Clinical Development

CNT0312

C0168T67

Anonymisation Data Derivation Specification Document

Document Type	Reference document
Document Version	Final Version
Date	February 11, 2015

Table of contents

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 Name will not be provided.
- Date of birth will not be provided, only age in years.
- 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.
- Subjects with ages above 89 will be assigned to 90+
- 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.
- Waiver granted by – Inclusion/ Exclusion information will not be provided.
- Primary Cause of Death is free text 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.
- Country information will be grouped to protect PII information.
- Screen failure data will not be provided.
- Remove all original dates after deriving relative day, please note partial dates does not contain relative day.
- Relative day will be calculated for every date variable.

1.3.   Data Files

The C0168T67 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4.   Data Domains

1.4.1. Demographics – DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Demographics
Unique identifier	STUDYID, DSITEID, DSUBJID,VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID,VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, DMCONDT, DMDT, DEMOG, SUBJINIT, BIRTHDT, DMDTC, DMCONDTC, and BIRTHDTC. Programming Note: Keep only Randomized subjects.

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
HEIGHT	num	Height in Centimeters		Collected at CRF
WEIGHT	num	Weight in Kilograms		Collected at CRF
DMDY	num	Relative Day of Visit		If DMDTC and REFDT not missing then perform below logic to calculate relative day. If DMDTC less than REFDT then (DMDTC- REFDT). Else if DMDTC is greater than equal to REFDT then (DMDTC- REFDT) +1.
DMCONDY	num	Relative Day of Informed Consent		If DMCONDTC and REFDT not missing then perform below logic to calculate relative day. If DMCONDTC less than REFDT then (DMCONDTC - REFDT). Else if DMCONDTC is greater than equal to REFDT then (DMCONDTC - REFDT) +1.

Variable	Type	Label	Codes	Comments
RANDOMC	char	Subject Randomized (Character)		Subject Randomized identification flag.
TRT_PLNC	char	Planned Treatment (Character)		Planned Treatment information.
TRT_ACTC	char	Actual Treatment (Character)		Actual Treatment information.

1.4.2. Adverse Events – AE

Dataset	AE
Creating program	ae.sas
Description	Adverse Events (
Unique identifier	STUDYID, DSITEID, DSUBJID,VISITNUM,AESEQ
Sorted by	STUDYID, DSITEID, DSUBJID,VISITNUM,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 missing values or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, AEREPRTN, AETERM, AESERN, AESTDT, AEENDT, AEONGON, AESEVN, AERELINN, AESTDTC, AEENDTC and AERELORN

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

Variable	Type	Label	Codes	Comments
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
AEREPRT	char	Were Any AEs Reported?		Collected at CRF
AESEQ	num	Sequence Number		Collected at CRF
AESER	char	Seriousness Criteria		Collected at CRF
SAEDTH	char	Results in Death		Collected at CRF
SAELIFE	char	Is Life-Threatening		Collected at CRF
SAEHOSP	char	Requires/Prolongs Hospitalization		Collected at CRF

Variable	Type	Label	Codes	Comments
SAEDISAB	char	Permanent/Serious Disability/Incapacity		Collected at CRF
SAECONG	char	Congenital Anomaly/Birth Defect		Collected at CRF
SAEOTH	char	Other Medically Important		Collected at CRF
AESTTM	num	Start Time of Event, 24 Hr Clock		Collected at CRF
AEONGO	char	Ongoing Adverse Event		Collected at CRF
AEDUR	num	Duration of Event (in Days)		Collected at CRF
AESEV	char	Severity/Intensity of Event		Collected at CRF
AESEVN	num	Severity/Intensity of Event num		Collected at CRF
AERELINF	char	Causality (Relation to Infused Tmt)		Collected at CRF
RELATINF	char	Reasonably Related to Infused Treatment		Collected at CRF
AERELORL	char	Causality (Relation to Oral Treatment)		Collected at CRF
RELATORL	char	Reasonably Related to Oral Treatment		Collected at CRF
AEACTINF	char	Action Taken with Infused Treatment		Collected at CRF
AEACTORL	char	Action Taken with Oral Treatment		Collected at CRF
AECD	char	WHOART Adverse Event Code		Collected at CRF
AEDECOD	char	Dictionary Term		Collected at CRF
AEBODSYS	char	Body System/Organ Class		Collected at CRF

Variable	Type	Label	Codes	Comments
AEBODSCD	char	Dictionary Body System Code		Collected at CRF
AEPREFCD	char	Dictionary Preferred Term Code		Collected at CRF
AEMPTCD	char	MedDRA Preferred Term Code		Collected at CRF
AEMPT	char	MedDRA Preferred Term		Collected at CRF
AEMLLTCD	char	MedDRA Lower Level Term Code		Collected at CRF
AEMLLT	char	MedDRA Lower Level Term		Collected at CRF
AEMSOCCD	char	MedDRA System Organ Class Code		Collected at CRF
AEMSOC	char	MedDRA System Organ Class		Collected at CRF
AESTDY	num	Relative Start Day of Event		If AESTDTC and REFDT not missing then perform below logic to calculate relative day. If AESTDTC less than REFDT then (AESTDTC - REFDT). Else if AESTDTC is greater than equal to REFDT then (AESTDTC - REFDT) +1.
AEENDY	num	Relative End Day of Event		If AEENDTC and REFDT not missing then perform below logic to calculate relative day. If AEENDTC less than REFDT then (AEENDTC - REFDT). Else if AEENDTC is greater than equal to REFDT then (AEENDTC - REFDT) +1.

1.4.3. Crohn's Disease Activity Index - CDAI

Dataset	CDAI
Creating program	cdai.sas
Description	Crohn's Disease Activity Index
Unique identifier	STUDYID, DSITEID, DSUBJID,VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID,VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, DIADT, ARTHRITN, IRITISN, ERYTHMAN, ANALFISN, OTHFISTN, ANTIDITN, OPIATTXN, DIADTC and ABDOMASN

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
STOOLS	num	Total number stools from previous 7 days		Collected at CRF
CRAMPS	num	Sum of abdominal cramp ratings		Collected at CRF
GENWELL	num	Sum of general well being ratings		Collected at CRF
DIARYDYS	num	Number days diary card completed		Collected at CRF
HEMAT	num	Hematocrit value		Collected at CRF
TOTSCORE	char	Calculated CDAI score		Collected at CRF
ARTHRIT	char	Related to disease - Arthritis		Collected at CRF
IRITIS	char	Related to disease - Iritis		Collected at CRF
ERYTHMA	char	Related to disease - Erythema nodosum		Collected at CRF
ANALFISS	char	Related to disease - Anal fissure		Collected at CRF
OTHFIST	char	Related to disease - Other fistula		Collected at CRF

Variable	Type	Label	Codes	Comments
FEVER	char	Related to disease - Fever		Collected at CRF
FEVERN	num	Related to disease - Fever num		Collected at CRF
ANTIDITX	char	Received antidiarrheal therapy		Collected at CRF
OPIATTX	char	Received opiate therapy		Collected at CRF
ABDOMASS	char	Abdominal mass		Collected at CRF
DIADY	num	Relative Diary Card day		If DIADTC and REFDT not missing then perform below logic to calculate relative day. If DIADTC less than REFDT then (DIADTC - REFDT). Else if DIADTC is greater than equal to REFDT then (DIADTC - REFDT) +1.

1.4.4. Crohn's disease hospitalizations/surgeries - CDHX

Dataset	CDHX
Creating program	cdhx.sas
Description	Crohn's disease hospitalizations/surgeries
Unique identifier	STUDYID, DSITEID, DSUBJID,VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID,VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, CDHXDT, ANYHOSPN, ANYSURGN, SURGDT, CDHXDTC, SURGDTC and SURGOTH

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
ANYHOSP	char	Hospitalized since last visit?		Collected at CRF
NUMHOSP	num	Number of hospitalizations		Collected at CRF
NUMRAD	num	Number of radiologic procedures		Collected at CRF
NUMENDO	num	Number of endoscopies		Collected at CRF
ANYSURG	char	Surgery since last visit?		Collected at CRF
SURGERY	char	Surgery performed		Collected at CRF
CDHXDY	num	Relative Crohn's Disease History Day		If CDHXDTC and REFDT not missing then perform below logic to calculate relative day. If CDHXDTC less than REFDT then (CDHXDTC - REFDT). Else if CDHXDTC is greater than equal to REFDT then (CDHXDTC - REFDT) +1.

Variable	Type	Label	Codes	Comments
SURGDY	num	Relative Surgery Day		If SURGDTC and REFDT not missing then perform below logic to calculate relative day. If SURGDTC less than REFDT then (SURGDTC - REFDT). Else if SURGDTC is greater than equal to REFDT then (SURGDTC - REFDT) +1.

1.4.5. Crohn's Disease medical history – CDMHX

Dataset	CDMHX
Creating program	cdmhx.sas
Description	Crohn's Disease medical history
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, CDMHXDT, INITDT, PASTFISN, PRESFISN, SMOKERN, SMOKSTAN, HXEXIBDN, HXBWLRSN, CDMHXDTC, INITDTC and HSPCRNSN

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
GIAREA1	char	Involved gastro-intestinal areas		Collected at CRF
GIAREA2	char	Involved gastro-intestinal areas		Collected at CRF
GIAREA3	char	Involved gastro-intestinal areas		Collected at CRF
PASTFIST	char	Fistulas in the past		Collected at CRF
PASTYP1	char	Type of past fistulas		Collected at CRF
PASTYP2	char	Type of past fistulas		Collected at CRF
PASTYP3	char	Type of past fistulas		Collected at CRF
PASTPERI	num	Number of past perianal fistulas		Collected at CRF
PASTENTR	num	Number of past enterocutaneous fistulas		Collected at CRF

Variable	Type	Label	Codes	Comments
PASTRECT	num	Number of past rectovaginal fistulas		Collected at CRF
PRESFIST	char	Fistulas in the present		Collected at CRF
PRESTYP1	char	Type of current fistula		Collected at CRF
PRESTYP2	char	Type of current fistula		Collected at CRF
PRESTYP3	char	Type of current fistula		Collected at CRF
PRESPERI	num	Number of perianal fistulas		Collected at CRF
PRESENTR	num	Number of enterocutaneous fistulas		Collected at CRF
PRESRECT	num	Number of rectovaginal fistulas		Collected at CRF
SMOKER	char	Current cigarette smoker		Collected at CRF
SMOKSTAT	char	Smoking Status		Collected at CRF
HXEXIBD	char	History of extraintestinal IBD		Collected at CRF
EXTIBD1	char	Extraintestinal IBD type		Collected at CRF
EXTIBD2	char	Extraintestinal IBD type		Collected at CRF
EXTIBD3	char	Extraintestinal IBD type		Collected at CRF
EXTIBD4	char	Extraintestinal IBD type		Collected at CRF
EXTIBD5	char	Extraintestinal IBD type		Collected at CRF
EXTIBD6	char	Extraintestinal IBD type		Collected at CRF
HXBWLRS	char	History of bowel resections		Collected at CRF

Variable	Type	Label	Codes	Comments
NUMRSCT	num	Number of resections		Collected at CRF
HSPCRNS	char	Hosp. for disease in past 12 months		Collected at CRF
CDMHXDY	num	Relative Crohn's Disease History Day		If CDMHXDTC and REFDT not missing then perform below logic to calculate relative day. If CDMHXDTC less than REFDT then (CDMHXDTC - REFDT). Else if CDMHXDTC is greater than equal to REFDT then (CDMHXDTC - REFDT) +1.
INITDY	num	Relative Day of initial diagnosis		If INITDTC and REFDT not missing then perform below logic to calculate relative day. If INITDTC less than REFDT then (INITDTC - REFDT). Else if INITDTC is greater than equal to REFDT then (INITDTC - REFDT) +1.

1.4.6. Crohn's Disease Surgical History - CDSHX

Dataset	CDSHX
Creating program	cdshx.sas
Description	Crohn's Disease Surgical History
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, CDSHDT, SURGDT, ANYCDSHN, CDSHDTC, SURGDTC and SURGOTH

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
ANYCDSHX	char	Any Crohn's disease-related surgeries?		Collected at CRF
SURGERY	char	Surgery performed		Collected at CRF
CDSHDY	num	Relative Surgical History Day		If CDSHDTC and REFDT not missing then perform below logic to calculate relative day. If CDSHDTC less than REFDT then (CDSHDTC - REFDT). Else if CDSHDTC is greater than equal to REFDT then (CDSHDTC - REFDT) +1.
SURGDY	num	Relative Surgery Day		If SURGDTC and REFDT not missing then perform below logic to calculate relative day. If SURGDTC less than REFDT then (SURGDTC - REFDT). Else if SURGDTC is greater than equal to REFDT then (SURGDTC - REFDT) +1.

1.4.7. Concomitant Medications – CMD

Dataset	CMD
Creating program	cmd.sas
Description	Concomitant Medications
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM, CMDSEQ
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM, CMDSEQ
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, CMDREPRN, CMDTERM, CMDROUTN, CMDREASN, CMDSTDT, CMDENDT, CMDONGON, DRECNO, SEQ1, CMDSTDTC, CMDENDTC and SEQ2

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
CMDREPRT	char	Were Any Medications Reported?		Collected at CRF
CMDSEQ	num	Medication Sequence Number		Collected at CRF
CMDROUTE	char	Route		Collected at CRF
CMDREAS	char	Reason for Medication		Collected at CRF
CMDONGO	char	Ongoing Medication		Collected at CRF
CMDPRIOR	char	Taken Prior to First Study Agent Exposure		Collected at CRF
CMDECOD	char	Dictionary Term		Collected at CRF
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF
ATC_CODE	char	ATC Code		Collected at CRF

Variable	Type	Label	Codes	Comments
ATCTEXT	char	ATC Text		Collected at CRF
ATC_CD2	char	ATC Level 2 Code		Collected at CRF
CMDSTDY	num	Relative Start Day of Medication		If CMDSTDTC and REFDT not missing then perform below logic to calculate relative day. If CMDSTDTC less than REFDT then (CMDSTDTC - REFDT). Else if CMDSTDTC is greater than equal to REFDT then (CMDSTDTC - REFDT) +1.
CMDENDY	num	Relative End Day of Medication		If CMDENDTC and REFDT not missing then perform below logic to calculate relative day. If CMDENDTC less than REFDT then (CMDENDTC - REFDT). Else if CMDENDTC is greater than equal to REFDT then (CMDENDTC - REFDT) +1.

1.4.8. Systemic Corticosteroid Medication Record - CMR

Dataset	CMR
Creating program	cmr.sas
Description	Systemic Corticosteroid Medication Record
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM, CMRSEQ
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM, CMRSEQ
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, CMRREPRN, CMRTERM, CMRROUTN, CMRREASN, CMRSTDT, CMRENDT, CMRDOSEN, CMRFREQN, CMRONGON, DRECNO, SEQ1, CMRSTDTC, CMRENDTC and SEQ2

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
CMRREPRT	char	Were Any Medications Reported?		Collected at CRF
CMRSEQ	num	Medication Sequence Number		Collected at CRF
CMRROUTE	char	Route		Collected at CRF
CMRREAS	char	Reason for Medication		Collected at CRF
CMRDOSE	char	Dose		Collected at CRF
CMRUNIT	char	Dose Unit		Collected at CRF
CMRFREQ	char	Frequency		Collected at CRF
CMRONGO	char	Ongoing Medication		Collected at CRF
CMRPRIOR	char	Taken Prior to First Study Agent Exposure		Collected at CRF
CMDECOD	char	Dictionary Term		Collected at CRF

Variable	Type	Label	Codes	Comments
CMDECOD1	char	Dictionary Preferred Term		Collected at CRF
ATC_CODE	char	ATC Code		Collected at CRF
ATCTEXT	char	ATC Text		Collected at CRF
ATC_CD2	char	ATC Level 2 Code		Collected at CRF
CMRSTDY	num	Relative Start Day of Medication		If CMRSTDTC and REFDT not missing then perform below logic to calculate relative day. If CMRSTDTC less than REFDT then (CMRSTDTC - REFDT). Else if CMRSTDTC is greater than equal to REFDT then (CMRSTDTC - REFDT) +1.
CMRENDY	num	Relative End Day of Medication		If CMRENDTC and REFDT not missing then perform below logic to calculate relative day. If CMRENDTC less than REFDT then (CMRENDTC - REFDT). Else if CMRENDTC is greater than equal to REFDT then (CMRENDTC - REFDT) +1.

1.4.9. Selection Criteria - CRITERIA

Dataset	CRITERIA
Creating program	criteria.sas
Description	Selection Criteria
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, CRDT, CRPROTN, INCRITN, EXCRITN, INCWAIVN, INCWVDT, INCGRANT, EXCWAIVN, EXCWVDT, CRDTC, INCWVDTC, EXCWVDTC and EXCGRANT

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
CRCAT	char	Selection Criteria Category		Collected at CRF
CRPROT	char	Which amendment was used to determine eligibility?		Collected at CRF
INCRIT	char	Inclusion Criterion		Collected at CRF
EXCRIT	char	Exclusion Criterion		Collected at CRF
CRSEQ	num	Criterion Sequence		Collected at CRF
INCWAIV	char	Waiver granted - Inclusion		Collected at CRF
INCCRIT5	char	Which criterion met for Incl. 5		Collected at CRF
INCCRT5N	num	Which criterion met for Incl. 5 num		Collected at CRF
EXCWAIV	char	Waiver granted - Exclusion		Collected at CRF

Variable	Type	Label	Codes	Comments
CRDY	num	Relative Day of Visit		If CRDTC and REFDT not missing then perform below logic to calculate relative day. If CRDTC less than REFDT then (CRDTC - REFDT). Else if CRDTC is greater than equal to REFDT then (CRDTC - REFDT) +1.
INCWVDY	num	Relative Day waiver granted - Inclusion		If INCWVDTC and REFDT not missing then perform below logic to calculate relative day. If INCWVDTC less than REFDT then (INCWVDTC - REFDT). Else if INCWVDTC is greater than equal to REFDT then (INCWVDTC - REFDT) +1.
EXCWVDY	num	Relative Day waiver granted - Exclusion		If EXCWVDTC and REFDT not missing then perform below logic to calculate relative day. If EXCWVDTC less than REFDT then (EXCWVDTC - REFDT). Else if EXCWVDTC is greater than equal to REFDT then (EXCWVDTC - REFDT)+1.

1.4.10. Death - DEATH

Dataset	DEATH
Creating program	death.sas
Description	Death
Unique identifier	STUDYID, DSITEID, DSUBJID, VISIT
Sorted by	STUDYID, DSITEID, DSUBJID, 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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, DTDT, DTDTC and DTCAUSE

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
DTDY	num	Relative Day of Death		If DTDTC and REFDT not missing then perform below logic to calculate relative day. If DTDTC less than REFDT then (DTDTC - REFDT). Else if DTDTC is greater than equal to REFDT then (DTDTC - REFDT) +1.

1.4.11.   Disposition - DISPOSIT

Dataset	DISPOSIT
Creating program	disposit.sas
Description	Disposition
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, DSUNBN, DSUNBDT, DSDSCDT, DSRSOTH, DSDT, DLOTDT, STUDYEXN, SIGNDT, POP_EFF, POP_SAF, DSTSTAT, DSLSVIS, DSCUMDS, DSCUMDSU, DSTNUM, DSIATDT, DSATNUM, DSUNBDTC, DSDSCDTC, DSDTC, DLOTDTC, SIGNDTC and DSLSUVIS

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
DSUNB	char	Treatment Unblinded		Collected at CRF
DSSTAT	char	Disposition Status		Collected at CRF
DSREAS	char	Reason for Non-Completion		Collected at CRF
STUDYEXT	char	Subject Entered Study Extension		Collected at CRF
DSUNBDY	num	Relative Day of Treatment Unblinding		If DSUNBDTC and REFDT not missing then perform below logic to calculate relative day. If DSUNBDTC less than REFDT then (DSUNBDTC - REFDT). Else if DSUNBDTC is greater than equal to REFDT then (DSUNBDTC - REFDT)+1.

Variable	Type	Label	Codes	Comments
DSDSCDY	num	Relative Day of Study Discontinuation		If DSDSCDTC and REFDT not missing then perform below logic to calculate relative day. If DSDSCDTC less than REFDT then (DSDSCDTC - REFDT). Else if DSDSCDTC is greater than equal to REFDT then (DSDSCDTC - REFDT)+1.
DSDY	num	Relative Day of Disposition Status		If DSDTC and REFDT not missing then perform below logic to calculate relative day. If DSDTC less than REFDT then (DSDTC - REFDT). Else if DSDTC is greater than equal to REFDT then (DSDTC - REFDT)+1.
DLOTDY	num	Relative Day of Last Oral Treatment		If DLOTDTC and REFDT not missing then perform below logic to calculate relative day. If DLOTDTC less than REFDT then (DLOTDTC - REFDT). Else if DLOTDTC is greater than equal to REFDT then (DLOTDTC - REFDT)+1.
SIGNDY	num	Relative Day of informed consent		If SIGNDTC and REFDT not missing then perform below logic to calculate relative day. If SIGNDTC less than REFDT then (SIGNDTC - REFDT). Else if SIGNDTC is greater than equal to REFDT then (SIGNDTC - REFDT)+1.

1.4.12.   Date of Visit - DOV

Dataset	DOV
Creating program	dov.sas
Description	Date of Visit
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, VISDT, VIS_D, VIS_M, VISDTC and VIS_Y

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
VISDY	num	Relative Day of Visit		If VISDTC and REFDT not missing then perform below logic to calculate relative day. If VISDTC less than REFDT then (VISDTC - REFDT). Else if VISDTC is greater than equal to REFDT then (VISDTC - REFDT)+1.

1.4.13.   Health Economics - ECONOM

Dataset	ECONOM
Creating program	econom.sas
Description	Health Economics
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, ECDT, ECMVSN, ECWORK, ECWORKN, ECWRKFP, ECWRKFPN, ECHRSWK, ECDYSAB, ECILRSN, ECILRSNN, ECCNWRK, ECCNWRKN, ECRETRE, ECRETREN, ECERTRE, ECERTREN, ECDISAB, ECDISABN, ECSTUD, ECSTUDN, ECSTUFP, ECSTUFPN, ECDTC , and ECPSNDN

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
ECMVS	char	Received Medical Care		Collected at CRF
ECFPMC	num	Family Physician Medical Care Visits		Collected at CRF
ECSPMC	num	Specialist Medical Care Visits		Collected at CRF
ECERMC	num	Emergency Room Medical Care Visits		Collected at CRF
ECNRVIS	num	Nursing Visits		Collected at CRF
ECPROD	num	Number of days less than 50% productive		Collected at CRF
ECPSCLE	num	Productivity Scale (cm)		Collected at CRF
ECPSND	char	Productivity Scale Not Done		Collected at CRF

Variable	Type	Label	Codes	Comments
ECCGMSDY	num	Days Caregivers Missed		Collected at CRF
ECHAVIS	num	Household Assistance Visits		Collected at CRF
ECHAHRS	num	Household Assistance Avg Hours Per Visit		Collected at CRF
ECDY	num	Relative Day of HECON Questionnaire		If ECDTC and REFDT not missing then perform below logic to calculate relative day. If ECDTC less than REFDT then (ECDTC - REFDT). Else if ECDTC is greater than equal to REFDT then (ECDTC - REFDT) +1.

1.4.14.   Endoscopy Results - ENDO

Dataset	ENDO
Creating program	endo.sas
Description	Endoscopy Results
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, VISDT, INITIALS, ACCNO, ULCRTNN, ACCNO2, ENDOSCPN, VISDTC, ENDODTC and ENDODT

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
ULCRTN	char	Ulceration visible		Collected at CRF
ENDOSCP	char	Endoscopy performed?		Collected at CRF
VISDY	num	Relative Visit Day		If VISDTC and REFDT not missing then perform below logic to calculate relative day. If VISDTC less than REFDT then (VISDTC - REFDT). Else if VISDTC is greater than equal to REFDT then (VISDTC - REFDT)+1.
ENDODY	num	Relative Day of endoscopy		If ENDODTC and REFDT not missing then perform below logic to calculate relative day. If ENDODTC less than REFDT then (ENDODTC - REFDT). Else if ENDODTC is greater than equal to REFDT then (ENDODTC - REFDT)+1.

1.4.15.   Infused Study Agent Exposure - EXPI

Dataset	EXPI
Creating program	expi.sas
Description	Infused Study Agent Exposure
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, EINDN, EISTDT, EIENDT, EIDUR, EIDURU, VIALNUM, EIACTTRT, EIDOSE, EIDOSEUN, EISTDTC, EIENDTC and EIDOSFRQ.

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
EIDSDSC	char	Dose Descriptor		Collected at CRF
DOSENUM	num	Sequential Dose Number		Collected at CRF
EIND	char	Dose Not Done		Collected at CRF
EIVWDRWN	num	Volume Withdrawn From Vial(s) in Milliliters		Collected at CRF
EIVPREP	num	Volume Prepared in Milliliters		Collected at CRF
EISTTM	num	Start Time of Dose, 24 Hr Clock		Collected at CRF
EIENTM	num	End Time of Dose, 24 Hr Clock		Collected at CRF
AMTADM	num	Amount Administered		Collected at CRF
TOTVIALS	num	Total number of vials used		Collected at CRF
EIROUTE	char	Route of Administration		Collected at CRF

Variable	Type	Label	Codes	Comments
EISEQ	num	Exposure Sequence Number		Collected at CRF
EISTDY	num	Relative Start Day of Dose		If EISTDTC and REFDT not missing then perform below logic to calculate relative day. If EISTDTC less than REFDT then (EISTDTC - REFDT). Else if EISTDTC is greater than equal to REFDT then (EISTDTC - REFDT)+1.
EIENDY	num	Relative End Day of Dose		If EIENDTC and REFDT not missing then perform below logic to calculate relative day. If EIENDTC less than REFDT then (EIENDTC - REFDT). Else if EIENDTC is greater than equal to REFDT then (EIENDTC - REFDT)+1.

1.4.16.   Oral Study Agent Exposure - EXPO

Dataset	EXPO
Creating program	expo.sas
Description	Oral Study Agent Exposure
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, EONDN, EOSTDT, EOSTTM, EOENDT, EOENTM, EODUR, EODURU, DOSECHGN, CHNGDT, BOTLNUM, EOACTTRT, EODOSE, EODOSEUN, EOSTDTC, EOENDTC, CHNGDTC , and EODOSFRQ

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
EODSDSC	char	Dose Descriptor		Collected at CRF
DOSENUM	num	Sequential Dose Number		Collected at CRF
EOND	char	Dose Not Done		Collected at CRF
CAPDISP	num	Number of capsules dispensed		Collected at CRF
BOTDISP	num	Total number of bottles dispensed		Collected at CRF
CAPSRET	num	Number of capsules returned		Collected at CRF
CAPSTAK	num	Total number of capsules taken		Collected at CRF
DOSECHG	char	Was oral study agent dose changed?		Collected at CRF
EOROUTE	char	Route of Administration		Collected at CRF

Variable	Type	Label	Codes	Comments
EOSEQ	num	Exposure Sequence Number		Collected at CRF
EOSDY	num	Relative Start Day of Dose		If EOSTDTC and REFDT not missing then perform below logic to calculate relative day. If EOSTDTC less than REFDT then (EOSTDTC - REFDT). Else if EOSTDTC is greater than equal to REFDT then (EOSTDTC - REFDT)+1.
EOENDY	num	Relative End Day of Dose		If EOENDTC and REFDT not missing then perform below logic to calculate relative day. If EOENDTC less than REFDT then (EOENDTC - REFDT). Else if EOENDTC is greater than equal to REFDT then (EOENDTC - REFDT)+1.
CHNGDY	num	Relative Day dose changed		If CHNGDTC and REFDT not missing then perform below logic to calculate relative day. If CHNGDTC less than REFDT then (CHNGDTC - REFDT). Else if CHNGDTC is greater than equal to REFDT then (CHNGDTC - REFDT)+1.

1.4.17.   Inflammatory Bowel Disease Questionnaire - IBDQ

Dataset	IBDQ
Creating program	ibdq.sas
Description	Inflammatory Bowel Disease Questionnaire
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, IBDQDTC and IBDQDT

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF

Variable	Type	Label	Codes	Comments
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
IBDQ_1	char	Score for IBDQ question 1		Collected at CRF
IBDQ_1N	num	Score for IBDQ question 1 num		Collected at CRF
IBDQ_2	char	Score for IBDQ question 2		Collected at CRF
IBDQ_2N	num	Score for IBDQ question 2 num		Collected at CRF
IBDQ_3	char	Score for IBDQ question 3		Collected at CRF
IBDQ_3N	num	Score for IBDQ question 3 num		Collected at CRF
IBDQ_4	char	Score for IBDQ question 4		Collected at CRF
IBDQ_4N	num	Score for IBDQ question 4 num		Collected at CRF
IBDQ_5	char	Score for IBDQ question 5		Collected at CRF
IBDQ_5N	num	Score for IBDQ question 5 num		Collected at CRF
IBDQ_6	char	Score for IBDQ question 6		Collected at CRF

Variable	Type	Label	Codes	Comments
IBDQ_6N	num	Score for IBDQ question 6 num		Collected at CRF
IBDQ_7	char	Score for IBDQ question 7		Collected at CRF
IBDQ_7N	num	Score for IBDQ question 7 num		Collected at CRF
IBDQ_8	char	Score for IBDQ question 8		Collected at CRF
IBDQ_8N	num	Score for IBDQ question 8 num		Collected at CRF
IBDQ_9	char	Score for IBDQ question 9		Collected at CRF
IBDQ_9N	num	Score for IBDQ question 9 num		Collected at CRF
IBDQ_10	char	Score for IBDQ question 10		Collected at CRF
IBDQ_10N	num	Score for IBDQ question 10 num		Collected at CRF
IBDQ_11	char	Score for IBDQ question 11		Collected at CRF
IBDQ_11N	num	Score for IBDQ question 11 num		Collected at CRF
IBDQ_12	char	Score for IBDQ question 12		Collected at CRF
IBDQ_12N	num	Score for IBDQ question 12 num		Collected at CRF
IBDQ_13	char	Score for IBDQ question 13		Collected at CRF
IBDQ_13N	num	Score for IBDQ question 13 num		Collected at CRF
IBDQ_14	char	Score for IBDQ question 14		Collected at CRF
IBDQ_14N	num	Score for IBDQ question 14 num		Collected at CRF
IBDQ_15	char	Score for IBDQ question 15		Collected at CRF
IBDQ_15N	num	Score for IBDQ question 15 num		Collected at CRF

Variable	Type	Label	Codes	Comments
IBDQ_16	char	Score for IBDQ question 16		Collected at CRF
IBDQ_16N	num	Score for IBDQ question 16 num		Collected at CRF
IBDQ_17	char	Score for IBDQ question 17		Collected at CRF
IBDQ_17N	num	Score for IBDQ question 17 num		Collected at CRF
IBDQ_18	char	Score for IBDQ question 18		Collected at CRF
IBDQ_18N	num	Score for IBDQ question 18 num		Collected at CRF
IBDQ_19	char	Score for IBDQ question 19		Collected at CRF
IBDQ_19N	num	Score for IBDQ question 19 num		Collected at CRF
IBDQ_20	char	Score for IBDQ question 20		Collected at CRF
IBDQ_20N	num	Score for IBDQ question 20 num		Collected at CRF
IBDQ_21	char	Score for IBDQ question 21		Collected at CRF
IBDQ_21N	num	Score for IBDQ question 21 num		Collected at CRF
IBDQ_22	char	Score for IBDQ question 22		Collected at CRF
IBDQ_22N	num	Score for IBDQ question 22 num		Collected at CRF
IBDQ_23	char	Score for IBDQ question 23		Collected at CRF
IBDQ_23N	num	Score for IBDQ question 23 num		Collected at CRF
IBDQ_24	char	Score for IBDQ question 24		Collected at CRF
IBDQ_24N	num	Score for IBDQ question 24 num		Collected at CRF
IBDQ_25	char	Score for IBDQ question 25		Collected at CRF

Variable	Type	Label	Codes	Comments
IBDQ_25N	num	Score for IBDQ question 25 num		Collected at CRF
IBDQ_26	char	Score for IBDQ question 26		Collected at CRF
IBDQ_26N	num	Score for IBDQ question 26 num		Collected at CRF
IBDQ_27	char	Score for IBDQ question 27		Collected at CRF
IBDQ_27N	num	Score for IBDQ question 27 num		Collected at CRF
IBDQ_28	char	Score for IBDQ question 28		Collected at CRF
IBDQ_28N	num	Score for IBDQ question 28 num		Collected at CRF
IBDQ_29	char	Score for IBDQ question 29		Collected at CRF
IBDQ_29N	num	Score for IBDQ question 29 num		Collected at CRF
IBDQ_30	char	Score for IBDQ question 30		Collected at CRF
IBDQ_30N	num	Score for IBDQ question 30 num		Collected at CRF
IBDQ_31	char	Score for IBDQ question 31		Collected at CRF
IBDQ_31N	num	Score for IBDQ question 31 num		Collected at CRF
IBDQ_32	char	Score for IBDQ question 32		Collected at CRF
IBDQ_32N	num	Score for IBDQ question 32 num		Collected at CRF
IBDQDY	num	Relative IBD questionnaire Day		If IBDQDTC and REFDT not missing then perform below logic to calculate relative day. If IBDQDTC less than REFDT then (IBDQDTC - REFDT). Else if IBDQDTC is greater than equal to REFDT then (IBDQDTC - REFDT)+1.

1.4.18.   All Laboratory Results - LAB

Dataset	LAB
Creating program	lab.sas
Description	All Laboratory Results
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM, LBSEQ
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM, 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 missing values or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, ANYLABN, LBDT, LBLBLNUM, LBKTTYP, LBCOM, LBTSTORD, LBRELBAS, LBRELFLG, STDCHGBL, LBDTC and LBID

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
ANYLAB	char	Samples collected for central laboratory?		Collected at CRF
LBSEQ	num	Lab Sequence Number		Collected at CRF
LBACTTM	num	Time of Collection, 24 Hr Clock		Collected at CRF
LBTESTCD	char	Lab Test Code		Collected at CRF
LBTEST	char	Lab Test Name		Collected at CRF
LBSTRESN	num	Analysis Numeric Result in Std Units		Collected at CRF
LBSTUNIT	char	Standard Units		Collected at CRF
LBSTNRLO	num	Normal Range Lower Limit in Std Units		Collected at CRF

Variable	Type	Label	Codes	Comments
LBSTNRHI	num	Normal Range Upper Limit in Std Units		Collected at CRF
LBSTRESC	char	Analysis Character Result in Std Units		Collected at CRF
LBSTDNRC	char	Normal Range for Char Rslt in Std Units		Collected at CRF
LBORRES	char	Result in Original Units		Collected at CRF
LBORUNIT	char	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
LBORNRLN	num	Numeric - Normal Range Lower Limit in Orig Units		Collected at CRF
LBORNRHN	num	Numeric - Normal Range Upper Limit in Orig Units		Collected at CRF
LBORNRC	char	Normal Range for Char Rslt in Orig Units		Collected at CRF
LBNRIND	char	Normal Range Indicator		Collected at CRF

Variable	Type	Label	Codes	Comments
LBDY	num	Relative Day of Specimen Collection		If LBDTC and REFDT not missing then perform below logic to calculate relative day. If LBDTC less than REFDT then (LBDTC - REFDT). Else if LBDTC is greater than equal to REFDT then (LBDTC - REFDT)+1.

1.4.19. Randomized but Never Treated - NOTTX

Dataset	NOTTX
Creating program	nottx.sas
Description	Randomized but Never Treated
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, NTREAS, NTREASN and NTRSOTH

Variable	Type	Label	Codes	Comments
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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.

1.4.20.   Pharmacokinetic - PK

Dataset	PK
Creating program	pk.sas
Description	Pharmacokinetic
Unique identifier	
Sorted by	
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 or due to insignificant information[like example CRF page name]): CPLABID, CPLABEL, CPCMT2CD, CPCMT2, ATDT, ATTM, ATEVQL, EVENT_ID, PAG_NAME, ATKTTYP, ATNTCOL, and ATSMTYP

Variable	Type	Label	Codes	Comments
STUDYID	char	Study ID		Collected at CRF
DCNO	char	Centre Number Assigned for De-identity		Randomly assigned Centre No for De-identity
DPATNO	char	Patient Number Assigned for De-identity		Randomly assigned Patient No for De-identity
CPPERIOD	char	CP Period		Collected at CRF
CPASYCD	char	CP Assay Code		Collected at CRF
CPASY	char	CP Assay		Collected at CRF

Variable	Type	Label	Codes	Comments
CPTESTCD	char	CP Test Code		Collected at CRF
CPTEST	char	CP Test Name		Collected at CRF
CPRESCAT	char	CP Results Category		Collected at CRF
CPRESC	char	CP Results		Collected at CRF
CPUNIT	char	CP Units		Collected at CRF
CPLLOQ	num	CP Lower Limit of Quantification		Collected at CRF
CPCMT1CD	char	CP CM Code		Collected at CRF
CPCMT1	char	CP CM Text		Collected at CRF

1.4.21.   Subject Status - SUBSTAT

Dataset	SUBSTAT
Creating program	substat.sas
Description	Subject Status
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, SSDSCDT, SSREASN, SSDSCDTC and SSRSOTH

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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity

Variable	Type	Label	Codes	Comments
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
SSENT	char	Subject Entered Next Study Period		Collected at CRF
SSREAS	char	Reason for Discontinuation		Collected at CRF
SSDSCDY	num	Relative Day of Study Discontinuation		If SSDSCDTC and REFDT not missing then perform below logic to calculate relative day. If SSDSCDTC less than REFDT then (SSDSCDTC - REFDT). Else if SSDSCDTC is greater than equal to REFDT then (SSDSCDTC - REFDT)+1.

1.4.22.   Central Laboratory Results - VENDLAB

Dataset	VENDLAB
Creating program	vendlab.sas
Description	Central Laboratory Results
Unique identifier	
Sorted by	
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 or due to insignificant information[like example CRF page name]): LINECNT, PROTOCOL, SITENUM, INVNAME, SITE2NUM, PTNO, FAIL_SCR, INITIALS, DOB, ACC_NO, DELTA, TOX, COM_PANL, COM_TEST, ALIEN_ID, EXTRA1, EXTRA2, COLLDT, CREATEDT, RECD_DT and UNIQUE_P.

Variable	Type	Label	Codes	Comments
VTYPE	char	Visit Type		Collected at CRF
COLLTM	num	Collection Time		Collected at CRF
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
DSCR_NUM	char	Screening Number Assigned for De-identity		Randomly assigned Screening Number for De-identity

Variable	Type	Label	Codes	Comments
SEX	char	Sex		Collected at CRF
AGE	num	Age		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
VISIT	char	Visit Name		Collected at CRF
PANEL_NM	char	Panel Name		Collected at CRF
PAN_CODE	char	Panel Code		Collected at CRF
TEST_ID	char	Test Code		Collected at CRF
TESTDESC	char	Test Description		Collected at CRF
TEST_MAP	char	Test Mapping		Collected at CRF
RES_TYPE	char	Result Type		Collected at CRF
MODIFIER	char	Modifier		Collected at CRF
RES_TEXT	char	Textual Result		Collected at CRF
CV_RES	num	CV Numeric Result		Collected at CRF
CV_UNIT	char	CV Units		Collected at CRF
SI_RES	num	SI Numeric Result		Collected at CRF
SI_UNIT	char	SI Units		Collected at CRF
LLN_TEXT	char	Textual Range		Collected at CRF
LLN_CV	num	CV Numeric LLN		Collected at CRF
ULN_CV	num	CV Numeric ULN		Collected at CRF

Variable	Type	Label	Codes	Comments
LLN_SI	num	SI Numeric LLN		Collected at CRF
ULN_SI	num	SI Numeric ULN		Collected at CRF
ALERT	char	Alert Flags		Collected at CRF
EXCL	char	Exclusion Flags		Collected at CRF
REV_FLAG	char	Revision on Record		Collected at CRF
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITEID	char	Site ID Assigned for De-identity		Randomly assigned Site ID for De-identity
VISIT	char	Visit Name		Collected at CRF
STUDYID	char	Study ID		Collected at CRF
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
COLLDY	num	Relative Collection Day		If COLLDT and REFDT not missing then perform below logic to calculate relative day. If COLLDT less than REFDT then (COLLDT - REFDT). Else if COLLDT is greater than equal to REFDT then (COLLDT - REFDT)+1.
CREATEDY	num	Relative File Creation Day		If CREATEDT and REFDT not missing then perform below logic to calculate relative day. If CREATEDT less than REFDT then (CREATEDT - REFDT). Else if CREATEDT is greater than equal to REFDT then (CREATEDT - REFDT)+1.

Variable	Type	Label	Codes	Comments
RECDY	num	Relative Received Day		If RECD_DT and REFDT not missing then perform below logic to calculate relative day. If RECD_DT less than REFDT then (RECD_DT - REFDT). Else if RECD_DT is greater than equal to REFDT then (RECD_DT - REFDT)+1.

1.4.23.   Vital Signs - VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	Vital Signs
Unique identifier	STUDYID, DSITEID, DSUBJID, VISITNUM
Sorted by	STUDYID, DSITEID, DSUBJID, VISITNUM
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 or due to insignificant information[like example CRF page name]): UNIQUE_P, TRTCD, TRTGRP, PAG_NAME, VSDT, VSRELBAS, VSRELFLG, VSCHGBL, VSDTC and VSNRIND

Variable	Type	Label	Codes	Comments
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
DUSUBJID	char	Unique Subject ID Assigned for De-identity		Randomly assigned Unique Subject ID for De-identity
DSUBJID	char	Subject ID Assigned for De-identity		Randomly assigned Subject ID for De-identity
DSITESUBJ	char	Site-Subject ID Assigned for De-identity		Randomly assigned Site-Subject ID for De-identity
VISITNUM	num	Visit Number		Collected at CRF
VISIT	char	Visit Name		Collected at CRF
AGE	num	Age in Years		If age is greater than 89 then group to "90+". Grouping is performed based on HIPAA privacy rules.
SEX	char	Sex		Collected at CRF
RACE	char	Race		Collected at CRF
COUNTRY	char	Country		DENMARK, NORWAY, and SWEDEN countries will be grouped as "SCANDINAVIAN" to protect PII Information.
VSTEST	char	Vital Signs Test Name		Collected at CRF
VSTESTCD	char	Vital Signs Test Short Name		Collected at CRF
VSSTRES	num	Result in Standard Units		Collected at CRF
VSSTUNIT	char	Standard Units		Collected at CRF
VSSEQ	num	Vital Signs Sequence		Collected at CRF

Variable	Type	Label	Codes	Comments
VSDY	num	Relative Day of Visit		If VSDTC and REFDT not missing then perform below logic to calculate relative day. If VSDTC less than REFDT then (VSDTC - REFDT). Else if VSDTC is greater than equal to REFDT then (VSDTC - REFDT) +1.