

Clinical Development

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RIS-USA-150

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.
- Empty comments dataset COMMNTDB will be submitted due to sensitivity of data.
- MAP Dataset is containing insignificant information will not be submitted
- For randomized subjects, DEMO.VISITDAT will be used as Reference Date (referred as REF. DATE in the document) to derive relative days. For screen failure subjects, RAND.VISITDAT will be used as a Reference date (referred as REF. DATE in the document) to derive relative day.

1.3. Data Files

The RIS-USA-150 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. Demographics – DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Demographics
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,LIVSPEC,EDUSPEC,VISITDAT,DOBV

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
GENDER	num	Gender		Collected at CRF.
GENDER_C	char	Gender (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
ETHNICIT	num	Ethnicity		Collected at CRF.
ETHNICIT_C	char	Ethnicity (char)		Collected at CRF.
LIVARRG	num	Living Arrangement		Collected at CRF.
LIVARRG_C	char	Living Arrangement (char)		Collected at CRF.
EDUPLACE	num	Educational Placement		Collected at CRF.
EDUPLACE_C	char	Educational Placement (char)		Collected at CRF.
EDULEVEL	num	Educational Level		Collected at CRF.
EDULEVEL_C	char	Educational Level (char)		Collected at CRF.
INCOME	num	Annual Household Income		Collected at CRF.
INCOME_C	char	Annual Household Income (char)		Collected at CRF.
NUMADULT	num	Total Number of Adults Living In Home		Collected at CRF.
NUMCHILD	num	Total Number of Children Living In Home		Collected at CRF.
AGE	char	Age in Years		If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.

1.4.2. Aberrant Behavior Checklist – ABC

Dataset	ABC
Creating program	abc.sas
Description	Aberrant Behavior Checklist
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,RATERID,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
Q01	num	Excessively Active		Collected at CRF.
Q01_C	char	Excessively Active (char)		Collected at CRF.
Q02	num	Injures Self On Purpose		Collected at CRF.
Q02_C	char	Injures Self On Purpose (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q03	num	Listless, Sluggish, Inactive		Collected at CRF.
Q03_C	char	Listless, Sluggish, Inactive (char)		Collected at CRF.
Q04	num	Aggressive To Others		Collected at CRF.
Q04_C	char	Aggressive To Others (char)		Collected at CRF.
Q05	num	Seeks Isolation From Others		Collected at CRF.
Q05_C	char	Seeks Isolation From Others (char)		Collected at CRF.
Q06	num	Meaningless, Recurring Body Movements		Collected at CRF.
Q06_C	char	Meaningless, Recurring Body Movements (char)		Collected at CRF.
Q07	num	Boisterous		Collected at CRF.
Q07_C	char	Boisterous (char)		Collected at CRF.
Q08	num	Screams Inappropriately		Collected at CRF.
Q08_C	char	Screams Inappropriately (char)		Collected at CRF.
Q09	num	Talks Excessively		Collected at CRF.
Q09_C	char	Talks Excessively (char)		Collected at CRF.
Q10	num	Temper Tantrums		Collected at CRF.
Q10_C	char	Temper Tantrums (char)		Collected at CRF.
Q11	num	Stereotyped Behavior		Collected at CRF.
Q11_C	char	Stereotyped Behavior (char)		Collected at CRF.
Q12	num	Preoccupied; Stares Into Space		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q12_C	char	Preoccupied; Stares Into Space (char)		Collected at CRF.
Q13	num	Impulsive		Collected at CRF.
Q13_C	char	Impulsive (char)		Collected at CRF.
Q14	num	Irritable And Whiny		Collected at CRF.
Q14_C	char	Irritable And Whiny (char)		Collected at CRF.
Q15	num	Restless		Collected at CRF.
Q15_C	char	Restless (char)		Collected at CRF.
Q16	num	Withdrawn		Collected at CRF.
Q16_C	char	Withdrawn (char)		Collected at CRF.
Q17	num	Odd, Bizarre In Behavior		Collected at CRF.
Q17_C	char	Odd, Bizarre In Behavior (char)		Collected at CRF.
Q18	num	Disobedient		Collected at CRF.
Q18_C	char	Disobedient (char)		Collected at CRF.
Q19	num	Yells At Inappropriate Times		Collected at CRF.
Q19_C	char	Yells At Inappropriate Times (char)		Collected at CRF.
Q20	num	Fixed Facial Expression		Collected at CRF.
Q20_C	char	Fixed Facial Expression (char)		Collected at CRF.
Q21	num	Disturbs Others		Collected at CRF.
Q21_C	char	Disturbs Others (char)		Collected at CRF.
Q22	num	Repetitive Speech		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q22_C	char	Repetitive Speech (char)		Collected at CRF.
Q23	num	Does Nothing But Sit And Watch Others		Collected at CRF.
Q23_C	char	Does Nothing But Sit And Watch Others (char)		Collected at CRF.
Q24	num	Uncooperative		Collected at CRF.
Q24_C	char	Uncooperative (char)		Collected at CRF.
Q25	num	Depressed Mood		Collected at CRF.
Q25_C	char	Depressed Mood (char)		Collected at CRF.
Q26	num	Resists Any Form of Physical Contact		Collected at CRF.
Q26_C	char	Resists Any Form of Physical Contact (char)		Collected at CRF.
Q27	num	Moves or Rolls Head Back And Forth		Collected at CRF.
Q27_C	char	Moves or Rolls Head Back And Forth (char)		Collected at CRF.
Q28	num	Does Not Pay Attention To Instructions		Collected at CRF.
Q28_C	char	Does Not Pay Attention To Instructions (char)		Collected at CRF.
Q29	num	Demands Must Be Met Immediately		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q29_C	char	Demands Must Be Met Immediately (char)		Collected at CRF.
Q30	num	Isolates Him/Her Self From Others		Collected at CRF.
Q30_C	char	Isolates Him/Her Self From Others (char)		Collected at CRF.
Q31	num	Disrupts Group Activities		Collected at CRF.
Q31_C	char	Disrupts Group Activities (char)		Collected at CRF.
Q32	num	Sits or Stands In One Position		Collected at CRF.
Q32_C	char	Sits or Stands In One Position (char)		Collected at CRF.
Q33	num	Talks To Self Loudly		Collected at CRF.
Q33_C	char	Talks To Self Loudly (char)		Collected at CRF.
Q34	num	Cries Over Minor Annoyances And Hurts		Collected at CRF.
Q34_C	char	Cries Over Minor Annoyances And Hurts (char)		Collected at CRF.
Q35	num	Repetitive Hand, Body, or Head Movements		Collected at CRF.
Q35_C	char	Repetitive Hand, Body, or Head Movements (char)		Collected at CRF.
Q36	num	Moods Change Quickly		Collected at CRF.
Q36_C	char	Moods Change Quickly (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q37	num	Unresponsive To Structured Activities		Collected at CRF.
Q37_C	char	Unresponsive To Structured Activities (char)		Collected at CRF.
Q38	num	Does Not Stay In Seat		Collected at CRF.
Q38_C	char	Does Not Stay In Seat (char)		Collected at CRF.
Q39	num	Will Not Sit For Any Length of Time		Collected at CRF.
Q39_C	char	Will Not Sit For Any Length of Time (char)		Collected at CRF.
Q40	num	Is Difficult To Reach, Contact, or Get		Collected at CRF.
Q40_C	char	Is Difficult To Reach, Contact, or Get (char)		Collected at CRF.
Q41	num	Cries And Screams Inappropriately		Collected at CRF.
Q41_C	char	Cries And Screams Inappropriately (char)		Collected at CRF.
Q42	num	Prefers To Be Alone		Collected at CRF.
Q42_C	char	Prefers To Be Alone (char)		Collected at CRF.
Q43	num	Does Not Try To Communicate By Words		Collected at CRF.
Q43_C	char	Does Not Try To Communicate By Words (char)		Collected at CRF.
Q44	num	Easily Distractible		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q44_C	char	Easily Distractible (char)		Collected at CRF.
Q45	num	Waves or Shakes Extremities Repeatedly		Collected at CRF.
Q45_C	char	Waves or Shakes Extremities Repeatedly (char)		Collected at CRF.
Q46	num	Repeats A Word or Phrase Over And Over		Collected at CRF.
Q46_C	char	Repeats A Word or Phrase Over And Over (char)		Collected at CRF.
Q47	num	Stamps Feet, Bangs Objects, Slams Doors		Collected at CRF.
Q47_C	char	Stamps Feet, Bangs Objects, Slams Doors (char)		Collected at CRF.
Q48	num	Constantly Runs or Jumps Around The Room		Collected at CRF.
Q48_C	char	Constantly Runs or Jumps Around The Room (char)		Collected at CRF.
Q49	num	Rocks Body Back And Forth Repeatedly		Collected at CRF.
Q49_C	char	Rocks Body Back And Forth Repeatedly (char)		Collected at CRF.
Q50	num	Deliberately Hurts Him/Her Self		Collected at CRF.
Q50_C	char	Deliberately Hurts Him/Her Self (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q51	num	Pays No Attention When Spoken To		Collected at CRF.
Q51_C	char	Pays No Attention When Spoken To (char)		Collected at CRF.
Q52	num	Does Physical Violence To Self		Collected at CRF.
Q52_C	char	Does Physical Violence To Self (char)		Collected at CRF.
Q53	num	Inactive, Never Moves Spontaneously		Collected at CRF.
Q53_C	char	Inactive, Never Moves Spontaneously (char)		Collected at CRF.
Q54	num	Tends To Be Excessively Active		Collected at CRF.
Q54_C	char	Tends To Be Excessively Active (char)		Collected at CRF.
Q55	num	Responds Negatively To Affection		Collected at CRF.
Q55_C	char	Responds Negatively To Affection (char)		Collected at CRF.
Q56	num	Deliberately Ignores Directions		Collected at CRF.
Q56_C	char	Deliberately Ignores Directions (char)		Collected at CRF.
Q57	num	Temper Outburst/Tantrums When Frustrated		Collected at CRF.
Q57_C	char	Temper Outburst/Tantrums When Frustrated (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q58	num	Shows Few Social Reactions To Others		Collected at CRF.
Q58_C	char	Shows Few Social Reactions To Others (char)		Collected at CRF.
SUBITL	num	Subscale I (Irritability), Total		Collected at CRF.
SUBIITL	num	Subscale Ii (Lethargy), Total		Collected at CRF.
SUBIIITL	num	Subscale Iii (Stereotypy), Total		Collected at CRF.
SUBIVTL	num	Subscale Iv (Hyperactivity), Total		Collected at CRF.
SUBVTL	num	Subscale V (Inappropriate Speech), Total		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.3. Aberrant Behavior Checklist and Target Symptoms – ABCC

Dataset	ABCC
Creating program	abcc.sas
Description	Aberrant Behavior Checklist and Target Symptoms
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,RATERID, SYMPTOM1, SYMPTOM2,FRQSEV1A,FRQSEV1B, FRQSEV1C,FRQSEV2A,FRQSEV2B,FRQSEV2C,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
Q02	num	2. Injures Self		Collected at CRF.
Q02_C	char	2. Injures Self (char)		Collected at CRF.
Q04	num	4. Aggressive To Others		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q04_C	char	4. Aggressive To Others (char)		Collected at CRF.
Q08	num	8. Screams Inappropriately		Collected at CRF.
Q08_C	char	8. Screams Inappropriately (char)		Collected at CRF.
Q10	num	10. Temper Tantrums		Collected at CRF.
Q10_C	char	10. Temper Tantrums (char)		Collected at CRF.
Q14	num	14. Irritable		Collected at CRF.
Q14_C	char	14. Irritable (char)		Collected at CRF.
Q19	num	19. Yells At Inappropriate Times		Collected at CRF.
Q19_C	char	19. Yells At Inappropriate Times (char)		Collected at CRF.
Q25	num	25. Depressed Mood		Collected at CRF.
Q25_C	char	25. Depressed Mood (char)		Collected at CRF.
Q29	num	29. Demands Must Be Met Immediately		Collected at CRF.
Q29_C	char	29. Demands Must Be Met Immediately (char)		Collected at CRF.
Q34	num	34. Cries Over Minor Annoyances		Collected at CRF.
Q34_C	char	34. Cries Over Minor Annoyances (char)		Collected at CRF.
Q36	num	36. Mood Changes Quickly		Collected at CRF.
Q36_C	char	36. Mood Changes Quickly (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q41	num	41. Cries And Screams Inappropriately		Collected at CRF.
Q41_C	char	41. Cries And Screams Inappropriately (char)		Collected at CRF.
Q47	num	47. Stamps Feet or Bangs Objects		Collected at CRF.
Q47_C	char	47. Stamps Feet or Bangs Objects (char)		Collected at CRF.
Q50	num	50. Deliberately Hurts Him or Her Self		Collected at CRF.
Q50_C	char	50. Deliberately Hurts Him or Her Self (char)		Collected at CRF.
Q52	num	52. Does Physical Violence To Self		Collected at CRF.
Q52_C	char	52. Does Physical Violence To Self (char)		Collected at CRF.
Q57	num	57. Throws Temper Tantrums		Collected at CRF.
Q57_C	char	57. Throws Temper Tantrums (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.4. Autism Diagnostic Interview – ADI

Dataset	ADI
Creating program	adi.sas
Description	Autism Diagnostic Interview
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,RATERID,VISITDAT,ADIDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
B1_42	num	B1. Direct Gaze		Collected at CRF.
B1_43	num	B2. Social Smiling		Collected at CRF.
B1_52	num	B3. Range of Facial Expressions		Collected at CRF.
B1_TOTAL	num	B1. Total		Collected at CRF.

Variable	Type	Label	Codes	Comments
B2_64	num	B2. Imaginative Play W/Peers (> 4 Y.O.)		Collected at CRF.
B2_66	num	B2. Interest In Children		Collected at CRF.
B2_67	num	B2. Response To Children's Approaches		Collected at CRF.
B2_68_69	num	B2. Group Play With Peers or Friends		Collected at CRF.
B2_TOTAL	num	B2. Total		Collected at CRF.
B3_45	num	B3. Showing And Directing Attention		Collected at CRF.
B3_46	num	B3. offering To Share		Collected at CRF.
B3_47	num	B3. Seek To Share Own Enjoyment W/Others		Collected at CRF.
B3_TOTAL	num	B3. Total		Collected at CRF.
B4_11	num	B4. Use of Other's Body (Ever)		Collected at CRF.
B4_49	num	B4. offers Comfort		Collected at CRF.
B4_51	num	B4. Quality of Social Overtures		Collected at CRF.
B4_53	num	B4. Inappropriate Facial Express. (Ever)		Collected at CRF.
B4_57	num	B4. Appropriateness of Social Response		Collected at CRF.
B4_TOTAL	num	B4. Total		Collected at CRF.
B_GRAND	num	Total B		Collected at CRF.

Variable	Type	Label	Codes	Comments
C1_30	num	C1. Pointing To Express Interest		Collected at CRF.
C1_31	num	C1. Conventional Instrumental Gestures		Collected at CRF.
C1_32	num	C1. Nodding		Collected at CRF.
C1_33	num	C1. Headshaking		Collected at CRF.
C1_TOTAL	num	C1. Total		Collected at CRF.
C4_29	num	C4. Spontaneous Imitation of Actions		Collected at CRF.
C4_63	num	C4. Imaginative Play		Collected at CRF.
C4_65	num	C4. Imitative Social Play		Collected at CRF.
C4_TOTAL	num	C4. Total		Collected at CRF.
CVERBCH	num	Is Child Verbal		Collected at CRF.
C2V_16	num	C2V. Social Chat (Current)		Collected at CRF.
C2V_20	num	C2V. Reciprocal Conversation (Current)		Collected at CRF.
C2V_TL	num	C2V. Total		Collected at CRF.
C3V_18	num	Stereotyped Utterances (Ever)		Collected at CRF.
C3V_22	num	Inappropriate Questions (Ever)		Collected at CRF.
C3V_23	num	Pronominal Reversal (Ever)		Collected at CRF.
C3V_24	num	Neologisms/Idiosyncratic Language (Ever)		Collected at CRF.
C3V_TL	num	C3V. Total		Collected at CRF.

Variable	Type	Label	Codes	Comments
C_VERBAL	num	Verbal Total		Collected at CRF.
C_NONVER	num	Non-Verbal Total		Collected at CRF.
D1_70	num	D1. Circumscribed Interests (>= 4 Years)		Collected at CRF.
D1_71	num	D1. Unusual Preoccupations		Collected at CRF.
D2_25	num	D2. Verbal Rituals		Collected at CRF.
D2_75	num	D2. Compulsions/Rituals		Collected at CRF.
D3_81	num	D3. Hand And Finger Movements		Collected at CRF.
D3_84	num	D3. Complex Mannerisms		Collected at CRF.
D3_81_84	num	D3. Higher Score of Items		Collected at CRF.
D4_72	num	D4. Repetitive Use of Objects		Collected at CRF.
D4_77	num	D4. Unusual Sensory Interests		Collected at CRF.
D4_72_77	num	D4. Higher Score of Items		Collected at CRF.
D_TOTAL	num	Total D		Collected at CRF.
ABNRM_2	num	Abnormality: Age Parents First Noticed		Collected at CRF.
ABNRM_93	num	Abnormality: Age When First Evident		Collected at CRF.
ABNRM_94	num	Abnormality: Judgement On Age Manifest		Collected at CRF.
ABNRM_12	num	Abnormality: Age At First Single Words		Collected at CRF.

Variable	Type	Label	Codes	Comments
ABNRM_13	num	Abnormality: Age At First Phrases		Collected at CRF.
ABNRM_TL	num	Abnormality Total		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
ADIDY	num	Relative Day Adi Was Completed		If ADIDAT and REF.DATE not missing then perform below logic to calculate ADIDY, If ADIDAT less than REF.DATE then (ADIDAT - REF.DATE). Else if ADIDAT is greater than equal to REF.DATE then (ADIDAT- REF.DATE) +1.

1.4.5. Anticonvulsant Drug Levels – ADL

Dataset	ADL
Creating program	adl.sas
Description	Anticonvulsant Drug Levels
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RANDNBR,FMCOMPBY ,SPEC2,VISITDAT,DRAWDAT,MEDDAT,ANTIDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
BLOOD	num	Was Blood Drawn For Tests? (1=Yes, 2=No)		Collected at CRF.
BLOOD_C	char	Was Blood Drawn For Tests? (1=Yes, 2=No) (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
DRAWTIME	char	Time of Draw (Hh:Mm Military Time)		Collected at CRF.
MEDTIME	char	Time of Last Dose (Study Medication)		Collected at CRF.
ANTITIME	char	Time of Last Dose (Anticonvulsant)		Collected at CRF.
PHENYTN	num	Phenytoin		Collected at CRF.
PHENYTN_C	char	Phenytoin (char)		Collected at CRF.
CARBAMAZ	num	Carbamazepine		Collected at CRF.
CARBAMAZ_C	char	Carbamazepine (char)		Collected at CRF.
VALPROAT	num	Valproate		Collected at CRF.
VALPROAT_C	char	Valproate (char)		Collected at CRF.
LAMOTRIG	num	Lamotrigine		Collected at CRF.
LAMOTRIG_C	char	Lamotrigine (char)		Collected at CRF.
GABAPENT	num	Gabapentin		Collected at CRF.
GABAPENT_C	char	Gabapentin (char)		Collected at CRF.
OTHER1	num	Other (1)		Collected at CRF.
OTHER1_C	char	Other (1) (char)		Collected at CRF.
OTHER2	num	Other (2)		Collected at CRF.
OTHER2_C	char	Other (2) (char)		Collected at CRF.
SPEC1	char	Specify (1)		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
DRAWDY	num	Relative Day of Draw		If DRAWDAT and REF.DATE not missing then perform below logic to calculate DRAWDY, If DRAWDAT less than REF.DATE then (DRAWDAT - REF.DATE). Else if DRAWDAT is greater than equal to REF.DATE then (DRAWDAT- REF.DATE) +1.
MEDDY	num	Relative Day of Last Dose Stdy Medication		If MEDDAT and REF.DATE not missing then perform below logic to calculate MEDDY, If MEDDAT less than REF.DATE then (MEDDAT - REF.DATE). Else if MEDDAT is greater than equal to REF.DATE then (MEDDAT- REF.DATE) +1.
ANTIDY	num	Relative Day of Last Dose Anticonvulsant		If ANTIDAT and REF.DATE not missing then perform below logic to calculate ANTIDY, If ANTIDAT less than REF.DATE then (ANTIDAT - REF.DATE). Else if ANTIDAT is greater than equal to REF.DATE then (ANTIDAT- REF.DATE) +1.

1.4.6. Adverse Event – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Event
Unique identifier	STUDYID,DPATID,AESOC,AEPREF,INTERVAL ,AESEQNO
Sorted by	STUDYID,DPATID,AESOC,AEPREF,INTERVAL,AESEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,AEDESC,COMMENTS,VISITDAT,ONSETDAT,RESDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
AESEQNO	num	Ae Seq.		Collected at CRF.
NOEVENT	num	New Adverse Event		Collected at CRF.
NOEVENT_C	char	New Adverse Event (char)		Collected at CRF.
DSMBCODE	num	Dsmb Event Code		Collected at CRF.
ONSETTM	char	Onset Time		Collected at CRF.
RESTIME	char	Resolution Time		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEVERITY	num	Severity		Collected at CRF.
SEVERITY_C	char	Severity (char)		Collected at CRF.
SERIOUS	num	Serious		Collected at CRF.
STDYDRUG	num	Study Drug Related		Collected at CRF.
STDYDRUG_C	char	Study Drug Related (char)		Collected at CRF.
ACTTAKEN	num	Action Taken		Collected at CRF.
ACTTAKEN_C	char	Action Taken (char)		Collected at CRF.
ACTION1	num	Other Action 1		Collected at CRF.
ACTION1_C	char	Other Action 1 (char)		Collected at CRF.
ACTION2	num	Other Action 2		Collected at CRF.
ACTION2_C	char	Other Action 2 (char)		Collected at CRF.
ACTION3	num	Other Action 3		Collected at CRF.
ACTION3_C	char	Other Action 3 (char)		Collected at CRF.
OUTCOME	num	Outcome		Collected at CRF.
OUTCOME_C	char	Outcome (char)		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
AEINCL	char	Ae Included Term		Collected at CRF.
AEWHONUM	char	Ae Who Code		Collected at CRF.
AEPREF	char	Adverse Event Preferred Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
AESOC	char	Ae System Organ Class		Collected at CRF.
AESOC1	char	Ae System Organ Class 1		Collected at CRF.
AESOC2	char	Ae System Organ Class 2		Collected at CRF.
AESOC3	char	Ae System Organ Class 3		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
ONSETDY	num	Relative Day of Onset		If ONSETDAT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDAT less than REF.DATE then (ONSETDAT - REF.DATE). Else if ONSETDAT is greater than equal to REF.DATE then (ONSETDAT- REF.DATE) +1.
RESDY	num	Relative Day of Resolution		If RESDAT and REF.DATE not missing then perform below logic to calculate RESDY, If RESDAT less than REF.DATE then (RESDAT - REF.DATE). Else if RESDAT is greater than equal to REF.DATE then (RESDAT- REF.DATE) +1.

1.4.7. Abnormal Involuntary Movement Scale – AIMS

Dataset	AIMS
Creating program	aims.sas
Description	Abnormal Involuntary Movement Scale
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,RATERID,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
Q01	num	1. Muscles of Facial Expression		Collected at CRF.
Q01_C	char	1. Muscles of Facial Expression (char)		Collected at CRF.
Q02	num	2. Lips And Perioral Area		Collected at CRF.
Q02_C	char	2. Lips And Perioral Area (char)		Collected at CRF.
Q03	num	3. Jaw		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q03_C	char	3. Jaw (char)		Collected at CRF.
Q04	num	4. Tongue		Collected at CRF.
Q04_C	char	4. Tongue (char)		Collected at CRF.
Q05	num	5. Upper Extremity		Collected at CRF.
Q05_C	char	5. Upper Extremity (char)		Collected at CRF.
Q06	num	6. Lower Extremity		Collected at CRF.
Q06_C	char	6. Lower Extremity (char)		Collected at CRF.
Q07	num	7. Neck, Shoulders, Hips		Collected at CRF.
Q07_C	char	7. Neck, Shoulders, Hips (char)		Collected at CRF.
Q08	num	8. Severity of Abnormal Movements		Collected at CRF.
Q08_C	char	8. Severity of Abnormal Movements (char)		Collected at CRF.
Q09	num	9. Incapacitation, Abnormal Movements		Collected at CRF.
Q09_C	char	9. Incapacitation, Abnormal Movements (char)		Collected at CRF.
Q10	num	10. Subject Awareness, Abnormal Movement		Collected at CRF.
Q10_C	char	10. Subject Awareness, Abnormal Movement (char)		Collected at CRF.
Q11	num	11. Current Problem With Teeth, Dentures		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q11_C	char	11. Current Problem With Teeth, Dentures (char)		Collected at CRF.
Q12	num	12. Does Subject Usually Wear Dentures?		Collected at CRF.
Q12_C	char	12. Does Subject Usually Wear Dentures? (char)		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, if VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.8. Autism Symptom Inventory – ASI

Dataset	ASI
Creating program	asi.sas
Description	Autism Symptom Inventory
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
CATA_Q1	num	Fails To Give Close Attention To Details		Collected at CRF.
CATA_Q1_C	char	Fails To Give Close Attention To Details (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATA_Q2	num	Has Difficulty Paying Attention To Tasks		Collected at CRF.
CATA_Q2_C	char	Has Difficulty Paying Attention To Tasks (char)		Collected at CRF.
CATA_Q3	num	Does Not Seem To Listen When Spoken To		Collected at CRF.
CATA_Q3_C	char	Does Not Seem To Listen When Spoken To (char)		Collected at CRF.
CATA_Q4	num	Has Difficulty Following Instructions		Collected at CRF.
CATA_Q4_C	char	Has Difficulty Following Instructions (char)		Collected at CRF.
CATA_Q5	num	Has Difficulty Organizing Tasks		Collected at CRF.
CATA_Q5_C	char	Has Difficulty Organizing Tasks (char)		Collected at CRF.
CATA_Q6	num	Avoids Tasks Requiring Mental Effort		Collected at CRF.
CATA_Q6_C	char	Avoids Tasks Requiring Mental Effort (char)		Collected at CRF.
CATA_Q7	num	Loses Things Necessary For Activities		Collected at CRF.
CATA_Q7_C	char	Loses Things Necessary For Activities (char)		Collected at CRF.
CATA_Q8	num	Easily Distracted By Other Things		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATA_Q8_C	char	Easily Distracted By Other Things (char)		Collected at CRF.
CATA_Q9	num	Forgetful In Daily Activities		Collected at CRF.
CATA_Q9_C	char	Forgetful In Daily Activities (char)		Collected at CRF.
CATA_Q10	num	Fidgets With Hands or Feet, Squirms		Collected at CRF.
CATA_Q10_C	char	Fidgets With Hands or Feet, Squirms (char)		Collected at CRF.
CATA_Q11	num	Has Difficulty Remaining Seated		Collected at CRF.
CATA_Q11_C	char	Has Difficulty Remaining Seated (char)		Collected at CRF.
CATA_Q12	num	Runs About, Climbs On Things		Collected at CRF.
CATA_Q12_C	char	Runs About, Climbs On Things (char)		Collected at CRF.
CATA_Q13	num	Has Difficulty Doing Things Quietly		Collected at CRF.
CATA_Q13_C	char	Has Difficulty Doing Things Quietly (char)		Collected at CRF.
CATA_Q14	num	Is 'On The Go'		Collected at CRF.
CATA_Q14_C	char	Is 'On The Go' (char)		Collected at CRF.
CATA_Q15	num	Talks Excessively		Collected at CRF.
CATA_Q15_C	char	Talks Excessively (char)		Collected at CRF.
CATA_Q16	num	Blurts Out Answers To Questions		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATA_Q16_C	char	Blurts Out Answers To Questions (char)		Collected at CRF.
CATA_Q17	num	Has Difficulty Awaiting Turn In Group		Collected at CRF.
CATA_Q17_C	char	Has Difficulty Awaiting Turn In Group (char)		Collected at CRF.
CATA_Q18	num	Interrupts People, Butts Into Activities		Collected at CRF.
CATA_Q18_C	char	Interrupts People, Butts Into Activities (char)		Collected at CRF.
CATB_Q19	num	Plays Hooky From School		Collected at CRF.
CATB_Q19_C	char	Plays Hooky From School (char)		Collected at CRF.
CATB_Q20	num	Stays Out At Night When Not Supposed To		Collected at CRF.
CATB_Q20_C	char	Stays Out At Night When Not Supposed To (char)		Collected at CRF.
CATB_Q21	num	Lies To Get Things/Avoid Responsibility		Collected at CRF.
CATB_Q21_C	char	Lies To Get Things/Avoid Responsibility (char)		Collected at CRF.
CATB_Q22	num	Bullies, Threatens or Intimidates Others		Collected at CRF.
CATB_Q22_C	char	Bullies, Threatens or Intimidates Others (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATB_Q23	num	Starts Physical Fights		Collected at CRF.
CATB_Q23_C	char	Starts Physical Fights (char)		Collected at CRF.
CATB_Q24	num	Has Run Away From Home Overnight		Collected at CRF.
CATB_Q24_C	char	Has Run Away From Home Overnight (char)		Collected at CRF.
CATB_Q25	num	Stole Things When Others Not Looking		Collected at CRF.
CATB_Q25_C	char	Stole Things When Others Not Looking (char)		Collected at CRF.
CATB_Q26	num	Has Deliberately Destroyed Property		Collected at CRF.
CATB_Q26_C	char	Has Deliberately Destroyed Property (char)		Collected at CRF.
CATB_Q27	num	Has Deliberately Started Fires		Collected at CRF.
CATB_Q27_C	char	Has Deliberately Started Fires (char)		Collected at CRF.
CATB_Q28	num	Stole Things From Others Using Force		Collected at CRF.
CATB_Q28_C	char	Stole Things From Others Using Force (char)		Collected at CRF.
CATB_Q29	num	Has Broken Into House/Building/Car		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATB_Q29_C	char	Has Broken Into House/Building/Car (char)		Collected at CRF.
CATB_Q30	num	Has Used A Weapon When Fighting		Collected at CRF.
CATB_Q30_C	char	Has Used A Weapon When Fighting (char)		Collected at CRF.
CATB_Q31	num	Has Been Physically Cruel To Animals		Collected at CRF.
CATB_Q31_C	char	Has Been Physically Cruel To Animals (char)		Collected at CRF.
CATB_Q32	num	Has Been Physically Cruel To People		Collected at CRF.
CATB_Q32_C	char	Has Been Physically Cruel To People (char)		Collected at CRF.
CATB_Q33	num	Preoccupied With Sexual Activity		Collected at CRF.
CATB_Q33_C	char	Preoccupied With Sexual Activity (char)		Collected at CRF.
CATC_Q39	num	Loses Temper		Collected at CRF.
CATC_Q39_C	char	Loses Temper (char)		Collected at CRF.
CATC_Q40	num	Argues With Adults		Collected at CRF.
CATC_Q40_C	char	Argues With Adults (char)		Collected at CRF.
CATC_Q41	num	Defies or Refuses What You Tell Him/Her		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATC_Q41_C	char	Defies or Refuses What You Tell Him/Her (char)		Collected at CRF.
CATC_Q42	num	Does Things To Deliberately Annoy Others		Collected at CRF.
CATC_Q42_C	char	Does Things To Deliberately Annoy Others (char)		Collected at CRF.
CATC_Q43	num	Blames Other For Own Misbehavior/Mistake		Collected at CRF.
CATC_Q43_C	char	Blames Other For Own Misbehavior/Mistake (char)		Collected at CRF.
CATC_Q44	num	Is Touchy or Easily Annoyed By Others		Collected at CRF.
CATC_Q44_C	char	Is Touchy or Easily Annoyed By Others (char)		Collected at CRF.
CATC_Q45	num	Is Angry And Resentful		Collected at CRF.
CATC_Q45_C	char	Is Angry And Resentful (char)		Collected at CRF.
CATC_Q46	num	Takes Anger Out On Others, Seeks Revenge		Collected at CRF.
CATC_Q46_C	char	Takes Anger Out On Others, Seeks Revenge (char)		Collected at CRF.
CATD_Q47	num	Over concerned About Abilities In School		Collected at CRF.
CATD_Q47_C	char	Over concerned About Abilities In School (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATD_Q48	num	Has Difficulty Controlling Worries		Collected at CRF.
CATD_Q48_C	char	Has Difficulty Controlling Worries (char)		Collected at CRF.
CATD_Q49	num	Acts Restless or Edgy		Collected at CRF.
CATD_Q49_C	char	Acts Restless or Edgy (char)		Collected at CRF.
CATD_Q50	num	Is Irritable For Most of The Day		Collected at CRF.
CATD_Q50_C	char	Is Irritable For Most of The Day (char)		Collected at CRF.
CATD_Q51	num	Is Extremely Tense or Unable To Relax		Collected at CRF.
CATD_Q51_C	char	Is Extremely Tense or Unable To Relax (char)		Collected at CRF.
CATD_Q52	num	Has Difficulty Falling/Staying Asleep		Collected at CRF.
CATD_Q52_C	char	Has Difficulty Falling/Staying Asleep (char)		Collected at CRF.
CATE_Q53	num	Overly Fearful, Specific Obj./Situations		Collected at CRF.
CATE_Q53_C	char	Overly Fearful, Specific Obj./Situations (char)		Collected at CRF.
CATE_Q54	num	Complains About Heart Pounding, Etc.		Collected at CRF.
CATE_Q54_C	char	Complains About Heart Pounding, Etc. (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATE_Q55	num	Cannot Get Certain Thoughts Out of Mind		Collected at CRF.
CATE_Q55_C	char	Cannot Get Certain Thoughts Out of Mind (char)		Collected at CRF.
CATE_Q56	num	Compelled To Perform Unusual Habits		Collected at CRF.
CATE_Q56_C	char	Compelled To Perform Unusual Habits (char)		Collected at CRF.
CATE_Q57	num	Experienced/Bothered By Upsetting Event		Collected at CRF.
CATE_Q57_C	char	Experienced/Bothered By Upsetting Event (char)		Collected at CRF.
CATE_Q58	num	Distressing Memories/Dreams of Event		Collected at CRF.
CATE_Q58_C	char	Distressing Memories/Dreams of Event (char)		Collected at CRF.
CATE_Q59	num	Makes Twitching/Jerking Movements		Collected at CRF.
CATE_Q59_C	char	Makes Twitching/Jerking Movements (char)		Collected at CRF.
CATE_Q60	num	Makes Vocal Sounds For No Reason		Collected at CRF.
CATE_Q60_C	char	Makes Vocal Sounds For No Reason (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATE_Q61	num	Complains About Physical Problems		Collected at CRF.
CATE_Q61_C	char	Complains About Physical Problems (char)		Collected at CRF.
CATE_Q62	num	Worries About Physical Health		Collected at CRF.
CATE_Q62_C	char	Worries About Physical Health (char)		Collected at CRF.
CATF_Q63	num	Is More Anxious In Social Situations		Collected at CRF.
CATF_Q63_C	char	Is More Anxious In Social Situations (char)		Collected at CRF.
CATF_Q64	num	Is Excessively Shy With Peers		Collected at CRF.
CATF_Q64_C	char	Is Excessively Shy With Peers (char)		Collected at CRF.
CATG_Q65	num	Gets Very Upset When Separation Expected		Collected at CRF.
CATG_Q65_C	char	Gets Very Upset When Separation Expected (char)		Collected at CRF.
CATG_Q66	num	Worries Parents Will Be Hurt or Leave		Collected at CRF.
CATG_Q66_C	char	Worries Parents Will Be Hurt or Leave (char)		Collected at CRF.
CATG_Q67	num	Worries Disaster Will Cause Separation		Collected at CRF.
CATG_Q67_C	char	Worries Disaster Will Cause Separation (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATG_Q68	num	Tries To Avoid Going To School		Collected at CRF.
CATG_Q68_C	char	Tries To Avoid Going To School (char)		Collected at CRF.
CATG_Q69	num	Worries About Being Left Home Alone		Collected at CRF.
CATG_Q69_C	char	Worries About Being Left Home Alone (char)		Collected at CRF.
CATG_Q70	num	Afraid To Sleep Unless Parent Is Near		Collected at CRF.
CATG_Q70_C	char	Afraid To Sleep Unless Parent Is Near (char)		Collected at CRF.
CATG_Q71	num	Nightmares, Being Separated From Parents		Collected at CRF.
CATG_Q71_C	char	Nightmares, Being Separated From Parents (char)		Collected at CRF.
CATG_Q72	num	Complains Sickness If Separation Expecte		Collected at CRF.
CATG_Q72_C	char	Complains Sickness If Separation Expecte (char)		Collected at CRF.
CATH_Q73	num	Prefers To Be Alone		Collected at CRF.
CATH_Q73_C	char	Prefers To Be Alone (char)		Collected at CRF.
CATH_Q74	num	Little Interest In Close Relationships		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATH_Q74_C	char	Little Interest In Close Relationships (char)		Collected at CRF.
CATH_Q75	num	Emotionally Cold/Indifferent To People		Collected at CRF.
CATH_Q75_C	char	Emotionally Cold/Indifferent To People (char)		Collected at CRF.
CATI_Q76	num	Has Strange/Unreal Ideas or Beliefs		Collected at CRF.
CATI_Q76_C	char	Has Strange/Unreal Ideas or Beliefs (char)		Collected at CRF.
CATI_Q77	num	Has Auditory Hallucinations/Hears Voices		Collected at CRF.
CATI_Q77_C	char	Has Auditory Hallucinations/Hears Voices (char)		Collected at CRF.
CATI_Q78	num	Has Disorganized Speech		Collected at CRF.
CATI_Q78_C	char	Has Disorganized Speech (char)		Collected at CRF.
CATI_Q79	num	Behaves In Extremely Strange Ways		Collected at CRF.
CATI_Q79_C	char	Behaves In Extremely Strange Ways (char)		Collected at CRF.
CATI_Q80	num	Laughs or Cries At Inappropriate Times		Collected at CRF.
CATI_Q80_C	char	Laughs or Cries At Inappropriate Times (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATI_Q81	num	Has Lost Interest In Things And People		Collected at CRF.
CATI_Q81_C	char	Has Lost Interest In Things And People (char)		Collected at CRF.
CATJQ82A	num	Wets Bed At Night		Collected at CRF.
CATJQ82A_C	char	Wets Bed At Night (char)		Collected at CRF.
CATJQ82B	num	Wets Underwear During Daytime Hours		Collected at CRF.
CATJQ82B_C	char	Wets Underwear During Daytime Hours (char)		Collected at CRF.
CATJQ83	num	Soils Underwear During Daytime Hours		Collected at CRF.
CATJQ83_C	char	Soils Underwear During Daytime Hours (char)		Collected at CRF.
A_INATT	num	Score A: Items 1-9 (Inattentive)		Collected at CRF.
A_HYPER	num	Score A: Items 10-18 (Hyperactive)		Collected at CRF.
A_COMBO	num	Score A: Items 1-18 (Combined)		Collected at CRF.
B_CONDUCT	num	Score B: Items 19-33 (Conduct Disorder)		Collected at CRF.
C_OPP	num	Score C: Items 39-46 (Oppositional)		Collected at CRF.
D_GNAX47	num	Score D: Item 47 (General Anxiety)		Collected at CRF.
D_GNAX48	num	Score D: Item 48 (General Anxiety)		Collected at CRF.
D_GNAX49	num	Score D: Items 49-52, A-2, K-88		Collected at CRF.

Variable	Type	Label	Codes	Comments
E_PHOBIA	num	Score E: Item 53 (Specific Phobia)		Collected at CRF.
E_OBSESS	num	Score E: Item 55 (Obsessive)		Collected at CRF.
E_COMP	num	Score E: Item 56 (Compulsions)		Collected at CRF.
E_TRAUMA	num	Score E: Items 57-58 (Post-Traumatic)		Collected at CRF.
E_MTICS	num	Score E: Item 59 (Motor Tics)		Collected at CRF.
E_VTICS	num	Score E: Item 60 (Vocal Tics)		Collected at CRF.
E_PANIC	num	Score E: Item 54 (Panic Attack)		Collected at CRF.
E_SOMA	num	Score E: Items 61-62 (Somatization)		Collected at CRF.
F_SOCIAL	num	Score F: Items 63-64 (Social Phobia)		Collected at CRF.
G_SEPANX	num	Score G: Items 65-72 (Sep Anxiety)		Collected at CRF.
H_SCHZD	num	Score H: Items 73-75 (Schizoid)		Collected at CRF.
I_SCHZ77	num	Score I: Item 77 (Schizophrenia)		Collected at CRF.
I_SCHZ76	num	Score I: Items 76, 78-81 (Schizophrenia)		Collected at CRF.
J_ENU	num	Score J: Items 82A, 82B (Enuresis)		Collected at CRF.
J_ENC	num	Score J: Item 83 (Encopresis)		Collected at CRF.
CATK_Q84	num	Is Depressed For Most of The Day		Collected at CRF.
CATK_Q84_C	char	Is Depressed For Most of The Day (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATK_Q85	num	Lacks Interest In Pleasurable Activities		Collected at CRF.
CATK_Q85_C	char	Lacks Interest In Pleasurable Activities (char)		Collected at CRF.
CATK_Q86	num	Talks About Death or Suicide		Collected at CRF.
CATK_Q86_C	char	Talks About Death or Suicide (char)		Collected at CRF.
CATK_Q87	num	Feels Worthless or Guilty		Collected at CRF.
CATK_Q87_C	char	Feels Worthless or Guilty (char)		Collected at CRF.
CATK_Q88	num	Has Low Energy Levels		Collected at CRF.
CATK_Q88_C	char	Has Low Energy Levels (char)		Collected at CRF.
CATK_Q89	num	Has Little Confidence or Feels Inferior		Collected at CRF.
CATK_Q89_C	char	Has Little Confidence or Feels Inferior (char)		Collected at CRF.
CATK_Q90	num	Feels That Things Never Work Out Right		Collected at CRF.
CATK_Q90_C	char	Feels That Things Never Work Out Right (char)		Collected at CRF.
CATK_Q91	num	Change In Normal Appetite/Weight		Collected at CRF.
CATK_Q91_C	char	Change In Normal Appetite/Weight (char)		Collected at CRF.
CATK_Q92	num	Change In Normal Sleeping Habits		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATK_Q92_C	char	Change In Normal Sleeping Habits (char)		Collected at CRF.
CATK_Q93	num	Change In Normal Activity Level		Collected at CRF.
CATK_Q93_C	char	Change In Normal Activity Level (char)		Collected at CRF.
CATK_Q94	num	Change In Ability To Concentrate/Decide		Collected at CRF.
CATK_Q94_C	char	Change In Ability To Concentrate/Decide (char)		Collected at CRF.
CATK_Q95	num	Big Drop In School Grades/Work		Collected at CRF.
CATK_Q95_C	char	Big Drop In School Grades/Work (char)		Collected at CRF.
CATK_Q96	num	Has Become More Sensitive Than Usual		Collected at CRF.
CATK_Q96_C	char	Has Become More Sensitive Than Usual (char)		Collected at CRF.
CATK_Q97	num	Has Experienced A Very Stressful Event		Collected at CRF.
CATK_Q97_C	char	Has Experienced A Very Stressful Event (char)		Collected at CRF.
CATL_Q98	num	Is Much More Cheerful Than Usual		Collected at CRF.
CATL_Q98_C	char	Is Much More Cheerful Than Usual (char)		Collected at CRF.
CATL_Q99	num	Is Much More Irritable Than Usual		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATL_Q99_C	char	Is Much More Irritable Than Usual (char)		Collected at CRF.
CATLQ100	num	Becomes Much More Active Than Usual		Collected at CRF.
CATLQ100_C	char	Becomes Much More Active Than Usual (char)		Collected at CRF.
CATLQ101	num	Needs Far Less Sleep Than Usual		Collected at CRF.
CATLQ101_C	char	Needs Far Less Sleep Than Usual (char)		Collected at CRF.
CATLQ102	num	Is Much More Talkative Than Usual		Collected at CRF.
CATLQ102_C	char	Is Much More Talkative Than Usual (char)		Collected at CRF.
CATLQ103	num	Is Far More Distractable Than Usual		Collected at CRF.
CATLQ103_C	char	Is Far More Distractable Than Usual (char)		Collected at CRF.
CATLQ104	num	Does Far More Reckless/Silly Things		Collected at CRF.
CATLQ104_C	char	Does Far More Reckless/Silly Things (char)		Collected at CRF.
CATLQ105	num	Switches Rapidly From Topic To Topic		Collected at CRF.
CATLQ105_C	char	Switches Rapidly From Topic To Topic (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATLQ106	num	Believes He/She Has Special Abilities		Collected at CRF.
CATLQ106_C	char	Believes He/She Has Special Abilities (char)		Collected at CRF.
CATMQ107	num	Unusually Thin or Underweight		Collected at CRF.
CATMQ107_C	char	Unusually Thin or Underweight (char)		Collected at CRF.
CATMQ108	num	Not Eating Enough To Maintain Weight		Collected at CRF.
CATMQ108_C	char	Not Eating Enough To Maintain Weight (char)		Collected at CRF.
CATMQ109	num	Has Excessive Worries About Getting Fat		Collected at CRF.
CATMQ109_C	char	Has Excessive Worries About Getting Fat (char)		Collected at CRF.
CATMQ110	num	Thinks He/She Is Fat But Really Isn't		Collected at CRF.
CATMQ110_C	char	Thinks He/She Is Fat But Really Isn't (char)		Collected at CRF.
CATNQ111	num	Has Eating Binges		Collected at CRF.
CATNQ111_C	char	Has Eating Binges (char)		Collected at CRF.
CATNQ112	num	Cannot Stop/Control Eating		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATNQ112_C	char	Cannot Stop/Control Eating (char)		Collected at CRF.
CATNQ113	num	Uses Diet/Vomiting/Laxatives For Weight		Collected at CRF.
CATNQ113_C	char	Uses Diet/Vomiting/Laxatives For Weight (char)		Collected at CRF.
CATNQ114	num	Seems Overconcerned About His/Her Weight		Collected at CRF.
CATNQ114_C	char	Seems Overconcerned About His/Her Weight (char)		Collected at CRF.
CATOQ115	num	Smokes Tobacco Cigarettes		Collected at CRF.
CATOQ115_C	char	Smokes Tobacco Cigarettes (char)		Collected at CRF.
CATOQ116	num	Drinks Alcoholic Beverages		Collected at CRF.
CATOQ116_C	char	Drinks Alcoholic Beverages (char)		Collected at CRF.
CATOQ117	num	Gets Into Trouble Because of Alcohol Use		Collected at CRF.
CATOQ117_C	char	Gets Into Trouble Because of Alcohol Use (char)		Collected at CRF.
CATOQ118	num	Smokes Marijuana		Collected at CRF.
CATOQ118_C	char	Smokes Marijuana (char)		Collected at CRF.
CATOQ119	num	Uses Other Illegal Drugs		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATOQ119_C	char	Uses Other Illegal Drugs (char)		Collected at CRF.
CATOQ120	num	Gets Into Trouble From Illegal Drug Use		Collected at CRF.
CATOQ120_C	char	Gets Into Trouble From Illegal Drug Use (char)		Collected at CRF.
CATPQ121	num	Has Peculiar Way of Relating To Others		Collected at CRF.
CATPQ121_C	char	Has Peculiar Way of Relating To Others (char)		Collected at CRF.
CATPQ122	num	Doesn'T Play Well/Relate To Other Kids		Collected at CRF.
CATPQ122_C	char	Doesn'T Play Well/Relate To Other Kids (char)		Collected at CRF.
CATPQ123	num	Not Interested In Making Friends		Collected at CRF.
CATPQ123_C	char	Not Interested In Making Friends (char)		Collected at CRF.
CATPQ124	num	Unaware/No Interest In Other's Feelings		Collected at CRF.
CATPQ124_C	char	Unaware/No Interest In Other's Feelings (char)		Collected at CRF.
CATPQ125	num	Has A Significant Problem With Language		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATPQ125_C	char	Has A Significant Problem With Language (char)		Collected at CRF.
CATPQ126	num	Difficulty With Social Conversation		Collected at CRF.
CATPQ126_C	char	Difficulty With Social Conversation (char)		Collected at CRF.
CATPQ127	num	Talks In A Strange Manner		Collected at CRF.
CATPQ127_C	char	Talks In A Strange Manner (char)		Collected at CRF.
CATPQ128	num	Is Unable To Pretend When Playing		Collected at CRF.
CATPQ128_C	char	Is Unable To Pretend When Playing (char)		Collected at CRF.
CATPQ129	num	Excessive Preoccupation With One Topic		Collected at CRF.
CATPQ129_C	char	Excessive Preoccupation With One Topic (char)		Collected at CRF.
CATPQ130	num	Gets Very Upset Over Changes In Routine		Collected at CRF.
CATPQ130_C	char	Gets Very Upset Over Changes In Routine (char)		Collected at CRF.
CATPQ131	num	Make Strange Repetitive Movements		Collected at CRF.
CATPQ131_C	char	Make Strange Repetitive Movements (char)		Collected at CRF.
CATPQ132	num	Strange Fascination For Parts of Objects		Collected at CRF.

Variable	Type	Label	Codes	Comments
CATPQ132_C	char	Strange Fascination For Parts of Objects (char)		Collected at CRF.
K_MDDA	num	Score K: Items 84-85, D-50 (Mdd)		Collected at CRF.
K_Mddb	num	Score K: Items 86-88, 91-94 (Mdd)		Collected at CRF.
K_DYSA	num	Score K: Items 84, D-50 (Dysthymic Dis)		Collected at CRF.
K_DYSB	num	Score K: Items 88-92, 94 (Dysthymic Dis)		Collected at CRF.
K_ALTA	num	Score K: Items 84, D-50 (Alt Res Crit)		Collected at CRF.
K_ALTB	num	Score K: Items 85,87-90,94-95,D-50,I-81		Collected at CRF.
L_BIPA	num	Score L: Items 98-99, D-50 (Bipolar Dis)		Collected at CRF.
L_BIPB	num	Score L: Items 100-106 (Bipolar Dis)		Collected at CRF.
M_ANOX	num	Score M: Items 107-110 (Anorexia)		Collected at CRF.
N_BULIM	num	Score N: Items 111-114 (Bulimia)		Collected at CRF.
P_AUT121	num	Score P: Items 121-124 (Autistic Dis)		Collected at CRF.
P_AUT125	num	Score P: Items 125-128 (Autistic Dis)		Collected at CRF.
P_AUT129	num	Score P: Items 129-132 (Autistic Dis)		Collected at CRF.

Variable	Type	Label	Codes	Comments
P_AUTTL	num	Score P: Total (Autistic Disorder)		Collected at CRF.
P_ASP121	num	Score P: Items 121-124 (Asperger's Dis)		Collected at CRF.
P_ASP129	num	Score P: Items 129-132 (Asperger's Dis)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, if VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.9. After Study Knowledge Questionnaire – ASQ

Dataset	ASQ
Creating program	asq.sas
Description	After Study Knowledge Questionnaire
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,VISITDAT,Q02

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
Q03	num	Your Relationship To The Child		Collected at CRF.
Q03_C	char	Your Relationship To The Child (char)		Collected at CRF.
Q04	num	Your Education Level		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q04_C	char	Your Education Level (char)		Collected at CRF.
Q05	num	Main Goal of Doctors		Collected at CRF.
Q05_C	char	Main Goal of Doctors (char)		Collected at CRF.
Q06	num	Active Medication Being Studied		Collected at CRF.
Q06_C	char	Active Medication Being Studied (char)		Collected at CRF.
Q07	num	Informed Before Child Received Med.		Collected at CRF.
Q07_C	char	Informed Before Child Received Med. (char)		Collected at CRF.
Q08	num	Permission Before Child Received Med.		Collected at CRF.
Q08_C	char	Permission Before Child Received Med. (char)		Collected at CRF.
Q09	num	In This Study...		Collected at CRF.
Q09_C	char	In This Study... (char)		Collected at CRF.
Q10	num	...The Chance of Being Assigned Placebo		Collected at CRF.
Q10_C	char	...The Chance of Being Assigned Placebo (char)		Collected at CRF.
Q11	num	When The Study Started...		Collected at CRF.
Q11_C	char	When The Study Started... (char)		Collected at CRF.
Q12	num	Before Start, Risks/Benefits...		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q12_C	char	Before Start, Risks/Benefits... (char)		Collected at CRF.
Q13	num	Side Effects		Collected at CRF.
Q13_C	char	Side Effects (char)		Collected at CRF.
Q14	num	At The Time I Agreed, Study Med...		Collected at CRF.
Q14_C	char	At The Time I Agreed, Study Med... (char)		Collected at CRF.
Q15	num	After Consent, Drop Out Was...		Collected at CRF.
Q15_C	char	After Consent, Drop Out Was... (char)		Collected at CRF.
Q16	num	If Dropout, Treatment Would...		Collected at CRF.
Q16_C	char	If Dropout, Treatment Would... (char)		Collected at CRF.
Q17	num	Study Treatment Assignment		Collected at CRF.
Q17_C	char	Study Treatment Assignment (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.10. Clinical Global Impressions – CGI

Dataset	CGI
Creating program	cgi.sas
Description	Clinical Global Impressions
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,RATERID,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
ILLNESS	num	Severity of Illness		Collected at CRF.
ILLNESS_C	char	Severity of Illness (char)		Collected at CRF.
IMPROVE	num	Global Improvement		Collected at CRF.
IMPROVE_C	char	Global Improvement (char)		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.

Variable	Type	Label	Codes	Comments
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.11. Clinical Laboratory Results – CLR

Dataset	CLR
Creating program	clr.sas
Description	Clinical Laboratory Results
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect pii as per hipaa and ema guidelines or due to missing values: RANDNBR,CHARBASO,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
LABTEST	num	Were Laboratory Tests Performed		Collected at CRF.
LABTEST_C	char	Were Laboratory Tests Performed (char)		Collected at CRF.
WBC	num	Total Wbc Value		Collected at CRF.
WBCND	num	Total Wbc Not Done		Collected at CRF.
RBC	num	Total Rbc Value		Collected at CRF.
RBCND	num	Total Rbc Not Done		Collected at CRF.
PLT	num	Platelets Value		Collected at CRF.
PLTND	num	Plts Not Done		Collected at CRF.
HGB	num	Hgb Value		Collected at CRF.
HGBND	num	Hgb Not Done		Collected at CRF.
HCT	num	Hct Value		Collected at CRF.
HCTND	num	Hct Not Done		Collected at CRF.
NEUT	num	Neutrophil Percent		Collected at CRF.
NEUTND	num	Neut Not Done		Collected at CRF.
LYMPH	num	Lymphocytes Percent		Collected at CRF.
LYMPHND	num	Lymph Not Done		Collected at CRF.
MONO	num	Monocytes Percent		Collected at CRF.
MONOND	num	Mono Not Done		Collected at CRF.
CHAREOS	char	Eos: Character, Such As <, If Needed		Collected at CRF.

Variable	Type	Label	Codes	Comments
EOS	num	Eosinophils Percent		Collected at CRF.
EOSND	num	Eos Not Done		Collected at CRF.
BASO	num	Basophils Percent		Collected at CRF.
BASOND	num	Baso Not Done		Collected at CRF.
NA	num	Sodium (Na) Value		Collected at CRF.
NAND	num	Sodium (Na) Not Done		Collected at CRF.
BUN	num	Bun Value		Collected at CRF.
BUNND	num	Bun Not Done		Collected at CRF.
K	num	Potassium (K) Value		Collected at CRF.
KND	num	Potassium (K) Not Done		Collected at CRF.
CHL	num	Chloride Value		Collected at CRF.
CHLND	num	Chloride Not Done		Collected at CRF.
CRE	num	Creatinine Value		Collected at CRF.
CREND	num	Creatinine Not Done		Collected at CRF.
AST	num	Ast (Sgot) Value		Collected at CRF.
ASTND	num	Ast Not Done		Collected at CRF.
CHARTB	char	Tb: Character, Such As <, If Needed		Collected at CRF.
TB	num	Total Bilirubin (Tb) Value		Collected at CRF.
TBND	num	Total Bilirubin (Tb) Not Done		Collected at CRF.
CHARDB	char	Db: Character, Such As <, If Needed		Collected at CRF.

Variable	Type	Label	Codes	Comments
DB	num	Direct Bilirubin (Db) Value		Collected at CRF.
DBND	num	Direct Bilirubin (Db) Not Done		Collected at CRF.
CPK	num	Cpk Value		Collected at CRF.
CPKND	num	Cpk Not Done		Collected at CRF.
NAME	char	Form Completed By		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
LSGPT	num	Sgpt Value		Collected at CRF.
LSGPTND	num	Sgpt Not Done		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.12. Dictionary Version Control – CODE

Dataset	CODE
Creating program	code.sas
Description	Dictionary Version Control
Unique identifier	CODELIST
Sorted by	CODELIST
Notes	

Variable	Type	Label	Codes	Comments
TRIAL	char	Trail Id.		Collected at CRF.
CODELIST	char	Codelist		Collected at CRF.
VALID_D	num	Valid Date		Collected at CRF.

1.4.13. Cognitive Assessments – COG

Dataset	COG
Creating program	cog.sas
Description	Cognitive Assessments
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
A_DONE	num	Part A Completed (Purdue Pegboard)		Collected at CRF.
A_DONE_C	char	Part A Completed (Purdue Pegboard) (char)		Collected at CRF.
B_DONE	num	Part B Completed (Dot Test)		Collected at CRF.

Variable	Type	Label	Codes	Comments
B_DONE_C	char	Part B Completed (Dot Test) (char)		Collected at CRF.
C_DONE	num	Part C Completed (Vlt)		Collected at CRF.
C_DONE_C	char	Part C Completed (Vlt) (char)		Collected at CRF.
D_DONE	num	Part D Completed (Cancellation Task)		Collected at CRF.
D_DONE_C	char	Part D Completed (Cancellation Task) (char)		Collected at CRF.
E_DONE	num	Part E Completed (Analogue Task)		Collected at CRF.
E_DONE_C	char	Part E Completed (Analogue Task) (char)		Collected at CRF.
PG1CORDE	num	Scenario A - Page 1 - Correct Detections		Collected at CRF.
PG2CORDE	num	Scenario A - Page 2 - Correct Detections		Collected at CRF.
PG3CORDE	num	Scenario A - Page 3 - Correct Detections		Collected at CRF.
PG4CORDE	num	Scenario A - Page 4 - Correct Detections		Collected at CRF.
PG5CORDE	num	Scenario A - Page 5 - Correct Detections		Collected at CRF.
PG6CORDE	num	Scenario A - Page 6 - Correct Detections		Collected at CRF.
PG1ERROM	num	Scenario A - Page 1 - Errors Omission		Collected at CRF.

Variable	Type	Label	Codes	Comments
PG2ERROM	num	Scenario A - Page 2 - Errors Omission		Collected at CRF.
PG3ERROM	num	Scenario A - Page 3 - Errors Omission		Collected at CRF.
PG4ERROM	num	Scenario A - Page 4 - Errors Omission		Collected at CRF.
PG6ERROM	num	Scenario A - Page 6 - Errors Omission		Collected at CRF.
PG5ERROM	num	Scenario A - Page 5 - Errors Omission		Collected at CRF.
PG1ERRCM	num	Scenario A - Page 1 - Errors Commission		Collected at CRF.
PG2ERRCM	num	Scenario A - Page 2 - Errors Commission		Collected at CRF.
PG3ERRCM	num	Scenario A - Page 3 - Errors Commission		Collected at CRF.
PG4ERRCM	num	Scenario A - Page 4 - Errors Commission		Collected at CRF.
PG5ERRCM	num	Scenario A - Page 5 - Errors Commission		Collected at CRF.
PG6ERRCM	num	Scenario A - Page 6 - Errors Commission		Collected at CRF.
ACORDE	num	Scenario A - Total Correct Detections		Collected at CRF.

Variable	Type	Label	Codes	Comments
AERROM	num	Scenario A - Total Errors Omission		Collected at CRF.
AERRCM	num	Scenario A - Total Errors Commission		Collected at CRF.
VLQ01	num	The Vlt - Version of Cvlt Used		Collected at CRF.
VLQ01_C	char	The Vlt - Version of Cvlt Used (char)		Collected at CRF.
VLQ02	num	The Vlt - If Mcvlt, Picture Supplements?		Collected at CRF.
VLQ02_C	char	The Vlt - If Mcvlt, Picture Supplements? (char)		Collected at CRF.
VLQ03_1	num	The Vlt - Total -Trial 1		Collected at CRF.
VLQ03_2	num	The Vlt - Total -Trial 2		Collected at CRF.
VLQ03_3	num	The Vlt - Total -Trial 3		Collected at CRF.
VLQ03_4	num	The Vlt - Total -Trial 4		Collected at CRF.
VLQ03_5	num	The Vlt - Total -Trial 5		Collected at CRF.
VLQ03_T	num	The Vlt - Total -Total		Collected at CRF.
VLQ04	num	The Vlt - Total Lone Delay Free Recall		Collected at CRF.
VLQ05	num	The Vlt - No. of Correct Recognitions		Collected at CRF.
VLQ06	num	The Vlt - No. of Correct Rejections		Collected at CRF.
VLQ07	num	The Vlt - Score Vlt		Collected at CRF.
ACTQ01	num	Act - Level Used		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTQ02	char	Act - Version Used		Collected at CRF.
ACTQ03	num	Act - No. of Problems Attempted		Collected at CRF.
ACTQ04	num	Act - No. Correct		Collected at CRF.
PPTHAND	num	Pegbrd - Dominant Hand		Collected at CRF.
PPTHAND_C	char	Pegbrd - Dominant Hand (char)		Collected at CRF.
PPTQ01DH	num	Pegbrd - No. Ins, Dominant Hand 1		Collected at CRF.
PPTQ01ND	num	Pegbrd - No. Ins, Non Dominant Hand 1		Collected at CRF.
PPTQ1DRH	num	Pegbrd - No. Ins, Drops, Dominant Hand 1		Collected at CRF.
PPTQ1DRN	num	Pegbrd - No. Ins, Drops, Non Dom. Hand 1		Collected at CRF.
PPTQ02DH	num	Pegbrd - No. Ins, Dominant Hand 2		Collected at CRF.
PPTQ02ND	num	Pegbrd - No. Ins, Non Dominant Hand 2		Collected at CRF.
PPTQ2DRH	num	Pegbrd - No. Ins, Drops, Dominant Hand 2		Collected at CRF.
PPTQ2DRN	num	Pegbrd - No. Ins, Drops, Non Dom. Hand 2		Collected at CRF.
PPTQ03DH	num	Pegbrd - No. Ins, Dominant Hand 3		Collected at CRF.
PPTQ03ND	num	Pegbrd - No. Ins, Non Dominant Hand 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
PPTQ3DRH	num	Pegbrd - No. Ins, Drops, Dominant Hand 3		Collected at CRF.
PPTQ3DRN	num	Pegbrd - No. Ins, Drops, Non Dom. Hand 3		Collected at CRF.
PPTDH	num	Pegbrd - No. Ins, Dominant Hand - Tot		Collected at CRF.
PPTND	num	Pegbrd - No. Ins, Non Dominant Hand -Tot		Collected at CRF.
PPTDRDH	num	Pegbrd - Drops, Dominant Hand - Tot		Collected at CRF.
PPTDRND	num	Pegbrd - Drops, Non Dominant Hand -Tot		Collected at CRF.
DOTQ01	num	1. Dot Test - No Delay		Collected at CRF.
DOTQ02	num	2. Dot Test - No Delay		Collected at CRF.
DOTQ03	num	3. Dot Test - No Delay		Collected at CRF.
DOTQ04	num	4. Dot Test - No Delay		Collected at CRF.
DOTQ05	num	5. Dot Test - No Delay		Collected at CRF.
DOTQ06	num	6. Dot Test - No Delay		Collected at CRF.
DOTQ07	num	7. Dot Test - No Delay		Collected at CRF.
DOTQ08	num	8. Dot Test - No Delay		Collected at CRF.
DOT_ND	num	Dot Test - Average No Delay Distance		Collected at CRF.
DOTQ09	num	9. Dot Test - 10 Second Delay		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOTQ10	num	10. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ11	num	11. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ12	num	12. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ13	num	13. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ14	num	14. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ15	num	15. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ16	num	16. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ17	num	17. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ18	num	18. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ19	num	19. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ20	num	20. Dot Test - 10 Second Delay		Collected at CRF.
DOT_D	num	Dot Test - Avg 10 Second Delay Distance		Collected at CRF.
DOT_DIFF	num	Dot Test - Difference Between Averages		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.14. Cognitive Assessments Adaptations Form – COGADAP

Dataset	COGADAP
Creating program	cogadap.sas
Description	Cognitive Assessments Adaptations Form
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,A_SPECIF,B_SPECIF,C_SPECIF,D_SPECIF,E_SPECIF,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
A_TASK	num	A. Completed Purdue Pegboard Task		Collected at CRF.
A_TASK_C	char	A. Completed Purdue Pegboard Task (char)		Collected at CRF.
A_VERS	num	A. Version Used		Collected at CRF.

Variable	Type	Label	Codes	Comments
A_VERS_C	char	A. Version Used (char)		Collected at CRF.
A_QUALIT	num	A. Quality of Test Results		Collected at CRF.
A_QUALIT_C	char	A. Quality of Test Results (char)		Collected at CRF.
A_SIT1	num	A. Situation-Did Not Comprehend Instr.		Collected at CRF.
A_SIT1_C	char	A. Situation-Did Not Comprehend Instr. (char)		Collected at CRF.
A_SIT2	num	A. Situation-Completely Distracted		Collected at CRF.
A_SIT2_C	char	A. Situation-Completely Distracted (char)		Collected at CRF.
A_SIT3	num	A. Situation-Refused To Comply		Collected at CRF.
A_SIT3_C	char	A. Situation-Refused To Comply (char)		Collected at CRF.
A_SIT4	num	A. Situation-Tantrum		Collected at CRF.
A_SIT4_C	char	A. Situation-Tantrum (char)		Collected at CRF.
A_SIT5	num	A. Situation-Used Both Hands		Collected at CRF.
A_SIT5_C	char	A. Situation-Used Both Hands (char)		Collected at CRF.
A_SIT6	num	A. Situation-Took Peg From Opposite Dish		Collected at CRF.
A_SIT6_C	char	A. Situation-Took Peg From Opposite Dish (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
A_SIT7	num	A. Situation-Added Pegs Out of Sequence		Collected at CRF.
A_SIT7_C	char	A. Situation-Added Pegs Out of Sequence (char)		Collected at CRF.
A_SIT8	num	A. Situation-Took Multiple Pegs		Collected at CRF.
A_SIT8_C	char	A. Situation-Took Multiple Pegs (char)		Collected at CRF.
A_SIT9	num	A. Situation-Dropped And Picked Up		Collected at CRF.
A_SIT9_C	char	A. Situation-Dropped And Picked Up (char)		Collected at CRF.
A_SIT10	num	A. Situation-Other		Collected at CRF.
A_SIT10_C	char	A. Situation-Other (char)		Collected at CRF.
B_TASK	num	B. Subject Completed Dot Test		Collected at CRF.
B_TASK_C	char	B. Subject Completed Dot Test (char)		Collected at CRF.
B_VERS	num	B. Version Used		Collected at CRF.
B_VERS_C	char	B. Version Used (char)		Collected at CRF.
B_QUALIT	num	B. Quality of Test Results		Collected at CRF.
B_QUALIT_C	char	B. Quality of Test Results (char)		Collected at CRF.
B_SIT1	num	B. Situation-Did Not Comprehend Instr.		Collected at CRF.

Variable	Type	Label	Codes	Comments
B_SIT1_C	char	B. Situation-Did Not Comprehend Instr. (char)		Collected at CRF.
B_SIT2	num	B. Situation-Completely Distracted		Collected at CRF.
B_SIT2_C	char	B. Situation-Completely Distracted (char)		Collected at CRF.
B_SIT3	num	B. Situation-Refused To Comply		Collected at CRF.
B_SIT3_C	char	B. Situation-Refused To Comply (char)		Collected at CRF.
B_SIT4	num	B. Situation-Tantrum		Collected at CRF.
B_SIT4_C	char	B. Situation-Tantrum (char)		Collected at CRF.
B_SIT5	num	B. Situation-Unable To Draw or Use		Collected at CRF.
B_SIT5_C	char	B. Situation-Unable To Draw or Use (char)		Collected at CRF.
B_SIT6	num	B. Situation-Other		Collected at CRF.
B_SIT6_C	char	B. Situation-Other (char)		Collected at CRF.
C_TASK	num	C. Completed Verbal Learning Task		Collected at CRF.
C_TASK_C	char	C. Completed Verbal Learning Task (char)		Collected at CRF.
C_VERS	num	C. Version Used		Collected at CRF.
C_VERS_C	char	C. Version Used (char)		Collected at CRF.
C_QUALIT	num	C. Quality of Test Results		Collected at CRF.
C_QUALIT_C	char	C. Quality of Test Results (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
C_SIT1	num	C. Situation-Did Not Comprehend Instr.		Collected at CRF.
C_SIT1_C	char	C. Situation-Did Not Comprehend Instr. (char)		Collected at CRF.
C_SIT2	num	C. Situation-Completely Distracted		Collected at CRF.
C_SIT2_C	char	C. Situation-Completely Distracted (char)		Collected at CRF.
C_SIT3	num	C. Situation-Refused To Comply		Collected at CRF.
C_SIT3_C	char	C. Situation-Refused To Comply (char)		Collected at CRF.
C_SIT4	num	C. Situation-Tantrum		Collected at CRF.
C_SIT4_C	char	C. Situation-Tantrum (char)		Collected at CRF.
C_SIT5	num	C. Situation-Subject Non-Verbal		Collected at CRF.
C_SIT5_C	char	C. Situation-Subject Non-Verbal (char)		Collected at CRF.
C_SIT6	num	C. Situation-Refused Immediate Recall		Collected at CRF.
C_SIT6_C	char	C. Situation-Refused Immediate Recall (char)		Collected at CRF.
C_SIT7	num	C. Situation-Refused Delayed Recall		Collected at CRF.
C_SIT7_C	char	C. Situation-Refused Delayed Recall (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
C_SIT8	num	C. Situation-Refused Recognition Task		Collected at CRF.
C_SIT8_C	char	C. Situation-Refused Recognition Task (char)		Collected at CRF.
C_SIT9	num	C. Situation-Other		Collected at CRF.
C_SIT9_C	char	C. Situation-Other (char)		Collected at CRF.
D_TASK	num	D. Completed Cancellation Task		Collected at CRF.
D_TASK_C	char	D. Completed Cancellation Task (char)		Collected at CRF.
D_VERS	num	D. Version Used		Collected at CRF.
D_VERS_C	char	D. Version Used (char)		Collected at CRF.
D_QUALIT	num	D. Quality of Test Results		Collected at CRF.
D_QUALIT_C	char	D. Quality of Test Results (char)		Collected at CRF.
D_SIT1	num	D. Situation-Did Not Comprehend Instr.		Collected at CRF.
D_SIT1_C	char	D. Situation-Did Not Comprehend Instr. (char)		Collected at CRF.
D_SIT2	num	D. Situation-Completely Distracted		Collected at CRF.
D_SIT2_C	char	D. Situation-Completely Distracted (char)		Collected at CRF.
D_SIT3	num	D. Situation-Refused To Comply		Collected at CRF.
D_SIT3_C	char	D. Situation-Refused To Comply (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
D_SIT4	num	D. Situation-Tantrum		Collected at CRF.
D_SIT4_C	char	D. Situation-Tantrum (char)		Collected at CRF.
D_SIT5	num	D. Situation-Did Not Begin At Top		Collected at CRF.
D_SIT5_C	char	D. Situation-Did Not Begin At Top (char)		Collected at CRF.
D_SIT6	num	D. Situation-Did Not Cancel Left - Right		Collected at CRF.
D_SIT6_C	char	D. Situation-Did Not Cancel Left - Right (char)		Collected at CRF.
D_SIT7	num	D. Situation-Drew One Line Through		Collected at CRF.
D_SIT7_C	char	D. Situation-Drew One Line Through (char)		Collected at CRF.
D_SIT8	num	D. Situation-Unable To Draw or Use		Collected at CRF.
D_SIT8_C	char	D. Situation-Unable To Draw or Use (char)		Collected at CRF.
D_SIT9	num	D. Situation-Other		Collected at CRF.
D_SIT9_C	char	D. Situation-Other (char)		Collected at CRF.
E_TASK	num	E. Completed Analog Classroom Task		Collected at CRF.
E_TASK_C	char	E. Completed Analog Classroom Task (char)		Collected at CRF.
E_VERS	num	E. Version Used		Collected at CRF.

Variable	Type	Label	Codes	Comments
E_VERS_C	char	E. Version Used (char)		Collected at CRF.
E_QUALIT	num	E. Quality of Test Results		Collected at CRF.
E_QUALIT_C	char	E. Quality of Test Results (char)		Collected at CRF.
E_SIT1	num	E. Situation-Did Not Comprehend Instr.		Collected at CRF.
E_SIT1_C	char	E. Situation-Did Not Comprehend Instr. (char)		Collected at CRF.
E_SIT2	num	E. Situation-Completely Distracted		Collected at CRF.
E_SIT2_C	char	E. Situation-Completely Distracted (char)		Collected at CRF.
E_SIT3	num	E. Situation-Refused To Comply		Collected at CRF.
E_SIT3_C	char	E. Situation-Refused To Comply (char)		Collected at CRF.
E_SIT4	num	E. Situation-Tantrum		Collected at CRF.
E_SIT4_C	char	E. Situation-Tantrum (char)		Collected at CRF.
E_SIT5	num	E. Situation-Unable To Draw or Use		Collected at CRF.
E_SIT5_C	char	E. Situation-Unable To Draw or Use (char)		Collected at CRF.
E_SIT6	num	E. Situation-Other		Collected at CRF.

Variable	Type	Label	Codes	Comments
E_SIT6_C	char	E. Situation-Other (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.15. Cognitive Assessments Mastery – COGMAST

Dataset	COGMAST
Creating program	cogmast.sas
Description	Cognitive Assessments Mastery
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
A_DONE	num	Part A Completed (Purdue Pegboard)		Collected at CRF.
A_DONE_C	char	Part A Completed (Purdue Pegboard) (char)		Collected at CRF.
B_DONE	num	Part B Completed (Dot Test)		Collected at CRF.
B_DONE_C	char	Part B Completed (Dot Test) (char)		Collected at CRF.
C_DONE	num	Part C Completed (Vlt)		Collected at CRF.
C_DONE_C	char	Part C Completed (Vlt) (char)		Collected at CRF.
D_DONE	num	Part D Completed (Cancellation Task)		Collected at CRF.
D_DONE_C	char	Part D Completed (Cancellation Task) (char)		Collected at CRF.
E_DONE	num	Part E Completed (Analogue Task)		Collected at CRF.
E_DONE_C	char	Part E Completed (Analogue Task) (char)		Collected at CRF.
A_MASTER	num	Part A Mastery (Purdue Pegboard)		Collected at CRF.
A_MASTER_C	char	Part A Mastery (Purdue Pegboard) (char)		Collected at CRF.
B_MASTER	num	Part B Mastery (Dot Test)		Collected at CRF.
B_MASTER_C	char	Part B Mastery (Dot Test) (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
C_MASTER	num	Part C Mastery (Vlt)		Collected at CRF.
C_MASTER_C	char	Part C Mastery (Vlt) (char)		Collected at CRF.
D_MASTER	num	Part D Mastery (Cancellation Task)		Collected at CRF.
D_MASTER_C	char	Part D Mastery (Cancellation Task) (char)		Collected at CRF.
E_MASTER	num	Part E Mastery (Analogue Task)		Collected at CRF.
E_MASTER_C	char	Part E Mastery (Analogue Task) (char)		Collected at CRF.
A_USABLE	num	Part A Usable (Purdue Pegboard)		Collected at CRF.
A_USABLE_C	char	Part A Usable (Purdue Pegboard) (char)		Collected at CRF.
B_USABLE	num	Part B Usable (Dot Test)		Collected at CRF.
B_USABLE_C	char	Part B Usable (Dot Test) (char)		Collected at CRF.
C_USABLE	num	Part C Usable (Vlt)		Collected at CRF.
C_USABLE_C	char	Part C Usable (Vlt) (char)		Collected at CRF.
D_USABLE	num	Part D Usable (Cancellation Task)		Collected at CRF.
D_USABLE_C	char	Part D Usable (Cancellation Task) (char)		Collected at CRF.
E_USABLE	num	Part E Usable (Analogue Task)		Collected at CRF.
E_USABLE_C	char	Part E Usable (Analogue Task) (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
PG1CORDE	num	Scenario A - Page 1 - Correct Detections		Collected at CRF.
PG2CORDE	num	Scenario A - Page 2 - Correct Detections		Collected at CRF.
PG3CORDE	num	Scenario A - Page 3 - Correct Detections		Collected at CRF.
PG4CORDE	num	Scenario A - Page 4 - Correct Detections		Collected at CRF.
PG5CORDE	num	Scenario A - Page 5 - Correct Detections		Collected at CRF.
PG6CORDE	num	Scenario A - Page 6 - Correct Detections		Collected at CRF.
PG1ERROM	num	Scenario A - Page 1 - Errors Omission		Collected at CRF.
PG2ERROM	num	Scenario A - Page 2 - Errors Omission		Collected at CRF.
PG3ERROM	num	Scenario A - Page 3 - Errors Omission		Collected at CRF.
PG4ERROM	num	Scenario A - Page 4 - Errors Omission		Collected at CRF.
PG6ERROM	num	Scenario A - Page 6 - Errors Omission		Collected at CRF.
PG5ERROM	num	Scenario A - Page 5 - Errors Omission		Collected at CRF.

Variable	Type	Label	Codes	Comments
PG1ERRCM	num	Scenario A - Page 1 - Errors Commission		Collected at CRF.
PG2ERRCM	num	Scenario A - Page 2 - Errors Commission		Collected at CRF.
PG3ERRCM	num	Scenario A - Page 3 - Errors Commission		Collected at CRF.
PG4ERRCM	num	Scenario A - Page 4 - Errors Commission		Collected at CRF.
PG5ERRCM	num	Scenario A - Page 5 - Errors Commission		Collected at CRF.
PG6ERRCM	num	Scenario A - Page 6 - Errors Commission		Collected at CRF.
ACORDE	num	Scenario A - Total Correct Detections		Collected at CRF.
AERROM	num	Scenario A - Total Errors Omission		Collected at CRF.
AERRCM	num	Scenario A - Total Errors Commission		Collected at CRF.
VLQ01	num	The Vlt - Version of Cvlt Used		Collected at CRF.
VLQ01_C	char	The Vlt - Version of Cvlt Used (char)		Collected at CRF.
VLQ02	num	The Vlt - If Mcvlt, Picture Supplements?		Collected at CRF.
VLQ02_C	char	The Vlt - If Mcvlt, Picture Supplements? (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
VLQ03_1	num	The Vlt - Total -Trial 1		Collected at CRF.
VLQ03_2	num	The Vlt - Total -Trial 2		Collected at CRF.
VLQ03_3	num	The Vlt - Total -Trial 3		Collected at CRF.
VLQ03_4	num	The Vlt - Total -Trial 4		Collected at CRF.
VLQ03_5	num	The Vlt - Total -Trial 5		Collected at CRF.
VLQ03_T	num	The Vlt - Total -Total		Collected at CRF.
VLQ04	num	The Vlt - Total Lone Delay Free Recall		Collected at CRF.
VLQ05	num	The Vlt - No. Correct Recognitions		Collected at CRF.
VLQ06	num	The Vlt - No. Correct Rejections		Collected at CRF.
VLQ07	num	The Vlt - Score Vlt		Collected at CRF.
ACTQ01	num	Act - Level Used		Collected at CRF.
ACTQ02	char	Act - Version Used		Collected at CRF.
ACTQ03	num	Act - No. of Problems Attempted		Collected at CRF.
ACTQ04	num	Act - No. Correct		Collected at CRF.
PPTHAND	num	Pegbrd - Dominant Hand		Collected at CRF.
PPTHAND_C	char	Pegbrd - Dominant Hand (char)		Collected at CRF.
PPTQ01DH	num	Pegbrd - No. Ins, Dominant Hand 1		Collected at CRF.
PPTQ01ND	num	Pegbrd - No. Ins, Non Dominant Hand 1		Collected at CRF.
PPTQ1DRH	num	Pegbrd - No. Ins, Drops, Dominant Hand 1		Collected at CRF.

Variable	Type	Label	Codes	Comments
PPTQ1DRN	num	Pegbrd - No. Ins, Drops, Non Dom. Hand 1		Collected at CRF.
PPTQ02DH	num	Pegbrd - No. Ins, Dominant Hand 2		Collected at CRF.
PPTQ02ND	num	Pegbrd - No. Ins, Non Dominant Hand 2		Collected at CRF.
PPTQ2DRH	num	Pegbrd - No. Ins, Drops, Dominant Hand 2		Collected at CRF.
PPTQ2DRN	num	Pegbrd - No. Ins, Drops, Non Dom. Hand 2		Collected at CRF.
PPTQ03DH	num	Pegbrd - No. Ins, Dominant Hand 3		Collected at CRF.
PPTQ03ND	num	Pegbrd - No. Ins, Non Dominant Hand 3		Collected at CRF.
PPTQ3DRH	num	Pegbrd - No. Ins, Drops, Dominant Hand 3		Collected at CRF.
PPTQ3DRN	num	Pegbrd - No. Ins, Drops, Non Dom. Hand 3		Collected at CRF.
PPTDH	num	Pegbrd - No. Ins, Dominant Hand - Tot		Collected at CRF.
PPTND	num	Pegbrd - No. Ins, Non Dominant Hand -Tot		Collected at CRF.
PPTDRDH	num	Pegbrd - Drops, Dominant Hand - Tot		Collected at CRF.
PPTDRND	num	Pegbrd - Drops, Non Dominant Hand -Tot		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOTQ01	num	1. Dot Test - No Delay		Collected at CRF.
DOTQ02	num	2. Dot Test - No Delay		Collected at CRF.
DOTQ03	num	3. Dot Test - No Delay		Collected at CRF.
DOTQ04	num	4. Dot Test - No Delay		Collected at CRF.
DOTQ05	num	5. Dot Test - No Delay		Collected at CRF.
DOTQ06	num	6. Dot Test - No Delay		Collected at CRF.
DOTQ07	num	7. Dot Test - No Delay		Collected at CRF.
DOTQ08	num	8. Dot Test - No Delay		Collected at CRF.
DOT_ND	num	Dot Test - Average No Delay Distance		Collected at CRF.
DOTQ09	num	9. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ10	num	10. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ11	num	11. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ12	num	12. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ13	num	13. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ14	num	14. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ15	num	15. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ16	num	16. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ17	num	17. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ18	num	18. Dot Test - 10 Second Delay		Collected at CRF.
DOTQ19	num	19. Dot Test - 10 Second Delay		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOTQ20	num	20. Dot Test - 10 Second Delay		Collected at CRF.
DOT_D	num	Dot Test - Avg 10 Second Delay Distance		Collected at CRF.
DOT_DIFF	num	Dot Test - Difference Between Averages		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, if VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.16. Comment Dataset – COMMNTDB

Dataset	COMMNTDB
Creating program	commntdb.sas
Description	Comment Dataset
Unique identifier	Not applicable
Sorted by	Not applicable
Notes	Comment dataset contains sensitive information. Hence dataset will be submitted with zero observation.

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-identity		Empty dataset will be submitted
STUDYID	char	Study Id		Empty dataset will be submitted
DPATID	char	Patient Id Assigned For De-Identity		Empty dataset will be submitted
INTERVAL	num	Week Number		Empty dataset will be submitted
FRMCOMP	num	Form Completed		Empty dataset will be submitted
RPTFRM1	char	Name of Case Report Form 1		Empty dataset will be submitted
RPTFRM2	char	Name of Case Report Form 2		Empty dataset will be submitted
RPTFRM3	char	Name of Case Report Form 3		Empty dataset will be submitted
RPTFRM4	char	Name of Case Report Form 4		Empty dataset will be submitted
RPTFRM5	char	Name of Case Report Form 5		Empty dataset will be submitted
RPTFRM6	char	Name of Case Report Form 6		Empty dataset will be submitted

Variable	Type	Label	Codes	Comments
VISITDY	num	Relative Day of Visit		Empty dataset will be submitted
COMM1DY	num	Relative Comment Day 1		Empty dataset will be submitted
COMM2DY	num	Relative Comment Day 2		Empty dataset will be submitted
COMM3DY	num	Relative Comment Day 3		Empty dataset will be submitted
COMM4DY	num	Relative Comment Day 4		Empty dataset will be submitted
COMM5DY	num	Relative Comment Day 5		Empty dataset will be submitted
COMM6DY	num	Relative Comment Day 6		Empty dataset will be submitted

1.4.17. Concomitant Treatments – COTHER

Dataset	COTHER
Creating program	cother.sas
Description	Concomitant Treatments
Unique identifier	STUDYID,DPATID,MEDS,INTERVAL,MEDSTDY,CTSEQNO
Sorted by	STUDYID,DPATID,MEDS,INTERVAL,MEDSTDY,CTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RANDNBR,VISITDAT,MEDSDAT,MEDENDAT,TRTSTDAT,TRTENDAT, ATCCODE9,ATCTEXT9

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
CTSEQNO	num	Co-Rx Seq.		Collected at CRF.
NOMEDS	num	No Concomitant Medications		Collected at CRF.
MEDS	char	Medication		Collected at CRF.
PURPOSE	char	Purpose/Indication		Collected at CRF.
ROUTE	num	Route		Collected at CRF.
ROUTE_C	char	Route (char)		Collected at CRF.
DOSE	num	Dose		Collected at CRF.
UNITS	char	Units		Collected at CRF.
FREQ	num	Frequency		Collected at CRF.
CONTMED	num	Continue Medication		Collected at CRF.
OTHRTRT	num	Received Any Treatments Other Than Meds		Collected at CRF.
TREATMNT	char	Treatment		Collected at CRF.
INDICATE	char	Indication		Collected at CRF.
CONTRT	num	Continue Other Treatment		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
RXWHONUM	char	Who Drug Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
ATCCODE8	char	Atc Code 8		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.
ATCTEXT8	char	Atc Text 8		Collected at CRF.
RXPREF	char	Preferred Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
MEDSTDY	num	Relative Day Medication Added/Changed		If MEDSTDAT and REF.DATE not missing then perform below logic to calculate MEDSTDY, If MEDSTDAT less than REF.DATE then (MEDSTDAT - REF.DATE). Else if MEDSTDAT is greater than equal to REF.DATE then (MEDSTDAT- REF.DATE) +1.
MEDENDY	num	Relative Day Medication Discontinued		If MEDENDAT and REF.DATE not missing then perform below logic to calculate MEDENDY, If MEDENDAT less than REF.DATE then (MEDENDAT - REF.DATE). Else if MEDENDAT is greater than equal to REF.DATE then (MEDENDAT- REF.DATE) +1.
TRTSTDY	num	Relative Day Treatment Started		If TRTSTDAT and REF.DATE not missing then perform below logic to calculate TRTSTDY, If TRTSTDAT less than REF.DATE then (TRTSTDAT - REF.DATE). Else if TRTSTDAT is greater than equal to REF.DATE then (TRTSTDAT- REF.DATE) +1.
TRTENDY	num	Relative Day Treatment Discontinued		If TRTENDAT and REF.DATE not missing then perform below logic to calculate TRTENDY, If TRTENDAT less than REF.DATE then (TRTENDAT - REF.DATE). Else if TRTENDAT is greater than equal to REF.DATE then (TRTENDAT- REF.DATE) +1.

1.4.18. C-Ybocs (Compulsions) – CYBOCS

Dataset	CYBOCS
Creating program	cybocs.sas
Description	C-Ybocs (Compulsions)
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,INFORMNT,RATERID,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
Q01A	num	Time Spent Performing Comp. Behavior		Collected at CRF.
Q01A_C	char	Time Spent Performing Comp. Behavior (char)		Collected at CRF.
Q01B	num	Compulsive-Free Interval		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q01B_C	char	Compulsive-Free Interval (char)		Collected at CRF.
Q02	num	Interference Due To Comp. Behavior		Collected at CRF.
Q02_C	char	Interference Due To Comp. Behavior (char)		Collected at CRF.
Q03	num	Distress Assoc. With Comp. Behavior		Collected at CRF.
Q03_C	char	Distress Assoc. With Comp. Behavior (char)		Collected at CRF.
Q04	num	Resistance Against Compulsions		Collected at CRF.
Q04_C	char	Resistance Against Compulsions (char)		Collected at CRF.
Q05	num	Degree of Control Over Comp. Behavior		Collected at CRF.
Q05_C	char	Degree of Control Over Comp. Behavior (char)		Collected at CRF.
TOTAL	num	Add Items 1-4 (Without 1B)		Collected at CRF.
Q06	num	Reliability		Collected at CRF.
Q06_C	char	Reliability (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.19. End of Double Blind Treatment (Clinician) – EDBC

Dataset	EDBC
Creating program	edbc.sas
Description	End Of Double Blind Treatment (Clinician)
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,NAME,Q03EXP,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
Q01	num	1. Best Guess About Study Treatment		Collected at CRF.
Q02	num	2. If A or B Were Selected		Collected at CRF.
Q03A	num	3A. Lack of Efficacy		Collected at CRF.
Q03A_C	char	3A. Lack of Efficacy (char)		Collected at CRF.
Q03B	num	3B. Presence of Efficacy		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q03B_C	char	3B. Presence of Efficacy (char)		Collected at CRF.
Q03C	num	3C. Absence of Side Effects		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
Q03D	num	3D. Presence of Side Effects		Collected at CRF.
Q03E	num	3E. Other		Collected at CRF.
Q03E_C	char	3E. Other (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.20. End of Double Blind Treatment (Parent) – EDBP

Dataset	EDBP
Creating program	edbp.sas
Description	End of Double Blind Treatment (Parent)
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,Q02EXP,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
Q01	num	1. Best Guess About Study Treatment		Collected at CRF.
Q02A	num	2A. It Did Not Work		Collected at CRF.
Q02A_C	char	2A. It Did Not Work (char)		Collected at CRF.
Q02B	num	2B. It Worked		Collected at CRF.
Q02B_C	char	2B. It Worked (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q02C	num	2C. It Caused Bad, Unwanted Effects		Collected at CRF.
Q02C_C	char	2C. It Caused Bad, Unwanted Effects (char)		Collected at CRF.
Q02D	num	2D. It Did Not Bother My Child		Collected at CRF.
Q02D_C	char	2D. It Did Not Bother My Child (char)		Collected at CRF.
Q02E	num	2E. Other		Collected at CRF.
Q02E_C	char	2E. Other (char)		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, if VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.21. Electrocardiogram – EKG

Dataset	EKG
Creating program	ekg.sas
Description	Electrocardiogram
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
Q01	num	Was Electrocardiogram Done		Collected at CRF.
Q01_C	char	Was Electrocardiogram Done (char)		Collected at CRF.
Q02	num	Ecg Results		Collected at CRF.
Q03VR	num	Vr - Question 3: Specific Results		Collected at CRF.
Q03QT	num	Qt - Question 3: Specific Results		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q03PR	num	Pr - Question 3: Specific Results		Collected at CRF.
Q03QTC	num	Qtc - Question 3: Specific Results		Collected at CRF.
Q03QRS	num	Qr - Question 3: Specific Results		Collected at CRF.
Q04	num	Left Atrial Hypertrophy		Collected at CRF.
Q05	num	Right Atrial Hypertrophy		Collected at CRF.
Q06	num	Left Ventricular Hypertrophy		Collected at CRF.
Q07	num	Right Ventricular Hypertrophy		Collected at CRF.
Q08	num	Acute Infarction		Collected at CRF.
Q09	num	Subacute Infarction		Collected at CRF.
Q10	num	Old Infarction		Collected at CRF.
Q11	num	Myocardial Ischemia		Collected at CRF.
Q12	num	Digitalis Effect		Collected at CRF.
Q13	num	Symmetrical T-Wave Inversions		Collected at CRF.
Q14	num	Poor R-Wave Progression		Collected at CRF.
Q15	num	Other Nonspecific St/T		Collected at CRF.
Q16	num	Sinus Tachycardia		Collected at CRF.
Q17	num	Sinus Bradycardia		Collected at CRF.
Q18	num	Supraventricular Premature Beat		Collected at CRF.
Q19	num	Ventricular Premature Beat		Collected at CRF.
Q20	num	Supraventricular Tachycardia		Collected at CRF.
Q21	num	Ventricular Tachycardia		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q22	num	Atrial Fibrillation		Collected at CRF.
Q23	num	Atrial Flutter		Collected at CRF.
Q24	num	Other Rhythm Abnormalities		Collected at CRF.
Q25	num	Implanted Pacemaker		Collected at CRF.
Q26	num	1St Degree Av Block		Collected at CRF.
Q27	num	2Nd Degree Av Block		Collected at CRF.
Q28	num	3Rd Degree Av Block		Collected at CRF.
Q29	num	Lbb Block		Collected at CRF.
Q30	num	Rbb Block		Collected at CRF.
Q31	num	Preexcitation Syndrome		Collected at CRF.
Q32	num	Other Intraventricular Cond Block		Collected at CRF.
Q33	char	Other		Collected at CRF.
Q34	num	Exclude Individual		Collected at CRF.
Q34_C	char	Exclude Individual (char)		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.22. Inclusion/Exclusion Criteria – INCEXC

Dataset	INCEXC
Creating program	incexc.sas
Description	Inclusion/Exclusion Criteria
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
INC1	num	Between Age 5 - 17.2 Months		Collected at CRF.
INC1_C	char	Between Age 5 - 17.2 Months (char)		Collected at CRF.
INC2	num	Meets Dsm-Iv Criteria		Collected at CRF.
INC2_C	char	Meets Dsm-Iv Criteria (char)		Collected at CRF.
INC3	num	Medication Free		Collected at CRF.

Variable	Type	Label	Codes	Comments
INC3_C	char	Medication Free (char)		Collected at CRF.
INC4	num	Free of Anticonvulsants		Collected at CRF.
INC4_C	char	Free of Anticonvulsants (char)		Collected at CRF.
INC5	num	Achieves Scores (Cgi,Abc,Ritvo-Freeman)		Collected at CRF.
INC5_C	char	Achieves Scores (Cgi,Abc,Ritvo-Freeman) (char)		Collected at CRF.
INC6	num	Mental Age of 18 Months		Collected at CRF.
INC6_C	char	Mental Age of 18 Months (char)		Collected at CRF.
INC7	num	In Good Physical Health		Collected at CRF.
INC7_C	char	In Good Physical Health (char)		Collected at CRF.
INC8	num	Parent Gave Written Informed Consent		Collected at CRF.
INC8_C	char	Parent Gave Written Informed Consent (char)		Collected at CRF.
EXC1	num	Iq Below Mental Age of 18 Months		Collected at CRF.
EXC1_C	char	Iq Below Mental Age of 18 Months (char)		Collected at CRF.
EXC2	num	Female With Positive Beta Hcg Test		Collected at CRF.
EXC2_C	char	Female With Positive Beta Hcg Test (char)		Collected at CRF.
EXC3	num	Prior Adequate Trial With Risperidone		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXC3_C	char	Prior Adequate Trial With Risperidone (char)		Collected at CRF.
EXC4	num	Hypersensitivity To Risperidone		Collected at CRF.
EXC4_C	char	Hypersensitivity To Risperidone (char)		Collected at CRF.
EXC5	num	History, Neuroleptic Malignant Syndrome		Collected at CRF.
EXC5_C	char	History, Neuroleptic Malignant Syndrome (char)		Collected at CRF.
EXC6	num	Dsm-iv Diagnosis,Pervasive Dev. Disorder		Collected at CRF.
EXC6_C	char	Dsm-iv Diagnosis,Pervasive Dev. Disorder (char)		Collected at CRF.
EXC7	num	Significant Medical Condition		Collected at CRF.
EXC7_C	char	Significant Medical Condition (char)		Collected at CRF.
EXC8	num	Weight Is Less Than 20 Kg		Collected at CRF.
EXC8_C	char	Weight Is Less Than 20 Kg (char)		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.

Variable	Type	Label	Codes	Comments
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.23. Intelligence Testing – INTTEST

Dataset	INTTEST
Creating program	inttest.sas
Description	Intelligence Testing
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,RATERID,VISITDAT,IQ_DAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
TEST	num	Which Test Was Administered?		Collected at CRF.
TEST_C	char	Which Test Was Administered? (char)		Collected at CRF.
WISC_Q1R	num	Wisc:Picture Completion - Raw Score		Collected at CRF.
WISC_Q1S	num	Wisc:Picture Completion - Scaled Score		Collected at CRF.
WISC_Q1M	num	Wisc:Picture Completion - Missing		Collected at CRF.
WISC_Q2R	num	Wisc:Information - Raw Score		Collected at CRF.
WISC_Q2S	num	Wisc:Information - Scaled Score		Collected at CRF.
WISC_Q2M	num	Wisc:Information - Missing		Collected at CRF.
WISC_Q3R	num	Wisc:Coding - Raw Score		Collected at CRF.
WISC_Q3S	num	Wisc:Coding - Scaled Score		Collected at CRF.
WISC_Q3M	num	Wisc:Coding - Missing		Collected at CRF.
WISC_Q4R	num	Wisc:Similarities - Raw Score		Collected at CRF.
WISC_Q4S	num	Wisc:Similarities - Scaled Score		Collected at CRF.
WISC_Q4M	num	Wisc:Similarities - Missing		Collected at CRF.
WISC_Q5R	num	Wisc:Picture Arrangement - Raw Score		Collected at CRF.

Variable	Type	Label	Codes	Comments
WISC_Q5S	num	Wisc:Picture Arrangement - Scaled Score		Collected at CRF.
WISC_Q5M	num	Wisc:Picture Arrangement - Missing		Collected at CRF.
WISC_Q6R	num	Wisc:Arithmetic - Raw Score		Collected at CRF.
WISC_Q6S	num	Wisc:Arithmetic - Scaled Score		Collected at CRF.
WISC_Q6M	num	Wisc:Arithmetic - Missing		Collected at CRF.
WISC_Q7R	num	Wisc:Block Design - Raw Score		Collected at CRF.
WISC_Q7S	num	Wisc:Block Design - Scaled Score		Collected at CRF.
WISC_Q7M	num	Wisc:Block Design - Missing		Collected at CRF.
WISC_Q8R	num	Wisc:Vocabulary - Raw Score		Collected at CRF.
WISC_Q8S	num	Wisc:Vocabulary - Scaled Score		Collected at CRF.
WISC_Q8M	num	Wisc:Vocabulary - Missing		Collected at CRF.
WISC_Q9R	num	Wisc:Object Assembly - Raw Score		Collected at CRF.
WISC_Q9S	num	Wisc:Object Assembly - Scaled Score		Collected at CRF.
WISC_Q9M	num	Wisc:Object Assembly - Missing		Collected at CRF.
WISCQ10R	num	Wisc:Comprehension - Raw Score		Collected at CRF.
WISCQ10S	num	Wisc:Comprehension - Scaled Score		Collected at CRF.
WISCQ10M	num	Wisc:Comprehension - Missing		Collected at CRF.
WISCQ11S	num	Wisc:Verbal Score		Collected at CRF.

Variable	Type	Label	Codes	Comments
WISCQ11I	num	Wisc:Verbal Iq/Index		Collected at CRF.
WISCQ11M	num	Wisc:Verbal - Missing		Collected at CRF.
WISCQ12S	num	Wisc:Performance Score		Collected at CRF.
WISCQ12I	num	Wisc:Performance Iq/Index		Collected at CRF.
WISCQ12M	num	Wisc:Performance - Missing		Collected at CRF.
WISCQ13S	num	Wisc:Full Scale Score		Collected at CRF.
WISCQ13I	num	Wisc:Full Scale Iq/Index		Collected at CRF.
WISCQ13M	num	Wisc:Full Scale - Missing		Collected at CRF.
WISCQ14S	num	Wisc:Vc Score		Collected at CRF.
WISCQ14I	num	Wisc:Vc Iq/Index		Collected at CRF.
WISCQ14M	num	Wisc:Vc - Missing		Collected at CRF.
WISCQ15S	num	Wisc:Po Score		Collected at CRF.
WISCQ15I	num	Wisc:Po Iq/Index		Collected at CRF.
WISCQ15M	num	Wisc:Po - Missing		Collected at CRF.
WISCQ16S	num	Wisc:Fd Score		Collected at CRF.
WISCQ16I	num	Wisc:Fd Iq/Index		Collected at CRF.
WISCQ16M	num	Wisc:Fd - Missing		Collected at CRF.
WISCQ17S	num	Wisc:Ps Score		Collected at CRF.
WISCQ17I	num	Wisc:Ps Iq/Index		Collected at CRF.
WISCQ17M	num	Wisc:Ps - Missing		Collected at CRF.
WISC_SC	num	Wisc:Full Scale Score		Collected at CRF.

Variable	Type	Label	Codes	Comments
WISC_SCM	num	Wisc:Full Scale Score - Missing		Collected at CRF.
WPPSIQ1R	num	Wpsi:Perf Test, Obj Assem, Raw Score		Collected at CRF.
WPPSIQ1S	num	Wpsi:Perf Test, Obj Assem, Scaled Score		Collected at CRF.
WPPSIQ1M	num	Wpsi:Perf Test, Obj Assem, Missing		Collected at CRF.
WPPSIQ2R	num	Wpsi:Perf Test, Geom Des, Raw Score		Collected at CRF.
WPPSIQ2S	num	Wpsi:Perf Test, Geom Des, Scaled Score		Collected at CRF.
WPPSIQ2M	num	Wpsi:Perf Test, Geom Des, Missing		Collected at CRF.
WPPSIQ3R	num	Wpsi:Perf Test, Block Des, Raw Score		Collected at CRF.
WPPSIQ3S	num	Wpsi:Perf Test, Block Des, Scaled Score		Collected at CRF.
WPPSIQ3M	num	Wpsi:Perf Test, Block Des, Missing		Collected at CRF.
WPPSIQ4R	num	Wpsi:Perf Test, Mazes - Raw Score		Collected at CRF.
WPPSIQ4S	num	Wpsi:Perf Test, Mazes - Scaled Score		Collected at CRF.
WPPSIQ4M	num	Wpsi:Perf Test, Mazes - Missing		Collected at CRF.

Variable	Type	Label	Codes	Comments
WPPSIQ5R	num	Wpsi:Perf Test, Pict Comp, Raw Score		Collected at CRF.
WPPSIQ5S	num	Wpsi:Perf Test, Pict Comp, Scaled Score		Collected at CRF.
WPPSIQ5M	num	Wpsi:Perf Test, Pict Comp, Missing		Collected at CRF.
WPPSIPRM	num	Wpsi:Total Performance Tests		Collected at CRF.
WPPSIPM	num	Wpsi:Total Performance Tests - Missing		Collected at CRF.
WPPSIQ6R	num	Wpsi:Verbal Test, Info - Raw Score		Collected at CRF.
WPPSIQ6S	num	Wpsi:Verbal Test, Info - Scaled Score		Collected at CRF.
WPPSIQ6M	num	Wpsi:Verbal Test, Info - Missing		Collected at CRF.
WPPSIQ7R	num	Wpsi:Verbal Test, Comp - Raw Score		Collected at CRF.
WPPSIQ7S	num	Wpsi:Verbal Test, Comp - Scaled Score		Collected at CRF.
WPPSIQ7M	num	Wpsi:Verbal Test, Comp - Missing		Collected at CRF.
WPPSIQ8R	num	Wpsi:Verbal Test, Arith - Raw Score		Collected at CRF.
WPPSIQ8S	num	Wpsi:Verbal Test, Arith - Scaled Score		Collected at CRF.
WPPSIQ8M	num	Wpsi:Verbal Test, Arith - Missing		Collected at CRF.

Variable	Type	Label	Codes	Comments
WPPSIQ9R	num	Wpsi:Verbal Test, Vocab - Raw Score		Collected at CRF.
WPPSIQ9S	num	Wpsi:Verbal Test, Vocab - Scaled Score		Collected at CRF.
WPPSIQ9M	num	Wpsi:Verbal Test, Vocab - Missing		Collected at CRF.
WPPSQ10R	num	Wpsi:Verbal Test, Similar, Raw Score		Collected at CRF.
WPPSQ10S	num	Wpsi:Verbal Test, Similar, Scaled Score		Collected at CRF.
WPPSQ10M	num	Wpsi:Verbal Test, Similar, Missing		Collected at CRF.
WPPSIVER	num	Wpsi:Total Verbal Tests		Collected at CRF.
WPPSIVM	num	Wpsi:Total Verbal Tests - Missing		Collected at CRF.
WPPSQ11S	num	Wpsi:Performance Score - Scaled Score		Collected at CRF.
WPPSQ11I	num	Wpsi:Performance Score - Iq		Collected at CRF.
WPPSQ11M	num	Wpsi:Performance Score - Missing		Collected at CRF.
WPPSQ12S	num	Wpsi:Verbal Score - Scaled Score		Collected at CRF.
WPPSQ12I	num	Wpsi:Verbal Score - Iq		Collected at CRF.
WPPSQ12M	num	Wpsi:Verbal Score - Missing		Collected at CRF.
WPPSQ13S	num	Wpsi:Full Scale - Scaled Score		Collected at CRF.
WPPSQ13I	num	Wpsi:Full Scale - Iq		Collected at CRF.
WPPSQ13M	num	Wpsi:Full Scale - Missing		Collected at CRF.

Variable	Type	Label	Codes	Comments
L_FG_R	num	Leiter:Figure Ground - Raw Score		Collected at CRF.
L_FG_S	num	Leiter:Figure Ground - Scaled Score		Collected at CRF.
L_FG_M	num	Leiter:Figure Ground - Missing		Collected at CRF.
L_FC_R	num	Leiter:Form Completion - Raw Score		Collected at CRF.
L_FC_S	num	Leiter:Form Completion - Scaled Score		Collected at CRF.
L_FC_M	num	Leiter:Form Completion - Missing		Collected at CRF.
L_SO_R	num	Leiter:Sequential Order - Raw Score		Collected at CRF.
L_SO_S	num	Leiter:Sequential Order - Scaled Score		Collected at CRF.
L_SO_M	num	Leiter:Sequential Order - Missing		Collected at CRF.
L_RP_R	num	Leiter:Repeated Patterns - Raw Score		Collected at CRF.
L_RP_S	num	Leiter:Repeated Patterns - Scaled Score		Collected at CRF.
L_RP_M	num	Leiter:Repeated Patterns - Missing		Collected at CRF.
L_BIQ_SM	num	Leiter:Brief Iq - Sum of Scaled Scores		Collected at CRF.
L_BIQ_IQ	num	Leiter:Brief Iq - Iq		Collected at CRF.
L_BIQ_PE	num	Leiter:Brief Iq - Percentile		Collected at CRF.

Variable	Type	Label	Codes	Comments
L_BIQ_IN	num	Leiter: Brief Iq - % Confidence Interval		Collected at CRF.
L_BIQ_M	num	Leiter: Brief Iq - Missing		Collected at CRF.
MUL_Q1R	num	Mullen: Gross Motor - Raw Score		Collected at CRF.
MUL_Q1S	num	Mullen: Gross Motor - Scaled Score		Collected at CRF.
MUL_Q1M	num	Mullen: Gross Motor - Missing		Collected at CRF.
MUL_Q2R	num	Mullen: Visual Reception - Raw Score		Collected at CRF.
MUL_Q2S	num	Mullen: Visual Reception - Scaled Score		Collected at CRF.
MUL_Q2M	num	Mullen: Visual Reception - Missing		Collected at CRF.
MUL_Q3R	num	Mullen: Fine Motor - Raw Score		Collected at CRF.
MUL_Q3S	num	Mullen: Fine Motor - Scaled Score		Collected at CRF.
MUL_Q3M	num	Mullen: Fine Motor - Missing		Collected at CRF.
MUL_Q4R	num	Mullen: Receptive Language - Raw Score		Collected at CRF.
MUL_Q4S	num	Mullen: Receptive Language - Scaled Score		Collected at CRF.
MUL_Q4M	num	Mullen: Receptive Language - Missing		Collected at CRF.
MUL_Q5R	num	Mullen: Expressive Language, Raw Score		Collected at CRF.

Variable	Type	Label	Codes	Comments
MUL_Q5S	num	Mullen:Expressive Language, Scaled Score		Collected at CRF.
MUL_Q5M	num	Mullen:Expressive Language, Missing		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
IQ_DY	num	Relative Day Iq Test Administered		If IQ_DAT and REF.DATE not missing then perform below logic to calculate IQ_DY, If IQ_DAT less than REF.DATE then (IQ_DAT - REF.DATE). Else if IQ_DAT is greater than equal to REF.DATE then (IQ_DAT- REF.DATE) +1.

1.4.24. Lab Pathology – LABPATHO

Dataset	LABPATHO
Creating program	labpatho.sas
Description	Lab Pathology
Unique identifier	LABTEST
Sorted by	LABTEST
Notes	

Variable	Type	Label	Codes	Comments
LABTEST	char	Lab Test		Collected at CRF.
SEX	char	Sex		Collected at CRF.
LOWAGE	num	Low Age		Collected at CRF.
HIGHAGE	num	High Age		Collected at CRF.
LOWLIMIT	num	Lower Limit		Collected at CRF.
UPPLIMIT	num	Upper Limit		Collected at CRF.
UNITS	char	Units		Collected at CRF.
CFACTOR	num	Conversion Factor		Collected at CRF.
SIUNIT	char	Standard International Unit		Collected at CRF.

1.4.25. Lab Range – LABRANGE

Dataset	LABRANGE
Creating program	labrange.sas
Description	Lab Range
Unique identifier	TESTNAME
Sorted by	TESTNAME
Notes	

Variable	Type	Label	Codes	Comments
TESTNAME	char	Testname		Collected at CRF.
TESTCODE	char	Testcode		Collected at CRF.
KKI_LO	num	Kki_Lo		Collected at CRF.
KKI_HI	num	Kki_Hi		Collected at CRF.
IU_LO	num	Iu_Lo		Collected at CRF.
IU_HI	num	Iu_Hi		Collected at CRF.
OSU_LO	num	Osu_Lo		Collected at CRF.
OSU_HI	num	Osu_Hi		Collected at CRF.
UCLA_LO	num	Ucla_Lo		Collected at CRF.
UCLA_HI	num	Ucla_Hi		Collected at CRF.
YALE_LO	num	Yale_Lo		Collected at CRF.
YALE_HI	num	Yale_Hi		Collected at CRF.

1.4.26. Medical History and Status – MHS

Dataset	MHS
Creating program	mhs.sas
Description	Medical History and Status
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,PHYSNAME,Q01B,Q02B,Q03B,Q04B,Q05B,Q06B,Q07B,Q08B, Q09B,Q10B,Q11B,Q12B,Q13B,Q14B,Q15B,Q16B,Q17B,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
Q01A	num	Metabolic		Collected at CRF.
Q01A_C	char	Metabolic (char)		Collected at CRF.
Q01C	num	Metabolic Clinically Relevant		Collected at CRF.
Q01C_C	char	Metabolic Clinically Relevant (char)		Collected at CRF.
Q02A	num	Respiratory/Pulmonary System		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q02A_C	char	Respiratory/Pulmonary System (char)		Collected at CRF.
Q02C	num	Respiratory/Pulmonary Clin. Relevant		Collected at CRF.
Q02C_C	char	Respiratory/Pulmonary Clin. Relevant (char)		Collected at CRF.
Q03A	num	Cardiovascular Disease		Collected at CRF.
Q03A_C	char	Cardiovascular Disease (char)		Collected at CRF.
Q03C	num	Cardiovascular Disease Clin. Relevant		Collected at CRF.
Q03C_C	char	Cardiovascular Disease Clin. Relevant (char)		Collected at CRF.
Q04A	num	Endocrinological System		Collected at CRF.
Q04A_C	char	Endocrinological System (char)		Collected at CRF.
Q04C	num	Endocrinological System Clin. Relevant		Collected at CRF.
Q04C_C	char	Endocrinological System Clin. Relevant (char)		Collected at CRF.
Q05A	num	Gastrointestinal System		Collected at CRF.
Q05A_C	char	Gastrointestinal System (char)		Collected at CRF.
Q05C	num	Gastrointestinal System Clin. Relevant		Collected at CRF.
Q05C_C	char	Gastrointestinal System Clin. Relevant (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q06A	num	Genitourinary/Reproductive Sys		Collected at CRF.
Q06A_C	char	Genitourinary/Reproductive Sys (char)		Collected at CRF.
Q06C	num	Genitourinary/Reproductive Sys Clin. Rel		Collected at CRF.
Q06C_C	char	Genitourinary/Reproductive Sys Clin. Rel (char)		Collected at CRF.
Q07A	num	Musculoskeletal System		Collected at CRF.
Q07A_C	char	Musculoskeletal System (char)		Collected at CRF.
Q07C	num	Musculoskeletal System Clin. Relevant		Collected at CRF.
Q07C_C	char	Musculoskeletal System Clin. Relevant (char)		Collected at CRF.
Q08A	num	Skin/Appendages		Collected at CRF.
Q08A_C	char	Skin/Appendages (char)		Collected at CRF.
Q08C	num	Skin/Appendages Clinically Relevant		Collected at CRF.
Q08C_C	char	Skin/Appendages Clinically Relevant (char)		Collected at CRF.
Q09A	num	Allergies		Collected at CRF.
Q09A_C	char	Allergies (char)		Collected at CRF.
Q09C	num	Allergies Clinically Relevant		Collected at CRF.
Q09C_C	char	Allergies Clinically Relevant (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q10A	num	Neurological System		Collected at CRF.
Q10A_C	char	Neurological System (char)		Collected at CRF.
Q10C	num	Neurological System Clinically Relevant		Collected at CRF.
Q10C_C	char	Neurological System Clinically Relevant (char)		Collected at CRF.
Q11A	num	Ophthalmologic		Collected at CRF.
Q11A_C	char	Ophthalmologic (char)		Collected at CRF.
Q11C	num	Ophthalmologic Clinically Relevant		Collected at CRF.
Q11C_C	char	Ophthalmologic Clinically Relevant (char)		Collected at CRF.
Q12A	num	Renal		Collected at CRF.
Q12A_C	char	Renal (char)		Collected at CRF.
Q12C	num	Renal Clinically Relevant		Collected at CRF.
Q12C_C	char	Renal Clinically Relevant (char)		Collected at CRF.
Q13A	num	Hepatic		Collected at CRF.
Q13A_C	char	Hepatic (char)		Collected at CRF.
Q13C	num	Hepatic Clinically Relevant		Collected at CRF.
Q13C_C	char	Hepatic Clinically Relevant (char)		Collected at CRF.
Q14A	num	Hematopoietic System		Collected at CRF.
Q14A_C	char	Hematopoietic System (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q14C	num	Hematopoietic System Clinically Relevant		Collected at CRF.
Q14C_C	char	Hematopoietic System Clinically Relevant (char)		Collected at CRF.
Q15	char	Other 1 Name		Collected at CRF.
Q15A	num	Other 1		Collected at CRF.
Q15A_C	char	Other 1 (char)		Collected at CRF.
Q15C	num	Other 1 Clinically Relevant		Collected at CRF.
Q15C_C	char	Other 1 Clinically Relevant (char)		Collected at CRF.
Q16	char	Other 2 Name		Collected at CRF.
Q16A	num	Other 2		Collected at CRF.
Q16A_C	char	Other 2 (char)		Collected at CRF.
Q16C	num	Other 2 Clinically Relevant		Collected at CRF.
Q16C_C	char	Other 2 Clinically Relevant (char)		Collected at CRF.
Q17	char	Other 3 Name		Collected at CRF.
Q17A	num	Other 3		Collected at CRF.
Q17A_C	char	Other 3 (char)		Collected at CRF.
Q17C	num	Other 3 Clinically Relevant		Collected at CRF.
Q17C_C	char	Other 3 Clinically Relevant (char)		Collected at CRF.
Q18	num	Adverse Psycho-Social		Collected at CRF.
Q18_C	char	Adverse Psycho-Social (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q19	num	Fragile X Syndrome		Collected at CRF.
Q19_C	char	Fragile X Syndrome (char)		Collected at CRF.
Q20	num	Cornelia De Lange Syndrome		Collected at CRF.
Q20_C	char	Cornelia De Lange Syndrome (char)		Collected at CRF.
Q21	num	Landau-Kleffner Syndrome		Collected at CRF.
Q21_C	char	Landau-Kleffner Syndrome (char)		Collected at CRF.
Q22	num	Sturge Weber Syndrome		Collected at CRF.
Q22_C	char	Sturge Weber Syndrome (char)		Collected at CRF.
Q23	num	Other Genetic Syndrome		Collected at CRF.
Q23_C	char	Other Genetic Syndrome (char)		Collected at CRF.
Q23A	char	Other Genetic Syndrome, Specify		Collected at CRF.
Q24	num	Neurofibromatosis		Collected at CRF.
Q24_C	char	Neurofibromatosis (char)		Collected at CRF.
Q25	num	Metabolic Disorder		Collected at CRF.
Q25_C	char	Metabolic Disorder (char)		Collected at CRF.
Q26	num	Tuberous Sclerosis		Collected at CRF.
Q26_C	char	Tuberous Sclerosis (char)		Collected at CRF.
Q27	num	Conigenital Rubella Exposure		Collected at CRF.
Q27_C	char	Conigenital Rubella Exposure (char)		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.

Variable	Type	Label	Codes	Comments
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.27. Physical Exam – PHYSEXAM

Dataset	PHYSEXAM
Creating program	physexam.sas
Description	Physical Exam
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RANDNBR,Q35,Q37,Q49,Q52,Q55,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q06	num	General Appearance Result		Collected at CRF.
Q06_C	char	General Appearance Result (char)		Collected at CRF.
Q07	char	General Appearance Abnormality		Collected at CRF.
Q08	num	General Appearance Clinically Relevant		Collected at CRF.
Q08_C	char	General Appearance Clinically Relevant (char)		Collected at CRF.
Q09	num	Head Result		Collected at CRF.
Q09_C	char	Head Result (char)		Collected at CRF.
Q10	char	Head Abnormality		Collected at CRF.
Q11	num	Head Clinically Relevant		Collected at CRF.
Q11_C	char	Head Clinically Relevant (char)		Collected at CRF.
Q12	num	Ears Result		Collected at CRF.
Q12_C	char	Ears Result (char)		Collected at CRF.
Q13	char	Ears Abnormality		Collected at CRF.
Q14	num	Ears Clinically Relevant		Collected at CRF.
Q14_C	char	Ears Clinically Relevant (char)		Collected at CRF.
Q15	num	Eyes Result		Collected at CRF.
Q15_C	char	Eyes Result (char)		Collected at CRF.
Q16	char	Eyes Abnormality		Collected at CRF.
Q17	num	Eyes Clinically Relevant		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q17_C	char	Eyes Clinically Relevant (char)		Collected at CRF.
Q18	num	Ocular Fundi Result		Collected at CRF.
Q18_C	char	Ocular Fundi Result (char)		Collected at CRF.
Q19	char	Ocular Fundi Abnormality		Collected at CRF.
Q20	num	Ocular Fundi Clinically Relevant		Collected at CRF.
Q20_C	char	Ocular Fundi Clinically Relevant (char)		Collected at CRF.
Q21	num	Nose Result		Collected at CRF.
Q21_C	char	Nose Result (char)		Collected at CRF.
Q22	char	Nose Abnormality		Collected at CRF.
Q23	num	Nose Clinically Relevant		Collected at CRF.
Q23_C	char	Nose Clinically Relevant (char)		Collected at CRF.
Q24	num	Mouth Result		Collected at CRF.
Q24_C	char	Mouth Result (char)		Collected at CRF.
Q25	char	Mouth Abnormality		Collected at CRF.
Q26	num	Mouth Clinically Relevant		Collected at CRF.
Q26_C	char	Mouth Clinically Relevant (char)		Collected at CRF.
Q27	num	Throat Result		Collected at CRF.
Q27_C	char	Throat Result (char)		Collected at CRF.
Q28	char	Throat Abnormality		Collected at CRF.
Q29	num	Throat Clinically Relevant		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q29_C	char	Throat Clinically Relevant (char)		Collected at CRF.
Q30	num	Neck Result		Collected at CRF.
Q30_C	char	Neck Result (char)		Collected at CRF.
Q31	char	Neck Abnormality		Collected at CRF.
Q32	num	Neck Clinically Relevant		Collected at CRF.
Q32_C	char	Neck Clinically Relevant (char)		Collected at CRF.
Q33	num	Thyroid Result		Collected at CRF.
Q33_C	char	Thyroid Result (char)		Collected at CRF.
Q34	char	Thyroid Abnormality		Collected at CRF.
Q36	num	Lungs Result		Collected at CRF.
Q36_C	char	Lungs Result (char)		Collected at CRF.
Q37	char	Lungs Abnormality		Collected at CRF.
Q38	num	Lungs Clinically Relevant		Collected at CRF.
Q38_C	char	Lungs Clinically Relevant (char)		Collected at CRF.
Q39	num	Heart Result		Collected at CRF.
Q39_C	char	Heart Result (char)		Collected at CRF.
Q40	char	Heart Abnormality		Collected at CRF.
Q41	num	Heart Clinically Relevant		Collected at CRF.
Q41_C	char	Heart Clinically Relevant (char)		Collected at CRF.
Q42	num	Breasts Result		Collected at CRF.
Q42_C	char	Breasts Result (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q43	char	Breasts Abnormality		Collected at CRF.
Q44	num	Breasts Clinically Relevant		Collected at CRF.
Q44_C	char	Breasts Clinically Relevant (char)		Collected at CRF.
Q45	num	Abdomen Result		Collected at CRF.
Q45_C	char	Abdomen Result (char)		Collected at CRF.
Q46	char	Abdomen Abnormality		Collected at CRF.
Q47	num	Abdomen Clinically Relevant		Collected at CRF.
Q47_C	char	Abdomen Clinically Relevant (char)		Collected at CRF.
Q48	num	Musculoskeletal Result		Collected at CRF.
Q48_C	char	Musculoskeletal Result (char)		Collected at CRF.
Q50	num	Musculoskeletal Clinically Relevant		Collected at CRF.
Q50_C	char	Musculoskeletal Clinically Relevant (char)		Collected at CRF.
Q51	num	Extremities Result		Collected at CRF.
Q51_C	char	Extremities Result (char)		Collected at CRF.
Q53	num	Extremities Clinically Relevant		Collected at CRF.
Q53_C	char	Extremities Clinically Relevant (char)		Collected at CRF.
Q54	num	Skin Result		Collected at CRF.
Q54_C	char	Skin Result (char)		Collected at CRF.
Q56	num	Skin Clinically Relevant		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q56_C	char	Skin Clinically Relevant (char)		Collected at CRF.
Q57	num	Lymph Nodes Result		Collected at CRF.
Q57_C	char	Lymph Nodes Result (char)		Collected at CRF.
Q58	char	Lymph Nodes Abnormality		Collected at CRF.
Q59	num	Lymph Nodes Clinically Relevant		Collected at CRF.
Q59_C	char	Lymph Nodes Clinically Relevant (char)		Collected at CRF.
Q60	num	Pulses Result		Collected at CRF.
Q60_C	char	Pulses Result (char)		Collected at CRF.
Q61	char	Pulses Abnormality		Collected at CRF.
Q62	num	Pulses Clinically Relevant		Collected at CRF.
Q62_C	char	Pulses Clinically Relevant (char)		Collected at CRF.
Q63	num	Neurological Result		Collected at CRF.
Q63_C	char	Neurological Result (char)		Collected at CRF.
Q64	char	Neurological Abnormality		Collected at CRF.
Q65	num	Neurological Clinically Relevant		Collected at CRF.
Q65_C	char	Neurological Clinically Relevant (char)		Collected at CRF.
Q66	num	Genitourinary Result		Collected at CRF.
Q66_C	char	Genitourinary Result (char)		Collected at CRF.
Q67	char	Genitourinary Abnormality		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q68	num	Genitourinary Clinically Relevant		Collected at CRF.
Q68_C	char	Genitourinary Clinically Relevant (char)		Collected at CRF.
Q69	num	Rectal Result		Collected at CRF.
Q69_C	char	Rectal Result (char)		Collected at CRF.
Q70	char	Rectal Abnormality		Collected at CRF.
Q71	num	Rectal Clinically Relevant		Collected at CRF.
Q71_C	char	Rectal Clinically Relevant (char)		Collected at CRF.
Q72	num	Tanner Stage		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.28. Plasma – PLASMA

Dataset	PLASMA
Creating program	plasma.sas
Description	Plasma
Unique identifier	DPATID,WEEK,DRAWDY
Sorted by	DPATID,WEEK,DRAWDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DRAWDATE,RISP_V,R9OH_V

Variable	Type	Label	Codes	Comments
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned patient id for De-Identity
STATUS	char	Status From Pk		Collected at CRF.
WEEK	num	Week Number From Pk		Collected at CRF.
DRAWTIME	num	Time of Sample		Collected at CRF.
RISP	num	Risperidone (Ng/MI)		Collected at CRF.
RISP_9OH	num	9-Oh Risperidone (Ng/MI)		Collected at CRF.
DRAWDY	num	Relative Day of Sample		If DRAWDATE and REF.DATE not missing then perform below logic to calculate DRAWDY, If DRAWDATE less than REF.DATE then (DRAWDATE - REF.DATE). Else if DRAWDATE is greater than equal to REF.DATE then (DRAWDATE- REF.DATE) +1.

1.4.29. Pregnancy Test – PREGTEST

Dataset	PREGTEST
Creating program	pregtest.sas
Description	Pregnancy Test
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RANDNBR,Q04,COMPNAME,VISITDAT,MENARDAT,NAME

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
Q01	num	Child Bearing Potential		Collected at CRF.
Q01_C	char	Child Bearing Potential (char)		Collected at CRF.
Q03	num	Birth Control Method		Collected at CRF.
Q03_C	char	Birth Control Method (char)		Collected at CRF.
Q05	num	Pregnancy Test		Collected at CRF.
Q05_C	char	Pregnancy Test (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
MENARDY	num	Relative Day of Menarche		If MENARDAT and REF.DATE not missing then perform below logic to calculate MENARDY, If MENARDAT less than REF.DATE then (MENARDAT - REF.DATE). Else if MENARDAT is greater than equal to REF.DATE then (MENARDAT- REF.DATE) +1.

1.4.30. Pre-Screening – PRESCRN

Dataset	PRESCRN
Creating program	prescrn.sas
Description	Pre-Screening
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RANDNBR , Q04T,Q05EOM,VISITDAT,Q11_DAT,Q12_DAT, Q13T, Q14T

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
INTERVAL	num	Week Number		Collected at CRF.
Q01	char	Age		Element will be grouped to protect subject PII as per HIPPA rules: If age is greater than 89 then "90+"
Q02	num	2. Weight > 30 Pounds		Collected at CRF.
Q03	num	3. Gender		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q03_C	char	3. Gender (char)		Collected at CRF.
Q04	num	4. Source of Referral		Collected at CRF.
Q05APM	char	5A. Psychotropic Medication		Collected at CRF.
Q05BPM	char	5B. Psychotropic Medication		Collected at CRF.
Q05CPM	char	5C. Psychotropic Medication		Collected at CRF.
Q05DPM	char	5D. Psychotropic Medication		Collected at CRF.
Q05EPM	char	5E. Psychotropic Medication		Collected at CRF.
Q05AOM	char	5A. Other Medication		Collected at CRF.
Q05BOM	char	5B. Other Medication		Collected at CRF.
Q05COM	char	5C. Other Medication		Collected at CRF.
Q05DOM	char	5D. Other Medication		Collected at CRF.
Q06	num	6. Has History of Seizures		Collected at CRF.
Q06A	num	6A. Seizure Free For 6 Months		Collected at CRF.
Q07	num	7. Receiving Anti-Convulsant Meds		Collected at CRF.
Q07A	num	7A. Stable Dose For 4 Weeks		Collected at CRF.
Q08	num	8. Had Prior Treatment With Risperidone		Collected at CRF.
Q08A	num	8A. Had Hypersensitivity To Risperidone		Collected at CRF.
Q08B	num	8B. Had Adverse Event From Risperidone		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q08C	num	8C. Potentially Serious Adverse Event		Collected at CRF.
Q09	num	9. Taking Psychotropic Meds		Collected at CRF.
Q10	num	10. Medication Free		Collected at CRF.
Q11	num	11. Appointment Scheduled		Collected at CRF.
Q11_TIME	char	11. Time Appointment Scheduled		Collected at CRF.
Q12	num	12. Follow-Up Call		Collected at CRF.
Q13_1	num	13. Subject Excluded For Age		Collected at CRF.
Q13_6A	num	13. Subject Excluded For Seizure		Collected at CRF.
Q13_7A	num	13. Subject Excluded For Unstable Ac Med		Collected at CRF.
Q13_8	num	13. Subject Excluded For Prior Trt		Collected at CRF.
Q13_8A	num	13. Subject Excluded, Hypersensitivity		Collected at CRF.
Q13_8B	num	13. Subject Excluded For Risp Ae		Collected at CRF.
Q13_8C	num	13. Subject Excluded For Risp Sae		Collected at CRF.
Q13_10	num	13. Subject Excluded For Med Free		Collected at CRF.
Q13_O	num	13. Subject Excluded For Other Reason		Collected at CRF.
Q14	num	14. Other Action(S) Taken		Collected at CRF.
Q15	num	15. Will Participate, Pharm Studies		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q16	num	16. Will Participate, Non-Pharm Studies		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
Q11_DY	num	Relative Day Appointment Scheduled		If Q11_DAT and REF.DATE not missing then perform below logic to calculate Q11_DY, If Q11_DAT less than REF.DATE then (Q11_DAT - REF.DATE). Else if Q11_DAT is greater than equal to REF.DATE then (Q11_DAT- REF.DATE) +1.
Q12_DY	num	Relative Follow-Up Day		If Q12_DAT and REF.DATE not missing then perform below logic to calculate Q12_DY, If Q12_DAT less than REF.DATE then (Q12_DAT - REF.DATE). Else if Q12_DAT is greater than equal to REF.DATE then (Q12_DAT- REF.DATE) +1.

1.4.31. Previous Therapy – PRETHER

Dataset	PRETHER
Creating program	prether.sas
Description	Previous Therapy
Unique identifier	STUDYID,DPATID,MEDNAME,INTERVAL,VISITDY,PTSEQNO
Sorted by	STUDYID,DPATID ,MEDNAME ,INTERVAL,VISITDY,PTSEQNO
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: RANDNBR,VISITDAT,ADDDAT,STOPDAT,ATCCODE6,ATCCODE7,ATCCODE8, ATCCODE9,ATCTEXT6,ATCTEXT7,ATCTEXT8,ATCTEXT9

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
PTSEQNO	num	Prev.Rx Seq		Collected at CRF.
NOMEDS	num	No Previous Therapy		Collected at CRF.
NOMEDS_C	char	No Previous Therapy (char)		Collected at CRF.
ANTIMED	num	Taking Anticonvulsant Medications?		Collected at CRF.

Variable	Type	Label	Codes	Comments
ANTIMED_C	char	Taking Anticonvulsant Medications? (char)		Collected at CRF.
MEDNAME	char	Medication (Generic/Brand Name)		Collected at CRF.
PURPIND	char	Purpose/Indication		Collected at CRF.
ROUTE	num	Route		Collected at CRF.
ROUTE_C	char	Route (char)		Collected at CRF.
DOSE	num	Dose		Collected at CRF.
UNITS	char	Units		Collected at CRF.
FREQ	num	Frequency		Collected at CRF.
CONTINUE	num	Continuing Medication		Collected at CRF.
CONTINUE_C	char	Continuing Medication (char)		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
PRVRX	char	Prev. Rx		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.

Variable	Type	Label	Codes	Comments
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.
RXPREF	char	Rxpref		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
ADDDY	num	Relative Medication Add Day		If ADDDAT and REF.DATE not missing then perform below logic to calculate ADDDY, If ADDDAT less than REF.DATE then (ADDDAT - REF.DATE). Else if ADDDAT is greater than equal to REF.DATE then (ADDDAT- REF.DATE) +1.
STOPDY	num	Relative Medication Stop Day		If STOPDAT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDAT less than REF.DATE then (STOPDAT - REF.DATE). Else if STOPDAT is greater than equal to REF.DATE then (STOPDAT- REF.DATE) +1.

1.4.32. Participant Satisfaction Survey – PTSAT

Dataset	PTSAT
Creating program	ptsat.sas
Description	Participant Satisfaction Survey
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: DISCOM,LIKEDCOM,RANDNBR,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITS	num	Feelings About The Number of Visits		Collected at CRF.
VISITS_C	char	Feelings About The Number of Visits (char)		Collected at CRF.
ADI	num	Feelings About The Adi		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADI_C	char	Feelings About The Adi (char)		Collected at CRF.
BLDTST	num	Feelings About The Blood Tests		Collected at CRF.
BLDTST_C	char	Feelings About The Blood Tests (char)		Collected at CRF.
BEHAVIOR	num	Feelings About Behavioral Assessments		Collected at CRF.
BEHAVIOR_C	char	Feelings About Behavioral Assessments (char)		Collected at CRF.
SIDEEFF	num	Feelings About Side Effect Assessments		Collected at CRF.
SIDEEFF_C	char	Feelings About Side Effect Assessments (char)		Collected at CRF.
LEARNG	num	Feelings About Learning Assessments		Collected at CRF.
LEARNG_C	char	Feelings About Learning Assessments (char)		Collected at CRF.
OBSERVE	num	Feelings About Playroom/Observation		Collected at CRF.
RECOMD	num	Would Recommend Study To Other Parents		Collected at CRF.
RECOMD_C	char	Would Recommend Study To Other Parents (char)		Collected at CRF.
AGAIN	num	If You Had It To Do All Over Again....		Collected at CRF.

Variable	Type	Label	Codes	Comments
AGAIN_C	char	If You Had It To Do All Over Again.... (char)		Collected at CRF.
DISLIKED	num	Aspects of Study You Did Not Like		Collected at CRF.
DISLIKED_C	char	Aspects of Study You Did Not Like (char)		Collected at CRF.
LIKED	num	Aspects of Study You Did Like		Collected at CRF.
LIKED_C	char	Aspects of Study You Did Like (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.33. Subject Randomization – RAND

Dataset	RAND
Creating program	rand.sas
Description	Subject Randomization
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,Q02SPEC,Q04SPEC,Q07SPEC,Q08SPEC,Q09SPEC,Q10SPEC, COMPNAME,VISITDAT,ENROLDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
ENROLLED	num	Was Subject Enrolled In Study		Collected at CRF.
Q01	num	1. Parent Did Not Want Child To Take Med		Collected at CRF.
Q01_C	char	1. Parent Did Not Want Child To Take Med (char)		Collected at CRF.
Q02	num	2. Parent Declined		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q02_C	char	2. Parent Declined (char)		Collected at CRF.
Q03	num	3. Subject Refused To Take Meds		Collected at CRF.
Q03_C	char	3. Subject Refused To Take Meds (char)		Collected at CRF.
Q04	num	4. Subject Refused - Other Reason		Collected at CRF.
Q04_C	char	4. Subject Refused - Other Reason (char)		Collected at CRF.
Q05	num	5. Failed To Return To Clinic		Collected at CRF.
Q05_C	char	5. Failed To Return To Clinic (char)		Collected at CRF.
Q06	num	6. Subject Improved Prior To Randomizing		Collected at CRF.
Q06_C	char	6. Subject Improved Prior To Randomizing (char)		Collected at CRF.
Q07	num	7. Severe Family Problems		Collected at CRF.
Q07_C	char	7. Severe Family Problems (char)		Collected at CRF.
Q08	num	8. Failed Other Inclusion Criteria		Collected at CRF.
Q08_C	char	8. Failed Other Inclusion Criteria (char)		Collected at CRF.
Q09	num	9. Subject Met Exclusion Criteria		Collected at CRF.
Q09_C	char	9. Subject Met Exclusion Criteria (char)		Collected at CRF.
Q10	num	10. Other		Collected at CRF.
Q10_C	char	10. Other (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
ENROLDY	num	Relative Randomization Day		If ENROLDAT and REF.DATE not missing then perform below logic to calculate ENROLDY, If ENROLDAT less than REF.DATE then (ENROLDAT - REF.DATE). Else if ENROLDAT is greater than equal to REF.DATE then (ENROLDAT- REF.DATE) +1.

1.4.34. Random Assignment – RANDASGN

Dataset	RANDASGN
Creating program	randasgn.sas
Description	Random Assignment
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR

Variable	Type	Label	Codes	Comments
ANTICONV	char	Anticonvulsant Use		Collected at CRF.
TREATGRP	char	Treatment Group		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned patient id for De-Identity
DSITE	char	Site Id Assigned for De-identity		Randomly assigned site id for De-identity
STUDYID	char	Study Id		Collected at CRF.

1.4.35. Ritvo Freeman Parent Rating Scale – RITVO

Dataset	RITVO
Creating program	ritvo.sas
Description	Ritvo Freeman Parent Rating Scale
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,RATERID,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
Q01	num	Whirls		Collected at CRF.
Q01_C	char	Whirls (char)		Collected at CRF.
Q02	num	Flaps Arms, Hands or Fingers		Collected at CRF.
Q02_C	char	Flaps Arms, Hands or Fingers (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q03	num	Pacing		Collected at CRF.
Q03_C	char	Pacing (char)		Collected at CRF.
Q04	num	Bangs Head or Hits Self		Collected at CRF.
Q04_C	char	Bangs Head or Hits Self (char)		Collected at CRF.
Q05	num	Rocks Head, Body Back/Forth or Side/Side		Collected at CRF.
Q05_C	char	Rocks Head, Body Back/Forth or Side/Side (char)		Collected at CRF.
Q06	num	Toe Walks		Collected at CRF.
Q06_C	char	Toe Walks (char)		Collected at CRF.
Q07	num	Risky or Dangerous Behaviors		Collected at CRF.
Q07_C	char	Risky or Dangerous Behaviors (char)		Collected at CRF.
Q08	num	Ignores or Withdraws From Interaction		Collected at CRF.
Q08_C	char	Ignores or Withdraws From Interaction (char)		Collected at CRF.
Q09	num	Physically Provokes or Disturbs Others		Collected at CRF.
Q09_C	char	Physically Provokes or Disturbs Others (char)		Collected at CRF.
Q10	num	Changes Activities For No Reason		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q10_C	char	Changes Activities For No Reason (char)		Collected at CRF.
Q11	num	Touches or Plays With Own Sex Organs		Collected at CRF.
Q11_C	char	Touches or Plays With Own Sex Organs (char)		Collected at CRF.
Q12	num	Isolates Self From The Group		Collected at CRF.
Q12_C	char	Isolates Self From The Group (char)		Collected at CRF.
Q13	num	Responds To Hugs		Collected at CRF.
Q13_C	char	Responds To Hugs (char)		Collected at CRF.
Q14	num	Abrupt Changes In Emotions		Collected at CRF.
Q14_C	char	Abrupt Changes In Emotions (char)		Collected at CRF.
Q15	num	Grimaces		Collected at CRF.
Q15_C	char	Grimaces (char)		Collected at CRF.
Q16	num	Temper Outbursts		Collected at CRF.
Q16_C	char	Temper Outbursts (char)		Collected at CRF.
Q17	num	Cries or Whines Inappropriately		Collected at CRF.
Q17_C	char	Cries or Whines Inappropriately (char)		Collected at CRF.
Q18	num	Agitated, Upset By Loud or Sudden Noises		Collected at CRF.
Q18_C	char	Agitated, Upset By Loud or Sudden Noises (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q19	num	Whirls or Spins Objects		Collected at CRF.
Q19_C	char	Whirls or Spins Objects (char)		Collected at CRF.
Q20	num	Rubs Surfaces		Collected at CRF.
Q20_C	char	Rubs Surfaces (char)		Collected at CRF.
Q21	num	Agitated or Upset By New Activities		Collected at CRF.
Q21_C	char	Agitated or Upset By New Activities (char)		Collected at CRF.
Q22	num	Watches Motion of Own Hands		Collected at CRF.
Q22_C	char	Watches Motion of Own Hands (char)		Collected at CRF.
Q23	num	Repetitive Movements With Objects		Collected at CRF.
Q23_C	char	Repetitive Movements With Objects (char)		Collected at CRF.
Q24	num	Sniffs or Smells Self or Objects		Collected at CRF.
Q24_C	char	Sniffs or Smells Self or Objects (char)		Collected at CRF.
Q25	num	Lines Up Objects Like Toys		Collected at CRF.
Q25_C	char	Lines Up Objects Like Toys (char)		Collected at CRF.
Q26	num	Scrutinizes Small Details of Objects		Collected at CRF.
Q26_C	char	Scrutinizes Small Details of Objects (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q27	num	Destructive To Toys		Collected at CRF.
Q27_C	char	Destructive To Toys (char)		Collected at CRF.
Q28	num	Repetitive Sounds		Collected at CRF.
Q28_C	char	Repetitive Sounds (char)		Collected at CRF.
Q29	num	Stares		Collected at CRF.
Q29_C	char	Stares (char)		Collected at CRF.
Q30	num	Covers Eyes		Collected at CRF.
Q30_C	char	Covers Eyes (char)		Collected at CRF.
Q31	num	Uses Fingers To Flick Objects		Collected at CRF.
Q31_C	char	Uses Fingers To Flick Objects (char)		Collected at CRF.
Q32	num	Licking, Tasting Objects		Collected at CRF.
Q32_C	char	Licking, Tasting Objects (char)		Collected at CRF.
Q33	num	Says Words, Phrases Heard In The Past		Collected at CRF.
Q33_C	char	Says Words, Phrases Heard In The Past (char)		Collected at CRF.
Q34	num	Repeats Words Immediately After Hearing		Collected at CRF.
Q34_C	char	Repeats Words Immediately After Hearing (char)		Collected at CRF.
Q35	num	Delusions		Collected at CRF.
Q35_C	char	Delusions (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q36	num	Hears Things That Are Not There		Collected at CRF.
Q36_C	char	Hears Things That Are Not There (char)		Collected at CRF.
Q37	num	Sees Things That Are Not There		Collected at CRF.
Q37_C	char	Sees Things That Are Not There (char)		Collected at CRF.
Q38	num	Makes Sounds That Are Not Words		Collected at CRF.
Q38_C	char	Makes Sounds That Are Not Words (char)		Collected at CRF.
Q39	num	Little or No Response When Spoken To		Collected at CRF.
Q39_C	char	Little or No Response When Spoken To (char)		Collected at CRF.
OTHR_Q01	num	Appropriate Response When Approached		Collected at CRF.
OTHR_Q01_C	char	Appropriate Response When Approached (char)		Collected at CRF.
OTHR_Q02	num	Appropriate Response To Conversation		Collected at CRF.
OTHR_Q02_C	char	Appropriate Response To Conversation (char)		Collected at CRF.
OTHR_Q03	num	Appropriate Physical Interactions		Collected at CRF.
OTHR_Q03_C	char	Appropriate Physical Interactions (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
OTHR_Q04	num	Appropriate Use of Objects, Toys		Collected at CRF.
OTHR_Q04_C	char	Appropriate Use of Objects, Toys (char)		Collected at CRF.
OTHR_Q05	num	Uses Words To Organize And Name Things		Collected at CRF.
OTHR_Q05_C	char	Uses Words To Organize And Name Things (char)		Collected at CRF.
OTHR_Q06	num	Uses Gestures To Communicate		Collected at CRF.
OTHR_Q06_C	char	Uses Gestures To Communicate (char)		Collected at CRF.
OTHR_Q07	num	Starts Up Appropriate Conversations		Collected at CRF.
OTHR_Q07_C	char	Starts Up Appropriate Conversations (char)		Collected at CRF.
OTHR_Q08	num	Tells Others What He/She Needs, Wants		Collected at CRF.
OTHR_Q08_C	char	Tells Others What He/She Needs, Wants (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.36. Side Effects Review – SIDEFX

Dataset	SIDEFX
Creating program	sidefx.sas
Description	Side Effects Review
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,INFORMAN, Q29EXP,Q31SPEC,Q32SPEC,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
Q01	num	1. Increased Difficulty Falling Asleep		Collected at CRF.
Q01_C	char	1. Increased Difficulty Falling Asleep (char)		Collected at CRF.
Q02	num	2. Tired During The Day		Collected at CRF.
Q02_C	char	2. Tired During The Day (char)		Collected at CRF.
Q03	num	3. Increased Difficulty Waking Up		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q03_C	char	3. Increased Difficulty Waking Up (char)		Collected at CRF.
Q04	num	4. Shakiness In Arms,Legs,Hands: Tremors		Collected at CRF.
Q04_C	char	4. Shakiness In Arms,Legs,Hands: Tremors (char)		Collected at CRF.
Q05	num	5. Twisting, Repetitive Tongue Movement		Collected at CRF.
Q05_C	char	5. Twisting, Repetitive Tongue Movement (char)		Collected at CRF.
Q06	num	6. Muscles Appearing Stiff or Stuck		Collected at CRF.
Q06_C	char	6. Muscles Appearing Stiff or Stuck (char)		Collected at CRF.
Q07	num	7. Eyes Appearing Stuck In One Position		Collected at CRF.
Q07_C	char	7. Eyes Appearing Stuck In One Position (char)		Collected at CRF.
Q08	num	8. Headaches		Collected at CRF.
Q08_C	char	8. Headaches (char)		Collected at CRF.
Q09	num	9. Dizziness or Loss of Balance		Collected at CRF.
Q09_C	char	9. Dizziness or Loss of Balance (char)		Collected at CRF.
Q10	num	10. Constipation		Collected at CRF.
Q10_C	char	10. Constipation (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q11	num	11. Diarrhea/Loose Stools		Collected at CRF.
Q11_C	char	11. Diarrhea/Loose Stools (char)		Collected at CRF.
Q12	num	12. Dyspepsia (Acid Stomach)		Collected at CRF.
Q12_C	char	12. Dyspepsia (Acid Stomach) (char)		Collected at CRF.
Q13	num	13. Nausea or Vomiting		Collected at CRF.
Q13_C	char	13. Nausea or Vomiting (char)		Collected at CRF.
Q14	num	14. Anxiety		Collected at CRF.
Q14_C	char	14. Anxiety (char)		Collected at CRF.
Q15	num	15. Increased Saliva, Drooling		Collected at CRF.
Q15_C	char	15. Increased Saliva, Drooling (char)		Collected at CRF.
Q16	num	16. Increased Appetite		Collected at CRF.
Q16_C	char	16. Increased Appetite (char)		Collected at CRF.
Q17	num	17. Dry Mouth/Increased Beverage Intake		Collected at CRF.
Q17_C	char	17. Dry Mouth/Increased Beverage Intake (char)		Collected at CRF.
Q18	num	18. Blurred Vision		Collected at CRF.
Q18_C	char	18. Blurred Vision (char)		Collected at CRF.
Q19A	num	19A. Urinary Problem - Enuresis, Bed-Wet		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q19A_C	char	19A. Urinary Problem - Enuresis, Bed-Wet (char)		Collected at CRF.
Q19B	num	19B. Urinary Problem - Trouble Emptying		Collected at CRF.
Q19B_C	char	19B. Urinary Problem - Trouble Emptying (char)		Collected at CRF.
Q20	num	20. Rhinitis (Runny Nose)		Collected at CRF.
Q20_C	char	20. Rhinitis (Runny Nose) (char)		Collected at CRF.
Q21	num	21. Gynecomastia (Enlarged Breasts)		Collected at CRF.
Q21_C	char	21. Gynecomastia (Enlarged Breasts) (char)		Collected at CRF.
Q22	num	22. Galactorrhea		Collected at CRF.
Q22_C	char	22. Galactorrhea (char)		Collected at CRF.
Q23	num	23. Menstrual Problems		Collected at CRF.
Q23_C	char	23. Menstrual Problems (char)		Collected at CRF.
Q24	num	24. Coughing		Collected at CRF.
Q24_C	char	24. Coughing (char)		Collected at CRF.
Q25	num	25. Tachycardia (Rapid Heartbeat)		Collected at CRF.
Q25_C	char	25. Tachycardia (Rapid Heartbeat) (char)		Collected at CRF.
Q26	num	26. Seizures		Collected at CRF.
Q26_C	char	26. Seizures (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q27	num	27. Skin Rash		Collected at CRF.
Q27_C	char	27. Skin Rash (char)		Collected at CRF.
Q28	num	28. Tinnitus (Ringing In The Ears)		Collected at CRF.
Q28_C	char	28. Tinnitus (Ringing In The Ears) (char)		Collected at CRF.
Q29	num	29. Other		Collected at CRF.
Q29_C	char	29. Other (char)		Collected at CRF.
Q30BED	char	30. Bedtime		Collected at CRF.
Q30WAKE	char	30. Wake Up Time		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
CURRHLTH	num	Current Health Complaints		Collected at CRF.
RECINJUR	num	Recent Injuries, Illness Requiring Meds		Collected at CRF.
RECILL	num	Recent Illness		Collected at CRF.
CONMED	num	Concurrent Medication		Collected at CRF.
Q31	num	Peculiar Eating Habits?		Collected at CRF.
Q31_C	char	Peculiar Eating Habits? (char)		Collected at CRF.
Q32	num	Change In Eating Habits?		Collected at CRF.

Variable	Type	Label	Codes	Comments
Q32_C	char	Change In Eating Habits? (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.37. Simpson Angus Rating Scale – SIMPANG

Dataset	SIMPANG
Creating program	simpang.sas
Description	Simpson Angus Rating Scale
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,RATERID,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
GAIT	num	Gait		Collected at CRF.
GAIT_C	char	Gait (char)		Collected at CRF.
ARM	num	Arm Dropping		Collected at CRF.
ARM_C	char	Arm Dropping (char)		Collected at CRF.
SHOULDER	num	Shoulder Shaking		Collected at CRF.
SHOULDER_C	char	Shoulder Shaking (char)		Collected at CRF.
ELBOW	num	Elbow Rigidity		Collected at CRF.
ELBOW_C	char	Elbow Rigidity (char)		Collected at CRF.
WRIST	num	Wrist Rigidity		Collected at CRF.
WRIST_C	char	Wrist Rigidity (char)		Collected at CRF.
LEG	num	Leg Pendulousness		Collected at CRF.
LEG_C	char	Leg Pendulousness (char)		Collected at CRF.
HEAD	num	Head Rotation		Collected at CRF.
HEAD_C	char	Head Rotation (char)		Collected at CRF.
TAP	num	Glabellar Tap		Collected at CRF.
TAP_C	char	Glabellar Tap (char)		Collected at CRF.
TREMOR	num	Tremor		Collected at CRF.
TREMOR_C	char	Tremor (char)		Collected at CRF.
SALIVA	num	Salivation		Collected at CRF.
SALIVA_C	char	Salivation (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.38. Study Medication, Genetic, Leptin and Prolactin Testing – SMGL

Dataset	SMGL
Creating program	smgl.sas
Description	Study Medication, Genetic, Leptin and Prolactin Testing
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,FMCOMPBY,VISITDAT,DRAWDAT,LASTDAT,MEALDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity

Variable	Type	Label	Codes	Comments
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
BLOOD	num	Was Blood Drawn For Tests? (1=Yes, 2=No)		Collected at CRF.
BLOOD_C	char	Was Blood Drawn For Tests? (1=Yes, 2=No) (char)		Collected at CRF.
DRAWTIME	char	Time of Draw (Hh:Mm Military Time)		Collected at CRF.
LASTTIME	char	Time of Last Dose		Collected at CRF.
MEALTIME	char	Time of Last Meal		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
DRAWDY	num	Relative Day of Draw		If DRAWDAT and REF.DATE not missing then perform below logic to calculate DRAWDY, If DRAWDAT less than REF.DATE then (DRAWDAT - REF.DATE). Else if DRAWDAT is greater than equal to REF.DATE then (DRAWDAT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
LASTDY	num	Relative Day of Last Dose		If LASTDAT and REF.DATE not missing then perform below logic to calculate LASTDY, If LASTDAT less than REF.DATE then (LASTDAT - REF.DATE). Else if LASTDAT is greater than equal to REF.DATE then (LASTDAT- REF.DATE) +1.
MEALDY	num	Relative Day of Last Meal		If MEALDAT and REF.DATE not missing then perform below logic to calculate MEALDY, If MEALDAT less than REF.DATE then (MEALDAT - REF.DATE). Else if MEALDAT is greater than equal to REF.DATE then (MEALDAT- REF.DATE) +1.

1.4.39. CTS Enrollment – STDYENRL

Dataset	STDYENRL
Creating program	stdyenrl.sas
Description	Cts Enrollment
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,INITIALS,CNSNTDAT,ENROLDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
STATUS	num	Status		Collected at CRF.
INTERVAL	num	Week Number		Collected at CRF.
TAKEDRUG	num	Is Subject Taking Anti-Convulsant Med.?		Collected at CRF.
TAKEDRUG_C	char	Is Subject Taking Anti-Convulsant Med.? (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
CNSNTDY	num	Relative Day of Consent		If CNSNDDAT and REF.DATE not missing then perform below logic to calculate CNSNTDY, If CNSNDDAT less than REF.DATE then (CNSNDDAT - REF.DATE). Else if CNSNDDAT is greater than equal to REF.DATE then (CNSNDDAT- REF.DATE) +1.
ENROLDY	num	Relative Randomization Day		If ENROLDAT and REF.DATE not missing then perform below logic to calculate ENROLDY, If ENROLDAT less than REF.DATE then (ENROLDAT - REF.DATE). Else if ENROLDAT is greater than equal to REF.DATE then (ENROLDAT- REF.DATE) +1.

1.4.40. Study Term – STDYTERM

Dataset	STDYTERM
Creating program	stdyterm.sas
Description	Study Term
Unique identifier	STUDYID,DPATID
Sorted by	STUDYID,DPATID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,SPECIFY,VISITDAT,LASTVDAT,TERMDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
TRREAS	char	Term.Reason		Collected at CRF.
INTERVAL	num	Week Number		Collected at CRF.
COMPLETE	num	Study Completed		Collected at CRF.
COMPLETE_C	char	Study Completed (char)		Collected at CRF.
EARLYTRM	num	Reason For Early Termination		Collected at CRF.
EARLYTRM_C	num	Reason For Early Termination (char)		Collected at CRF.

Variable	Type	Label	Codes	Comments
WEEKTERM	num	Week Subject Was Terminated		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
LASTVDY	num	Relative Day of Last Visit		If LASTVDAT and REF.DATE not missing then perform below logic to calculate LASTVDY, If LASTVDAT less than REF.DATE then (LASTVDAT - REF.DATE). Else if LASTVDAT is greater than equal to REF.DATE then (LASTVDAT- REF.DATE) +1.
TERMDY	num	Relative Day of Termination		If TERMDAT and REF.DATE not missing then perform below logic to calculate TERMDY, If TERMDAT less than REF.DATE then (TERMDAT - REF.DATE). Else if TERMDAT is greater than equal to REF.DATE then (TERMDAT- REF.DATE) +1.

1.4.41. Study Medication – STUDYMED

Dataset	STUDYMED
Creating program	studymed.sas
Description	Study Medication
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: REASON1,REASON2,REASON3,REASON4,REASON5,REASON6,REASON7, REASON8,REASON9,REASON10,RANDNBR,TABAM7,TABPM7,TOTALMG7, DAY8,DAY9,DAY10,VISITDAT,DOSEDAT,MED1SDAT,MED2SDAT,MED3SDAT, MED4SDAT,MED5SDAT,MED6SDAT,MED7SDAT,MED1EDAT,MED2EDAT, MED3EDAT,MED4EDAT,MED5EDAT,MED6EDAT,MED7EDAT,PRB01DAT, PRB02DAT,PRB03DAT,PRB04DAT,PRB05DAT,PRB06DAT,PRB07DAT, PRB08DAT,PRB09DAT,PRB10DAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
TABAM1	num	Number of Tablets Am 1		Collected at CRF.
TABPM1	num	Number of Tablets Pm 1		Collected at CRF.
TOTALMG1	num	Total Number of Mg/Day 1		Collected at CRF.
TABAM2	num	Number of Tablets Am 2		Collected at CRF.
TABPM2	num	Number of Tablets Pm 2		Collected at CRF.
TOTALMG2	num	Total Number of Mg/Day 2		Collected at CRF.
TABAM3	num	Number of Tablets Am 3		Collected at CRF.
TABPM3	num	Number of Tablets Pm 3		Collected at CRF.
TOTALMG3	num	Total Number of Mg/Day 3		Collected at CRF.
TABAM4	num	Number of Tablets Am 4		Collected at CRF.
TABPM4	num	Number of Tablets Pm 4		Collected at CRF.
TOTALMG4	num	Total Number of Mg/Day 4		Collected at CRF.
TABAM5	num	Number of Tablets Am 5		Collected at CRF.
TABPM5	num	Number of Tablets Pm 5		Collected at CRF.
TOTALMG5	num	Total Number of Mg/Day 5		Collected at CRF.
TABAM6	num	Number of Tablets Am 6		Collected at CRF.
TABPM6	num	Number of Tablets Pm 6		Collected at CRF.
TOTALMG6	num	Total Number of Mg/Day 6		Collected at CRF.
NUMDISP	num	Number of Tablets Dispensed		Collected at CRF.
NUMPRES	num	Number of Tablets Prescribed		Collected at CRF.

Variable	Type	Label	Codes	Comments
NUMRTRN	num	Actual Number of Tablets Returned		Collected at CRF.
TIMEDOSE	char	Time of Last Dose		Collected at CRF.
TAKEMED	num	Take All Medication Doses As Prescribed		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
DAY1	num	Day 1 Medication Was Not Taken		Collected at CRF.
AMPM_1	num	Am or Pm, Date 1		Collected at CRF.
AMPM_1_C	char	Am or Pm, Date 1 (char)		Collected at CRF.
DAY2	num	Day 2 Medication Was Not Taken		Collected at CRF.
AMPM_2	num	Am or Pm, Date 2		Collected at CRF.
AMPM_2_C	char	Am or Pm, Date 2 (char)		Collected at CRF.
DAY3	num	Day 3 Medication Was Not Taken		Collected at CRF.
AMPM_3	num	Am or Pm, Date 3		Collected at CRF.
AMPM_3_C	char	Am or Pm, Date 3 (char)		Collected at CRF.
DAY4	num	Day 4 Medication Was Not Taken		Collected at CRF.
AMPM_4	num	Am or Pm, Date 4		Collected at CRF.
AMPM_4_C	char	Am or Pm, Date 4 (char)		Collected at CRF.
DAY5	num	Day 5 Medication Was Not Taken		Collected at CRF.
AMPM_5	num	Am or Pm, Date 5		Collected at CRF.

Variable	Type	Label	Codes	Comments
AMPM_5_C	char	Am or Pm, Date 5 (char)		Collected at CRF.
DAY6	num	Day 6 Medication Was Not Taken		Collected at CRF.
AMPM_6	num	Am or Pm, Date 6		Collected at CRF.
AMPM_6_C	char	Am or Pm, Date 6 (char)		Collected at CRF.
DAY7	num	Day 7 Medication Was Not Taken		Collected at CRF.
AMPM_7	num	Am or Pm, Date 7		Collected at CRF.
AMPM_7_C	char	Am or Pm, Date 7 (char)		Collected at CRF.
AMPM_8	num	Am or Pm, Date 8		Collected at CRF.
AMPM_8_C	char	Am or Pm, Date 8 (char)		Collected at CRF.
AMPM_9	num	Am or Pm, Date 9		Collected at CRF.
AMPM_9_C	char	Am or Pm, Date 9 (char)		Collected at CRF.
AMPM_10	num	Am or Pm, Date 10		Collected at CRF.
AMPM_10_C	char	Am or Pm, Date 10 (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.
DOSEDY	num	Relative Day of Last Dose		If DOSEDAT and REF.DATE not missing then perform below logic to calculate DOSEDY, If DOSEDAT less than REF.DATE then (DOSEDAT - REF.DATE). Else if DOSEDAT is greater than equal to REF.DATE then (DOSEDAT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
MED1SDY	num	Relative Medication 1 Start Day		If MED1SDAT and REF.DATE not missing then perform below logic to calculate MED1SDY, If MED1SDAT less than REF.DATE then (MED1SDAT - REF.DATE). Else if MED1SDAT is greater than equal to REF.DATE then (MED1SDAT- REF.DATE) +1.
MED2SDY	num	Relative Medication 2 Start Day		If MED2SDAT and REF.DATE not missing then perform below logic to calculate MED2SDY, If MED2SDAT less than REF.DATE then (MED2SDAT - REF.DATE). Else if MED2SDAT is greater than equal to REF.DATE then (MED2SDAT- REF.DATE) +1.
MED3SDY	num	Relative Medication 3 Start Day		If MED3SDAT and REF.DATE not missing then perform below logic to calculate MED3SDY, If MED3SDAT less than REF.DATE then (MED3SDAT - REF.DATE). Else if MED3SDAT is greater than equal to REF.DATE then (MED3SDAT- REF.DATE) +1.
MED4SDY	num	Relative Medication 4 Start Day		If MED4SDAT and REF.DATE not missing then perform below logic to calculate MED4SDY, If MED4SDAT less than REF.DATE then (MED4SDAT - REF.DATE). Else if MED4SDAT is greater than equal to REF.DATE then (MED4SDAT- REF.DATE) +1.
MED5SDY	num	Relative Medication 5 Start Day		If MED5SDAT and REF.DATE not missing then perform below logic to calculate MED5SDY, If MED5SDAT less than REF.DATE then (MED5SDAT - REF.DATE). Else if MED5SDAT is greater than equal to REF.DATE then (MED5SDAT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
MED6SDY	num	Relative Medication 6 Start Day		If MED6SDAT and REF.DATE not missing then perform below logic to calculate MED6SDY, If MED6SDAT less than REF.DATE then (MED6SDAT - REF.DATE). Else if MED6SDAT is greater than equal to REF.DATE then (MED6SDAT- REF.DATE) +1.
MED1EDY	num	Relative Medication 1 End Day		If MED1EDAT and REF.DATE not missing then perform below logic to calculate MED1EDY, If MED1EDAT less than REF.DATE then (MED1EDAT - REF.DATE). Else if MED1EDAT is greater than equal to REF.DATE then (MED1EDAT- REF.DATE) +1.
MED2EDY	num	Relative Medication 2 End Day		If MED2EDAT and REF.DATE not missing then perform below logic to calculate MED2EDY, If MED2EDAT less than REF.DATE then (MED2EDAT - REF.DATE). Else if MED2EDAT is greater than equal to REF.DATE then (MED2EDAT- REF.DATE) +1.
MED3EDY	num	Relative Medication 3 End Day		If MED3EDAT and REF.DATE not missing then perform below logic to calculate MED3EDY, If MED3EDAT less than REF.DATE then (MED3EDAT - REF.DATE). Else if MED3EDAT is greater than equal to REF.DATE then (MED3EDAT- REF.DATE) +1.
MED4EDY	num	Relative Medication 4 End Day		If MED4EDAT and REF.DATE not missing then perform below logic to calculate MED4EDY, If MED4EDAT less than REF.DATE then (MED4EDAT - REF.DATE). Else if MED4EDAT is greater than equal to REF.DATE then (MED4EDAT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
MED5EDY	num	Relative Medication 5 End Day		If MED5EDAT and REF.DATE not missing then perform below logic to calculate MED5EDY, If MED5EDAT less than REF.DATE then (MED5EDAT - REF.DATE). Else if MED5EDAT is greater than equal to REF.DATE then (MED5EDAT- REF.DATE) +1.
MED6EDY	num	Relative Medication 6 End Day		If MED6EDAT and REF.DATE not missing then perform below logic to calculate MED6EDY, If MED6EDAT less than REF.DATE then (MED6EDAT - REF.DATE). Else if MED6EDAT is greater than equal to REF.DATE then (MED6EDAT- REF.DATE) +1.
PRB01DY	num	Relative Day 1 Medication Was Not Taken		If PRB01DAT and REF.DATE not missing then perform below logic to calculate PRB01DY, If PRB01DAT less than REF.DATE then (PRB01DAT - REF.DATE). Else if PRB01DAT is greater than equal to REF.DATE then (PRB01DAT- REF.DATE) +1.
PRB02DY	num	Relative Day 2 Medication Was Not Taken		If PRB02DAT and REF.DATE not missing then perform below logic to calculate PRB02DY, If PRB02DAT less than REF.DATE then (PRB02DAT - REF.DATE). Else if PRB02DAT is greater than equal to REF.DATE then (PRB02DAT- REF.DATE) +1.
PRB03DY	num	Relative Day 3 Medication Was Not Taken		If PRB03DAT and REF.DATE not missing then perform below logic to calculate PRB03DY, If PRB03DAT less than REF.DATE then (PRB03DAT - REF.DATE). Else if PRB03DAT is greater than equal to REF.DATE then (PRB03DAT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
PRB04DY	num	Relative Day 4 Medication Was Not Taken		If PRB04DAT and REF.DATE not missing then perform below logic to calculate PRB04DY, If PRB04DAT less than REF.DATE then (PRB04DAT - REF.DATE). Else if PRB04DAT is greater than equal to REF.DATE then (PRB04DAT- REF.DATE) +1.
PRB05DY	num	Relative Day 5 Medication Was Not Taken		If PRB05DAT and REF.DATE not missing then perform below logic to calculate PRB05DY, If PRB05DAT less than REF.DATE then (PRB05DAT - REF.DATE). Else if PRB05DAT is greater than equal to REF.DATE then (PRB05DAT- REF.DATE) +1.
PRB06DY	num	Relative Day 6 Medication Was Not Taken		If PRB06DAT and REF.DATE not missing then perform below logic to calculate PRB06DY, If PRB06DAT less than REF.DATE then (PRB06DAT - REF.DATE). Else if PRB06DAT is greater than equal to REF.DATE then (PRB06DAT- REF.DATE) +1.
PRB07DY	num	Relative Day 7 Medication Was Not Taken		If PRB07DAT and REF.DATE not missing then perform below logic to calculate PRB07DY, If PRB07DAT less than REF.DATE then (PRB07DAT - REF.DATE). Else if PRB07DAT is greater than equal to REF.DATE then (PRB07DAT- REF.DATE) +1.
PRB08DY	num	Relative Day 8 Medication Was Not Taken		If PRB08DAT and REF.DATE not missing then perform below logic to calculate PRB08DY, If PRB08DAT less than REF.DATE then (PRB08DAT - REF.DATE). Else if PRB08DAT is greater than equal to REF.DATE then (PRB08DAT- REF.DATE) +1.

Variable	Type	Label	Codes	Comments
PRB09DY	num	Relative Day 9 Medication Was Not Taken		If PRB09DAT and REF.DATE not missing then perform below logic to calculate PRB09DY, If PRB09DAT less than REF.DATE then (PRB09DAT - REF.DATE). Else if PRB09DAT is greater than equal to REF.DATE then (PRB09DAT- REF.DATE) +1.
PRB10DY	num	Relative Day 10 Medication Was Not Taken		If PRB10DAT and REF.DATE not missing then perform below logic to calculate PRB10DY, If PRB10DAT less than REF.DATE then (PRB10DAT - REF.DATE). Else if PRB10DAT is greater than equal to REF.DATE then (PRB10DAT- REF.DATE) +1.

1.4.42. Urinalysis – UA

Dataset	UA
Creating program	ua.sas
Description	Urinalysis
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,COMPBY,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
PERFORM	num	Was A Urinalysis Performed?		Collected at CRF.
PERFORM_C	char	Was A Urinalysis Performed? (char)		Collected at CRF.
COLOR	char	Color		Collected at CRF.
APPEAR	char	Appearance		Collected at CRF.
GRAVITY	num	Specific Gravity		Collected at CRF.
REACTION	num	Reaction (Ph)		Collected at CRF.
PROTEIN	num	Protein		Collected at CRF.
PROTEIN_C	char	Protein (char)		Collected at CRF.
GLUCOSE	num	Glucose		Collected at CRF.
GLUCOSE_C	char	Glucose (char)		Collected at CRF.
KETONES	num	Ketones		Collected at CRF.
KETONES_C	char	Ketones (char)		Collected at CRF.
OCCULT	num	Occult Blood		Collected at CRF.
OCCULT_C	char	Occult Blood (char)		Collected at CRF.
ESTERASE	num	Leukocyte Esterase		Collected at CRF.

Variable	Type	Label	Codes	Comments
ESTERASE_C	char	Leukocyte Esterase (char)		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.43. Vineland – VINELAND

Dataset	VINELAND
Creating program	vineland.sas
Description	Vineland
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,ADMINDAT,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
COMMDOM	num	Communication Domain		Collected at CRF.
CHARDL	char	Less Than Sign (<) Daily Living Skills		Collected at CRF.
DAILYLIV	num	Daily Living		Collected at CRF.
SOCDOM	num	Social Domain		Collected at CRF.
MOTORDOM	num	Motor Skills Domain		Collected at CRF.
ADAPTBEH	num	Adaptive Behavior Composite		Collected at CRF.
A_MDB1RS	num	A: Mal. Behav Domain, Part 1 Raw Score		Collected at CRF.
A_MDB2RS	num	A: Mal. Behav Domain, Part 1-2 Raw Score		Collected at CRF.
B_MDB1RS	num	B: Mal. Behav Domain, Part 1 Raw Score		Collected at CRF.
B_MDB2RS	num	B: Mal. Behav Domain, Part 1-2 Raw Score		Collected at CRF.

Variable	Type	Label	Codes	Comments
ADMINDY	num	Relative Day Vineland Administered		If ADMINDAT and REF.DATE not missing then perform below logic to calculate ADMINDY, If ADMINDAT less than REF.DATE then (ADMINDAT - REF.DATE). Else if ADMINDAT is greater than equal to REF.DATE then (ADMINDAT- REF.DATE) +1.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.

1.4.44. Visit – VISIT

Dataset	VISIT
Creating program	visit.sas
Description	Visit
Unique identifier	STUDYID,DPATID,INTERVAL
Sorted by	STUDYID,DPATID,INTERVAL
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: RANDNBR,COMPBY,VISITDAT

Variable	Type	Label	Codes	Comments
DSITE	char	Site Id Assigned for De-Identity		Randomly assigned Site Id for De-Identity

Variable	Type	Label	Codes	Comments
STUDYID	char	Study Id		Collected at CRF.
DPATID	char	Patient Id Assigned For De-Identity		Randomly assigned Patient Id For De-Identity
INTERVAL	num	Week Number		Collected at CRF.
SYSTOLIC	num	Blood Pressure Systolic		Collected at CRF.
DIASTOL	num	Blood Pressure Diastolic		Collected at CRF.
PULSE	num	Pulse		Collected at CRF.
WEIGHT	num	Weight (In Kilograms)		Collected at CRF.
ATTEND	num	Did Subject Attend Visit		Collected at CRF.
ATTEND_C	char	Did Subject Attend Visit (char)		Collected at CRF.
FRMCOMP	num	Form Completed		Collected at CRF.
FRMCOMP_C	char	Form Completed (char)		Collected at CRF.
HEIGHT	num	Height (In Centimeters)		Collected at CRF.
BODYTEMP	num	Temperature		Collected at CRF.
VISITDY	num	Relative Day of Visit		If VISITDAT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDAT less than REF.DATE then (VISITDAT - REF.DATE). Else if VISITDAT is greater than equal to REF.DATE then (VISITDAT- REF.DATE) +1.