Clinical Development

Risperidone®

JNJ410397_USA121

Anonymisation Data Derivation Specification Document

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Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

Dataset	Name of dataset
Creating Program	The program that created the dataset
Description	Short description
Unique Identifier	Unique key
Sorted by	Sort key
Notes	Any useful notes

Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
Codes	Codelist name
Comments	Variable source derivation explanation if variable derived.

1.2. Guidelines for Preparing Data

The data will be provided according to the De-identified/ Anonymisation data guidelines standards with the following exceptions:

- Subject initials will not be provided.
- Investigator Information will not be provided.
- Date of birth will not be provided, only age in years will be provided.
- Age will be grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and site/ center numbers will be assigned in a random manner so they are not matching the subject and site/ center numbers that were used in the actual trial.
- Remove the free text verbatim terms.
- Remove “Other” free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial and Bottle number will not be provided.

- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Due to sensitivity of the data, INVEST dataset will not be submitted.
- After dropping sensitive information from the dataset, no information is left in TRLLIST dataset, for further analysis. Hence, TRLLIST dataset will not be submitted.
- TEMPLATE & MAP datasets contains dataset information and variables attributes, no significant information is available for further analysis. Hence, dataset will not be submitted.
- VISIT.VISIT_D(Visit Date when Visit=1) will be used as Reference Date to derive relative days (referred as Ref. Date in the document).

1.3. Data Files

The JNJ410397_USA121 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Subject Characteristics – SUBJCHAR

Dataset	SUBJCHAR
Creating program	subjchar.sas
Description	Subject Characteristics
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: BREAK_V,BREAK_D,ZCOINV,COINV,MEDNO,RBIRTH_D,RAND_D,BIRTH_D, ZINVEST,INITIALS,INVEST Below listed variables were not a part of the Raw dataset. These have been added to retain the Treatment and Country related information in the de-identified datasets: RANDCODE (Source: TRLLIST dataset) DCOUNTRY (Source: INVEST dataset)

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
DSITEID	num	SITEID ASSIGNED FOR DE-IDENTITY		Randomly assigned siteid for de-identity
SEX	char	SEX		Collected at CRF.

Variable	Type	Label	Codes	Comments
RACE	char	RACE		Group element to protect PII.
HEIGHT	num	HEIGHT		Collected at CRF.
HEIGHT_U	char	HEIGHT UNIT		Collected at CRF.
ONAGE	char	ONSET AGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
TIMEAGE	char	FIRST PSYCHIATRIC HOSP. AGE		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.
HOSPNO	num	NO. OF PREVIOUS HOSP.		Collected at CRF.
PREGRES	char	RESULT OF PREGNANCY TEST		Collected at CRF.
RPANSS	num	PANSS SCORE		Collected at CRF.
SUBJECT	char	SUBJECT STATUS		Collected at CRF.
BREAK	char	HAS CODE BROKEN		Collected at CRF.
ENTRYCOM	char	ENTRY COMPLETED		Collected at CRF.
DISCVIS	num	D/C VISIT		Collected at CRF.
DRYRUN	char	DRY-RUN READY		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGE	char	AGE IN YEARS		Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule: AGE= int((REF.DATE – BIRTH_D)/365.25) If age greater than 89+ years then will be grouped as per HIPAA rules.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.
DCOUNTRY	char	DE-IDENTIFY COUNTRY		Element will be grouped to protect PII.
RAND_DY	num	RELATIVE RANDOMIZATION DAY		If RAND_D and REF.DATE not missing then perform below logic to calculate RAND_DY, If RAND_D less than REF.DATE then (RAND_D - REF.DATE). Else if RAND_D is greater than equal to REF.DATE then (RAND_D-REF.DATE) +1.
BREAK_DY	num	RELATIVE DAY CODE BREAKING		If BREAK_D and REF.DATE not missing then perform below logic to calculate BREAK_DY, If BREAK_D less than REF.DATE then (BREAK_D - REF.DATE). Else if BREAK_D is greater than equal to REF.DATE then (BREAK_D-REF.DATE) +1.

1.4.2. Administration of Trial Medication – ADMMED

Dataset	ADMMED
Creating program	admmed.sas
Description	Administration of Trial Medication
Unique identifier	DCRFID,PHASE,BOX,AMTO_DY,AMFREQ
Sorted by	DCRFID,PHASE,BOX,AMTO_DY,AMFREQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: AMTO_D,AMFROM_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
BOX	char	BOX		Collected at CRF.
AMFROM_T	num	ADMIN. FROM TIME		Collected at CRF.
AMSITE	char	ADMIN. SITE		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
AMFREQ	char	ADMIN. FREQ.		Collected at CRF.
AMREAS	char	REGIMEN CHANGE REASON		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZAMREAS	char	REGIMEN CHANGE REASON CODE		Collected at CRF.
AMDOSE	num	DOSE SCHEDULE		Collected at CRF.
AMDOSE_U	char	DOSE UNIT		Collected at CRF.
AMFROMDY	num	RELATIVE ADMIN. FROM DAY		If AMFROM_D and REF.DATE not missing then perform below logic to calculate AMFROM_DY, If AMFROM_D less than REF.DATE then (AMFROM_D - REF.DATE). Else if AMFROM_D is greater than equal to REF.DATE then (AMFROM_D- REF.DATE) +1.
AMTO_DY	num	RELATIVE ADMIN. TO DAY		If AMTO_D and REF.DATE not missing then perform below logic to calculate AMTO_DY, If AMTO_D less than REF.DATE then (AMTO_D - REF.DATE). Else if AMTO_D is greater than equal to REF.DATE then (AMTO_D- REF.DATE) +1.

1.4.3. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DCRFID,AEPREF,AETO_DY,AESEQNO
Sorted by	DCRFID,AEPREF,AETO_DY,AESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: AEFROM_D,AETO_D, AEINCL ,PHASE,SAEREFNO,AE_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
AESEQNO	num	AE SEQ.		Collected at CRF.
AEFROM_C	char	AE FROM CODE		Collected at CRF.
AETO_C	char	AE TO CODE		Collected at CRF.
AESEV	char	AE SEVERITY		Collected at CRF.
ZAESEV	num	AE SEVERITY CODE		Collected at CRF.
AEACT	char	AE ACTION TAKEN		Collected at CRF.
ZAEACT	num	AE ACTION TAKEN CODE		Collected at CRF.
AECONRX	char	AE CO-RX START		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZAECONRX	num	AE CO-RX START CODE		Collected at CRF.
AERELAT	char	AE DRUG RELATION		Collected at CRF.
ZAERELAT	num	AE DRUG RELATION CODE		Collected at CRF.
AEOUT	char	AE OUTCOME		Collected at CRF.
ZAEOUT	num	AE OUTCOME CODE		Collected at CRF.
AESER	char	AE SERIOUSNESS		Collected at CRF.
ZAESER	num	AE SERIOUSNESS CODE		Collected at CRF.
AEWHONUM	char	AE WHO CODE		Collected at CRF.
AEPREF	char	ADVERSE EVENT PREFERRED TERM		Collected at CRF.
AESOC	char	ADVERSE EVENT SYSTEM ORGAN CLASS		Collected at CRF.
AEFROMDY	num	RELATIVE AE FROM DAY		If AEFROM_D and REF.DATE not missing then perform below logic to calculate AEFROM_DY, If AEFROM_D less than REF.DATE then (AEFROM_D - REF.DATE). Else if AEFROM_D is greater than equal to REF.DATE then (AEFROM_D- REF.DATE) +1.
AETO_DY	num	RELATIVE AE TO DAY		If AETO_D and REF.DATE not missing then perform below logic to calculate AETO_DY, If AETO_D less than REF.DATE then (AETO_D - REF.DATE). Else if AETO_D is greater than equal to REF.DATE then (AETO_D- REF.DATE) +1.

1.4.4. Ban Results – BANRES

Dataset	BANRES
Creating program	banres.sas
Description	Ban Results
Unique identifier	SUBST,BRVAL,BRQUANT,TRIAL,SPECIMEN
Sorted by	SUBST,BRVAL,BRQUANT,TRIAL,SPECIMEN
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LABINTNO

Variable	Type	Label	Codes	Comments
SUBST	char	SUBSTANCE		Collected at CRF.
BRVAL	num	BAN MEASUREMENT		Collected at CRF.
BRVAL_V	char	BAN MEASUREMENT (VERB.)		Collected at CRF.
BRVAL_U	char	UNIT		Collected at CRF.
BRQUANT	char	LIMIT OF QUANTIFICATION		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
SPECIMEN	char	SPECIMEN		Collected at CRF.

1.4.5. Code – CODE

Dataset	CODE
Creating program	code.sas
Description	Code
Unique identifier	TRIAL,CODELIST,VALID_D
Sorted by	TRIAL,CODELIST,VALID_D
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
CODELIST	char	CODELIST		Collected at CRF.
VALID_D	num	VALID DATE		Collected at CRF.

1.4.6. Concomitant Medication – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Medication
Unique identifier	DCRFID,CTTYPE,RXPREF,CTSEQNO
Sorted by	DCRFID,CTTYPE,RXPREF,CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: CTIND_V,CONRX_V,CTFROM_D,ATCTEXT9,ATCCODE9,ATCCODE8,ATCTEXT8, CTTO_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CONRX	char	CO-RX		Collected at CRF.
CTSCHED	char	CO-RX DAILY SCHEDULE		Collected at CRF.
CTIND	char	INDICATION		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.
CTFROM_C	char	CO-RX START CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTONGO	char	CO-RX ONGOING		Collected at CRF.
CTTO_C	char	CO-RX END CODE		Collected at CRF.
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCCODE2	char	ATC CODE 2		Collected at CRF.
ATCCODE3	char	ATC CODE 3		Collected at CRF.
ATCCODE4	char	ATC CODE 4		Collected at CRF.
ATCCODE5	char	ATC CODE 5		Collected at CRF.
ATCCODE6	char	ATC CODE 6		Collected at CRF.
ATCCODE7	char	ATC CODE 7		Collected at CRF.
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
ATCTEXT1	char	ATC TEXT 1		Collected at CRF.
ATCTEXT2	char	ATC TEXT 2		Collected at CRF.
ATCTEXT3	char	ATC TEXT 3		Collected at CRF.
ATCTEXT4	char	ATC TEXT 4		Collected at CRF.
ATCTEXT5	char	ATC TEXT 5		Collected at CRF.
ATCTEXT6	char	ATC TEXT 6		Collected at CRF.
ATCTEXT7	char	ATC TEXT 7		Collected at CRF.
RXPREF	char	PREFERRED TERM		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTFROMDY	num	RELATIVE CO-RX START DAY		If CTFROM_D and REF.DATE not missing then perform below logic to calculate CTFROM_DY, If CTFROM_D less than REF.DATE then (CTFROM_D - REF.DATE). Else if CTFROM_D is greater than equal to REF.DATE then (CTFROM_D- REF.DATE) +1.
CTTO_DY	num	RELATIVE CO-RX END DAY		If CTTO_D and REF.DATE not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than REF.DATE then (CTTO_D - REF.DATE). Else if CTTO_D is greater than equal to REF.DATE then (CTTO_D- REF.DATE) +1.

1.4.7. Concomitant Medication 2 – COTHER2

Dataset	COTHER2
Creating program	cother2.sas
Description	Concomitant Medication 2
Unique identifier	DCRFID,CTTYPE,RXPREF,CTSEQNO
Sorted by	DCRFID,CTTYPE,RXPREF,CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: ATCTEXT9,ATCTEXT8,ATCCODE9,ATCCODE8,CTTO_D,CTFROM_D,CTIND_V, CONRX_V

Variable	Type	Label	Codes	Comments
RXWHONUM	char	WHO DRUG CODE		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
CTTYPE	char	CO-RX TYPE		Collected at CRF.
CTSEQNO	num	CO-RX SEQ.		Collected at CRF.
CONRX	char	CO-RX		Collected at CRF.
CTSCHED	char	CO-RX DAILY SCHEDULE		Collected at CRF.
CTIND	char	INDICATION		Collected at CRF.
CTPRIOR	char	CO-RX PRE-TRIAL		Collected at CRF.

Variable	Type	Label	Codes	Comments
CTFROM_C	char	CO-RX START CODE		Collected at CRF.
CTONGO	char	CO-RX ONGOING		Collected at CRF.
CTTO_C	char	CO-RX END CODE		Collected at CRF.
ATCCODE0	char	ATC CODE 0		Collected at CRF.
ATCCODE1	char	ATC CODE 1		Collected at CRF.
ATCCODE2	char	ATC CODE 2		Collected at CRF.
ATCCODE3	char	ATC CODE 3		Collected at CRF.
ATCCODE4	char	ATC CODE 4		Collected at CRF.
ATCCODE5	char	ATC CODE 5		Collected at CRF.
ATCCODE6	char	ATC CODE 6		Collected at CRF.
ATCCODE7	char	ATC CODE 7		Collected at CRF.
ATCTEXT0	char	ATC TEXT 0		Collected at CRF.
ATCTEXT1	char	ATC TEXT 1		Collected at CRF.
ATCTEXT2	char	ATC TEXT 2		Collected at CRF.
ATCTEXT3	char	ATC TEXT 3		Collected at CRF.
ATCTEXT4	char	ATC TEXT 4		Collected at CRF.
ATCTEXT5	char	ATC TEXT 5		Collected at CRF.
ATCTEXT6	char	ATC TEXT 6		Collected at CRF.
ATCTEXT7	char	ATC TEXT 7		Collected at CRF.
RXPREF	char	PREFERRED TERM		Collected at CRF.
ATCCODE	char	ATC CODE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATCTEXT	char	ATC TEXT		Collected at CRF.
CTFROMDY	num	RELATIVE CO-RX START DAY		If CTFROM_D and REF.DATE not missing then perform below logic to calculate CTFROM_DY, If CTFROM_D less than REF.DATE then (CTFROM_D - REF.DATE). Else if CTFROM_D is greater than equal to REF.DATE then (CTFROM_D- REF.DATE) +1.
CTTO_DY	num	RELATIVE CO-RX END DAY		If CTTO_D and REF.DATE not missing then perform below logic to calculate CTTO_DY, If CTTO_D less than REF.DATE then (CTTO_D - REF.DATE). Else if CTTO_D is greater than equal to REF.DATE then (CTTO_D- REF.DATE) +1.

1.4.8. Death – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death
Unique identifier	DCRFID
Sorted by	DCRFID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: DTREAS_V,DEATH_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
DTREAS	char	DEATH CAUSE		Collected at CRF.
DEATH_DY	num	RELATIVE DEATH DAY		If DEATH_D and REF.DATE not missing then perform below logic to calculate DEATH_DY, If DEATH_D less than REF.DATE then (DEATH_D - REF.DATE). Else if DEATH_D is greater than equal to REF.DATE then (DEATH_D- REF.DATE) +1.

1.4.9. Protocol Deviation – DEVIATN

Dataset	DEVIATN
Creating program	deviatn.sas
Description	Protocol Deviation
Unique identifier	DCRFID,DEVIAT
Sorted by	DCRFID,DEVIAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DEVIAT_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
DEVIAT	char	DEVIATION		Collected at CRF.
ZDEVIAT	char	DEVIATION CODE		Collected at CRF.
DVTYPE	char	TYPE OF DEVIATION		Collected at CRF.

1.4.10. Diagnosis – DIAGNOS

Dataset	DIAGNOS
Creating program	diagnos.sas
Description	Diagnosis
Unique identifier	DCRFID,DIAGN,DXAXIS
Sorted by	DCRFID,DIAGN,DXAXIS
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
DXAXIS	char	AXIS		Collected at CRF.
DIAGN	char	DIAGNOSIS		Collected at CRF.
ZDIAGN	char	DIAGNOSIS CODE		Collected at CRF.

1.4.11. Diseases – DISEASES

Dataset	DISEASES
Creating program	diseases.sas
Description	Diseases
Unique identifier	DCRFID,DSSYSTEM,DSCOND
Sorted by	DCRFID,DSSYSTEM,DSCOND
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DISEAS_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
DSSYSTEM	char	DISEASE BODY SYSTEM		Collected at CRF.
DSCOND	char	CONDITION		Collected at CRF.
DISEASE	char	DISEASE		Collected at CRF.

1.4.12. Electrocardiogram – ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DCRFID,EGLIMITS,EGRELCHA,ECG_DY
Sorted by	DCRFID,EGLIMITS,EGRELCHA,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.
EGRELCHA	char	CLIN. RELEVANT CHANGES		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

1.4.13. ECG Abnormalities – ECGABN

Dataset	ECGABN
Creating program	ecgabn.sas
Description	ECG Abnormalities
Unique identifier	DCRFID,ECG_DY,EASEQNO
Sorted by	DCRFID,ECG_DY,EASEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EASEQNO	num	SEQUENCE NUMBER		Collected at CRF.
ECGOTH_V	char	ECG OTHER ABN. (VERB.)		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

1.4.14. ECG Description – ECGVAL

Dataset	ECGEVAL
Creating program	ecgeval.sas
Description	ECG Description
Unique identifier	DCRFID,EEASPECT,EEEVAL,ECG_DY
Sorted by	DCRFID,EEASPECT,EEEVAL,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
EEASPECT	char	ECG ASPECT		Collected at CRF.
EEEVAL	char	ECG EVALUATION		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

1.4.15. ECG Measurements – ECGPAR

Dataset	ECGPAR
Creating program	ecgpar.sas
Description	ECG Measurements
Unique identifier	DCRFID,ZECGPAR,ECG_DY
Sorted by	DCRFID,ZECGPAR,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
EPSEQNO	num	SEQUENCE NUMBER		Collected at CRF.
ECG_T	num	ECG TIME		Collected at CRF.
ECGSRCE	char	SOURCE ECG DATA		Collected at CRF.
ZECGPAR	char	ECG PARAMETER CODE		Collected at CRF.
ECGPAR	char	ECG PARAMETER		Collected at CRF.
ECGPAR_U	char	ECG MEASUREMENT UNIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECGVAL	num	ECG MEASUREMENT		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

1.4.16. ECG Requisition Numbers – ECGREF

Dataset	ECGREF
Creating program	ecgref.sas
Description	ECG Requisition Numbers
Unique identifier	DCRFID,EGLIMITS,VISIT,ECG_DY
Sorted by	DCRFID,EGLIMITS,VISIT,ECG_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: ECG_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECG_T	num	ECG TIME		Collected at CRF.
EGLIMITS	char	ECG WITHIN NORMAL LIMITS		Collected at CRF.
EGRELCHA	char	CLIN. RELEVANT CHANGES		Collected at CRF.
ECG_DY	num	RELATIVE ECG DAY		If ECG_D and REF.DATE not missing then perform below logic to calculate ECG_DY, If ECG_D less than REF.DATE then (ECG_D - REF.DATE). Else if ECG_D is greater than equal to REF.DATE then (ECG_D- REF.DATE) +1.

1.4.17. ESRS – ESRS

Dataset	ESRS
Creating program	esrs.sas
Description	Extrapyramidal Symptom Rating Scale
Unique identifier	DCRFID,ESGROUP,ESITEM,ESSCORE,SORT_NO,VISIT
Sorted by	DCRFID,ESGROUP,ESITEM,ESSCORE,SORT_NO,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity

Variable	Type	Label	Codes	Comments
VISIT	num	VISIT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
ESGROUP	char	ESRS SUBGROUP		Collected at CRF.
ESITEM	char	ESRS ITEM		Collected at CRF.
ESSCORE	char	ESRS SCORE		Collected at CRF.
ZESSCORE	num	ESRS SCORE CODE		Collected at CRF.

1.4.18. Evaluation of Injection– EVALINV

Dataset	EVALINV
Creating program	evalinv.sas
Description	Evaluation of Injection
Unique identifier	DCRFID,EITYPE,EISYMP,EISCORE,SORT_NO,VISIT
Sorted by	DCRFID,EITYPE,EISYMP,EISCORE,SORT_NO,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
EITYPE	char	EVALUATION OF INJECT. TYPE		Collected at CRF.
EISITE	char	EVALUATION OF INJECT. SITE		Collected at CRF.
EISYMP	char	EVALUATION OF INJECT. SYMPTOM		Collected at CRF.
EISCORE	char	EVALUATION OF INJECT. SCORE		Collected at CRF.

1.4.19. Inclusion and Exclusion Criteria – INEX

Dataset	INEX
Creating program	inex.sas
Description	Inclusion and Exclusion Criteria
Unique identifier	DCRFID,IETYPE,ZIECRIT
Sorted by	DCRFID,IETYPE,ZIECRIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
IETYPE	char	TYPE OF INCLUSION CRITERIA		Collected at CRF.

Variable	Type	Label	Codes	Comments
IECRIT	char	SELECTION CRITERIA		Collected at CRF.
ZIECRIT	char	SELECTION CRITERIA CODE		Collected at CRF.
IEYN	char	NON-ELIGIBILITY EXPR.		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

1.4.20. Laboratory Requisition Numbers – LABREF

Dataset	LABREF
Creating program	labref.sas
Description	Laboratory Requisition Numbers
Unique identifier	DCRFID ,VISIT,SAMPLEDY
Sorted by	DCRFID ,VISIT,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LSRELCHA,LABREFNO,ZLABID,LABID,SAMPLE_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLE_DY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D- REF.DATE) +1.

1.4.21. Laboratory Results – LABRES

Dataset	LABRES
Creating program	labres.sas
Description	Laboratory Results - Clinical Chemistry
Unique identifier	DCRFID,LABTEST,LABTSTNO,LABVAL,SAMPLEDY
Sorted by	DCRFID,LABTEST,LABTSTNO,LABVAL,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LABREFNO,ZLABID,LABID,SAMPLE_D

Variable	Type	Label	Codes	Comments
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LOWPATHO	num	LOWER PATH. LIMIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
UPPPATHO	num	UPPER PATH. LIMIT		Collected at CRF.
CFACTOR	num	CONVERSION FACTOR		Collected at CRF.
LABTSTNO	num	LAB. TEST NO.		Collected at CRF.
LABCLASS	char	LAB. TEST CLASS		Collected at CRF.
ENZYME	char	ENZYME		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
LABVAL	num	LAB. TEST VALUE		Collected at CRF.
LABVAL_V	char	LAB. TEST VALUE (VERB.)		Collected at CRF.
LABLOW	num	LOWER LIMIT		Collected at CRF.
LABUPP	num	UPPER LIMIT		Collected at CRF.
LABTST_U	char	LAB. TEST UNIT		Collected at CRF.
SIUNIT	char	STANDARD INTERNATIONAL UNIT		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLE_DY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D- REF.DATE) +1.

1.4.22. Laboratory Sample Info – LABSAM

Dataset	LABSAM
Creating program	labsam.sas
Description	Laboratory Sample Info
Unique identifier	DCRFID,HAEMOLYS ,SAMPLEDY
Sorted by	DCRFID,HAEMOLYS ,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: LABREFNO,FASTED,ZLABID,LABID,SAMPLE_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.
HAEMOLYS	char	SAMPLE HAEMOLYSED		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLE_DY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D- REF.DATE) +1.

1.4.23. Laboratory Urine Results – LABURI

Dataset	LABURI
Creating program	laburi.sas
Description	Laboratory Urine Results
Unique identifier	DCRFID,ZLABTEST ,SAMPLEDY
Sorted by	DCRFID,ZLABTEST ,SAMPLEDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: SAMPLE_D,LABID,LABREFNO,LUVAL,ZLABID

Variable	Type	Label	Codes	Comments
LABTEST	char	LAB. TEST		Collected at CRF.
ZLABTEST	char	LAB. TEST CODE		Collected at CRF.
LABTSTNO	num	LAB. TEST NO.		Collected at CRF.
LABCLASS	char	LAB. TEST CLASS		Collected at CRF.
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
SAMPLE_T	num	SAMPLING TIME		Collected at CRF.

Variable	Type	Label	Codes	Comments
LUVAL_V	char	URINE VALUE (VERB.)		Collected at CRF.
SAMPLEDY	num	RELATIVE SAMPLING DAY		If SAMPLE_D and REF.DATE not missing then perform below logic to calculate SAMPLE_DY, If SAMPLE_D less than REF.DATE then (SAMPLE_D - REF.DATE). Else if SAMPLE_D is greater than equal to REF.DATE then (SAMPLE_D- REF.DATE) +1.

1.4.24. Positive and Negative Syndrome Scale – PANSS

Dataset	PANSS
Creating program	panss.sas
Description	Positive and Negative Syndrome Scale
Unique identifier	DCRFID,PAGROUP,PASCORE,SORT_NO
Sorted by	DCRFID,PAGROUP,PASCORE,SORT_NO
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.

Variable	Type	Label	Codes	Comments
PAGROUP	char	PANSS SUBGROUP		Collected at CRF.
PAITEM	char	PANSS ITEM		Collected at CRF.
PASCORE	char	PANSS SCORE		Collected at CRF.
ZPASCORE	num	PANSS SCORE CODE		Collected at CRF.

1.4.25. Physical Examination – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	Physical Examination
Unique identifier	DCRFID,VISIT,PESYSTEM
Sorted by	DCRFID,VISIT,PESYSTEM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXAM_V

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
PESEQNO	num	SEQUENCE NUMBER		Collected at CRF.
PESYSTEM	char	PHYS. EXAM. BODY SYSTEM		Collected at CRF.
PERESULT	char	PHYS. EXAM. RESULT		Collected at CRF.
EXAM	char	PHYS. EXAM.		Collected at CRF.

1.4.26. Plasma Sample – PLASAM

Dataset	PLASAM
Creating program	plasam.sas
Description	Plasma Sample
Unique identifier	DCRFID,VISIT,PLASMADY
Sorted by	DCRFID,VISIT,PLASMADY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: PLASMA_D,PLREFNO,LABINTNO,LABREFNO

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
PLASMA_T	num	TIME OF PLASMA SAMP		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity

Variable	Type	Label	Codes	Comments
VISIT	char	VISIT		Collected at CRF.
PLASMADY	num	RELATIVE DAY OF PLASMA SAMP		If PLASMA_D and REF.DATE not missing then perform below logic to calculate PLASMADY, If PLASMA_D less than REF.DATE then (PLASMA_D - REF.DATE). Else if PLASMA_D is greater than equal to REF.DATE then (PLASMA_D- REF.DATE) +1.

1.4.27. Related AEs for Trial Termination or Death – RELAE

Dataset	RELAE
Creating program	relae.sas
Description	Related AEs for Trial Termination or Death
Unique identifier	DCRFID,RATYPE,AESEQNO
Sorted by	DCRFID,RATYPE,AESEQNO
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
RATYPE	char	AE CONSEQUENCE		Collected at CRF.
AESEQNO	num	AE SEQ.		Collected at CRF.

1.4.28. SF36 – SF36

Dataset	SF36
Creating program	sf36.sas
Description	SF-36 health survey
Unique identifier	DCRFID,SFITEM,SFSCORE,VISIT,SORT_NO
Sorted by	DCRFID,SFITEM,SFSCORE,VISIT,SORT_NO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SF36_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
SFITEM	char	SF-36 ITEM		Collected at CRF.
SFSCORE	char	SF-36 SCORE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZSFSCORE	num	SF-36 SCORE CODE		Collected at CRF.
SF36_DY	num	RELATIVE SF-36 VISIT DAY		If SF36_D and REF.DATE not missing then perform below logic to calculate SF36_DY, If SF36_D less than REF.DATE then (SF36_D - REF.DATE). Else if SF36_D is greater than equal to REF.DATE then (SF36_D- REF.DATE) +1.

1.4.29. Trial Description – TRLDESC

Dataset	TRLDESC
Creating program	trldesc.sas
Description	Trial Description
Unique identifier	TRIAL
Sorted by	TRIAL
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
COMPOND	char	COMPOUND NAME		Collected at CRF.
ZCOMPOND	char	COMPOUND NAME CODE		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

Variable	Type	Label	Codes	Comments
PLACONTR	char	PLACEBO CONTROL		Collected at CRF.
ACTCONTR	char	ACTIVE CONTROL		Collected at CRF.
DESIGN	char	DESIGN		Collected at CRF.
MULTCENT	char	MULTICENTRE		Collected at CRF.
BLKSIZE	num	BLOCK SIZE		Collected at CRF.
INDICAT	char	INDICATION		Collected at CRF.
AGEGRP	char	AGE GROUP		Collected at CRF.
SPECPOP	char	SPECIAL POPULATION		Collected at CRF.
SUBJTYPE	char	SUBJECT TYPE		Collected at CRF.
PRVPROT	char	PREV. PROTOCOL		Collected at CRF.

1.4.30. Trial Randomization – TRLRAND

Dataset	TRLRAND
Creating program	trlrand.sas
Description	Trial Randomization
Unique identifier	TRIAL,RANDGRP,RANDCODE
Sorted by	TRIAL,RANDGRP,RANDCODE
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
RANDCODE	char	RANDOMISATION CODE		Collected at CRF.

1.4.31. Trial Regimen – TRLREGM

Dataset	TRLREGM
Creating program	trlregm.sas
Description	Trial Regimen
Unique identifier	TRIAL,SEGMENT
Sorted by	TRIAL,SEGMENT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
RANDGRP	char	RANDOMISATION GROUP		Collected at CRF.
PHASE	char	TRIAL PHASE		Collected at CRF.
SEGMENT	num	TRIAL SEGMENT SEQ.		Collected at CRF.
BOX	char	BOX		Collected at CRF.
TREAT	char	TREATMENT		Collected at CRF.
FORMULAT	char	FORMULATION		Collected at CRF.
STRENGTH	num	STRENGTH OF 1 UNIT		Collected at CRF.
STRENG_U	char	STRENGTH UNIT		Collected at CRF.
NUMFORM	num	UNITS PER ADMIN.		Collected at CRF.
TMFREQ	char	ADMIN. FREQ.		Collected at CRF.
TMROUTE	char	ADMIN. ROUTE		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZTMROUTE	char	ADMIN. ROUTE CODE		Collected at CRF.
TMDUR	num	SEGMENT DURATION		Collected at CRF.
TMDUR_U	char	DURATION UNIT		Collected at CRF.
BLINDING	char	BLINDING		Collected at CRF.

1.4.32. Trial Termination – TRLTERM

Dataset	TRLTERM
Creating program	trlterm.sas
Description	Trial Termination
Unique identifier	DCRFID,TTFROMD,TTTYPE,TTREAS
Sorted by	DCRFID,TTFROMD,TTTYPE,TTREAS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: TTREAS_V,TTFROM_D

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
TTTYPE	char	TERM. TYPE		Collected at CRF.

Variable	Type	Label	Codes	Comments
TTREAS	char	TERM. REASON		Collected at CRF.
TTFROMDY	num	RELATIVE LAST CONTACT DAY		If TTFROM_D and REF.DATE not missing then perform below logic to calculate TTFROM_DY, If TTFROM_D less than REF.DATE then (TTFROM_D - REF.DATE). Else if TTFROM_D is greater than equal to REF.DATE then (TTFROM_D- REF.DATE) +1.

1.4.33. Vas – VAS

Dataset	VAS
Creating program	vas.sas
Description	Vas
Unique identifier	DCRFID,VASPAIN,VISIT
Sorted by	DCRFID,VASPAIN,VISIT
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
VASSYMPT	char	VAS TYPE		Collected at CRF.
VASPAIN	num	VAS SCORE		Collected at CRF.

1.4.34. Visit – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit
Unique identifier	DCRFID,VISIT,VISIT_DY
Sorted by	DCRFID,VISIT,VISIT_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: SUBINIT

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.
CGI	char	CLINICAL GLOBAL IMPRESSION		Collected at CRF.
CGICHA	char	CLINICAL GLOBAL IMPRESSION CHANGE		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISIT_DY	num	RELATIVE VISIT DAY		If VISIT_D and REF.DATE not missing then perform below logic to calculate VISIT_DY, If VISIT_D less than REF.DATE then (VISIT_D - REF.DATE). Else if VISIT_D is greater than equal to REF.DATE then (VISIT_D- REF.DATE) +1.

1.4.35. Vital Signs – VITSIGN

Dataset	VITSIGN
Creating program	vitsign.sas
Description	Vital Signs
Unique identifier	DCRFID,VISIT,SORT_NO,VSPOSIT,PULSE
Sorted by	DCRFID,VISIT,SORT_NO,VSPOSIT,PULSE
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	TRIAL ID.		Collected at CRF.
DCRFID	char	CRF ID ASSIGNED FOR DE-IDENTITY		Randomly assigned crf id for de-identity
VISIT	num	VISIT		Collected at CRF.
SORT_NO	num	PREFILL SORT NO		Collected at CRF.
VSPOSIT	char	POSITION		Collected at CRF.
PULSE	num	PULSE, BEATS/MIN		Collected at CRF.

Variable	Type	Label	Codes	Comments
SBP	num	SYSTOLIC BP, MMHG		Collected at CRF.
DBP	num	DIASTOLIC BP, MMHG		Collected at CRF.
WEIGHT	num	WEIGHT		Collected at CRF.
WEIGHT_U	char	WEIGHT UNIT		Collected at CRF.