

Data Set Name: abdimage_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ABDIMG	Num	8	Were abdominal imaging studies performed

Data Set Name: aclabflw_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ACAKP	Num	8	Alkaline Phosphatase results Available?
7	ACSTBULN	Num	8	Serum Total Bilirubin ULN
8	ACASTULN	Num	8	AST ULN
9	ACALBVAL	Num	8	Serum Albumin results
10	ACINR	Num	8	INR results Available?
11	ACAKPULN	Num	8	Alkaline Phosphatase ULN
12	ACASTVAL	Num	8	AST result
13	ACALBUN	Num	8	Serum Albumin results Available?
14	ACSTB	Num	8	Serum Total Bilirubin results Available?
15	ACSTBVAL	Num	8	Serum Total Bilirubin results
16	ACAKPVAL	Num	8	Alkaline Phosphatase results
17	ACALT	Num	8	ALT results Available?
18	ACALTVAL	Num	8	ALT results
19	ACLVISIT	Num	8	Visit
20	ACAST	Num	8	AST results Available?
21	ACSTBUNT	Num	8	Serum Total Bilirubin results unit
22	ACALBUNT	Num	8	Serum Albumin results unit
23	ACALTULN	Num	8	ALT ULN
24	ACINRATE	Num	8	INR results
25	ACLABTM	Num	8	Time of Acute Lab
26	ACLABFL	Num	8	Imputed flag: Date of Acute Lab
27	ACLABDT	Num	8	Studyday of Date of Acute Lab

Data Set Name: aconcam_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ACMCOMNM	Char	80	Common name
7	ACMCONT	Num	8	Continuing
8	ACMBRNM	Char	80	Brand or commercial name
9	ACMSPFL	Num	8	Imputed flag: Stop date
10	ACMSTFL	Num	8	Imputed flag: Start date
11	WHONAME	Char	80	Standardized Medication Name
12	WHOCODE	Char	11	WHO Drug Code
13	ACMSPDT	Num	8	Studyday of Stop date
14	ACMSTDT	Num	8	Studyday of Start date

Data Set Name: aconhx_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ACNMHXYN	Num	8	Any CAM products w/in 4wks of annual visit
7	ACNCHXYN	Num	8	Any medications w/in 4wks of annual visit

Data Set Name: aconmed_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	AMEDCONT	Num	8	Continuing
7	AMEDNAME	Char	80	Medication
8	AMEDSPFL	Num	8	Imputed flag: Stop date
9	AMEDSTFL	Num	8	Imputed flag: Start date
10	WHONAME	Char	80	Standardized Medication Name
11	WHOCODE	Char	11	WHO Drug Code
12	ATCCODE	Char	7	WHO ATC Code
13	ATCTERM	Char	100	WHO ATC Text
14	AMEDSPDT	Num	8	Studyday of Stop date
15	AMEDSTDT	Num	8	Studyday of Start date

Data Set Name: *acsamp_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ACSTATE	Num	8	When blood samples drawn, patient was?
7	ACRADM	Num	8	Admission date available?
8	ACRDSC	Num	8	Discharge date available?
9	ACRVISIT	Num	8	Visit
10	ACRADMFL	Num	8	Imputed flag: Date of admission
11	ACRDSCFL	Num	8	Imputed flag: Date of discharge
12	ACRLBFL	Num	8	Imputed flag: Date of collection
13	ACRADMDT	Num	8	Studyday of Date of admission
14	ACRDSCDT	Num	8	Studyday of Date of discharge
15	ACRLBDT	Num	8	Studyday of Date of collection

Data Set Name: acute_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ACBLOOD	Num	8	Were acute blood samples drawn?
7	ACDILI	Num	8	Were acute labs drawn?

Data Set Name: allrgyhx_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ALLGREAC	Char	200	Reaction
7	AGENT	Char	80	Agent
8	WHONAME	Char	80	Standardized Medication Name
9	WHOCODE	Char	11	WHO Drug Code

Data Set Name: antihbe_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ANTHBGRS	Num	8	Anti-HBe Result
7	ANTHBEFL	Num	8	Imputed flag: Anti-HBe date
8	ANTHBEDT	Num	8	Studyday of Anti-HBe date

Data Set Name: antihdv_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ANTHDVRS	Num	8	Anti-HDV Result
7	ANTHDVFL	Num	8	Imputed flag: Anti-HDV Date
8	ANTHDVDT	Num	8	Studyday of Anti-HDV Date

Data Set Name: antihev_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	25	Testing Visit
5	ALTID	Char	15	Alternate ID Number
6	VISITID	Num	8	Inform generated visit number

Data Set Name: *aphxq2_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	APHQ2TUN	Num	8	To Date available?
7	APHQ2FUN	Num	8	From Date available?
8	APHQ2TYP	Num	8	Type of Area
9	APHQCTRY	Char	50	Country
10	APHQ2FFL	Num	8	Imputed flag: From Date
11	APHQ2TFL	Num	8	Imputed flag: To Date
12	APHQ2FDT	Num	8	Studyday of From Date
13	APHQ2TDT	Num	8	Studyday of To Date

Data Set Name: *aphxq_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	APHQ9HSE	Num	8	Relationship with the person - Household exposure - siblings or children
7	APHQ3YN	Num	8	Received a blood transfusion?
8	APHQ6YN	Num	8	Are you a health care worker involves face-to-face contact with patients?
9	APHQ7RUN	Num	8	Year of Most Recent Exposure to Patient Body Fluids/secretions available?
10	APHQ5FUN	Num	8	Year of First cocaine or crack Exposure available
11	APHQ9SPS	Num	8	Relationship with the person - Spouse or Sexual Partner
12	APHQTRVL	Num	8	Travel outside USA in 6 months before sick with liver injury?
13	APHQ7YN	Num	8	Have you ever had any direct contact with patient body fluids/secretions such as blood, urine, feces, etc?
14	APHQ8RUN	Num	8	Year of Most Recent Needle Stick/Injury Exposure available?
15	APHQ4YN	Num	8	Used injection drugs, such as heroin, cocaine or crack?
16	APHQ5YN	Num	8	Ever snorted or sniffed cocaine or crack?
17	APHQ4FUN	Num	8	Year of First use of injection drugs available?
18	APHQ8YN	Num	8	Have you ever had history of needle stick exposure/contact with body fluids/secretions
19	APHQ9YN	Num	8	Ever exposed to someone with hepatitis/someone jaundiced six months before you sick with liver problem?
20	APHQ8FUN	Num	8	Year had history of needle stick exposure/contact with body fluids/secretions available?
21	APHQ9WRK	Num	8	Relationship with the person - Informal workplace/school exposure
22	APHQ3FUN	Num	8	Blood transfusion info available
23	APHQ7FDT	Num	8	Year of First Exposure to Patient Body Fluids/secretions
24	APHQ7RDT	Num	8	Year of Most Recent Exposure to Patient Body Fluids/secretions
25	APHQ5FDT	Num	8	Year of First Exposure
26	APHQ5RDT	Num	8	Year of Most Recent Exposure
27	APHQ4RDT	Num	8	Year of Most Recent use of Injection Drugs
28	APHQ4FDT	Num	8	Year of First injection drugs
29	APHQ3RDT	Num	8	Year of Most transfusion
30	APHQ3FDT	Num	8	Year of First Transfusion
31	APHQ8FDT	Num	8	Year of First Needle Stick/Injury Exposure
32	APHQ8RDT	Num	8	Year of Most Recent Needle Stick/Injury Exposure

Data Set Name: *appthist_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	DILILF	Num	8	Were liver function tests performed?
7	DILIABIM	Num	8	Were abdominal imaging studies performed
8	DILIREL	Num	8	Was the emergency room visit DILI-relate
9	MEDAPPFL	Num	8	Imputed flag: Appointment date
10	MEDAPPDT	Num	8	Studyday of Appointment date

Data Set Name: biopdem_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	SPECIMAN	Num	8	Specimen type
6	AUTOPHRS	Num	8	Specify time interval between death and
7	TPORTAL	Num	8	Total portal areas
8	LIVWT	Num	8	Liver weight
9	HE	Num	8	H&E
10	MASON	Num	8	Masson
11	IRON	Num	8	Iron
12	PAS	Num	8	PAS with diastase
13	COPPER	Num	8	Copper
14	STAINOTH	Num	8	Other
15	STAINSP	Char	200	Other (specify)
16	BPSYTYPE	Char	50	BPSYTYPE
17	LVBIOPFL	Num	8	Imputed flag: Date of biopsy
18	REVIEWFL	Num	8	Imputed flag: Date of Central review
19	LVBIOPDT	Num	8	Studyday of Date of biopsy
20	REVIEWDT	Num	8	Studyday of Date of Central review

Data Set Name: biopmisc_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	GRNDCHGE	Num	8	Hepatocyte ground glass change
7	GLOBINCL	Num	8	Hepatocyte globular cytoplasmic inclusio
8	MALLORY	Num	8	Mallory bodies
9	STELLATE	Num	8	Lipid-laden stellate cells
10	GLYCOGEN	Num	8	Hepatocellular glycogenesis
11	CRYSTALS	Num	8	Polarized talc crystals

Data Set Name: biopsy1_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	NECROSIS	Num	8	Bridging necrosis
7	TPORTAL	Num	8	Total portal areas
8	CYTOK7	Num	8	Stains available - Cytokeratin 7
9	MASON	Num	8	Stains available - Masson
10	COPPER	Num	8	Stains available - Copper
11	LIPOGRAN	Num	8	Lipogranulomas
12	EOSINO	Num	8	Eosinophils
13	PAS	Num	8	Stains available - PAS with diastase
14	IRON	Num	8	Stains available - Iron
15	CHOLANGI	Num	8	Cholangiolar
16	BIOPTYPK	Num	8	Biopsy Type
17	SPECIMAN	Num	8	Specimen Type
18	CANALICU	Num	8	Canalicular
19	RETICULN	Num	8	Stains available - Reticulin
20	ACUTCHOL	Num	8	Acute cholangitis
21	LOBULAR	Num	8	Lobular inflammation
22	LENGTH	Num	8	Liver length (mm)
23	PORTAL	Num	8	Portal inflammation
24	CONNECRO	Num	8	Confluent necrosis
25	NEUTRO	Num	8	Neutrophils
26	STAGE	Num	8	Stage
27	DUCTPAUC	Num	8	Duct paucity
28	DUCTAL	Num	8	Ductal
29	STAINOTH	Num	8	Stains available - Other
30	PERISIN	Num	8	Perisinusoidal
31	INTRFACE	Num	8	Interface hepatitis
32	BPDEGREE	Num	8	Degree
33	PLASMA	Num	8	Plasma cells
34	REVIEWFL	Num	8	Imputed flag: Date of central review
35	SITEBXFL	Num	8	Imputed flag: Date of Biopsy
36	REVIEWWDT	Num	8	Studyday of Date of central review

Num	Variable	Type	Len	Label
37	SITEBXDT	Num	8	Studyday of Date of Biopsy

Data Set Name: biopsy2_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	PORTVENO	Num	8	Portal venopathy
7	PASHEPA	Num	8	PAS/ diastase stain- PAS-positive hepatocellular inclusions
8	STELLATE	Num	8	Lipid-laden stellate cells
9	CNVNENDO	Num	8	Central vein endophlebitis
10	SINUIRON	Num	8	Iron stain- sinusoidal reticuloendothelial iron
11	COAGDGRE	Num	8	Coagulative/ Confluent necrosis degree
12	HEPAROS	Num	8	Hepatocyte rosettes
13	HEMORRHG	Num	8	Hemorrhage
14	CK7EVAL	Num	8	CK 7 Evaluation
15	APOPTOS	Num	8	Apoptosis
16	CRYSTALS	Num	8	Polarizeable talc crystals
17	GLOBINCL	Num	8	Hepatocyte globular cytoplasmic inclusions
18	LOBDISRY	Num	8	Lobular disarray
19	GLYCOGEN	Num	8	Hepatocellular glycogenosis
20	PATINJUR	Num	8	Pattern of Injury
21	HEPSTAIN	Num	8	CK 7 Hepatocyte Staining
22	SINUDILA	Num	8	Sinusoidal dilation
23	GRNDCHGE	Num	8	Hepatocyte ground glass change
24	BALDEGEN	Num	8	Ballooning degeneration
25	HEPACOPP	Num	8	Copper stain-hepatocellular copper
26	MALLORY	Num	8	Mallory bodies
27	VENOCCLU	Num	8	Veno-occlusive changes in central veins
28	COAGLOC	Num	8	Coagulative/ Confluent necrosis location
29	PASMACRO	Num	8	PAS/ diastase stain- PAS-positive macrophages
30	NODUTRAN	Num	8	Nodular transformation
31	RE VW3FL	Num	8	Imputed flag: Date of central review
32	RE VW3DT	Num	8	Studyday of Date of central review

Data Set Name: cammed1_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	MERGEVAR	Num	8	Merge variable between CAMMED1/CAMMED2
7	CAMSEQNO	Num	8	HDS #
8	CAMBRNM	Char	80	Product name
9	CAMCOMNM	Char	80	Product line
10	CAMINGYN	Num	8	HDS Ingredients available
11	CAMMANUF	Char	80	Manufacturer's Name
12	WHONAME	Char	80	Standardized Medication Name
13	WHOCODE	Char	11	WHO Drug Code

Data Set Name: cammed2_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	INGRDNUM	Num	8	CAM ingredient number
6	VISITID	Num	8	Inform generated visit number
7	MERGEVAR	Num	8	Merge variable between CAMMED1/CAMMED2
8	CAMINGRD	Char	100	List of ingredients

Data Set Name: cammed3_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	CAMSEQNO2	Num	8	CRF Sequence number 2
6	VISITID	Num	8	Inform generated visit number
7	CAMSP	Char	200	Indication specify
8	CFREQ	Num	8	Frequency
9	CAMSEQNO	Num	8	HDS #
10	CDOSE	Num	8	Dose
11	CRTESP	Char	100	Route specify
12	CFREQSP	Char	100	Frequency specify
13	CUNIT	Char	10	Unit
14	CAMCONT	Num	8	Continuing
15	CAMIND	Num	8	Indication
16	CROUTE	Num	8	Route
17	CAMSPFL	Num	8	Imputed flag: Stop Date
18	CAMSTFL	Num	8	Imputed flag: Start Date
19	CAMSPDT	Num	8	Studyday of Stop Date
20	CAMSTDT	Num	8	Studyday of Start Date

Data Set Name: *cammed4_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	MERGEVAR	Num	8	Merge variable between CAMMED1/CAMMED4
7	HDSRSNSP	Char	100	Reason
8	HDSMED	Char	100	Prescribed Medication

Data Set Name: causrucm_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	SEQNO	Num	8	Implicated Drug sequence number
5	REVIEW	Num	8	Reviewer
6	SCORE	Num	8	The calculated RUCAM score (total)
7	RUCAM	Num	8	RUCAM
8	RUSCORE	Num	8	Score (individual assessment)
9	IMPLDRUG	Char	128	Name of implicated drug/CAM
10	WHONAME	Char	128	Implicated Drug WHO Drug Name
11	WHOCODE	Char	32	Implicated Drug WHO Drug Code
12	RUCAMFL	Num	8	Imputed flag: Date completed
13	RUCAMDT	Num	8	Studyday of Date completed

Data Set Name: *cd4_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	CD4VAL	Num	8	CD4+ Value
7	CD4FL	Num	8	Imputed flag: CD4 date
8	CD4DT	Num	8	Studyday of CD4 date

Data Set Name: cholest_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	HEPACELL	Num	8	Hepatocellular
7	CANALICU	Num	8	Canalicular
8	CHOLANGI	Num	8	Cholangiolar
9	DUCTAL	Num	8	Ductal
10	CHOLESTA	Num	8	Cholestasis
11	DUCTREAC	Num	8	Ductalur reaction
12	DUCTINJ	Num	8	Duct injury
13	DUCTPAUC	Num	8	Duct paucity
14	ACUTCHOL	Num	8	Acute cholangitis
15	CHOLDGR	Num	8	Cholestasis degree

Data Set Name: *chronic_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	CINEXC6	Num	8	Chronic HBV or HCV prior to implicated med start
7	CINEXC2	Num	8	LFT > 1.25 * baseline on 2 occasions
8	CINEXC1	Num	8	Persistently elevated liver function test
9	CINEXC8	Num	8	Biopsy-proven cirrhosis prior to implicated med start
10	CINEXC5	Num	8	Radiological evidence after 6 mth DILI onset
11	CINEXC7	Num	8	Liver transplant by 6 mth visit
12	CINEXC10	Num	8	Alternative explanation for abnormalities
13	CINEXC4	Num	8	Histological evidence on biopsy after 6 mth
14	CINEXC9	Num	8	Medically reasonable explanation for chronic
15	CINEXC3	Num	8	Portal hypertension after 6 mth DILI onset

Data Set Name: collect1_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	CRYO3YN	Num	8	3rd Cryovial/Cryomold collected
7	CRYO2YN	Num	8	2nd Cryovial/Cryomold collected
8	BIOPS1	Char	10	Slides from
9	HXBIOP2	Char	10	Other/historic biopsies:Slides to
10	CRYO3	Char	10	Cryovial/Cryomold 3
11	CRYO1YN	Num	8	Cryovial/Cryomold collected
12	HXBIOP	Num	8	Prior to DILI event?historic biopsy ?
13	CRYO2	Char	10	Cryovial/Cryomold 2
14	HXBIOP1	Char	10	Other/historic biopsies:Slides from
15	BIOPTYPE	Num	8	DILI biopsy type
16	CRYO1	Char	10	Cryovial/Cryomold 1
17	BIOPS2	Char	10	Slides to
18	LVBIOPFL	Num	8	Imputed flag: Date of biopsy
19	SHIPFL	Num	8	Imputed flag: Date slides were shipped
20	LVBIOPDT	Num	8	Studyday of Date of biopsy
21	SHIPDT	Num	8	Studyday of Date slides were shipped

Data Set Name: concam_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	CAMBRAND	Char	80	Brand or commercial name
7	CAMCOMM	Char	80	Common name
8	CAMLCONT	Num	8	Continuing
9	CAMLSPFL	Num	8	Imputed flag: Stop Date/Last Dose
10	CAMLSTFL	Num	8	Imputed flag: Start Date
11	WHONAME	Char	80	Standardized Medication Name
12	WHOCODE	Char	11	WHO Drug Code
13	CAMLSPDT	Num	8	Studyday of Stop Date/Last Dose
14	CAMLSTDT	Num	8	Studyday of Start Date

Data Set Name: conhx_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	CONMHXYN	Num	8	Any CAM products during the study
7	CONCHXYN	Num	8	Any medications during the study

Data Set Name: conmed_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	MEDCONT	Num	8	Continuing
7	MEDNAME	Char	80	Medication
8	MEDSPFL	Num	8	Imputed flag: Stop Date/Last Dose
9	MEDSTFL	Num	8	Imputed flag: Start Date
10	WHONAME	Char	80	Standardized Medication Name
11	WHOCODE	Char	11	WHO Drug Code
12	ATCCODE	Char	7	WHO ATC Code
13	ATCTERM	Char	100	WHO ATC Text
14	MEDSPDT	Num	8	Studyday of Stop Date/Last Dose
15	MEDSTDT	Num	8	Studyday of Start Date

Data Set Name: demog_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	RACEOTHR	Num	8	Race Other (specify)
7	WHITE	Num	8	White
8	ASIAN	Num	8	Asian
9	BLACK	Num	8	Black or African American
10	SEX	Num	8	Sex
11	AGECAT	Num	8	Age category

Data Set Name: dilimed_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	RTESP	Char	100	Route specify
7	ROUTE	Num	8	Route
8	DILICONT	Num	8	Continuing
9	FREQ	Num	8	Frequency
10	FREQSP	Char	100	Frequency specify
11	DILISPEC	Char	200	Indication
12	DILINAME	Char	80	Medication
13	UNIT	Char	8	Unit
14	DOSE	Char	12	Dose
15	DILISPFL	Num	8	Imputed flag: Stop date
16	DILISTFL	Num	8	Imputed flag: Start date
17	WHONAME	Char	80	Standardized Medication Name
18	WHOCODE	Char	11	WHO Drug Code
19	ATCCODE	Char	7	WHO ATC Code
20	ATCTERM	Char	100	WHO ATC Text
21	DILISPDT	Num	8	Studyday of Stop date
22	DILISTDT	Num	8	Studyday of Start date

Data Set Name: *dilin_formats.sas7bdat*

Num	Variable	Type	Len	Label
1	FMTNAME	Char	32	Format name
2	START	Char	16	Starting value for format
3	END	Char	16	Ending value for format
4	LABEL	Char	105	Format value label
5	MIN	Num	3	Minimum length
6	MAX	Num	3	Maximum length
7	DEFAULT	Num	3	Default length
8	LENGTH	Num	3	Format length
9	FUZZ	Num	8	Fuzz value
10	PREFIX	Char	2	Prefix characters
11	MULT	Num	8	Multiplier
12	FILL	Char	1	Fill character
13	NOEDIT	Num	3	Is picture string noedit?
14	TYPE	Char	1	Type of format
15	SEXCL	Char	1	Start exclusion
16	EEXCL	Char	1	End exclusion
17	HLO	Char	13	Additional information
18	DECSEP	Char	1	Decimal separator
19	DIG3SEP	Char	1	Three-digit separator
20	DATATYPE	Char	8	Date/time/datetime?
21	LANGUAGE	Char	8	Language for date strings

Data Set Name: *dilin_hcv_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	STUDYNM	Char	10	STUDYNM
5	LOAD	Char	5	LOAD
6	VISIT	Char	25	VISIT
7	TESTTYPE	Char	25	TESTTYPE
8	RESULT	Char	25	RESULT
9	HCVCOMM	Char	50	HCVCOMM
10	HCVGENTYP	Char	25	HCVGENTYP
11	ARCHHCV	Char	25	ARCHHCV
12	ANTIHCV	Char	50	ANTIHCV
13	LOAD_DT	Num	8	LOAD_DT
14	VISITID	Num	8	Inform generated visit number
15	ALTID	Char	25	Alternate ID Number

Data Set Name: drugcomp_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SURRO2	Num	8	Surrogate respondent
7	RXLESS	Num	8	Take medication less freq than prescribed
8	RXMORE	Num	8	Take medication more freq than prescribed
9	RXNAME	Char	80	Drug name
10	RXLESTHN	Num	8	Take medication less than prescribed
11	RXFOLLOW	Num	8	Follow medication schedule
12	RXMORTHN	Num	8	Take medication more than prescribed

Data Set Name: *dxlab1_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	DLAB12	Num	8	Anti-HIV
7	DRSLT13	Num	8	Result - ANA
8	DRSLT14	Num	8	Result - ASMA
9	DLAB13	Num	8	Anti-nuclear antibodies (ANA)
10	DLAB14	Num	8	Anti-smooth muscle antibodies (ASMA)
11	DXTITR14	Num	8	Threshold - ASMA
12	DXULN13	Num	8	Threshold value - ANA
13	DLAB15	Num	8	Anti-mitochondrial antibodies (AMA)
14	DXULN15	Num	8	Threshold value - AMA
15	DLAB11	Num	8	Anti-HDV
16	DXVAL14	Num	8	Value - ASMA
17	DRSLT07	Num	8	Result - Anti-HBs
18	DRSLT17	Num	8	Result - Serum ceruloplasmin
19	DRSLT08	Num	8	Result - HBeAg
20	DXVAL13	Num	8	Value - ANA
21	DRSLT06	Num	8	Result - Anti-HBc IgM
22	DRSLT11	Num	8	Result - Anti-HDV
23	DLAB08	Num	8	HBeAg
24	DRSLT16	Num	8	Result - Heterophile antibody
25	DRSLT10	Num	8	Result - HBV-DNA
26	DRSLT05	Num	8	Result - Anti-HBc
27	DXTITR13	Num	8	Threshold - ANA
28	DXVAL15	Num	8	Value - AMA
29	DLAB17	Num	8	Serum ceruloplasmin
30	DLAB06	Num	8	Anti-HBc IgM
31	DLAB10	Num	8	HBV-DNA
32	DLABTP13	Num	8	Type of test - ANA
33	DXULN17	Num	8	Threshold value - Serum ceruloplasmin
34	DRSLT01	Num	8	Result - Anti-HAV IgM
35	DRSLT15	Num	8	Result - AMA
36	DRSLT02	Num	8	Result - Anti-HCV

Num	Variable	Type	Len	Label
37	DLAB03	Num	8	HCV RNA
38	DLABTP14	Num	8	Type of test - ASMA
39	DLAB09	Num	8	Anti-HBe
40	DRSLT12	Num	8	Result - Anti-HIV
41	DLAB16	Num	8	Heterophile antibody or monospot available?
42	DLABTP15	Num	8	Type of test - AMA
43	DXTITR15	Num	8	Threshold - AMA
44	DRSLT09	Num	8	Result - Anti-HBe
45	DLAB07	Num	8	Anti-HBs
46	DRSLT03	Num	8	Result - HCV RNA
47	DLAB04	Num	8	HBsAg
48	DRSLT04	Num	8	Result - HBsAg
49	DLAB02	Num	8	Anti-HCV
50	DXULN14	Num	8	Threshold value - ASMA
51	DLAB01	Num	8	Anti-HAV IgM
52	DLAB05	Num	8	Anti-HBc (Total or IgG) available?
53	DLABFL01	Num	8	Imputed flag: Date - Anti-HAV IgM
54	DLABFL02	Num	8	Imputed flag: Date - Anti-HCV
55	DLABFL03	Num	8	Imputed flag: Date - HCV RNA
56	DLABFL04	Num	8	Imputed flag: Date - HBsAg
57	DLABFL05	Num	8	Imputed flag: Date - Anti-HBc
58	DLABFL06	Num	8	Imputed flag: Date - Anti-HBc IgM
59	DLABFL07	Num	8	Imputed flag: Date - Anti-HBs
60	DLABFL08	Num	8	Imputed flag: Date - HBeAg
61	DLABFL09	Num	8	Imputed flag: Date - Anti-HBe
62	DLABFL10	Num	8	Imputed flag: Date - HBV-DNA
63	DLABFL11	Num	8	Imputed flag: Date - Anti-HDV
64	DLABFL12	Num	8	Imputed flag: Date - Anti-HIV
65	DLABFL13	Num	8	Imputed flag: Date - ANA
66	DLABFL14	Num	8	Imputed flag: Date - ASMA
67	DLABFL15	Num	8	Imputed flag: Date - AMA
68	DLABFL16	Num	8	Imputed flag: Date - Heterophile antibody
69	DLABFL17	Num	8	Imputed flag: Date - Serum ceruloplasmin
70	DLABDT01	Num	8	Studyday of Date - Anti-HAV IgM
71	DLABDT02	Num	8	Studyday of Date - Anti-HCV
72	DLABDT03	Num	8	Studyday of Date - HCV RNA
73	DLABDT04	Num	8	Studyday of Date - HBsAg
74	DLABDT05	Num	8	Studyday of Date - Anti-HBc
75	DLABDT06	Num	8	Studyday of Date - Anti-HBc IgM

Num	Variable	Type	Len	Label
76	DLABDT07	Num	8	Studyday of Date - Anti-HBs
77	DLABDT08	Num	8	Studyday of Date - HBeAg
78	DLABDT09	Num	8	Studyday of Date - Anti-HBe
79	DLABDT10	Num	8	Studyday of Date - HBV-DNA
80	DLABDT11	Num	8	Studyday of Date - Anti-HDV
81	DLABDT12	Num	8	Studyday of Date - Anti-HIV
82	DLABDT13	Num	8	Studyday of Date - ANA
83	DLABDT14	Num	8	Studyday of Date - ASMA
84	DLABDT15	Num	8	Studyday of Date - AMA
85	DLABDT16	Num	8	Studyday of Date - Heterophile antibody
86	DLABDT17	Num	8	Studyday of Date - Serum ceruloplasmin

Data Set Name: *dxlab2_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	DXULN21	Num	8	Threshold - Serum ferritin
7	DXRSLT22	Num	8	Value - Serum IgM
8	DXULN18	Num	8	Threshold - Serum alpha-1 antitrypsin
9	DXRSLT21	Num	8	Value - Serum ferritin
10	DXULN24	Num	8	Threshold - Serum IgA
11	DLAB24	Num	8	Serum IgA
12	DLAB20	Num	8	Serum transferrin
13	DXRSLT23	Num	8	Value - Serum IgG
14	DXULN20	Num	8	Threshold - Serum transferrin
15	DLAB23	Num	8	Serum IgG
16	DRSLT25	Num	8	Result - Anti CMV IgM
17	DXRSLT19	Num	8	Value - Serum iron
18	DXULN23	Num	8	Threshold - Serum IgG
19	DXULN19	Num	8	Threshold - Serum iron
20	DXRSLT18	Num	8	Value - Serum alpha-1 antitrypsin
21	DLAB21	Num	8	Serum ferritin
22	DXRSLT24	Num	8	Value - Serum IgA
23	DLAB26	Num	8	Anti-HAV (total)
24	DLAB25	Num	8	Anti CMV IgM
25	DXRSLT20	Num	8	Value - Serum transferrin
26	DLAB19	Num	8	Serum iron
27	DRSLT26	Num	8	Result - Anti HAV (total)
28	DLAB18	Num	8	Serum alpha-1 antitrypsin
29	DXULN22	Num	8	Threshold - Serum IgM
30	DLAB22	Num	8	Serum IgM
31	DLABFL18	Num	8	Imputed flag: Date - Serum alpha-1 antitrypsin
32	DLABFL19	Num	8	Imputed flag: Date - Serum iron
33	DLABFL20	Num	8	Imputed flag: Date - Serum transferrin
34	DLABFL21	Num	8	Imputed flag: Date - Serum ferritin
35	DLABFL22	Num	8	Imputed flag: Date - Serum IgM
36	DLABFL23	Num	8	Imputed flag: Date - Serum IgG

Num	Variable	Type	Len	Label
37	DLABFL24	Num	8	Imputed flag: Date - Serum IgA
38	DLABFL25	Num	8	Imputed flag: Date - Anti CMV IgM
39	DLABFL26	Num	8	Imputed flag: Date - Anti-HAV (total)
40	DLABDT18	Num	8	Studyday of Date - Serum alpha-1 antitrypsin
41	DLABDT19	Num	8	Studyday of Date - Serum iron
42	DLABDT20	Num	8	Studyday of Date - Serum transferrin
43	DLABDT21	Num	8	Studyday of Date - Serum ferritin
44	DLABDT22	Num	8	Studyday of Date - Serum IgM
45	DLABDT23	Num	8	Studyday of Date - Serum IgG
46	DLABDT24	Num	8	Studyday of Date - Serum IgA
47	DLABDT25	Num	8	Studyday of Date - Anti CMV IgM
48	DLABDT26	Num	8	Studyday of Date - Anti-HAV (total)

Data Set Name: *dxlab3_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SPEBETA	Num	8	Beta
7	SPEGAMMA	Num	8	Gamma
8	DXLABSPE	Num	8	Serum protein electrophoresis: Not Done
9	DXLABSER	Num	8	Additional ANA or ASMA results
10	SPETPRO	Num	8	Total protein
11	SPEALBUN	Num	8	Albumin
12	SPEALPH2	Num	8	Alpha-2
13	SPEALPH1	Num	8	Alpha-1
14	SPELABFL	Num	8	Imputed flag: Date sample drawn
15	SPELABDT	Num	8	Studyday of Date sample drawn

Data Set Name: enr_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	SCRNDT	Num	8	Studyday of Date of visit

Data Set Name: *errmhx_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ERDILIRD	Num	8	Was the emergency room visit DILI-relate
7	ERDTYP	Num	8	Dates or total days in hospital
8	ABNORIMA	Num	8	Were abdominal imaging studies performed
9	TOTNU	Num	8	Dates unavailable: Total # hospital days
10	LIVTEST	Num	8	Were liver function tests performed?
11	PHOSHR	Num	8	Hospitalized for > 24 hours
12	ERADMFL	Num	8	Imputed flag: Date of admittance
13	ERDISCFL	Num	8	Imputed flag: Date of discharge
14	ERADMDT	Num	8	Studyday of Date of admittance
15	ERDISCDT	Num	8	Studyday of Date of discharge

Data Set Name: fibro_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	WSUNIT	Num	8	Current Waist Circumference unit
7	CHUNIT	Num	8	Current Chest Circumference unit
8	HRTFALYN	Num	8	any evidence of right heart failure
9	WEIGHT1	Num	8	Current Weight
10	HIFIBROV	Num	8	Highest Fibroscan Velocit (meters/second)
11	INTRANV	Num	8	Interquartile range (%)
12	SEX1	Num	8	Sex
13	HPUNIT	Num	8	Current Hip Circumferenc unit
14	EJEFRAC	Num	8	Cardiac Ejection Fraction (%)
15	RADINTER	Num	8	Radiological Interpretation
16	MEDFIBROS	Num	8	Median Fibroscan stiffness score
17	ALCOHYN	Num	8	>=2 alcoholic beverages per day over the past 2 weeks
18	HIFIBROS	Num	8	Highest Fibroscan Stiffness score
19	FIBROVIS	Num	8	Visit
20	WAIST1	Num	8	Current Waist Circumference
21	SHORFRAC	Num	8	Shortening Fraction (%)
22	FIBROYN	Num	8	will the Fibroscan be performed at this visit
23	INTRANS	Num	8	Interquartile range to median ratio (%)
24	CAPYN	Num	8	CAP measurements obtained and recorded?
25	IMPLYS	Num	8	any implanted electrical devices
26	HIP1	Num	8	Current Hip Circumference
27	LOFIBROV	Num	8	Lowest Fibroscan Velocity (meters/second)
28	WGUNIT	Num	8	Current Weight unit
29	CONGESYN	Num	8	any evidence of passive congestion of the liver
30	PROBE	Num	8	Probe used
31	PREGYN	Num	8	is the patient pregnant
32	HEIGHT1	Num	8	Current Height
33	ASCITEYN	Num	8	any evidence of ascites on most recent abdominal imaging
34	MEDCAP	Num	8	Median CAP measurement (db/m)
35	HGUNIT	Num	8	Current Height unit
36	CHST	Num	8	Current Chest Circumference

Num	Variable	Type	Len	Label
37	CHEST2	Num	8	Current Chest Circumference
38	CHUNIT1	Num	8	Current Chest Circumference unit
39	HGHT	Num	8	Current Height
40	HEIGHT2	Num	8	Current Height
41	HGUNIT1	Num	8	Current Height unit
42	HP	Num	8	Current Hip Circumference
43	HIP2	Num	8	Current Hip Circumference
44	HPUNIT1	Num	8	Current Hip Circumferenc unit
45	WST	Num	8	Current Waist Circumference
46	WAIST2	Num	8	Current Waist Circumference
47	WSUNIT1	Num	8	Current Waist Circumference unit
48	WGHT	Num	8	Current Weight
49	WEIGHT2	Num	8	Current Weight
50	WGUNIT1	Num	8	Current Weight unit
51	MEFIBROV	Num	8	Median Fibroscan velocity
52	LOFIBROS	Num	8	Lowest Fibroscan Stiffness score (kPa)
53	HICAP	Num	8	Highest CAP measurement
54	FIBPERF1	Num	8	FIBROSCAN be performed this visit
55	SEX2	Num	8	Sex
56	PRGPERF	Num	8	will the pregnancy test be completed
57	PREGYN1	Num	8	is the patient pregnant
58	INTRANC	Num	8	Interequartile range to Median ratio (%)
59	LOCAP	Num	8	Lowest CAP measurement (db/m)
60	CHEST1	Num	8	Current Chest Circumference
61	FIBROHH	Num	8	FIBROSCAN: hour
62	FIBROMN	Num	8	FIBROSCAN: minute
63	FOODHH	Num	8	last food/drink: hour
64	FOODMN	Num	8	last food/drink: minute
65	PREGHH	Num	8	pregnancy test: hour
66	PREGMN	Num	8	pregnancy test: minute
67	PREGDTM1HH	Num	8	Pregnancy test: hour
68	PREGDTM1MN	Num	8	Pregnancy test: minute
69	SCRNHH	Num	8	Date Screening Assessment: hour
70	SCRNMN	Num	8	Date Screening Assessment: minute
71	SCRNDTM1HH	Num	8	Screening Assessment: hour
72	SCRNDTM1MN	Num	8	Screening Assessment: minute
73	ECHOFL	Num	8	Imputed flag: (ECHO date)
74	FIBROFL	Num	8	Imputed flag: (FIBROSCAN date)
75	FOODFL	Num	8	Imputed flag: (last food/drink date)

Num	Variable	Type	Len	Label
76	IMAGE2FL	Num	8	Imputed flag: (Image date)
77	PREGFL	Num	8	Imputed flag: (Date pregnancy test)
78	PREGDTM1FL	Num	8	Imputed flag: (date)
79	SCRNFL	Num	8	Imputed flag: (Date Screening Assessment)
80	SCRNDTM1FL	Num	8	Imputed flag: (date)
81	ECHODT	Num	8	Studyday of Studyday of (ECHO date)
82	FIBRODT	Num	8	Studyday of Studyday of (FIBROSCAN date)
83	FOODDT	Num	8	Studyday of Studyday of (last food/drink date)
84	IMAGE2DT	Num	8	Studyday of Studyday of (Image date)
85	PREGDT	Num	8	Studyday of Studyday of Date pregnancy test
86	PREGDTM1DT	Num	8	Studyday of Studyday of Date pregnancy test
87	SCRNDT	Num	8	Studyday of Studyday of Date Screening Assessment
88	SCRNDTM1DT	Num	8	Studyday of Studyday of Date Screening Assessment

Data Set Name: fibrosis_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	PERISIN	Num	8	Perisinusoidal
7	STAGE	Num	8	STAGE

Data Set Name: *gensmok6_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SMKINHA6	Num	8	Do you regularly inhale tobacco when smoking
7	PIPE6	Num	8	Smoking preference: Pipe
8	CIGARS6	Num	8	Smoking preference: Cigar
9	CIGARET6	Num	8	Smoking preference: Cigarette

Data Set Name: gensmoke_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	CIGARET	Num	8	Smoking preference: Cigarette
7	SMKLNTH	Num	8	How long did you smoke (in years)
8	CIGARS	Num	8	Smoking preference: Cigar
9	SMKINHAL	Num	8	Do you regularly inhale tobacco when smoking
10	PIPE	Num	8	Smoking preference: Pipe

Data Set Name: hbeag_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HBEAGRS	Num	8	HBeAg Result
7	HBEAGFL	Num	8	Imputed flag: HBeAg date
8	HBEAGDT	Num	8	Studyday of HBeAg date

Data Set Name: hbvdna_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HBVVAL	Num	8	HBV DNA Value
7	HBVUNIT	Num	8	HBV-DNA units
8	HBVRSLT	Num	8	HBV DNA results
9	HBVALNA	Num	8	Positive HBV DNA results
10	HBVFL	Num	8	Imputed flag: HBV DNA date
11	HBVDT	Num	8	Studyday of HBV DNA date

Data Set Name: *hcvrna_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HCVVAL	Num	8	HCV RNA Value
7	HCVALNA	Num	8	Positive HCV DNA results
8	HCVUNIT	Num	8	HCV RNA units
9	HCVRSLT	Num	8	HCV RNA results
10	HCVFL	Num	8	Imputed flag: HCV RNA date
11	HCVDT	Num	8	Studyday of HCV RNA date

Data Set Name: *hepabiop_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	HEPBIOP	Num	8	Not done OR Date
6	BIOPNO	Char	25	Biopsy No.
7	LENGSPEC	Num	8	Length of specimen
8	ADEQUATE	Num	8	Adequacy of biopsy
9	PERIPORT	Num	8	Periportal/inflammation
10	PINJURY	Num	8	Parenchymal injury
11	PORTINFL	Num	8	Portal inflammation
12	FIBROSIS	Num	8	Fibrosis (stage)
13	STEATOS	Num	8	Steatosis
14	FESTORE	Num	8	Iron storage
15	HEPBPFL	Num	8	Imputed flag: Biopsy date for hepatitis patients
16	HEPBPDT	Num	8	Studyday of Biopsy date for hepatitis patients

Data Set Name: hepainj_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	BALDEGEN	Num	8	Ballooning degeneration
6	APOPTOS	Num	8	Apoptosis
7	COAGLOC	Num	8	Coagulative necrosis location
8	COAGDGRE	Num	8	Coagulative necrosis degree
9	LOBDISRY	Num	8	Lobular disarray

Data Set Name: heplog_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HEPMED	Char	80	Medication
7	HEPCONT	Num	8	Continuing
8	HEPSPFL	Num	8	Imputed flag: Stop Date/Last Dose
9	HEPSTFL	Num	8	Imputed flag: Start Date
10	WHONAME	Char	80	Standardized Medication Name
11	WHOCODE	Char	11	WHO Drug Code
12	HEPSPDT	Num	8	Studyday of Stop Date/Last Dose
13	HEPSTDT	Num	8	Studyday of Start Date

Data Set Name: hepstat2_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HPMED2YN	Num	8	Non-implicated hepatitis meds since last visit

Data Set Name: *hepstat_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ANTHDVYN	Num	8	Anti-HDV result w/in 5 yrs not incl. this visit
7	HBEAGYN	Num	8	HBeAG result w/in 5 yrs not incl. this visit
8	HCVRNAYN	Num	8	HCV RNA result w/in 5 yrs not incl. this visit
9	ANTHBEYN	Num	8	Anti-HBe result w/in 5 yrs not incl. this visit
10	HEPMEDYN	Num	8	Non-implicated hepatitis med w/in 5 yrs Dili onset
11	HEPB	Num	8	Chronic Hepatitis B infection
12	HBVDNAYN	Num	8	HBV DNA result w/in 5 yrs not incl. this visit
13	DELTA	Num	8	Delta hepatitis
14	HEPC	Num	8	Chronic Hepatitis C infection

Data Set Name: hepstatc_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HEPAC	Num	8	Diagnosed with hepatitis C since last visit
7	HEPAB	Num	8	Diagnosed with hepatitis B since last visit
8	HBDNACYN	Num	8	Any HBV DNA results since last visit
9	HPMEDCYN	Num	8	Use non-implicated Hep C med since last visit
10	ATHBECYN	Num	8	Any Anti-HBe results since last visit
11	HCRNACYN	Num	8	Any HCV RNA results since last visit
12	HBAGCYN	Num	8	Any HBeAG results since last visit

Data Set Name: hivlog_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HIVCONT	Num	8	Continuing
7	HIVROUTE	Num	8	Route
8	HIVMED	Char	80	Medication
9	HIVDOSE	Char	5	Dose
10	HIVUNIT	Char	8	Unit
11	HIVFREQ	Num	8	Frequency
12	HIVSPFL	Num	8	Imputed flag: Stop date
13	HIVSTFL	Num	8	Imputed flag: Start date
14	WHONAME	Char	80	Standardized Medication Name
15	WHOCODE	Char	11	WHO Drug Code
16	HIVSPDT	Num	8	Studyday of Stop date
17	HIVSTDT	Num	8	Studyday of Start date

Data Set Name: *hivrna_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HIVRVAL	Num	8	HIV RNA Value
7	HIVRNAFL	Num	8	Imputed flag: HIV RNA date
8	HIVRNADT	Num	8	Studyday of HIV RNA date

Data Set Name: *hivstat1_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	EVIDYN03	Num	8	Syphilis by VDRL
7	HIVMEDYN	Num	8	Use non-impl anti-retrovirals-past 5 yrs
8	EVIDRS01	Num	8	Result: Active CMV infection
9	EVIDUK03	Num	8	Syphilis by VDRL: Unknown
10	EVIDUK01	Num	8	Active CMV infection: Unknown
11	EVIDUK05	Num	8	MAI infection: Unknown
12	HIVRNAYN	Num	8	Any available HIV RNA results within past 5 years
13	EVIDYN02	Num	8	Herpes simplex viral infection
14	EVIDUK04	Num	8	Syphilis by RPR: Unknown
15	EVIDRS02	Num	8	Result: Herpes simplex viral infection
16	URINSCRN	Num	8	Urine toxicology screen done
17	EVIDRS04	Num	8	Result: Syphilis by RPR
18	CD4RYN	Num	8	Any available CD4 results within past 5 years
19	EVIDYN01	Num	8	Active CMV infection
20	EVIDYN05	Num	8	MAI infection
21	EVIDYN04	Num	8	Syphilis by RPR
22	EVIDUK02	Num	8	Herpes simplex viral infection: Unknown
23	URINTOX	Num	8	Urine toxicology results
24	EVIDRS03	Num	8	Result: Syphilis by VDRL
25	EVIDRS05	Num	8	Result: MAI infection
26	EVIDPOS	Num	8	Positive? copies/mL
27	SEROYN	Num	8	Any pertinent serologies/serum levels performed
28	AIDS	Num	8	Did the condition progress to AIDS?
29	URINUNK	Num	8	Date of urine toxicology results: Unknown
30	AIDSDXFL	Num	8	Imputed flag: Date of AIDS diagnosis
31	EVIDFL01	Num	8	Imputed flag: Date of active CMV infection
32	EVIDFL02	Num	8	Imputed flag: Date of herpes simplex viral infection
33	EVIDFL03	Num	8	Imputed flag: Date of syphilis by VDRL
34	EVIDFL04	Num	8	Imputed flag: Date of syphilis by RPR
35	EVIDFL05	Num	8	Imputed flag: Date of MAI infection
36	URINFL	Num	8	Imputed flag: Date of results

Num	Variable	Type	Len	Label
37	AIDSDXDT	Num	8	Studyday of Date of AIDS diagnosis
38	EVIDDT01	Num	8	Studyday of Date of active CMV infection
39	EVIDDT02	Num	8	Studyday of Date of herpes simplex viral infection
40	EVIDDT03	Num	8	Studyday of Date of syphilis by VDRL
41	EVIDDT04	Num	8	Studyday of Date of syphilis by RPR
42	EVIDDT05	Num	8	Studyday of Date of MAI infection
43	URINDT	Num	8	Studyday of Date of results

Data Set Name: *hivstat2_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SERUMULN	Num	8	Serology ULN
7	SERUMUNT	Num	8	Serology unit
8	SERUM	Num	8	Serology type
9	SERORSLT	Char	100	Serology results
10	SEROTYPE	Char	80	Serology, other specify
11	SERUMVAL	Char	100	Serology value
12	SERUMFL	Num	8	Imputed flag: Serology Date
13	SERUMDT	Num	8	Studyday of Serology Date

Data Set Name: hivstat3_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	EVRTUK05	Num	8	MAI infection: Unknown
7	EVRTYN01	Num	8	Active CMV infection
8	EVIDRT04	Num	8	Result: Syphilis by RPR
9	EVRTYN02	Num	8	Herpes simplex viral infection
10	EVIDRT02	Num	8	Result: Herpes simplex viral infection
11	CD4RCYN	Num	8	Any available CD4 results since last visit
12	EVRTYN04	Num	8	Syphilis by RPR
13	EVID1VAL	Num	8	Value: Active CMV infection
14	EVIDRT05	Num	8	Result: MAI infection
15	EVRTYN03	Num	8	Syphilis by VDRL
16	EVRTUK03	Num	8	Syphilis by VDRL: Unknown
17	SEROCYN	Num	8	Any pertinent serologies/serum levels performed since the last visit
18	EVIDRT01	Num	8	Result: Active CMV infection
19	EVRTUK01	Num	8	Active CMV infection: Unknown
20	EVRTYN05	Num	8	MAI infection
21	HVRNACYN	Num	8	Any available HIV RNA results since the last visit
22	URTXYN	Num	8	Urine toxicology screen done since the last visit
23	EVIDRT03	Num	8	Result: Syphilis by VDRL
24	EVRTUK02	Num	8	Herpes simplex viral infection: Unknown
25	HVMEDCYN	Num	8	Use non-impl anti-retrovirals-last visit
26	URTXNK	Num	8	Date of urine toxicology results: Unknown
27	EVRTUK04	Num	8	Syphilis by RPR: Unknown
28	URTXSCR	Num	8	Urine toxicology results
29	EVRTFL01	Num	8	Imputed flag: Date of active CMV infection
30	EVRTFL02	Num	8	Imputed flag: Date of herpes simplex viral infection
31	EVRTFL03	Num	8	Imputed flag: Date of syphilis by VDRL
32	EVRTFL04	Num	8	Imputed flag: Date of syphilis by RPR
33	EVRTFL05	Num	8	Imputed flag: Date of MAI infection
34	URTXFL	Num	8	Imputed flag: Date of urine toxicology results
35	EVRTDT01	Num	8	Studyday of Date of active CMV infection
36	EVRTDT02	Num	8	Studyday of Date of herpes simplex viral infection

Num	Variable	Type	Len	Label
37	EVRTDT03	Num	8	Studyday of Date of syphilis by VDRL
38	EVRTDT04	Num	8	Studyday of Date of syphilis by RPR
39	EVRTDT05	Num	8	Studyday of Date of MAI infection
40	URTXDT	Num	8	Studyday of Date of urine toxicology results

Data Set Name: hivstat_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HIV	Num	8	Did the patient have known HIV infection
7	HIVDXFL	Num	8	Imputed flag: Date of HIV diagnosis
8	HIVDXDT	Num	8	Studyday of Date of HIV diagnosis

Data Set Name: hivstata_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SUBSTANC	Char	80	Positive substances from urine toxicology

Data Set Name: hivstatb_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	PSSBSTNC	Char	80	Positive test result substance

Data Set Name: *hivstatc_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HIVINF	Num	8	HIV infection at the last visit
7	HIVLV	Num	8	HIV infection since the last visit
8	AIDSLV	Num	8	HIV at last visit progressed to AIDS
9	AIDSPRO	Num	8	HIV since last visit and progressed to AIDS
10	AIDSFL	Num	8	Imputed flag: Date of HIV diagnosis
11	AIDSLVFL	Num	8	Imputed flag: Date of AIDS from HIV at last visit
12	HIVDIAFL	Num	8	Imputed flag: Date of AIDS from HIV since last visit
13	AIDSDT	Num	8	Studyday of Date of HIV diagnosis
14	AIDSLVDT	Num	8	Studyday of Date of AIDS from HIV at last visit
15	HIVDIADT	Num	8	Studyday of Date of AIDS from HIV since last visit

Data Set Name: hosphx_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HOSTYP	Num	8	Dates or total days in hospital
7	HOSLIVTS	Num	8	Liver function tests performed
8	HSDILIRD	Num	8	Hospitalization Dili related
9	HOSABIMG	Num	8	Abdominal imaging studies performed
10	HOSTOTNU	Num	8	Total days in hospital
11	HOSADMFL	Num	8	Imputed flag: Admitted date
12	HOSDISFL	Num	8	Imputed flag: Discharge date
13	HOSADMDT	Num	8	Studyday of Admitted date
14	HOSDISDT	Num	8	Studyday of Discharge date

Data Set Name: *hxinj1_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	DRGCAM	Num	8	Drug or CAM product
7	RECHCONT	Num	8	Rechallenged continued or stopped
8	RECHALL	Num	8	Rechallenged with the implicated drug/CAM
9	PRIORUSE	Num	8	Ever take this drug/CAM prior to this episode
10	DRGMANUF	Char	80	Name of drug/CAM manufacturer
11	IMPLDRUG	Char	80	Name of implicated drug/CAM
12	IMPLSPFL	Num	8	Imputed flag: Implicated drug stop date
13	IMPLSTFL	Num	8	Imputed flag: Implicated drug start date
14	RECHSPFL	Num	8	Imputed flag: Rechallenged Stop Date
15	RECHSTFL	Num	8	Imputed flag: Rechallenged Start Date
16	WHONAME	Char	80	Standardized Medication Name
17	WHOCODE	Char	11	WHO Drug Code
18	IMPLSPDT	Num	8	Studyday of Implicated drug stop date
19	IMPLSTDT	Num	8	Studyday of Implicated drug start date
20	RECHSPDT	Num	8	Studyday of Rechallenged Stop Date
21	RECHSTDT	Num	8	Studyday of Rechallenged Start Date

Data Set Name: *hxinj2_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	LIVTRX	Num	8	Liver transplant performed for this injury
7	HEPAOTHR	Num	8	Other manifestation
8	HOSPITAL	Num	8	Hospitalized for this liver injury
9	DISRUPT	Num	8	Disruption to daily living
10	PREVDX	Num	8	Previously diagnosed with a Dili event
11	GIHEP	Num	8	Seen by gastroenterologist/hepatologist for Dili event
12	THRMBPEN	Num	8	Thrombocytopenia
13	PTSICK	Num	8	How long sick with this injury
14	NEUTRPEN	Num	8	Neutropenia
15	SJSYNDRM	Num	8	Stevens-Johnson syndrome
16	LIVBIOP	Num	8	Liver biopsy performed for this injury
17	SERUMSCK	Num	8	Serum Sickness
18	NECROLY	Num	8	Toxic epidermal necrolysis
19	HMANEMIA	Num	8	Hemolytic anemia
20	DISRUPSP	Num	8	Length of disruption
21	STEROIDS	Num	8	Receive prednisone or corticosteroids for this injury
22	HEPATIC	Num	8	Extrahepatic manifestation
23	PRLGHOSP	Num	8	Non-Dili hospitalization prolonged by Dili event
24	PREGNANT	Num	8	Pregnant during the Dili event
25	BIOPFL	Num	8	Imputed flag: Date of Liver biopsy
26	ONSETFL	Num	8	Imputed flag: Date of onset of qualifying lab abnormal
27	PRESNFL	Num	8	Imputed flag: Date of first presentation of liver problems to health care provider
28	STERFL	Num	8	Imputed flag: Steroid Date
29	TRXFL	Num	8	Imputed flag: Liver Transplant Date
30	BIOPDT	Num	8	Studyday of Date of Liver biopsy
31	ONSETDT	Num	8	Studyday of Date of onset of qualifying lab abnormal
32	PRESNDT	Num	8	Studyday of Date of first presentation of liver problems to health care provider
33	STERDT	Num	8	Studyday of Steroid Date
34	TRXDT	Num	8	Studyday of Liver Transplant Date

Data Set Name: image_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	IMGSPNA	Num	8	Spleen diameter: Not applicable
7	IMGOTH	Num	8	Other
8	BILIARY	Num	8	Biliary dilation
9	ASCITES	Num	8	Ascites
10	IMSPLNO	Num	8	Splenomegaly
11	IMGSPN	Num	8	Spleen diameter
12	IMHEPATO	Num	8	Hepatomegaly
13	VARCIES	Num	8	Intra-abdominal varcies
14	NORMAL1	Num	8	Normal study
15	IMAGTYPE	Num	8	Type of Study
16	TUMOR	Num	8	Liver Tumor
17	NODULAR	Num	8	Nodular contour of liver
18	GALLSTON	Num	8	Gallstones
19	IMAGEFL	Num	8	Imputed flag: Date of study
20	IMAGEDT	Num	8	Studyday of Date of study

Data Set Name: inflamm_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	INTERFACE	Num	8	Interface hepatitis
6	LOBULAR	Num	8	Lobular inflammation
7	PORTAL	Num	8	Portal inflammation
8	GRANULOM	Num	8	Granulomas
9	PLASMA	Num	8	Plasma cells
10	EOSINO	Num	8	Eosinophils
11	NEUTRO	Num	8	Neutrophils
12	LYMPHOID	Num	8	Lymphoid aggregates
13	NECROSIS	Num	8	Bridging necrosis
14	LIPOGRAN	Num	8	Lipogranulomas
15	CONNECRO	Num	8	Confluent necrosis

Data Set Name: *inthx_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	PMEDHX	Num	8	Medical history changed since last visit
7	PLIVHX	Num	8	Liver-specific medical history changed
8	PSRGYHX	Num	8	Surgical history changed since last visit
9	PALGYHX	Num	8	Allergy history changed since last visit

Data Set Name: *judgmnt_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	CAUSPROC	Char	32	Causality process
5	SEQNO	Num	8	Implicated Drug sequence number
6	FORM	Char	20	Form
7	ASSESS	Num	8	What is your assessment of the causal relationship
8	ASSESSMT	Num	8	Implicated Drug assessment
9	REVIEW	Num	8	Reviewer
10	RVCODE	Char	30	Reviewer Code
11	SEVERITY	Num	8	DILIN's Severity Score
12	SYMPTOMATIC	Num	8	Case is symptomatic or asymptomatic
13	IMPLDRUG	Char	128	Name of implicated drug/CAM
14	WHONAME	Char	128	Implicated Drug WHO Drug Name
15	WHOCODE	Char	32	Implicated Drug WHO Drug Code
16	ALTDIAG	Char	100	Alternative diagnosis, possible/unlikely case
17	ALTDIAGSP	Char	100	Alternative diagnosis, other specify
18	DTH_DILI	Num	8	Death due to DILI
19	REASMT_RSN	Char	100	Re-assessment Reason
20	TRANSPLANT_LISTING	Char	100	TRANSPLANT_LISTING
21	TRANSPLANT_DISPOSITION	Char	100	TRANSPLANT_DISPOSITION
22	PATIENT_VITAL_STATUS	Char	100	PATIENT_VITAL_STATUS
23	DEATH_REVIEWER_A	Char	200	DEATH_REVIEWER_A
24	DEATH_REVIEWER_B	Char	200	DEATH_REVIEWER_B
25	CMTE_CAUSE_OF_DEATH	Char	200	CMTE_CAUSE_OF_DEATH
26	CMTE_CAUSE_OF_DEATH_COMMENTS	Char	1000	CMTE_CAUSE_OF_DEATH_COMMENTS
27	CMTE_TRANSPLANT_LISTING	Char	200	CMTE_TRANSPLANT_LISTING
28	CMTE_TRANSPLANT_DISPOSITION	Char	200	CMTE_TRANSPLANT_DISPOSITION
29	CMTE_DILI_ROLE	Char	200	CMTE_DILI_ROLE
30	CMTE_TRANSPLANT_COMMENTS	Char	1000	CMTE_TRANSPLANT_COMMENTS
31	CMTE_CAUSE_OF_DEATH_SPECIFY	Char	100	CMTE_CAUSE_OF_DEATH_SPECIFY
32	CMTE_TRANSPLANT_LISTNG_SPECIFY	Char	100	CMTE_TRANSPLANT_LISTNG_SPECIFY
33	CMTE_TRANSPLANT_DISP_SPECIFY	Char	100	CMTE_TRANSPLANT_DISP_SPECIFY
34	HDS_CLASSIFICATION_PRIMARY	Char	100	HDS_CLASSIFICATION_PRIMARY
35	HDS_CLASSIFICATION_SECONDARY	Char	100	HDS_CLASSIFICATION_SECONDARY
36	HDS_CLASSIFICATION_ANCILLARY	Char	100	HDS_CLASSIFICATION_ANCILLARY

Num	Variable	Type	Len	Label
37	DRUG_CLASSIFICATION_PRIMARY	Char	100	DRUG_CLASSIFICATION_PRIMARY
38	DRUG_CLASSIFICATION_SECONDARY	Char	100	DRUG_CLASSIFICATION_SECONDARY
39	DRUG_CLASSIFICATION_TERTIARY	Char	100	DRUG_CLASSIFICATION_TERTIARY
40	ASSESSFL	Num	8	Imputed flag: Date completed
41	ASSESSDT	Num	8	Studyday of Date completed

Data Set Name: labflow_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	SEQNO	Num	8	CRF Sequence number
6	VISITID	Num	8	Inform generated visit number
7	INR	Num	8	INR Not done
8	FLWRATIO	Num	8	(ALTVAL/ALTULN)/(AKPVAL/AKPULN)
9	ASTVAL	Num	8	AST Value
10	ASTCALC	Num	8	AST VAL/ULN
11	STBVAL	Num	8	Serum Total Bilirubin Value
12	AST	Num	8	AST Not done
13	INRRATE	Num	8	INR ratio
14	AKPULN	Num	8	Alkaline Phosphatase ULN
15	ASTULN	Num	8	AST ULN
16	STBULN	Num	8	Serum Total Bilirubin ULN
17	STBUNIT	Num	8	Serum Total Bilirubin Units
18	ALTULN	Num	8	ALT ULN
19	ALTVAL	Num	8	ALT Value
20	AKPVAL	Num	8	Alkaline Phosphatase Value
21	AKPCALC	Num	8	AKP VAL/ULN
22	ALTCALC	Num	8	ALT VAL/ULN
23	STB	Num	8	Serum Total Bilirubin Not done
24	AKP	Num	8	Alkaline Phosphatase Not done
25	ALT	Num	8	ALT Not done
26	STBCALC	Num	8	STB VAL/ULN
27	FCLABFL	Num	8	Imputed flag: Liver Test Date
28	FCLABDT	Num	8	Studyday of Liver Test Date

Data Set Name: livhx_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	MEDLIVHX	Num	8	Type of Liver Disease
7	LACTIVE	Num	8	Active condition

Data Set Name: mckesson_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	10	Visit
5	ALTID	Char	25	Alternate ID Number
6	VISITID	Num	8	Inform generated visit number

Data Set Name: medhx1_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ACTIVE	Num	8	Active condition
7	PASTHX	Num	8	Past Medical History

Data Set Name: medhx2_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	MEDHXYN	Num	8	History of medical conditions/diseases
7	PHQCOMP	Num	8	PHQ completed by
8	PHQYN	Num	8	PHQ completed
9	SURGERY	Num	8	Surgery
10	ALLERGY	Num	8	History of allergies
11	IMAGEYN	Num	8	Imaging studies performed
12	LIVHXYN	Num	8	History of liver conditions

Data Set Name: medhx3_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ERHX	Num	8	Admitted to emergency room since last visit
7	PHYSLV	Num	8	Seen by other physician since last visit
8	HOSHX	Num	8	Admitted to hospital since last visit

Data Set Name: medout_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	LIVTRANS	Num	8	Has the patient undergone a liver transplant
5	VISIT	Char	63	Inform visit name
6	VISITID	Num	8	Inform generated visit number
7	EXLSTVI	Num	8	Has the patient expired since the last visit
8	TRANSFL	Num	8	Imputed flag: Date of transplant
9	TRANSDT	Num	8	Studyday of Date of transplant

Data Set Name: pattern_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	PATINJUR	Num	8	Pattern of Injury

Data Set Name: *pex1_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	HRATE	Num	8	Heart rate
7	BPDIA	Num	8	Blood pressure: diastolic (mmHg)
8	WT	Num	8	Weight
9	HTUN	Num	8	Height units
10	BPSYS	Num	8	Blood pressure: systolic (mmHg)
11	HT	Num	8	Height
12	WTUN	Num	8	Weight units
13	PHEXFL	Num	8	Imputed flag: Date of examination
14	PHEXDT	Num	8	Studyday of Date of examination

Data Set Name: pex2_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ASSESS10	Num	8	Extremities
7	ASSESS01	Num	8	General appearance
8	ASSESS07	Num	8	Spleen
9	ASSESS03	Num	8	Neck
10	ASSESS09	Num	8	Lymph nodes
11	ASSESS05	Num	8	Lungs
12	ASSESS11	Num	8	Neurological
13	ASSESS02	Num	8	Head, eyes, ears, nose, throat
14	ASSESS12	Num	8	Skin
15	ASSESS06	Num	8	Abdomen
16	ASSESS04	Num	8	Heart
17	ASSESS13	Num	8	Musculoskeletal
18	ASSESS14	Num	8	Other
19	ASSESS08	Num	8	Liver

Data Set Name: pharm1_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	OTHRPHRX	Num	8	Other type
7	NATIONLX	Num	8	National pharmacy chain
8	PHARMSPX	Num	8	# times received samples from doctors
9	CLINICX	Num	8	Hospital or clinic-based pharmacy
10	DIFFPHRX	Num	8	During last 12 mo, # of pharmacies used
11	FILLPHRX	Num	8	Is there one pharmacy where you usually
12	MAILX	Num	8	Mail-order pharmacy
13	LOCAL1X	Num	8	Local independently owned pharmacy
14	UNSUREX	Num	8	Do not know/unsure
15	SAMPLESX	Num	8	During last 12 mo, doctor give samples

Data Set Name: *pharmacy_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	MAIL	Num	8	Mail-order pharmacy
7	FILLPHAR	Num	8	pharmacy where you usually go to fill most of prescriptions
8	DIFFPHAR	Num	8	how many different pharmacies During the last 12 months
9	LOCAL1	Num	8	Local independently owned pharmacy
10	NATIONAL1	Num	8	National pharmacy chain
11	UNSURE	Num	8	Do not know/unsure
12	OTHRPHAR	Num	8	Other type
13	SAMPLES	Num	8	give you samples of medications During the last 12 months
14	PHARMSMP	Num	8	how many times received samples from doctors office
15	CLINIC	Num	8	Hospital or clinic-based pharmacy

Data Set Name: phxq12_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	PHQ12A	Num	8	Q12A - Have you ever had direct contact with patient fluids/secretions
7	PHQ12B	Num	8	Q12B - Have you ever had history of needle stick exposure or injury at work

Data Set Name: phxq1_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	PHQ06S	Num	8	Is the meat usually well cooked
7	PHQ01	Num	8	Q1 - Do you currently have any pets at home
8	PHQCAT	Num	8	Cat
9	PHQWKP	Num	8	Informal workplace or school exposure
10	PHQ12	Num	8	Q12 - Are you a health care worker involves direct contact with patients
11	PHQ03	Num	8	Q3 - Did you travel and stay outside of your home
12	PHQ10	Num	8	Q10 - Have you ever used injection drugs
13	PHQOTHR	Num	8	Other
14	PHQBIRD	Num	8	Bird
15	PHQ04	Num	8	Q4 - What is your main source of drinking water
16	PHQ11	Num	8	Q11 - Have you ever snorted or sniffed cocaine or crack
17	PHQ05	Num	8	Q5 - Do you ever eat raw or undercooked meats
18	PHQFER	Num	8	Ferret
19	PHQ06	Num	8	Q6 - Do you ever eat the internal organs of animals
20	PHQEXP	Num	8	Household exposure such as to siblings or children
21	PHQ09	Num	8	Q9 - Have you ever received a blood transfusion
22	PHQPIG	Num	8	Pig
23	PHQ14	Num	8	Q14 - Have you ever been exposed to someone with hepatitis
24	PHQOTH	Char	255	Other
25	PHQ02	Num	8	Q2 - did you have any direct contact farm/wild animals?
26	PHQ13	Num	8	Q13 - Have you ever had any direct occupational contact with animal fluid
27	PHQ07	Num	8	Q7 - Do you ever eat meat that you or others have hunted
28	PHQPART	Num	8	Spouse or Sexual Partner
29	PHQ01PET	Num	8	How many pets
30	PHQDOG	Num	8	Dog

Data Set Name: phxq2_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	PHQ02A	Num	8	Q 2 - Type of Animal

Data Set Name: phxq3_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	PHQ3TAR	Num	8	Type of Area

Data Set Name: *phxq8_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	PHQ8G	Num	8	g - Innards or offal
7	PHQ8M	Num	8	m - Wild Boar
8	PHQ8J	Num	8	j - Beef, raw or rare
9	PHQ8C	Num	8	c - Crabs
10	PHQ8I	Num	8	I - Pork, raw or rare
11	PHQ8K	Num	8	k - Lamb, raw or rare
12	PHQ8B	Num	8	b - Raw or undercooked Shellfish
13	PHQ8E	Num	8	e - Other Crustaceans
14	PHQ8Q	Num	8	q - Other
15	PHQ8L	Num	8	l - Goat meat, raw or rare
16	PHQ8O	Num	8	o - Pig Liver
17	PHQ8F	Num	8	f - Unpasteurized Milk Products
18	PHQ8P	Num	8	p - Beef Liver
19	PHQ8N	Num	8	n - Other wild meat
20	PHQ8H	Num	8	h - Chicken, raw or rare
21	PHQ8A	Num	8	a - Raw Eggs
22	PHQ8D	Num	8	d - Lobsters

Data Set Name: *ptcompl_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SPLVTX	Num	8	Post liver transplant complications
7	CEREDEMA	Num	8	Cerebral edema
8	HEPATOCA	Num	8	Hepatocellular carcinoma
9	CHRONARR	Num	8	EOS Clinical Narrative sent to DCC
10	REASON	Num	8	Primary reason
11	SEPSIS	Num	8	Sepsis
12	RENLFAIL	Num	8	Renal failure
13	LRDTHOTH	Num	8	Other
14	FALF	Num	8	Fulminant/acute liver failure
15	VARCIBLD	Num	8	Variceal bleeding
16	NONDILI	Num	8	Non-DILI case
17	STUDYCOM	Num	8	Did the participant complete the study?
18	NLLRDTH	Num	8	Non liver or liver-related death
19	COMPLFL	Num	8	Imputed flag: End of study date
20	DEATHFL	Num	8	Imputed flag: Date of death
21	COMPLDT	Num	8	Studyday of End of study date
22	DEATHDT	Num	8	Studyday of Date of death

Data Set Name: *ptlexmpt_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	PTEX1	Num	8	Was the patient more than 2 years of age at the time of enrollment?
7	PTEX4	Num	8	If ALT, AST, or AP was normal prior to the implicated drug start date, was ALT or AST $> 5 \times$ ULN or AP $> 2 \times$ ULN on at least 2 consecutive blood draws?
8	PTEX19	Num	8	Specify AP above the ULN
9	PTEX12	Num	8	Did the patient have any elevation of serum ALT, AST, or AP above the ULN, associated with increased serum total bilirubin (> 2.5 mg/dL), absent of prior diagnosis of liver disease, Gilberts syndrome
10	PTEX7	Num	8	Was AP $> 2 \times$ ULN on at least 2 consecutive blood draws?
11	PTEX8	Num	8	If ALT, AST, or AP was elevated prior to the implicated drug start date, was ALT or AST $> 5 \times$ pre-drug average or AP $> 2 \times$ pre-drug average on at least 2 consecutive blood draws?
12	PECHG	Num	8	Did the inclusion/exclusion criteria change since enrollment?
13	PTEX16	Num	8	Did the patient have any elevation of serum ALT, AST, or AP above the ULN, associated with coagulopathy with INR > 1.5 , absent of coumadin therapy or known vitamin K deficiency?
14	PTEX25	Num	8	Was the patient previously enrolled?
15	PTEX22	Num	8	Did the patient have acetaminophen hepatotoxicity?
16	PTEX2	Num	8	Did the patient have evidence of liver injury that is known or suspected to be related to a drug product or to a CAM product in the 6 months prior to enrollment?
17	PTEX21	Num	8	Did the patient have a known, pre-existing liver problem that may confound the ability to make a diagnosis of DILI?
18	PTEX3	Num	8	Was the patient/legal guardian willing to sign informed consent?
19	PTEX24	Num	8	Eligibility
20	PTEX11	Num	8	Was AP $> 2 \times$ pre-drug average on at least 2 consecutive blood draws?
21	PTEX20	Num	8	Did the patient have a competing identifiable cause of acute liver injury that was felt to be the primary reason for the observed liver injury, supported by laboratory test, serologies, liver biopsy,
22	PTEX13	Num	8	Specify ALT above the ULN
23	PTEX9	Num	8	Was ALT $> 5 \times$ pre-drug average on at least 2 consecutive blood draws?
24	PTEX18	Num	8	Specify AST above the ULN
25	PTEX5	Num	8	Was ALT $> 5 \times$ ULN on at least 2 consecutive blood draws?
26	PTEX6	Num	8	Was AST $> 5 \times$ ULN on at least 2 consecutive blood draws?
27	PTEX23	Num	8	Did the patient have a liver/organ transplant prior to development of drug- or CAM-induced injury?
28	PTEX15	Num	8	Specify AP above the ULN
29	PTEX14	Num	8	Specify AST above the ULN
30	PTEX10	Num	8	Was AST $> 5 \times$ pre-drug average on at least 2 consecutive blood draws?
31	PTEX17	Num	8	Specify ALT above the ULN

Data Set Name: quests2_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	ALCOHOLX	Num	8	Since last visit, >= 1 drink of alcohol
7	SURRO4	Num	8	Surrogate respondent
8	QUITSMKM	Num	8	How many months since you quit smoking?
9	SMOKE6	Num	8	Since last visit, smoking habit

Data Set Name: *quests_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SMOKE	Num	8	Over the past 5 years, smoking habit
7	QUITSMKE	Num	8	How many years since you quit smoking?
8	ALCOHOL	Num	8	Over the past 5 yrs, drank alcohol
9	SURRO3	Num	8	Surrogate respondent
10	FILLRX	Num	8	During the last 12 mo, fill prescription

Data Set Name: randhs1_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	LIMIT02	Num	8	(Q4) Moderate activities
7	LIMIT05	Num	8	(Q7) Climbing one flight of stairs
8	HLTHNOW	Num	8	(Q2) how would you rate your health in general now
9	LIMIT06	Num	8	(Q8) Bending, kneeling or stooping
10	LIMIT01	Num	8	(Q3) Vigorous activities
11	LIMIT03	Num	8	(Q5) Lifting or carrying groceries
12	HEALTH	Num	8	(Q1) In general, would you say your health
13	LIMIT08	Num	8	(Q10) Walking several blocks
14	LIMIT04	Num	8	(Q6) Climbing several flights of stairs
15	LIMIT07	Num	8	(Q9) Walking more than a mile
16	LIMIT09	Num	8	(Q11) Walking one block
17	LIMIT10	Num	8	(Q12) Bathing or dressing yourself

Data Set Name: randhs2_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	WORKANS3	Num	8	(Q15) Were limited in the kind of work or activities
7	BODYPAIN	Num	8	(Q21) How much bodily pain have you had during the past 4 weeks
8	WORKANS6	Num	8	(Q18) Accomplished less than you would like
9	WORKANS4	Num	8	(Q16) Had difficulty performing the work or activities
10	HLTHPROB	Num	8	(Q20) what extent has your physical health or emotional problems interfered with normal
11	PAINWORK	Num	8	(Q22) how much did pain interfere with your normal work
12	WORKANS5	Num	8	(Q17) Cut down on the amount of time you spent on work or activities
13	WORKANS7	Num	8	(Q19) Didn't do work or other activities as carefully as usual
14	WORKANS1	Num	8	(Q13) Cut down on the amount of time you spent on work or activities
15	WORKANS2	Num	8	(Q14) Accomplished less than you would like

Data Set Name: randhs3_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	FEELANS5	Num	8	(Q27) Did you have a lot of energy
7	FEELANS7	Num	8	(Q29) Did you feel worn out
8	TRFSANS4	Num	8	(Q36) My health is excellent
9	FEELANS1	Num	8	(Q23) Did you feel full of pep
10	FEELANS2	Num	8	(Q24) Have you been a very nervous person
11	TRFSANS2	Num	8	(Q34) I am as healthy as anybody I know
12	FEELANS3	Num	8	(Q25) Have you felt so down in the dumps that nothing could cheer you up
13	FEELANS8	Num	8	(Q30) Have you been a happy person
14	TRFSANS3	Num	8	(Q35) I expect my health to get worse
15	FEELANS9	Num	8	(Q31) Did you feel tired
16	HLTHSOCL	Num	8	(Q32) how much of the time has your physical health or emotional problems interfered
17	TRFSANS1	Num	8	(Q33) I seem to get sick a little easier than other people
18	FEELANS4	Num	8	(Q26) Have you felt calm and peaceful
19	FEELANS6	Num	8	(Q28) Have you felt downhearted and blue

Data Set Name: rsample_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	BLDSAMP	Num	8	Blood sample provided?
7	LVBIOPYN	Num	8	Did the subject receive a liver biopsy
8	URNSAMP	Num	8	Urine sample provided?
9	BLOODFL	Num	8	Imputed flag: Date of blood collection
10	URINEFL	Num	8	Imputed flag: Date of urine collection
11	BLOODDT	Num	8	Studyday of Date of blood collection
12	URINEDT	Num	8	Studyday of Date of urine collection

Data Set Name: rucdr_ct_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	SHIPSTAT	Char	5	Shipment Status
5	DNAYLD	Char	9	DNA Yield (ug)
6	TOTALTUB	Char	256	TOTALTUB
7	VOLUME	Char	256	VOLUME
8	ALTID	Char	32	Alternate ID Number
9	CRYODT	Num	8	Studyday of Cryopreserved Date
10	RUCDRDT	Num	8	Studyday of Blood Received Date
11	SAMPLEDT	Num	8	Studyday of Sample Drawn Date

Data Set Name: rxcomply_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	FREQMORE	Num	8	Do you ever take medications more frequently than prescribed
7	FREQLESS	Num	8	Do you ever take medications less frequently than prescribed
8	FOLLOW	Num	8	how closely do you usually follow the medication schedule
9	SURRO1	Num	8	Surrogate respondent

Data Set Name: saqsympt_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SYMPSC4	Num	8	Poor appetite
7	SYMPSC9	Num	8	Skin rash
8	SYMPSC2	Num	8	Nausea
9	SYMPSC3	Num	8	Pain over the liver area
10	SYMPSC1	Num	8	Tired or fatigued
11	SYMPSC7	Num	8	Itching of the skin
12	SYMPSC5	Num	8	Muscle/joint aches or pains
13	SYMPSC8	Num	8	Fever and chills
14	SYMPSC6	Num	8	Weakness of the arms or legs
15	SYMPSC10	Num	8	Depressed/sadness
16	SYMPSC11	Num	8	How you feel overall

Data Set Name: scr_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	INEX6A	Num	8	Elevated LFT tests w/increased STB (>2.5 mg/dL)
7	INEXC5	Num	8	LFT elevated prior to implicated drug/CAM and were > pre-drug average on consecutive draws
8	INEXC9	Num	8	Acetaminophen hepatotoxicity
9	INEXC10	Num	8	Liver or allogeneic bone marrow transplant prior to development of drug/CAM induced injury
10	INEXC5B	Num	8	AST>5 x pre-drug average on at least 2 consecutive draws
11	ELIGIBLE	Num	8	Eligibility
12	INEXB6C	Num	8	AKP above the ULN w/coagulopathy w/INR>1.5
13	INEXC3	Num	8	Willing to sign informed consent
14	INEXA6C	Num	8	AKP above the ULN w/increased STB (>2.5 mg/dL)
15	INEXC2	Num	8	Evidence of liver injury suspected to be drug/CAM related 6 months prior to enrollment
16	INEXC4C	Num	8	AKP>2 x ULN on at least 2 consecutive draws
17	INEXC1	Num	8	More than 2 years of age at enrollment
18	INEXC4B	Num	8	AST>5 x ULN on at least 2 consecutive draws
19	INEXC5A	Num	8	ALT>5 x pre-drug average on at least 2 consecutive draws
20	INEXC4	Num	8	LFT normal prior to implicated drug/CAM and were LFT elevated on consecutive draws
21	INEXC8	Num	8	Known, pre-existing liver problem
22	INEXB6B	Num	8	AST above the ULN w/coagulopathy w/INR>1.5
23	INEXC7	Num	8	Competing identifiable cause of acute liver injury
24	INEXA6A	Num	8	ALT above the ULN w/increased STB (>2.5 mg/dL)
25	INEXC4A	Num	8	ALT>5 x ULN on at least 2 consecutive draws
26	INEXC12	Num	8	Agreement that biological specimens may be used in genetic research
27	INEXB6A	Num	8	ALT above the ULN w/coagulopathy w/INR>1.5
28	INEX6B	Num	8	Elevated LFT tests w/coagulopathy w/INR>1.5
29	INEXC11	Num	8	Agreement that biological samples may be used in genetic research
30	INEXA6B	Num	8	AST above the ULN w/increased STB (>2.5 mg/dL)
31	INEXC5C	Num	8	AKP>2 x pre-drug average on at least 2 consecutive draws

Data Set Name: seroflow_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SEROLAB	Num	8	Serology type
7	SERTHVAL	Num	8	Threshold value
8	SERTRULN	Num	8	Threshold for positive results
9	SEROVIS	Num	8	Serology available?
10	SEROVAL	Num	8	Serology value
11	SEROIFEL	Num	8	Type of test
12	SERNPUNK	Num	8	Results
13	SEROFL	Num	8	Imputed flag: Date of serology
14	SERODT	Num	8	Studyday of Date of serology

Data Set Name: *sign_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SIGNNA	Num	8	Date of Signs and Symptoms Onset
7	SGNRES	Num	8	Signs and Symptoms
8	SGNSYMFL	Num	8	Imputed flag: Date of Signs and Symptoms Onset
9	SGNSYMDT	Num	8	Studyday of Studyday of Date of Signs and Symptoms Onset

Data Set Name: *skinner_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	DEATH	Num	8	Death
7	FAM	Num	8	Marital/Family
8	SOLDAGE	Num	8	Age Range Young to old - To
9	LIQUOR	Num	8	Liquor - % of alcohol consumption
10	MEDICAL	Num	8	Medical
11	EMOTION	Num	8	Emotional
12	STYLE	Num	8	Style
13	AVERAGE	Num	8	Average
14	JOB	Num	8	Work
15	SKFREQ	Num	8	Frequency
16	DRGABUSE	Num	8	Drug abuse
17	WINEY	Num	8	Wine Use
18	WINE	Num	8	Wine - % of alcohol consumption
19	FINANCE	Num	8	Financial
20	LIQUORY	Num	8	Liquor Use
21	SCHOOL	Num	8	Work
22	TREATMNT	Num	8	Treatment
23	BEERY	Num	8	Beer Use
24	BEER	Num	8	Beer - % of alcohol consumption
25	LIFEVNT	Num	8	Any Life Events that Influenced Drinking
26	MAXIMUM	Num	8	Maximum
27	RESIDENC	Num	8	Residence
28	SYNGAGE	Num	8	Age Range Young to old - From
29	PHASE2	Num	8	Phase of alcohol consumption
30	PEER	Num	8	Peer group
31	LEGAL	Num	8	Legal/jail

Data Set Name: *smokehx_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	PIPEPWK	Num	8	Pipes Per Week
7	OLDAGE	Num	8	Oldest Age
8	CIGPDAY	Num	8	Cigarettes Per Day
9	PHASE	Num	8	Phase
10	CIGPWK	Num	8	Cigars Per Week
11	YOUNGAGE	Num	8	Youngest Age

Data Set Name: stain_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	HEPAIRON	Num	8	Iron stain-hepatocellular iron
7	SINUIRON	Num	8	Iron stain-sinusoidal reticuloendothelia
8	HEPACOPP	Num	8	Copper stain-hepatocellular copper
9	PASMACRO	Num	8	PAS/diastase stain-PAS-positive macropha
10	PASHEPA	Num	8	PAS/diastase stain-PAS-positive hepatoce

Data Set Name: *stdflow_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	SEQNO	Num	8	CRF Sequence number
6	VISITID	Num	8	Inform generated visit number
7	SDBVAL	Num	8	Value - Serum direct bilirubin
8	CREAT	Num	8	Serum creatinine
9	HGBVAL	Num	8	Value - Hemoglobin
10	STDULN	Num	8	ULN - Serum direct bilirubin
11	EOSINVAL	Num	8	Value - % Eosinophils
12	WBCVAL	Num	8	Value - WBC
13	CRETVALU	Num	8	Unit - Serum creatinine
14	ALBUNVAL	Num	8	Value - Serum Albumin
15	EOSIVALU	Num	8	Units - % Eosinophils
16	EOSIN	Num	8	% Eosinophils
17	PLATE	Num	8	Blood platelets
18	SDB	Num	8	Serum direct bilirubin
19	PLATEVAL	Num	8	Value - Blood platelets
20	ALBUVALU	Num	8	Unit - Serum Albumin
21	CREATVAL	Num	8	Value - Serum creatinine
22	SDBVALU	Num	8	Unit - Serum direct bilirubin
23	HGB	Num	8	Hemoglobin
24	WBC	Num	8	WBC
25	ALBUN	Num	8	Serum albumin
26	STFLABFL	Num	8	Imputed flag: Date Lab sample
27	STFLABDT	Num	8	Studyday of Date Lab sample

Data Set Name: stdlab2_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	LABULN23	Num	8	ULN - Lipase
7	LABVAL13	Num	8	Value - Serum total protein
8	LABULN25	Num	8	ULN - GGTP
9	LABNAM22	Num	8	Amylase
10	LABVAL26	Num	8	Value - LDH
11	LABUNT13	Num	8	Unit - Serum total protein
12	LABULN26	Num	8	ULN - LDH
13	LABVAL15	Num	8	Value - INR
14	LABNAM25	Num	8	GGTP
15	LABNAM23	Num	8	Lipase
16	LABNAM18	Num	8	Serum direct bilirubin
17	LABVAL23	Num	8	Value - Lipase
18	LABUNT18	Num	8	Unit - Serum direct bilirubin
19	LABULN21	Num	8	ULN - Alkaline Phosphatase
20	LABULN19	Num	8	ULN - AST
21	LABULN18	Num	8	ULN - Serum direct bilirubin
22	LABNAM26	Num	8	LDH
23	LABNAM21	Num	8	Alkaline Phosphatase
24	LABVAL18	Num	8	Value - Serum direct bilirubin
25	LABVAL17	Num	8	Value - Serum total bilirubin
26	LABVAL20	Num	8	Value - ALT
27	LABNAM13	Num	8	Serum total protein
28	LABULN22	Num	8	ULN - Amylase
29	LABNAM17	Num	8	Serum total bilirubin
30	LABVAL24	Num	8	Value - CPK
31	LABNAM24	Num	8	CPK
32	LABVAL19	Num	8	Value - AST
33	LABUNT17	Num	8	Unit - Serum total bilirubin
34	LABUNT14	Num	8	Unit - Serum albumin
35	LABVAL21	Num	8	Value - Alkaline Phosphatase
36	LABNAM14	Num	8	Serum albumin

Num	Variable	Type	Len	Label
37	LABVAL25	Num	8	Value - GGTP
38	LABNAM20	Num	8	ALT
39	LABVAL22	Num	8	Value - Amylase
40	LABVAL16	Num	8	Value - Prothrombin time
41	LABNAM15	Num	8	INR
42	LABULN24	Num	8	ULN - CPK
43	LABNAM16	Num	8	Prothrombin time
44	LABNAM19	Num	8	AST
45	LABULN20	Num	8	ULN - ALT
46	LABVAL14	Num	8	Value - Serum albumin
47	LABULN17	Num	8	ULN - Serum total bilirubin

Data Set Name: stdlab_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	LABNAM02	Num	8	WBC
7	LABUNT11	Num	8	Unit - Cholesterol
8	LABNAM03	Num	8	Blood platelets
9	LABNAM07	Num	8	Sodium
10	LABNAM05	Num	8	% Lymphocytes
11	LABVAL05	Num	8	Value - % Lymphocytes
12	LABVAL04	Num	8	Value - % Neutrophils
13	LABUNT10	Num	8	Unit - BUN
14	LABNAM08	Num	8	Potassium
15	LABNAM11	Num	8	Cholesterol
16	LABUNT09	Num	8	Unit - Serum creatinine
17	LABVAL10	Num	8	Value - BUN
18	LABVAL07	Num	8	Value - Sodium
19	LABNAM12	Num	8	Triglycerides
20	LABNAM09	Num	8	Serum creatinine
21	LABVAL02	Num	8	Value - WBC
22	LABVAL01	Num	8	Value - Hemoglobin
23	LABUNT12	Num	8	Unit - Triglycerides
24	LABVAL08	Num	8	Value - Potassium
25	LABUNT06	Num	8	Unit - % Eosinophils
26	LABVAL03	Num	8	Value - Blood platelets
27	LABNAM04	Num	8	% Neutrophils
28	LABUNT05	Num	8	Unit - % Lymphocytes
29	LABNAM01	Num	8	Hemoglobin
30	BLDSTATE	Num	8	When blood samples were drawn, patient w
31	LABNAM10	Num	8	BUN
32	LABVAL09	Num	8	Value - Serum creatinine
33	LABVAL11	Num	8	Value - Cholesterol
34	LABUNT04	Num	8	Unit - % Neutrophils
35	LABNAM06	Num	8	% Eosinophils
36	LABVAL12	Num	8	Value - Triglycerides

Num	Variable	Type	Len	Label
37	LABVAL06	Num	8	Value - % Eosinophils
38	STDLABFL	Num	8	Imputed flag: Standard Lab Flow Date
39	STDLABDT	Num	8	Studyday of Standard Lab Flow Date

Data Set Name: stdlabhx_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	LABHXL18	Num	8	ULN - Serum direct bilirubin
7	LABHXU12	Num	8	Unit - Triglycerides
8	LABH XV10	Num	8	Value - BUN
9	LABH XV15	Num	8	Value - INR
10	LABH XV04	Num	8	Value - % Neutrophils
11	LABH XV09	Num	8	Value - Serum creatinine
12	LABH XN03	Num	8	Blood platelets
13	LABH XN12	Num	8	Triglycerides
14	LABHXU11	Num	8	Unit - Cholesterol
15	LABHXL16	Num	8	ULN - Prothrombin time
16	LABH XV14	Num	8	Value - Serum albumin
17	LABH XN10	Num	8	BUN
18	LABH XN14	Num	8	Serum albumin
19	LABH XN05	Num	8	% Lymphocytes
20	LABH XN08	Num	8	Potassium
21	LABHXU13	Num	8	Unit - Serum total protein
22	LABHXL17	Num	8	ULN - Serum total bilirubin
23	LABH XN09	Num	8	Serum creatinine
24	LABH XN16	Num	8	Prothrombin time
25	LABH XN15	Num	8	INR
26	LABHXU06	Num	8	Unit - % Eosinophils
27	BLDXSTAT	Num	8	Subject status at sample time
28	LABH XV01	Num	8	Value - Hemoglobin
29	LABH XN04	Num	8	% Neutrophils
30	LABH XN17	Num	8	Serum total bilirubin
31	LABHXU05	Num	8	Unit - % Lymphocytes
32	LABH XN02	Num	8	WBC
33	LABH XV05	Num	8	Value - % Lymphocytes
34	LABH XN07	Num	8	Sodium
35	LABH XV12	Num	8	Value - Triglycerides
36	LABH XV08	Num	8	Value - Potassium

Num	Variable	Type	Len	Label
37	LABHXV11	Num	8	Value - Cholesterol
38	LABHXN11	Num	8	Cholesterol
39	LABHXV02	Num	8	Value - WBC
40	LABHXL14	Num	8	ULN - Serum albumin
41	LABHXV13	Num	8	Value - Serum total protein
42	LABHXV18	Num	8	Value - Serum direct bilirubin
43	LABHXV07	Num	8	Value - Sodium
44	LABHXN01	Num	8	Hemoglobin
45	LABHXL15	Num	8	ULN - INR
46	LABHXV06	Num	8	Value - % Eosinophils
47	LABHXN06	Num	8	% Eosinophils
48	LABHXV16	Num	8	Value - Prothrombin time
49	LABHXU10	Num	8	Unit - BUN
50	LABHXV03	Num	8	Value - Blood platelets
51	LABHXU09	Num	8	Unit - Serum creatinine
52	LABHXN13	Num	8	Serum total protein
53	LABHXU04	Num	8	Unit - % Neutrophils
54	LABHXN18	Num	8	Serum direct bilirubin
55	LABHXV17	Num	8	Value - Serum total bilirubin
56	LABHXFL	Num	8	Imputed flag: Date lab Sample
57	LABHXDT	Num	8	Studyday of Date lab Sample

Data Set Name: *steatos_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	CHARACTR	Num	8	Character
7	LOCATION	Num	8	Location
8	DEGREE	Num	8	Degree

Data Set Name: surghx_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	SXFL	Num	8	Imputed flag: Date of Surgery
7	SXDT	Num	8	Studyday of Date of Surgery

Data Set Name: sympsign2_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	MERGEVAR	Num	8	Merge variable between SYMPSIGN2/SYMPSIGN or SYMPSIGN3
7	SYMPFL	Num	8	Imputed flag: First symptom onset Date
8	SYMPDT	Num	8	Studyday of First symptom onset Date

Data Set Name: sympsign3_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	MERGEVAR	Num	8	Merge variable between SYMPSIGN2/SYMPSIGN3
7	SIGNINJ	Num	8	Signs of liver injury

Data Set Name: sympsign_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	MERGEVAR	Num	8	Merge variable between SYMPSIGN/SYMPSIGN2
7	SYMPINJ	Num	8	Symptoms of liver injury
8	SYMOTHSP	Char	100	Symptoms of liver injury - Specify

Data Set Name: urine_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	CRSTUNIT	Num	8	Crystals unit
7	GRAVITY	Num	8	Specific gravity value
8	WBCUNIT	Num	8	WBC unit
9	BILRUBYN	Num	8	Bilirubin available
10	PROTOTH	Char	50	Other Specify
11	GLUCOSYN	Num	8	Glucose available
12	CASTVAL	Char	20	Casts value
13	BILIOTH	Char	50	Other Specify
14	CASTYN	Num	8	Casts available
15	GRAVTYN	Num	8	Specific gravity available
16	LEUKOCYT	Num	8	Leukocyte esterase value
17	BACUNIT	Num	8	Bacteria value unit
18	RBCVAL	Char	20	RBC value
19	PHYN	Num	8	pH available
20	PH	Num	8	pH value
21	URWBCVAL	Char	20	WBC value
22	BACYN	Num	8	Bacteria available
23	RBCYN	Num	8	RBC available
24	GLUCOTH	Char	50	Other Specify
25	CRSTVAL	Char	20	Crystals value
26	CASTUNIT	Num	8	Casts value unit
27	BILRUBIN	Num	8	Bilirubin value
28	RBCUNIT	Num	8	RBC unit
29	BACVAL	Char	20	Bacteria value
30	CRSTYN	Num	8	Crystals available
31	GLUCOSE	Num	8	Glucose value
32	WBCYN	Num	8	WBC available
33	LEUKOTH	Char	50	Other Specify
34	PROTEYN	Num	8	Protein/albumin available
35	PROTEIN	Num	8	Protein/albumin value
36	LEUKOCYN	Num	8	Leukocyte esterase available

Num	Variable	Type	Len	Label
37	URINEFL	Num	8	Imputed flag: Date of urine collection
38	URINEDT	Num	8	Studyday of Date of urine collection

Data Set Name: vascular_ret.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	VENOCCLU	Num	8	Veno-occlusive changes in central veins
7	PORTVENO	Num	8	Portal venopathy
8	HEMORRHG	Num	8	Hemorrhage
9	SINUDILA	Num	8	Sinusoidal dilation
10	NODUTRAN	Num	8	Nodular transformation
11	CNVNENDO	Num	8	Central vein endophlebitis

Data Set Name: *visstat_ret.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VISIT	Char	63	Inform visit name
5	VISITID	Num	8	Inform generated visit number
6	COMPVST	Num	8	Did the patient complete the visit
7	DILSTAT	Num	8	Patient enrolled in:
8	SAQFL	Num	8	Imputed flag: Date of Visit
9	SAQDT	Num	8	Studyday of Date of Visit

Data Set Name: causrucm.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	SEQNO	Num	8	Implicated Drug sequence number
5	REVIEW	Num	8	Reviewer
6	SCORE	Num	8	The calculated RUCAM score (total)
7	RUCAM	Num	8	RUCAM
8	RUSCORE	Num	8	Score (individual assessment)
9	IMPLDRUG	Char	128	Name of implicated drug/CAM
10	WHONAME	Char	128	Standardized Medication Name
11	WHOCODE	Char	32	Implicated Drug WHO Drug Code
12	RUCAMFL	Num	8	Imputed flag: Date RUCAM assessment completed
13	RUCAMDT	Num	8	Studyday of Date RUCAM assessment completed

Data Set Name: complete.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	COMPALL	Num	8	Completed screening/interview/blood draw
7	CONTACT	Num	8	Re-contacted participant for interview
8	COMPINT	Num	8	After re-contacted, completed interview
9	BDAPPT	Num	8	Agreed to make blood draw appointment
10	BDSAMP	Num	8	Participant provided blood sample
11	NOAPPT	Num	8	Number of missed appointments
12	NOTINTRS	Num	8	No longer interested
13	LENGTH	Num	8	Reason for term., required too much time
14	TOOINFO	Num	8	Felt study asked too much information
15	NOBLDRW	Num	8	Unwilling to have blood drawn
16	NOGENEST	Num	8	Unwilling to participate in genetics study
17	REASONOT	Num	8	Reasons for termination: Other

Data Set Name: datachk.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	LINKVAR	Num	8	Links DATACHK/DATACOMP/DATAINFO/DATASCR
6	NODATA	Num	8	1 if page is present & has no data
7	REVIEW	Num	8	Reviewer
8	DATAQA	Num	8	Data Completeness Checklist Questions
9	DATAANS	Num	8	Data Completeness Checklist Answers
10	DATCOMFL	Num	8	Imputed flag: Date completed
11	DATCOMDT	Num	8	Studyday of Date completed

Data Set Name: datacomp.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	LINKVAR	Num	8	Links DATACHK/DATACOMP/DATAINFO/DATASCR
5	NODATA	Num	8	1 if page is present & has no data
6	DATAOK	Num	8	Assessment of completeness of data

Data Set Name: datainfo.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	LINKVAR	Num	8	Links DATACHK/DATACOMP/DATAINFO/DATASCR
5	NODATA	Num	8	1 if page is present & has no data
6	NOINFO	Num	8	No further info needed to assess causality
7	SEQNO	Num	8	Sequence Number
8	INFO	Char	200	Info

Data Set Name: datascr.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	LINKVAR	Num	8	Links DATACHK/DATACOMP/DATAINFO/DATASCR
5	NODATA	Num	8	1 if page is present & has no data
6	TOTAL	Num	8	Total Sum of DATAANS

Data Set Name: demog.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	NODATA	Num	8	1 if page is present & has no data
5	SEX	Num	8	What is your sex?
6	BLACK	Num	8	Black or African American
7	WHITE	Num	8	White
8	RACEOTHR	Num	8	Race Other

Data Set Name: *diliepsd.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	SEQNO	Num	8	Sequence Number
7	DILIMED	Num	8	DILI medication
8	DOSE	Num	8	Dose
9	UNIT	Char	10	Unit
10	FREQ	Num	8	Frequency
11	ROUTE	Num	8	Route
12	DRGIND	Num	8	Indication
13	FREQSP	Char	100	Frequency, other specify
14	RTESP	Char	100	Route, other specify
15	DRGSPFL	Num	8	Imputed flag: Drug Stop date
16	DRGSTFL	Num	8	Imputed flag: Drug Start date
17	DRGSPDT	Num	8	Studyday of Drug Stop date
18	DRGSTDT	Num	8	Studyday of Drug Start date

Data Set Name: dillionst.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	DILIDRUG	Num	8	Implicated DILI medication
7	ONSETVAL	Num	8	Onset value
8	ONSETFL	Num	8	Imputed flag: First date of hospitalization
9	ONSETDT	Num	8	Studyday of First date of hospitalization

Data Set Name: dilisymp.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	JAUNDICE	Num	8	Jaundice
7	NAUSEA	Num	8	Nausea
8	ANOREXIA	Num	8	Anorexia
9	DKURINE	Num	8	Dark urine
10	FEVER	Num	8	Fever
11	ABDPAIN	Num	8	Abdominal pain
12	VOMIT	Num	8	Vomiting
13	RASH	Num	8	Rash
14	ITCH	Num	8	Itching
15	MENTAL	Num	8	Changes in mental states
16	DROWSY	Num	8	Drowsiness
17	ENCEPHAL	Num	8	Encephalopathy
18	ASCITES	Num	8	Ascites
19	HEPATOMG	Num	8	Hepatomegaly
20	SPLENOMG	Num	8	Splenomegaly
21	LYMPHADN	Num	8	Lymphadenopathy
22	SYMOTHR	Num	8	Other signs and symptoms
23	BREATH	Num	8	Difficulty breathing
24	EDEMA	Num	8	Edema
25	FATIGUE	Num	8	Fatigue
26	GRYSTOOL	Num	8	Grey stool
27	CHILLS	Num	8	Chills

Data Set Name: *dilitx1.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	DILIHOSP	Num	8	Hospitalized for this episode
7	STEROIDS	Num	8	Received prednisone or corticosteroids
8	HEPATIC	Num	8	Extrahepatic manifestation during DILI episode
9	NEUTRPEN	Num	8	Neutropenia
10	THRMBPEN	Num	8	Thrombocytopenia
11	SJSYNDRM	Num	8	Stevens-Johnson syndrome
12	NECROLY	Num	8	Toxic epidermal necrolysis
13	HMANEMIA	Num	8	Hemolytic anemia
14	SERUMSCK	Num	8	Serum Sickness
15	HEPAOTHR	Num	8	Extrahepatic manifestation, other
16	STERODFL	Num	8	Imputed flag: Date of Steroid
17	TXHOSPFL	Num	8	Imputed flag: Date of Treatment Hospitalized
18	STERODDT	Num	8	Studyday of Date of Steroid
19	TXHOSPDT	Num	8	Studyday of Date of Treatment Hospitalized

Data Set Name: dilitx2.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	TXBIOP	Num	8	Liver biopsy performed for this episode
7	TXTRANS	Num	8	Liver transplant performed for this episode
8	TXRECHAL	Num	8	Participant Rechallenged w/implicated drug
9	TXBPFL	Num	8	Imputed flag: Biopsy Date
10	TXSPFL	Num	8	Imputed flag: Stop date
11	TXSTFL	Num	8	Imputed flag: Start date
12	TXTRFL	Num	8	Imputed flag: Date of Transplant
13	TXBPDT	Num	8	Studyday of Biopsy Date
14	TXSPDT	Num	8	Studyday of Stop date
15	TXSTDt	Num	8	Studyday of Start date
16	TXTRDT	Num	8	Studyday of Date of Transplant

Data Set Name: hxcammed.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	PHASE	Char	100	Concomitant medications phase
5	SEQNO	Num	8	Sequence Number
6	HXHRBMED	Char	80	Herbal Medication
7	WHOCODE	Char	11	WHO Drug Code
8	WHONAME	Char	80	Standardized Medication Name

Data Set Name: hxconmed.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	PHASE	Char	100	Concomitant medications phase
5	HXCOMED	Num	8	Take any other prescription drugs

Data Set Name: *hxxosp.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	HXHOSPI	Num	8	Were you hospitalized for this injury?

Data Set Name: hxotcmed.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	PHASE	Char	100	Concomitant medications phase
5	SEQNO	Num	8	Sequence Number
6	HXOCMED	Char	80	Over-The-Counter Medication
7	WHOCODE	Char	11	WHO Drug Code
8	WHONAME	Char	80	Standardized Medication Name

Data Set Name: *hxrmed.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	PHASE	Char	100	Concomitant medications phase
5	SEQNO	Num	8	Sequence Number
6	HXPRMED	Char	80	Prescription Drug
7	WHOCODE	Char	11	WHO Drug Code
8	WHONAME	Char	80	Standardized Medication Name

Data Set Name: illness1.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	NODATA	Num	8	1 if page is present & has no data
5	CONILLN	Num	8	Concomitant Medical Condition/Illness
6	MTHPRIOR	Num	8	One Month Prior
7	TMPRIOR	Num	8	Time Period Prior

Data Set Name: illness2.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	NODATA	Num	8	1 if page is present & has no data
5	CONILLN	Num	8	Concomitant Medical Condition/Illness
6	MTHPRIOR	Num	8	One Month Prior
7	TMPRIOR	Num	8	Time Period Prior

Data Set Name: image.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	IMAGING	Num	8	Imaging Studies
7	IMGSP	Char	25	Imaging Studies, Other
8	IMGND	Num	8	Imaging Not done
9	IMGRSLT	Num	8	Results
10	ABNRSLT	Num	8	If Abnormal, Specify

Data Set Name: imgspldm.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	IMGSPND	Num	8	Not Done
5	IMGVAL	Num	8	Results
6	IMGNA	Num	8	Results, NA

Data Set Name: intdraw.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	INTBDFL	Num	8	Imputed flag: Date of blood draw appointment
6	INTBDDT	Num	8	Studyday of Date of blood draw appointment
7	INTBDTM	Num	8	Studyday of Date and time of blood draw appointment

Data Set Name: *judgmnt.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	CAUSPROC	Char	32	Causality process
5	SEQNO	Num	8	Implicated Drug sequence number
6	FORM	Char	20	Form
7	ASSESS	Num	8	Assessment of the causal relationship
8	ASSESSMT	Num	8	Implicated Drug assessment
9	REVIEW	Num	8	Reviewer
10	RVCODE	Char	30	Reviewer Code
11	SEVERITY	Num	8	DILIN's Severity Score
12	SYMPTOMATIC	Num	8	Case is symptomatic or asymptomatic
13	IMPLDRUG	Char	128	Name of implicated drug/CAM
14	WHONAME	Char	128	Standardized Medication Name
15	WHOCODE	Char	32	Implicated Drug WHO Drug Code
16	ALTDIAG	Char	100	Alternative diagnosis, possible/unlikely case
17	ALTDIAGSP	Char	100	Alternative diagnosis, other specify
18	DTH_DILI	Num	8	Death due to DILI
19	REASMT_RSN	Char	100	Re-assessment Reason
20	TRANSPLANT_LISTING	Char	100	TRANSPLANT_LISTING
21	TRANSPLANT_DISPOSITION	Char	100	TRANSPLANT_DISPOSITION
22	PATIENT_VITAL_STATUS	Char	100	PATIENT_VITAL_STATUS
23	DEATH_REVIEWER_A	Char	200	DEATH_REVIEWER_A
24	DEATH_REVIEWER_B	Char	200	DEATH_REVIEWER_B
25	CMTE_CAUSE_OF_DEATH	Char	200	CMTE_CAUSE_OF_DEATH
26	CMTE_CAUSE_OF_DEATH_COMMENTS	Char	1000	CMTE_CAUSE_OF_DEATH_COMMENTS
27	CMTE_TRANSPLANT_LISTING	Char	200	CMTE_TRANSPLANT_LISTING
28	CMTE_TRANSPLANT_DISPOSITION	Char	200	CMTE_TRANSPLANT_DISPOSITION
29	CMTE_DILI_ROLE	Char	200	CMTE_DILI_ROLE
30	CMTE_TRANSPLANT_COMMENTS	Char	1000	CMTE_TRANSPLANT_COMMENTS
31	CMTE_CAUSE_OF_DEATH_SPECIFY	Char	100	CMTE_CAUSE_OF_DEATH_SPECIFY
32	CMTE_TRANSPLANT_LISTNG_SPECIFY	Char	100	CMTE_TRANSPLANT_LISTNG_SPECIFY
33	CMTE_TRANSPLANT_DISP_SPECIFY	Char	100	CMTE_TRANSPLANT_DISP_SPECIFY
34	HDS_CLASSIFICATION_PRIMARY	Char	100	HDS_CLASSIFICATION_PRIMARY
35	HDS_CLASSIFICATION_SECONDARY	Char	100	HDS_CLASSIFICATION_SECONDARY
36	HDS_CLASSIFICATION_ANCILLARY	Char	100	HDS_CLASSIFICATION_ANCILLARY

Num	Variable	Type	Len	Label
37	DRUG_CLASSIFICATION_PRIMARY	Char	100	DRUG_CLASSIFICATION_PRIMARY
38	DRUG_CLASSIFICATION_SECONDARY	Char	100	DRUG_CLASSIFICATION_SECONDARY
39	DRUG_CLASSIFICATION_TERTIARY	Char	100	DRUG_CLASSIFICATION_TERTIARY
40	ASSESSFL	Num	8	Imputed flag: Date completed
41	ASSESSDT	Num	8	Studyday of Date completed

Data Set Name: lab1.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	LABNAME	Num	8	Parameter
7	ONSTND	Num	8	Value Not done at Onset/Within 2 Wks of Onset
8	ONSTVAL	Num	8	Value at Onset/Within 2 Wks of Onset
9	ABNND	Num	8	Most Abnormal Value Not done
10	ABNVAL	Num	8	Most Abnormal Value
11	ONSTUNIT	Num	8	Unit Value at Onset/Within 2 Wks of Onset
12	ABNUNIT	Num	8	Most Abnormal Value Unit
13	ONSTULN	Num	8	Value at Onset or Within 2 Weeks of Onse
14	ABNULN	Num	8	Most Abnormal Value Date ULN
15	ABNFL	Num	8	Imputed flag: Most Abnormal Value Date
16	ONSTFL	Num	8	Imputed flag: Value at Onset/Within 2 Wks of Onset
17	ABNDT	Num	8	Studyday of Most Abnormal Value Date
18	ONSTDT	Num	8	Studyday of Value at Onset/Within 2 Wks of Onset

Data Set Name: lab2.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	LABNAME	Num	8	Parameter
7	ONSTND	Num	8	Value Not done at Onset/Within 2 Wks of Onset
8	ONSTVAL	Num	8	Value at Onset/Within 2 Wks of Onset
9	ONSTUNIT	Num	8	Unit Value at Onset/Within 2 Wks of Onset
10	ABNND	Num	8	Most Abnormal Value Not done
11	ABNVAL	Num	8	Most Abnormal Value
12	ABNUNIT	Num	8	Most Abnormal Value Unit
13	ABNFL	Num	8	Imputed flag: Most Abnormal Value Date
14	ONSTFL	Num	8	Imputed flag: Value at Onset/Within 2 Wks of Onset
15	ABNDT	Num	8	Studyday of Most Abnormal Value Date
16	ONSTDT	Num	8	Studyday of Value at Onset/Within 2 Wks of Onset

Data Set Name: labflow.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	SEQNO	Num	8	Sequence Number
7	LABFLW	Num	8	Timing of lab sample
8	AST	Num	8	AST Not done
9	ASTVAL	Num	8	AST Value
10	ASTULN	Num	8	AST ULN
11	ALT	Num	8	ALT Not done
12	ALTVAL	Num	8	ALT Value
13	ALTULN	Num	8	ALT ULN
14	AKP	Num	8	Alkaline Phosphatase Not done
15	AKPVAL	Num	8	Alkaline Phosphatase Value
16	AKPULN	Num	8	Alkaline Phosphatase ULN
17	STB	Num	8	Serum Total Bilirubin Not done
18	STBVAL	Num	8	Serum Total Bilirubin Value
19	STBULN	Num	8	Serum Total Bilirubin ULN
20	INR	Num	8	INR Not done
21	INRRATE	Num	8	INR ratio
22	PTT	Num	8	Prothrombin Time Not done
23	PTTSECS	Num	8	Prothrombin Time seconds
24	ASTCALC	Num	8	AST VAL/ULN
25	ALTCALC	Num	8	ALT VAL/ULN
26	AKPCALC	Num	8	AKP VAL/ULN
27	STBCALC	Num	8	STB VAL/ULN
28	FLWRATIO	Num	8	ALTCALC/AKPCALC
29	STBUNIT	Num	8	Serum Total Bilirubin Unit
30	LABFL	Num	8	Imputed flag: Labs Date
31	LABDT	Num	8	Studyday of Labs Date

Data Set Name: labrcnt.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	LABRCT	Num	8	Parameter for most recent lab sample
7	LABVAL	Num	8	Value
8	LABULN	Num	8	ULN
9	LABCALC	Num	8	Value/ULN
10	LABRATIO	Num	8	LAB ratio
11	LABUNIT	Num	8	Unit
12	LABFL	Num	8	Imputed flag: Labs Date
13	LABDT	Num	8	Studyday of Labs Date

Data Set Name: *livrhx1.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	HXBIOP	Num	8	Was a liver biopsy performed?

Data Set Name: livrhx2.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	HXLIVTRX	Num	8	Was a liver transplant performed?
7	LIVRSICK	Num	8	How long were you sick with this injury?
8	LIVRWORK	Num	8	Missed work or school because of injury
9	LTIME	Num	8	Time missed from work/school due to injury
10	PERSIST	Num	8	Persistent symptom or medical condition
11	CURRHLTH	Num	8	Current health
12	HXRECHAL	Num	8	Rechallenged
13	LIVREACT	Num	8	Suffered a bad reaction during rechallenge
14	RASHRCH	Num	8	Rash bad reaction
15	FEVERRCH	Num	8	Fever bad reaction
16	SWELL	Num	8	Swelling
17	BREATH	Num	8	Difficulty breathing
18	PROBLEM	Num	8	Liver problem
19	REACTOTH	Num	8	Other bad reaction
20	REACTSP	Char	200	Other bad reaction, specify
21	JAUNDICE	Num	8	Jaundice
22	NAUSEA	Num	8	Nausea
23	ANOREXIA	Num	8	Anorexia
24	DRKURINE	Num	8	Dark urine
25	ABDPAIN	Num	8	Abdominal pain
26	VOMIT	Num	8	Vomiting
27	ITCH	Num	8	Itching
28	MENTAL	Num	8	Changes in mental states
29	ASCITES	Num	8	Ascites
30	EDEMA	Num	8	Edema
31	HEPTMGLY	Num	8	Hepatomegaly
32	SPLNMGLY	Num	8	Splenomegaly
33	LYPMHDPY	Num	8	Lymphadenopathy
34	FATIGUE	Num	8	Fatigue
35	GRYSTOOL	Num	8	Grey stool
36	CHILLS	Num	8	Chills

Num	Variable	Type	Len	Label
37	OTHER2	Num	8	Second Other
38	OTHER2SP	Char	200	Second Other, specify

Data Set Name: mccomplt.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	REVCOMPL	Num	8	Was the Medical Chart Review completed?
5	NOCOMPL	Num	8	Reason medical chart not completed

Data Set Name: medhx.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	PHASE	Char	100	Medical history phase
5	FORM	Char	40	Form Name - Block ID
6	NODATA	Num	8	1 if page is present & has no data
7	DRINK	Num	8	How often did you drink
8	AVGDRNK	Num	8	How many drinks on average consumed
9	SMOKE	Num	8	During this time period, did you smoke?
10	SMOKEDAY	Num	8	# cigarettes typically smoked per day
11	ACETAMIN	Num	8	Acetaminophen taken during this period
12	ASA	Num	8	ASA taken during this time period
13	LCARNTN	Num	8	L-cartinine taken during this period

Data Set Name: pmedhx.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	HXREACT	Num	8	Suffered a bad reaction to a drug
7	SEQNO	Num	8	Sequence Number
8	DRGREACT	Char	80	Drug

Data Set Name: pmedhx1.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	HXMED	Char	80	Drug name
7	HXDRG	Num	8	Took drug prior to this date for any reason
8	HXJAUND	Num	8	Were you ever jaundiced or told you were
9	HXLIVPRB	Num	8	Previous history of liver problems
10	ABNLT	Num	8	Abnormal liver tests
11	HEPA	Num	8	Hepatitis A (infectious)
12	HEPB	Num	8	Hepatitis B
13	HEPC	Num	8	Hepatitis C
14	ARLD	Num	8	Alcohol-related liver disease
15	FLNRA	Num	8	Fatty liver not related to alcohol
16	AIMD	Num	8	Autoimmune disease
17	PBCIRRH	Num	8	Primary biliary cirrhosis
18	HEMCHROM	Num	8	Hemochromatosis
19	WILSON	Num	8	Wilson's disease
20	AATDEF	Num	8	A1AT deficiency
21	CIRRHUN	Num	8	Cirrhosis-unspecified
22	UNK	Num	8	Unknown liver problem
23	OTHER	Num	8	Other liver problem
24	PROBSP	Char	200	Other liver problem (specify)
25	PSCHLANG	Num	8	Primary sclerosing cholangitis
26	GILBERT	Num	8	Gilbert's syndrome
27	HEPISCHM	Num	8	Ischemic hepatitis
28	LIVERTRX	Num	8	Liver transplantation
29	FAMHXLIV	Num	8	Family history of liver disease
30	WHOCODE	Char	11	WHO Drug Code
31	WHONAME	Char	80	Standardized Medication Name

Data Set Name: *proc.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	BIOPROC	Num	8	Biopsy Not Done
7	PROCRSLT	Num	8	Biopsy Results
8	TRXPROC	Num	8	Transplant Not Done
9	OTH1PRSP	Char	25	Other Procedure
10	OTH1PROC	Char	25	Other Procedure Results
11	OTH2PRSP	Char	25	Second Other Procedure
12	OTH2PROC	Char	25	Second Other Procedure Results
13	OTH1PRND	Num	8	Other Procedure Not Done
14	OTH2PRND	Num	8	Second Other Procedure Not Done

Data Set Name: retblood.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	ALTID	Char	25	Alternate ID Number

Data Set Name: retro_formats.sas7bdat

Num	Variable	Type	Len	Label
1	FMTNAME	Char	32	Format name
2	START	Char	16	Starting value for format
3	END	Char	16	Ending value for format
4	LABEL	Char	80	Format value label
5	MIN	Num	3	Minimum length
6	MAX	Num	3	Maximum length
7	DEFAULT	Num	3	Default length
8	LENGTH	Num	3	Format length
9	FUZZ	Num	8	Fuzz value
10	PREFIX	Char	2	Prefix characters
11	MULT	Num	8	Multiplier
12	FILL	Char	1	Fill character
13	NOEDIT	Num	3	Is picture string noedit?
14	TYPE	Char	1	Type of format
15	SEXCL	Char	1	Start exclusion
16	EEXCL	Char	1	End exclusion
17	HLO	Char	13	Additional information
18	DECSEP	Char	1	Decimal separator
19	DIG3SEP	Char	1	Three-digit separator
20	DATATYPE	Char	8	Date/time/datetime?
21	LANGUAGE	Char	8	Language for date strings

Data Set Name: rtilab.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	ALTID	Char	25	Alternate ID Number
5	DNASOURC	Char	9	DNASOURC

Data Set Name: rxmed1.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	TYPE	Char	100	Prescription/Non-prescription
5	SEQNO	Num	8	Sequence Number
6	RX1MED	Char	80	Prescription Med: 1 Mth Prior to Imp Med
7	WHOCODE	Char	11	WHO Drug Code
8	WHONAME	Char	80	Standardized Medication Name

Data Set Name: rxmed2.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	TYPE	Char	100	Prescription/Non-prescription
5	SEQNO	Num	8	Sequence Number
6	RX2MED	Char	80	Prescription Med: Prior to Liver Problem
7	WHOCODE	Char	11	WHO Drug Code
8	WHONAME	Char	80	Standardized Medication Name

Data Set Name: screen.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	INH	Num	8	Isoniazid (INH)
6	PHENYT	Num	8	Phenytoin (Dilantin)
7	AUGMENT	Num	8	Clavulanic acid/amoxicillin (Augmentin)
8	VALPACID	Num	8	Valproic acid (Valproate, Depakote)
9	SCRDRGOT	Num	8	Drug that caused reaction, other
10	SCRDRGCR	Num	8	Cannot remember
11	SCRCOLOR	Num	8	Skin or whites of eyes turned yellow
12	RTNONDIL	Num	8	Non-DILI subject
13	REFNA	Num	8	Referred
14	NITROFTN	Num	8	Nitrofurtoin
15	MINOCYLN	Num	8	Minocycline
16	BACTRIM	Num	8	Trimethoprin-Sulfamethoxazole
17	QUINLNE	Num	8	Quinolone antibiotics
18	SCRNFL	Num	8	Imputed flag: Screening Date
19	AGECAT	Num	8	Age category
20	SCRNDT	Num	8	Studyday of Screening Date

Data Set Name: screen2.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	FORM	Char	40	Form Name - Block ID
5	NODATA	Num	8	1 if page is present & has no data
6	SCRBLOOD	Num	8	Willing to provide a blood sample
7	SCRCONT	Num	8	Willing to participate in study
8	UNDERAGE	Num	8	Under the age of 2
9	TOOEARLY	Num	8	Event occurred before January 1994
10	OVRDRUG	Num	8	Received more than one of the implicated
11	NOINTRST	Num	8	Not interested
12	TOOLONG	Num	8	Felt study required too much time
13	NOBLOOD	Num	8	Not willing to give a blood sample
14	NOGENE	Num	8	Did not want to be in a genetics study
15	NOTCONT	Num	8	Reason given to not participate, other
16	PROTEXMP	Num	8	Participant is an approved protocol exem
17	ICF1	Num	8	ICF Liver research allowed only
18	ICF2	Num	8	ICF All research allowed

Data Set Name: serology.sas7bdat

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	NODATA	Num	8	1 if page is present & has no data
5	SEROL	Num	8	Serological and Other Assays During DILI
6	SEROND	Num	8	Serology parameter not done
7	SERORSLT	Num	8	Serology parameter result
8	SEROVAL	Num	8	Serology parameter value
9	SEROIFEL	Num	8	IF or ELISA

Data Set Name: *valacid.sas7bdat*

Num	Variable	Type	Len	Label
1	DEIDNUM	Num	8	Deidentified Subject Number
2	STUDY	Char	13	Prospective or Retrospective Study
3	UNIQUEID	Num	8	unique deidnum across both protocol
4	VALHOSP	Num	8	Was this patient hospitalized?
5	INRPAT	Num	8	Was the INR > 1.5 for this patient?
6	SERPAT	Num	8	AST or ALT > 3 x ULN or 3 x baseline
7	BILPAT	Num	8	Bilirubin > 1 x ULN or > 1 x baseline
8	ELEVART	Num	8	Unexplained elevated arterial/venous NH3
9	LIVBPSTE	Num	8	Did this patient undergo a liver biopsy