

Data Set Name: causrucm.sas7bdat

Num	Variable	Type	Len	Format	Label
1	DEIDNUM	Num	8		Deidentified Subject Number
2	SEQNO	Num	8		Implicated Drug sequence number
3	REVIEW	Num	8	CARVWR.	Reviewer
4	SCORE	Num	8		The calculated RUCAM score (total)
5	RUCAM	Num	8	CARUCM.	RUCAM
6	RUSCORE	Num	8	CASCOR.	Score (individual assessment)
7	IMPLDRUG	Char	128		Name of implicated drug/CAM
8	WHONAME	Char	128		Standardized Medication Name
9	WHOCODE	Char	32		Implicated Drug WHO Drug Code
10	RUCAMFL	Num	8		Imputed flag: Date RUCAM assessment completed
11	RUCAMDT	Num	8		Studyday of Date RUCAM assessment completed

Data Set Name: complete.sas7bdat

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

Data Set Name: *datachk.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	DEIDNUM	Num	8		Deidentified Subject Number
2	FORM	Char	40		Form Name - Block ID
3	LINKVAR	Num	8		Links DATACHK/DATACOMP/DATAINFO/DATASCR
4	NODATA	Num	8	ZYES.	1 if page is present & has no data
5	REVIEW	Num	8	CARVWR.	Reviewer
6	DATAQA	Num	8	CACHCK.	Data Completeness Checklist Questions
7	DATAANS	Num	8	ZYESNO.	Data Completeness Checklist Answers
8	DATCOMFL	Num	8		Imputed flag: Date completed
9	DATCOMDT	Num	8		Studyday of Date completed

Data Set Name: *datacomp.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	LINKVAR	Num	8		Links DATACHK/DATACOMP/DATAINFO/DATASCR
2	NODATA	Num	8	ZYES.	1 if page is present & has no data
3	DATAOK	Num	8	CAQUAL.	Assessment of completeness of data
4	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: datainfo.sas7bdat

Num	Variable	Type	Len	Format	Label
1	LINKVAR	Num	8		Links DATACHK/DATACOMP/DATAINFO/DATASCR
2	NODATA	Num	8	ZYES.	1 if page is present & has no data
3	NOINFO	Num	8	ZYES.	No further info needed to assess causality
4	SEQNO	Num	8		Sequence Number
5	INFO	Char	200		Info
6	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: *datascr.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	LINKVAR	Num	8		Links DATACHK/DATACOMP/DATAINFO/DATASCR
2	NODATA	Num	8	ZYES.	1 if page is present & has no data
3	TOTAL	Num	8		Total Sum of DATAANS
4	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: demog.sas7bdat

Num	Variable	Type	Len	Format	Label
1	NODATA	Num	8	ZYES.	1 if page is present & has no data
2	SEX	Num	8	RTSEX.	What is your sex?
3	BLACK	Num	8	ZYES.	Black or African American
4	WHITE	Num	8	ZYES.	White
5	RACEOTHR	Num	8	ZYES.	Race Other (specify)
6	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: *diliepsd.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	DEIDNUM	Num	8		Deidentified Subject Number
2	FORM	Char	40		Form Name - Block ID
3	NODATA	Num	8	ZYES.	1 if page is present & has no data
4	SEQNO	Num	8		Sequence Number
5	DILIMED	Num	8	RTDRUG.	DILI medication
6	DOSE	Num	8		Dose
7	UNIT	Char	10		Unit
8	FREQ	Num	8	RTFREQ.	Frequency
9	ROUTE	Num	8	RTRTE.	Route
10	DRGIND	Num	8	RTINDC.	Indication
11	FREQSP	Char	100		Frequency, other specify
12	RTESP	Char	100		Route, other specify
13	DRGSPFL	Num	8		Imputed flag: Drug Stop date
14	DRGSTFL	Num	8		Imputed flag: Drug Start date
15	DRGSPDT	Num	8		Studyday of Drug Stop date
16	DRGSTDT	Num	8		Studyday of Drug Start date

Data Set Name: *dilionst.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	DEIDNUM	Num	8		Deidentified Subject Number
2	FORM	Char	40		Form Name - Block ID
3	NODATA	Num	8	ZYES.	1 if page is present & has no data
4	DILIDRUG	Num	8	RTDLON.	Implicated DILI medication
5	ONSETVAL	Num	8		Onset value
6	ONSETFL	Num	8		Imputed flag: First date of hospitalization
7	ONSETDT	Num	8		Studyday of First date of hospitalization

Data Set Name: dilisymp.sas7bdat

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

Data Set Name: *dilitx1.sas7bdat*

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

Data Set Name: dilitx2.sas7bdat

Num	Variable	Type	Len	Format	Label
1	DEIDNUM	Num	8		Deidentified Subject Number
2	FORM	Char	40		Form Name - Block ID
3	NODATA	Num	8	ZYES.	1 if page is present & has no data
4	TXBIOP	Num	8	ZYESNO.	Liver biopsy performed for this episode
5	TXTRANS	Num	8	ZYESNO.	Liver transplant performed for this episode
6	TXRECHAL	Num	8	ZYESNO.	Participant Rechallenged w/implicated drug
7	TXBPFL	Num	8		Imputed flag: Biopsy Date
8	TXSPFL	Num	8		Imputed flag: Stop date
9	TXSTFL	Num	8		Imputed flag: Start date
10	TXTRFL	Num	8		Imputed flag: Date of Transplant
11	TXBPDT	Num	8		Studyday of Biopsy Date
12	TXSPDT	Num	8		Studyday of Stop date
13	TXSTDT	Num	8		Studyday of Start date
14	TXTRDT	Num	8		Studyday of Date of Transplant

Data Set Name: *hxcammed.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	PHASE	Char	100			Concomitant medications phase
2	SEQNO	Num	8			Sequence Number
3	HXHRBMED	Char	80			Herbal Medication
4	WHOCODE	Char	11	\$22.	\$22.	WHO Drug Code
5	WHONAME	Char	80	\$400.	\$400.	Standardized Medication Name
6	DEIDNUM	Num	8			Deidentified Subject Number

Data Set Name: *hxconmed.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	PHASE	Char	100		Concomitant medications phase
2	HXCOMED	Num	8	RTYNCR.	Take any other prescription drugs
3	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: hxhosp.sas7bdat

Num	Variable	Type	Len	Format	Label
1	HXHOSPI	Num	8	RTYNCR.	Were you hospitalized for this injury?
2	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: *hxtocmed.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	PHASE	Char	100			Concomitant medications phase
2	SEQNO	Num	8			Sequence Number
3	HXOCMED	Char	80			Over-The-Counter Medication
4	WHOCODE	Char	11	\$22.	\$22.	WHO Drug Code
5	WHONAME	Char	80	\$400.	\$400.	Standardized Medication Name
6	DEIDNUM	Num	8			Deidentified Subject Number

Data Set Name: *hxrmed.sas7bdat*

Num	Variable	Type	Len	Format	Informat	Label
1	PHASE	Char	100			Concomitant medications phase
2	SEQNO	Num	8			Sequence Number
3	HXPAMED	Char	80			Prescription Drug
4	WHOCODE	Char	11	\$22.	\$22.	WHO Drug Code
5	WHONAME	Char	80	\$400.	\$400.	Standardized Medication Name
6	DEIDNUM	Num	8			Deidentified Subject Number

Data Set Name: *illness1.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	NODATA	Num	8	ZYES.	1 if page is present & has no data
2	CONILLN	Num	8	RTILLN.	Concomitant Medical Condition/Illness
3	MTHPRIOR	Num	8	ZYESNO.	One Month Prior
4	TMPRIOR	Num	8	ZYESNO.	Time Period Prior
5	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: *illness2.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	NODATA	Num	8	ZYES.	1 if page is present & has no data
2	CONILLN	Num	8	RTILLN.	Concomitant Medical Condition/Illness
3	MTHPRIOR	Num	8	ZYESNO.	One Month Prior
4	TMPRIOR	Num	8	ZYESNO.	Time Period Prior
5	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: image.sas7bdat

Num	Variable	Type	Len	Format	Label
1	FORM	Char	40		Form Name - Block ID
2	NODATA	Num	8	ZYES.	1 if page is present & has no data
3	IMAGING	Num	8	RTIMGE.	Imaging Studies
4	IMGSP	Char	25		Imaging Studies, Other
5	IMGND	Num	8	ZYES.	Imaging Not done
6	IMGRSLT	Num	8	RTNABN.	Results
7	ABNRSLT	Num	8	RTABNR.	If Abnormal, Specify
8	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: imgspldm.sas7bdat

Num	Variable	Type	Len	Format	Label
1	IMGSPND	Num	8	ZYES.	Not Done
2	IMGVAL	Num	8		Results
3	IMGNA	Num	8	ZYES.	Results, NA
4	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: *intdraw.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	DEIDNUM	Num	8		Deidentified Subject Number
2	FORM	Char	40		Form Name - Block ID
3	INTBDFL	Num	8		Imputed flag: Date of blood draw appointment
4	INTBDDT	Num	8		Studyday of Date of blood draw appointment
5	INTBDTM	Num	8	13.5	Studyday of Date and time of blood draw appointment

Data Set Name: *judgmt.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	DEIDNUM	Num	8		Deidentified Subject Number
2	CAUSPROC	Char	32		Causality process
3	SEQNO	Num	8		Implicated Drug sequence number
4	FORM	Char	20		Form
5	ASSESS	Num	8	CAJUDG.	Assessment of the causal relationship
6	ASSESSMT	Num	8	CAJUDG.	Implicated Drug assessment
7	REVIEW	Num	8	CARVWR.	Reviewer
8	RVCODE	Char	30		Reviewer Code
9	SEVERITY	Num	8	PRSVRT.	DILIN's Severity Score
10	SYMPTOMATIC	Num	8	ASYMP.	Case is symptomatic or asymptomatic
11	IMPLDRUG	Char	128		Name of implicated drug/CAM
12	WHONAME	Char	128		Standardized Medication Name
13	WHOCODE	Char	32		Implicated Drug WHO Drug Code
14	ALTDIAG	Char	100		Alternative diagnosis, possible/unlikely case
15	ALTDIAGSP	Char	100		Alternative diagnosis, other specify
16	DTH_DILI	Num	8	DTH_DILI.	Death due to DILI
17	REASMT_RSN	Char	100		Re-assessment Reason
18	ASSESSFL	Num	8		Imputed flag: Date completed
19	ASSESSDT	Num	8		Studyday of Date completed

Data Set Name: lab1.sas7bdat

Num	Variable	Type	Len	Format	Label
1	DEIDNUM	Num	8		Deidentified Subject Number
2	FORM	Char	40		Form Name - Block ID
3	NODATA	Num	8	ZYES.	1 if page is present & has no data
4	LABNAME	Num	8	RTLAB.	Parameter
5	ONSTND	Num	8	ZYES.	Value Not done at Onset/Within 2 Wks of Onset
6	ONSTVAL	Num	8		Value at Onset/Within 2 Wks of Onset
7	ABNND	Num	8	ZYES.	Most Abnormal Value Not done
8	ABNVAL	Num	8		Most Abnormal Value
9	ONSTUNIT	Num	8	RTUNIT.	Unit Value at Onset/Within 2 Wks of Onset
10	ABNUNIT	Num	8	RTUNIT.	Most Abnormal Value Unit
11	ONSTULN	Num	8		Value at Onset or Within 2 Weeks of Onse
12	ABNULN	Num	8		Most Abnormal Value Date ULN
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: lab2.sas7bdat

Num	Variable	Type	Len	Format	Label
1	DEIDNUM	Num	8		Deidentified Subject Number
2	FORM	Char	40		Form Name - Block ID
3	NODATA	Num	8	ZYES.	1 if page is present & has no data
4	LABNAME	Num	8	RTLAB.	Parameter
5	ONSTND	Num	8	ZYES.	Value Not done at Onset/Within 2 Wks of Onset
6	ONSTVAL	Num	8		Value at Onset/Within 2 Wks of Onset
7	ONSTUNIT	Num	8	RTUNIT.	Unit Value at Onset/Within 2 Wks of Onset
8	ABNND	Num	8	ZYES.	Most Abnormal Value Not done
9	ABNVAL	Num	8		Most Abnormal Value
10	ABNUNIT	Num	8	RTUNIT.	Most Abnormal Value units
11	ABNFL	Num	8		Imputed flag: Most Abnormal Value Date
12	ONSTFL	Num	8		Imputed flag: Value at Onset/Within 2 Wks of Onset
13	ABNDT	Num	8		Studyday of Most Abnormal Value Date
14	ONSTDT	Num	8		Studyday of Value at Onset/Within 2 Wks of Onset

Data Set Name: labflow.sas7bdat

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

Data Set Name: labrcnt.sas7bdat

Num	Variable	Type	Len	Format	Label
1	DEIDNUM	Num	8		Deidentified Subject Number
2	FORM	Char	40		Form Name - Block ID
3	NODATA	Num	8	ZYES.	1 if page is present & has no data
4	LABRCT	Num	8	RTRCNT.	Parameter for most recent lab sample
5	LABVAL	Num	8		Value
6	LABULN	Num	8		ULN
7	LABCALC	Num	8		Value/ULN
8	LABRATIO	Num	8		LAB ratio
9	LABUNIT	Num	8	RTUNIT.	Unit
10	LABFL	Num	8		Imputed flag: Labs Date
11	LABDT	Num	8		Studyday of Labs Date

Data Set Name: *livrhx1.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	HXBIOP	Num	8	RTYNCR.	Was a liver biopsy performed?
2	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: livrhx2.sas7bdat

Num	Variable	Type	Len	Format	Label
1	FORM	Char	40		Form Name - Block ID
2	NODATA	Num	8	ZYES.	1 if page is present & has no data
3	HXLIVTRX	Num	8	ZYESNO.	Was a liver transplant performed?
4	LIVRSICK	Num	8	RTLGTH.	How long were you sick with this injury?
5	LIVRWORK	Num	8	ZYESNO.	Missed work or school because of injury
6	LTIME	Num	8	RTLGTH.	Time missed from work/school due to injury
7	PERSIST	Num	8	ZYESNO.	Persistent symptom or medical condition
8	CURRHLTH	Num	8	ZHLTH.	Current health
9	HXRECHAL	Num	8	RTYNCR.	Rechallenged
10	LIVREACT	Num	8	ZYESNO.	Suffered a bad reaction during rechallenge
11	RASHRCH	Num	8	ZYES.	Rash bad reaction
12	FEVERRCH	Num	8	ZYES.	Fever bad reaction
13	SWELL	Num	8	ZYES.	Swelling
14	BREATH	Num	8	ZYES.	Difficulty breathing
15	PROBLEM	Num	8	ZYES.	Liver problem
16	REACTOTH	Num	8	ZYES.	Other bad reaction
17	REACTSP	Char	200		Other bad reaction, specify
18	JAUNDICE	Num	8	ZYESNO.	Jaundice
19	NAUSEA	Num	8	ZYESNO.	Nausea
20	ANOREXIA	Num	8	ZYESNO.	Anorexia
21	DRKURINE	Num	8	ZYESNO.	Dark urine
22	ABDPAIN	Num	8	ZYESNO.	Abdominal pain
23	VOMIT	Num	8	ZYESNO.	Vomiting
24	ITCH	Num	8	ZYESNO.	Itching
25	MENTAL	Num	8	ZYESNO.	Changes in mental states
26	ASCITES	Num	8	ZYESNO.	Ascites
27	EDEMA	Num	8	ZYESNO.	Edema
28	HEPTMGLY	Num	8	ZYESNO.	Hepatomegaly
29	SPLNMGLY	Num	8	ZYESNO.	Splenomegaly
30	LYPMHDPY	Num	8	ZYESNO.	Lymphadenopathy
31	FATIGUE	Num	8	ZYESNO.	Fatigue
32	GRYSTOOL	Num	8	ZYESNO.	Grey stool
33	CHILLS	Num	8	ZYESNO.	Chills
34	OTHER2	Num	8	ZYES.	Second Other
35	OTHER2SP	Char	200		Second Other, specify
36	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: mcomplt.sas7bdat

Num	Variable	Type	Len	Format	Label
1	REVCOMPL	Num	8	ZYESNO.	Was the Medical Chart Review completed?
2	NOCOMPL	Num	8	RTCOMP.	Reason medical chart not completed
3	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: medhx.sas7bdat

Num	Variable	Type	Len	Format	Label
1	PHASE	Char	100		Medical history phase
2	FORM	Char	40		Form Name - Block ID
3	NODATA	Num	8	ZYES.	1 if page is present & has no data
4	DRINK	Num	8	RTDRNK.	How often did you drink
5	AVGDRNK	Num	8	RTAVG.	How many drinks on average consumed
6	SMOKE	Num	8	ZYESNO.	During this time period, did you smoke?
7	SMOKEDAY	Num	8	RTSMKE.	# cigarettes typically smoked per day
8	ACETAMIN	Num	8	RTYNCR.	Acetaminophen taken during this period
9	ASA	Num	8	RTYNCR.	ASA taken during this time period
10	LCARNTN	Num	8	RTL CAR.	L-cartinine taken during this period
11	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: pmedhx.sas7bdat

Num	Variable	Type	Len	Format	Label
1	FORM	Char	40		Form Name - Block ID
2	NODATA	Num	8	ZYES.	1 if page is present & has no data
3	HXREACT	Num	8	RTYNCR.	Suffered a bad reaction to a drug
4	SEQNO	Num	8		Sequence Number
5	DRGREACT	Char	80		Drug
6	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: pmedhx1.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	FORM	Char	40			Form Name - Block ID
2	NODATA	Num	8	ZYES.		1 if page is present & has no data
3	HXMED	Char	80			Drug name
4	HXDRG	Num	8	RTYNCR.		Took drug prior to this date for any reason
5	HXJAUND	Num	8	RTYNCR.		Were you ever jaundiced or told you were
6	HXLIVPRB	Num	8	RTYNCR.		Previous history of liver problems
7	ABNLT	Num	8	ZYES.		Abnormal liver tests
8	HEPA	Num	8	ZYES.		Hepatitis A (infectious)
9	HEPB	Num	8	ZYES.		Hepatitis B
10	HEPC	Num	8	ZYES.		Hepatitis C
11	ARLD	Num	8	ZYES.		Alcohol-related liver disease
12	FLNRA	Num	8	ZYES.		Fatty liver not related to alcohol
13	AIMD	Num	8	ZYES.		Autoimmune disease
14	PBCIRRH	Num	8	ZYES.		Primary biliary cirrhosis
15	HEMCHROM	Num	8	ZYES.		Hemochromatosis
16	WILSON	Num	8	ZYES.		Wilson's disease
17	AATDEF	Num	8	ZYES.		A1AT deficiency
18	CIRRHUN	Num	8	ZYES.		Cirrhosis-unspecified
19	UNK	Num	8	ZYES.		Unknown liver problem
20	OTHER	Num	8	ZYES.		Other liver problem
21	PROBSP	Char	200			Other liver problem, specify
22	PSCHLANG	Num	8	ZYESNO.		Primary sclerosing cholangitis
23	GILBERT	Num	8	ZYESNO.		Gilbert's syndrome
24	HEPISCHM	Num	8	ZYESNO.		Ischemic hepatitis
25	LIVERTRX	Num	8	ZYESNO.		Liver transplantation
26	FAMHXLIV	Num	8	ZYESNO.		Family history of liver disease
27	WHOCODE	Char	11	\$22.	\$22.	WHO Drug Code
28	WHONAME	Char	80	\$400.	\$400.	Standardized Medication Name
29	DEIDNUM	Num	8			Deidentified Subject Number

Data Set Name: *proc.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	FORM	Char	40		Form Name - Block ID
2	NODATA	Num	8	ZYES.	1 if page is present & has no data
3	BIOPROC	Num	8	ZYES.	Biopsy Not Done
4	PROCRSLT	Num	8	RTNABN.	Biopsy Results
5	TRXPROC	Num	8	ZYES.	Transplant Not Done
6	OTH1PRSP	Char	25		Other Procedure
7	OTH1PROC	Char	25		Other Procedure Results
8	OTH2PRSP	Char	25		Second Other Procedure
9	OTH2PROC	Char	25		Second Other Procedure Results
10	OTH1PRND	Num	8	ZYES.	Other Procedure Not Done
11	OTH2PRND	Num	8	ZYES.	Second Other Procedure Not Done
12	DEIDNUM	Num	8		Deidentified Subject 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	11	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: rxmed1.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	TYPE	Char	100			Prescription/Non-prescription
2	SEQNO	Num	8			Sequence Number
3	RX1MED	Char	80			Prescription Med: 1 Mth Prior to Imp Med
4	WHOCODE	Char	11	\$22.	\$22.	WHO Drug Code
5	WHONAME	Char	80	\$400.	\$400.	Standardized Medication Name
6	DEIDNUM	Num	8			Deidentified Subject Number

Data Set Name: rxmed2.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	TYPE	Char	100			Prescription/Non-prescription
2	SEQNO	Num	8			Sequence Number
3	RX2MED	Char	80			Prescription Med: Prior to Liver Problem
4	WHOCODE	Char	11	\$22.	\$22.	WHO Drug Code
5	WHONAME	Char	80	\$400.	\$400.	Standardized Medication Name
6	DEIDNUM	Num	8			Deidentified Subject Number

Data Set Name: screen.sas7bdat

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

Data Set Name: screen2.sas7bdat

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

Data Set Name: serology.sas7bdat

Num	Variable	Type	Len	Format	Label
1	NODATA	Num	8	ZYES.	1 if page is present & has no data
2	SEROL	Num	8	RTSERO.	Serological and Other Assays During DILI
3	SEROND	Num	8	ZYES.	Serology parameter not done
4	SERORSLT	Num	8	RTNPUN.	Serology parameter result
5	SEROVAL	Num	8		Serology parameter value
6	SEROIFEL	Num	8	RTIFEL.	IF or ELISA
7	DEIDNUM	Num	8		Deidentified Subject Number

Data Set Name: valacid.sas7bdat

Num	Variable	Type	Len	Format	Label
1	VALHOSP	Num	8	ZYESNO.	Was this patient hospitalized?
2	INRPAT	Num	8	ZYESNO.	Was the INR > 1.5 for this patient?
3	SERPAT	Num	8	ZYESNO.	AST or ALT > 3 x ULN or 3 x baseline
4	BILPAT	Num	8	ZYESNO.	Bilirubin > 1 x ULN or > 1 x baseline
5	ELEVART	Num	8	ZYESNO.	Unexplained elevated arterial/venous NH3
6	LIVBPSTE	Num	8	ZYESNO.	Did this patient undergo a liver biopsy
7	DEIDNUM	Num	8		Deidentified Subject Number