Clinical Development

Ustekinumab

C0743T09

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final
Date	27 JUN 2017

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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 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.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Remove Child-bearing potential information.
- Dataset with zero observations will not be submitted (ex. SCRNDTH).
- For randomized subjects, combination of IVRS.LCENR_DT and VISITS.VISITDT (when VISIT="Week 0") will be used as Reference Date (referred as REF. DATE in the document) to derive relative days. For screen failure subjects, SCRNDEMO.DMCONDT will be used as a Reference date (referred as REF. DATE in the document) to derive relative day.

1.3.   Data Files

The C0743T09 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	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SUBJINIT,BIRTHDT,DMCONDT,DEMOG,BIRTHDTC,DMCONDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
HEIGHT	num	Height in Centimeters		Collected at CRF.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DMCONDY	num	Relative Day of Informed Consent		If DMCONDT and REF.DATE not missing then perform below logic to calculate DMCONDY, If DMCONDT less than REF.DATE then (DMCONDT - REF.DATE). Else if DMCONDT is greater than equal to REF.DATE then (DMCONDT- REF.DATE) +1.

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUSUBJID,AEDECOD,AESTDY,AESEQ
Sorted by	DUSUBJID,AEDECOD,AESTDY,AESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: AETERM,AEMODIFY,AESTDT,AEENDT,AEPRSPEC,AESTDTC,AEENDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
AESTTM	num	Start Time of Event		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
AEHLTCD	char	High Level Term Code		Collected at CRF.
AEHLGTCD	char	High Level Group Term Code		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AELLT	char	Low Level Term Name		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEHLT	char	High Level Term Name		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
AEHLGT	char	High Level Group Term Name		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
SAERHOS	char	Hospitalization Required		Collected at CRF.
SAEPHOS	char	Prolonged Hospitalization		Collected at CRF.
SAEOTH	char	Other Medically Important		Collected at CRF.
SAENS	char	Not Serious		Collected at CRF.
SAECONG	char	Congenital Anomaly/Birth Defect		Collected at CRF.
INFECT	char	Infection		Collected at CRF.
AERELPR	char	Related to Trial Procedure		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AEASR	char	Administration Site Reaction		Collected at CRF.
AEACTTRT	char	Action Taken with Study Treatment		Collected at CRF.

Variable	Type	Label	Codes	Comments
AELOC	char	Adverse Event Location		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AESEV	char	Severity/Intensity of Event		Collected at CRF.
INFECTRT	char	Infection Treated		Collected at CRF.
SAEDISAB	char	Permanent/Serious Disability/Incapacity		Collected at CRF.
SAEDTH	char	Results in Death		Collected at CRF.
SAELIFE	char	Is Life-Threatening		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

Variable	Type	Label	Codes	Comments
AESTDY	num	Relative Start Day of Event		If AESTDT and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDT less than REF.DATE then (AESTDT - REF.DATE). Else if AESTDT is greater than equal to REF.DATE then (AESTDT- REF.DATE) +1.
AEENDY	num	Relative End Day of Event		If AEENDT and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDT less than REF.DATE then (AEENDT - REF.DATE). Else if AEENDT is greater than equal to REF.DATE then (AEENDT- REF.DATE) +1.

1.4.3. Algnvis – ALGNVIS

Dataset	ALGNVIS
Creating program	algnvis.sas
Description	Algnvis
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
AVVISIT	char	Alignment Visit		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.4. Assay Tracking – ATRACK

Dataset	ATRACK
Creating program	atrack.sas
Description	Assay Tracking
Unique identifier	DUSUBJID,ATKTTYP,ATPTM,ATDY
Sorted by	DUSUBJID,ATKTTYP,ATPTM,ATDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: ATKITNUM,ATDT,ATDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
ATTM	num	Assay Tracking Time		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
ATEVQL	char	Event Qualifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
ATKTTYP	char	Kit Type		Collected at CRF.
ATNTCOL	char	Sample Not Collected		Collected at CRF.
ATPTM	char	Planned Timepoint		Collected at CRF.
ATSMTYP	char	Sample Type		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
ATDY	num	Relative Assay Tracking Day		If ATDT and REF.DATE not missing then perform below logic to calculate ATDY, If ATDT less than REF.DATE then (ATDT - REF.DATE). Else if ATDT is greater than equal to REF.DATE then (ATDT-REF.DATE) +1.

1.4.5. Body Surface Area – BSA

Dataset	BSA
Creating program	bsa.sas
Description	Body Surface Area
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
BSBSA	num	Body surface area covered by disease(%)		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.6. Past Medical History/Current Diagnoses – CONDHIST

Dataset	CONDHIST
Creating program	condhist.sas
Description	Past Medical History/Current Diagnoses
Unique identifier	DUSUBJID,CHHIST,CHCONDD
Sorted by	DUSUBJID,CHHIST,CHCONDD
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
CHALUNWK	num	Number of Alcoholic Units Per Week		Collected at CRF.
CHSMCIG	num	Number of Cigarettes Per Day		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHSMYRS	num	Number of Years of Smoking		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
CHCONDD	char	Condition		Collected at CRF.
CHHIST	char	History of Condition		Collected at CRF.
CHIHDCAB	char	Coronary Artery Bypass Graft		Collected at CRF.
CHIHDCAP	char	History of Angina Pectoris		Collected at CRF.
CHIHDMI	char	Myocardial Infarction		Collected at CRF.
CHIHDOTH	char	Other Ischemic Heart Disease		Collected at CRF.
CHIHDPCI	char	Percutaneous Coronary Intervention		Collected at CRF.
CHPSTYR	char	Condition Within Past 1 Year		Collected at CRF.
CHSCBCC	char	Basal Cell Skin Cancer		Collected at CRF.
CHSCSCC	char	Squamous Cell Skin Cancer		Collected at CRF.
CHSMSTAT	char	Status of Smoking		Collected at CRF.
CHTRT	char	Treated		Collected at CRF.

Variable	Type	Label	Codes	Comments
CHINSULN	char	Requiring Insulin for Diabetes Mellitus		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.7. Concomitant Medications – CONMEDS

Dataset	CONMEDS
Creating program	conmeds.sas
Description	Concomitant Medications
Unique identifier	DUSUBJID,CMDECOD,CMSTDY,CMSEQ
Sorted by	DUSUBJID,CMDECOD,CMSTDY,CMSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: CMTERM,CMMODIFY,CMSTDY,CMSTMO,CMSTYR,CMSTDT,CMENDT, CMENDTC,CMSTDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
PAGE_SEQ	num	Page of Series		Collected at CRF.
CMSEQ	num	Medication Sequence Number		Collected at CRF.
CMRTECD	num	Route Code		Collected at CRF.
DRECNO	char	Drug Record Number		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
SEQ2	char	Drug Sequence 2		Collected at CRF.
CMDECOD	char	Dictionary Term		Collected at CRF.

Variable	Type	Label	Codes	Comments
CMDECOD1	char	Dictionary Preferred Term		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
CMROUTE	char	Route		Collected at CRF.
CMONGO	char	Ongoing Medication		Collected at CRF.
CMREAS	char	Reason for Medication		Collected at CRF.
CMSTPR	char	Started Prior to Study		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

Variable	Type	Label	Codes	Comments
CMSTDY	num	Relative Start Day of Medication		If CMSTDT and REF.DATE not missing then perform below logic to calculate CMSTDY, If CMSTDT less than REF.DATE then (CMSTDT - REF.DATE). Else if CMSTDT is greater than equal to REF.DATE then (CMSTDT- REF.DATE) +1.
CMENDY	num	Relative End Day of Medication		If CMENDT and REF.DATE not missing then perform below logic to calculate CMENDY, If CMENDT less than REF.DATE then (CMENDT - REF.DATE). Else if CMENDT is greater than equal to REF.DATE then (CMENDT- REF.DATE) +1.

1.4.8. Concentration Result – CRESUL

Dataset	CRESUL
Creating program	cresul.sas
Description	Concentration Result
Unique identifier	CPPERIOD,CPTEST,CPRESCAT
Sorted by	CPPERIOD,CPTEST,CPRESCAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CPLABID,CPLABEL

Variable	Type	Label	Codes	Comments
CPPERIOD	char	Cpperiod		Collected at CRF.

Variable	Type	Label	Codes	Comments
CPASYCD	char	Cpasycd		Collected at CRF.
CPASY	char	Cpasy		Collected at CRF.
CPTESTCD	char	Cptestcd		Collected at CRF.
CPTEST	char	Cptest		Collected at CRF.
CPRESCAT	char	Cprescat		Collected at CRF.
CPRESC	char	Cpresc		Collected at CRF.
CPUNIT	char	Cpunit		Collected at CRF.
CPLLOQ	num	Cplloq		Collected at CRF.
CPCMT1CD	char	Cpcmt1Cd		Collected at CRF.
CPCMT1	char	Cpcmt1		Collected at CRF.
CPCMT2CD	char	Cpcmt2Cd		Collected at CRF.
CPCMT2	char	Cpcmt2		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.9. Subject Selection Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Subject Selection Criteria
Unique identifier	DUSUBJID,INCRIT,EXCRIT
Sorted by	DUSUBJID,INCRIT,EXCRIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
CRSEQ	num	Criterion Sequence		Collected at CRF.
INCRIT	char	Inclusion Criterion Not Met		Collected at CRF.
EXCRIT	char	Exclusion Criterion Present		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.10.　　Csu – CSU

Dataset	CSU
Creating program	csu.sas
Description	Csu
Unique identifier	ACTTRT,EXPLNDS
Sorted by	ACTTRT,EXPLNDS
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: EXKITNO,EXLOTNO,EXCNTRID

Variable	Type	Label	Codes	Comments
CSSEQ	num	Sequence Number		Collected at CRF.
EXVPREP	num	Volume in Container in mL		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXPLNDS	num	Planned Dose		Collected at CRF.
ACTTRT	char	Actual Treatment		Collected at CRF.
DOSEUNIT	char	Dose Unit		Collected at CRF.

1.4.11.   Death – DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DTCAUSE,DTDT,DTDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	Sex		Collected at CRF.
DTAUTP	char	Autopsy Performed		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DTDY	num	Relative Day of Death		If DTDT and REF.DATE not missing then perform below logic to calculate DTDY, If DTDT less than REF.DATE then (DTDT - REF.DATE). Else if DTDT is greater than equal to REF.DATE then (DTDT-REF.DATE) +1.

1.4.12.　　Psoriasis Diagnosis Information – DIAGINFO

Dataset	DIAGINFO
Creating program	diaginfo.sas
Description	Psoriasis Diagnosis Information
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DGPSODT,DGPSODTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DGPSODY	num	Relative Day of Psoriasis Diagnosis		If DGPSODT and REF.DATE not missing then perform below logic to calculate DGPSODY, If DGPSODT less than REF.DATE then (DGPSODT - REF.DATE). Else if DGPSODT is greater than equal to REF.DATE then (DGPSODT- REF.DATE) +1.

1.4.13. Physician's Static Global Assessment – DIS_EVAL

Dataset	DIS_EVAL
Creating program	dis_eval.sas
Description	Physician's Static Global Assessment
Unique identifier	DUSUBJID,DEPSGA,VISIT
Sorted by	DUSUBJID,DEPSGA,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DEPSGA	char	Physicians Static Global Assessment		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.14.   Dermatology Life Quality Index – DLQI

Dataset	DLQI
Creating program	dlqi.sas
Description	Dermatology Life Quality Index
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DLCLTH	char	Skin influenced the clothes worn		Collected at CRF.
DLEMBR	char	Embarrassment due to skin		Collected at CRF.

Variable	Type	Label	Codes	Comments
DLHOME	char	Skin interfered with home activities		Collected at CRF.
DLHWPRB	char	How problematic to work or study		Collected at CRF.
DLLEIS	char	Skin affected social/leisure activities		Collected at CRF.
DLPAIN	char	Painful skin		Collected at CRF.
DLPART	char	Skin created probs with prtnr or friends		Collected at CRF.
DLSEXL	char	Skin caused sexual difficulties		Collected at CRF.
DLSPRT	char	Difficulty playing a sport due to skin		Collected at CRF.
DLTRT	char	Problem with skin treatment		Collected at CRF.
DLWORK	char	Skin prevented working or studying		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.15.   Disposition Status – DSTATUS

Dataset	DSTATUS
Creating program	dstatus.sas
Description	Disposition Status
Unique identifier	DUSUBJID,DSEREAS,DSUNB,VISIT,DSUNBDY,DSDSCDY
Sorted by	DUSUBJID,DSEREAS,DSUNB,VISIT,DSUNBDY,DSDSCDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: DSTRSOTH,DSUNBDT,DSDSCDT,DSRSOTH,DSDSCDTC,DSUNBDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
DSDSCEND	char	Study Participation End		Collected at CRF.
DSEREAS	char	Reason for Study Participation End		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSREAS	char	Reason for Non-Completion		Collected at CRF.
DSTDSC	char	Study Treatment Discontinuation		Collected at CRF.
DSTREAS	char	Reason for Treatment Discontinuation		Collected at CRF.
DSTWSTD	char	Worsening of Study Disease		Collected at CRF.
DSUNB	char	Treatment Unblinded		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUNBDY	num	Relative Day of Treatment Unblinding		If DSUNBDT and REF.DATE not missing then perform below logic to calculate DSUNBDY, If DSUNBDT less than REF.DATE then (DSUNBDT - REF.DATE). Else if DSUNBDT is greater than equal to REF.DATE then (DSUNBDT- REF.DATE) +1.
DSDSCDY	num	Relative Day of Study Termination		If DSDSCDT and REF.DATE not missing then perform below logic to calculate DSDSCDY, If DSDSCDT less than REF.DATE then (DSDSCDT - REF.DATE). Else if DSDSCDT is greater than equal to REF.DATE then (DSDSCDT- REF.DATE) +1.

1.4.16. Health Economic Questionnaire – ECONOM

Dataset	ECONOM
Creating program	econom.sas
Description	Health Economic Questionnaire
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
ECHRSWK	num	Average Number of Hours Worked		Collected at CRF.
ECDYSAB	num	Days of Absence		Collected at CRF.
ECPSCLE	num	Productivity Scale (cm)		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
ECCNWRK	char	Could Work If Job Available		Collected at CRF.
ECDISAB	char	Receiving Disability Compensation		Collected at CRF.
ECERTRE	char	Early Retirement		Collected at CRF.
ECILRSN	char	Illness Reason For Not Working		Collected at CRF.
ECPSND	char	Productivity Scale Not Done		Collected at CRF.
ECRETRE	char	Retired		Collected at CRF.
ECSTUD	char	Student		Collected at CRF.
ECSTUFP	char	Full or Part-time Student		Collected at CRF.
ECWORK	char	Currently Working		Collected at CRF.
ECWRKFP	char	Working Full or Part-time		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.17.   Subcutaneous Study Agent Exposure – EXPOSURE

Dataset	EXPOSURE
Creating program	exposure.sas
Description	Subcutaneous Study Agent Exposure
Unique identifier	DUSUBJID,EXSAADM,EXSITE,VISIT,EXSTDY,EXSEQ
Sorted by	DUSUBJID,EXSAADM,EXSITE,VISIT,EXSTDY,EXSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: EXSTDT,EXCNTRID,EXSTDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
EXSEQ	num	Exposure Sequence Number		Collected at CRF.
EXSTTM	num	Start Time of Dose, 24 Hour Clock		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXND	char	Dose Not Done		Collected at CRF.
EXSAADM	char	Study Agent Administrator		Collected at CRF.
EXSITE	char	Exposure Site		Collected at CRF.
EXTOTADM	char	Total Dose Administered		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
EXSTDY	num	Relative Start Day of Dose		If EXSTDT and REF.DATE not missing then perform below logic to calculate EXSTDY, If EXSTDT less than REF.DATE then (EXSTDT - REF.DATE). Else if EXSTDT is greater than equal to REF.DATE then (EXSTDT- REF.DATE) +1.

1.4.18.   Hospital Anxiety and Depression Scale – HADS

Dataset	HADS
Creating program	hads.sas
Description	Hospital Anxiety and Depression Scale
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
HDAPPEAR	char	Appearance		Collected at CRF.
HDBTRFLY	char	Butterflies in Stomach		Collected at CRF.
HDCHRFUL	char	Cheerful		Collected at CRF.

Variable	Type	Label	Codes	Comments
HDENJBK	char	Enjoy Book or Radio or Television		Collected at CRF.
HDENTHNG	char	Enjoy Things		Collected at CRF.
HDFRIGHT	char	Frightened		Collected at CRF.
HDFWDENJ	char	Look Forward with Enjoyment		Collected at CRF.
HDLAUGH	char	Laugh		Collected at CRF.
HDPANIC	char	Panic		Collected at CRF.
HDRELAX	char	Relaxed		Collected at CRF.
HDRSTLSS	char	Restless		Collected at CRF.
HDSLWDWN	char	Slowed Down		Collected at CRF.
HDTNSWND	char	Tense and Wound Up		Collected at CRF.
HDWORRY	char	Worry		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.19. Ivrsdose – IVRSDOSE

Dataset	IVRSDOSE
Creating program	ivrsdose.sas
Description	Ivrsdose
Unique identifier	DUSUBJID,IDCRDOS,VISIT
Sorted by	DUSUBJID,IDCRDOS,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: IDCTID

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
IDSEQ	num	IVRS Sequence Number		Collected at CRF.
IDPASI	num	PASI Total Score		Collected at CRF.
IDPASIPI	num	Percent Improvement in PASI		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
IDCRDOS	char	Current Dose		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.20. Ivrsrand – IVRSRAND

Dataset	IVRSRAND
Creating program	ivrsrand.sas
Description	Ivrsrand
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: LCENR_DT

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
IVRSCD	num	Dose Assignment at Week 0		Collected at CRF.
IVRSCD28	num	Dose Assignment at Week 28		Collected at CRF.
IVRSCD40	num	Dose Assignment at Week 40		Collected at CRF.
WGT	num	Weight Entered into IVRS		Collected at CRF.
THERP	num	Prior Therapies Number Entered into IVRS		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.

Variable	Type	Label	Codes	Comments
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
STHERCAT	char	Number of Prior Therapies Category		Collected at CRF.
IVRSGRP	char	Treatment Group (Week 0)		Collected at CRF.
IVRSGR28	char	Treatment Group (Week 28)		Collected at CRF.
IVRSGR40	char	Treatment Group (Week 40)		Collected at CRF.
SWGTCAT	char	Weight Category (IVRS)		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.21. Laboratory Tests – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Tests
Unique identifier	DUSUBJID,LBTEST,LBCAT,LBDY,LBSEQ
Sorted by	DUSUBJID,LBTEST,LBCAT,LBDY,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: LBLBLNUM,LBDT,LBCOM,LBDTC,LBID

Variable	Type	Label	Codes	Comments
LBORUNIT	char	Original Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORNRLO	char	Normal Range Lower Limit in Orig Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBORNRHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
LBSTRES	char	Analysis Result in Standard Units		Collected at CRF.
LBSTNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
LBSTNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LBSTDNRC	char	Normal Range for Char Rslt in Std Units		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBSCAT	char	Subcategory for Lab Test		Collected at CRF.
LBTSTORD	num	Lab Test Order		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
LBFAST	char	Fasting		Collected at CRF.
LBHIQL	char	Upper Bound Qualifier		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
LBLOQL	char	Lower Bound Qualifier		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBPTM	char	Planned Timepoint Name		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
LBDY	num	Relative Day of Specimen Collection		If LBDT and REF.DATE not missing then perform below logic to calculate LBDY, If LBDT less than REF.DATE then (LBDT - REF.DATE). Else if LBDT is greater than equal to REF.DATE then (LBDT-REF.DATE) +1.

1.4.22.   Lscna – LSCNA

Dataset	LSCNA
Creating program	lscna.sas
Description	Lscna
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
LSSEQ	num	Lab Sequence		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LSPTM	char	Planned Timepoint Name		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.23. Medication Class – MEDCLASS

Dataset	MEDCLASS
Creating program	medclass.sas
Description	Medication Class
Unique identifier	ATC_CODE
Sorted by	ATC_CODE
Notes	

Variable	Type	Label	Codes	Comments
DRECNO	char	Drug Record Number		Collected at CRF.
SEQ1	char	Drug Sequence 1		Collected at CRF.
LEVEL1	char	4th Level, ATC Class		Collected at CRF.
LEVEL2	char	2nd Level, ATC Class		Collected at CRF.

Variable	Type	Label	Codes	Comments
LEVEL3	char	3rd Level, ATC Class		Collected at CRF.
LEVEL4	char	4th Level, ATC Class		Collected at CRF.
ATC_CODE	char	ATC Code		Collected at CRF.

1.4.24.   Nabresul – NABRESUL

Dataset	NABRESUL
Creating program	nabresul.sas
Description	Nabresul
Unique identifier	CPPERIOD,CPTEST,CPRESCAT
Sorted by	CPPERIOD,CPTEST,CPRESCAT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: CPLABID,CPLABEL

Variable	Type	Label	Codes	Comments
CPPERIOD	char	Cpperiod		Collected at CRF.
CPASYCD	char	Cpasycd		Collected at CRF.
CPASY	char	Cpasy		Collected at CRF.
CPTESTCD	char	Cptestcd		Collected at CRF.
CPTEST	char	Cptest		Collected at CRF.

Variable	Type	Label	Codes	Comments
CPRESCAT	char	Cprescat		Collected at CRF.
CPRESC	char	Cpresc		Collected at CRF.
CPUNIT	char	Cpunit		Collected at CRF.
CPLLOQ	num	Cplloq		Collected at CRF.
CPCMT1CD	char	Cpcmt1Cd		Collected at CRF.
CPCMT1	char	Cpcmt1		Collected at CRF.
CPCMT2CD	char	Cpcmt2Cd		Collected at CRF.
CPCMT2	char	Cpcmt2		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.25.   Psoriasis Area and Severity Index – PASI

Dataset	PASI
Creating program	pasi.sas
Description	Psoriasis Area and Severity Index
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
PAERHEAD	num	Erythema of the Head		Collected at CRF.
PAERTRNK	num	Erythema of the Trunk		Collected at CRF.
PAERULMB	num	Erythema of the Upper Limbs		Collected at CRF.
PAERLLMB	num	Erythema of the Lower Limbs		Collected at CRF.
PAINHEAD	num	Induration of the Head		Collected at CRF.
PAINTRNK	num	Induration of the Trunk		Collected at CRF.
PAINULMB	num	Induration of Upper Limbs		Collected at CRF.
PAINLLMB	num	Induration of Lower Limbs		Collected at CRF.
PASCHEAD	num	Scaling of the Head		Collected at CRF.
PASCTRNK	num	Scaling of the Trunk		Collected at CRF.

Variable	Type	Label	Codes	Comments
PASCULMB	num	Scaling of Upper Limbs		Collected at CRF.
PASCLLMB	num	Scaling of Lower Limbs		Collected at CRF.
PAASHEAD	num	Area Score for the Head		Collected at CRF.
PAASTRNK	num	Area Score for the Trunk		Collected at CRF.
PAASULMB	num	Area Score for the Upper Limbs		Collected at CRF.
PAASLLMB	num	Area Score for the Lower Limbs		Collected at CRF.
PAPASI	num	PASI Total Score		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.26.   Psoriasis Systemics Medication History – PSMDHX

Dataset	PSMDHX
Creating program	psmdhx.sas
Description	Psoriasis Systemics Medication History
Unique identifier	DUSUBJID,PSMED,PSMEDBIO,PSSEQ
Sorted by	DUSUBJID,PSMED,PSMEDBIO,PSSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to missing values: PSMEDOTH,PSCONT3

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
PSSEQ	num	Psoriasis Medication Sequence		Collected at CRF.
PSCSTNUM	num	Num of Inappropriate Conventional Sys Tx		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
PSCONT1	char	Psoriasis Medication Contraindication 1		Collected at CRF.
PSCONT2	char	Psoriasis Medication Contraindication 2		Collected at CRF.
PSCONTR	char	Psoriasis Medication Contraindication		Collected at CRF.
PSMED	char	Psoriasis Medication		Collected at CRF.
PSMEDAE	char	Discontinued Medication Adverse Event		Collected at CRF.
PSMEDBIO	char	Biologic Medication		Collected at CRF.
PSMEDEX	char	Psoriasis Medication Exposure		Collected at CRF.
PSMEDIN	char	Discontinued Medication Inadeq Response		Collected at CRF.
PSTOPTX	char	Topical Therapies for Psoriasis		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.27. Adverse Events for Screen Failures – SCRNAE

Dataset	SCRNAE
Creating program	scrnae.sas
Description	Adverse Events for Screen Failures
Unique identifier	DUSUBJID,AEDECOD,AESTDY,AESEQ
Sorted by	DUSUBJID,AEDECOD,AESTDY,AESEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: AETERM,AEMODIFY,AESTDT,AEENDT,AEPRSPEC,AESTDTC,AEENDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
AESEQ	num	Sequence Number		Collected at CRF.
AESTTM	num	Start Time of Event		Collected at CRF.
AECD	char	Adverse Event Code		Collected at CRF.
AEHLTCD	char	High Level Term Code		Collected at CRF.
AEHLGTCD	char	High Level Group Term Code		Collected at CRF.
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF.
AEBODSCD	char	Dictionary Body System Code		Collected at CRF.

Variable	Type	Label	Codes	Comments
AELLT	char	Low Level Term Name		Collected at CRF.
AEDECOD	char	Dictionary Term		Collected at CRF.
AEHLT	char	High Level Term Name		Collected at CRF.
AEBODSYS	char	Body System/Organ Class		Collected at CRF.
MDVD	char	MEDDRA Version Used to Decode		Collected at CRF.
AEHLGT	char	High Level Group Term Name		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
SAERHOS	char	Hospitalization Required		Collected at CRF.
SAEPHOS	char	Prolonged Hospitalization		Collected at CRF.
SAEOTH	char	Other Medically Important		Collected at CRF.
SAENS	char	Not Serious		Collected at CRF.
SAECONG	char	Congenital Anomaly/Birth Defect		Collected at CRF.
INFECT	char	Infection		Collected at CRF.
AERELPR	char	Related to Trial Procedure		Collected at CRF.
AEONGO	char	Ongoing Adverse Event		Collected at CRF.
AEASR	char	Administration Site Reaction		Collected at CRF.
AEACTTRT	char	Action Taken with Study Treatment		Collected at CRF.

Variable	Type	Label	Codes	Comments
AELOC	char	Adverse Event Location		Collected at CRF.
AEREL	char	Causality (Relation to Treatment)		Collected at CRF.
AESEV	char	Severity/Intensity of Event		Collected at CRF.
INFECTRT	char	Infection Treated		Collected at CRF.
SAEDISAB	char	Permanent/Serious Disability/Incapacity		Collected at CRF.
SAEDTH	char	Results in Death		Collected at CRF.
SAELIFE	char	Is Life-Threatening		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

Variable	Type	Label	Codes	Comments
AESTDY	num	Relative Start Day of Event		If AESTDT and REF.DATE not missing then perform below logic to calculate AESTDY, If AESTDT less than REF.DATE then (AESTDT - REF.DATE). Else if AESTDT is greater than equal to REF.DATE then (AESTDT- REF.DATE) +1.
AEENDY	num	Relative End Day of Event		If AEENDT and REF.DATE not missing then perform below logic to calculate AEENDY, If AEENDT less than REF.DATE then (AEENDT - REF.DATE). Else if AEENDT is greater than equal to REF.DATE then (AEENDT- REF.DATE) +1.

1.4.28.   Assay Tracking for Screen Failures – SCRNATRACK

Dataset	SCRNATRACK
Creating program	scrnatrack.sas
Description	Assay Tracking for Screen Failures
Unique identifier	DUSUBJID,ATKTTYP,ATPTM,ATDY
Sorted by	DUSUBJID,ATKTTYP,ATPTM,ATDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: ATKITNUM,ATDT,ATDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
ATTM	num	Assay Tracking Time		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
ATEVQL	char	Event Qualifier		Collected at CRF.
ATKTTYP	char	Kit Type		Collected at CRF.
ATNTCOL	char	Sample Not Collected		Collected at CRF.
ATPTM	char	Planned Timepoint		Collected at CRF.
ATSMTYP	char	Sample Type		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
ATDY	num	Relative Assay Tracking Day		If ATDT and REF.DATE not missing then perform below logic to calculate ATDY, If ATDT less than REF.DATE then (ATDT - REF.DATE). Else if ATDT is greater than equal to REF.DATE then (ATDT-REF.DATE) +1.

1.4.29. Selection Criteria for Screen Failures – SCRNCRIT

Dataset	SCRNCRIT
Creating program	scrncrit.sas
Description	Selection Criteria for Screen Failures
Unique identifier	DUSUBJID,INCRIT,EXCRIT
Sorted by	DUSUBJID,INCRIT,EXCRIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
CRSEQ	num	Criterion Sequence		Collected at CRF.
INCRIT	char	Inclusion Criterion Not Met		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXCRIT	char	Exclusion Criterion Present		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.30.   Demographics for Screen Failures – SCRNDEMO

Dataset	SCRNDEMO
Creating program	scrndemo.sas
Description	Demographics for Screen Failures
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SUBJINIT,BIRTHDT,DMCONDT,DEMOG,BIRTHDTC,DMCONDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
HEIGHT	num	Height in Centimeters		Collected at CRF.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.

Variable	Type	Label	Codes	Comments
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.31.   Lab Data for Screen Failures – SCRNLAB

Dataset	SCRNLAB
Creating program	scrnlab.sas
Description	Lab Data for Screen Failures
Unique identifier	DUSUBJID,LBTEST,LBCAT,LBDY,LBSEQ
Sorted by	DUSUBJID,LBTEST,LBCAT,LBDY,LBSEQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LBLBLNUM,LBDT,LBCOM,LBDTC,LBHIQL,LBID

Variable	Type	Label	Codes	Comments
LBORUNIT	char	Original Units		Collected at CRF.
LBSTUNIT	char	Standard Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
LBSEQ	num	Lab Sequence Number		Collected at CRF.
LBTSTCD	char	Lab Test Code		Collected at CRF.
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF.
LBORRES	char	Result in Original Units		Collected at CRF.
LBORNRLO	char	Normal Range Lower Limit in Orig Units		Collected at CRF.
LBORNRHI	char	Normal Range Upper Limit in Orig Units		Collected at CRF.
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF.
LBSTRES	char	Analysis Result in Standard Units		Collected at CRF.
LBSTNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF.
LBSTNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF.
LBSTDNRC	char	Normal Range for Char Rslt in Std Units		Collected at CRF.
LBTEST	char	Lab Test Name		Collected at CRF.
LBCAT	char	Category for Lab Test		Collected at CRF.
LBSCAT	char	Subcategory for Lab Test		Collected at CRF.
LBTSTORD	num	Lab Test Order		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
LBEVQL	char	Event Qualifier		Collected at CRF.
LBFAST	char	Fasting		Collected at CRF.
LBKTTYP	char	Kit Type		Collected at CRF.
LBLOQL	char	Lower Bound Qualifier		Collected at CRF.
LBNRIND	char	Normal Range Indicator		Collected at CRF.
LBPTM	char	Planned Timepoint Name		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
LBDY	num	Relative Day of Specimen Collection		If LBDT and REF.DATE not missing then perform below logic to calculate LBDY, If LBDT less than REF.DATE then (LBDT - REF.DATE). Else if LBDT is greater than equal to REF.DATE then (LBDT-REF.DATE) +1.

1.4.32.   Visit Data for Screen Failures – SCRNVIS

Dataset	SCRNVIS
Creating program	scrnvis.sas
Description	Visit Data for Screen Failures
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: VISITDT,VISITDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.

Variable	Type	Label	Codes	Comments
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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITDY	num	Relative Day of Subject Visit		If VISITDT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDT less than REF.DATE then (VISITDT - REF.DATE). Else if VISITDT is greater than equal to REF.DATE then (VISITDT- REF.DATE) +1.

1.4.33. Studypar – STUDYPAR

Dataset	STUDYPAR
Creating program	studypar.sas
Description	Studypar
Unique identifier	DUSUBJID
Sorted by	DUSUBJID
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
SPVS	char	Vaccine Substudy		Collected at CRF.

1.4.34.   Subject Status – SUBSTAT

Dataset	SUBSTAT
Creating program	substat.sas
Description	Subject Status
Unique identifier	DUSUBJID,SSREAS,SSDSCDY
Sorted by	DUSUBJID,SSREAS,SSDSCDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: SSDSCDT,SSRSOTH,SSDSCDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
SSENT	char	Subject Entered Next Study Period		Collected at CRF.
SSREAS	char	Reason for Discontinuation		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
SSDSCDY	num	Relative Day of Study Discontinuation		If SSDSCDT and REF.DATE not missing then perform below logic to calculate SSDSCDY, If SSDSCDT less than REF.DATE then (SSDSCDT - REF.DATE). Else if SSDSCDT is greater than equal to REF.DATE then (SSDSCDT- REF.DATE) +1.

1.4.35.   Vaccin – VACCIN

Dataset	VACCIN
Creating program	vaccin.sas
Description	Vaccin
Unique identifier	DUSUBJID,VCSITE,VCVACDY
Sorted by	DUSUBJID,VCSITE,VCVACDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: VCVACDT,VCVACDTC,VCCNTRD,VCND

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
VCSEQ	num	Vaccination Sequence Number		Collected at CRF.
VCVACTM	num	Time of Vaccination, 24 Hour Clock		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF.
VCSITE	char	Vaccine injection site		Collected at CRF.
VCTOTADM	char	Total Dose Administered		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VCVACDY	num	Relative Day of Vaccination		If VCVACDT and REF.DATE not missing then perform below logic to calculate VCVACDY, If VCVACDT less than REF.DATE then (VCVACDT - REF.DATE). Else if VCVACDT is greater than equal to REF.DATE then (VCVACDT- REF.DATE) +1.

1.4.36. Vaccinab – VACCINAB

Dataset	VACCINAB
Creating program	vaccinab.sas
Description	Vaccinab
Unique identifier	DUSUBJID,ABTEST,ABDY
Sorted by	DUSUBJID,ABTEST,ABDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: ABDT,ABDTC,ABACCNM,ABNOTES,ABCOMNT

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
ABTM	num	Time of Specimen Collection		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.
SEX	char	Sex		Collected at CRF.
RACE	char	Race		Collected at CRF.

Variable	Type	Label	Codes	Comments
ABEVQL	char	Event Qualifier		Collected at CRF.
ABSPEC	char	Specimen Type		Collected at CRF.
ABKTTYP	char	Kit Type		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		Collected at CRF.
ABTSTCD	char	Antibody Test Code		Collected at CRF.
ABRESC	char	Antibody Character Result		Collected at CRF.
ABTEST	char	Antibody Test		Collected at CRF.
ABUNIT	char	Units		Collected at CRF.
ABDY	num	Relative Day of Specimen Collection		If ABDT and REF.DATE not missing then perform below logic to calculate ABDY, If ABDT less than REF.DATE then (ABDT - REF.DATE). Else if ABDT is greater than equal to REF.DATE then (ABDT-REF.DATE) +1.

1.4.37. Subject Visits – VISITS

Dataset	VISITS
Creating program	visits.sas
Description	Subject Visits
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: VISITDT,VISITDTC

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity

Variable	Type	Label	Codes	Comments
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
VISITDY	num	Relative Day of Subject Visit		If VISITDT and REF.DATE not missing then perform below logic to calculate VISITDY, If VISITDT less than REF.DATE then (VISITDT - REF.DATE). Else if VISITDT is greater than equal to REF.DATE then (VISITDT- REF.DATE) +1.

1.4.38.   Vital Signs – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vital Signs
Unique identifier	DUSUBJID,VSPTM,VISIT
Sorted by	DUSUBJID,VSPTM,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.

Variable	Type	Label	Codes	Comments
PAG_NAME	char	Page		Collected at CRF.
VSSEQ	num	Vital Signs Sequence		Collected at CRF.
SYSBP1	num	Systolic Blood Pressure in mmHg (Pos 1)		Collected at CRF.
DIABP1	num	Diastolic Blood Pressure in mmHg (Pos 1)		Collected at CRF.
VSWGT	num	Weight in Kilograms		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
VSPTM	char	Planned Timepoint Name		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

1.4.39. Work Limitations Questionnaire – WLQ

Dataset	WLQ
Creating program	wlq.sas
Description	Work Limitations Questionnaire
Unique identifier	DUSUBJID,VISIT
Sorted by	DUSUBJID,VISIT
Notes	

Variable	Type	Label	Codes	Comments
DCOUNTRY	char	De-identify Country		Group element to protect PII.
PAG_NAME	char	Page		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.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
VISIT	char	Visit Name		Collected at CRF.
VISITNUM	num	Visit Number		Collected at CRF.
WL1A	char	Work Required Number of Hours		Collected at CRF.
WL1B	char	Get Workday Going Easily		Collected at CRF.
WL1C	char	Start Job as Soon as Arrival		Collected at CRF.

Variable	Type	Label	Codes	Comments
WL1D	char	Work Without Stopping for Breaks		Collected at CRF.
WL1E	char	Stick to a Routine or Schedule		Collected at CRF.
WL2A	char	Walk or Move Around Without Difficulty		Collected at CRF.
WL2B	char	Lift, Carry, or Move Objects		Collected at CRF.
WL2C	char	Sit, Stand, or Stay More Than 15 Minutes		Collected at CRF.
WL2D	char	Repeat Same Motions		Collected at CRF.
WL2E	char	Bend, Twist, or Reach		Collected at CRF.
WL2F	char	Use Hand-Held Tools		Collected at CRF.
WL3A	char	Keep Mind on Work		Collected at CRF.
WL3B	char	Think Clearly When Working		Collected at CRF.
WL3C	char	Do Work Carefully		Collected at CRF.
WL3D	char	Concentrate on Your Work		Collected at CRF.
WL3E	char	Work Without Losing Train of Thought		Collected at CRF.
WL3F	char	Easily Read When Working		Collected at CRF.
WL4A	char	Speak With People		Collected at CRF.
WL4B	char	Control Your Temper		Collected at CRF.
WL4C	char	Help Other People		Collected at CRF.
WL5A	char	Handle the Workload		Collected at CRF.
WL5B	char	Work Fast Enough		Collected at CRF.

Variable	Type	Label	Codes	Comments
WL5C	char	Finish Work on Time		Collected at CRF.
WL5D	char	Work Without Mistakes		Collected at CRF.
WL5E	char	Done What You're Capable of Doing		Collected at CRF.
WRKFPAY	char	Work for pay		Collected at CRF.
STUDYID	char	Study ID		Collected at CRF.
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
DUSUBJID	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity