precision of Dur_D (secon-ds).	No	No	0	NULL	No
REF_P	DATE	Precision of Ref_T.	No	No		NULL	No
REF_DY	NUMBER	Sponsor-assigned "study day" for Reference	No	No	0	NULL	No
E_AFTER	NUMBER	True if event continuing past observation	No	No	0	NULL	No
ST_T	DATE	Nominal date/ time of Start.	No	No		NULL	No
ST_P	DATE	Precision of St_T.	No	No		NULL	No
ST_DY	NUMBER	Sponsor-assigned "study day" of Start.	No	No	0	NULL	No
REF_T	DATE	Nominal date/ time of Reference.	No	No		NULL	No
ST_BEFORE	NUMBER	True if event began before observation.	No	No	0	NULL	No

Is In Index(s) of "EVENT_ID" Column

Name	Type	Unique
PK_EVENTS	PK	Yes

Is In Index(s) of "COLL_DOM_CODELIST_ID" Column

Name	Type	Unique
IDX_EVENTS4	IF1	No

Is In Index(s) of "COLL_TIME_PT_TID" Column

Name	Type	Unique
IDX_EVENTS7	IF4	No

Is In Index(s) of "E_TIME_PT_TID" Column

Name	Type	Unique
IDX_EVENTS9	IF6	No

Is In Index(s) of "EVENT_CODELIST_ID" Column

Name	Type	Unique
IDX_EVENTS2	IE1	No
IDX_EVENTS5	IF2	No

Is In Index(s) of "REF_TIME_PT_TID" Column

Name	Type	Unique
IDX_EVENTS10	IF7	No

Is In Index(s) of "ST_TIME_PT_TID" Column

Name	Type	Unique
IDX_EVENTS8	IF5	No

Is In Index(s) of "SUBJECT_ID" Column

Name	Type	Unique
IDX_EVENTS13	AK1	Yes
IDX_EVENTS3	IE2	No
IDX_EVENTS12	IE3	No

IDX_EVENTS6	IF3	No

Is In Index(s) of "VISIT_ID" Column		
Name	**Type**	**Unique**
IDX_EVENTS11	IF8	No

Is In Index(s) of "COLL_DOM_CODE" Column		
Name	**Type**	**Unique**
IDX_EVENTS13	AK1	Yes
IDX_EVENTS3	IE2	No

Is In Index(s) of "EVENT_CODE" Column		
Name	**Type**	**Unique**
IDX_EVENTS2	IE1	No

Is In Index(s) of "SEQ" Column		
Name	**Type**	**Unique**
IDX_EVENTS13	AK1	Yes
IDX_EVENTS12	IE3	No

Column(s) of "FINDINGS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
FINDING_ID	NUMBER	System-generated to identify uniquely a Finding.	Yes	No	0	NOT NULL	No
CAT_VALUE_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
COLL_DOM_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
COLL_TIME_PT_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
DENSE_DATA_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
E_TIME_PT_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
EVALUATOR_ID	NUMBER	System generated to identify uniquely an Evaluator.	No	Yes	0	NULL	No
REF_TIME_PT_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
ST_TIME_PT_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
SUBJECT_ID	NUMBER	System-generated to identify uniquely a Subject.	No	Yes	0	NOT NULL	No
TEST_TID	NUMBER	System-generated to identify uniquely a Test Type.	No	Yes	0	NOT NULL	No
VISIT_ID	NUMBER	System-generated to identify uniquely a Visit.	No	Yes	0	NOT NULL	No

CAT_VALU-E_CODE	VARCHAR2 (2000)	Key to specified code list	No	No	2000	NULL	No
COLL_DOM-_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
CONTINUO-US_VALUE	FLOAT	For continuous-valued observ-ations, the numeric result.	No	No		NULL	No
DENSE_DATA	BLOB	HL7 annotated waveform, image data, or other "source" data object	No	No	0	NULL	No
DENSE_DA-TA_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
LOCAL_LLN	FLOAT	Local lower limit of normal	No	No		NULL	No
LOCAL_ULN	FLOAT	Local upper limit of normal	No	No		NULL	No
MEASUREM-ENT_P	FLOAT	Resolution for Continuous_-Value	No	No		NULL	No
SEQ	NUMBER	Connection for related Events, Findings, & Interventions at the record level.	No	No	0	NULL	No
COLL_T	DATE	Nominal date/ time of Collection.	No	No		NULL	No
COLL_P	DATE	Precision of Coll_T.	No	No		NULL	No
COLL_DY	NUMBER	Sponsor-assigned "study day" of Collection.	No	No	0	NULL	No
ST_P	DATE	Precision of St_T	No	No		NULL	No
ST_DY	NUMBER	Sponsor-assigned "study day" of Start	No	No	0	NULL	No
ST_BEFORE	NUMBER	True if event began before observation	No	No	0	NULL	No
REF_T	DATE	Nominal date/ time of Reference	No	No		NULL	No
REF_P	DATE	Precision of Ref_T.	No	No		NULL	No
REF_DY	NUMBER	Sponsor-assigned "study day" of Reference.	No	No	0	NULL	No
ST_T	DATE	Nominal date/ time of Start	No	No		NULL	No
E_T	DATE	Nominal date/ timeof End.	No	No		NULL	No
E_P	DATE	Precision of E_T.	No	No		NULL	No
E_DY	NUMBER	Sponsor-assigned "study day" of End	No	No	0	NULL	No
DUR_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No

DUR_P	NUMBER	Precision of Dur_D (seconds).	No	No	0	NULL	No
E_AFTER	NUMBER	SDTM-TIMING. ONGO True if event continuing past observation	No	No	0	NULL	No

Is In Index(s) of "FINDING_ID" Column		
Name	**Type**	**Unique**
PK_FINDINGS	PK	Yes

Is In Index(s) of "CAT_VALUE_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS3	IF1	No

Is In Index(s) of "COLL_DOM_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS4	IF2	No

Is In Index(s) of "COLL_TIME_PT_TID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS12	IF10	No

Is In Index(s) of "DENSE_DATA_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS5	IF3	No

Is In Index(s) of "E_TIME_PT_TID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS10	IF8	No

Is In Index(s) of "EVALUATOR_ID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS6	IF4	No

Is In Index(s) of "REF_TIME_PT_TID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS11	IF9	No

Is In Index(s) of "ST_TIME_PT_TID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS9	IF7	No

Is In Index(s) of "SUBJECT_ID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS15	AK1	Yes
IDX_FINDINGS2	IE4	No
IDX_FINDINGS14	IE5	No
IDX_FINDINGS7	IF5	No

Is In Index(s) of "TEST_TID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS15	AK1	Yes
IDX_FINDINGS2	IE4	No
IDX_FINDINGS8	IF6	No

Is In Index(s) of "VISIT_ID" Column		
Name	**Type**	**Unique**
IDX_FINDINGS13	IF11	No

Is In Index(s) of "COLL_DOM_CODE" Column		
Name	**Type**	**Unique**
IDX_FINDINGS15	AK1	Yes
IDX_FINDINGS2	IE4	No

Is In Index(s) of "SEQ" Column		
Name	**Type**	**Unique**
IDX_FINDINGS15	AK1	Yes
IDX_FINDINGS14	IE5	No

Column(s) of "INCLUSION_TYPES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
INC_TID	NUMBER	System-generated to identify uniquely an Inc_Type.	Yes	No	0	NOT NULL	No
STUDY_ID	NUMBER	System-generated to identify uniquely a Study.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2(20)	Single word term for inclusion/exclusion criterion.	No	No	20	NULL	No
DESCR	VARCHAR2(50)	Description of inclusion/exclusion criterion.	No	No	50	NULL	No
RULE	VARCHAR2 (4000)	Boolean function for evaluating a criterion. A qualifying subject should have this rule evaluate TRUE.	No	No	4000	NULL	No

Is In Index(s) of "INC_TID" Column		
Name	**Type**	**Unique**
PK_INCLUSION_TYPES	PK	Yes

Is In Index(s) of "STUDY_ID" Column		
Name	**Type**	**Unique**
IDX_INCLUSION_TYPES2	IF1	No

Column(s) of "INCLUSIONS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
INC_ID	NUMBER	System-generated to identify uniquely an Inclusion.	Yes	No	0	NOT NULL	No
COLL_TIME-_PT_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
INC_TID	NUMBER	System-generated to identify uniquely an Inclusion_-Type.	No	Yes	0	NOT NULL	No
SUBJECT_ID	NUMBER	System-generated to identify uniquely a Subject.	No	Yes	0	NOT NULL	No
COLL_T	DATE	Nominal date/time to nearest second; can be implemented as long integer offset in seconds from midnight 1/1/-1960.	No	No		NULL	No
COLL_P	DATE	Precision of X_T; can be implemented as long integer (seconds).	No	No		NULL	No
COLL_DY	NUMBER	Sponsor-assigned "study day"	No	No	0	NULL	No

IS_PASS	NUMBER	Investigator-evaluated eligibility assessment; TRUE if inclusion is	No	No	0	NULL	No

Is In Index(s) of "INC_ID" Column		
Name	**Type**	**Unique**
PK_INCLUSIONS	PK	Yes

Is In Index(s) of "COLL_TIME_PT_TID" Column		
Name	**Type**	**Unique**
IDX_INCLUSIONS4	IF3	No

Is In Index(s) of "INC_TID" Column		
Name	**Type**	**Unique**
IDX_INCLUSIONS3	IF1	No

Is In Index(s) of "SUBJECT_ID" Column		
Name	**Type**	**Unique**
IDX_INCLUSIONS2	IF2	No

Column(s) of "INGREDIENTS" Table

Name	Datatype	Comment	Is PK	Is FK	Average Width	Null Option	Physical Only
INGREDIENT_ID	NUMBER	System-generated to identify uniquely an Ingredient.	Yes	No	0	NOT NULL	No
UNIT_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
LOT_ID	NUMBER	System-generated to identify uniquely a Lot.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2 (255)	Name of ingredient	No	No	255	NULL	No
UNIT_CODE	VARCHAR2 (255)	Key to specified code list	No	No	255	NULL	No
AMT	FLOAT(63)	Amount of ingredient in formulated product	No	No		NULL	No

Is In Index(s) of "INGREDIENT_ID" Column		
Name	**Type**	**Unique**
PK_INGREDIENTS	PK	Yes

Is In Index(s) of "UNIT_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_INGREDIENTS2	IF1	No

Is In Index(s) of "LOT_ID" Column		
Name	**Type**	**Unique**
IDX_INGREDIENTS4	AK1	Yes
IDX_INGREDIENTS3	IF2	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_INGREDIENTS4	AK1	Yes

Is In Index(s) of "UNIT_CODE" Column		
Name	**Type**	**Unique**
IDX_INGREDIENTS4	AK1	Yes

Is In Index(s) of "AMT" Column		
Name	**Type**	**Unique**
IDX_INGREDIENTS4	AK1	Yes

Column(s) of "INTERVENTION_TYPES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
INTERVENT-ION_TID	NUMBER	System-gener-ated to identify uniquely an Intervention Type	Yes	No	0	NOT NULL	No
DOSING_U-NIT_CODEL-IST_ID	NUMBER	System-gener-ated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
ROUTE_CO-DELIST_ID	NUMBER	System-gener-ated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
LOT_ID	NUMBER	System-gener-ated to identify uniquely a Lot.	No	Yes	0	NULL	No
NAME	VARCHAR2 (255)	SDTM-INTERV. ACTTRT Short name for the intervention.	No	No	255	NULL	No
DESCR	VARCHAR2(50)	Description of the intervention.	No	No	50	NULL	No
DOSING_IN-TERVAL_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
DOSING_IN-TERVAL_P	NUMBER	Precision of X_D (seconds).	No	No	0	NULL	No
DOSING_U-NIT_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
ROUTE_CODE	VARCHAR2 (255)	Key to specified code list	No	No	255	NULL	No

Is In Index(s) of "INTERVENTION_TID" Column		
Name	**Type**	**Unique**
PK_INTERVENTION_TYPES	PK	Yes

Is In Index(s) of "DOSING_UNIT_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_INTERVENTION_TYPES2	IF1	No

Is In Index(s) of "ROUTE_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_INTERVENTION_TYPES3	IF2	No

Is In Index(s) of "LOT_ID" Column		
Name	**Type**	**Unique**
IDX_INTERVENTION_TYPES5	AK1	Yes
IDX_INTERVENTION_TYPES4	IF3	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_INTERVENTION_TYPES5	AK1	Yes

Is In Index(s) of "DOSING_UNIT_CODE" Column		
Name	**Type**	**Unique**
IDX_INTERVENTION_TYPES5	AK1	Yes

Is In Index(s) of "ROUTE_CODE" Column		
Name	**Type**	**Unique**
IDX_INTERVENTION_TYPES5	AK1	Yes

Column(s) of "INTERVENTIONS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
INTERVENT-ION_ID	NUMBER	System-gener-ated to identify uniquely an Intervention.	Yes	No	0	NOT NULL	No
COLL_DOM-_CODELIST_ID	NUMBER	System-gener-ated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
COLL_TIME-_PT_TID	NUMBER	System-gener-ated to identify uniquely a Time Point.	No	Yes	0	NULL	No
E_TIME_PT-_TID	NUMBER	System-gener-ated to identify uniquely a Time Point.	No	Yes	0	NULL	No
INTERVENT-ION_TID	NUMBER	System-gener-ated to identify uniquely an Intervention Type.	No	Yes	0	NOT NULL	No
REF_TIME_-PT_TID	NUMBER	System-gener-ated to identify uniquely a Time Point.	No	Yes	0	NULL	No
ST_TIME_P-T_TID	NUMBER	System-gener-ated to identify uniquely a Time Point.	No	Yes	0	NULL	No
SUBJECT_ID	NUMBER	System-gener-ated to identify uniquely a Subject.	No	Yes	0	NOT NULL	No
VISIT_ID	NUMBER	System-gener-ated to identify uniquely a Visit.	No	Yes	0	NOT NULL	No
COLL_DOM-_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
DOSE	FLOAT	SDTM-INTERV. DOSE The dose; schedule, units, and route via Intervention_-Types.	No	No		NULL	No
SEQ	NUMBER	Connection for related Events, Findings, & Interventions at the record level.	No	No	0	NULL	No
COLL_T	DATE	Nominal date/ time of Collection..	No	No		NULL	No
COLL_P	DATE	Precision of Coll_T.	No	No		NULL	No
COLL_DY	NUMBER	Sponsor-assigned "study day" of Collection.	No	No	0	NULL	No
E_T	DATE	Nominal date/ time of End.	No	No		NULL	No
E_P	DATE	Precision of E_T.	No	No		NULL	No
E_DY	NUMBER	Sponsor-assigned "study day" of End.	No	No	0	NULL	No
DUR_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
DUR_P	NUMBER	Precision of Dur_D (secon-ds).	No	No	0	NULL	No

E_AFTER	NUMBER	SDTM-TIMING. ONGO True if event continuing past observation	No	No	0	NULL	No
REF_P	DATE	Precision of Ref_T.	No	No		NULL	No
REF_DY	NUMBER	Sponsor-assigned "study day" of Reference.	No	No	0	NULL	No
ST_T	DATE	Nominal date/ time of Start.	No	No		NULL	No
ST_P	DATE	Precision of St_T.	No	No		NULL	No
ST_DY	NUMBER	Sponsor-assigned "study day" of Start.	No	No	0	NULL	No
ST_BEFORE	NUMBER	True if event began before observation	No	No	0	NULL	No
REF_T	DATE	Nominal date/ time of Reference.	No	No		NULL	No

Is In Index(s) of "INTERVENTION_ID" Column

Name	Type	Unique
PK_INTERVENTIONS	PK	Yes

Is In Index(s) of "COLL_DOM_CODELIST_ID" Column

Name	Type	Unique
IDX_INTERVENTIONS4	IF1	No

Is In Index(s) of "COLL_TIME_PT_TID" Column

Name	Type	Unique
IDX_INTERVENTIONS7	IF4	No

Is In Index(s) of "E_TIME_PT_TID" Column

Name	Type	Unique
IDX_INTERVENTIONS9	IF6	No

Is In Index(s) of "INTERVENTION_TID" Column

Name	Type	Unique
IDX_INTERVENTIONS3	IE2	No
IDX_INTERVENTIONS5	IF2	No

Is In Index(s) of "REF_TIME_PT_TID" Column

Name	Type	Unique
IDX_INTERVENTIONS10	IF7	No

Is In Index(s) of "ST_TIME_PT_TID" Column

Name	Type	Unique
IDX_INTERVENTIONS8	IF5	No

Is In Index(s) of "SUBJECT_ID" Column

Name	Type	Unique
IDX_INTERVENTIONS13	AK1	Yes
IDX_INTERVENTIONS2	IE1	No
IDX_INTERVENTIONS3	IE2	No
IDX_INTERVENTIONS12	IE3	No
IDX_INTERVENTIONS6	IF3	No

Is In Index(s) of "VISIT_ID" Column

Name	Type	Unique
IDX_INTERVENTIONS11	IF8	No

Is In Index(s) of "COLL_DOM_CODE" Column		
Name	**Type**	**Unique**
IDX_INTERVENTIONS13	AK1	Yes
IDX_INTERVENTIONS2	IE1	No

Is In Index(s) of "SEQ" Column		
Name	**Type**	**Unique**
IDX_INTERVENTIONS13	AK1	Yes
IDX_INTERVENTIONS12	IE3	No

Column(s) of "LOTS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
LOT_ID	NUMBER	System-generated to identify uniquely a Lot.	Yes	No	0	NOT NULL	No
DRUG_ID	NUMBER	System-generated to identify uniquely a Drug.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2 (255)	SDTM-INTERV. LOT Lot serial number assigned to a drug	No	No	255	NOT NULL	No

Is In Index(s) of "LOT_ID" Column		
Name	**Type**	**Unique**
PK_LOTS	PK	Yes

Is In Index(s) of "DRUG_ID" Column		
Name	**Type**	**Unique**
IDX_LOTS3	AK1	Yes
IDX_LOTS2	IF1	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_LOTS3	AK1	Yes

Column(s) of "MAPPINGS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
MAPPING_ID	NUMBER	System-generated to identify uniquely a Mapping.	Yes	No	0	NOT NULL	No
SRC_CODE-LIST_ID	NUMBER	System-generated to identify uniquely a Codelist. This is the "source" or "reference" list.	No	Yes	0	NOT NULL	No
DST_CODE-LIST_ID	NUMBER	System-generated to identify uniquely a Codelist. This is the "destination" or "alternative" list.	No	Yes	0	NOT NULL	No
SRC_CODE	VARCHAR2(12)	Code value in Src_Codelist. If NULL, Dst_-Code extends the domain of Src_Codelist.	No	No	12	NULL	No
DST_CODE	VARCHAR2(12)	Code value in Dst_Codelist.	No	No	12	NOT NULL	No
MAPPING	VARCHAR2(20)	Relatiopnship between Src_-Code and Dst_Code.	No	No	20	NULL	No

Is In Index(s) of "MAPPING_ID" Column		
Name	**Type**	**Unique**

PK_MAPPINGS	PK	Yes

Is In Index(s) of "SRC_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_MAPPINGS1	IF1	No

Is In Index(s) of "DST_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_MAPPINGS2	IF2	No

Column(s) of "PLANNED_ASSESSMENTS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
PLAN_ASSE-SSMENT_ID	NUMBER	System-generated to identify uniquely a Planned_Assessment	Yes	No	0	NOT NULL	No
ELEMENT_ID	NUMBER	System-generated to identify uniquely an Element.	No	Yes	0	NULL	No
PLAN_VISIT-_ID	NUMBER	System-generated to identify uniquely a Planned_Visit.	No	Yes	0	NULL	No
TEST_TID	NUMBER	System-generated to identify uniquely a Test Type.	No	Yes	0	NOT NULL	No
TIME_PT_TID	NUMBER	System-generated to identify uniquely a Time_Pt_Type.	No	Yes	0	NULL	No
OFFSET_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
OFFSET_P	NUMBER	Precision of X_D (seconds).	No	No	0	NULL	No
SEQ	NUMBER	Ordering of assessments scheduled nominally at the same time	No	No	0	NULL	No
IS_BLINDED	NUMBER	TRUE if evaluator does not know treatment	No	No	0	NULL	No

Is In Index(s) of "PLAN_ASSESSMENT_ID" Column		
Name	**Type**	**Unique**
PK_PLANNED_ASSESSMENTS	PK	Yes

Is In Index(s) of "ELEMENT_ID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_ASSESSMENTS3	IF1	No

Is In Index(s) of "PLAN_VISIT_ID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_ASSESSMENTS4	IF2	No

Is In Index(s) of "TEST_TID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_ASSESSMENTS2	IF3	No

Is In Index(s) of "TIME_PT_TID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_ASSESSMENTS5	IF4	No

Column(s) of "PLANNED_ELEMENT_SEQUENCES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
PLAN_ELEMENT_SEQ_ID	NUMBER	System-generated to identify uniquely a Planned_Element_Seq.	Yes	No	0	NOT NULL	No
ARM_ID	NUMBER	System-generated to identify uniquely an Arm.	No	Yes	0	NOT NULL	No
ELEMENT_ID	NUMBER	System-generated to identify uniquely an Element.	No	Yes	0	NOT NULL	No
RANDOMIZATION_TID	NUMBER	System-generated to identify uniquely a Randomization Type	No	Yes	0	NULL	No
NAME	VARCHAR2(40)	Name of the Element Sequence, corresponding to the SDTM Element.	No	No	40	NULL	No
SEQ	NUMBER	Ordering of Elements within Arms	No	No	0	NOT NULL	No
BRANCH_RULE	VARCHAR2 (4000)	Rule governing branch at the end of this element, for example, "Randomization".	No	No	4000	NULL	No
TRANSITION_RULE	VARCHAR2 (4000)	Conditions under which to transition from this element to one other than the next one in sequence.	No	No	4000	NULL	No
TRANSITION_TO_SEQ	NUMBER	Next element in sequence if Transition_Rule evaluates TRUE	No	No	0	NULL	No

Is In Index(s) of "PLAN_ELEMENT_SEQ_ID" Column		
Name	**Type**	**Unique**
PK_PLANNED_ELEMENT_SEQUENCES	PK	Yes

Is In Index(s) of "ARM_ID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_ELEMENT_SEQUENCES5	AK1	Yes
IDX_PLANNED_ELEMENT_SEQUENCES2	IF1	No

Is In Index(s) of "ELEMENT_ID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_ELEMENT_SEQUENCES5	AK1	Yes
IDX_PLANNED_ELEMENT_SEQUENCES3	IF2	No

Is In Index(s) of "RANDOMIZATION_TID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_ELEMENT_SEQUENCES4	IF3	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_PLANNED_ELEMENT_SEQUENCES5	AK1	Yes

Column(s) of "PLANNED_INTERVENTIONS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
PLAN_INTE-RVENTION_ID	NUMBER	System-gener-ated to identify uniquely a Planned_Int-ervention.	Yes	No	0	NOT NULL	No
ELEMENT_ID	NUMBER	System-gener-ated to identify uniquely an Element.	No	Yes	0	NULL	No
INTERVENT-ION_TID	NUMBER	System-gener-ated to identify uniquely an Intervention Type.	No	Yes	0	NOT NULL	No
PLAN_VISIT-_ID	NUMBER	System-gener-ated to identify uniquely a Planned_Visit.	No	Yes	0	NULL	No
TIME_PT_TID	NUMBER	System-gener-ated to identify uniquely a time point.	No	Yes	0	NULL	No
DOSE	FLOAT	The dose; schedule, units, and route via Intervention_-Types.	No	No		NULL	No
OFFSET_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
OFFSET_P	NUMBER	Precision of X_D (seconds).	No	No	0	NULL	No
DUR_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
DUR_P	NUMBER	Precision of X_D (seconds).	No	No	0	NULL	No
RULE	VARCHAR2 (4000)	The rule that determines w-hether or not that intervention is made.	No	No	4000	NULL	No

Is In Index(s) of "PLAN_INTERVENTION_ID" Column		
Name	**Type**	**Unique**
PK_PLANNED_INTERVENTIONS	PK	Yes

Is In Index(s) of "ELEMENT_ID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_INTERVENTIONS6	AK1	Yes
IDX_PLANNED_INTERVENTIONS2	IF1	No

Is In Index(s) of "INTERVENTION_TID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_INTERVENTIONS6	AK1	Yes
IDX_PLANNED_INTERVENTIONS3	IF2	No

Is In Index(s) of "PLAN_VISIT_ID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_INTERVENTIONS4	IF3	No

Is In Index(s) of "TIME_PT_TID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_INTERVENTIONS5	IF4	No

Column(s) of "PLANNED_VISITS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
PLAN_VISIT-_ID	NUMBER	System-generated to identify uniquely a Planned Visit.	Yes	No	0	NOT NULL	No
ARM_ID	NUMBER	System-generated to identify uniquely an Arm.	No	Yes	0	NULL	No
NAME	VARCHAR2 (255)	Name of protocol-specified visit. Represents the protocol-defined description for a clinical encounter.	No	No	255	NULL	No
NUM	VARCHAR2(10)	Alternative name of protocol-specified visit. Also referred to as a clinical encounter number.	No	No	10	NULL	No
ST_ELEME-NT_SEQ	NUMBER	Element_Sequence reference for start of visit	No	No	0	NULL	No
ST_OFFSET_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
ST_OFFSET_P	NUMBER	Precision of X_D (seconds).	No	No	0	NULL	No
ST_DY	NUMBER	Planned or nominal study day	No	No	0	NULL	No
ST_RULE	VARCHAR2 (4000)	Rule specified start of a Visit	No	No	4000	NULL	No
IS_ST_CON-STRAINED	NUMBER	TRUE is Visit may occur after the referenced Element ends.	No	No	0	NULL	No
E_ELEMEN-T_SEQ	NUMBER	Element_Sequence reference for end of visit	No	No	0	NULL	No
E_OFFSET_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
E_OFFSET_P	NUMBER	Precision of X_D (seconds).	No	No	0	NULL	No
E_RULE	VARCHAR2 (4000)	Rule specified end of Visit	No	No	4000	NULL	No
DUR_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
DUR_P	NUMBER	Precision of X_D (seconds).	No	No	0	NULL	No
DUR_RULE	VARCHAR2 (4000)	Rule for determining the duration of a protocol-specified visit.	No	No	4000	NULL	No

Is In Index(s) of "PLAN_VISIT_ID" Column		
Name	**Type**	**Unique**
PK_PLANNED_VISITS	PK	Yes

Is In Index(s) of "ARM_ID" Column		
Name	**Type**	**Unique**
IDX_PLANNED_VISITS3	AK1	Yes
IDX_PLANNED_VISITS2	IF1	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**

IDX_PLANNED_VISITS3	AK1	Yes

Column(s) of "PROGRAMS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
PROGRAM_ID	NUMBER	System-generated to identify uniquely a Program.	Yes	No	0	NOT NULL	No
STUDY_ID	NUMBER	System-generated to identify uniquely a Study.	No	Yes	0	NULL	No
SPONSOR	VARCHAR2(20)	Owner of the program and study data	No	No	20	NOT NULL	No
INDICATION	VARCHAR2(50)	Proposed use for drug.	No	No	50	NOT NULL	No

Is In Index(s) of "PROGRAM_ID" Column		
Name	**Type**	**Unique**
PK_PROGRAMS	PK	Yes

Is In Index(s) of "STUDY_ID" Column		
Name	**Type**	**Unique**
IDX_PROGRAMS2	IF1	No

Column(s) of "QUALIFIERS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
QUALIFIER_ID	NUMBER	System-generated to identify uniquely a Qualifier.	Yes	No	0	NOT NULL	No
CAT_CODE-LIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
COLL_TIME-_PT_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
VALUE_CO-DELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
EVALUATO-R_ID	NUMBER	System-generated to identify uniquely an Evaluator.	No	Yes	0	NOT NULL	No
TBL	VARCHAR2(20)	Name of table to which attribution is associated	No	No	20	NULL	No
TBL_ID	NUMBER	Identifies the related observation in Findings, Interventions, Events, or some other Tbl.	No	No	0	NULL	No
SUBJECT_ID	NUMBER	Not for JOINs! Provided to support partitioning	No	No	0	NULL	No
CAT_CODE	VARCHAR2 (255)	Key to specified code list	No	No	255	NULL	No
VALUE_CODE	VARCHAR2 (2000)	Key to specified code list	No	No	2000	NULL	No

COLL_T	DATE	Nominal date/ time to nearest second; can be implemented as long integer offset in	No	No		NULL	No
COLL_P	DATE	Precision of X_T; can be implemented as long integer (seconds).	No	No		NULL	No
COLL_DY	NUMBER	Sponsor-assigned "study day"	No	No	0	NULL	No

Is In Index(s) of "QUALIFIER_ID" Column		
Name	**Type**	**Unique**
PK_QUALIFIERS	PK	Yes

Is In Index(s) of "CAT_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_QUALIFIERS3	IE2	No
IDX_QUALIFIERS5	IF1	No

Is In Index(s) of "COLL_TIME_PT_TID" Column		
Name	**Type**	**Unique**
IDX_QUALIFIERS8	IF4	No

Is In Index(s) of "VALUE_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_QUALIFIERS4	IE3	No
IDX_QUALIFIERS6	IF2	No

Is In Index(s) of "EVALUATOR_ID" Column		
Name	**Type**	**Unique**
IDX_QUALIFIERS7	IF3	No

Is In Index(s) of "TBL" Column		
Name	**Type**	**Unique**
IDX_QUALIFIERS10	AK2	Yes
IDX_QUALIFIERS9	IE4	No

Is In Index(s) of "TBL_ID" Column		
Name	**Type**	**Unique**
IDX_QUALIFIERS10	AK2	Yes
IDX_QUALIFIERS9	IE4	No

Is In Index(s) of "SUBJECT_ID" Column		
Name	**Type**	**Unique**
IDX_QUALIFIERS10	AK2	Yes
IDX_QUALIFIERS2	IE1	No

Is In Index(s) of "CAT_CODE" Column		
Name	**Type**	**Unique**
IDX_QUALIFIERS10	AK2	Yes
IDX_QUALIFIERS3	IE2	No

Is In Index(s) of "VALUE_CODE" Column		
Name	**Type**	**Unique**
IDX_QUALIFIERS4	IE3	No

Column(s) of "RANDOMIZATION_TYPES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
RANDOMIZ-ATION_TID	NUMBER	System-gener-ated to identify uniquely a Randomization Type	Yes	No	0	NOT NULL	No

BLOCKING_ID	NUMBER	System-generated to identify uniquely	No	Yes	0	NOT NULL	No
NAME	VARCHAR2(20)	Single word description of the randomization plan.	No	No	20	NULL	No
DESCR	VARCHAR2(50)	Detailed description of randomization plan.	No	No	50	NULL	No

Is In Index(s) of "RANDOMIZATION_TID" Column

Name	Type	Unique
PK_RANDOMIZATION_TYPES	PK	Yes

Is In Index(s) of "BLOCKING_ID" Column

Name	Type	Unique
IDX_RANDOMIZATION_TYPES2	IF1	No

Column(s) of "RESULTS" Table

Name	Datatype	Comment	Is PK	Is FK	Average Width	Null Option	Physical Only
RESULT_ID	NUMBER	System-generated to identify uniquely a Result.	Yes	No	0	NOT NULL	No
ANALYSIS_ID	NUMBER	System-generated to identify uniquely an Analysis.	No	Yes	0	NOT NULL	No
ROLE_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
UNIT_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2(20)	Short name of result parameter	No	No	20	NOT NULL	No
DESCR	VARCHAR2(50)	Description of result parameter	No	No	50	NULL	No
ROLE_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
X	FLOAT(63)	First array index for reported values	No	No		NULL	No
Y	FLOAT(63)	Second array index for reported values	No	No		NULL	No
VALUE	FLOAT(63)	Numerical value of result	No	No		NULL	No
UNIT_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No

Is In Index(s) of "RESULT_ID" Column

Name	Type	Unique
PK_RESULTS	PK	Yes

Is In Index(s) of "ANALYSIS_ID" Column

Name	Type	Unique
IDX_RESULTS2	IF1	No

Is In Index(s) of "ROLE_CODELIST_ID" Column

Name	Type	Unique

IDX_RESULTS3	IF2	No

Is In Index(s) of "UNIT_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_RESULTS4	IF3	No

Column(s) of "SITES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
SITE_ID	NUMBER	System-generated to identify uniquely a Site.	Yes	No	0	NOT NULL	No
COUNTRY_-CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
STUDY_ID	NUMBER	System-generated to identify uniquely a Study.	No	Yes	0	NOT NULL	No
STUDY_SITE	VARCHAR2 (255)	SDTM-DEM. SITEID Unique number assigned to a study site within a submission. Sponsor may somtimes send the Investigator ID within the SiteID field in special cases where Site ID is equivalent to Investigator ID.	No	No	255	NULL	No
INVESTIGA-TOR_NAME	VARCHAR2 (100)	SDTM-DEM. INVNAM Name of the investigator responsible for the study at the site.	No	No	100	NULL	No
INVESTIGA-TOR_NUM	VARCHAR2(10)	Investigator identifier within a study. Not needed if Site ID is equivalent to Investigator ID.	No	No	10	NULL	No
INSTITUTION	VARCHAR2 (255)	Institution where study was performed.	No	No	255	NULL	No
COUNTRY_-CODE	VARCHAR2 (255)	Key to specified code list	No	No	255	NULL	No

Is In Index(s) of "SITE_ID" Column		
Name	**Type**	**Unique**
PK_SITES	PK	Yes

Is In Index(s) of "COUNTRY_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_SITES2	IE1	No
IDX_SITES3	IF1	No

Is In Index(s) of "STUDY_ID" Column		
Name	**Type**	**Unique**
IDX_SITES5	AK1	Yes
IDX_SITES2	IE1	No
IDX_SITES4	IF2	No

Is In Index(s) of "STUDY_SITE" Column		
Name	**Type**	**Unique**
IDX_SITES5	AK1	Yes

Column(s) of "STRATIFICATIONS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
STRATIFIC-ATION_ID	NUMBER	System-generated to identify uniquely a Stratification.	Yes	No	0	NOT NULL	No
RANDOMIZ-ATION_TID	NUMBER	System-generated to identify uniquely a Randomization Type.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2(20)	Name of stratification; e.g., "BY GENDER"	No	No	20	NOT NULL	No
DESCR	VARCHAR2(50)	Description of rule for determining stratum	No	No	50	NULL	No
RULE	VARCHAR2 (4000)	Rule to determine stratum for a given subject.	No	No	4000	NULL	No

Is In Index(s) of "STRATIFICATION_ID" Column		
Name	**Type**	**Unique**
PK_STRATIFICATIONS	PK	Yes

Is In Index(s) of "RANDOMIZATION_TID" Column		
Name	**Type**	**Unique**
IDX_STRATIFICATIONS2	IF1	No

Column(s) of "STUDIES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
STUDY_ID	NUMBER	System-generated to identify uniquely a Study.	Yes	No	0	NOT NULL	No
APPLICATI-ON_ID	NUMBER	System-generated to identify uniquely an Application.	No	Yes	0	NOT NULL	No
ANALYTIC_-PLAN_COD-ELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
DESIGN_TID	NUMBER	System-generated to identify uniquely a Design Type.	No	Yes	0	NULL	No
SUPERSTU-DY_ID	NUMBER	System-generated to identify uniquely a Superstudy.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2(30)	The short name of the study.	No	No	30	NULL	No
NUM	VARCHAR2(30)	SDTM-DEM. STUDYID Sponsor-assigned study number	No	No	30	NULL	No
TITLE	VARCHAR2 (500)	The full title of the study.	No	No	500	NULL	No
VERSION	VARCHAR2(40)	Amendment or effective date for protocol version	No	No	40	NULL	No
SUBMISSIO-N_DATE	DATE	Use with Application_ID to identify source of study	No	No		NULL	No

CRF_PDF	BLOB	Case report forms in PDF format.	No	No	0	NULL	No
GE_RULE	VARCHAR2 (4000)	SQL code to produce the group effects (GE) domain	No	No	4000	NULL	No
IE_RULE	VARCHAR2 (4000)	SQL statement to build the individual effects (IE) domain view from other submission domains	No	No	4000	NULL	No
ANALYTIC_-PLAN_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No

Is In Index(s) of "STUDY_ID" Column		
Name	**Type**	**Unique**
PK_STUDIES	PK	Yes

Is In Index(s) of "APPLICATION_ID" Column		
Name	**Type**	**Unique**
IDX_STUDIES6	AK1	Yes
IDX_STUDIES3	IF1	No

Is In Index(s) of "ANALYTIC_PLAN_CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_STUDIES4	IF2	No

Is In Index(s) of "DESIGN_TID" Column		
Name	**Type**	**Unique**
IDX_STUDIES5	IF3	No

Is In Index(s) of "SUPERSTUDY_ID" Column		
Name	**Type**	**Unique**
IDX_STUDIES6	AK1	Yes
IDX_STUDIES2	IF4	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_STUDIES6	AK1	Yes

Column(s) of "SUBJECTS" Table

Name	Datatype	Comment	Is PK	Is FK	Average Width	Null Option	Physical Only
SUBJECT_ID	NUMBER	System-gener-ated to identify uniquely a Subject.	Yes	No	0	NOT NULL	No
ARM_ID	NUMBER	System-gener-ated to identify uniquely an Arm.	No	Yes	0	NOT NULL	No
SITE_ID	NUMBER	System-gener-ated to identify uniquely a Site.	No	Yes	0	NOT NULL	No
INITIALS	VARCHAR2(4)	The subjects initials.	No	No	4	NULL	No
SITE_SUBJECT	VARCHAR2(10)	Subject identifier within site	No	No	10	NULL	No
STUDY_SU-BJECT	VARCHAR2(30)	Subject identifier within study = SDTM SUBJID	No	No	30	NULL	No

SUBMISSIO-N_SUBJECT	VARCHAR2(20)	Subject identifier within submis-sion = SDTM USUBJID	No	No	20	NOT NULL	No

Is In Index(s) of "SUBJECT_ID" Column		
Name	**Type**	**Unique**
PK_SUBJECTS	PK	Yes

Is In Index(s) of "ARM_ID" Column		
Name	**Type**	**Unique**
IDX_SUBJECTS2	IF1	No

Is In Index(s) of "SITE_ID" Column		
Name	**Type**	**Unique**
IDX_SUBJECTS3	IF2	No

Is In Index(s) of "SUBMISSION_SUBJECT" Column		
Name	**Type**	**Unique**
IDX_SUBJECTS4	AK1	Yes

Column(s) of "SUPERSTUDIES" Table

Name	Datatype	Comment	Is PK	Is FK	Average Width	Null Option	Physical Only
SUPERSTU-DY_ID	NUMBER	System-gener-ated to identify uniquely a Superstudy.	Yes	No	0	NOT NULL	No
SUPERSTU-DY_SEQUE-NCE_ID	NUMBER	System-gener-ated to identify uniquely a Superstudy-_Sequence.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2(30)	The short name of the study	No	No	30	NULL	No
NUM	VARCHAR2(20)	SDTM-DEM. STUDYID S-ponsor-assigned study number	No	No	20	NULL	No
TITLE	VARCHAR2 (500)	The full title of the study	No	No	500	NULL	No
SEQ	NUMBER	Order of Superstudy within Supers-tudy_Sequences	No	No	0	NULL	No

Is In Index(s) of "SUPERSTUDY_ID" Column		
Name	**Type**	**Unique**
PK_SUPERSTUDIES	PK	Yes

Is In Index(s) of "SUPERSTUDY_SEQUENCE_ID" Column		
Name	**Type**	**Unique**
IDX_SUPERSTUDIES2	IF1	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_SUPERSTUDIES3	AK1	Yes

Column(s) of "SUPERSTUDY_SEQUENCES" Table

Name	Datatype	Comment	Is PK	Is FK	Average Width	Null Option	Physical Only
SUPERSTU-DY_SEQUE-NCE_ID	NUMBER	System-gener-ated to identify uniquely a Superstudy-_Sequence.	Yes	No	0	NOT NULL	No
NAME	VARCHAR2(30)	Name for an ordered set of super-studies.	No	No	30	NULL	No

DESCR	VARCHAR2 (255)	Description of an ordered set of super-studies.	No	No	255	NULL	No

Is In Index(s) of "SUPERSTUDY_SEQUENCE_ID" Column		
Name	**Type**	**Unique**
PK_SUPERSTUDY_SEQUENCES	PK	Yes

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_SUPERSTUDY_SEQUENCES2	AK1	Yes

Column(s) of "TEST_TYPES" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
TEST_TID	NUMBER	System-generated to identify uniquely a Test Type.	Yes	No	0	NOT NULL	No
METHOD_CODELIST_ID	NUMBER	System-generated to identfy uniquely a Codelist.	No	Yes	0	NOT NULL	No
PARENT_TEST_TID	NUMBER	System-generated to identify uniquely a Test Type.	No	Yes	0	NULL	No
TEST_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
UNIT_CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
TEST_CODE	VARCHAR2 (255)	Key to specified code list	No	No	255	NULL	No
METHOD_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
IS_INTERVAL	NUMBER	TRUE if assessment is an interval scaled categorical measurement.	No	No	0	NULL	No
IS_ORDINAL	NUMBER	TRUE if assessment is an ordered categorical variable	No	No	0	NULL	No
RESULT	VARCHAR2(10)	Type of test result, e.g., CONTINUOUS, CATEGORICAL, WAVEFORM	No	No	10	NOT NULL	No
UNIT_CODE	VARCHAR2(12)	Key to specified code list	No	No	12	NULL	No
SCORING_RULE	VARCHAR2 (4000)	How to combine subcategories to total score	No	No	4000	NULL	No
MIN_VALUE	FLOAT	Smallest physically possible result	No	No		NULL	No
MAX_VALUE	FLOAT	Largest physically possible result	No	No		NULL	No

LLN	FLOAT	Lower limit of normal	No	No		NULL	No
ULN	FLOAT	Upper limit of normal	No	No		NULL	No

Is In Index(s) of "TEST_TID" Column

Name	Type	Unique
PK_TEST_TYPES	PK	Yes

Is In Index(s) of "METHOD_CODELIST_ID" Column

Name	Type	Unique
IDX_TEST_TYPES2	IF1	No

Is In Index(s) of "PARENT_TEST_TID" Column

Name	Type	Unique
IDX_TEST_TYPES5	IF4	No

Is In Index(s) of "TEST_CODELIST_ID" Column

Name	Type	Unique
IDX_TEST_TYPES3	IF2	No

Is In Index(s) of "UNIT_CODELIST_ID" Column

Name	Type	Unique
IDX_TEST_TYPES4	IF3	No

Column(s) of "TIME_PT_TYPES" Table

Name	Datatype	Comment	Is PK	Is FK	Average Width	Null Option	Physical Only
TIME_PT_TID	NUMBER	System-generated to identify uniquely a time point.	Yes	No	0	NOT NULL	No
NAME	VARCHAR2(20)	Name of reference time point	No	No	20	NOT NULL	No
DESCR	VARCHAR2(50)	Description of reference time point.	No	No	50	NULL	No

Is In Index(s) of "TIME_PT_TID" Column

Name	Type	Unique
PK_TIME_PT_TYPES	PK	Yes

Column(s) of "USAGES" Table

Name	Datatype	Comment	Is PK	Is FK	Average Width	Null Option	Physical Only
USAGE_ID	NUMBER	System-generated to identify uniquely a Usage.	Yes	No	0	NOT NULL	No
CODELIST_ID	NUMBER	System-generated to identify uniquely a Codelist.	No	Yes	0	NOT NULL	No
TBL	VARCHAR2(20)	Name of table in Janus where Codelist is referenced.	No	No	20	NOT NULL	No
COL	VARCHAR2(20)	Name of Col in Tbl where Codelist is referenced.	No	No	20	NOT NULL	No
IS_PREFERRED	NUMBER	TRUE if this Codelist is a preferred list for this usage.	No	No	0	NOT NULL	No

Is In Index(s) of "USAGE_ID" Column

Name	Type	Unique

PK_USAGES	PK	Yes

Is In Index(s) of "CODELIST_ID" Column		
Name	**Type**	**Unique**
IDX_USAGES1	IF1	No

Column(s) of "VISITS" Table							
Name	**Datatype**	**Comment**	**Is PK**	**Is FK**	**Average Width**	**Null Option**	**Physical Only**
VISIT_ID	NUMBER	System generated to identify uniquely a Visit.	Yes	No	0	NOT NULL	No
E_TIME_PT_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
PLAN_VISIT_ID	NUMBER	System-generated to identify uniquely a Planned Visit.	No	Yes	0	NULL	No
ST_TIME_PT_TID	NUMBER	System-generated to identify uniquely a Time Point.	No	Yes	0	NULL	No
SUBJECT_ID	NUMBER	System-generated to identify uniquely a Subject.	No	Yes	0	NOT NULL	No
NAME	VARCHAR2 (255)	Name of actual visit.	No	No	255	NULL	No
NUM	VARCHAR2(10)	Alternative name of actual visit.	No	No	10	NULL	No
ST_T	DATE	Nominal date/ time to nearest second; can be implemented as long integer offset in seconds from midnight 1/1/-1960.	No	No		NULL	No
ST_P	DATE	Precision of X_T; can be implemented as long integer (seconds).	No	No		NULL	No
ST_DY	NUMBER	Sponsor-assigned "study day"	No	No	0	NULL	No
E_T	DATE	Nominal date/ time to nearest second; can be implemented as long integer offset in seconds from midnight 1/1/-1960.	No	No		NULL	No
E_P	DATE	Precision of X_T; can be implemented as long integer (seconds).	No	No		NULL	No
E_DY	NUMBER	Sponsor-assigned "study day"	No	No	0	NULL	No
DUR_D	NUMBER	Nominal value of duration (seconds)	No	No	0	NULL	No
DUR_P	NUMBER	Precision of X_D (seconds).	No	No	0	NULL	No

Is In Index(s) of "VISIT_ID" Column		
Name	**Type**	**Unique**
PK_VISITS	PK	Yes

Is In Index(s) of "E_TIME_PT_TID" Column		
Name	**Type**	**Unique**

IDX_VISITS4	IF4	No

Is In Index(s) of "PLAN_VISIT_ID" Column		
Name	**Type**	**Unique**
IDX_VISITS1	IF1	No

Is In Index(s) of "ST_TIME_PT_TID" Column		
Name	**Type**	**Unique**
IDX_VISITS3	IF3	No

Is In Index(s) of "SUBJECT_ID" Column		
Name	**Type**	**Unique**
IDX_VISITS5	AK1	Yes
IDX_VISITS2	IF2	No

Is In Index(s) of "NAME" Column		
Name	**Type**	**Unique**
IDX_VISITS5	AK1	Yes