Remicade Study ACT-1 (C0168T37)
Prophylactic Medication (ADMIN)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
EXSTTM	Num	Administration start time		Collected at CRF
EXENTM	Num	Administration end time		Collected at CRF
AMTADM	Num	Total ml administered		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
EXTVAAE	Char	Reason total vol not adm is AE		Collected at CRF
EXPROP	Char	Prophylactic medication given		Collected at CRF
EXTOTADM	Char	Total dose administered		Collected at CRF
EXND	Char	Administration not done		Collected at CRF
CORTADM	Char	Corticosteroids given		Collected at CRF
EXINRPT	Char	Infusion interrupted		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
EXSTDTD	Num	REL. DAY OF Administration start date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Adverse Events (AE)

Variable	Type	Label	Codes	Comments
AECD	Char	WHOART Adverse Event Code		Collected at CRF
AEBODSCD	Char	Dictionary Body System Code		Collected at CRF
AEBODSYS	Char	Body System/Organ Class		Collected at CRF
AEPREFCD	Char	Dictionary Preferred Term Code		Collected at CRF
AEDECOD	Char	Dictionary Term		Collected at CRF
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
PAGE_SEQ	Num	Page of series		Collected at CRF
AESEQ	Num	Line number		Collected at CRF
AESTTM	Num	Onset time		Collected at CRF
AEENTM	Num	Resolution time		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
AESEV	Char	AE intensity		Collected at CRF
SAEDTH	Char	Fatal		Collected at CRF
AEACTTRT	Char	Action taken with study agent		Collected at CRF
AEREL	Char	Relationship to study agent		Collected at CRF
AEONGO	Char	Event continuing		Collected at CRF
INFECT	Char	AE infection		Collected at CRF
SAELIFE	Char	Life-threatening		Collected at CRF
SAENS	Char	Not serious		Collected at CRF
SAECONG	Char	Congenital anomaly		Collected at CRF
SAEDISAB	Char	Significant disability		Collected at CRF
SAEHOSP	Char	Hospitalization		Collected at CRF
SAEOTH	Char	Other serious		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
AEENDTD	Num	REL. DAY OF Resolution date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
AESTDTD	Num	REL. DAY OF Onset date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date

Remicade Study ACT-1 (C0168T37)
Adverse Events (AE)

Variable	Type	Label	Codes	Comments
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

Remicade Study ACT-1 (C0168T37)
PK Sample Sequence (ATRACK)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
LABEVNT	Char	Lab event		Collected at CRF
ASSAY	Char	Assay code		Collected at CRF
COLLNUM	Char	Collection number		Collected at CRF
ACCNUM	Char	Accession number		Collected at CRF
SAMP_TM	Num	Sample time		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
PERIOD	Char	Period		Collected at CRF
NOT_COL	Char	Sample not collected		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
SAMP_DTD	Num	REL. DAY OF Sample date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Surgery/Procedure (CONPROC)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
PAGE_SEQ	Num	Page of series		Collected at CRF
LINE_NO	Num	Line number		Collected at CRF
PRSPEC	Char	Procedure specify		Collected at CRF
PRREASON	Char	Procedure reason		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
PRTYPE	Char	Procedure type		Collected at CRF
PRONGO	Char	Procedure ongoing		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
PRENDTD	Num	REL. DAY OF Stop date of procedure		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
PRSTDTD	Num	REL. DAY OF Start date of procedure		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Corticosteroid Dosage (CORTSUM)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
PAGE_SEQ	Num	Page of series		Collected at CRF
LINE_NO	Num	Line number		Collected at CRF
CSDOSE	Num	Medication dose		Collected at CRF
DRECNO	Char	Drug record number		Collected at CRF
SEQ1	Char	Drug sequence 1		Collected at CRF
SEQ2	Char	Drug sequence 2		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
CMDECOD	Char	Dictionary Term		Collected at CRF
CMDECOD1	Char	Dictionary Preferred Term		Collected at CRF
CSSTOP	Char	Medication stopped		Collected at CRF
CSUNITCD	Char	Code for units of medication		Collected at CRF
CSFREQ	Char	Frequency of medication		Collected at CRF
CSSI	Char	Medication started or increased		Collected at CRF
CSIRP	Char	Med for infusion reaction prophylaxis		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
CSCHDTD	Num	REL. DAY OF Date of medication change		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
PK Samples (CRESUL)

Variable	Type	Label	Codes	Comments
CPLABID	Char	CPLABID		Collected at CRF
CPLABEL	Char	CPLABEL		Collected at CRF
CPPERIOD	Char	CPPERIOD		Collected at CRF
CPASYCD	Char	CPASYCD		Collected at CRF
CPASY	Char	CPASY		Collected at CRF
CPTESTCD	Char	CPTESTCD		Collected at CRF
CPTEST	Char	CPTEST		Collected at CRF
CPRESCAT	Char	CPRESCAT		Collected at CRF
CPRESC	Char	CPRESC		Collected at CRF
CPUNIT	Char	CPUNIT		Collected at CRF
CPLLOQ	Num	CPLLOQ		Collected at CRF
CPCMT1CD	Char	CPCMT1CD		Collected at CRF
CPCMT1	Char	CPCMT1		Collected at CRF
CPCMT2CD	Char	CPCMT2CD		Collected at CRF
CPCMT2	Char	CPCMT2		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Patient Selection Criteria (CRITERIA)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
INCRIT	Char	Inclusion criterion not met		Collected at CRF
EXCRIT	Char	Exclusion criterion present		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Demography (DEMOG)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
SEX	Char	Sex		Collected at CRF
RACE	Char	Race		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
PK Samples (DERVD_PK)

Variable	Type	Label	Codes	Comments
DPLABEL	Char	Parameter Names		Collected at CRF
DPRESC	Char	Parameter Results		Collected at CRF
DPINC	Char	Parameter Inclusion for Analysis		Collected at CRF
DPRSNINC	Char	Parameter Exclusion Reason		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
UC Surgical History (DISEASHX)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
DHSYMDUR	Num	Duration of symptoms (years)		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
DHRESECT	Char	Have intestines been resected		Collected at CRF
DHOGISRG	Char	Other related GI surgery		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
DHDXDTD	Num	REL. DAY OF Date of diagnosis		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Drug Preparation (DRUGACCT)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
EXLOTNO1	Char	Lot used 1		Collected at CRF
EXLOTNO2	Char	Lot used 2		Collected at CRF
EXLOTNO3	Char	Lot used 3		Collected at CRF
EXVWDRWN	Num	Volume withdrawn (mL)		Collected at CRF
EXVPREP	Num	Total diluted volume (mL)		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
EXPLNDS	Char	Plan dose		Collected at CRF
EXND	Char	Not done		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
EXPDTD	Num	REL. DAY OF Date prepared		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Economic Questionnaire (ECONOM)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
HEFPVIS	Num	Disease-related family physician visits		Collected at CRF
HESPVIS	Num	Disease-related specialist visits		Collected at CRF
HEERVIS	Num	Disease-related emergency room visits		Collected at CRF
HENRVIS	Num	Disease-related nursing visits		Collected at CRF
HEMEDAMT	Num	Amount spent on non-prescription meds		Collected at CRF
HEEQPAMT	Num	Amount spent on equip/supply/devices		Collected at CRF
HEMISSHR	Num	Hours missed due to illness		Collected at CRF
HEHRSWRK	Num	Number of hours worked		Collected at CRF
HEPROD	Num	Productivity scale (0-100)		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
HEWRKING	Char	Patient currently actively employed		Collected at CRF
HEWRKFP	Char	Working full or part-time		Collected at CRF
HESCHOOL	Char	School attendance		Collected at CRF
HEUNEMP	Char	None above (unemployed status)		Collected at CRF
HEPSND	Char	Productivity scale not done		Collected at CRF
HERETIRE	Char	Retired		Collected at CRF
HESTUDNT	Char	Patient currently attending school		Collected at CRF
HEMEDCUR	Char	Currency type for medications		Collected at CRF
HECANWRK	Char	Could work if job available		Collected at CRF
HEDISAB	Char	Receiving disability compensation		Collected at CRF
HEND	Char	Economic questionnaire not done		Collected at CRF
HEEQPCUR	Char	Currency type for equipment		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Endoscopy Information (ENDOSCOP)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
ENMAYO	Num	Endoscopy findings		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
ENND	Char	Not done		Collected at CRF
ENDISEXT	Char	Extent of disease		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
ENDTD	Num	REL. DAY OF Date of endoscopy		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
EQ5D (EQ5D)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
EQ5DMB	Num	EQ5D - mobility		Collected at CRF
EQ5DSC	Num	EQ5D - self-care		Collected at CRF
EQ5DUA	Num	EQ5D - usual activities		Collected at CRF
EQ5DPD	Num	EQ5D - pain/discomfort		Collected at CRF
EQ5DAD	Num	EQ5D - anxiety/depression		Collected at CRF
EQHSS	Num	Health state scale (0-100)		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
EQHSSND	Char	Health state scale not done		Collected at CRF
EQ5DND	Char	EQ5D not done		Collected at CRF
STUDYID	Char	Study ID		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

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
SCRNCOL	Num	Screening colonoscopy with biopsy		Collected at CRF
EVDYSP	Num	Biopsy showed evidence of dysplasia		Collected at CRF
INFLAM	Num	Inconclusive due to inflammation		Collected at CRF
OTHRSN	Num	Inconclusive due to other reason		Collected at CRF
INCONRSN	Char	Inconclusive reason		Collected at CRF
AI_DX	Num	Autoimmune disease diagnosed		Collected at CRF
MALIG	Num	Developed malignancy		Collected at CRF
SER_INF	Num	Developed serious infection		Collected at CRF
ARTHRLG	Num	Arthralgia		Collected at CRF
MYALGIA	Num	Myalgia		Collected at CRF
FEVER	Num	Fever		Collected at CRF
RASH	Num	Rash		Collected at CRF
REL_SYM	Num	Likely relationship of symptoms		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
FUCMTRT	Char	Commercial treatment		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
UC Histological Response Biopsy (HISTOLGY)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
HISTRCHG	Char	Structural change		Collected at CRF
HICII	Char	Chronic inflammatory infiltrate		Collected at CRF
HIEOSLPA	Char	Eosinophil infltrtn in Lamina Propria(A)		Collected at CRF
HINPHLPB	Char	Neutrophil infltrtn in Lamina Propria(B)		Collected at CRF
HINPHEPI	Char	Neutrophils in Epithelium		Collected at CRF
HICRYPTD	Char	Crypt destruction		Collected at CRF
HIERULC	Char	Presence of erosion/ulceration		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
HINORSLT	Char	No results		Collected at CRF
STUDYID	Char	Study ID		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

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
PAGE_SEQ	Num	Page of series		Collected at CRF
PAGE_OF	Num	Total pages in series		Collected at CRF
HOICUDYS	Num	Total number of days in ICU		Collected at CRF
HODIAG	Char	Diagnoses		Collected at CRF
HOTPNDYS	Num	Number of days TPN received		Collected at CRF
HOTFDYS	Num	Number of days of tube feeding		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
HOTPNNA	Char	TPN not applicable		Collected at CRF
HOTFNA	Char	Tube feeding not applicable		Collected at CRF
HOPRPERF	Char	Surgery/procedure performed		Collected at CRF
HONODSCH	Char	Not discharged		Collected at CRF
HODRHOSP	Char	Disease-related hospitalization		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
HOADMDTD	Num	REL. DAY OF Hospital admission date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
HODISDTD	Num	REL. DAY OF Hospital discharge date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Inflammatory Bowel Disease Questionnaire (IBDQSCR)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		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
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
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
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically

Remicade Study ACT-1 (C0168T37)
Inflammatory Bowel Disease Questionnaire (IBDQSCR)

Variable	Type	Label	Codes	Comments
IBDQND	Char	Not done		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Immunohistochemistry (IM_CHEM)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
IMTSTSEQ	Num	Test sequence		Collected at CRF
IMTSTCD	Char	Test code		Collected at CRF
IMORRES	Char	Test result		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
IMORUNIT	Char	Units - test result		Collected at CRF
IMCOM	Char	Test comment		Collected at CRF
IMTEST	Char	Decode of TESTCOD		Collected at CRF
STUDYID	Char	Study ID		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

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
PAGE_SEQ	Num	Page of series		Collected at CRF
PAGE_OF	Num	Total pages in series		Collected at CRF
AEPG	Num	AE CRF page		Collected at CRF
AESEQ	Num	AE page sequence		Collected at CRF
AEOF	Num	Number of AE pages in series		Collected at CRF
AELN	Num	AE CRF line number		Collected at CRF
AEPG2	Num	AE CRF page 2		Collected at CRF
AESEQ2	Num	AE page sequence 2		Collected at CRF
AEOF2	Num	Number of AE pages in series 2		Collected at CRF
AELN2	Num	AE CRF line number 2		Collected at CRF
AEPG3	Num	AE CRF page 3		Collected at CRF
AESEQ3	Num	AE page sequence 3		Collected at CRF
AEOF3	Num	Number of AE pages in series 3		Collected at CRF
AELN3	Num	AE CRF line number 3		Collected at CRF
AEPG4	Num	AE CRF page 4		Collected at CRF
AESEQ4	Num	AE page sequence 4		Collected at CRF
AEOF4	Num	Number of AE pages in series 4		Collected at CRF
AELN4	Num	AE CRF line number 4		Collected at CRF
MEDPG	Num	Medication CRF page		Collected at CRF
MEDSEQ	Num	Medication page sequence		Collected at CRF
MEDOF	Num	Number of medication pages in series		Collected at CRF
MEDLN	Num	Medication CRF line number		Collected at CRF
MEDPG2	Num	Medication CRF page 2		Collected at CRF
MEDSEQ2	Num	Medication page sequence 2		Collected at CRF
MEDOF2	Num	Number of medication pages in series 2		Collected at CRF
MEDLN2	Num	Medication CRF line number 2		Collected at CRF
MEDPG3	Num	Medication CRF page 3		Collected at CRF
MEDSEQ3	Num	Medication page sequence 3		Collected at CRF
MEDOF3	Num	Number of medication pages in series 3		Collected at CRF
MEDLN3	Num	Medication CRF line number 3		Collected at CRF
MEDPG4	Num	Medication CRF page 4		Collected at CRF
MEDSEQ4	Num	Medication page sequence 4		Collected at CRF
MEDOF4	Num	Number of medication pages in series 4		Collected at CRF
MEDLN4	Num	Medication CRF line number 4		Collected at CRF
MEDPG5	Num	Medication CRF page 5		Collected at CRF

Variable	Type	Label	Codes	Comments
MEDSEQ5	Num	Medication page sequence 5		Collected at CRF
MEDOF5	Num	Number of medication pages in series 5		Collected at CRF
MEDLN5	Num	Medication CRF line number 5		Collected at CRF
MEDPG6	Num	Medication CRF page 6		Collected at CRF
MEDSEQ6	Num	Medication page sequence 6		Collected at CRF
MEDOF6	Num	Number of medication pages in series 6		Collected at CRF
MEDLN6	Num	Medication CRF line number 6		Collected at CRF
MEDPG7	Num	Medication CRF page 7		Collected at CRF
MEDSEQ7	Num	Medication page sequence 7		Collected at CRF
MEDOF7	Num	Number of medication pages in series 7		Collected at CRF
MEDLN7	Num	Medication CRF line number 7		Collected at CRF
MEDPG8	Num	Medication CRF page 8		Collected at CRF
MEDSEQ8	Num	Medication page sequence 8		Collected at CRF
MEDOF8	Num	Number of medication pages in series 8		Collected at CRF
MEDLN8	Num	Medication CRF line number 8		Collected at CRF
MEDPG9	Num	Medication CRF page 9		Collected at CRF
MEDSEQ9	Num	Medication page sequence 9		Collected at CRF
MEDOF9	Num	Number of medication pages in series 9		Collected at CRF
MEDLN9	Num	Medication CRF line number 9		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
IFWNDCLT	Char	Wound or drainage cultured		Collected at CRF
IFVIRAL	Char	Viral		Collected at CRF
IFSTREP	Char	Streptococcus infection		Collected at CRF
IFSPUCLT	Char	Sputum cultured		Collected at CRF
IFOTHINF	Char	Other infection		Collected at CRF
IFANTIMC	Char	Antimicrobial tx given for infection		Collected at CRF
IFBLDCLT	Char	Blood cultured		Collected at CRF
IFCLTPOS	Char	Cultures indicated infection		Collected at CRF
IFCLT	Char	Cultures performed		Collected at CRF
IFFUNGAL	Char	Fungal		Collected at CRF
IFGRMNEG	Char	Gram negative		Collected at CRF
IFGRMPOS	Char	Other gram positive		Collected at CRF
IFHX	Char	History of similar infections		Collected at CRF
IFMYCBCT	Char	Mycobacterial		Collected at CRF
IFOTHCLT	Char	Other culture		Collected at CRF

Remicade Study ACT-1 (C0168T37)
Infection Summary (INFCTSUM)

Variable	Type	Label	Codes	Comments
IFPROTZ	Char	Protozoal		Collected at CRF
IFSTAPHA	Char	Staph aureus infection		Collected at CRF
IFURICLT	Char	Urine cultured		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Laboratory (LAB)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
LBEVNT	Char	Lab event		Collected at CRF
LBTSTCD	Char	Test code		Collected at CRF
LBACTTM	Num	Time of sample		Collected at CRF
LBORRES	Char	Test result		Collected at CRF
LBORNRLO	Char	Lower normal range - test result		Collected at CRF
LBORNRHI	Char	Upper normal range - test result		Collected at CRF
LBSTRES	Char	Standardized test result		Collected at CRF
LBSTNRLO	Char	Lower normal range - standard result		Collected at CRF
LBSTNRHI	Char	Upper normal range - standard result		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
LBORUNIT	Char	Units - test result		Collected at CRF
LBCOM	Char	Test comment		Collected at CRF
LBNRIND	Char	Out of range flag		Collected at CRF
LBSTUNIT	Char	Units - standard result		Collected at CRF
LBTEST	Char	Decode of TESTCOD		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
LBDTD	Num	REL. DAY OF Date of sample		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Samples for Central Laboratory (LTRACK)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
SAMPOBT	Char	Lab sample obtained/sent		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Mayo Subscore (MAYOSCR)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
MYSTLFRQ	Num	Stool frequency		Collected at CRF
MYRBLD	Num	Rectal bleeding		Collected at CRF
MYPGA	Num	Physician global assessment		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
MYND	Char	Not done		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
UC Screening Medical Conditions (MEDHX)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
HXITEM	Char	Medical history category		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Concomitant Medication (MEDS)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
PAGE_SEQ	Num	Page of series		Collected at CRF
LINE_NO	Num	Line number		Collected at CRF
CMRTE_V	Char	Route specified on the CRF		Collected at CRF
CMIND_V	Char	Indication specified on CRF		Collected at CRF
DRECNO	Char	Drug record number		Collected at CRF
SEQ1	Char	Drug sequence 1		Collected at CRF
SEQ2	Char	Drug sequence 2		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
CMDECOD	Char	Dictionary Term		Collected at CRF
CMDECOD1	Char	Dictionary Preferred Term		Collected at CRF
CMSTPR	Char	Prior start of medication		Collected at CRF
CMONGO	Char	Pt. continues taking medication		Collected at CRF
CMROUTE	Char	Route code		Collected at CRF
CMIND	Char	Medication indication		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
CMENDTD	Num	REL. DAY OF Medication end date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
CMSTDTD	Num	REL. DAY OF Medication start date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Medication Review (MEDSUMM)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
MSDOSE	Num	Medication dose		Collected at CRF
MSINDSPC	Char	Indication specified on CRF		Collected at CRF
DRECNO	Char	Drug record number		Collected at CRF
SEQ1	Char	Drug sequence 1		Collected at CRF
SEQ2	Char	Drug sequence 2		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
CMDECOD	Char	Dictionary Term		Collected at CRF
CMDECOD1	Char	Dictionary Preferred Term		Collected at CRF
MSFREQ	Char	Frequency of medication		Collected at CRF
MSIND	Char	Medication indication		Collected at CRF
MSCAT	Char	Medication category		Collected at CRF
MSUNIT	Char	Code for units of medication		Collected at CRF
MSLOECHG	Char	Change due to lack of efficacy		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Corrected IVRS Strata (MISSTRAT)

Variable	Type	Label	Codes	Comments
NEWREFR	Num	Corrected IVRS Strata		Collected at CRF
STUDYID	Char	Study ID		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

Variable	Type	Label	Codes	Comments
PERIOD	Char	PERIOD		Collected at CRF
VISIT	Char	VISIT		Collected at CRF
ALIQUOT	Char	ALIQUOT		Collected at CRF
RNACONNG	Num	RNACONNG		Collected at CRF
RNACONUL	Num	RNACONUL		Collected at CRF
RNATOT	Num	RNATOT		Collected at CRF
RNAQUAL	Char	RNAQUAL		Collected at CRF
A1U1	Num	A1U1		Collected at CRF
A1UG	Num	A1UG		Collected at CRF
A2UL	Num	A2UL		Collected at CRF
A2UG	Num	A2UG		Collected at CRF
A3UL	Num	A3UL		Collected at CRF
A3UG	Num	A3UG		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Other UC Related GI Surgical Procedure (OGISURG)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
OGPROC	Char	Other GI procedure type		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
CRF Page Information (PAGE_SEQ)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
PAGE_SEQ	Num	Page of series		Collected at CRF
PAGE_OF	Num	Total pages in series		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Randomization (PATRAND)

Variable	Type	Label	Codes	Comments
STUDYID	Char	Study ID		Collected at CRF
TRTGRP	Num	Randomized Treatment Group	1=Placebo, 2=Infliximab 5 mg/kg, 3=Infliximab 10 mg/kg	Collected at CRF
REFR_TX	Num	IVRS current strata		Collected at CRF
SS_MRNA	Char	Enrolled in mRNA substudy		Collected at CRF
SS_HISTO	Char	Enrolled in Histological substudy		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

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
QLGH1	Num	Score for QOL question 1		Collected at CRF
QLHT	Num	Score for QOL question 2		Collected at CRF
QLPF01	Num	Score for QOL question 3A		Collected at CRF
QLPF02	Num	Score for QOL question 3B		Collected at CRF
QLPF03	Num	Score for QOL question 3C		Collected at CRF
QLPF04	Num	Score for QOL question 3D		Collected at CRF
QLPF05	Num	Score for QOL question 3E		Collected at CRF
QLPF06	Num	Score for QOL question 3F		Collected at CRF
QLPF07	Num	Score for QOL question 3G		Collected at CRF
QLPF08	Num	Score for QOL question 3H		Collected at CRF
QLPF09	Num	Score for QOL question 3I		Collected at CRF
QLPF10	Num	Score for QOL question 3J		Collected at CRF
QLRP1	Num	Score for QOL question 4A		Collected at CRF
QLRP2	Num	Score for QOL question 4B		Collected at CRF
QLRP3	Num	Score for QOL question 4C		Collected at CRF
QLRP4	Num	Score for QOL question 4D		Collected at CRF
QLRE1	Num	Score for QOL question 5A		Collected at CRF
QLRE2	Num	Score for QOL question 5B		Collected at CRF
QLRE3	Num	Score for QOL question 5C		Collected at CRF
QLSF1	Num	Score for QOL question 6		Collected at CRF
QLBP1	Num	Score for QOL question 7		Collected at CRF
QLBP2	Num	Score for QOL question 8		Collected at CRF
QLVT1	Num	Score for QOL question 9A		Collected at CRF
QLMH1	Num	Score for QOL question 9B		Collected at CRF
QLMH2	Num	Score for QOL question 9C		Collected at CRF
QLMH3	Num	Score for QOL question 9D		Collected at CRF
QLVT2	Num	Score for QOL question 9E		Collected at CRF
QLMH4	Num	Score for QOL question 9F		Collected at CRF
QLVT3	Num	Score for QOL question 9G		Collected at CRF
QLMH5	Num	Score for QOL question 9H		Collected at CRF
QLVT4	Num	Score for QOL question 9I		Collected at CRF
QLSF2	Num	Score for QOL question 10		Collected at CRF
QLGH2	Num	Score for QOL question 11A		Collected at CRF
QLGH3	Num	Score for QOL question 11B		Collected at CRF
QLGH4	Num	Score for QOL question 11C		Collected at CRF

Remicade Study ACT-1 (C0168T37)
SF36 (QOL)

Variable	Type	Label	Codes	Comments
QLGH5	Num	Score for QOL question 11D		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
QLND	Char	Not done		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
UC Surgical History Resection Status (RESECT)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
RSTYPE	Char	Type of resection		Collected at CRF
RSPROC	Char	Procedure type		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Concurrent Treatment (RX_CLASS)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
RCRTFCRT	Char	Response/taper failure - Corticosteroids		Collected at CRF
RCMCCORT	Char	Med. complications - Corticosteroids		Collected at CRF
RCCTCORT	Char	Concurrent treatment with Corticosteroid		Collected at CRF
RCCT6MP	Char	Concurrent treatment with 6-MP		Collected at CRF
RCCTAZA	Char	Concurrent treatment with Azathioprine		Collected at CRF
RCMC6MAZ	Char	Med. complications - 6-MP, Azathioprine		Collected at CRF
RCNOCRIT	Char	No criteria met		Collected at CRF
RCRF6MAZ	Char	Response failure - 6-MP, Azathioprine		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Drug History (RX_HX)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
DRECNO	Char	Drug record number		Collected at CRF
SEQ1	Char	Drug sequence 1		Collected at CRF
SEQ2	Char	Drug sequence 2		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
CMDECOD	Char	Dictionary Term		Collected at CRF
CMDECOD1	Char	Dictionary Preferred Term		Collected at CRF
RXTIMUSD	Char	Length of time taken		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Smoking History (SMOKING)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
SMHIST	Char	Prior smoking history		Collected at CRF
SMSMOKER	Char	Current cigarette smoker		Collected at CRF
SMPACKS	Char	Smoking frequency		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
SMQDTD	Num	REL. DAY OF Date patient quit smoking		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Substudy Information (SUBSTUDY)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
SSNAME	Char	Substudy		Collected at CRF
SSENRL	Char	Enrolled in a substudy		Collected at CRF
STUDYID	Char	Study ID		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

Remicade Study ACT-1 (C0168T37)
Tuberculosis History and PPD Results (TB_INFO)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
TBPPDRES	Char	PPD results (induration)		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
TBTRTREQ	Char	Treatment required		Collected at CRF
TBPTLTB	Char	Prev completed treatment for latent TB		Collected at CRF
TBPTATB	Char	Previously treated active TB		Collected at CRF
TBBCG	Char	Previous BCG vaccination		Collected at CRF
TBPPDNR	Char	PPD test not required		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
TBPPDDTD	Num	REL. DAY OF PPD date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Discontinuation of Study Infusions (TERMDOSE)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
DAEPG	Num	Adverse event page		Collected at CRF
DAEPGSEQ	Num	Adverse event page sequence		Collected at CRF
DAEPGOF	Num	Number of AE pages in series		Collected at CRF
DAELN	Num	Adverse event line number		Collected at CRF
DAEPG2	Num	Adverse event page 2		Collected at CRF
DAEPGSQ2	Num	Adverse event page sequence 2		Collected at CRF
DAEPGOF2	Num	Number of AE pages in series 2		Collected at CRF
DAELN2	Num	Adverse event line number 2		Collected at CRF
DAEPG3	Num	Adverse event page 3		Collected at CRF
DAEPGSQ3	Num	Adverse event page sequence 3		Collected at CRF
DAEPGOF3	Num	Number of AE pages in series 3		Collected at CRF
DAELN3	Num	Adverse event line number 3		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
DSTREAS	Char	Dosing termination reason code		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
DSTRMDTD	Num	REL. DAY OF Dosing termination date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
DTTM	Num	Time of death		Collected at CRF
DTCAUSE	Char	Stated cause of death		Collected at CRF
SAEPG	Num	Adverse event page		Collected at CRF
SAEPGSEQ	Num	Adverse event page sequence		Collected at CRF
SAEPGOF	Num	Number of AE pages in series		Collected at CRF
SAELN	Num	Adverse event line number		Collected at CRF
SAEPG2	Num	Adverse event page 2		Collected at CRF
SAEPGSQ2	Num	Adverse event page sequence 2		Collected at CRF
SAEPGOF2	Num	Number of AE pages in series 2		Collected at CRF
SAELN2	Num	Adverse event line number 2		Collected at CRF
SAEPG3	Num	Adverse event page 3		Collected at CRF
SAEPGSQ3	Num	Adverse event page sequence 3		Collected at CRF
SAEPGOF3	Num	Number of AE pages in series 3		Collected at CRF
SAELN3	Num	Adverse event line number 3		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
DSWCD	Char	Use of data permitted		Collected at CRF
DSREAS	Char	Reason for study termination code		Collected at CRF
DSWCAE	Char	Consent withdrawn due to AE		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
DSDSCDTD	Num	REL. DAY OF Study termination date		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
DTDTD	Num	REL. DAY OF Date of death		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Visit Information (VISITS)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
VISITND	Char	Visit not done		Collected at CRF
STUDYID	Char	Study ID		Collected at CRF
VISITDTD	Num	REL. DAY OF Date of patient visit		Derived related day of event: event date - reference date + 1 if event date >= reference date, or event date - reference date if event date < reference date
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

Remicade Study ACT-1 (C0168T37)
Vital Signs (VITALS)

Variable	Type	Label	Codes	Comments
EVENT_ID	Char	Event Identifier		Collected at CRF
PAG_NAME	Char	Page		Collected at CRF
ZWGT	Num	Entered weight		Collected at CRF
WGT	Num	Weight (kg)		Collected at CRF
CRF_PAGE	Char	CRF Page		Collected at CRF
VISIT	Char	Visit Name		Collected at CRF
VISITNUM	Num	Visit Number		Derived Number assigned to sequence visits chronologically
ZWGT_UN	Char	Units for entered weight		Collected at CRF
STUDYID	Char	Study ID		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