Clinical Development

Infliximab

C0168T26

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	Code list 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 Name will not be provided.
- Date of birth will not be provided, only age in years and 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.
- 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.
- Dataset used for data reconciliation, CRF page information will not be submitted (e.g. ANY_NONE, ATRACK, PAGE_SEQ, PGSUMM, LTRACK).
- Datasets CRESUL contains PK related information hence will be dropped.
- UNBLIND dataset will not be submitted to protect PII.
- CONPROC dataset will not submit to protect PII.
- No deaths reported in the study, hence DEATH dataset will not be submitted.
- Surgery data will not be submitted, it may reveal PII info.
- Medical History data will not be submitted.
- PHOTOS dataset will not be submitted.
- ECONOM dataset will not be submitted as it captures personal information of subject's economic status hence may lead to PII.
- Screen failure data will be removed from all domains, which has no impact on secondary analysis.

1.3. Data Files

The C0168T26 Clinical Study Report (CSR) data should be used for converting to de-identification. Use the C0168T26 CSR data from the following folders.

1.4. Data Domains

1.4.1. Demographics – DEMOG

Dataset	DEMOG
Creating program	demog.sas
Description	Demographics
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, INITIALS, DOB_DY, DOB_MO, DOB_YR, DOB_DT, RACE_OTH, CRF_PAGE, ZWGT, ZWGT_UN

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
ZHGT	num	Entered height		Collected at CRF.

Variable	Type	Label	Codes	Comments
HGT	num	Height (cm)		Collected at CRF.
WGT	char	Weight (kg)		Group the element to protect PII.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
RACE	char	Race		Collected at CRF.
SEX	char	Sex		Collected at CRF.
ZHGT_UN	char	Units for entered height		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
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. Abscesses – ABSCESS

Dataset	ABSCESS
Creating program	abscess.sas
Description	Abscesses
Unique identifier	DUNIQUEP, VISIT , DIAG_DY, FIST_NUM
Sorted by	DUNIQUEP, VISIT , DIAG_DY, FIST_NUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, LINE_NO, DIAG_DY, DIAG_MO, DIAG_YR, CRF_PAGE, DIAG_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
FIST_NUM	num	Fistula number		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
ABTREAT	char	Was abscess treated		Collected at CRF.

Variable	Type	Label	Codes	Comments
INCISED	char	Was abscess incised and drained		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
DIAG_DY	num	Relative Day of diagnosis		If DIAG_DT and RAND_DT not missing then perform below logic to calculate DIAG_DY, If DIAG_DT less than RAND_DT then (DIAG_DT - RAND_DT).Else if DIAG_DT is greater than equal to RAND_DT then (DIAG_DT- RAND_DT) +1.

1.4.3. Administration – ADMIN

Dataset	ADMIN
Creating program	admin.sas
Description	Administration
Unique identifier	DUNIQUEP, VISIT
Sorted by	DUNIQUEP, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAG_NAME, START_DY, START_MO, START_YR, STP1SPEC, STP2SPEC, TVA_SPEC, TVA_CNS, CRF_PAGE, START_DT, STP2_AD

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
START_HR	num	Administration start hour		Collected at CRF.
START_MI	num	Administration start minute		Collected at CRF.

Variable	Type	Label	Codes	Comments
START_TM	num	Administration start time		Collected at CRF.
END_HR	num	Administration end hour		Collected at CRF.
END_MI	num	Administration end minute		Collected at CRF.
END_TM	num	Administration end time		Collected at CRF.
STP1_HR	num	First admin stop hour		Collected at CRF.
STP1_MI	num	First admin stop minute		Collected at CRF.
STP1_TM	num	First admin stop time		Collected at CRF.
RST1_HR	num	First admin restart hour		Collected at CRF.
RST1_MI	num	First admin restart minute		Collected at CRF.
RST1_TM	num	First admin restart time		Collected at CRF.
STP2_HR	num	Second admin stop hour		Collected at CRF.
STP2_MI	num	Second admin stop minute		Collected at CRF.
STP2_TM	num	Second admin stop time		Collected at CRF.
RST2_HR	num	Second admin restart hour		Collected at CRF.
RST2_MI	num	Second admin restart minute		Collected at CRF.
RST2_TM	num	Second admin restart time		Collected at CRF.
TOTAL_ML	num	Total ml administered		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
ADMN_ND	char	Administration not done		Collected at CRF.
INTRRPT	char	Infusion interrupted		Collected at CRF.

Variable	Type	Label	Codes	Comments
PROPGIV	char	Prophylactic medication given		Collected at CRF.
STP1_AD	char	First interrupt. administrative		Collected at CRF.
STP1_AE	char	First interruption reason is AE		Collected at CRF.
STP2_AE	char	Second interruption reason is AE		Collected at CRF.
TESTADM	char	Test dose administered		Collected at CRF.
TOT_ADM	char	Total dose administered		Collected at CRF.
TVA_ADM	char	Rsn total not adm administrative		Collected at CRF.
TVA_AE	char	Reason total vol not adm is AE		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
START_DY	num	Relative Start Day		If START_DT and RAND_DT not missing then perform below logic to calculate START_DY,If START_DT less than RAND_DT then (START_DT - RAND_DT).Else if START_DT is greater than equal to RAND_DT then (START_DT- RAND_DT) +1.

1.4.4. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events
Unique identifier	DUNIQUEP, PREFTRMD, VISIT, ONSET_DY, RESOL_DY
Sorted by	DUNIQUEP, PREFTRMD, VISIT, ONSET_DY, RESOL_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAG_NAME, AE_LINE,AE_DESC, ONSET_DY, ONSET_MO, ONSET_YR, RESOL_DY, RESOL_MO, RESOL_YR, SER_1, SER_2, SER_3, SER_4, SER_5, CRF_PAGE, ONSET_DT, RESOL_DT, PAGE_SEQ

Variable	Type	Label	Codes	Comments
WHOART	char	WHOART AE code		Collected at CRF.
CLASS	char	System organ class code		Collected at CRF.
CLASSD	char	System organ class		Collected at CRF.
PREFTRM	char	Preferred term code		Collected at CRF.
PREFTRMD	char	Preferred term		Collected at CRF.
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
ONSET_HR	num	Onset hour		Collected at CRF.
ONSET_MI	num	Onset minute		Collected at CRF.
ONSET_TM	num	Onset time		Collected at CRF.
RESOL_HR	num	Resolution hour		Collected at CRF.
RESOL_MI	num	Resolution minute		Collected at CRF.
RESOL_TM	num	Resolution time		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
ACT_TAK	char	Action taken with study agent		Collected at CRF.
AETREAT	char	Event treated		Collected at CRF.
AE_REL	char	Relationship to study agent		Collected at CRF.
CATEGRY	char	AE category		Collected at CRF.
CONT	char	Event continuing		Collected at CRF.
SER_6	char	Other serious		Collected at CRF.
SER_7	char	Not serious		Collected at CRF.
SEV	char	AE Intensity		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
ONSET_DY	num	Relative Onset Day		If ONSET_DT and RAND_DT not missing then perform below logic to calculate ONSET_DY, If ONSET_DT less than RAND_DT then (ONSET_DT - RAND_DT).Else if ONSET_DT is greater than equal to RAND_DT then (ONSET_DT- RAND_DT) +1.
RESOL_DY	num	Relative Resolution Day		If RESOL_DT and RAND_DT not missing then perform below logic to calculate RESOL_DY, If RESOL_DT less than RAND_DT then (RESOL_DT - RAND_DT).Else if RESOL_DT is greater than equal to RAND_DT then (RESOL_DT- RAND_DT) +1.

1.4.5. Allergies – ALLERGY

Dataset	ALLERGY
Creating program	allergy.sas
Description	Allergies
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, DRUGSPEC, FOODSPEC, POLLSPEC, OTHRSPEC, CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
DRUG	char	History of drug allergies		Collected at CRF.
FOOD	char	History of food allergies		Collected at CRF.

Variable	Type	Label	Codes	Comments
OTHER	char	History of other allergies		Collected at CRF.
POLLEN	char	History of pollen allergies		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity

1.4.6. Crohn's Disease Activity Index – CDAI

Dataset	CDAI
Creating program	cdai.sas
Description	Crohn's Disease Activity Index
Unique identifier	DUNIQUEP, VISIT
Sorted by	DUNIQUEP, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME,CRF_PAGE, CDAIZWGT, ZWGT_UN

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.

Variable	Type	Label	Codes	Comments
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
DRG_THR	num	Pt. received antidiarrheal tx.		Collected at CRF.
DRGTHR2	num	Pt. received opiate therapy		Collected at CRF.
NO_STOOL	num	Number of liquid or soft stools		Collected at CRF.
ABD_PAIN	num	Abdominal pain/cramps rating		Collected at CRF.
WELL_BE	num	General well being rating		Collected at CRF.
COMP_CRD	num	Days pt. completed diary card		Collected at CRF.
ABD_MAS	num	Indicates abdominal mass		Collected at CRF.
CDAIWGT	char	Weight (kg)		Group the element to protect PII.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
ABSCESS	char	Indicates anal abscess		Collected at CRF.
APHTHOU	char	Indicates aphthous stomatitis		Collected at CRF.
ARTHRIT	char	Indicates arthritis		Collected at CRF.
ARTHRLG	char	Indicates arthralgia		Collected at CRF.
DIARYEX	char	Comments pg. has an explanation		Collected at CRF.
ERYTHEM	char	Indicates erythema nodosum		Collected at CRF.
FEVER	char	Indicates pt. has or had a fever		Collected at CRF.
FISSURE	char	Indicates anal fissure		Collected at CRF.

Variable	Type	Label	Codes	Comments
FISTULA	char	Indicates anal fistula		Collected at CRF.
IRITIS	char	Indicates iritis		Collected at CRF.
OTHRFIS	char	Indicates other fistula		Collected at CRF.
PYODERM	char	Indicates pyoderma gangrenosum		Collected at CRF.
UVEITIS	char	Indicates uveitis		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity

1.4.7. Crohn's Disease History – CD_HX

Dataset	CD_HX
Creating program	cd_hx.sas
Description	Crohn's Disease History
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, DIAG_DY, DIAG_MO, DIAG_YR, CRF_PAGE, DIAG_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
COLON	char	Indicates Colon Involvement		Collected at CRF.

Variable	Type	Label	Codes	Comments
GASDUOD	char	Indicates Gas-Duod. Involvement		Collected at CRF.
ILEUM	char	Indicates Ileum Involvement		Collected at CRF.
OGISURG	char	Other Crohns related GI surgery		Collected at CRF.
RESECT	char	Have intestines been resected		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
DIAG_DY	num	Relative Day of diagnosis		If DIAG_DT and RAND_DT not missing then perform below logic to calculate DIAG_DY, If DIAG_DT less than RAND_DT then (DIAG_DT - RAND_DT).Else if DIAG_DT is greater than equal to RAND_DT then (DIAG_DT- RAND_DT) +1.

1.4.8. Comments – COMMENT

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

Variable	Type	Label	Codes	Comments
DCNO	char	Center ID Assigned for De-identity		Empty dataset will be submitted.
DPATNO	char	Patient Number Assigned for De-identity		Empty dataset will be submitted.
DPATID	char	Pat. Id. number Assigned for De-identity		Empty dataset will be submitted.
DUNIQUEP	char	Unique_P Assigned for De-identity		Empty dataset will be submitted.

1.4.9. Concomitant Treatment – COMTREAT

Dataset	COMTREAT
Creating program	comtreat.sas
Description	Concomitant Treatment Data
Unique identifier	DUNIQUEP, RXST_DY
Sorted by	DUNIQUEP, RXST_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAG_NAME, LINE_NO, RXST_DY, RXST_MO, RXST_YR, CRF_PAGE, RXST_DT

Variable	Type	Label	Codes	Comments
TAREA	char	Program Identifier - Therapeutic Area		Collected at CRF.
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
AE_SPEC	char	Specified adverse event		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
AE_1	char	First adverse event		Collected at CRF.
AE_2	char	Second adverse event		Collected at CRF.
AE_3	char	Third adverse event		Collected at CRF.
AE_4	char	Fourth adverse event		Collected at CRF.
AE_5	char	Fifth adverse event		Collected at CRF.
NO_AES	char	No adverse events		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
RXST_DY	num	Relative Medication start Day		If RXST_DT and RAND_DT not missing then perform below logic to calculate RXST_DY,If RXST_DT less than RAND_DT then (RXST_DT - RAND_DT).Else if RXST_DT is greater than equal to RAND_DT then (RXST_DT- RAND_DT) +1.

1.4.10. Patient Selection Criteria – CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Patient Selection Criteria
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAG_NAME,CRIT_2, CRIT_3, CRIT_5, CRIT_6, CONS_DY, CONS_MO, CONS_YR, CRF_PAGE, CONS_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
CRIT_1	char	First criterion number not met		Collected at CRF.

Variable	Type	Label	Codes	Comments
CRIT_4	char	Fourth criterion number not met		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
CRITMET	char	All criteria met		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
CONS_DY	num	Relative Informed consent Day		If CONS_DT and RAND_DT not missing then perform below logic to calculate CONS_DY, If CONS_DT less than RAND_DT then (CONS_DT - RAND_DT).Else if CONS_DT is greater than equal to RAND_DT then (CONS_DT- RAND_DT) +1.

1.4.11. Fistula Medication History – FISTMEDS

Dataset	FISTMEDS
Creating program	fistmeds.sas
Description	Fistula Medication History
Unique identifier	DUNIQUEP, VISIT, FISTMED
Sorted by	DUNIQUEP, VISIT, FISTMED
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, MEDSPEC, CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
FISTMED	char	Fistula medication code		Collected at CRF.

Variable	Type	Label	Codes	Comments
IADQCON	char	Disc. due to inadequate control		Collected at CRF.
MEDDISC	char	Was medication discontinued		Collected at CRF.
NORESP	char	Disc. due to lack of response		Collected at CRF.
NVRUSED	char	Medication never used		Collected at CRF.
OTH_RSN	char	Disc. due to other reason		Collected at CRF.
TOXIC	char	Disc. due to toxicity		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity

1.4.12. Fistulas – FISTULA

Dataset	FISTULA
Creating program	fistula.sas
Description	Fistulas
Unique identifier	DUNIQUEP, VISIT, FIST_NUM
Sorted by	DUNIQUEP, VISIT, FIST_NUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, ONSET_MO, ONSET_YR, CRF_PAGE, PAGE_SEQ

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
FIST_NUM	num	Fistula number		Collected at CRF.
FIS_STAT	num	Fistula status (closed or not)		Collected at CRF.
DUR_NC	num	Duration fistula not closed		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
FISTLOC	char	Fistula location		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity

1.4.13. Follow Up – FUP

Dataset	FUP
Creating program	fup.sas
Description	Follow Up data
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAG_NAME, FUP_DY, FUP_MO, FUP_YR, LTF_DY, LTF_MO, LTF_YR, PROBCAUS, DOD_MO, DOD_YR, CRF_PAGE, FUP_DT, LTF_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
AI_DX	char	Autoimmune disease diagnosed		Collected at CRF.
CMTREAT	char	Commercial treatment		Collected at CRF.
DEATH	char	Patient died		Collected at CRF.
MALIG	char	Developed malignancy		Collected at CRF.
SER_INF	char	Developed serious infection		Collected at CRF.
WC_STDY	char	Cons wthdrwn for study particip.		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity

Variable	Type	Label	Codes	Comments
FUP_DY	num	Relative Follow-up Day		If FUP_DT and RAND_DT not missing then perform below logic to calculate FUP_DY, If FUP_DT less than RAND_DT then (FUP_DT - RAND_DT).Else if FUP_DT is greater than equal to RAND_DT then (FUP_DT- RAND_DT) +1.
LTF_DY	num	Relative Lost to follow-up Day		If LTF_DT and RAND_DT not missing then perform below logic to calculate LTF_DY, If LTF_DT less than RAND_DT then (LTF_DT - RAND_DT).Else if LTF_DT is greater than equal to RAND_DT then (LTF_DT- RAND_DT) +1.

1.4.14. Hospitalizations – HOSPIN

Dataset	HOSPIN
Creating program	hospin.sas
Description	Hospitalizations
Unique identifier	DUNIQUEP, VISIT, HADM_DY
Sorted by	DUNIQUEP, VISIT, HADM_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, LINE_NO, HADM_DY, HADM_MO, HADM_YR, HDIS_DY, HDIS_MO, HDIS_YR, CRF_PAGE, HADM_DT, HDIS_DT, PAGE_SEQ, ICU_DAYS

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
NODSCHG	char	Not discharged		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
HADM_DY	num	Relative Hospital admission Day		If HADM_DT and RAND_DT not missing then perform below logic to calculate HADM_DY, If HADM_DT less than RAND_DT then (HADM_DT - RAND_DT).Else if HADM_DT is greater than equal to RAND_DT then (HADM_DT- RAND_DT) +1.
HDIS_DY	num	Relative Hospital discharge Day		If HDIS_DT and RAND_DT not missing then perform below logic to calculate HDIS_DY, If HDIS_DT less than RAND_DT then (HDIS_DT - RAND_DT).Else if HDIS_DT is greater than equal to RAND_DT then (HDIS_DT- RAND_DT) +1.

1.4.15. IBD Questionnaire (IBDQ) – IBDQSCR

Dataset	IBDQSCR
Creating program	ibdqscr.sas
Description	Inflammatory Bowel Disease Questionnaire (IBDQ)
Unique identifier	DUNIQUEP , VISIT
Sorted by	DUNIQUEP , VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME,CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
IBDQ_1	num	Score for IBDQ question 1		Collected at CRF.
IBDQ_2	num	Score for IBDQ question 2		Collected at CRF.
IBDQ_3	num	Score for IBDQ question 3		Collected at CRF.

Variable	Type	Label	Codes	Comments
IBDQ_4	num	Score for IBDQ question 4		Collected at CRF.
IBDQ_5	num	Score for IBDQ question 5		Collected at CRF.
IBDQ_6	num	Score for IBDQ question 6		Collected at CRF.
IBDQ_7	num	Score for IBDQ question 7		Collected at CRF.
IBDQ_8	num	Score for IBDQ question 8		Collected at CRF.
IBDQ_9	num	Score for IBDQ question 9		Collected at CRF.
IBDQ_10	num	Score for IBDQ question 10		Collected at CRF.
IBDQ_11	num	Score for IBDQ question 11		Collected at CRF.
IBDQ_12	num	Score for IBDQ question 12		Collected at CRF.
IBDQ_13	num	Score for IBDQ question 13		Collected at CRF.
IBDQ_14	num	Score for IBDQ question 14		Collected at CRF.
IBDQ_15	num	Score for IBDQ question 15		Collected at CRF.
IBDQ_16	num	Score for IBDQ question 16		Collected at CRF.
IBDQ_17	num	Score for IBDQ question 17		Collected at CRF.
IBDQ_18	num	Score for IBDQ question 18		Collected at CRF.
IBDQ_19	num	Score for IBDQ question 19		Collected at CRF.
IBDQ_20	num	Score for IBDQ question 20		Collected at CRF.
IBDQ_21	num	Score for IBDQ question 21		Collected at CRF.
IBDQ_22	num	Score for IBDQ question 22		Collected at CRF.
IBDQ_23	num	Score for IBDQ question 23		Collected at CRF.
IBDQ_24	num	Score for IBDQ question 24		Collected at CRF.

Variable	Type	Label	Codes	Comments
IBDQ_25	num	Score for IBDQ question 25		Collected at CRF.
IBDQ_26	num	Score for IBDQ question 26		Collected at CRF.
IBDQ_27	num	Score for IBDQ question 27		Collected at CRF.
IBDQ_28	num	Score for IBDQ question 28		Collected at CRF.
IBDQ_29	num	Score for IBDQ question 29		Collected at CRF.
IBDQ_30	num	Score for IBDQ question 30		Collected at CRF.
IBDQ_31	num	Score for IBDQ question 31		Collected at CRF.
IBDQ_32	num	Score for IBDQ question 32		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
NOTDONE	char	Not done		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity

1.4.16. Laboratory Test Results – LAB

Dataset	LAB
Creating program	lab.sas
Description	Laboratory Test Results
Unique identifier	DUNIQUEP , TESTCODD, LABEVNT , LAB_DY
Sorted by	DUNIQUEP , TESTCODD, LABEVNT , LAB_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: LABELNUM, LAB_DY, LAB_MO, LAB_YR, LAB_CODE,TESTCOM, CRF_PAGE, LAB_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol Identifier - Number		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Study Visit		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
LABEVNT	char	Lab event		Collected at CRF.
TESTCOD	char	Test code		Collected at CRF.

Variable	Type	Label	Codes	Comments
LAB_HR	num	Hour of sample		Collected at CRF.
LAB_MI	num	Minute of sample		Collected at CRF.
LAB_TM	num	Time of sample		Collected at CRF.
ENT_RES	char	Test result		Collected at CRF.
NORM_LOW	char	Lower normal rng - test result		Collected at CRF.
NORM_HI	char	Upper normal rng - test result		Collected at CRF.
UNITS	char	Units - test result		Collected at CRF.
STDRES	char	Standardized test result		Collected at CRF.
STDUNIT	char	Units - std result		Collected at CRF.
STDNRMLO	char	Lower normal rng - std result		Collected at CRF.
STDNRMHI	char	Upper normal rng - std result		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
HILOFLG	char	Out of range flag		Collected at CRF.
TESTCODD	char	Decode of TESTCOD		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
STDUNITD	char	Decode of STDUNIT		Collected at CRF.

Variable	Type	Label	Codes	Comments
UNITSD	char	Decode of UNITS		Collected at CRF.
LAB_DY	num	Relative Day of sample		If LAB_DT and RAND_DT not missing then perform below logic to calculate LAB_DY,If LAB_DT less than RAND_DT then (LAB_DT - RAND_DT).Else if LAB_DT is greater than equal to RAND_DT then (LAB_DT- RAND_DT) +1.

1.4.17. Con Med for Crohn's Disease – MEDS

Dataset	MEDS
Creating program	meds.sas
Description	Concomitant Medication Record for Crohn's Disease
Unique identifier	DUNIQUEP, RX_CODE , VISIT, RXST_DY
Sorted by	DUNIQUEP, RX_CODE , VISIT, RXST_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, LINE_NO, RX_NAME, RX_IND, RXST_DY, RXST_MO, RXST_YR, RXEND_DY, RXEND_MO, RXEND_YR, CRF_PAGE, RXST_DT, RXEND_DT, PAGE_SEQ

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
ROUTE_CD	num	Route code		Collected at CRF.
ROUTE_V	char	Route specified on the CRF		Collected at CRF.
DOSAGE	char	Dose of concomitant medication		Collected at CRF.
DOSEUNT	num	Code for units of medication		Collected at CRF.
D_UNITV	char	Dose unit specified on the CRF		Collected at CRF.
RX_FREQ	num	Frequency of medication		Collected at CRF.
FREQ_V	char	Frequency specified on CRF		Collected at CRF.
RX_CODE	char	Medication code		Collected at CRF.
DOSEUNTD	char	Decode of DOSEUNT		Collected at CRF.
RX_FREQD	char	Decode of RX_FREQ		Collected at CRF.
RX_CODED	char	Decode of RX_CODE		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
DOSECHG	char	Dose change		Collected at CRF.
MEDSTAT	char	Medication status		Collected at CRF.

Variable	Type	Label	Codes	Comments
RX_CONT	char	Pt. continues taking medication		Collected at CRF.
STARTPR	char	Prior start of med.		Collected at CRF.
ROUTE_C_	char	Decode of ROUTE_CD		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
RXST_DY	num	Relative Medication start Day		If RXST_DT and RAND_DT not missing then perform below logic to calculate RXST_DY, If RXST_DT less than RAND_DT then (RXST_DT - RAND_DT).Else if RXST_DT is greater than equal to RAND_DT then (RXST_DT- RAND_DT) +1.
RXEND_DY	num	Relative Medication end Day		If RXEND_DT and RAND_DT not missing then perform below logic to calculate RXEND_DY, If RXEND_DT less than RAND_DT then (RXEND_DT - RAND_DT).Else if RXEND_DT is greater than equal to RAND_DT then (RXEND_DT- RAND_DT) +1.

1.4.18. Crohn's Disease Surgical History – OGISURG

Dataset	OGISURG
Creating program	ogisurg.sas
Description	Crohn's Disease Surgical History
Unique identifier	DUNIQUEP, PROCTYP
Sorted by	DUNIQUEP, PROCTYP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, PROCSPEC, CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
PROCTYP	num	Procedure type		Collected at CRF.
PROCTYPD	char	Decode of PROCTYP		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.

Variable	Type	Label	Codes	Comments
PRCRESP	char	Indicates if Procedure Performed		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity

1.4.19. PK and ATI results – PK_ATI

Dataset	PK_ATI
Creating program	Pk_ati.sas
Description	PK and ATI results
Unique identifier	DUNIQUEP,TRTGRPD,RELBASE,ST_PHASE,WEEKCAT,VISIT,SAMP_DY
Sorted by	DUNIQUEP,TRTGRPD,RELBASE,ST_PHASE,WEEKCAT,VISIT,SAMP_DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: BLNDPAT, DEMOG , SAMP_DY, SAMP_MO, SAMP_YR, SAMP_HR, SAMP_MI, NOT_COL, CNTONUM, SAMP_DT

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
TRTGRPD	char	Decode of TRTGRP		Collected at CRF.
TRTGRPAD	char	Decode of TRTGRPA		Collected at CRF.

Variable	Type	Label	Codes	Comments
RELBASE	char	Relative to baseline description		Collected at CRF.
ST_PHASE	char	Study phase		Collected at CRF.
VISIT	char	Event Identifier		Collected at CRF.
VISTYPE	char	Type of visit		Collected at CRF.
PERIOD	char	Period		Collected at CRF.
STUDYDAY	num	Study day of event		Collected at CRF.
CUM_INF	char	Cumulative Infusion Count		Collected at CRF.
C_CA2	char	Serum cA2 concentration(ug/ml)		Collected at CRF.
CA2	num	Serum cA2 conc.(ug/ml) (numeric)		Collected at CRF.
C_OD	char	mean O.D.		Collected at CRF.
OD	num	Mean O.D.(numeric)		Collected at CRF.
C_TITER	char	Antibodies to Infliximab titer		Collected at CRF.
C_CA2INH	char	% inhibition to cA2		Collected at CRF.
CA2INH	num	% inhibition to cA2 (numeric)		Collected at CRF.
SAMPRES	char	Sample ATI result		Collected at CRF.
CMNTPKD	char	decode of CMNTPK		Collected at CRF.
CMTATID1	char	decode of CMNTATI1		Collected at CRF.
CMTATID2	char	decode of CMNTATI2		Collected at CRF.
CA2_INC	char	cA2 included for W54 analysis		Collected at CRF.

Variable	Type	Label	Codes	Comments
UNDETECT	char	cA2 concentration undetectable?		Collected at CRF.
SAMP_TM	num	Sample time		Collected at CRF.
TMPOSTL	char	Time post last/previous infusion		Collected at CRF.
PAG_NAME	char	Page		Collected at CRF.
CMNTPK	char	ACOMNT1 for PK result		Collected at CRF.
CMNTATI1	char	ACOMNT1/2 for PK result		Collected at CRF.
CMNTATI2	char	ACOMNT1/2 for PK result		Collected at CRF.
POP_XVR	char	Crossed over to Trtmnt w/Increased Dose		Collected at CRF.
POP_TRT	char	Treated at any week		Collected at CRF.
POP_RESP	char	Randomized as responder		Collected at CRF.
POP_RAND	char	Randomized		Collected at CRF.
INF_NBR	num	Infusion number		Collected at CRF.
STUDYWK	num	Study week of event		Collected at CRF.
WEEKCAT	char	Study week range		Collected at CRF.
RELFLAG	char	Relative to baseline indicator		Collected at CRF.
TRTGRPA	num	Actual treatment group code		Collected at CRF.
TRTGRP	num	Randomized treatment group		Collected at CRF.
HGT	num	Height (cm)		Collected at CRF.
WGT	char	Weight (kg)		Group the element to protect PII.

Variable	Type	Label	Codes	Comments
AGE	char	Patient Age(yrs)		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.
PNO	char	Protocol Identifier-Number		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
SAMP_DY	num	Relative Sample Day		If SAMP_DT and RAND_DT not missing then perform below logic to calculate SAMP_DY, If SAMP_DT less than RAND_DT then (SAMP_DT - RAND_DT).Else if SAMP_DT is greater than equal to RAND_DT then (SAMP_DT- RAND_DT) +1

1.4.20. SF-36 Health Survey – QOL

Dataset	QOL
Creating program	qol.sas
Description	SF-36 Health Survey
Unique identifier	DUNIQUEP, VISIT
Sorted by	DUNIQUEP, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
GH1	num	Score for QOL question 1		Collected at CRF.
HT	num	Score for QOL question 2		Collected at CRF.
PF01	num	Score for QOL question 3A		Collected at CRF.

Variable	Type	Label	Codes	Comments
PF02	num	Score for QOL question 3B		Collected at CRF.
PF03	num	Score for QOL question 3C		Collected at CRF.
PF04	num	Score for QOL question 3D		Collected at CRF.
PF05	num	Score for QOL question 3E		Collected at CRF.
PF06	num	Score for QOL question 3F		Collected at CRF.
PF07	num	Score for QOL question 3G		Collected at CRF.
PF08	num	Score for QOL question 3H		Collected at CRF.
PF09	num	Score for QOL question 3I		Collected at CRF.
PF10	num	Score for QOL question 3J		Collected at CRF.
RP1	num	Score for QOL question 4A		Collected at CRF.
RP2	num	Score for QOL question 4B		Collected at CRF.
RP3	num	Score for QOL question 4C		Collected at CRF.
RP4	num	Score for QOL question 4D		Collected at CRF.
RE1	num	Score for QOL question 5A		Collected at CRF.
RE2	num	Score for QOL question 5B		Collected at CRF.
RE3	num	Score for QOL question 5C		Collected at CRF.
SF1	num	Score for QOL question 6		Collected at CRF.
BP1	num	Score for QOL question 7		Collected at CRF.
BP2	num	Score for QOL question 8		Collected at CRF.
VT1	num	Score for QOL question 9A		Collected at CRF.
MH1	num	Score for QOL question 9B		Collected at CRF.

Variable	Type	Label	Codes	Comments
MH2	num	Score for QOL question 9C		Collected at CRF.
MH3	num	Score for QOL question 9D		Collected at CRF.
VT2	num	Score for QOL question 9E		Collected at CRF.
MH4	num	Score for QOL question 9F		Collected at CRF.
VT3	num	Score for QOL question 9G		Collected at CRF.
MH5	num	Score for QOL question 9H		Collected at CRF.
VT4	num	Score for QOL question 9I		Collected at CRF.
SF2	num	Score for QOL question 10		Collected at CRF.
GH2	num	Score for QOL question 11A		Collected at CRF.
GH3	num	Score for QOL question 11B		Collected at CRF.
GH4	num	Score for QOL question 11C		Collected at CRF.
GH5	num	Score for QOL question 11D		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
NOTDONE	char	Not done		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity

1.4.21. Randomization – RANDCODE

Dataset	RANDCODE
Creating program	randcode.sas
Description	Randomization
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements or due to missing values: PAG_NAME,RANDCODE,RAND_DY,RAND_MO,RAND_YR, RAND_DT, RSN_SPEC, ALT_TX,ILLNESS,CRF_PAGE, AE, CONSENT, OTH_RSN

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
TRTGRPD	char	Decode of TRTGRP		Collected at CRF.
TRTGRPAD	char	Decode of TRTGRPA		Collected at CRF.
VISIT	char	Event identifier		Collected at CRF.
RANDMZD	char	Indicates if patient randomized		Collected at CRF.
PNO	char	Protocol identifier		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.

1.4.22. Resection – RESECT

Dataset	RESECT
Creating program	resect.sas
Description	Resection
Unique identifier	DUNIQUEP, PROCTYP
Sorted by	DUNIQUEP, PROCTYP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, PROC_MO, PROC_YR,CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
PROCTYP	num	Procedure type		Collected at CRF.
PROCTYPD	char	Decode of PROCTYP		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.

Variable	Type	Label	Codes	Comments
RESTYPE	char	Indicates Type of Resection		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity

1.4.23. Smoking history – SMOKING

Dataset	SMOKING
Creating program	smoking.sas
Description	Smoking History
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, QUIT_DY, QUIT_MO, QUIT_YR, QUIT_DT, CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF
F_STATUS	char	Record Status		Collected at CRF
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity

Variable	Type	Label	Codes	Comments
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity
VISIT	char	Event identifier		Collected at CRF
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Patient identification number for De-identity
PACKS	char	Smoking frequency		Collected at CRF
SMOKER	char	Current cigarette smoker		Collected at CRF
SMOKHST	char	Prior smoking history		Collected at CRF
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
QUIT_DY	num	Relative Day patient quit smoking		If QUIT_DT and RAND_DT not missing then perform below logic to calculate QUIT_DY, If QUIT_DT less than RAND_DT then (QUIT_DT - RAND_DT).Else if QUIT_DT is greater than equal to RAND_DT then (QUIT_DT - RAND_DT) +1.

1.4.24. Dosing Termination – TERMDOSE

Dataset	TERMDOSE
Creating program	termdose.sas
Description	Dosing Termination
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, DTRM_DY, DTRM_MO, DTRM_YR, DRSNSPEC, COMMENT, CRF_PAGE, DTRM_DT, DAEPG , DAEPGSEQ, DAEPGOF , DAEPGLN

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
DRSNCOD	char	Dosing termination rsn code		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
DTRM_DY	num	Relative Dosing termination Day		If DTRM_DT and RAND_DT not missing then perform below logic to calculate DYRM_DY, If DTRM_DT less than RAND_DT then (DTRM_DT - RAND_DT).Else if DTRM_DT is greater than equal to RAND_DT then (DTRM_DT- RAND_DT) +1.

1.4.25. Study Termination – TERMSTDY

Dataset	TERMSTDY
Creating program	termstdy.sas
Description	Study Termination
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, STRM_DY, STRM_MO, STRM_YR, SRSNSPEC, COMMENT, CRF_PAGE, STRM_DT, SAEPG , SAEPGSEQ , SAEPGOF, SAEPGLN

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.

Variable	Type	Label	Codes	Comments
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
SRSNCOD	char	Reason for study term code		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
STRM_DY	num	Relative Study termination date		If STRM_DT and RAND_DT not missing then perform below logic to calculate STRM_DY, If STRM_DT less than RAND_DT then (STRM_DT - RAND_DT).Else if STRM_DT is greater than equal to RAND_DT then (STRM_DT- RAND_DT) +1.

1.4.26. Visit – VISITS

Dataset	VISITS
Creating program	visits.sas
Description	Visit data
Unique identifier	DUNIQUEP, VISIT
Sorted by	DUNIQUEP, 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 or due missing values): PAG_NAME, VISIT_DY, VISIT_MO, VISIT_YR, RSN_SPEC, CRF_PAGE, VISIT_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
EW_WK	num	Early withdrawal week number		Collected at CRF.
VIS_REAS	num	Indicates reason for visit		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
CROSOVR	char	Entering crossover phase		Collected at CRF.
NOTCOMP	char	Indicates visit not done		Collected at CRF.
REAS_ND	char	Reason visit not done		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
VISIT_DY	num	Relative Day of patient visit		If VISIT_DT and RAND_DT not missing then perform below logic to calculate VISIT_DY, If VISIT_DT less than RAND_DT then (VISIT_DT - RAND_DT).Else if VISIT_DT is greater than equal to RAND_DT then (VISIT_DT- RAND_DT) +1.

1.4.27. Vital Signs – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vital Signs
Unique identifier	DUNIQUEP, VISIT
Sorted by	DUNIQUEP, VISIT
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME,LINE_NO,CRF_PAGE

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
SYST	num	Systolic BP (mmHg)		Collected at CRF.
DIAS	num	Diastolic BP (mmHg)		Collected at CRF.
HR	num	Heart rate in beats/minute		Collected at CRF.

Variable	Type	Label	Codes	Comments
ZTEMP	num	Entered body temperature		Collected at CRF.
TEMP	num	Body temperature (degrees C)		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
PE_PERF	char	Physical exam performed		Collected at CRF.
ZTMPMTH	char	Method to measure body temp.		Collected at CRF.
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity

1.4.28. Chest X-Ray – XRAY

Dataset	XRAY
Creating program	xray.sas
Description	CHEST X-RAY
Unique identifier	DUNIQUEP
Sorted by	DUNIQUEP
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: PAG_NAME, XRAY_DY, XRAY_MO, XRAY_YR, CRF_PAGE, XRAY_DT

Variable	Type	Label	Codes	Comments
PNO	char	Protocol identifier		Collected at CRF.
F_STATUS	char	Record Status		Collected at CRF.
DCNO	char	Center ID Assigned for De-identity		Randomly assigned Center ID for De-identity.
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient Number for De-identity.
VISIT	char	Event identifier		Collected at CRF.
DPATID	char	Pat. Id. number Assigned for De-identity		Randomly assigned Pat. Id. number for De-identity.
XRYRSLT	char	X-ray result		Collected at CRF.
XRYTYPE	char	X-ray type		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUNIQUEP	char	Unique_P Assigned for De-identity		Randomly assigned Unique_P for De-identity
XRAY_DY	num	Relative Day of X-ray		If XRAY_DT and RAND_DT not missing then perform below logic to calculate XRAY_DY, If XRAY_DT less than RAND_DT then (XRAY_DT - RAND_DT).Else if XRAY_DT is greater than equal to RAND_DT then (XRAY_DT- RAND_DT) +1.