

Clinical Development

JNJ-16977831

R092670-PSY3008

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 value variables will be removed.
- Partial date's relative day cannot be calculated.
- Empty comments data will be submitted due to sensitivity of data.
- Due to sensitive information SURGERY dataset will be removed.
- POPU_OLD ,POPU and TEAE are analysis datasets, hence it will not be submitted.

1.3. Data Files

The R092670-PSY3008 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demography – DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Demography
Unique identifier	DPANO
Sorted by	DPANO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: INIT, RANDNO, INFDMY, DOBDMY, RACE_O, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGE	char	Age in Years		<p>Date of birth collected but can not be submitted as per HIPAA rules hence deriving AGE element derivation follows below rule:</p> $\text{AGE} = \text{int}((\text{INFDMY} - \text{BIRTHDT})/365.25)$ <p>If age greater than 89+ years then will be grouped as per HIPAA rules.</p>

1.4.2. Addate – ADDATE

Dataset	ADDATE
Creating program	addate.sas
Description	Addate
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements:</p> <p>ADVISMV, PAGE</p>

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity

Variable	Type	Label	Codes	Comments
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
ADVISDY	num	Relative Visit Day of Administration		If ADVISDMY and INFDMY not missing then perform below logic to calculate ADVISDY, If ADVISDMY less than INFDMY then (ADVISDMY - INFDMY).Else if ADVISDMY is greater than equal to INFDMY then (ADVISDMY- INFDMY) +1.

1.4.3. Administration – ADM

Dataset	ADM
Creating program	adm.sas
Description	Administration
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: REASON, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
NA	num	Not Applicable		Collected at CRF.
GROUP	char	Group		Collected at CRF.
PODOSE	char	Dose of per os		Collected at CRF.
IMDOSE	char	Dose of injection intramuscular		Collected at CRF.
DOADJ	char	Dose adjusted		Collected at CRF.

Variable	Type	Label	Codes	Comments
GROUP1	num	GROUP1		Collected at CRF.
FLAG	num	Flag		Collected at CRF.

1.4.4. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DPANO,PT_CODE,SOC_CODE,SEV,ACT,OUT, SAE
Sorted by	DPANO,PT_CODE,SOC_CODE,SEV,ACT,OUT, SAE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: AENME, STADMY, ENDDMY, PAGE, AENME_ENG

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
AE	char	Were any AE		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
SEV	char	Severity		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACT	char	Action Taken		Collected at CRF.
THERAPY	char	If Therapy		Collected at CRF.
REL	char	Relationship		Collected at CRF.
OUT	char	Outcome		Collected at CRF.
SAE	char	If Serious Adverse Event		Collected at CRF.
PT_NAME	char	Pt_name		Collected at CRF.
PT_CODE	char	pt_code		Collected at CRF.
SOC_NAME	char	Soc_name		Collected at CRF.
SOC_CODE	char	Soc_code		Collected at CRF.
LLT_NAME	char	llt_name		Collected at CRF.
LLT_CODE	char	llt_code		Collected at CRF.
STADY	num	Relative Start Day		If STADMY and INFDMY not missing then perform below logic to calculate STADY, If STADMY less than INFDMY then (STADMY - INFDMY).Else if STADMY is greater than equal to INFDMY then (STADMY- INFDMY) +1.
ENDDY	num	Relative End Day		If ENDDMY and INFDMY not missing then perform below logic to calculate ENDDY, If ENDDMY less than INFDMY then (ENDDMY - INFDMY).Else if ENDDMY is greater than equal to INFDMY then (ENDDMY- INFDMY) +1.

1.4.5. Abnormal Involuntary Movement Scale - AIMS

Dataset	AIMS
Creating program	aims.sas
Description	Abnormal Involuntary Movement Scale
Unique identifier	DPANO,VISIT, REPEATSN
Sorted by	DPANO,VISIT, REPEATSN
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
AIMSG	num	Group of Abnormal Involuntary Movement Scale Code		Collected at CRF.
AIMSG_C	char	Group of Abnormal Involuntary Movement Scale		Collected at CRF.

Variable	Type	Label	Codes	Comments
AIMSITEM	num	Item of Abnormal Involuntary Movement Scale Code		Collected at CRF.
AIMSITEM_C	char	Item of Abnormal Involuntary Movement Scale		Collected at CRF.
AIMS	num	Abnormal Involuntary Movement Scale		Collected at CRF.

1.4.6. Barnes Akathisia Rating Scale - BARS

Dataset	BARS
Creating program	bars.sas
Description	Barnes Akathisia Rating Scale
Unique identifier	DPANO,VISIT, REPEATSN
Sorted by	DPANO,VISIT, REPEATSN
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Number		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
BARSTEM	num	Item of Barnes Code		Collected at CRF.
BARSTEM_C	char	Item of Barnes		Collected at CRF.
BARS	num	Barnes		Collected at CRF.

1.4.7.Brdate - BRDATE

Dataset	BRDATE
Creating program	brdate.sas
Description	Brdate
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: BRVISDMY, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity

Variable	Type	Label	Codes	Comments
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
BRVISDY	num	Relative Visit Day of Blinded Rater		If BRVISDMY and INFDMY not missing then perform below logic to calculate BRVISDY, If BRVISDMY less than INFDMY then (BRVISDMY - INFDMY).Else if BRVISDMY is greater than equal to INFDMY then (BRVISDMY- INFDMY) +1.

1.4.8. Clinical Global Impression - CGI

Dataset	CGI
Creating program	cgi.sas
Description	Clinical Global Impression
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity

Variable	Type	Label	Codes	Comments
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
CGIS	num	CGI-S Code		Collected at CRF.
CGIS_C	char	CGI-S		Collected at CRF.
CGII	num	CGI-I Code		Collected at CRF.
CGII_C	char	CGI-I		Collected at CRF.
EFF	num	Efficacy Index		Collected at CRF.

1.4.9. Comments - COMM

Dataset	COMM
Creating program	comm.sas
Description	Comments
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comments data is sensitive data, contains free text information. Will be submitted empty dataset.

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Empty data will be submitted.
DPANO	char	Subject No. Assigned for De-identity		Empty data will be submitted.
REPEATSN	num	Repeat Number		Empty data will be submitted.
ITEM	char	Item		Empty data will be submitted.

1.4.10. Concomitant Medication - CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	Concomitant Medication
Unique identifier	DPANO, REPEATSN
Sorted by	DPANO, REPEATSN
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 or due to non significant elements: DRGNME, INDIC, STADMY, ENDDMY, PAGE, DRGNME_ENG, CM_TERM, INDIC_ENG, TEXT, ATC1CHN, ATC2CHN, ATC3CHN, ATC4CHN, TEXT_CHN

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
CONMED	char	Were any concomitant medication		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
DOSE	char	Dose		Collected at CRF.
FREQ	char	Frequency		Collected at CRF.
ROUTE	char	Route		Collected at CRF.

Variable	Type	Label	Codes	Comments
STA	char	Start Status		Collected at CRF.
END	char	End Status		Collected at CRF.
ATC_CODE	char	ATC_CODE		Collected at CRF.
PTNME	char	PTNME		Collected at CRF.
ATC1	char	Anatomical Main Group		Collected at CRF.
ATC2	char	Therapeutic Subgroup		Collected at CRF.
ATC3	char	Pharmacological Subgroup		Collected at CRF.
ATC4	char	Chemicals Subgroup		Collected at CRF.
STADY	num	Relative Start Day		If STADMY and INFDMY not missing then perform below logic to calculate STADY, If STADMY less than INFDMY then (STADMY - INFDMY).Else if STADMY is greater than equal to INFDMY then (STADMY- INFDMY) +1.
ENDDY	num	Relative End Day		If ENDDMY and INFDMY not missing then perform below logic to calculate ENDDY, If ENDDMY less than INFDMY then (ENDDMY - INFDMY).Else if ENDDMY is greater than equal to INFDMY then (ENDDMY- INFDMY) +1.

1.4.11. Visit Date - DATE

Dataset	DATE
Creating program	date.sas
Description	Visit Date
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: VISDMY, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
VISDY	num	Relative Visit Day		If VISDMY and INFDMY not missing then perform below logic to calculate VISDY, If VISDMY less than INFDMY then (VISDMY - INFDMY).Else if VISDMY is greater than equal to INFDMY then (VISDMY- INFDMY) +1.

1.4.12. Drug - DRUG

Dataset	DRUG
Creating program	drug.sas
Description	Drug
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: IMDMY, PODMY, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
GROUP	char	Group		Collected at CRF.
IMNA	num	Not Applicable Injection Intramuscular		Collected at CRF.
IMNO	char	Number of Injection Intramuscular		Collected at CRF.
IMDOSE	char	Dose of injection intramuscular		Collected at CRF.
PONA	num	Not Applicable per os		Collected at CRF.

Variable	Type	Label	Codes	Comments
PONO	char	Number of per os		Collected at CRF.
PODOSE	char	Dose of per os		Collected at CRF.
SITE	char	Site		Collected at CRF.
PART	char	Part		Collected at CRF.
IMDY	num	Relative Day of Injection Intramuscular		If IMDMY and INFDMY not missing then perform below logic to calculate IMDY, If IMDMY less than INFDMY then (IMDMY - INFDMY).Else if IMDMY is greater than equal to INFDMY then (IMDMY- INFDMY) +1.
PODY	num	Relative Day of per os		If PODMY and INFDMY not missing then perform below logic to calculate PODY, If PODMY less than INFDMY then (PODMY - INFDMY).Else if PODMY is greater than equal to INFDMY then (PODMY- INFDMY) +1.

1.4.13. Electrocardiogram - ECG

Dataset	ECG
Creating program	ecg.sas
Description	Electrocardiogram
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: SPEC, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
PR	num	PR		Collected at CRF.
QRS	num	QRS		Collected at CRF.
QTC	num	QTc		Collected at CRF.
QT	num	QT		Collected at CRF.
ECGRSL	char	ECG Result		Collected at CRF.
ECGCH	char	ECG Result Change		Collected at CRF.

1.4.14. Eligible - ELIG

Dataset	ELIG
Creating program	elig.sas
Description	Eligible
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
ELIG	char	Eligible		Collected at CRF.

1.4.15. End of Trial Information - EOS

Dataset	EOS
Creating program	eos.sas
Description	End of Trial Information
Unique identifier	DPANO, TERM, COMP
Sorted by	DPANO, TERM, COMP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: LVDMY, LIMDMY, REASON, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
COMP	char	If Study Completed		Collected at CRF.
TERM	char	Primary Cause of Withdrawal		Collected at CRF.

Variable	Type	Label	Codes	Comments
LVDY	num	Relative Last Visit Day		If LVDMY and INFDMY not missing then perform below logic to calculate LVDY, If LVDMY less than INFDMY then (LVDMY - INFDMY).Else if LVDMY is greater than equal to INFDMY then (LVDMY- INFDMY) +1.
LIMDY	num	Relative Last Injection Day		If LIMDMY and INFDMY not missing then perform below logic to calculate LIMDY, If LIMDMY less than INFDMY then (LIMDMY - INFDMY).Else if LIMDMY is greater than equal to INFDMY then (LIMDMY- INFDMY) +1.

1.4.16. Evaluation of Injection Site - EVAINJ

Dataset	EVAINJ
Creating program	evainj.sas
Description	Drug Administrator Evaluation of Injection Site
Unique identifier	DPANO,VISIT, REPEATSN
Sorted by	DPANO,VISIT, REPEATSN
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
EVANA	num	Not Applicable		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
ITEM	num	Item Code		Collected at CRF.
ITEM_C	char	Item		Collected at CRF.
EVA	num	Evaluation Code		Collected at CRF.
EVA_C	char	Evaluation		Collected at CRF.

1.4.17. Group - GROUP

Dataset	GROUP
Creating program	group.sas
Description	Group
Unique identifier	DPANO, GROUP
Sorted by	DPANO, GROUP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: RANDDMY, RANDNO, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
GROUP	char	Group		Collected at CRF.
RANDDY	num	Relative Day of Randomization		If RANDDMY and INFDMY not missing then perform below logic to calculate RANDDY, If RANDDMY less than INFDMY then (RANDDMY - INFDMY).Else if RANDDMY is greater than equal to INFDMY then (RANDDMY- INFDMY) +1.

1.4.18. Inclusion/Exclusion Criteria - INCEXC

Dataset	INCEXC
Creating program	incexc.sas
Description	Inclusion/Exclusion Criteria
Unique identifier	DPANO
Sorted by	DPANO
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
IN1	char	Inclusion criterion 1		Collected at CRF.
IN2	char	Inclusion criterion 2		Collected at CRF.
IN3	char	Inclusion criterion 3		Collected at CRF.
IN4	char	Inclusion criterion 4		Collected at CRF.
IN5	char	Inclusion criterion 5		Collected at CRF.
IN6	char	Inclusion criterion 6		Collected at CRF.
IN7	char	Inclusion criterion 7		Collected at CRF.

Variable	Type	Label	Codes	Comments
IN8	char	Inclusion criterion 8		Collected at CRF.
EX1	char	Exclusion criterion 1		Collected at CRF.
EX2	char	Exclusion criterion 2		Collected at CRF.
EX3	char	Exclusion criterion 3		Collected at CRF.
EX4	char	Exclusion criterion 4		Collected at CRF.
EX5	char	Exclusion criterion 5		Collected at CRF.
EX6	char	Exclusion criterion 6		Collected at CRF.
EX7	char	Exclusion criterion 7		Collected at CRF.
EX8	char	Exclusion criterion 8		Collected at CRF.
EX9	char	Exclusion criterion 9		Collected at CRF.
EX10	char	Exclusion criterion 10		Collected at CRF.
EX11	char	Exclusion criterion 11		Collected at CRF.
EX12	char	Exclusion criterion 12		Collected at CRF.
EX13	char	Exclusion criterion 13		Collected at CRF.
EX14	char	Exclusion criterion 14		Collected at CRF.
EX15	char	Exclusion criterion 15		Collected at CRF.
EX16	char	Exclusion criterion 16		Collected at CRF.
EX17	char	Exclusion criterion 17		Collected at CRF.
EX18	char	Exclusion criterion 18		Collected at CRF.
EX19	char	Exclusion criterion 19		Collected at CRF.

Variable	Type	Label	Codes	Comments
EX20	char	Exclusion criterion 20		Collected at CRF.
EX21	char	Exclusion criterion 21		Collected at CRF.

1.4.19. Laboratory Evaluation - LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Evaluation
Unique identifier	DPANO,VISIT, REPEATSN
Sorted by	DPANO,VISIT, REPEATSN
Notes	Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information: LABVAL, PAGE, LLN, ULN, UNIT

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
OUNIT	char	Other Unit		Collected at CRF.

Variable	Type	Label	Codes	Comments
NORM	char	If Normal		Collected at CRF.
CLIN	char	Clinically Significant		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBTEST	char	Lab Test or Examination Name		Collected at CRF.
LABVAL_ENG	char	Lab Test Value, English Translated		Collected at CRF.
LLN_ENG	char	Lower Limit of Normal Range, English Translated		Collected at CRF.
ULN_ENG	char	Upper Limit of Normal Range, English Translated		Collected at CRF.
UNIT_ENG	char	Unit, English Translated		Collected at CRF.
STD_LLN	char	Lower Limit of Normal Range, standardize		Collected at CRF.
STD_ULN	char	Upper Limit of Normal Range, standardize		Collected at CRF.
STD_UNIT	char	Unit, standardized		Collected at CRF.
STD_LABVAL	char	Lab Test Value, standardized		Collected at CRF.

1.4.20. Medical History - MEDHIS

Dataset	MEDHIS
Creating program	medhis.sas
Description	Medical History
Unique identifier	DPANO, REPEATSN
Sorted by	DPANO, REPEATSN
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: MH, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
REPEATSN	num	Repeat Number		Collected at CRF.
NORM	char	If Normal		Collected at CRF.

1.4.21. Opsyhis - OPSYHIS

Dataset	OPSYHIS
Creating program	opsyhis.sas
Description	Opsyhis
Unique identifier	DPANO, REPEATSN
Sorted by	DPANO, REPEATSN
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: DIANME, DIADMY, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
OPS	char	Other Psychiatric History		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
ACTIVE	char	Currently Active		Collected at CRF.
DIADY	num	Relative Diagnosis Day		If DIADMY and INFDMY not missing then perform below logic to calculate DIADY, If DIADMY less than INFDMY then (DIADMY - INFDMY).Else if DIADMY is greater than equal to INFDMY then (DIADMY- INFDMY) +1.

1.4.22. Positive and Negative Syndrome Scale - PANSS

Dataset	PANSS
Creating program	panss.sas
Description	Positive and Negative Syndrome Scale
Unique identifier	DPANO,VISIT, REPEATSN
Sorted by	DPANO,VISIT, REPEATSN
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
PANSSG	num	PANSS Group Code		Collected at CRF.
PANSSG_C	char	PANSS Group		Collected at CRF.
PANSSIT	num	PANSS Item Code		Collected at CRF.
PANSSIT_C	char	PANSS Item		Collected at CRF.

Variable	Type	Label	Codes	Comments
PANSS	num	Positive and Negative Syndrome Scale Code		Collected at CRF.
PANSS_C	char	Positive and Negative Syndrome Scale		Collected at CRF.
TOTAL	num	Total Scale		Collected at CRF.

1.4.23. Physical Examination - PHY

Dataset	PHY
Creating program	phy.sas
Description	Physical Examination
Unique identifier	DPANO,VISIT, REPEATSN
Sorted by	DPANO,VISIT, REPEATSN
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PHY, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
REPEATSN	num	Repeat Number		Collected at CRF.
NORM	char	If Normal		Collected at CRF.

1.4.24. Pregnancy Test - PREG

Dataset	PREG
Creating program	preg.sas
Description	Pregnancy Test
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
PREG	char	Pregnancy Result		Collected at CRF.

1.4.25. Personal And Society Performance Scale - PSP

Dataset	PSP
Creating program	psp.sas
Description	Personal And Society Performance Scale
Unique identifier	DPANO,VISIT, REPEATSN
Sorted by	DPANO,VISIT, REPEATSN
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
PSPITEM	num	PSP Item Code		Collected at CRF.
PSPITEM_C	char	PSP Item		Collected at CRF.
PSP	num	PSP Code		Collected at CRF.
PSP_C	char	PSP		Collected at CRF.
SCORE	num	Score		Collected at CRF.

1.4.26. Randomization - RAND

Dataset	RAND
Creating program	rand.sas
Description	Randomization
Unique identifier	DPANO
Sorted by	DPANO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: RANDDMY, RANDNO, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
RANDDY	num	Relative Day of Randomization		If RANDDMY and INFDMY not missing then perform below logic to calculate RANDDY, If RANDDMY less than INFDMY then (RANDDMY - INFDMY).Else if RANDDMY is greater than equal to INFDMY then (RANDDMY- INFDMY) +1.

1.4.27. Risperdal - RISPERDAL

Dataset	RISPERDAL
Creating program	risperdal.sas
Description	Risperdal
Unique identifier	DPANO, REPEATSN
Sorted by	DPANO, REPEATSN
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: TAKEDMY, REASON, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
NA	num	Not Applicable		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
ANTIDOSE	char	Anticipant Dose		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTUDOSE	char	Actual Dose		Collected at CRF.
TAKEDY	num	Relative Taken day		If TAKEDMY and INFDMY not missing then perform below logic to calculate TAKEDY, If TAKEDMY less than INFDMY then (TAKEDMY - INFDMY).Else if TAKEDMY is greater than equal to INFDMY then (TAKEDMY- INFDMY) +1.

1.4.28. Serious Adverse Event - SAE

Dataset	SAE
Creating program	sae.sas
Description	Serious Adverse Event
Unique identifier	DPANO, REPEATSN
Sorted by	DPANO, REPEATSN
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 or due to non significant elements or due to missing values: SUBINIT, SUBNUM, SEX, DOBDMY, AENME, STADMY, ENDDMY, DEADMY, REASON, HOPDMY, RANDNO, MEDNO, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity

Variable	Type	Label	Codes	Comments
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
HT	num	Height		Collected at CRF.
HTUNIT	char	Height Unit		Collected at CRF.
WT	num	Weight (kg)		Collected at CRF.
WTUNIT	char	Weight Unit		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
STAHM	char	Start Time		Collected at CRF.
SEV	char	Severity		Collected at CRF.
RELPA	char	Relation to Primary Agent		Collected at CRF.
RELTP	char	Relation to Trial Procedure		Collected at CRF.
OUT	char	Outcome		Collected at CRF.
SAECAT	char	SAE Category		Collected at CRF.
CONMED	char	ConMed taken for AE		Collected at CRF.
AUTOPSY	num	Was autopsy performed		Collected at CRF.
TRDE	char	Trial Design		Collected at CRF.
MUPH	char	Multi-phased		Collected at CRF.
BLIND	char	Blind Broken		Collected at CRF.

Variable	Type	Label	Codes	Comments
STADY	num	Relative Start Day		If STADMY and INFDMY not missing then perform below logic to calculate STADY, If STADMY less than INFDMY then (STADMY - INFDMY).Else if STADMY is greater than equal to INFDMY then (STADMY- INFDMY) +1.
ENDDY	num	Relative End Day		If ENDDMY and INFDMY not missing then perform below logic to calculate ENDDY, If ENDDMY less than INFDMY then (ENDDMY - INFDMY).Else if ENDDMY is greater than equal to INFDMY then (ENDDMY- INFDMY) +1.
DEADY	num	Relative Day of death		If DEADMY and INFDMY not missing then perform below logic to calculate DEADY, If DEADMY less than INFDMY then (DEADMY - INFDMY).Else if DEADMY is greater than equal to INFDMY then (DEADMY- INFDMY) +1.
HOPDY	num	Relative Day of hospital admission		If HOPDMY and INFDMY not missing then perform below logic to calculate HOPDY, If HOPDMY less than INFDMY then (HOPDMY - INFDMY).Else if HOPDMY is greater than equal to INFDMY then (HOPDMY- INFDMY) +1.

1.4.29. Simpson and Angus Rating Scale - SAS

Dataset	SAS
Creating program	sas.sas
Description	Simpson and Angus Rating Scale
Unique identifier	DPANO,VISIT, REPEATSN
Sorted by	DPANO,VISIT, REPEATSN
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
SASITEM	num	Item of SAS Code		Collected at CRF.
SASITEM_C	char	Item of SAS		Collected at CRF.
SAS	num	Simpson-Angus Code		Collected at CRF.
SAS_C	char	Simpson-Angus		Collected at CRF.

1.4.30. Simpson – Angus Adverse Event - SASAE

Dataset	SASAE
Creating program	sasae.sas
Description	Simpson -Angus Adverse Event
Unique identifier	DPANO, REPEATSN
Sorted by	DPANO, REPEATSN
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: SM, STADMY, ENDDMY, PAGE, SM_ENG, EPS_TERM

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
SAS	char	Were any SAS AE		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
SASAE	char	Simpson-Angus Adverse Event		Collected at CRF.
SEV	char	Severity		Collected at CRF.
ACT	char	Action Taken		Collected at CRF.
THERAPY	char	If Therapy		Collected at CRF.
REL	char	Relationship		Collected at CRF.

Variable	Type	Label	Codes	Comments
OUT	char	Outcome		Collected at CRF.
SAE	char	If Serious Adverse Event		Collected at CRF.
MEPSCAT	char	mepscat CRF		Collected at CRF.
PT_NAME	char	Pt_name		Collected at CRF.
PT_CODE	char	pt_code		Collected at CRF.
SOC_NAME	char	Soc_name		Collected at CRF.
SOC_CODE	char	Soc_code		Collected at CRF.
LLT_NAME	char	llt_name		Collected at CRF.
LLT_CODE	char	llt_code		Collected at CRF.
STADY	num	Relative Start Day		If STADMY and INFDMY not missing then perform below logic to calculate STADY, If STADMY less than INFDMY then (STADMY - INFDMY).Else if STADMY is greater than equal to INFDMY then (STADMY- INFDMY) +1.
ENDDY	num	Relative End Day		If ENDDMY and INFDMY not missing then perform below logic to calculate ENDDY, If ENDDMY less than INFDMY then (ENDDMY - INFDMY).Else if ENDDMY is greater than equal to INFDMY then (ENDDMY- INFDMY) +1.

1.4.31. Schizophrenia History - SCHIZOHIS

Dataset	SCHIZOHIS
Creating program	schizohis.sas
Description	Schizophrenia History
Unique identifier	DPANO, FDIADY
Sorted by	DPANO, FDIADY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: FDIADMY, FTRTDMY, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
FDNK	char	Unknown First Diagnosis Date for Schizophrenia		Collected at CRF.
FTNK	char	Unknown First Treatment Date for Schizophrenia		Collected at CRF.
EPISODE	char	No. of Episodes		Collected at CRF.
EPNK	char	Unknown the episodes number of Schizophrenia		Collected at CRF.

Variable	Type	Label	Codes	Comments
FDIADY	num	Relative First Diagnosis Day for Schizophrenia		If FDIADMY and INFDMY not missing then perform below logic to calculate FDIADY, If FDIADMY less than INFDMY then (FDIADMY - INFDMY).Else if FDIADMY is greater than equal to INFDMY then (FDIADMY- INFDMY) +1.
FTRTDY	num	Relative First Treatment Day for Schizophrenia		If FTRTDMY and INFDMY not missing then perform below logic to calculate FTRTDY, If FTRTDMY less than INFDMY then (FTRTDMY - INFDMY).Else if FTRTDMY is greater than equal to INFDMY then (FTRTDMY- INFDMY) +1.

1.4.32. Schizophrenia Type - SCHIZOT

Dataset	SCHIZOT
Creating program	schizot.sas
Description	Schizophrenia Type
Unique identifier	DPANO, SCHIZOT
Sorted by	DPANO, SCHIZOT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: DIADMY, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
SCHIZOT	char	Schizophrenia Type		Collected at CRF.
DIADY	num	Relative Diagnosis Day		If DIADMY and INFDMY not missing then perform below logic to calculate DIADY, If DIADMY less than INFDMY then (DIADMY - INFDMY).Else if DIADMY is greater than equal to INFDMY then (DIADMY- INFDMY) +1.

1.4.33. Stagent - STAGENT

Dataset	STAGENT
Creating program	stagent.sas
Description	Stagent
Unique identifier	DPANO, REPEATSN
Sorted by	DPANO, REPEATSN
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: STAGENT, BANO, STADMY, ENDDMY, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
REPEATSN	num	Repeat Number		Collected at CRF.
AGENT	char	Study agent		Collected at CRF.
DOSE	char	Dose		Collected at CRF.
UNIT	char	Unit		Collected at CRF.
ROUTE	char	Route		Collected at CRF.
STAHM	char	Start Time		Collected at CRF.

Variable	Type	Label	Codes	Comments
ENDHM	char	End Time		Collected at CRF.
ACT	char	Action Taken		Collected at CRF.
STADY	num	Relative Start Day		If STADMY and INFDMY not missing then perform below logic to calculate STADY, If STADMY less than INFDMY then (STADMY - INFDMY).Else if STADMY is greater than equal to INFDMY then (STADMY- INFDMY) +1.
ENDDY	num	Relative End Day		If ENDDMY and INFDMY not missing then perform below logic to calculate ENDDY, If ENDDMY less than INFDMY then (ENDDMY - INFDMY).Else if ENDDMY is greater than equal to INFDMY then (ENDDMY- INFDMY) +1.

1.4.34. Tolerance Test - TOLT

Dataset	TOLT
Creating program	tolt.sas
Description	Tolerance Test
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: SPEC, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
TOL	char	Tolerance		Collected at CRF.

1.4.35. Toltpa - TOLTPA

Dataset	TOLTPA
Creating program	toltpa.sas
Description	Toltpa
Unique identifier	DPANO, REPEATSN
Sorted by	DPANO, REPEATSN
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: DISPDMY, MEDNO, TAKEDMY, REASON, PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
TOL	char	Tolerance		Collected at CRF.
REPEATSN	num	Repeat Number		Collected at CRF.
ANTIDOSE	char	Anticipant Dose		Collected at CRF.
ACTUDOSE	char	Actual Dose		Collected at CRF.

Variable	Type	Label	Codes	Comments
DISPDY	num	Relative Day of Dispensed		If DISPDMY and INFDMY not missing then perform below logic to calculate DISPDY, If DISPDMY less than INFDMY then (DISPDMY - INFDMY).Else if DISPDMY is greater than equal to INFDMY then (DISPDMY- INFDMY) +1.
TAKEDY	num	Relative Taken day		If TAKEDMY and INFDMY not missing then perform below logic to calculate TAKEDY, If TAKEDMY less than INFDMY then (TAKEDMY - INFDMY).Else if TAKEDMY is greater than equal to INFDMY then (TAKEDMY- INFDMY) +1.

1.4.36. Visual Analogue Scale - VAS

Dataset	VAS
Creating program	vas.sas
Description	Visual Analogue Scale
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
SLS	num	Scale of Sleep Quality		Collected at CRF.
DRS	num	Scale of Drowsiness		Collected at CRF.

1.4.37. Vass - VASS

Dataset	VASS
Creating program	vass.sas
Description	Vass
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
FSSNA	num	Not Applicable Soreness of feeling		Collected at CRF.
FSS	num	Soreness of feeling		Collected at CRF.
INJSNA	num	Not Applicable Injection site		Collected at CRF.
INJS	num	Soreness of Injection site		Collected at CRF.

1.4.38. Vital Signs- VITAL

Dataset	VITAL
Creating program	vital.sas
Description	Vital Signs
Unique identifier	DPANO, VISIT
Sorted by	DPANO, VISIT
Notes	Below listed variables will be dropped from dataset due to non significant elements: PAGE

Variable	Type	Label	Codes	Comments
DCENTER	char	Center No. Assigned for De-identity		Randomly assigned Center No. for De-identity
DPANO	char	Subject No. Assigned for De-identity		Randomly assigned Subject No. for De-identity
VISIT	char	Visit Number		Collected at CRF.
SUPHR	num	Heart Rate (Supine after 5 min)		Collected at CRF.
STHR	num	Heart Rate (Standing after 2 min)		Collected at CRF.
SUPSBP	num	Systolic Blood Pressure (Supine after 5 min)		Collected at CRF.
SUPDBP	num	Diastolic Blood Pressure (Supine after 5 min)		Collected at CRF.

Variable	Type	Label	Codes	Comments
STSBP	num	Systolic Blood Pressure (Standing after 2 min)		Collected at CRF.
STDBP	num	Diastolic Blood Pressure (Standing after 2 min)		Collected at CRF.
HT	num	Height		Collected at CRF.
WT	num	Weight		Collected at CRF.
BMI	num	BMI		Collected at CRF.
WL	num	Waistline		Collected at CRF.