

Project Details	
Name	WAIHA
Organisation(s)	UHS

Versioning	
Version	v0.1 (DRAFT)
Version Notes	Cohort: 70 Study period: JAN 2017 - MAR 2023

Cohort	
Inclusion Criteria	Aged at least 18 years at initial wAIHA diagnosis, or the legal age of consent in the jurisdiction in which the study is taking place. Have a diagnosis of primary or secondary wAIHA, defined by documented evidence in the medical record as determined by the participating physician, for at least three months. Have received at least one treatment for wAIHA, as determined from evidence in the medical record, including any patient history captured in physician's notes. If waiver not allowed by local laws, informed consent or any locally required authorization obtained from the patient prior to collecting any data from the medical records.
Exclusion Criteria	Ever diagnosed prior to the start of the data collection period with cold antibody AIHA, cold agglutinin disease, mixed type AIHA, warm and cold AIHA, or paroxysmal cold hemoglobinuria, as defined by documented evidence in the medical record, including physician notes. Was enrolled in an interventional study during the study period or has been enrolled at any time in an interventional study with nipocalimab.

Metadata	
Template Version	v1.1
Tables	27
Columns	356
Issues	None

Table	Description	CHECKS
AE	Adverse Events	OK
CE	Clinical Events	OK
DM	Demographics	OK
DS	Disposition	OK
DV	Protocol Deviations	OK
EC	Exposure as Collected	OK
EX	Exposure	OK
FA	Findings About Events or Interventions	OK
HO	Healthcare Encounters	OK
IE	Inclusion/Exclusion Criteria Not Met	OK
LB	Laboratory Test Results	OK
LC	Laboratory Test Results Conversion	OK
MH	Medical History	OK
PR	Procedures	OK
RELREC	Related Records	OK
SE	Subject Elements	OK
SUPPCE	Supplemental Qualifiers for Clinical Events	OK
SUPPDM	Supplemental Qualifiers for Demographics	OK
SUPPDV	Supplemental Qualifiers for Protocol Deviations	OK
SUPPEC	Supplemental Qualifiers for Exposure as Collected	OK
SUPPMH	Supplemental Qualifiers for Medical History	OK
SUPPPR	Supplemental Qualifiers for Procedures	OK
TA	Trial Arms	OK
TE	Trial Elements	OK
TI	Trial Inclusion/Exclusion Criteria	OK
TS	Trial Summary	OK
VS	Vital Signs	OK

Table	Column	Order	Data Type	Length	Vocabularies	Enumeration	Primary Key	Foreign Key Target	Column Description	CHECKS
AE	AEACN	1	Text	250					Action Taken with Study Treatment	OK
AE	AEBDSYCD	2	Float						Body System or Organ Class Code	OK
AE	AEDECOD	3	Text	250					Dictionary-Derived Term	OK
AE	AEENDTC	4	Text	30					End Date/Time of Adverse Event	OK
AE	AEREL	5	Text	250					Causality	OK
AE	AESEQ	6	Integer				4		Sequence Number	OK
AE	AESER	7	Text	250					Serious Event	OK
AE	AESOC	8	Text	250					Primary System Organ Class	OK
AE	AESOCCD	9	Float						Primary System Organ Class Code	OK
AE	AESTDTC	10	Text	30					Start Date/Time of Adverse Event	OK
AE	AETERM	11	Text	250					Reported Term for the Adverse Event	OK
AE	DOMAIN	12	Text	10			2		Domain Abbreviation	OK
AE	STUDYID	13	Text	64			1		Study Identifier	OK
AE	USUBJID	14	Text	64			3		Unique Subject Identifier	OK
CE	CEENDTC	1	Text	30					End Date/Time of Clinical Event	OK
CE	CEENDY	2	Float						Study Day of End of Event	OK
CE	CEENRTPPT	3	Text	30					End Relative to Reference Time Point	OK
CE	CEENTPT	4	Text	30					End Reference Time Point	OK
CE	CELNKGRP	5	Text	250					Celinkgrp	OK
CE	CEOUT	6	Text	250					Outcome of Event	OK
CE	CESEQ	7	Integer				4		Sequence Number	OK
CE	CESEV	8	Text	250					Severity/Intensity	OK
CE	CESPID	9	Text	64					Sponsor-Defined Identifier	OK
CE	CESTDTC	10	Text	30					Start Date/Time of Clinical Event	OK
CE	CESTDY	11	Float						Study Day of Start of Event	OK
CE	CETERM	12	Text	250					Reported Term for the Clinical Event	OK
CE	DOMAIN	13	Text	10			2		Domain Abbreviation	OK
CE	EPOCH	14	Text	64					Epoch	OK
CE	STUDYID	15	Text	64			1		Study Identifier	OK
CE	USUBJID	16	Text	64			3		Unique Subject Identifier	OK
DM	ACTARM	1	Text	250					Description of Actual Arm	OK
DM	ACTARMCD	2	Text	30					Actual Arm Code	OK
DM	ACTARMUD	3	Text	250					Description of Unplanned Actual Arm	OK
DM	AGE	4	Float						Age	OK
DM	AGEU	5	Text	30					Age Units	OK
DM	ARM	6	Text	250					Description of Planned Arm	OK
DM	ARMCD	7	Text	30					Planned Arm Code	OK
DM	ARMNRS	8	Text	250					Reason Arm and/or Actual Arm is Null	OK
DM	BRTHDTC	9	Text	30					Date/Time of Birth	OK
DM	COUNTRY	10	Text	100					Country	OK

DM	DOMAIN	11 Text	10		Domain Abbreviation	OK
DM	DTHDTC	12 Text	30		Date/Time of Death	OK
DM	DTHFL	13 Text	30		Subject Death Flag	OK
DM	ETHNIC	14 Text	100		Ethnicity	OK
DM	RACE	15 Text	100		Race	OK
DM	RFENDTC	16 Text	30		Subject Reference End Date/Time	OK
DM	RFICDTC	17 Text	30		Date/Time of Informed Consent	OK
DM	RFPENDTC	18 Text	30		Date/Time of End of Participation	OK
DM	RFSTDTC	19 Text	30		Subject Reference Start Date/Time	OK
DM	RFXENDTC	20 Text	30		Date/Time of Last Study Treatment	OK
DM	RFXSTDTC	21 Text	30		Date/Time of First Study Treatment	OK
DM	SEX	22 Text	30		Sex	OK
DM	SITEID	23 Text	64		Study Site Identifier	OK
DM	STUDYID	24 Text	64	1	Study Identifier	OK
DM	SUBJID	25 Text	64		Subject Identifier for the Study	OK
DM	USUBJID	26 Text	64	2	Unique Subject Identifier	OK
DS	DOMAIN	1 Text	10	2	Domain Abbreviation	OK
DS	DSCAT	2 Text	250		Category for Disposition Event	OK
DS	DSDECOD	3 Text	250		Standardized Disposition Term	OK
DS	DSSCAT	4 Text	250		Subcategory for Disposition Event	OK
DS	DSSEQ	5 Integer		4	Sequence Number	OK
DS	DSSTDTC	6 Text	30		Start Date/Time of Disposition Event	OK
DS	DSSTDY	7 Float			Study Day of Start of Disposition Event	OK
DS	DSTERM	8 Text	100		Reported Term for the Disposition Event	OK
DS	EPOCH	9 Text	64		Epoch	OK
DS	STUDYID	10 Text	64	1	Study Identifier	OK
DS	USUBJID	11 Text	64	3	Unique Subject Identifier	OK
DV	DOMAIN	1 Text	2	2	Domain Abbreviation	OK
DV	DVCAT	2 Text	50		Category for Protocol Deviation	OK
DV	DVSEQ	3 Integer	8	4	Sequence Number	OK
DV	DVSPID	4 Text	50		Sponsor-Defined Identifier	OK
DV	DVSTDTC	5 Timestamp			Start Date/Time of Deviation	OK
DV	DVSTDY	6 Integer	8		Study Day of Start of Deviation Event	OK
DV	DVTERM	7 Text	50		Protocol Deviation Term	OK
DV	EPOCH	8 Text	22		Epoch	OK
DV	STUDYID	9 Text	15	1	Study Identifier	OK
DV	USUBJID	10 Text	29	3	Unique Subject Identifier	OK
EC	DOMAIN	1 Text	10	2	Domain Abbreviation	OK
EC	ECCAT	2 Text	250		Category of Treatment	OK
EC	ECDOSE	3 Float			Dose	OK
EC	ECDOSFRM	4 Text	100		Dose Form	OK

EC	ECDOSFRQ	5 Text	100		Dosing Frequency per Interval	OK
EC	ECDOSU	6 Text	30		Dose Units	OK
EC	ECENDTC	7 Text	30		End Date/Time of Treatment	OK
EC	ECENDY	8 Float			Study Day of End of Treatment	OK
EC	ECENRTPT	9 Text	30		End Relative to Reference Time Point	OK
EC	ECENTPT	10 Text	30		End Reference Time Point	OK
EC	ECINDC	11 Text	250		Indication	OK
EC	ECLNKID	12 Text	64		Link ID	OK
EC	ECROUTE	13 Text	100		Route of Administration	OK
EC	ECSCAT	14 Text	250		Subcategory of Treatment	OK
EC	ECSEQ	15 Integer		4	Sequence Number	OK
EC	ECSPID	16 Text	64		Sponsor-Defined Identifier	OK
EC	ECSTDTC	17 Text	30		Start Date/Time of Treatment	OK
EC	ECSTDY	18 Float			Study Day of Start of Treatment	OK
EC	ECTRTR	19 Text	250		Name of Treatment	OK
EC	EPOCH	20 Text	64		Epoch	OK
EC	STUDYID	21 Text	64	1	Study Identifier	OK
EC	USUBJID	22 Text	64	3	Unique Subject Identifier	OK
EX	DOMAIN	1 Text	10	2	Domain Abbreviation	OK
EX	EPOCH	2 Text	64		Epoch	OK
EX	EXDOSE	3 Float			Dose	OK
EX	EXDOSFRM	4 Text	250		Dose Form	OK
EX	EXDOSU	5 Text	30		Dose Units	OK
EX	EXENDTC	6 Text	30		End Date/Time of Treatment	OK
EX	EXENDY	7 Float			Study Day of End of Treatment	OK
EX	EXENRTPT	8 Text	30		End Relative to Reference Time Point	OK
EX	EXENTPT	9 Text	30		End Reference Time Point	OK
EX	EXSEQ	10 Integer		4	Sequence Number	OK
EX	EXSTDTC	11 Text	30		Start Date/Time of Treatment	OK
EX	EXSTDY	12 Float			Study Day of Start of Treatment	OK
EX	EXTRTR	13 Text	250		Name of Treatment	OK
EX	STUDYID	14 Text	64	1	Study Identifier	OK
EX	USUBJID	15 Text	64	3	Unique Subject Identifier	OK
FA	DOMAIN	1 Text	10	2	Domain Abbreviation	OK
FA	EPOCH	2 Text	64		Epoch	OK
FA	FADTC	3 Text	30		Date/Time of Collection	OK
FA	FADY	4 Float			Study Day of Collection	OK
FA	FALNKGRP	5 Text	64		Link Group ID	OK
FA	FAOBJ	6 Text	250		Object of the Observation	OK
FA	FAORRES	7 Text	30		Result or Finding in Original Units	OK
FA	FAORRESU	8 Text	30		Original Units	OK

FA	FASEQ	9 Integer		4	Sequence Number	OK
FA	FASPID	10 Text	64		Sponsor-Defined Identifier	OK
FA	FASTRESC	11 Text	250		Character Result/Finding in Std Format	OK
FA	FASTRESN	12 Float			Numeric Result/Finding in Standard Units	OK
FA	FASTRESU	13 Text	30		Standard Units	OK
FA	FATEST	14 Text	250		Findings About Test Name	OK
FA	FATESTCD	15 Text	64		Findings About Test Short Name	OK
FA	STUDYID	16 Text	64	1	Study Identifier	OK
FA	USUBJID	17 Text	64	3	Unique Subject Identifier	OK
FA	VISITNUM	18 Float			Visit Number	OK
HO	DOMAIN	1 Text	10	2	Domain Abbreviation	OK
HO	EPOCH	2 Text	64		Epoch	OK
HO	HOENDTC	3 Text	30		End Date/Time of Healthcare Encounter	OK
HO	HOENDY	4 Float			Study Day of End of Healthcare Encounter	OK
HO	HOENRTPT	5 Text	30		End Relative to Reference Time Point	OK
HO	HOENTPT	6 Text	30		End Reference Time Point	OK
HO	HOLNKID	7 Text	250		Holnkid	OK
HO	HOSEQ	8 Integer		4	Sequence Number	OK
HO	HOSPID	9 Text	64		Sponsor-Defined Identifier	OK
HO	HOSTDTC	10 Text	30		Start Date/Time of Healthcare Encounter	OK
HO	HOSTDY	11 Float			Study Day of Start of Encounter	OK
HO	HOTERM	12 Text	250		Healthcare Encounter Term	OK
HO	STUDYID	13 Text	64	1	Study Identifier	OK
HO	USUBJID	14 Text	64	3	Unique Subject Identifier	OK
IE	DOMAIN	1 Text	10	2	Domain Abbreviation	OK
IE	IECAT	2 Text	250		Inclusion/Exclusion Category	OK
IE	IEORRES	3 Text	250		I/E Criterion Original Result	OK
IE	IESEQ	4 Integer		4	Sequence Number	OK
IE	IESTRESC	5 Text	250		I/E Criterion Result in Std Format	OK
IE	IETEST	6 Text	250		Inclusion/Exclusion Criterion	OK
IE	IETESTCD	7 Text	250		Inclusion/Exclusion Criterion Short Name	OK
IE	STUDYID	8 Text	64	1	Study Identifier	OK
IE	USUBJID	9 Text	64	3	Unique Subject Identifier	OK
LB	DOMAIN	1 Text	10	2	Domain Abbreviation	OK
LB	EPOCH	2 Text	64		Epoch	OK
LB	LBCAT	3 Text	100		Category for Lab Test	OK
LB	LBDC	4 Text	30		Date/Time of Specimen Collection	OK
LB	LBDY	5 Float			Study Day of Specimen Collection	OK
LB	LBLNKGRP	6 Text	64		Link Group ID	OK
LB	LBLNKID	7 Text	64		Link ID	OK
LB	LBLOBXFL	8 Text	30		Last Observation Before Exposure Flag	OK

LB	LBNRIND	9 Text	30		Reference Range Indicator	OK
LB	LBORNHI	10 Text	30		Reference Range Upper Limit in Orig Unit	OK
LB	LBORNLO	11 Text	30		Reference Range Lower Limit in Orig Unit	OK
LB	LBORRES	12 Text	30		Result or Finding in Original Units	OK
LB	LBORRESU	13 Text	30		Original Units	OK
LB	LBSEQ	14 Integer		4	Sequence Number	OK
LB	LBSPID	15 Text	64		Sponsor-Defined Identifier	OK
LB	LBSTNRHI	16 Float			Reference Range Upper Limit-Std Units	OK
LB	LBSTNRLO	17 Float			Reference Range Lower Limit-Std Units	OK
LB	LBSTRESC	18 Text	100		Character Result/Finding in Std Format	OK
LB	LBSTRESN	19 Float			Numeric Result/Finding in Standard Units	OK
LB	LBSTRESU	20 Text	30		Standard Units	OK
LB	LBTEST	21 Text	100		Lab Test or Examination Name	OK
LB	LBTESTCD	22 Text	64		Lab Test or Examination Short Name	OK
LB	STUDYID	23 Text	64	1	Study Identifier	OK
LB	USUBJID	24 Text	64	3	Unique Subject Identifier	OK
LB	VISITNUM	25 Float			Visit Number	OK
LC	DOMAIN	1 Text	10	2	Domain Abbreviation	OK
LC	EPOCH	2 Text	64		Epoch	OK
LC	LCCAT	3 Text	100		Category	OK
LC	LCDTC	4 Text	30		Date/Time of Collection	OK
LC	LCDY	5 Float			Study Day of Visit/Collection/Exam	OK
LC	LCLNKGRP	6 Text	64		Link Group ID	OK
LC	LCLNKID	7 Text	64		Link ID	OK
LC	LCLOBXFL	8 Text	100		Last Observation Before Exposure Flag	OK
LC	LCNRIND	9 Text	100		Normal/Reference Range Indicator	OK
LC	LCORNHI	10 Text	30		Normal Range Upper Limit-Original Units	OK
LC	LCORNLO	11 Text	30		Normal Range Lower Limit-Original Units	OK
LC	LCORRES	12 Text	30		Result or Finding in Original Units	OK
LC	LCORRESU	13 Text	30		Original Units	OK
LC	LCSEQ	14 Integer		4	Sequence Number	OK
LC	LCSPID	15 Text	64		Sponsor-Defined Identifier	OK
LC	LCSTNRHI	16 Float			Normal Range Upper Limit-Standard Units	OK
LC	LCSTNRLO	17 Float			Normal Range Lower Limit-Standard Units	OK
LC	LCSTRESC	18 Text	100		Result or Finding in Standard Format	OK
LC	LCSTRESN	19 Float			Numeric Result/Finding in Standard Units	OK
LC	LCSTRESU	20 Text	30		Standard Units	OK
LC	LCTEST	21 Text	100		Name of Measurement, Test, or Exam	OK
LC	LCTESTCD	22 Text	64		Short Name of Measurement, Test, or Exam	OK
LC	STUDYID	23 Text	64	1	Study Identifier	OK
LC	USUBJID	24 Text	64	3	Unique Subject Identifier	OK

LC	VISITNUM	25	Float			Visit Number	OK
MH	DOMAIN	1	Text	10	2	Domain Abbreviation	OK
MH	EPOCH	2	Text	64		Epoch	OK
MH	MHCAT	3	Text	100		Category for Medical History	OK
MH	MHEVDTYP	4	Text	30		Medical History Event Date Type	OK
MH	MHLNKID	5	Text	64		Link ID	OK
MH	MHSEQ	6	Integer		4	Sequence Number	OK
MH	MHSPID	7	Text	64		Sponsor-Defined Identifier	OK
MH	MHSTDTC	8	Text	30		Start Date/Time of Medical History Event	OK
MH	MHSTDY	9	Float			Study Day of Start of Observation	OK
MH	MHSTRPT	10	Text	30		Start Relative to Reference Time Point	OK
MH	MHSTTPT	11	Text	30		Start Reference Time Point	OK
MH	MHTERM	12	Text	250		Reported Term for the Medical History	OK
MH	STUDYID	13	Text	64	1	Study Identifier	OK
MH	USUBJID	14	Text	64	3	Unique Subject Identifier	OK
PR	DOMAIN	1	Text	10	2	Domain Abbreviation	OK
PR	EPOCH	2	Text	64		Epoch	OK
PR	PRCAT	3	Text	100		Category	OK
PR	PRINDC	4	Text	250		Indication	OK
PR	PRSEQ	5	Integer		4	Sequence Number	OK
PR	PRSPID	6	Text	64		Sponsor-Defined Identifier	OK
PR	PRSTDTC	7	Text	30		Start Date/Time of Procedure	OK
PR	PRSTDY	8	Float			Study Day of Start of Procedure	OK
PR	PRTRT	9	Text	250		Reported Name of Procedure	OK
PR	STUDYID	10	Text	64	1	Study Identifier	OK
PR	USUBJID	11	Text	64	3	Unique Subject Identifier	OK
RELREC	IDVAR	1	Text	64	4	Identifying Variable	OK
RELREC	IDVARVAL	2	Text	64	5	Identifying Variable Value	OK
RELREC	RDOMAIN	3	Text	10	2	Related Domain Abbreviation	OK
RELREC	RELID	4	Text	64	6	Relationship Identifier	OK
RELREC	RELTYPE	5	Text	100		Relationship Type	OK
RELREC	STUDYID	6	Text	64	1	Study Identifier	OK
RELREC	USUBJID	7	Text	64	3	Unique Subject Identifier	OK
SE	DOMAIN	1	Text	10	2	Domain Abbreviation	OK
SE	ELEMENT	2	Text	250		Description of Element	OK
SE	EPOCH	3	Text	64		Epoch	OK
SE	ETCD	4	Text	64		Element Code	OK
SE	SEENDTC	5	Text	30		End Date/Time of Element	OK
SE	SEENDY	6	Float			Study Day of End of Element	OK
SE	SESEQ	7	Integer		4	Sequence Number	OK
SE	SESTDTC	8	Text	30		Start Date/Time of Element	OK

SE	SESTDY	9	Float			Study Day of Start of Element	OK
SE	STUDYID	10	Text	64	1	Study Identifier	OK
SE	TAETORD	11	Integer			Planned Order of Element within Arm	OK
SE	USUBJID	12	Text	64	3	Unique Subject Identifier	OK
SUPPCE	IDVAR	1	Text	100	4	Identifying Variable	OK
SUPPCE	IDVARVAL	2	Text	100	5	Identifying Variable Value	OK
SUPPCE	QEQVAL	3	Text	100		Evaluator	OK
SUPPCE	QLABEL	4	Text	100		Qualifier Variable Label	OK
SUPPCE	QEQNAM	5	Text	100	6	Qualifier Variable Name	OK
SUPPCE	QEQORIG	6	Text	100		Origin	OK
SUPPCE	QEQVAL	7	Text	100		Data Value	OK
SUPPCE	RDOMAIN	8	Text	10	2	Related Domain Abbreviation	OK
SUPPCE	STUDYID	9	Text	64	1	Study Identifier	OK
SUPPCE	USUBJID	10	Text	64	3	Unique Subject Identifier	OK
SUPPDM	IDVAR	1	Text	100	4	Identifying Variable	OK
SUPPDM	IDVARVAL	2	Text	64	5	Identifying Variable Value	OK
SUPPDM	QEQVAL	3	Text	100		Evaluator	OK
SUPPDM	QLABEL	4	Text	100		Qualifier Variable Label	OK
SUPPDM	QEQNAM	5	Text	64	6	Qualifier Variable Name	OK
SUPPDM	QEQORIG	6	Text	100		Origin	OK
SUPPDM	QEQVAL	7	Text	100		Data Value	OK
SUPPDM	RDOMAIN	8	Text	10	2	Related Domain Abbreviation	OK
SUPPDM	STUDYID	9	Text	64	1	Study Identifier	OK
SUPPDM	USUBJID	10	Text	64	3	Unique Subject Identifier	OK
SUPPDV	IDVAR	1	Text	1	4	Identifying Variable	OK
SUPPDV	IDVARVAL	2	Text	1	5	Identifying Variable Value	OK
SUPPDV	QEQVAL	3	Text	1		Evaluator	OK
SUPPDV	QLABEL	4	Text	37		Qualifier Variable Label	OK
SUPPDV	QEQNAM	5	Text	8	6	Qualifier Variable Name	OK
SUPPDV	QEQORIG	6	Text	3		Origin	OK
SUPPDV	QEQVAL	7	Text	3		Data Value	OK
SUPPDV	RDOMAIN	8	Text	2	2	Related Domain Abbreviation	OK
SUPPDV	STUDYID	9	Text	15	1	Study Identifier	OK
SUPPDV	USUBJID	10	Text	29	3	Unique Subject Identifier	OK
SUPPEC	IDVAR	1	Text	100	4	Identifying Variable	OK
SUPPEC	IDVARVAL	2	Text	64	5	Identifying Variable Value	OK
SUPPEC	QEQVAL	3	Text	100		Evaluator	OK
SUPPEC	QLABEL	4	Text	100		Qualifier Variable Label	OK
SUPPEC	QEQNAM	5	Text	64	6	Qualifier Variable Name	OK
SUPPEC	QEQORIG	6	Text	100		Origin	OK
SUPPEC	QEQVAL	7	Text	100		Data Value	OK

SUPPEC	RDOMAIN	8 Text	10	2	Related Domain Abbreviation	OK
SUPPEC	STUDYID	9 Text	64	1	Study Identifier	OK
SUPPEC	USUBJID	10 Text	64	3	Unique Subject Identifier	OK
SUPPMH	IDVAR	1 Text	100	4	Identifying Variable	OK
SUPPMH	IDVARVAL	2 Text	64	5	Identifying Variable Value	OK
SUPPMH	QVAL	3 Text	100		Evaluator	OK
SUPPMH	QLABEL	4 Text	100		Qualifier Variable Label	OK
SUPPMH	QNAM	5 Text	64	6	Qualifier Variable Name	OK
SUPPMH	QORIG	6 Text	100		Origin	OK
SUPPMH	QVAL	7 Text	100		Data Value	OK
SUPPMH	RDOMAIN	8 Text	10	2	Related Domain Abbreviation	OK
SUPPMH	STUDYID	9 Text	64	1	Study Identifier	OK
SUPPMH	USUBJID	10 Text	64	3	Unique Subject Identifier	OK
SUPPPR	IDVAR	1 Text	100	4	Identifying Variable	OK
SUPPPR	IDVARVAL	2 Text	64	5	Identifying Variable Value	OK
SUPPPR	QVAL	3 Text	100		Evaluator	OK
SUPPPR	QLABEL	4 Text	100		Qualifier Variable Label	OK
SUPPPR	QNAM	5 Text	64	6	Qualifier Variable Name	OK
SUPPPR	QORIG	6 Text	100		Origin	OK
SUPPPR	QVAL	7 Text	100		Data Value	OK
SUPPPR	RDOMAIN	8 Text	10	2	Related Domain Abbreviation	OK
SUPPPR	STUDYID	9 Text	64	1	Study Identifier	OK
SUPPPR	USUBJID	10 Text	64	3	Unique Subject Identifier	OK
TA	ARM	1 Text	250		Description of Planned Arm	OK
TA	ARMCD	2 Text	30	2	Planned Arm Code	OK
TA	DOMAIN	3 Text	10		Domain Abbreviation	OK
TA	ELEMENT	4 Text	250		Description of Element	OK
TA	EPOCH	5 Text	64		Epoch	OK
TA	ETCD	6 Text	30	3	Element Code	OK
TA	STUDYID	7 Text	64	1	Study Identifier	OK
TA	TABRANCH	8 Text	64		Branch	OK
TA	TAETORD	9 Float			Planned Order of Element within Arm	OK
TA	TATRANS	10 Text	250		Transition Rule	OK
TE	DOMAIN	1 Text	10		Domain Abbreviation	OK
TE	ELEMENT	2 Text	250		Description of Element	OK
TE	ETCD	3 Text	64	2	Element Code	OK
TE	STUDYID	4 Text	64	1	Study Identifier	OK
TE	TEDUR	5 Text	250		Planned Duration of Element	OK
TE	TEENRL	6 Text	250		Rule for End of Element	OK
TE	TESTRL	7 Text	250		Rule for Start of Element	OK
TI	DOMAIN	1 Text	10		Domain Abbreviation	OK

TI	IECAT	2 Text	250		Inclusion/Exclusion Category	OK
TI	IETEST	3 Text	250		Inclusion/Exclusion Criterion	OK
TI	IETESTCD	4 Text	64	2	Incl/Excl Criterion Short Name	OK
TI	STUDYID	5 Text	64	1	Study Identifier	OK
TS	DOMAIN	1 Text	10		Domain Abbreviation	OK
TS	STUDYID	2 Text	64	1	Study Identifier	OK
TS	TSGRPID	3 Text	64		Group ID	OK
TS	TSPARM	4 Text	260		Trial Summary Parameter	OK
TS	TSPARMCD	5 Text	64	2	Trial Summary Parameter Short Name	OK
TS	TSSEQ	6 Integer		3	Sequence Number	OK
TS	TSVAL	7 Text	250		Parameter Value	OK
TS	TSVALCD	8 Text	30		Parameter Value Code	OK
TS	TSVALNF	9 Text	100		Parameter Value Null Flavor	OK
TS	TSVCDREF	10 Text	100		Name of the Reference Terminology	OK
TS	TSVCDVER	11 Text	30		Version of the Reference Terminology	OK
VS	DOMAIN	1 Text	10	2	Domain Abbreviation	OK
VS	STUDYID	2 Text	64	1	Study Identifier	OK
VS	USUBJID	3 Text	64	3	Unique Subject Identifier	OK
VS	VISITNUM	4 Float			Visit Number	OK
VS	VSDTC	5 Text	30		Date/Time of Measurements	OK
VS	VSLOBXFL	6 Text	30		Last Observation Before Exposure Flag	OK
VS	VSORRES	7 Text	30		Result or Finding in Original Units	OK
VS	VSORRESU	8 Text	30		Original Units	OK
VS	VSSEQ	9 Integer		4	Sequence Number	OK
VS	VSSTRESC	10 Text	100		Character Result/Finding in Std Format	OK
VS	VSSTRESN	11 Float			Numeric Result/Finding in Standard Units	OK
VS	VSSTRESU	12 Text	30		Standard Units	OK
VS	VSTEST	13 Text	100		Vital Signs Test Name	OK
VS	VSTESTCD	14 Text	30		Vital Signs Test Short Name	OK

Table	Column	Code	Name	Description	CHECKS

Data Type	Description
Text	Free text (string)
Integer	Numerical (Integer)
Float	Numerical (Decimal)
Date	Date (date only)
Timestamp	Datetime (including time)
File	Whole file for upload