

DILIN

Annotated Design For Trial: dilin

Protocol: DILIN PRO

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Time and Events Schedule For Study: dilin											
	Assessment	CRF	Screening Visit (PREI SV) [S]	Initial Study Visit (BASE) [S]	MONTH6 (M6) [S]	Cross Active Study (CAS) [S]	Termination (TERM) [S]	MONTH 12 (M12) [S/D]	MONTH 24 (M24) [S/D]	Conflict (Conflict) [U/R/D]	Auxiliary (AUX) [S/D]
1	VISIT STATUS	VISSTAT	1	1	1			1	1		
2	DEMOGRAPHICS	DEMOG	2								
3	FAMILY HISTORY	FAMHX1	3								
4	FAMILY HISTORY 2	FAMHX2	4-RF-DF								
5	PAST MEDICAL HISTORY	MEDHX2	5								
6	PAST MEDICAL HISTORY	MEDHX1	6-RF-DF		3-RF-DF			3-RF-DF	3-RF-DF		
7	PAST ALLERGY HISTORY	ALLRGYHX	7-RF-DF		4-RF-DF			4-RF-DF	4-RF-DF		
8	PAST SURGICAL HISTORY	SURGHX	8-RF-DF		5-RF-DF			5-RF-DF	5-RF-DF		
9	PAST MEDICAL HISTORY-LIVER SPECIFIC	LIVHX	9-RF-DF		6-RF-DF			6-RF-DF	6-RF-DF		
10	GENERAL MEDICATION COMPLIANCE	RXCOMPLY	10								
11	DRUG SPECIFIC MEDICATION COMPLIANCE	DRUGCOMP	11-RF								
12	QUESTIONNAIRES	QUESTS	12								
13	SOURCE OF RX MEDICATIONS	PHARMACY	13-DF								
14	GENERAL SMOKING HISTORY	GENSMOKE	14-DF								
15	SMOKING HISTORY	SMOKEHX	15-RF-DF		33-RF-DF			32-RF-DF	32-RF-DF		
16	SKINNER ALCOHOL CONSUMPTION	SKINNER	16-RF-DF		34-RF-DF			33-RF-DF	33-RF-DF		
17	SYMPTOMS	SAQSYMPT	17		30			29	29		
18	RAND 36 HEALTH SURVEY	RANDHS1	18-DF		35-DF			34-DF	34-DF		
19	RAND 36 HEALTH SURVEY 2	RANDHS2	19-DF		36-DF			35-DF	35-DF		
20	RAND 36 HEALTH SURVEY 3	RANDHS3	20-DF		37-DF			36-DF	36-DF		
21	PEDIATRIC QUALITY OF LIFE INVENTORY	PEDSQL1	21-DF		38-DF			37-DF	37-DF		
22	PEDIATRIC QUALITY OF LIFE INVENTORY 2	PEDSQL2	22-DF		39-DF			38-DF	38-DF		
23	PEDIATRIC QUALITY OF LIFE INVENTORY 3	PEDSQL3	23-DF		40-DF			39-DF	39-DF		
24	PEDIATRIC QUALITY OF LIFE INVENTORY 4	PEDSQL4	24-DF		41-DF			40-DF	40-DF		
25	PEDIATRIC QUALITY OF LIFE INVENTORY 5	PEDSQL5	25-DF		42-DF			41-DF	41-DF		
26	PEDIATRIC QUALITY OF LIFE INVENTORY 6	PEDSQL6	26-DF		43-DF			42-DF	42-DF		
27	PEDIATRIC QUALITY OF LIFE INVENTORY 7	PEDSQL7	27-DF		44-DF			43-DF	43-DF		
28	PEDIATRIC QUALITY OF LIFE INVENTORY 8	PEDSQL8	28-DF		45-DF			44-DF	44-DF		
29	HISTORY OF INJURY	HXINJ1	29-RF								
30	HISTORY OF INJURY 2	HXINJ2	30								
31	HISTORY OF INJURY 3	HXINJ3	31-RF-DF								
32	SIGNS AND SYMPTOMS	SIGN	32-RF								
33	IMPLICATED DILI MEDICATION	DILIMED	33-RF-DF								
34	CAMMED	CAMMED1	34-RF-DF								
35	LIVER TEST FLOW CHART	LABFLOW	35-RF		11-RF-DF			11-RF-DF	11-RF-DF		
36	STANDARD LABS (w/in 4wks prior to ONSET)	STDLABHX	36								
37	STANDARD LAB FLOW CHART	STDFLOW	37-RF								
38	IMAGING STUDIES	IMAGE	38-RF-DF		13-RF-DF			13-RF-DF	13-RF-DF		
39	HEPATITIS STATUS	HEPSTAT	39								
40	HBeAG FLOW CHART	HBEAG	40-RF-DF		16-RF-DF						
41	Anti-HBe FLOW CHART	ANTIHBE	41-RF-DF		17-RF-DF						
42	Anti-HDV (total) FLOW CHART	ANTIHDV	42-RF-DF								
43	HBV DNA FLOW CHART	HBVDNA	43-RF-DF		18-RF-DF						
44	HCV RNA FLOW CHART	HCVRNA	44-RF-DF		19-RF-DF						
45	HIV STATUS	HIVSTAT	45								
46	HIV STATUS	HIVSTAT1	46-DF								
47	HIV STATUS 2	HIVSTAT2	47-RF-DF		22-RF-DF			20-RF-DF	20-RF-DF		
48	CD4 FLOW CHART	CD4	48-RF-DF		23-RF-DF			21-RF-DF	21-RF-DF		

49	HIV RNA FLOW CHART	HIVRNA	49-RF-DF		24-RF-DF			22-RF-DF	22-RF-DF		
50	PHYSICAL EXAM	PEX1		2	25			24	24		
51	PHYSICAL EXAM 2	PEX2		3	26			25	25		
52	DIAGNOSTIC LABS 1	DXLAB1		4							
53	DIAGNOSTIC LABS 2	DXLAB2		5							
54	DIAGNOSTIC LABS 3	DXLAB3		6							
55	STANDARD LABS	STDLAB		7	27			26	26		
56	STANDARD LABS	STDLAB2		8	28			27	27		
57	URINALYSIS	URINE		9							
58	RESEARCH SAMPLES	RSAMPLE		10	29			28	28		
59	INTERVAL HISTORY/QUESTIONNAIRES	INTHX			2			2	2		
60	ER/HOSPITAL/MED APPT HISTORY	MEDHX3			7			7	7		
61	EMERGENCY ROOM VISIT	ERRMHX			8-RF-DF			8-RF-DF	8-RF-DF		
62	HOSPITALIZATION VISIT	HOSPHX			9-RF-DF			9-RF-DF	9-RF-DF		
63	MEDICAL APPOINTMENT HISTORY	APPTHIST			10-RF-DF			10-RF-DF	10-RF-DF		
64	IMAGING STUDIES	ABDIMAGE			12			12	12		
65	MAJOR MEDICAL OUTCOMES	MEDOUT			14			23	23		
66	INTERVAL HEPATITIS STATUS	HEPSTATC			15						
67	INTERVAL HIV STATUS	HIVSTATC			20			18	18		
68	INTERVAL HIV STATUS	HIVSTAT3			21-DF			19-DF	19-DF		
69	INTERVAL QUESTIONNAIRES	QUESTS2			31			30	30		
70	INTERVAL GENERAL SMOKING HISTORY	GENSMOK6			32-DF			31-DF	31-DF		
71	CHRONIC INCLUSION/EXCLUSION	CHRONIC			46						
72	CONCOMITANT HISTORY	CONHX				1					
73	CONCOMITANT MEDICATIONS	CONMED				2-RF-DF					
74	CONCOMITANT CAM PRODUCTS	CONCAM				3-RF-DF					
75	HEPATITIS MEDICATIONS LOG	HEPLOG				4-RF-DF					
76	HIV MEDICATION LOG	HIVLOG				5-RF-DF					
77	BIOPSY COLLECTION	COLLECT				6-RF-DF					
78	ADVERSE EVENTS	AE				7					
79	ADVERSE EVENTS	AE1				8-RF-DF					
80	SERIOUS ADVERSE EVENTS	SAE				9-RF-DF					
81	RUCDR DNA	RUCDR				10-RF-DF					
82	Fisher Repository Blooddraw	NIDDKSER				11-RF					
83	FISHER REPOSITORY	NIDDKBPY				12-RF-DF					
84	Serology Flowchart	SEROFLOW				13-RF-DF					
85	Protocol Exemption	PTLEXMPT				14					
86	NARRATIVES	NARR				15					
87	EARLY WITHDRAWAL and STUDY COMPLETION	PTCOMPL					1				
88	INVESTIGATOR SIGNATURE	SIGNATUR					2				
89	Annual CONCOMITANT HISTORY	ACONHX						14	14		
90	Annual CONCOMITANT MEDICATIONS	ACONMED						15-RF-DF	15-RF-DF		
91	Annual CONCOMITANT CAM PRODUCTS	ACONCAM						16-RF-DF	16-RF-DF		
92	INTERVAL HEPATITIS STATUS 2	HEPSTAT2						17	17		
93	Personal History Questionnaire	PHXQ1									1
94	Personal History Questionnaire	PHXQ2									2-RF-DF
95	Personal History Questionnaire	PHXQ3									3-RF-DF
96	Personal History Questionnaire	PHXQ8									4-DF
97	Personal History Questionnaire	PHXQ12									5-DF

Key: [S] = Scheduled Visit [O] = Optional Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit
C = Common Form DF = Dynamic Form RF = Repeating Form

dilin : Screening (SCR)	
Screening	
1. Birthdate	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (1910-2020) (dilincdd: SCR.SCRDOBDT)
2. Sex	(dilincdd: SCR.SCRSEX) [1] <input type="radio"/> Male [2] <input type="radio"/> Female
3. PI [read-only]	A3 (dilincdd: SCR.INVSITE)
4. Patient Number	A4 (dilincdd: SCR.PATID)
Inclusion Criteria	
5. Was the patient more than 2 years of age at the time of enrollment?	(dilincdd: SCR.INEXC1) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6. 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?	(dilincdd: SCR.INEXC2) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
7. Was the patient/legal guardian willing to sign informed consent?	(dilincdd: SCR.INEXC3) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
8. If ALT, AST, or AP was normal prior to the implicated drug start date, was ALT or AST > 5 × ULN or AP > 2 × ULN on at least 2 consecutive blood draws?	(dilincdd: SCR.INEXC4) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: SCR.INEXC4A) If Yes, was ALT > 5 × ULN on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: SCR.INEXC4B) If Yes, was AST > 5 × ULN on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: SCR.INEXC4C) If Yes, was AP > 2 × ULN on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes
9. If ALT, AST, or AP was elevated prior to the implicated drug start date, was ALT or AST > 5 × pre-drug average or AP > 2 × pre-drug average on at least 2 consecutive blood draws?	(dilincdd: SCR.INEXC5) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: SCR.INEXC5A) If Yes, was ALT > 5 × pre-drug average on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: SCR.INEXC5B) If Yes, was AST > 5 × pre-drug average on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: SCR.INEXC5C) If Yes, was AP > 2 × pre-drug average on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes
10. 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, or evidence of hemolysis?	(dilincdd: SCR.INEX6A) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: SCR.INEXA6A) If Yes Specify ALT above the ULN [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: SCR.INEXA6B) If Yes Specify AST above the ULN [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: SCR.INEXA6C) If Yes Specify AP above the ULN [0] <input type="radio"/> No

		[1] <input type="radio"/> Yes
11.	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?	(dillncdd:SCR.INEX6B) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:SCR.INEXB6A) If Yes Specify ALT above the ULN [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:SCR.INEXB6B) If Yes Specify AST above the ULN [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:SCR.INEXB6C) If Yes Specify AP above the ULN [0] <input type="radio"/> No [1] <input type="radio"/> Yes
Exclusion Criteria		
12.	Did the patient have a competing identifiable cause of acute liver injury (e.g., hepatic ischemia) that was felt to be the primary reason for the observed liver injury, supported by laboratory test, serologies, liver biopsy, or radiology?	(dillncdd:SCR.INEXC7) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
13.	Did the patient have a known, pre-existing liver problem that may confound the ability to make a diagnosis of DILI? (e.g. autoimmune hepatitis, primary biliary cirrhosis, primary sclerosing cholangitis, other chronic biliary tract disease)	(dillncdd:SCR.INEXC8) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
14.	Did the patient have acetaminophen hepatotoxicity?	(dillncdd:SCR.INEXC9) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
15.	Did the patient have a liver or allogeneic bone marrow transplant prior to the development of drug- or CAM-induced injury?	(dillncdd:SCR.INEXC10) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
Eligibility		
16.*	ICF: Patient agrees to contribute biological samples and associated data and allow medical information to be used in this study and for future research related to liver injury or liver disease (genetic research included).	(dillncdd:SCR.INEXC11) (dillncdd:SCR.INEXC11) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
17.*	ICF: In addition, patient agrees that biological specimens and associated data collected can be used for future research for conditions including but not limited to heart disease, cancer or mental illness (genetic research included).	(dillncdd:SCR.INEXC12) (dillncdd:SCR.INEXC12) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
18.	Eligibility	(dillncdd:SCR.ELIGIBILE) [1] <input type="radio"/> Satisfied all criteria [2] <input type="radio"/> Entered per protocol exemption
* Item is not required		

Item Design Notes:	
Item No.	Design Note
1.	mapped from Screening form to Demographics form

CDD: dillncdd	Table: SCR	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
INEXC2	NUMERIC	
INVSITE	STRING(3) - A3	
INEX6B	NUMERIC	
INEXC1	NUMERIC	
INEXC7	NUMERIC	
SCRDOBDT	DATE - DDMONYYYY	
INEXC10	NUMERIC	

SCRSEX	NUMERIC	
ELIGIBLE	NUMERIC	
INEXA6A	NUMERIC	
PATID	STRING(4) - A4	
INEXB6C	NUMERIC	
INEX6A	NUMERIC	
INEXA6C	NUMERIC	
INEXC5A	NUMERIC	
INEXB6A	NUMERIC	
INEXC3	NUMERIC	
INEXC5C	NUMERIC	
INEXC4C	NUMERIC	
INEXB6B	NUMERIC	
INEXC4A	NUMERIC	
INEXC4B	NUMERIC	
INEXA6B	NUMERIC	
INEXC8	NUMERIC	
INEXC12	NUMERIC	
INEXC9	NUMERIC	
INEXC11	NUMERIC	
INEXC5	NUMERIC	
INEXC4	NUMERIC	
INEXC5B	NUMERIC	

dilin : Enrollment (ENR)	
.	
1. Patient Number	A15 (dilincdd:ENR.SUBJNO)
2. Enrolled Date	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2004-2020) (dilincdd:ENR.SCRNDT)

Column Name	Column Data Type	Design Note
SUBJNO	STRING(15) - A15	
SCRNDT	DATE - DDMONYYYY	

dilin : VISIT STATUS (VISSTAT)	
.	
1. Date of visit	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dilincdd:VISSTAT.SAQDT)
2. Did the patient complete the visit?	(dilincdd:VISSTAT.COMPVST) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If patient withdrew early or completed all expected visits, please complete the termination visit.

Column Name	Column Data Type	Design Note
SAQDT	DATE - DDMONYYYY	
COMPVST	NUMERIC	

dilin : DEMOGRAPHICS (DEMOG)	
Patient Information	
****WARNING: ANY CHANGES MADE TO THE PATIENT INFORMATION FIELDS BELOW WILL CHANGE THE IDENTIFICATION OF THIS SUBJECT. Changes that make these fields empty will not be acted upon and the prior values will remain for the purpose of identification.***	
1. Patient Number	A15 (dilincdd: DEMOG.SUBJNO)
2. Birthdate	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (1910-2020) (dilincdd: DEMOG.DOBBDT)
3. Sex	(dilincdd: DEMOG.SEX) [1] <input type="radio"/> Male [2] <input type="radio"/> Female
Demographics	
4. Do you consider yourself Hispanic, Latino, or Latina?	(dilincdd: DEMOG.LATINO) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: DEMOG.LATINORG) If Yes What is your Hispanic, Latino, or Latina origin [1] <input type="radio"/> Cuban [2] <input type="radio"/> Mexican [3] <input type="radio"/> Puerto Rican [98] <input type="radio"/> Other Other Specify A50 (dilincdd: DEMOG.ORGINSP)
5. What is your race? (Check all that apply)	(dilincdd: DEMOG.WHITE) [1] <input type="checkbox"/> White (dilincdd: DEMOG.BLACK) [1] <input type="checkbox"/> Black or African American (dilincdd: DEMOG.ASIAN) [1] <input type="checkbox"/> Asian (dilincdd: DEMOG.INDIAN) [1] <input type="checkbox"/> American Indian or Alaska Native (dilincdd: DEMOG.NATIVE) [1] <input type="checkbox"/> Native Hawaiian or Other Pacific Islander (dilincdd: DEMOG.RACEOTHR) [1] <input type="checkbox"/> Other Race Other Race (specify) A50 (dilincdd: DEMOG.RACESP)
6. In what country were you born	(dilincdd: DEMOG.BIRTHCTY) [1] <input type="radio"/> Continental U.S., Alaska, or Hawaii [98] <input type="radio"/> Other Specify Other Country A50 (dilincdd: DEMOG.BRCTRYSP)
7. Geographic area of residence State	Pulldown List 1 <input type="checkbox"/> (dilincdd: DEMOG.GEOSTATE) Specify other residence A50 (dilincdd: DEMOG.GEOSTSP)
8. Geographic area of residence County	A50 (dilincdd: DEMOG.GEOCTY)
9. Geographic area of residence Zip Code	A10 (dilincdd: DEMOG.GEOZIP)
10. Education (highest level completed)	Pulldown List 2 <input type="checkbox"/> (dilincdd: DEMOG.EDUCATE)
11. Marital status	(dilincdd: DEMOG.MARITAL) [1] <input type="radio"/> Single [2] <input type="radio"/> Married [3] <input type="radio"/> Widowed [4] <input type="radio"/> Divorced [5] <input type="radio"/> Separated [96] <input type="radio"/> Not applicable
12. Health insurance status	(dilincdd: DEMOG.INSURANC) [0] <input type="radio"/> None [1] <input type="radio"/> Private/HMO [2] <input type="radio"/> Medicare [3] <input type="radio"/> Medicaid/Medicaid HMO [4] <input type="radio"/> Private and Medicare [5] <input type="radio"/> Medicare and Medicaid
Agecalc	xxxxxxxx. (dilincdd: DEMOG.AGECALC)

13.*	Data Entry Reviewed (MIGRATION TEAM USE ONLY)	(dilincdd: DEMOG. DEMIGRAT) [?] <input type="radio"/> Yes
14.*	Queries Reviewed (MIGRATION TEAM USE ONLY)	(dilincdd: DEMOG. DMMIGRAT) [?] <input type="radio"/> Yes
* Item is not required		

Item Design Notes:	
Item No.	Design Note
2.	mapped from Screening form to Demographics form

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieUSAlabama	Alabama	1	
ieUSAlaska	Alaska	2	
ieUSArizona	Arizona	3	
ieUSArkansas	Arkansas	4	
ieUSCalifornia	California	5	
ieUSColorado	Colorado	6	
ieUSConnecticut	Connecticut	7	
ieUSDelaware	Delaware	8	
ieUSFlorida	Florida	9	
ieUSGeorgia	Georgia	10	
ieUSHawaii	Hawaii	11	
ieUSIdaho	Idaho	12	
ieUSIllinois	Illinois	13	
ieUSIndiana	Indiana	14	
ieUSIowa	Iowa	15	
ieUSKansas	Kansas	16	
ieUSKentucky	Kentucky	17	
ieUSLouisiana	Louisiana	18	
ieUSMaine	Maine	19	
ieUSMaryland	Maryland	20	
ieUSMassachuse	Massachusetts	21	
ieUSMichigan	Michigan	22	
ieUSMinnesota	Minnesota	23	
ieUSMississippi	Mississippi	24	
ieUSMissouri	Missouri	25	
ieUSMontana	Montana	26	
ieUSNebraska	Nebraska	27	
ieUSNevada	Nevada	28	
ieUSNewHamps	New Hampshire	29	
ieUSNewJersey	New Jersey	30	
ieUSNewMexico	New Mexico	31	
ieUSNewYork	New York	32	
ieUSNorthCarolina	North Carolina	33	
ieUSNorthDakota	North Dakota	34	
ieUSOhio	Ohio	35	
ieUSOklahoma	Oklahoma	36	
ieUSOregon	Oregon	37	
ieUSPennsylvania	Pennsylvania	38	

ieUSRhodeIsland	Rhode Island	39	
ieUSSouthCarolina	South Carolina	40	
ieUSSouthDakota	South Dakota	41	
ieUSTennessee	Tennessee	42	
ieUSTexas	Texas	43	
ieUSUtah	Utah	44	
ieUSVermont	Vermont	45	
ieUSVirginia	Virginia	46	
ieUSWashington	Washington	47	
ieUSWestVirginia	West Virginia	48	
ieUSWisconsin	Wisconsin	49	
ieUSWyoming	Wyoming	50	
ieUSOTH	Other	98	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieEDUNA	Not applicable (preschool age)	1	
ieEDU8	Elementary school (0 - 8th grade)	2	
ieEDU11gr	9 - 11th grade	3	
ieEDU12g	12th grade (or GED)	4	
ieEDUAD	Some college/Associate's degree	5	
ieEDUColle	College degree	6	
ieEDUPosGra	Postgraduate degree	7	

CDD: dilincdd Table: DEMOG Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ASIAN	NUMERIC	
SEX	NUMERIC	
RACEOTHR	NUMERIC	
GEOSTSP	STRING(50) - A50	
EDUCATE	NUMERIC - 1, 2, 3, 4, 5, 6, 7	
LATINO	NUMERIC	
MARITAL	NUMERIC	
INDIAN	NUMERIC	
SUBJNO	STRING(15) - A15	
DMMIGRAT	NUMERIC	
WHITE	NUMERIC	
ORGINSP	STRING(50) - A50	
AGECALC	FLOAT - F9.0	
GEOSTATE	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 98	
INSURANC	NUMERIC	
NATIVE	NUMERIC	
RACESP	STRING(50) - A50	
BLACK	NUMERIC	
DOBDT	DATE - DDMONYYYY	
LATINORG	NUMERIC	
DEMIGRAT	NUMERIC	
BIRTHCTY	NUMERIC	
BRCTRYSP	STRING(50) - A50	
GEOZIP	STRING(10) - A10	
GEOCTY	STRING(50) - A50	

dilin : FAMILY HISTORY (FAMHX1)		
Family History		
1.	Is your biological mother still living?	(dilincdd:FAMHX1.MOM) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes (dilincdd:FAMHX1.MOMPLTH) If Yes, what is her current health status [1] <input type="radio"/> Good [2] <input type="radio"/> Fair [3] <input type="radio"/> Poor [99] <input type="radio"/> Unknown
2.	Is your biological father still living?	(dilincdd:FAMHX1.DAD) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes (dilincdd:FAMHX1.DADPLTH) If Yes, what is his current health status [1] <input type="radio"/> Good [2] <input type="radio"/> Fair [3] <input type="radio"/> Poor [99] <input type="radio"/> Unknown
3.	Are you a twin or one of a multiple birth?	(dilincdd:FAMHX1.TWIN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd:FAMHX1.TWINIDNT) Are you identical? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
4.	How many biological brothers do you have?	(dilincdd:FAMHX1.BRONONE) [1] <input type="radio"/> xxx (dilincdd:FAMHX1.BRO) [0] <input type="radio"/> None
5.	How many biological sisters do you have?	(dilincdd:FAMHX1.SISNONE) [1] <input type="radio"/> xxx (dilincdd:FAMHX1.SIS) [0] <input type="radio"/> None
6.	How many of your biological siblings are still alive?	(dilincdd:FAMHX1.SIBNA) [1] <input type="radio"/> xxx (dilincdd:FAMHX1.SIBALIVE) [0] <input type="radio"/> None
7.	How many biological male children do you have?	(dilincdd:FAMHX1.MCNONE) [1] <input type="radio"/> xxx (dilincdd:FAMHX1.MCHILD) [0] <input type="radio"/> None
8.	How many biological female children do you have?	(dilincdd:FAMHX1.FCNONE) [1] <input type="radio"/> xxx (dilincdd:FAMHX1.FCHILD) [0] <input type="radio"/> None
9.	How many of your biological children are still alive?	(dilincdd:FAMHX1.CHILDNA) [1] <input type="radio"/> xxx (dilincdd:FAMHX1.CHALIVE) [0] <input type="radio"/> None
10.	Have any of your biological relatives ever suffered a drug allergy due to taking any medications that were severe enough to require a visit to a health care professional?	(dilincdd:FAMHX1.FALLERGY) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown [96] <input type="radio"/> Not applicable

Column Name	Column Data Type	Design Note
SIBNA	NUMERIC	

MCNONE	NUMERIC	
BRO	NUMERIC - N3	
MOMPHLTH	NUMERIC	
DAD	NUMERIC	
SIS	NUMERIC - N3	
FCNONE	NUMERIC	
TWINIDNT	NUMERIC	
MCHILD	NUMERIC - N3	
TWIN	NUMERIC	
FALLERGY	NUMERIC	
CHALIVE	NUMERIC - N3	
SIBALIVE	NUMERIC - N3	
CHILDNA	NUMERIC	
FCHILD	NUMERIC - N3	
SISNONE	NUMERIC	
DADPHLTH	NUMERIC	
BRONONE	NUMERIC	
MOM	NUMERIC	

dilin : FAMILY HISTORY 2 (FAMHX2) - Repeating Form				
#		Biological relative	Drug name	Type of Reaction
1	<input type="text"/>			
Family History continued				
1.	Biological relative		(dilincdd: FAMHX2.RELALLGY) [1] <input type="radio"/> Father [2] <input type="radio"/> Mother [3] <input type="radio"/> Sibling [4] <input type="radio"/> Children	
2.	Drug name		<input type="text" value="A80"/> (dilincdd: FAMHX2.FDRGNM)	
3.	Type of Reaction		(dilincdd: FAMHX2.DRGRACT) [1] <input type="radio"/> Allergic [2] <input type="radio"/> Liver Problem [99] <input type="radio"/> Unknown	

CDD: dilincdd Table: FAMHX2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
FDRGNM	STRING(80) - A80	
RELALLGY	NUMERIC	
DRGRACT	NUMERIC	

dilin : PAST MEDICAL HISTORY (MEDHX2)		
Past Medical History continued		
1.	Does the subject have a history of medical conditions/diseases?	(dilincdd: MEDHX2.MEDHXYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2.	Does the subject have a history of medical conditions-liver specific?	(dilincdd: MEDHX2.LIVHXYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
3.	Does the subject have a history of allergies to medications?	(dilincdd: MEDHX2.ALLERGY) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4.	Does the subject have a history of surgeries?	(dilincdd: MEDHX2.SURGERY) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
5.	Were any imaging studies performed?	(dilincdd: MEDHX2.IMAGEYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6.*	Was the PHQ completed?	(dilincdd: MEDHX2.PHQYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: MEDHX2.PHQCOMP) PHQ completed by [1] <input type="radio"/> Subject [98] <input type="radio"/> Other
* Item is not required		

Column Name	Column Data Type	Design Note
LIVHXYN	NUMERIC	
PHQCOMP	NUMERIC	
PHQYN	NUMERIC	
SURGERY	NUMERIC	
ALLERGY	NUMERIC	
IMAGEYN	NUMERIC	
MEDHXYN	NUMERIC	

dilin : PAST MEDICAL HISTORY (MEDHX1) - Repeating Form				
#	Name of System/Disease	Specify condition	Date of Diagnosis	Active condition
1				

Past Medical History	
1.	Name of System/Disease
2. *	Specify condition
3.	Date of Diagnosis
4.	Active condition

* Item is not required

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieMHXDIABETES	Diabetes/endocrine disorder	1	
ieMHXINFECTIOUS	Infectious disease	2	
ieMHXPSYCHIATRIC	Psychiatric disease	3	
ieMHXNEURO	Neurological disease	4	
ieMHXHEART	Heart disease	5	
ieMHXHYPERTENSION	Hypertension	6	
ieMHXRENAL	Renal disease	7	
ieMHXPULMONARY	Pulmonary disease	8	
ieMHXGASTRO	Gastrointestinal disease	9	
ieMHXMALIGNANCY	Malignancy	10	
ieMHXAUTOIMMUNE	Autoimmune/collagen vascular disease	11	
ieMHXCONGESTIVE	Congestive heart failure	12	
ieMHXHYPOTENSION	Hypotension	13	
ieMHXREPRODUCTIVE	Reproductive issues	14	
ieMHXORGANTRANSP	Organ transplantation (other than liver)	15	
ieMHXACUTEHYPOTENSION	Acute hypotension (one week prior to DILI onset)	16	
ieMHXACUTECONGESTIVE	Acute congestive heart failure (one week prior to DILI onset)	17	
ieMHXOTHER	Other (specify)	98	

CDD: dilincdd Table: MEDHX1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PASTHXDT	DATE - MONYYYY	
ACTIVE	NUMERIC	
CONDITN	STRING(100) - A100	
PASTHX	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 98	

dilin : PAST ALLERGY HISTORY (ALLRGYHX) - Repeating Form			
#		Agent	Reaction
1	<input type="text"/>		

Past Allergy History	
1. Agent	<input type="text" value="A80"/> (dilinccd: ALLRGYHX.AGENT)
2. Reaction	<input type="text" value="A200"/> (dilinccd: ALLRGYHX.ALLGREAC)

Column Name	Column Data Type	Design Note
ALLGREAC	STRING(200) - A200	
AGENT	STRING(80) - A80	

dilin : PAST SURGICAL HISTORY (SURGHX) - Repeating Form			
#		Specify surgery	Date of surgery
1	<input type="text"/>		
Past Surgical History			
1.	Specify surgery	A200	(dilincdd: SURGHX.SXTYPE)
2.	Date of surgery	Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020)	(dilincdd: SURGHX.SXDT)

Column Name	Column Data Type	Design Note
SXDT	DATE - DDMONYYYY	
SXTYPE	STRING(200) - A200	

dilin : PAST MEDICAL HISTORY-LIVER SPECIFIC (LIVHX) - Repeating Form				
#		Type of Liver Disease	Date of Diagnosis	Active condition
1	<input type="checkbox"/>			

NOTE-At initial study, only record chronic HCV & HBV. At follow up visits, only record acute/newly diagnosed HCV & HBV

Past Med History-Liver Specific	
1. Type of Liver Disease	Pulldown List 1 <input type="button" value="v"/> (dilincdd:LIVHX.MEDLIVHX) If Family History is checked, please specify condition (dilincdd:LIVHX.LCONDITN) <input type="text" value="A200"/>
2. Date of Diagnosis	Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dilincdd:LIVHX.LIVHXDT)
3. Active condition	(dilincdd:LIVHX.LACTIVE) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieLIVHCV	HCV	1	
ieLIVHBV	HBV	2	
ieLIVALCOHOL	Alcohol-related liver disease	3	
ieLIVNONALCOHO	Non-alcoholic fatty liver disease (NALFD/NASH)	4	
ieLIVWILSON	Wilson's disease	5	
ieLIVHEMOCHROM	Hemochromatosis	6	
ieLIVPRIMBC	Primary biliary cirrhosis	7	
ieLIVPRIMSC	Primary sclerosing cholangitis	8	
ieLIVGILBERT	Gilbert's syndrome	9	
ieLIVA1AT	A1AT deficiency	10	
ieLIVUNEXPALT	Unexplained abnormal liver tests	11	
ieLIVCIRRHOSIS	Cirrhosis-unspecified	12	
ieLIVISCHHEPAT	Ischemic hepatitis	13	
ieLIVLIVERTRAN	Liver transplantation	14	
ieLIVHEPATA	Hepatitis A	15	
ieLIVAUTOIMMUHEPAT	Autoimmune hepatitis	16	
ieLIVFHLD	Family history of liver disease	17	

CDD: dilincdd Table: LIVHX Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
MEDLIVHX	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17	
LIVHXDT	DATE - MONYYYY	
LCONDITN	STRING(200) - A200	
LACTIVE	NUMERIC	

dilin : GENERAL MEDICATION COMPLIANCE (RXCOMPLY)	
General Medication Compliance	
1. Surrogate respondent?	(dilincdd:RXCOMPLY.SURRO1) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd:RXCOMPLY.SURSPEC1) Specify Surrogate [1] <input type="radio"/> Relative [98] <input type="radio"/> Other
2. When a doctor prescribes a medication for you to take, how closely do you usually follow the medication schedule?	(dilincdd:RXCOMPLY.FOLLOW) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input type="radio"/> Most of the time [3] <input type="radio"/> Always
3. Sometimes, people take their medications more frequently than was prescribed. Do you ever do this with prescribed medications?	(dilincdd:RXCOMPLY.FREQMORE) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input type="radio"/> Most of the time [3] <input type="radio"/> Always
4. Sometimes, people take their medications less frequently than was prescribed. Do you ever do this with prescribed medications?	(dilincdd:RXCOMPLY.FREQLESS) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input type="radio"/> Most of the time [3] <input type="radio"/> Always

CDD: dilincdd Table: RXCOMPLY Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
FOLLOW	NUMERIC	
SURSPEC1	NUMERIC	
FREQLESS	NUMERIC	
SURRO1	NUMERIC	
FREQMORE	NUMERIC	

dilin : DRUG SPECIFIC MEDICATION COMPLIANCE (DRUGCOMP) - Repeating Form								
#	Surrogate respondent	Medication name	Follow medication schedule	More frequently than RX	Less frequently than RX	More medications than RX	Less medications than RX	
1	<input type="text"/>							

Drug Specific Medication Compliance	
1. Surrogate respondent?	(dilincdd: DRUGCOMP.SURRO2) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: DRUGCOMP.SURSPEC2) Specify Surrogate [1] <input type="radio"/> Relative [98] <input type="radio"/> Other
2. Now, I'd like you to think about your medication schedule with	<input type="text" value="A80"/> (dilincdd: DRUGCOMP.RXNAME)
3. How closely did you follow your medication schedule?	(dilincdd: DRUGCOMP.RXFOLLOW) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input type="radio"/> Most of the time [3] <input type="radio"/> Always
4. Did you ever take this medication more frequently than was prescribed?	(dilincdd: DRUGCOMP.RXMORE) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input type="radio"/> Most of the time [3] <input type="radio"/> Always
5. Did you ever take this medication less frequently than was prescribed?	(dilincdd: DRUGCOMP.RXLESS) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input type="radio"/> Most of the time [3] <input type="radio"/> Always
6. Sometimes, when people take their medications, they take more than they are supposed to. Did you ever take more of this medication than you were supposed to?	(dilincdd: DRUGCOMP.RXMORTHN) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input type="radio"/> Most of the time [3] <input type="radio"/> Always
7. Sometimes, when people take their medications, they take less than they are supposed to. Did you ever take less of this medication than you were supposed to?	(dilincdd: DRUGCOMP.RXLESTHN) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input type="radio"/> Most of the time [3] <input type="radio"/> Always

CDD: dilincdd Table: DRUGCOMP Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SURRO2	NUMERIC	
RXMORTHN	NUMERIC	
RXLESTHN	NUMERIC	
RXNAME	STRING(80) - A80	
RXLESS	NUMERIC	
RXMORE	NUMERIC	
RXFOLLOW	NUMERIC	
SURSPEC2	NUMERIC	

dilin : QUESTIONNAIRES (QUESTS)	
Questionnaires	
1. Surrogate respondent?	(dilincdd:QUESTS.SURRO3) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd:QUESTS.SURSPEC3) Specify Surrogate [1] <input type="radio"/> Relative [98] <input type="radio"/> Other
2. During the last 12 months, did you fill a prescription for a medicine that was prescribed for you?	(dilincdd:QUESTS.FILLRX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
3. Over the past 5 years, how would you describe your smoking habit?	(dilincdd:QUESTS.SMOKE) [1] <input type="radio"/> Never smoked [3] <input type="radio"/> Current smoker [2] <input type="radio"/> Ex-smoker How many years since you quit smoking? xxxxxxxx. (dilincdd:QUESTS.QUITSMKE)
4. Over the past 5 years, have you ever had at least one drink of alcohol, beer, liquor, wine, or wine coolers, per month during a 12-month time period, or at least three drinks per day for at least three consecutive days (over a regular period of time)?	(dilincdd:QUESTS.ALCOHOL) [0] <input type="radio"/> No [1] <input type="radio"/> Yes


CDD: dilincdd Table: QUESTS Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
FILLRX	NUMERIC	
ALCOHOL	NUMERIC	
QUITSMKE	FLOAT - F9.0	
SURRO3	NUMERIC	
SURSPEC3	NUMERIC	
SMOKE	NUMERIC	

dilin : SOURCE OF RX MEDICATIONS (PHARMACY)		
Source of Prescription Medications		
1.	Is there one pharmacy where you usually go to fill most of your prescriptions?	(dilincdd:PHARMACY.FILLPHAR) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2.	What is the name of the pharmacy you visited most recently to fill or refill a prescription?	A50 (dilincdd:PHARMACY.PHARMNM)
3.	Pharmacy Address	A50 (dilincdd:PHARMACY.PHARMADD)
4.	Pharmacy City	A25 (dilincdd:PHARMACY.PHARMCY)
5.	Pharmacy State	A5 (dilincdd:PHARMACY.PHARMST)
6.	Pharmacy Zip	A10 (dilincdd:PHARMACY.PHARMZIP)
7.	Pharmacy Telephone Number	A13 (dilincdd:PHARMACY.PHARMPH)
8.	During the last 12 months, which of the following types of pharmacies did you use to fill prescriptions for medicines that were prescribed for you (check all that apply)?	(dilincdd:PHARMACY.NATIONAL1) [1] <input type="checkbox"/> National pharmacy chain (dilincdd:PHARMACY.LOCAL1) [1] <input type="checkbox"/> Local independently owned pharmacy (dilincdd:PHARMACY.CLINIC) [1] <input type="checkbox"/> Hospital or clinic-based pharmacy (dilincdd:PHARMACY.MAIL) [1] <input type="checkbox"/> Mail-order pharmacy (dilincdd:PHARMACY.OTHRPHAR) [1] <input type="checkbox"/> Other type (dilincdd:PHARMACY.UNSURE) [1] <input type="checkbox"/> Do not know/unsure
9.	During the last 12 months, approximately how many different pharmacies filled prescription medications for you (check only one)?	(dilincdd:PHARMACY.DIFFPHAR) [1] <input type="radio"/> One - I always go to the same pharmacy [2] <input type="radio"/> Two pharmacies [3] <input type="radio"/> Three pharmacies [4] <input type="radio"/> More than three pharmacies [5] <input type="radio"/> Do not know/unsure
10.	During the last 12 months, did your doctors office ever give you samples of medications that you used instead of getting a prescription filled at a pharmacy?	(dilincdd:PHARMACY.SAMPLES) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes Please indicate how many times you received samples of prescription medications from your doctors office xxx (dilincdd:PHARMACY.PHARMSMP)

CDD: dilincdd Table: PHARMACY Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PHARMCY	STRING(25) - A25	
FILLPHAR	NUMERIC	
PHARMZIP	STRING(10) - A10	
LOCAL1	NUMERIC	
SAMPLES	NUMERIC	
PHARMSMP	NUMERIC - N3	
MAIL	NUMERIC	
DIFFPHAR	NUMERIC	
CLINIC	NUMERIC	
PHARMST	STRING(5) - A5	
PHARMADD	STRING(50) - A50	
PHARMNM	STRING(50) - A50	
NATIONAL1	NUMERIC	
OTHRPHAR	NUMERIC	
UNSURE	NUMERIC	
PHARMPH	STRING(13) - A13	

dilin : GENERAL SMOKING HISTORY (GENSMOKE)	
General Smoking History	
1. How long did you smoke (in years)	Pulldown List 1  (dilincdd: GENSMOKE.SMKLNGTH)
2. What is/was your smoking preference(s)?	(dilincdd: GENSMOKE.CIGARET) [1] <input type="checkbox"/> Cigarette (dilincdd: GENSMOKE.CIGARS) [1] <input type="checkbox"/> Cigar (dilincdd: GENSMOKE.PIPE) [1] <input type="checkbox"/> Pipe
3. Do/did you regularly inhale tobacco when smoking?	(dilincdd: GENSMOKE.SMKINHAL) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieSMOKE1	<1	1	
ieSMOKE10	1-10	2	
ieSMOKE14	11-14	3	
ieSMOKE19	15-19	4	
ieSMOKE29	20-29	5	
ieSMOKE30	>30	6	

CDD: dilincdd Table: GENSMOKE Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SMKINHAL	NUMERIC	
SMKLNTH	NUMERIC - 1, 2, 3, 4, 5, 6	
CIGARS	NUMERIC	
PIPE	NUMERIC	
CIGARET	NUMERIC	

dilin : SMOKING HISTORY (SMOKEHX) - Repeating Form							
#	Phase	Youngest Age	Oldest Age	Cigarettes Per Day	Cigars Per Week	Pipes Per Week	
1							

Smoking History	
1. Phase	xxx (dillncdd: SMOKEHX.PHASE)
2. Youngest Age	xxx (dillncdd: SMOKEHX.YOUNGAGE)
3. Oldest Age	xxx (dillncdd: SMOKEHX.OLDAGE)
4. Cigarettes Per Day	xxxxxxxx. (dillncdd: SMOKEHX.CIGPDAY)
5. Cigars Per Week	xxxxxxxx. (dillncdd: SMOKEHX.CIGPWK)
6. Pipes Per Week	xxxxxxxx. (dillncdd: SMOKEHX.PIPEPWK)

Column Name	Column Data Type	Design Note
OLDAGE	NUMERIC - N3	
PIPEPWK	FLOAT - F9.0	
CIGPDAY	FLOAT - F9.0	
CIGPWK	FLOAT - F9.0	
PHASE	NUMERIC - N3	
YOUNGAGE	NUMERIC - N3	

dilin : SKINNER ALCOHOL CONSUMPTION (SKINNER) - Repeating Form																					
#	Phase	Youngest Age	Oldest Age	Average Quantity of Drinks per day (If Average = 00 Skip to Style)	Maximum Quantity of Drinks per day	Frequency (Days/month)	Type (check all that apply)	Style	Any Life Events that Influenced Drinking	Perception of Effect on Your Marital / family	Perception of Effect on Your Work	Perception of Effect on Your School	Perception of Effect on Your Medical	Perception of Effect on Your Residence	Perception of Effect on Your Legal/jail	Perception of Effect on Your Financial	Perception of Effect on Your Peer group	Perception of Effect on Your Drug abuse	Perception of Effect on Your Treatment	Perception of Effect on Your Death	Perception of Effect on Your Emotional
1																					

Modified Skinner History of Alcohol Use	
1.	Phase xxx (dillncdd: SKINNER.PHASE2)
2.	Youngest Age xxxxxxxx. (dillncdd: SKINNER.SYNGAGE)
3.	Oldest Age xxxxxxxx. (dillncdd: SKINNER.SOLDAGE)
4.	Average Quantity of Drinks per day (If Average = 00 Skip to Style) xxx (dillncdd: SKINNER.AVERAGE)
5.*	Maximum Quantity of Drinks per day xxx (dillncdd: SKINNER.MAXIMUM)
6.*	Frequency (Days/month) xxx (dillncdd: SKINNER.SKFREQ)
7.*	Type (check all that apply) (dillncdd: SKINNER.BEERY) [1] <input type="checkbox"/> Beer % (dillncdd: SKINNER.BEER) xxx (dillncdd: SKINNER.LIQUORY) [1] <input type="checkbox"/> Liquor % (dillncdd: SKINNER.LIQUOR) xxx (dillncdd: SKINNER.WINEY) [1] <input type="checkbox"/> Wine % (dillncdd: SKINNER.WINE) xxx
8.	Style (dillncdd: SKINNER.STYLE) [1] <input type="radio"/> Abstinent [2] <input type="radio"/> Occasional [3] <input type="radio"/> Weekend [4] <input type="radio"/> Binge [5] <input type="radio"/> Frequent
9.	Any Life Events that Influenced Drinking? (If No Skip to next phase) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
10.*	Perception of Effect on Your Marital / family (dillncdd: SKINNER.FAM) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
11.*	Perception of Effect on Your Work (dillncdd: SKINNER.JOB) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
12.*	Perception of Effect on Your School (dillncdd: SKINNER.SCHOOL) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
13.*	Perception of Effect on Your Medical (dillncdd: SKINNER.MEDICAL) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
14.*	Perception of Effect on Your Residence (dillncdd: SKINNER.RESIDENC) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative

		[3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
15.*	Perception of Effect on Your Legal/jail	(dilinccd: SKINNER.LEGAL) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
16.*	Perception of Effect on Your Financial	(dilinccd: SKINNER.FINANCE) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
17.*	Perception of Effect on Your Peer group	(dilinccd: SKINNER.PEER) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
18.*	Perception of Effect on Your Drug abuse	(dilinccd: SKINNER.DRGABUSE) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
19.*	Perception of Effect on Your Treatment	(dilinccd: SKINNER.TREATMNT) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
20.*	Perception of Effect on Your Death	(dilinccd: SKINNER.DEATH) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
21.*	Perception of Effect on Your Emotional	(dilinccd: SKINNER.EMOTION) [1] <input type="radio"/> Positive [2] <input type="radio"/> Negative [3] <input type="radio"/> Neutral [4] <input type="radio"/> Did not occur
* Item is not required		

Column Name	Column Data Type	Design Note
LIQUOR	NUMERIC - N3	
EMOTION	NUMERIC	
FAM	NUMERIC	
DRGABUSE	NUMERIC	
MEDICAL	NUMERIC	
WINEY	NUMERIC	
AVERAGE	NUMERIC - N3	
PHASE2	NUMERIC - N3	
STYLE	NUMERIC	
TREATMNT	NUMERIC	
LIQUORY	NUMERIC	
RESIDENC	NUMERIC	
SCHOOL	NUMERIC	
WINE	NUMERIC - N3	
SKFREQ	NUMERIC - N3	

PEER	NUMERIC	
LEGAL	NUMERIC	
LIFEVNT	NUMERIC	
MAXIMUM	NUMERIC - N3	
SOLDAGE	FLOAT - F9.0	
DEATH	NUMERIC	
BEER	NUMERIC - N3	
SYNGAGE	FLOAT - F9.0	
JOB	NUMERIC	
BEERY	NUMERIC	
FINANCE	NUMERIC	

dilin : SYMPTOMS (SAQSYMPT)		
Symptoms		
Indicate the score to describe how you felt during the past week:		
1.	Tired or fatigued?	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC1)
2.	Nausea?	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC2)
3.	Pain over the liver area? (on the right side under your rib cage)	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC3)
4.	Poor appetite?	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC4)
5.	Muscle/joint aches or pains?	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC5)
6.	Weakness of the arms or legs?	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC6)
7.	Itching of the skin?	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC7)
8.	Fever and chills?	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC8)
9.	Skin rash?	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC9)
10.	Depressed/sadness?	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC10)
11.	How you feel overall?	xxxxxxxx. (dilincdd: SAQSYMPT.SYMPSC11)

CDD: dilincdd Table: SAQSYMPT Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SYMPSC11	FLOAT - F9.0	
SYMPSC6	FLOAT - F9.0	
SYMPSC9	FLOAT - F9.0	
SYMPSC3	FLOAT - F9.0	
SYMPSC7	FLOAT - F9.0	
SYMPSC5	FLOAT - F9.0	
SYMPSC2	FLOAT - F9.0	
SYMPSC10	FLOAT - F9.0	
SYMPSC8	FLOAT - F9.0	
SYMPSC1	FLOAT - F9.0	
SYMPSC4	FLOAT - F9.0	

dilin : RAND 36 HEALTH SURVEY (RANDHS1)		
RAND 36 Survey Q1-12		
1.	(Q1) In general, would you say your health is:	(dilincdd:RANDHS1.HEALTH) [1] <input type="radio"/> Excellent [2] <input type="radio"/> Very good [3] <input type="radio"/> Good [4] <input type="radio"/> Fair [5] <input type="radio"/> Poor
2.	(Q2) Compared to one year ago, how would you rate your health in general now?	(dilincdd:RANDHS1.HLTHNOW) [1] <input type="radio"/> Much better [2] <input type="radio"/> Somewhat better [3] <input type="radio"/> About the same [4] <input type="radio"/> Somewhat worse [5] <input type="radio"/> Much worse
.		
The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?		
3.	(Q3) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	(dilincdd:RANDHS1.LIMIT01) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
4.	(Q4) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	(dilincdd:RANDHS1.LIMIT02) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
5.	(Q5) Lifting or carrying groceries.	(dilincdd:RANDHS1.LIMIT03) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
6.	(Q6) Climbing several flights of stairs	(dilincdd:RANDHS1.LIMIT04) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
7.	(Q7) Climbing one flight of stairs	(dilincdd:RANDHS1.LIMIT05) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
8.	(Q8) Bending, kneeling or stooping	(dilincdd:RANDHS1.LIMIT06) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
9.	(Q9) Walking more than a mile	(dilincdd:RANDHS1.LIMIT07) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
10.	(Q10) Walking several blocks	(dilincdd:RANDHS1.LIMIT08) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
11.	(Q11) Walking one block	(dilincdd:RANDHS1.LIMIT09) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All
12.	(Q12) Bathing or dressing yourself	(dilincdd:RANDHS1.LIMIT10) [1] <input type="radio"/> Yes, Limited A Lot [2] <input type="radio"/> Yes, Limited A Little [3] <input type="radio"/> No, Not Limited At All

Column Name	Column Data Type	Design Note
CDD: dilincdd	Table: RANDHS1	Key Type: PATIENTVISIT

LIMIT02	NUMERIC	
LIMIT04	NUMERIC	
HLTHNOW	NUMERIC	
LIMIT10	NUMERIC	
LIMIT07	NUMERIC	
LIMIT01	NUMERIC	
LIMIT08	NUMERIC	
LIMIT09	NUMERIC	
LIMIT05	NUMERIC	
LIMIT03	NUMERIC	
LIMIT06	NUMERIC	
HEALTH	NUMERIC	

dilin : RAND 36 HEALTH SURVEY 2 (RANDHS2)		
RAND 36 Survey Q13-22		
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?		
1.	(Q13) Cut down on the amount of time you spent on work or other activities	(dilincdd: RANDHS2.WORKANS1) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2.	(Q14) Accomplished less than you would like	(dilincdd: RANDHS2.WORKANS2) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
3.	(Q15) Were limited in the kind of work or other activities	(dilincdd: RANDHS2.WORKANS3) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4.	(Q16) Had difficulty performing the work or other activities (for example, it took extra effort)	(dilincdd: RANDHS2.WORKANS4) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
.		
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems?		
5.	(Q17) Cut down on the amount of time you spent on work or other activities	(dilincdd: RANDHS2.WORKANS5) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6.	(Q18) Accomplished less than you would like	(dilincdd: RANDHS2.WORKANS6) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
7.	(Q19) Didn't do work or other activities as carefully as usual	(dilincdd: RANDHS2.WORKANS7) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
8.	(Q20) During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	(dilincdd: RANDHS2.HLTHPROB) [1] <input type="radio"/> Not at all [2] <input type="radio"/> Slightly [3] <input type="radio"/> Moderately [4] <input type="radio"/> Quite a bit [5] <input type="radio"/> Extremely
9.	(Q21) How much bodily pain have you had during the past 4 weeks?	(dilincdd: RANDHS2.BODYPAIN) [1] <input type="radio"/> None [2] <input type="radio"/> Very mild [3] <input type="radio"/> Mild [4] <input type="radio"/> Moderate [5] <input type="radio"/> Severe [6] <input type="radio"/> Very severe
10.	(Q22) During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	(dilincdd: RANDHS2.PAINWORK) [1] <input type="radio"/> Not at all [2] <input type="radio"/> Slightly [3] <input type="radio"/> Moderately [4] <input type="radio"/> Quite a bit [5] <input type="radio"/> Extremely

CDD: dilincdd Table: RANDHS2 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
WORKANS2	NUMERIC	
WORKANS3	NUMERIC	
WORKANS5	NUMERIC	
PAINWORK	NUMERIC	
WORKANS6	NUMERIC	
WORKANS4	NUMERIC	
HLTHPROB	NUMERIC	
BODYPAIN	NUMERIC	
WORKANS7	NUMERIC	

WORKANS1	NUMERIC	
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dilin : RAND 36 HEALTH SURVEY 3 (RANDHS3)	
RAND 36 Survey Q23-36	
How much of the time during the past 4 weeks	
1. (Q23) Did you feel full of pep?	Pulldown List 1 <input type="button" value="v"/> (dilincdd:RANDHS3.FEELANS1)
2. (Q24) Have you been a very nervous person?	Pulldown List 2 <input type="button" value="v"/> (dilincdd:RANDHS3.FEELANS2)
3. (Q25) Have you felt so down in the dumps that nothing could cheer you up?	Pulldown List 3 <input type="button" value="v"/> (dilincdd:RANDHS3.FEELANS3)
4. (Q26) Have you felt calm and peaceful?	Pulldown List 4 <input type="button" value="v"/> (dilincdd:RANDHS3.FEELANS4)
5. (Q27) Did you have a lot of energy?	Pulldown List 5 <input type="button" value="v"/> (dilincdd:RANDHS3.FEELANS5)
6. (Q28) Have you felt downhearted and blue?	Pulldown List 6 <input type="button" value="v"/> (dilincdd:RANDHS3.FEELANS6)
7. (Q29) Did you feel worn out?	Pulldown List 7 <input type="button" value="v"/> (dilincdd:RANDHS3.FEELANS7)
8. (Q30) Have you been a happy person?	Pulldown List 8 <input type="button" value="v"/> (dilincdd:RANDHS3.FEELANS8)
9. (Q31) Did you feel tired?	Pulldown List 9 <input type="button" value="v"/> (dilincdd:RANDHS3.FEELANS9)
10. (Q32) During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?	(dilincdd:RANDHS3.HLTHSOCL) [1] <input type="radio"/> All of the Time [2] <input type="radio"/> Most of the Time [4] <input type="radio"/> Some of the Time [5] <input type="radio"/> A Little of the Time [6] <input type="radio"/> None of the Time
.	
How TRUE or FALSE is each of the following statements for you?	
11. (Q33) I seem to get sick a little easier than other people	(dilincdd:RANDHS3.TRFSANS1) [1] <input type="radio"/> Definitely True [2] <input type="radio"/> Mostly True [3] <input type="radio"/> Don't know [4] <input type="radio"/> Mostly False [5] <input type="radio"/> Definitely False
12. (Q34) I am as healthy as anybody I know	(dilincdd:RANDHS3.TRFSANS2) [1] <input type="radio"/> Definitely True [2] <input type="radio"/> Mostly True [3] <input type="radio"/> Don't know [4] <input type="radio"/> Mostly False [5] <input type="radio"/> Definitely False
13. (Q35) I expect my health to get worse	(dilincdd:RANDHS3.TRFSANS3) [1] <input type="radio"/> Definitely True [2] <input type="radio"/> Mostly True [3] <input type="radio"/> Don't know [4] <input type="radio"/> Mostly False [5] <input type="radio"/> Definitely False
14. (Q36) My health is excellent.	(dilincdd:RANDHS3.TRFSANS4) [1] <input type="radio"/> Definitely True [2] <input type="radio"/> Mostly True [3] <input type="radio"/> Don't know [4] <input type="radio"/> Mostly False [5] <input type="radio"/> Definitely False

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieFEELALLTI	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMETI	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONETI	None of the Time	6	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieFEELALLTI	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMETI	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONETI	None of the Time	6	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
ieFEELALLTI	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMETI	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONETI	None of the Time	6	

Pulldown List 4:			
RefName	Display Text	Value	Design Note
ieFEELALLTI	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMETI	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONETI	None of the Time	6	

Pulldown List 5:			
RefName	Display Text	Value	Design Note
ieFEELALLTI	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMETI	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONETI	None of the Time	6	

Pulldown List 6:			
RefName	Display Text	Value	Design Note
ieFEELALLTI	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMETI	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONETI	None of the Time	6	

Pulldown List 7:			
RefName	Display Text	Value	Design Note
ieFEELALLTI	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMETI	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	

ieFEELNONETI	None of the Time	6	
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Pulldown List 8:			
RefName	Display Text	Value	Design Note
ieFEELALLTI	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMETI	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONETI	None of the Time	6	

Pulldown List 9:			
RefName	Display Text	Value	Design Note
ieFEELALLTI	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMETI	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONETI	None of the Time	6	

CDD: dilincdd Table: RANDHS3 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
FEELANS7	NUMERIC - 1, 2, 3, 4, 5, 6	
TRFSANS2	NUMERIC	
FEELANS5	NUMERIC - 1, 2, 3, 4, 5, 6	
HLTHSOCL	NUMERIC	
FEELANS6	NUMERIC - 1, 2, 3, 4, 5, 6	
FEELANS3	NUMERIC - 1, 2, 3, 4, 5, 6	
FEELANS8	NUMERIC - 1, 2, 3, 4, 5, 6	
FEELANS2	NUMERIC - 1, 2, 3, 4, 5, 6	
FEELANS9	NUMERIC - 1, 2, 3, 4, 5, 6	
FEELANS4	NUMERIC - 1, 2, 3, 4, 5, 6	
FEELANS1	NUMERIC - 1, 2, 3, 4, 5, 6	
TRFSANS1	NUMERIC	
TRFSANS4	NUMERIC	
TRFSANS3	NUMERIC	

dilin : PEDIATRIC QUALITY OF LIFE INVENTORY (PEDSQL1)		
PEDSQL Ages 2-4 (In the past ONE month, how much of a problem has your child had with)		
Physical Functioning:		
1.	(Q1) Walking	(dilincdd:PEDSQL1.PEDS01) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
2.	(Q2) Running	(dilincdd:PEDSQL1.PEDS02) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
3.	(Q3) Participating in active play or exercise	(dilincdd:PEDSQL1.PEDS03) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
4.	(Q4) Lifting something heavy	(dilincdd:PEDSQL1.PEDS04) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
5.	(Q5)Bathing	(dilincdd:PEDSQL1.PEDS05) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
6.	(Q6) Helping to pick up his or her toys	(dilincdd:PEDSQL1.PEDS06) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
7.	(Q7)Having hurts or aches	(dilincdd:PEDSQL1.PEDS07) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
8.	(Q8) Low energy level	(dilincdd:PEDSQL1.PEDS08) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
Emotional Functioning:		
9.	(Q1) Feeling afraid or scared	(dilincdd:PEDSQL1.PEDS09) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
10.	(Q2) Feeling sad or blue	(dilincdd:PEDSQL1.PEDS10) [0] <input type="radio"/> Never

		<p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
11.	(Q3)Feeling angry	<p>(dillncdd:PEDSQL1.PEDS11)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
12.	(Q4) Trouble sleeping	<p>(dillncdd:PEDSQL1.PEDS12)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
13.	(Q5) Worrying	<p>(dillncdd:PEDSQL1.PEDS13)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>

CDD: dillncdd Table: PEDSQL1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PEDS07	NUMERIC	
PEDS11	NUMERIC	
PEDS02	NUMERIC	
PEDS09	NUMERIC	
PEDS01	NUMERIC	
PEDS08	NUMERIC	
PEDS10	NUMERIC	
PEDS05	NUMERIC	
PEDS12	NUMERIC	
PEDS04	NUMERIC	
PEDS03	NUMERIC	
PEDS13	NUMERIC	
PEDS06	NUMERIC	

dilin : PEDIATRIC QUALITY OF LIFE INVENTORY 2 (PEDSQL2)	
PEDSQL Ages 2-4 con't (In the past ONE month, how much of a problem has your child had with)	
Social Functioning:	
1. (Q1) Playing with other children	(dilincdd:PEDSQL2.PEDS14) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
2. (Q2) Other kids not wanting to play with him or her	(dilincdd:PEDSQL2.PEDS15) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
3. (Q3) Getting teased by other children	(dilincdd:PEDSQL2.PEDS16) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
4. (Q4)Not able to do things that other children his or her age can do	(dilincdd:PEDSQL2.PEDS17) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
5. (Q5) Keeping up when playing with other children	(dilincdd:PEDSQL2.PEDS18) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
School Functioning:	
6. (Q1) Doing the same school activities as peers	(dilincdd:PEDSQL2.PEDS19) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
7. (Q2) Missing school/daycare because of not feeling well	(dilincdd:PEDSQL2.PEDS20) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
8. (Q3) Missing school/daycare to go to the doctor or hospital	(dilincdd:PEDSQL2.PEDS21) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always

CDD: dilincdd Table: PEDSQL2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PEDS18	NUMERIC	
PEDS14	NUMERIC	
PEDS16	NUMERIC	
PEDS15	NUMERIC	

PEDS21	NUMERIC	
PEDS17	NUMERIC	
PEDS19	NUMERIC	
PEDS20	NUMERIC	

dilin : PEDIATRIC QUALITY OF LIFE INVENTORY 3 (PEDSQL3)		
PEDSQL Ages 5-7 (In the past ONE month, how much of a problem has your child had with)		
Physical Functioning:		
1.	(Q1) Walking more than one block	(dilincdd:PEDSQL3.PEDS22) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
2.	(Q2) Running	(dilincdd:PEDSQL3.PEDS23) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
3.	(Q3) Participating in sports activity or exercise	(dilincdd:PEDSQL3.PEDS24) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
4.	(Q4) Lifting something heavy	(dilincdd:PEDSQL3.PEDS25) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
5.	(Q5) Taking a bath or shower by him or herself	(dilincdd:PEDSQL3.PEDS26) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
6.	(Q6) Doing chores, like picking up his or her toys	(dilincdd:PEDSQL3.PEDS27) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
7.	(Q7) Having hurts or aches	(dilincdd:PEDSQL3.PEDS28) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
8.	(Q8) Low energy level	(dilincdd:PEDSQL3.PEDS29) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
Emotional Functioning:		
9.	(Q1) Feeling afraid or scared	(dilincdd:PEDSQL3.PEDS30) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
10.	(Q2) Feeling sad or blue	(dilincdd:PEDSQL3.PEDS31) [0] <input type="radio"/> Never

		<p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
11.	(Q3) Feeling angry	<p>(dillncdd: PEDSQL3.PEDS32)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
12.	(Q4) Trouble sleeping	<p>(dillncdd: PEDSQL3.PEDS33)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
13.	(Q5) Worrying about what will happen to him or her	<p>(dillncdd: PEDSQL3.PEDS34)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>

CDD: dillncdd Table: PEDSQL3 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PEDS23	NUMERIC	
PEDS29	NUMERIC	
PEDS25	NUMERIC	
PEDS22	NUMERIC	
PEDS32	NUMERIC	
PEDS34	NUMERIC	
PEDS33	NUMERIC	
PEDS28	NUMERIC	
PEDS27	NUMERIC	
PEDS24	NUMERIC	
PEDS30	NUMERIC	
PEDS26	NUMERIC	
PEDS31	NUMERIC	

dilin : PEDIATRIC QUALITY OF LIFE INVENTORY 4 (PEDSQL4)		
PEDSQL Ages 5-7 con't (In the past ONE month, how much of a problem has your child had with)		
Social Functioning:		
1.	(Q1) Getting along with other children	(dilincdd:PEDSQL4.PEDS35) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
2.	(Q2) Other kids not wanting to be his or her friend	(dilincdd:PEDSQL4.PEDS36) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
3.	(Q3) Getting teased by other children	(dilincdd:PEDSQL4.PEDS37) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
4.	(Q4) Not able to do things that other children his or her age can do	(dilincdd:PEDSQL4.PEDS38) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
5.	(Q5) Keeping up when playing with other children	(dilincdd:PEDSQL4.PEDS39) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
School Functioning:		
6.	(Q1) Paying attention in class	(dilincdd:PEDSQL4.PEDS40) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
7.	(Q2) Forgetting things	(dilincdd:PEDSQL4.PEDS41) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
8.	(Q3) Keeping up with school activities	(dilincdd:PEDSQL4.PEDS42) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
9.	(Q4) Missing school because of not feeling well	(dilincdd:PEDSQL4.PEDS43) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
10.	(Q5) Missing school to go to the doctor or hospital	(dilincdd:PEDSQL4.PEDS44) [0] <input type="radio"/> Never

- [1] Almost Never
[2] Sometimes
[3] Often
[4] Almost Always

Column Name	Column Data Type	Design Note
PEDS40	NUMERIC	
PEDS36	NUMERIC	
PEDS41	NUMERIC	
PEDS39	NUMERIC	
PEDS37	NUMERIC	
PEDS35	NUMERIC	
PEDS42	NUMERIC	
PEDS38	NUMERIC	
PEDS43	NUMERIC	
PEDS44	NUMERIC	

dilin : PEDIATRIC QUALITY OF LIFE INVENTORY 5 (PESQL5)		
PESQL Ages 8-12 (In the past ONE month, how much of a problem has your child had with)		
Physical Functioning:		
1.	(Q1) Walking more than one block	(dilincdd:PESQL5.PES45) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
2.	(Q2) Running	(dilincdd:PESQL5.PES46) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
3.	(Q3) Participating in sports activity or exercise	(dilincdd:PESQL5.PES47) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
4.	(Q4) Lifting something heavy	(dilincdd:PESQL5.PES48) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
5.	(Q5) Taking a bath or shower by him or herself	(dilincdd:PESQL5.PES49) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
6.	(Q6) Doing chores around the house	(dilincdd:PESQL5.PES50) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
7.	(Q7) Having hurts or aches	(dilincdd:PESQL5.PES51) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
8.	(Q8) Low energy level	(dilincdd:PESQL5.PES52) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
Emotional Functioning:		
9.	(Q1) Feeling afraid or scared	(dilincdd:PESQL5.PES53) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
10.	(Q2) Feeling sad or blue	(dilincdd:PESQL5.PES54) [0] <input type="radio"/> Never

		<p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
11.	(Q3) Feeling angry	<p>(dillncdd: PEDSQL5.PEDS55)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
12.	(Q4) Trouble sleeping	<p>(dillncdd: PEDSQL5.PEDS56)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
13.	(Q5) Worrying about what will happen to him or her	<p>(dillncdd: PEDSQL5.PEDS57)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>

CDD: dillncdd Table: PEDSQL5 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PEDS45	NUMERIC	
PEDS51	NUMERIC	
PEDS50	NUMERIC	
PEDS47	NUMERIC	
PEDS57	NUMERIC	
PEDS53	NUMERIC	
PEDS55	NUMERIC	
PEDS52	NUMERIC	
PEDS49	NUMERIC	
PEDS54	NUMERIC	
PEDS48	NUMERIC	
PEDS56	NUMERIC	
PEDS46	NUMERIC	

dilin : PEDIATRIC QUALITY OF LIFE INVENTORY 6 (PEDSQL6)		
PEDSQL Ages 8-12 con't (In the past ONE month, how much of a problem has your child had with)		
Social Functioning:		
1.	(Q1) Getting along with other children	(dilinccd:PEDSQL6.PEDS58) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
2.	(Q2) Other kids not wanting to be his or her friend	(dilinccd:PEDSQL6.PEDS59) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
3.	(Q3) Getting teased by other children	(dilinccd:PEDSQL6.PEDS60) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
4.	(Q4) Not able to do things that other children his or her age can do	(dilinccd:PEDSQL6.PEDS61) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
5.	(Q5) Keeping up when playing with other children	(dilinccd:PEDSQL6.PEDS62) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
School Functioning:		
6.	(Q1) Paying attention in class	(dilinccd:PEDSQL6.PEDS63) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
7.	(Q2) Forgetting things	(dilinccd:PEDSQL6.PEDS64) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
8.	(Q3) Keeping up with schoolwork	(dilinccd:PEDSQL6.PEDS65) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
9.	(Q4) Missing school because of not feeling well	(dilinccd:PEDSQL6.PEDS66) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
10.	(Q5) Missing school to go to the doctor or hospital	(dilinccd:PEDSQL6.PEDS67) [0] <input type="radio"/> Never

- [1] Almost Never
[2] Sometimes
[3] Often
[4] Almost Always

Column Name	Column Data Type	Design Note
PEDS67	NUMERIC	
PEDS58	NUMERIC	
PEDS65	NUMERIC	
PEDS64	NUMERIC	
PEDS59	NUMERIC	
PEDS66	NUMERIC	
PEDS62	NUMERIC	
PEDS63	NUMERIC	
PEDS60	NUMERIC	
PEDS61	NUMERIC	

dilin : PEDIATRIC QUALITY OF LIFE INVENTORY 7 (PESQL7)		
PESQL Ages 13-18 (In the past ONE month, how much of a problem has your teen had with)		
Physical Functioning:		
1.	(Q1) Walking more than one block	(dilinccd:PESQL7.PES68) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
2.	(Q2) Running	(dilinccd:PESQL7.PES69) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
3.	(Q3) Participating in sports activity or exercise	(dilinccd:PESQL7.PES70) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
4.	(Q4) Lifting something heavy	(dilinccd:PESQL7.PES71) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
5.	(Q5) Taking a bath or shower by him or herself	(dilinccd:PESQL7.PES72) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
6.	(Q6) Doing chores around the house	(dilinccd:PESQL7.PES73) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
7.	(Q7) Having hurts or aches	(dilinccd:PESQL7.PES74) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
8.	(Q8) Low energy level	(dilinccd:PESQL7.PES75) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
Emotional Functioning:		
9.	(Q1) Feeling afraid or scared	(dilinccd:PESQL7.PES76) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
10.	(Q2) Feeling sad or blue	(dilinccd:PESQL7.PES77) [0] <input type="radio"/> Never

		<p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
11.	(Q3) Feeling angry	<p>(dillncdd: PEDSQL7.PEDS78)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
12.	(Q4) Trouble sleeping	<p>(dillncdd: PEDSQL7.PEDS79)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>
13.	(Q5) Worrying about what will happen to him or her	<p>(dillncdd: PEDSQL7.PEDS80)</p> <p>[0] <input type="radio"/> Never</p> <p>[1] <input type="radio"/> Almost Never</p> <p>[2] <input type="radio"/> Sometimes</p> <p>[3] <input type="radio"/> Often</p> <p>[4] <input type="radio"/> Almost Always</p>

CDD: dillncdd Table: PEDSQL7 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PEDS79	NUMERIC	
PEDS74	NUMERIC	
PEDS77	NUMERIC	
PEDS80	NUMERIC	
PEDS71	NUMERIC	
PEDS70	NUMERIC	
PEDS72	NUMERIC	
PEDS76	NUMERIC	
PEDS73	NUMERIC	
PEDS78	NUMERIC	
PEDS69	NUMERIC	
PEDS68	NUMERIC	
PEDS75	NUMERIC	

dilin : PEDIATRIC QUALITY OF LIFE INVENTORY 8 (PEDSQL8)		
PEDSQL Ages 13-18 con't (In the past ONE month, how much of a problem has your teen had with)		
Social Functioning:		
1.	(Q1) Getting along with other teens	(dilincdd:PEDSQL8.PEDS81) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
2.	(Q2) Other teens not wanting to be his or her friend	(dilincdd:PEDSQL8.PEDS82) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
3.	(Q3) Getting teased by other teens	(dilincdd:PEDSQL8.PEDS83) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
4.	(Q4) Not able to do things that other teens his or her age can do	(dilincdd:PEDSQL8.PEDS84) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
5.	(Q5) Keeping up when playing with other teens	(dilincdd:PEDSQL8.PEDS85) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
School Functioning:		
6.	(Q1) Paying attention in class	(dilincdd:PEDSQL8.PEDS86) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
7.	(Q2) Forgetting things	(dilincdd:PEDSQL8.PEDS87) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
8.	(Q3) Keeping up with schoolwork	(dilincdd:PEDSQL8.PEDS88) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
9.	(Q4) Missing school because of not feeling well	(dilincdd:PEDSQL8.PEDS89) [0] <input type="radio"/> Never [1] <input type="radio"/> Almost Never [2] <input type="radio"/> Sometimes [3] <input type="radio"/> Often [4] <input type="radio"/> Almost Always
10.	(Q5) Missing school to go to the doctor or hospital	(dilincdd:PEDSQL8.PEDS90) [0] <input type="radio"/> Never

- [1] Almost Never
[2] Sometimes
[3] Often
[4] Almost Always

Column Name	Column Data Type	Design Note
PEDS89	NUMERIC	
PEDS81	NUMERIC	
PEDS90	NUMERIC	
PEDS85	NUMERIC	
PEDS83	NUMERIC	
PEDS86	NUMERIC	
PEDS87	NUMERIC	
PEDS88	NUMERIC	
PEDS82	NUMERIC	
PEDS84	NUMERIC	

dilin : HISTORY OF INJURY (HXINJ1) - Repeating Form							
#	Drug or CAM	Name of implicated drug/CAM	Name of drug/CAM manufacturer	Implicated drug/CAM start date	Implicated drug/CAM stop date	Was the patient rechallenged	Did the patient ever take this drug/CAM prior
1							
History of Injury							
1.	Is this a drug or CAM product?				(dillncdd: HXINJ1.DRGCAM) [1] <input type="radio"/> Drug [2] <input type="radio"/> CAM		
2.	Name of implicated drug/CAM:				<input type="text" value="A80"/> (dillncdd: HXINJ1.IMPLDRUG)		
3.	Name of drug/CAM manufacturer:				<input type="text" value="A80"/> (dillncdd: HXINJ1.DRGMANUF)		
4.	Implicated drug/CAM start date:				Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dillncdd: HXINJ1.IMPLSTDT)		
5.	Implicated drug/CAM stop date:				Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dillncdd: HXINJ1.IMPLSPDT)		
6.	Was the patient rechallenged with the implicated drug/CAM?				(dillncdd: HXINJ1.RECHALL) [0] <input type="radio"/> No [1] <input type="radio"/> Yes-- If Yes: Please provide: Start date: Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dillncdd: HXINJ1.RECHSTDT) (dillncdd: HXINJ1.RECHCONT) [2] <input type="radio"/> Stop Date: Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dillncdd: HXINJ1.RECHSPDT) [1] <input type="radio"/> Continuing		
7.	Did the patient ever take this drug/CAM prior to this episode for any reason?				(dillncdd: HXINJ1.PRIORUSE) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [2] <input type="radio"/> Cannot remember		


Column Name	Column Data Type	Design Note
DRGCAM	NUMERIC	
IMPLSPDT	DATE - DDMONYYYY	
RECHALL	NUMERIC	
RECHCONT	NUMERIC	
PRIORUSE	NUMERIC	
RECHSTDT	DATE - DDMONYYYY	
IMPLSTDT	DATE - DDMONYYYY	
RECHSPDT	DATE - DDMONYYYY	
DRGMANUF	STRING(80) - A80	
IMPLDRUG	STRING(80) - A80	

dilin : HISTORY OF INJURY 2 (HXINJ2)	
History of Injury continued	
1. Date of onset of qualifying lab abnormalities	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1935-2020) (dillncdd:HXINJ2.ONSETDT)
2. Date of presentation of liver problems to health care provider	Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dillncdd:HXINJ2.PRESNDT)
3. Was the patient seen by a gastroenterologist/hepatologist for the DILI event?	(dillncdd:HXINJ2.GIHEP) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4. If the patient is female, was she pregnant during the DILI event?	(dillncdd:HXINJ2.PREGNANT) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [96] <input type="radio"/> NA
5. Was the patient hospitalized for this liver injury?	(dillncdd:HXINJ2.HOSPITAL) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6. Was a non-DILI hospital admission prolonged by the occurrence of a DILI event?	(dillncdd:HXINJ2.PRLGHOSP) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [96] <input type="radio"/> NA
7. How long was the patient sick with this injury (check only one)?	(dillncdd:HXINJ2.PTSICK) [1] <input type="radio"/> Less than a week [2] <input type="radio"/> 1 week [3] <input type="radio"/> 2-4 weeks [4] <input type="radio"/> More than 4 weeks
8. Did the patient have any disruption in their activities of daily living (e.g. missed work, school or housework)?	(dillncdd:HXINJ2.DISRUPT) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:HXINJ2.DISRUPSP) Please specify length of time [1] <input type="radio"/> Less than a week [2] <input type="radio"/> 1 week [3] <input type="radio"/> 2-4 weeks [4] <input type="radio"/> More than 4 weeks
9. Did the patient have extrahepatic manifestations during this injury?	(dillncdd:HXINJ2.HEPATIC) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:HXINJ2.NEUTRPEN) Check all that apply [1] <input type="checkbox"/> Neutropenia (dillncdd:HXINJ2.THRMBPEN) [1] <input type="checkbox"/> Thrombocytopenia (dillncdd:HXINJ2.SJSYNDRM) [1] <input type="checkbox"/> Stevens-Johnson syndrome (dillncdd:HXINJ2.NECROLY) [1] <input type="checkbox"/> Toxic epidermal necrolysis (dillncdd:HXINJ2.HMANEMIA) [1] <input type="checkbox"/> Hemolytic anemia (dillncdd:HXINJ2.SERUMSCK) [1] <input type="checkbox"/> Serum sickness (dillncdd:HXINJ2.HEPAOTHR) [1] <input type="checkbox"/> Other Other (specify) <input type="text" value="A200"/> (dillncdd:HXINJ2.HEPASP)
10. Was a liver biopsy performed for this injury?	(dillncdd:HXINJ2.LIVBIOP) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Which Hospital performed liver biopsy? (dillncdd:HXINJ2.BIOPHOSP) A50 Hospital City A25 (dillncdd:HXINJ2.BIOPCITY) Hospital State A5 (dillncdd:HXINJ2.BIOPST)

		Date liver biopsy performed Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dillncdd:HXINJ2.BIOPDT)
11.	Did the patient receive prednisone or corticosteroids for this injury?	(dillncdd:HXINJ2.STEROIDS) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Please provide date patient receive prednisone or corticosteroids for this injury Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dillncdd:HXINJ2.STERDT) Please record on CONMED form as well
12.	Was a liver transplant performed for this injury?	(dillncdd:HXINJ2.LIVTRX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Which Hospital performed liver transplant? (dillncdd:HXINJ2.TRXHOSP) A50 Hospital City A25 (dillncdd:HXINJ2.TRXCITY) Hospital State A5 (dillncdd:HXINJ2.TRXST) Date liver transplant performed Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dillncdd:HXINJ2.TRXDT)
13.	Was the patient previously diagnosed with a DILI event prior to this injury?	(dillncdd:HXINJ2.PREVDX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

Column Name	Column Data Type	Design Note
THRMBPEN	NUMERIC	
HEPAOTHR	NUMERIC	
LIVTRX	NUMERIC	
DISRUPSP	NUMERIC	
PRESNDT	DATE - DDMONYYYY	
SERUMSCK	NUMERIC	
ONSETDT	DATE - DDMONYYYY	
PTSICK	NUMERIC	
BIOPHOSP	STRING(50) - A50	
HOSPITAL	NUMERIC	
TRXST	STRING(5) - A5	
BIOPDT	DATE - DDMONYYYY	
NEUTRPEN	NUMERIC	
PREVDX	NUMERIC	
BIOPCITY	STRING(25) - A25	
PREGNANT	NUMERIC	
TRXDT	DATE - DDMONYYYY	
DISRUPT	NUMERIC	
STERDT	DATE - DDMONYYYY	
BIOPST	STRING(5) - A5	
TRXHOSP	STRING(50) - A50	
PRLGHOSP	NUMERIC	
LIVBIOP	NUMERIC	
SJSYNDRM	NUMERIC	
GIHEP	NUMERIC	
HMANEMIA	NUMERIC	
STEROIDS	NUMERIC	
TRXCITY	STRING(25) - A25	
NECROLY	NUMERIC	
HEPASP	STRING(200) - A200	

HEPATIC	NUMERIC	
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dilin : HISTORY OF INJURY 3 (HXINJ3) - Repeating Form					
#		Hospital Name for this liver injury?	Hospital City	Hospital State	Date hospitalized for liver injury
1					

History of Injury continued	
1. Hospital Name for this liver injury?	A50 (dilinccd: HXINJ3.HOSPNAME)
2. Hospital City	A25 (dilinccd: HXINJ3.HOSPCITY)
3. Hospital State	A50 (dilinccd: HXINJ3.HOSPST)
4. Date hospitalized for liver injury	Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dilinccd: HXINJ3.HOSPHXDT)

Column Name	Column Data Type	Design Note
HOSPHXDT	DATE - MONYYYY	
HOSPST	STRING(50) - A50	
HOSPNAME	STRING(50) - A50	
HOSPCITY	STRING(25) - A25	

dilin : SIGNS AND SYMPTOMS (SIGN) - Repeating Form			
#	Signs and Symptoms	Date of Signs and Symptoms Onset	
1			
Signs & Symptoms			
1.	Signs and Symptoms	Pulldown List 1 <input type="button" value="v"/> (dilincdd: SIGN.SGNRES) Other specify (dilincdd: SIGN.SIGNSP) <input type="text" value="A200"/>	
2.	Date of Signs and Symptoms Onset	(dilincdd: SIGN.SIGNNA) [1] <input type="radio"/> Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dilincdd: SIGN.SGNSYMDT) [96] <input type="radio"/> NA	

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieJAUND	Jaundice	1	
ieNAUS	Nausea	2	
ieANOR	Anorexia	3	
ieDARKU	Dark Urine	4	
ieFEVER	Fever	5	
ieABDOM	Abdominal Pain	6	
ieVOMIT	Vomiting	7	
ieRASH	Rash	8	
ieITCH	Itching	9	
ieCHGMEN	Change in Mental Status	10	
ieASCIT	Ascites	11	
ieEDEMA	Edema	12	
ieHEPAT	Hepatomegaly	13	
ieSPLEN	Splenomegaly	14	
ieLYMP	Lymphadenopathy	15	
ieFATIGUE	Fatigue	16	
ieGRAY	Gray Stool	17	
ieCHILLS	Chills	18	
ieOTHER	Other	98	

CDD: dilincdd Table: SIGN Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SGNRES	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 98	
SIGNSP	STRING(200) - A200	
SIGNNA	NUMERIC	
SGNSYMDT	DATE - DDMONYYYY	

dilin : IMPLICATED DILI MEDICATION (DILIMED) - Repeating Form									
#	Medication	Dose	Unit	Frequency	Route	Start Date	Stop Date	Indication	
1									

Implicated DILI Medication	
1. Medication	A80 (dilincdd:DILIMED.DILINAME)
2. Dose	A12 (dilincdd:DILIMED.DOSE)
3. Unit	A8 (dilincdd:DILIMED.UNIT)
4. Frequency	Pull-down List 1 (dilincdd:DILIMED.FREQ) Specify other frequency (dilincdd:DILIMED.FREQSP) A100
5. Route	Pull-down List 2 (dilincdd:DILIMED.ROUTE) Specify other route (dilincdd:DILIMED.RTESP) A100
6. Start Date	Req/Unk / Req/Unk / Req (1935-2020) (dilincdd:DILIMED.DILISTDT)
7. Stop Date	(dilincdd:DILIMED.DILICONT) [2] Req/Unk / Req/Unk / Req (1935-2020) (dilincdd:DILIMED.DILISPDT) [1] Continuing
8. Indication	A200 (dilincdd:DILIMED.DILISPEC)

Pull-down List 1:			
RefName	Display Text	Value	Design Note
ieFREQ1	QD	1	
ieFREQ2	BID	2	
ieFREQ3	TID	3	
ieFREQ4	QID	4	
ieFREQ5	PRN	5	
ieFREQ6	Weekly	6	
ieFREQ7	Monthly	7	
ieFREQ8	Once	8	
ieFREQ9	Every Other Day	9	
ieFREQ10	3 x per Week	10	
ieFREQ11	2 x per Week	11	
ieFREQ98	Other	98	

Pull-down List 2:			
RefName	Display Text	Value	Design Note
ieROUTE1	PO	1	
ieROUTE2	IV	2	
ieROUTE3	SC	3	
ieROUTE4	IM	4	
ieROUTE5	Topical/transdermal	5	
ieROUTE98	Other	98	

CDD: dilincdd Table: DILIMED Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
RTESP	STRING(100) - A100	

FREQ	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 98	
DILINAME	STRING(80) - A80	
DOSE	STRING(12) - A12	
ROUTE	NUMERIC - 1, 2, 3, 4, 5, 98	
UNIT	STRING(8) - A8	
DILISPDY	DATE - DDMONYYYY	
DILISTDY	DATE - DDMONYYYY	
DILISPEC	STRING(200) - A200	
FREQSP	STRING(100) - A100	
DILICONT	NUMERIC	

dilin : CAMMED (CAMMED1) - Repeating Form													
#	CAM #	Brand or commercial name	Common name	Lot number	Expiration date	Manufactures name	Manufacturers Address	Manufacturers City	Manufacturers State	Manufacturers ZIP	Manufacturers Phone number	Are CAM ingredients available?	CAMMED3
1													

Implicated CAM Product	
1.	CAM # xxx (dilinccd: CAMMED1.CAMSEQNO)
2.	Brand or commercial name A80 (dilinccd: CAMMED1.CAMBRNM)
3.	Common name A80 (dilinccd: CAMMED1.CAMCOMNM)
4.	Lot number A25 (dilinccd: CAMMED1.LOTNUM)
5.	Expiration date Req/Unk / Req/Unk / Req (1935-2020) (dilinccd: CAMMED1.CAMEXPDT)
6.	Manufacturers name A80 (dilinccd: CAMMED1.CAMMANUF)
7.	Manufacturers Address A50 (dilinccd: CAMMED1.CAMADD)
8.	Manufacturers City A25 (dilinccd: CAMMED1.CAMCITY)
9.	Manufacturers State A5 (dilinccd: CAMMED1.CAMST)
10.	Manufacturers ZIP A10 (dilinccd: CAMMED1.CAMZIP)
11.	Manufacturers Phone number A12 (dilinccd: CAMMED1.CAMPHONE)
12.	Are CAM ingredients available? (dilinccd: CAMMED1.CAMINGYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
List Each Implicated CAM Product ingredient	
13.	

Entry							
13.a	List Each Implicated CAM Product ingredient A100 (dilinccd: CAMMED2.CAMINGRD)						
CAM#	Dose	Unit	Frequency	Route	Start Date	Stop Date	Indication
14.							

CAMMED3 Entry	
14.a	CAM# xxx (dilinccd: CAMMED3.CAMSEQNO)
14.b	Dose xxxxxxx (dilinccd: CAMMED3.CDOSE)
14.c	Unit A10 (dilinccd: CAMMED3.CUNIT)
14.d	Frequency Pulldown List 1 (dilinccd: CAMMED3.CFREQ) Specify other frequency (dilinccd: CAMMED3.CFREQSP) A100
14.e	Route Pulldown List 2 (dilinccd: CAMMED3.CROUTE) Specify other route (dilinccd: CAMMED3.CRTEQSP) A100
14.f	Start Date Req/Unk / Req/Unk / Req (1935-2020) (dilinccd: CAMMED3.CAMSTDT)
14.g	Stop Date (dilinccd: CAMMED3.CAMCONT) [2] <input type="radio"/> Req/Unk / Req/Unk / Req (1935-2020) (dilinccd: CAMMED3.CAMSPDT) [1] <input type="radio"/> Continuing
14.h	Indication Pulldown List 3 (dilinccd: CAMMED3.CAMIND)

Other Indication (specify) (dilinccd:CAMMED3.CAMSP)

A200

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieFREQ1	QD	1	
ieFREQ2	BID	2	
ieFREQ3	TID	3	
ieFREQ4	QID	4	
ieFREQ5	PRN	5	
ieFREQ6	Weekly	6	
ieFREQ7	Monthly	7	
ieOther	Other	98	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieROUTE1	PO	1	
ieROUTE2	IV	2	
ieROUTE3	SC	3	
ieROUTE4	IM	4	
ieROUTE5	Topical/transdermal	5	
ieOTHER	Other	98	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
ieINDCAT1	Liver disease	1	
ieINDCAT2	Heart disease	2	
ieINDCAT3	Cancer	3	
ieINDCAT4	Depression	4	
ieINDCAT5	Disease prevention for Indications 1-4	5	
ieINDCAT6	General health	6	
ieOTHER	Other	98	

CDD: dilinccd Table: CAMMED1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CAMCOMNM	STRING(80) - A80	
CAMBRNM	STRING(80) - A80	
CAMPHONE	STRING(12) - A12	
CAMST	STRING(5) - A5	
CAMMANUF	STRING(80) - A80	
CAMZIP	STRING(10) - A10	
CAMSEQNO	NUMERIC - N3	
CAMEXPDT	DATE - DDMONYYYY	
LOTNUM	STRING(25) - A25	
CAMADD	STRING(50) - A50	
CAMCITY	STRING(25) - A25	
CAMINGYN	NUMERIC	

CDD: dilinccd Table: CAMMED2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CAMINGRD	STRING(100) - A100	

Column Name	Column Data Type	Design Note
CFREQ	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 98	
CAMSEQNO	NUMERIC - N3	
CAMCONT	NUMERIC	
CDOSE	FLOAT - F9.0	
CAMIND	NUMERIC - 1, 2, 3, 4, 5, 6, 98	
CRTESP	STRING(100) - A100	
CAMSP	STRING(200) - A200	
CAMSPDT	DATE - DDMONYYYY	
CROUTE	NUMERIC - 1, 2, 3, 4, 5, 98	
CAMSTDT	DATE - DDMONYYYY	
CFREQSP	STRING(100) - A100	
CUNIT	STRING(10) - A10	

dilin : LIVER TEST FLOW CHART (LABFLOW) - Repeating Form											
#	Lab Date	AST results	ALT results	Alkaline Phosphatase results	Serum Total Bilirubin results	INR results	AST Calculation	ALT Calculation	AKP Calculation	STB Calculation	FLOW RATIO
1											
Liver Test Flowchart											
1.	Lab Date	Req [v] / Req [v] / Req [v] (1935-2020) (dilincdd: LABFLOW.FCLABDT)									
2.	AST results Available?	(dilincdd: LABFLOW.AST) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes AST results xxxxxxxx. (dilincdd: LABFLOW.ASTVAL) AST ULN xxxxxxxx. (dilincdd: LABFLOW.ASTULN)									
3.	ALT results Available?	(dilincdd: LABFLOW.ALT) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes ALT results xxxxxxxx. (dilincdd: LABFLOW.ALTVAL) ALT ULN xxxxxxxx. (dilincdd: LABFLOW.ALTULN)									
4.	Alkaline Phosphatase results Available?	(dilincdd: LABFLOW.AKP) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Alkaline Phosphatase results xxxxxxxx. (dilincdd: LABFLOW.AKPVAL) Alkaline Phosphatase ULN xxxxxxxx. (dilincdd: LABFLOW.AKPULN)									
5.	Serum Total Bilirubin results Available?	(dilincdd: LABFLOW.STB) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum Total Bilirubin results xxxxxxxx. (dilincdd: LABFLOW.STBVAL) (dilincdd: LABFLOW.STBUNIT) Serum Total Bilirubin unit [5] <input type="radio"/> mg/dL [4] <input type="radio"/> μmol/L Serum Total Bilirubin ULN xxxxxxxx. (dilincdd: LABFLOW.STBULN)									
6.	INR results Available?	(dilincdd: LABFLOW.INR) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes INR results xxxxxxxx. (dilincdd: LABFLOW.INRRATE)									
	AST Calculation	xxxxxxxx. (dilincdd: LABFLOW.ASTCALC)									
	ALT Calculation	xxxxxxxx. (dilincdd: LABFLOW.ALTALC)									
	AKP Calculation	xxxxxxxx. (dilincdd: LABFLOW.AKPCALC)									
	STB Calculation	xxxxxxxx. (dilincdd: LABFLOW.STBCALC)									
	FLOW RATIO	xxxxxxxx. (dilincdd: LABFLOW.FLWRATIO)									

Column Name	Column Data Type	Design Note
ASTCALC	FLOAT - F9.0	
ALTULN	FLOAT - F9.0	
ASTVAL	FLOAT - F9.0	
AST	NUMERIC	
FLWRATIO	FLOAT - F9.0	
STBUNIT	NUMERIC	
INRRATE	FLOAT - F9.0	
AKP	NUMERIC	
FCLABDT	DATE - DDMONYYYY	

AKPVAL	FLOAT - F9.0	
ASTULN	FLOAT - F9.0	
STBVAL	FLOAT - F9.0	
INR	NUMERIC	
ALTVAL	FLOAT - F9.0	
AKPCALC	FLOAT - F9.0	
STBCALC	FLOAT - F9.0	
AKPULN	FLOAT - F9.0	
STBULN	FLOAT - F9.0	
ALT	NUMERIC	
ALTCALC	FLOAT - F9.0	
STB	NUMERIC	

dilin : STANDARD LABS (w/in 4wks prior to ONSET) (STDLABHX)	
Standard Labs within 4 weeks prior to onset	
1. Lab Date	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:STDLABHX.LABHXDT)
2. Hemoglobin results Available?	(dilincdd:STDLABHX.LABHXN01) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Hemoglobin results (g/dL) xxxxxxxx. (dilincdd:STDLABHX.LABHXV01)
3. WBC results Available?	(dilincdd:STDLABHX.LABHXN02) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes WBC results (10 ⁹ or 10 ³ /mm ³) xxxxxxxx. (dilincdd:STDLABHX.LABHXV02)
4. Blood platelets results Available?	(dilincdd:STDLABHX.LABHXN03) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Blood platelets results (10 ⁹ or 10 ³ /mm ³) xxxxxxxx. (dilincdd:STDLABHX.LABHXV03)
5. % Neutrophils results Available?	(dilincdd:STDLABHX.LABHXN04) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes % Neutrophils results xxxxxxxx. (dilincdd:STDLABHX.LABHXV04) (dilincdd:STDLABHX.LABHXU04) % Neutrophils unit [2] <input type="radio"/> 10 ⁹ /L OR 10 ³ /mm ³ [3] <input type="radio"/> %
6. % Lymphocytes results Available?	(dilincdd:STDLABHX.LABHXN05) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes % Lymphocytes results xxxxxxxx. (dilincdd:STDLABHX.LABHXV05) (dilincdd:STDLABHX.LABHXU05) % Lymphocytes unit [2] <input type="radio"/> 10 ⁹ /L OR 10 ³ /mm ³ [3] <input type="radio"/> %
7. % Eosinophils results Available?	(dilincdd:STDLABHX.LABHXN06) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes % Eosinophils results xxxxxxxx. (dilincdd:STDLABHX.LABHXV06) (dilincdd:STDLABHX.LABHXU06) % Eosinophils units [2] <input type="radio"/> 10 ⁹ /L OR 10 ³ /mm ³ [3] <input type="radio"/> %
8. Sodium results Available?	(dilincdd:STDLABHX.LABHXN07) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Sodium results (mmol/L) xxxxxxxx. (dilincdd:STDLABHX.LABHXV07)
9. Potassium results Available?	(dilincdd:STDLABHX.LABHXN08) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Potassium results (mmol/L) xxxxxxxx. (dilincdd:STDLABHX.LABHXV08)
10. Serum creatinine results Available?	(dilincdd:STDLABHX.LABHXN09) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum creatinine results xxxxxxxx. (dilincdd:STDLABHX.LABHXV09) (dilincdd:STDLABHX.LABHXU09) Serum creatinine unit [5] <input type="radio"/> mg/dL [4] <input type="radio"/> μmol/L
11. BUN results Available?	(dilincdd:STDLABHX.LABHXN10) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes BUN results xxxxxxxx. (dilincdd:STDLABHX.LABHXV10) (dilincdd:STDLABHX.LABHXU10)

		BUN unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L
12.	Cholesterol results Available?	(dillncdd: STDLABHX.LABHXN11) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Cholesterol results xxxxxxxx. (dillncdd: STDLABHX.LABHXV11) (dillncdd: STDLABHX.LABHXU11) Cholesterol unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L
13.	Triglycerides results Available?	(dillncdd: STDLABHX.LABHXN12) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Triglycerides results xxxxxxxx. (dillncdd: STDLABHX.LABHXV12) (dillncdd: STDLABHX.LABHXU12) Triglycerides unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L
14.	Serum total protein results Available?	(dillncdd: STDLABHX.LABHXN13) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum total protein results xxxxxxxx. (dillncdd: STDLABHX.LABHXV13) (dillncdd: STDLABHX.LABHXU13) Serum total protein unit [1] <input type="radio"/> g/dL [9] <input type="radio"/> g/L
15.	Amylase results Available?	(dillncdd: STDLABHX.LABHXN14) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Amylase results (U/L) xxxxxxxx. (dillncdd: STDLABHX.LABHXV14) Amylase ULN xxxxxxxx. (dillncdd: STDLABHX.LABHXL14)
16.	Lipase results Available?	(dillncdd: STDLABHX.LABHXN15) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Lipase results (U/L) xxxxxxxx. (dillncdd: STDLABHX.LABHXV15) Lipase ULN xxxxxxxx. (dillncdd: STDLABHX.LABHXL15)
17.	CPK results Available?	(dillncdd: STDLABHX.LABHXN16) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes CPK results (U/L) xxxxxxxx. (dillncdd: STDLABHX.LABHXV16) CPK ULN xxxxxxxx. (dillncdd: STDLABHX.LABHXL16)
18.	GGTP results Available?	(dillncdd: STDLABHX.LABHXN17) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes GGTP results (U/L) xxxxxxxx. (dillncdd: STDLABHX.LABHXV17) GGTP ULN xxxxxxxx. (dillncdd: STDLABHX.LABHXL17)
19.	LDH results Available?	(dillncdd: STDLABHX.LABHXN18) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes LDH results (U/L) xxxxxxxx. (dillncdd: STDLABHX.LABHXV18) LDH ULN xxxxxxxx. (dillncdd: STDLABHX.LABHXL18)
20.	When blood samples drawn, patient was	(dillncdd: STDLABHX.BLDXSTAT) [1] <input type="radio"/> Fasting [2] <input type="radio"/> Fed [99] <input type="radio"/> Unknown

CDD: dillncdd Table: STDLABHX Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note

LABHXV03	FLOAT - F9.0	
LABHXV16	FLOAT - F9.0	
LABHXL14	FLOAT - F9.0	
LABHXV05	FLOAT - F9.0	
LABHXN09	NUMERIC	
LABHXL15	FLOAT - F9.0	
LABHXU05	NUMERIC	
LABHXL18	FLOAT - F9.0	
LABHXN05	NUMERIC	
LABHXN02	NUMERIC	
LABHXN14	NUMERIC	
LABHXN06	NUMERIC	
LABHXU06	NUMERIC	
BLDXSTAT	NUMERIC	
LABHXV06	FLOAT - F9.0	
LABHXV04	FLOAT - F9.0	
LABHXU04	NUMERIC	
LABHXV07	FLOAT - F9.0	
LABHXV15	FLOAT - F9.0	
LABHXV12	FLOAT - F9.0	
LABHXV01	FLOAT - F9.0	
LABHXV18	FLOAT - F9.0	
LABHXN12	NUMERIC	
LABHXV14	FLOAT - F9.0	
LABHXN15	NUMERIC	
LABHXN03	NUMERIC	
LABHXL16	FLOAT - F9.0	
LABHXN08	NUMERIC	
LABHXN11	NUMERIC	
LABHXN07	NUMERIC	
LABHXU10	NUMERIC	
LABHXN16	NUMERIC	
LABHXV10	FLOAT - F9.0	
LABHXV09	FLOAT - F9.0	
LABHXV02	FLOAT - F9.0	
LABHXN17	NUMERIC	
LABHXN01	NUMERIC	
LABHXV11	FLOAT - F9.0	
LABHXN10	NUMERIC	
LABHXV08	FLOAT - F9.0	
LABHXV17	FLOAT - F9.0	
LABHXU12	NUMERIC	
LABHXDT	DATE - DDMONYYYY	
LABHXL17	FLOAT - F9.0	
LABHXN18	NUMERIC	
LABHXN04	NUMERIC	
LABHXV13	FLOAT - F9.0	
LABHXU11	NUMERIC	
LABHXU13	NUMERIC	
LABHXU09	NUMERIC	
LABHXN13	NUMERIC	

dilin : STANDARD LAB FLOW CHART (STDFLOW) - Repeating Form									
#	Lab Date	Hemoglobin results	WBC results	Blood Platelets results	Serum Creatinine results	Serum Albumin results	Serum Direct Bilirubin results	% Eosinophils results Available	
1									

Standard Lab Flowchart	
1. Lab Date	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:STDFLOW.STFLABDT)
2. Hemoglobin results Available?	(dilincdd:STDFLOW.HGB) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Hemoglobin results (g/dL) xxxxxxxx. (dilincdd:STDFLOW.HGBVAL)
3. WBC results Available?	(dilincdd:STDFLOW.WBC) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes WBC results (10^9 or 10^3/mm^3) xxxxxxxx. (dilincdd:STDFLOW.WBCVAL)
4. Blood Platelets results Available?	(dilincdd:STDFLOW.PLATE) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Blood Platelets results (10^9 or 10^3/mm^3) xxxxxxxx. (dilincdd:STDFLOW.PLATEVAL)
5. Serum Creatinine results Available?	(dilincdd:STDFLOW.CREAT) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum Creatinine results xxxxxxxx. (dilincdd:STDFLOW.CREATVAL) (dilincdd:STDFLOW.CRETVALU) Serum Creatinine unit [5] <input type="radio"/> mg/dL [4] <input type="radio"/> μmol/L
6. Serum Albumin results Available?	(dilincdd:STDFLOW.ALBUN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum Albumin results xxxxxxxx. (dilincdd:STDFLOW.ALBUNVAL) (dilincdd:STDFLOW.ALBUVALU) Serum Albumin unit [1] <input type="radio"/> g/dL [9] <input type="radio"/> g/L
7. Serum Direct Bilirubin results Available?	(dilincdd:STDFLOW.SDB) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum Direct Bilirubin results xxxxxxxx. (dilincdd:STDFLOW.SDBVAL) (dilincdd:STDFLOW.SDBVALU) Serum Direct Bilirubin unit [5] <input type="radio"/> mg/dL [4] <input type="radio"/> μmol/L Serum Direct Bilirubin ULN xxxxxxxx. (dilincdd:STDFLOW.STDULN)
8. % Eosinophils results Available?	(dilincdd:STDFLOW.EOSIN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes % Eosinophils value xxxxxxxx. (dilincdd:STDFLOW.EOSINVAL) (dilincdd:STDFLOW.EOSIVALU) % Eosinophils unit [2] <input type="radio"/> 10^9/L OR 10^3/mm^3 [3] <input type="radio"/> %

Column Name	Column Data Type	Design Note
ALBUN	NUMERIC	
CREAT	NUMERIC	
EOSINVAL	FLOAT - F9.0	
CREATVAL	FLOAT - F9.0	

PLATE	NUMERIC	
CRETVALU	NUMERIC	
HGB	NUMERIC	
STFLABDT	DATE - DDMONYYYY	
SDB	NUMERIC	
HGBVAL	FLOAT - F9.0	
WBCVAL	FLOAT - F9.0	
SDBVAL	FLOAT - F9.0	
STDULN	FLOAT - F9.0	
WBC	NUMERIC	
EOSIVALU	NUMERIC	
EOSIN	NUMERIC	
PLATEVAL	FLOAT - F9.0	
ALBUNVAL	FLOAT - F9.0	
SDBVALU	NUMERIC	
ALBUVALU	NUMERIC	

dilin : IMAGING STUDIES (IMAGE) - Repeating Form				
#	Type of Imaging Study	Date of Imaging Study	Imaging Study Results	Spleen Diameter
1				
Imaging Studies				
1.	Type of Imaging Study	Pulldown List 1 (dilinccd: IMAGE.IMAGTYPE)		
2.	Date of Imaging Study	Req / Req / Req (1935-2020) (dilinccd: IMAGE.IMAGEDT)		
3.	Imaging Study Results	Check all that apply (dilinccd: IMAGE.BILIARY) [1] <input type="checkbox"/> Biliary dilation (dilinccd: IMAGE.TUMOR) [1] <input type="checkbox"/> Liver tumor (dilinccd: IMAGE.IMSPLENO) [1] <input type="checkbox"/> Splenomegaly (dilinccd: IMAGE.ASCITES) [1] <input type="checkbox"/> Ascites (dilinccd: IMAGE.GALLSTON) [1] <input type="checkbox"/> Gallstones (dilinccd: IMAGE.IMHEPATO) [1] <input type="checkbox"/> Hepatomegaly (dilinccd: IMAGE.NORMAL1) [1] <input type="checkbox"/> Normal study (dilinccd: IMAGE.NODULAR) [1] <input type="checkbox"/> Nodular contour of liver (dilinccd: IMAGE.VARCIES) [1] <input type="checkbox"/> Intra-abdominal varices (dilinccd: IMAGE.IMGOTH) [1] <input type="checkbox"/> Other Other Specify A200 (dilinccd: IMAGE.IMGSP) Other Specify continue A200 (dilinccd: IMAGE.IMGSP2)		
4.	Spleen Diameter	(dilinccd: IMAGE.IMGSPNA) [1] <input type="radio"/> xxxxxxxx. (dilinccd: IMAGE.IMGSPNA) [96] <input type="radio"/> Not applicable		

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieLIVER	Liver ultrasound	1	
ieABCTSCAN	Abdominal CT Scan	2	
ieABMRI	Abdominal MRI	3	
ieERCP	ERCP	4	
ieMRCP	MRCP	5	
ieOTHER	Other	98	

CDD: dilinccd	Table: IMAGE	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
BILIARY	NUMERIC	
IMAGTYPE	NUMERIC - 1, 2, 3, 4, 5, 98	
IMGOTH	NUMERIC	
IMGSP	STRING(200) - A200	
IMGSP2	STRING(200) - A200	
IMGSPNA	NUMERIC	
VARCIES	NUMERIC	
IMAGEDT	DATE - DDMONYYYY	
ASCITES	NUMERIC	

IMHEPATO	NUMERIC	
TUMOR	NUMERIC	
GALLSTON	NUMERIC	
IMG SPLN	FLOAT - F9.0	
NODULAR	NUMERIC	
NORMAL1	NUMERIC	
IMSPLENO	NUMERIC	

dilin : HEPATITIS STATUS (HEPSTAT)	
Hepatitis Status	
1. Did the patient have chronic hepatitis B infection (detectable HBsAg)?	(dilincdd:HEPSTAT.HEPB) [0] <input type="radio"/> No [1] <input type="radio"/> (dilincdd:HEPSTAT.DELTA) Yes, Did the patient also have delta hepatitis? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown or not tested
2. Did the patient have chronic hepatitis C infection (detectable HCV RNA)?	(dilincdd:HEPSTAT.HEPC) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
3. Did the patient use any non-implicated hepatitis medications taken within 5 years of onset of DILI event?	(dilincdd:HEPSTAT.HEPMEDYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4. Did the patient have any available HBeAg results within 5 years up to but not including initial study visit?	(dilincdd:HEPSTAT.HBEAGYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
5. Did the patient have any available anti-HBe results within 5 years up to but not including initial study visit?	(dilincdd:HEPSTAT.ANTHBEYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6. Did the patient have any available Anti-HDV results within 5 years up to but not including initial study visit?	(dilincdd:HEPSTAT.ANTHDVYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
7. Did the patient have any available HBV DNA results within 5 years up to but not including initial study visit?	(dilincdd:HEPSTAT.HBVDNAYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
8. Did the patient have any available HCV RNA results within 5 years up to but not including initial study visit?	(dilincdd:HEPSTAT.HCVRNAYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilincdd Table: HEPSTAT Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
HBEAGYN	NUMERIC	
ANTHDVYN	NUMERIC	
HEPB	NUMERIC	
HCVRNAYN	NUMERIC	
HEPMEDYN	NUMERIC	
HEPC	NUMERIC	
DELTA	NUMERIC	
ANTHBEYN	NUMERIC	
HBVDNAYN	NUMERIC	

dilin : HBeAG FLOW CHART (HBEAG) - Repeating Form			
#		HBeAg Date	HBeAg Result
1	<input type="text"/>		

HBeAG Flowchart	
1. HBeAg Date	Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dilincdd:HBEAG.HBEAGDT)
2. HBeAg Result	(dilincdd:HBEAG.HBEAGRS) [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown

Column Name	Column Data Type	Design Note
HBEAGRS	NUMERIC	
HBEAGDT	DATE - DDMONYYYY	

dilin : Anti-HBe FLOW CHART (ANTIHBE) - Repeating Form			
#		Anti-HBe Date	Anti-HBe Result
1			

Anti-Hbe Flowchart	
1. Anti-HBe Date	Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dilincdd: ANTIHBE.ANTHBEDT)
2. Anti-HBe Result	(dilincdd: ANTIHBE.ANTHBGRS) [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown

Column Name	Column Data Type	Design Note
ANTHBGRS	NUMERIC	
ANTHBEDT	DATE - DDMONYYYY	

dilin : Anti-HDV (total) FLOW CHART (ANTIHDV) - Repeating Form			
#		Anti-HDV Date	Anti-HDV Result
1			

Anti-HDV (total) Flowchart	
1. Anti-HDV Date	Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dilincdd: ANTIHDV.ANTHDVDT)
2. Anti-HDV Result	(dilincdd: ANTIHDV.ANTHDVRS) [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown

Column Name	Column Data Type	Design Note
ANTHDVRS	NUMERIC	
ANTHDVDT	DATE - DDMONYYYY	

dilin : HBV DNA FLOW CHART (HBVDNA) - Repeating Form			
#		HBV DNA Date	HBV DNA Results
1	<input type="checkbox"/>		

HBV DNA Flowchart

1. HBV DNA Date	Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilinccd:HBVDNA.HBVDT)
2. HBV DNA Results	(dilinccd:HBVDNA.HBVRSLT) [96] <input type="radio"/> Not available [0] <input type="radio"/> Negative [1] <input type="radio"/> (dilinccd:HBVDNA.HBVALNA) Positive [96] <input type="radio"/> Not available [1] <input type="radio"/> HBV DNA Value xxxxxxxx. (dilinccd:HBVDNA.HBVVAL) (dilinccd:HBVDNA.HBVUNIT) [1] <input type="radio"/> copies/mL [2] <input type="radio"/> pg/mL [3] <input type="radio"/> IU/ML

Column Name	Column Data Type	Design Note
HBVDT	DATE - DDMYYYYY	
HBVVAL	FLOAT - F9.0	
HBVUNIT	NUMERIC	
HBVRSLT	NUMERIC	
HBVALNA	NUMERIC	

dilin : HCV RNA FLOW CHART (HCVRNA) - Repeating Form			
#		HCV RNA Date	HCV RNA Results
1	<input type="text"/>		
.			
1.	HCV RNA Date	Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dilincdd:HCVRNA.HCVDT)	
2.	HCV RNA Results	(dilincdd:HCVRNA.HCVRSLT) [96] <input type="radio"/> Not available [0] <input type="radio"/> Negative [1] <input type="radio"/> (dilincdd:HCVRNA.HCVVALNA) Positive [96] <input type="radio"/> Not available [1] <input type="radio"/> HCV RNA Value xxxxxxxx. (dilincdd:HCVRNA.HCVVAL) (dilincdd:HCVRNA.HCVUNIT) [1] <input type="radio"/> copies/mL [2] <input type="radio"/> IU/mL	

CDD: dilincdd Table: HCVRNA Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
HCVVAL	FLOAT - F9.0	
HCVUNIT	NUMERIC	
HCVRSLT	NUMERIC	
HCVDT	DATE - DDMONYYYY	
HCVVALNA	NUMERIC	

dilin : HIV STATUS (HIVSTAT)	
HIV Status	
1. Did the patient have known HIV infection?	(dilincdd:HIVSTAT.HIV) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: What was the date of diagnosis? Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTAT.HIVDXDT)

Column Name	Column Data Type	Design Note
HIV	NUMERIC	
HIVDXDT	DATE - DDMONYYYY	

dilin : HIV STATUS (HIVSTAT1)	
HIV Status continued	
1. Did the condition progress to AIDS?	(dilincdd:HIVSTAT1.AIDS) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: What was the date of this diagnosis? Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTAT1.AIDSDXT)
2. Was a urine toxicology screen done?	(dilincdd:HIVSTAT1.URINSCRN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT1.URINUNK) [1] <input type="radio"/> Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTAT1.URINDT) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT1.URINTOX) [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive
List all substances for which the test was positive	
3.	
. Entry	
3.a List all substances for which the test was positive	<input type="text" value="A80"/> (dilincdd:HIVSTAT1.SUBSTANC)
.	
4. Did the patient have evidence of active CMV infection (CMV DNA by RT-PCR)?	(dilincdd:HIVSTAT1.EVIDYN01) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT1.EVIDUK01) [1] <input type="radio"/> Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTAT1.EVIDDT01) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT1.EVIDRS01) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive CMV DNA value (copies/mL) (dilincdd:HIVSTAT1.EVIDPOS) xxxxxxxx.
5. Did the patient have evidence of herpes simplex viral infection (HSV IGM)?	(dilincdd:HIVSTAT1.EVIDYN02) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT1.EVIDUK02) [1] <input type="radio"/> Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTAT1.EVIDDT02) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT1.EVIDRS02) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive
6. Did the patient have evidence of syphilis by VDRL (Venereal Disease Research Laboratory)?	(dilincdd:HIVSTAT1.EVIDYN03) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT1.EVIDUK03) [1] <input type="radio"/> Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTAT1.EVIDDT03) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT1.EVIDRS03) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive
7. Did the patient have evidence of syphilis by RPR (Rapid Plasma Reagent)?	(dilincdd:HIVSTAT1.EVIDYN04) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT1.EVIDUK04) [1] <input type="radio"/> Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTAT1.EVIDDT04) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT1.EVIDRS04) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive
8. Did the patient have evidence of a MAI infection (mycobacterium avium intracellulare)?	(dilincdd:HIVSTAT1.EVIDYN05) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT1.EVIDUK05) [1] <input type="radio"/> Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTAT1.EVIDDT05) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT1.EVIDRS05) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive

9.	Did the patient have any pertinent serologies/serum levels performed?	(dilincdd: HIVSTAT1.SEROYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
10.	Did the patient use any non-implicated anti-retrovirals taken within 5 years of onset of DILI event?	(dilincdd: HIVSTAT1.HIVMEDYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
11.	Did the patient have any available HIV RNA results within 5 years up to but not including initial study visit?	(dilincdd: HIVSTAT1.HIVRNAYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
12.	Did the patient have any available CD4 results within 5 years up to but not including initial study visit?	(dilincdd: HIVSTAT1.CD4RYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilincdd Table: HIVSTAT1 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
EVIDRS05	NUMERIC	
EVIDUK01	NUMERIC	
CD4RYN	NUMERIC	
EVIDUK04	NUMERIC	
EVIDRS01	NUMERIC	
EVIDDT02	DATE - DDMONYYYY	
HIVMEDYN	NUMERIC	
EVIDPOS	FLOAT - F9.0	
URINDT	DATE - DDMONYYYY	
EVIDYN03	NUMERIC	
EVIDDT01	DATE - DDMONYYYY	
EVIDRS02	NUMERIC	
EVIDRS03	NUMERIC	
EVIDDT05	DATE - DDMONYYYY	
URINTOX	NUMERIC	
HIVRNAYN	NUMERIC	
URINUNK	NUMERIC	
EVIDDT04	DATE - DDMONYYYY	
EVIDRS04	NUMERIC	
EVIDYN02	NUMERIC	
AIDS	NUMERIC	
EVIDYN01	NUMERIC	
EVIDUK02	NUMERIC	
EVIDUK05	NUMERIC	
EVIDYN04	NUMERIC	
URINSCRN	NUMERIC	
SEROYN	NUMERIC	
AIDSDXDT	DATE - DDMONYYYY	
EVIDUK03	NUMERIC	
EVIDDT03	DATE - DDMONYYYY	
EVIDYN05	NUMERIC	

CDD: dilincdd Table: HIVSTATA Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SUBSTANC	STRING(80) - A80	

dilin : HIV STATUS 2 (HIVSTAT2) - Repeating Form							
#		Serology Type	Serology Date	Serology Value	Serology Value Unit	Serology Value ULN	Serology Results
1	<input type="checkbox"/>						
1. Serology Type (dilincdd:HIVSTAT2.SERUM) [1] <input type="radio"/> Serum lactate levels? [2] <input type="radio"/> Serum amylase levels? [3] <input type="radio"/> Serum lipase levels? [4] <input type="radio"/> Serum CPK levels? [98] <input type="radio"/> Other pertinent serologies Specify Other pertinent serologies <input type="text" value="A80"/> (dilincdd:HIVSTAT2.SEROTYPE)							
2. Serology Date		Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilincdd:HIVSTAT2.SERUMDT)					
3.* Serology Value		<input type="text" value="A100"/> (dilincdd:HIVSTAT2.SERUMVAL)					
4.* Serology Value Unit		Pulldown List 1 <input type="checkbox"/> (dilincdd:HIVSTAT2.SERUMUNT)					
5.* Serology Value ULN		<input type="text" value="xxxxxxx."/> (dilincdd:HIVSTAT2.SERUMULN)					
6.* Serology Results		<input type="text" value="A100"/> (dilincdd:HIVSTAT2.SERORSLT)					
* Item is not required							

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieULIT	U/L	13	
ieMGDL	mg/dL	5	
ieLITORMM	10^9/L OR 10^3/mm^3	2	
ieMICROMOLL	µmol/L	4	
ieMMOLL	mmol/L	6	
ieMICRUT	µL	8	
ieGL	g/L	9	
ieGDL	g/dL	1	

CDD: dilincdd Table: HIVSTAT2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SERUMUNT	NUMERIC - 13, 5, 2, 4, 6, 8, 9, 1	
SERUM	NUMERIC	
SEROTYPE	STRING(80) - A80	
SERUMVAL	STRING(100) - A100	
SERUMULN	FLOAT - F9.0	
SERUMDT	DATE - DDMONYYYY	
SERORSLT	STRING(100) - A100	

dilin : CD4 FLOW CHART (CD4) - Repeating Form			
#		CD4 Date	CD4 Value (cells/mm ³)
1	<input type="text"/>		

CD4 Flowchart	
1. CD4 Date	Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilinccd:CD4.CD4DT)
2. CD4 Value (cells/mm ³)	xxxxxxx. (dilinccd:CD4.CD4VAL)

Column Name	Column Data Type	Design Note
CD4VAL	FLOAT - F9.0	
CD4DT	DATE - DDMONYYYY	

dilin : HIV RNA FLOW CHART (HIVRNA) - Repeating Form			
#		HIV RNA Date	HIV RNA Value (copies/mL)
1	<input type="text"/>		

HIV RNA Flowchart	
1. HIV RNA Date	Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilinccd:HIVRNA.HIVRNADT)
2. HIV RNA Value (copies/mL)	xxxxxxx. (dilinccd:HIVRNA.HIVRVAL)

Column Name	Column Data Type	Design Note
HIVRVAL	FLOAT - F9.0	
HIVRNADT	DATE - DDMONYYYY	

dilin : PHYSICAL EXAM (PEX1)	
Physical Exam	
1. Date of Physical Examination	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dillncdd:PEX1.PHEXDT)
2. Weight (required)	xxxxxxx. (dillncdd:PEX1.WT)
3. Weight Unit	(dillncdd:PEX1.WTUN) [1] <input type="radio"/> kg [2] <input type="radio"/> lbs
4. Height (required)	xxxxxxx. (dillncdd:PEX1.HT)
5. Height Unit	(dillncdd:PEX1.HTUN) [1] <input type="radio"/> cm [2] <input type="radio"/> in
6. Heart rate (bpm)	xxx (dillncdd:PEX1.HRATE)
7. Blood pressure systolic	xxx (dillncdd:PEX1.BPSYS)
8. Blood pressure diastolic	xxx (dillncdd:PEX1.BPDIA)

Column Name	Column Data Type	Design Note
BPSYS	NUMERIC - N3	
HRATE	NUMERIC - N3	
BPDIA	NUMERIC - N3	
HTUN	NUMERIC	
HT	FLOAT - F9.0	
WTUN	NUMERIC	
PHEXDT	DATE - DDMONYYYY	
WT	FLOAT - F9.0	

dilin : PHYSICAL EXAM 2 (PEX2)	
Physical Exam Con't	
1. General appearance	(dilincdd:PEX2.ASSESS01) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd:PEX2.PXABNL01) A200
2. Head, eyes, ears, nose, throat	(dilincdd:PEX2.ASSESS02) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd:PEX2.PXABNL02) A200
3. Neck	(dilincdd:PEX2.ASSESS03) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd:PEX2.PXABNL03) A200
4. Heart	(dilincdd:PEX2.ASSESS04) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd:PEX2.PXABNL04) A200
5. Lungs	(dilincdd:PEX2.ASSESS05) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd:PEX2.PXABNL05) A200
6. Abdomen	(dilincdd:PEX2.ASSESS06) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd:PEX2.PXABNL06) A200
7. Spleen	(dilincdd:PEX2.ASSESS07) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd:PEX2.PXABNL07) A200
8. Liver	(dilincdd:PEX2.ASSESS08) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd:PEX2.PXABNL08) A200
9. Lymph nodes	(dilincdd:PEX2.ASSESS09) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal

		<p>[2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dillncdd:PEX2.PXABNL09) <input type="text" value="A200"/></p>
10.	Extremities	<p>(dillncdd:PEX2.ASSESS10) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dillncdd:PEX2.PXABNL10) <input type="text" value="A200"/></p>
11.	Neurological	<p>(dillncdd:PEX2.ASSESS11) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dillncdd:PEX2.PXABNL11) <input type="text" value="A200"/></p>
12.	Skin	<p>(dillncdd:PEX2.ASSESS12) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dillncdd:PEX2.PXABNL12) <input type="text" value="A200"/></p>
13.	Musculoskeletal	<p>(dillncdd:PEX2.ASSESS13) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dillncdd:PEX2.PXABNL13) <input type="text" value="A200"/></p>
14.	Other	<p>(dillncdd:PEX2.ASSESS14) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dillncdd:PEX2.PXABNL14) <input type="text" value="A200"/></p>

CDD: dillncdd Table: PEX2 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PXABNL12	STRING(200) - A200	
PXABNL09	STRING(200) - A200	
ASSESS13	NUMERIC	
ASSESS08	NUMERIC	
ASSESS02	NUMERIC	
PXABNL08	STRING(200) - A200	
ASSESS03	NUMERIC	
ASSESS06	NUMERIC	
ASSESS01	NUMERIC	
PXABNL01	STRING(200) - A200	
ASSESS07	NUMERIC	
ASSESS04	NUMERIC	
ASSESS14	NUMERIC	
ASSESS10	NUMERIC	
PXABNL10	STRING(200) - A200	

PXABNL03	STRING(200) - A200	
PXABNL04	STRING(200) - A200	
ASSESS09	NUMERIC	
PXABNL14	STRING(200) - A200	
ASSESS05	NUMERIC	
PXABNL07	STRING(200) - A200	
PXABNL05	STRING(200) - A200	
PXABNL13	STRING(200) - A200	
PXABNL02	STRING(200) - A200	
ASSESS11	NUMERIC	
PXABNL06	STRING(200) - A200	
PXABNL11	STRING(200) - A200	
ASSESS12	NUMERIC	

dilin : DIAGNOSTIC LABS 1 (DXLAB1)		
Diagnostic Labs		
1.	Anti-HAV IgM available?	(dilincdd: DXLAB1.DLAB01) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Anti-HAV IgM Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB1.DLABDT01) (dilincdd: DXLAB1.DRSLT01) Anti-HAV IgM Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown
2.	Anti-HCV available?	(dilincdd: DXLAB1.DLAB02) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Anti-HCV Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB1.DLABDT02) (dilincdd: DXLAB1.DRSLT02) Anti-HCV Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown
3.	HCV RNA available?	(dilincdd: DXLAB1.DLAB03) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes HCV RNA Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB1.DLABDT03) (dilincdd: DXLAB1.DRSLT03) HCV RNA Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown
4.	HBsAg available?	(dilincdd: DXLAB1.DLAB04) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes HBsAg Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB1.DLABDT04) (dilincdd: DXLAB1.DRSLT04) HBsAg Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown
5.	Anti-HBc available?	(dilincdd: DXLAB1.DLAB05) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Anti-HBc Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB1.DLABDT05) (dilincdd: DXLAB1.DRSLT05) Anti-HBc Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown
6.	Anti-HBc IgM available?	(dilincdd: DXLAB1.DLAB06) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Anti-HBc IgM Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB1.DLABDT06) (dilincdd: DXLAB1.DRSLT06) Anti-HBc IgM Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown
7.	Anti-HBs available?	(dilincdd: DXLAB1.DLAB07) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Anti-HBs Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB1.DLABDT07) (dilincdd: DXLAB1.DRSLT07) Anti-HBs Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown
8.	HBsAg available?	(dilincdd: DXLAB1.DLAB08)

		<p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>HBeAg Date Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2004-2020) (dillncdd: DXLAB1.DLABDT08)</p> <p>(dillncdd: DXLAB1.DRSLT08)</p> <p>HBeAg Result [0] <input type="radio"/> Negative</p> <p>[1] <input type="radio"/> Positive</p> <p>[99] <input type="radio"/> Unknown</p>
9.	Anti-HBe available?	<p>(dillncdd: DXLAB1.DLAB09)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>Anti-HBe Date Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2004-2020) (dillncdd: DXLAB1.DLABDT09)</p> <p>(dillncdd: DXLAB1.DRSLT09)</p> <p>Anti-HBe Result [0] <input type="radio"/> Negative</p> <p>[1] <input type="radio"/> Positive</p> <p>[99] <input type="radio"/> Unknown</p>
10.	HBV-DNA available?	<p>(dillncdd: DXLAB1.DLAB10)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>HBV-DNA Date Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2004-2020) (dillncdd: DXLAB1.DLABDT10)</p> <p>(dillncdd: DXLAB1.DRSLT10)</p> <p>HBV-DNA Result [0] <input type="radio"/> Negative</p> <p>[1] <input type="radio"/> Positive</p> <p>[99] <input type="radio"/> Unknown</p>
11.	Anti-HDV available?	<p>(dillncdd: DXLAB1.DLAB11)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>Anti-HDV Date Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2004-2020) (dillncdd: DXLAB1.DLABDT11)</p> <p>(dillncdd: DXLAB1.DRSLT11)</p> <p>Anti-HDV Result [0] <input type="radio"/> Negative</p> <p>[1] <input type="radio"/> Positive</p> <p>[99] <input type="radio"/> Unknown</p>
12.	Anti-HIV available?	<p>(dillncdd: DXLAB1.DLAB12)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>Anti-HIV Date Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2004-2020) (dillncdd: DXLAB1.DLABDT12)</p> <p>(dillncdd: DXLAB1.DRSLT12)</p> <p>Anti-HIV Result [0] <input type="radio"/> Negative</p> <p>[1] <input type="radio"/> Positive</p> <p>[99] <input type="radio"/> Unknown</p>
13.	ANA available?	<p>(dillncdd: DXLAB1.DLAB13)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>ANA Date Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2004-2020) (dillncdd: DXLAB1.DLABDT13)</p> <p>(dillncdd: DXLAB1.DLABTP13)</p> <p>Type of test [1] <input type="radio"/> IF [2] <input type="radio"/> ELISA</p> <p>(dillncdd: DXLAB1.DXTITR13)</p> <p>Threshold for positive results [1] <input type="radio"/> Titer 1: [2] <input type="radio"/> ULN</p> <p>Threshold Value xxxxxxxx. (dillncdd: DXLAB1.DXULN13)</p> <p>(dillncdd: DXLAB1.DRSLT13)</p> <p>Results [99] <input type="radio"/> Unknown</p> <p>[0] <input type="radio"/> Negative</p> <p>[1] <input type="radio"/> Positive</p> <p>ANA Value xxxxxxxx. (dillncdd: DXLAB1.DXVAL13)</p>
14.	ASMA available?	<p>(dillncdd: DXLAB1.DLAB14)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>ASMA Date Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2004-2020) (dillncdd: DXLAB1.DLABDT14)</p> <p>(dillncdd: DXLAB1.DLABTP14)</p> <p>Type of test [1] <input type="radio"/> IF [2] <input type="radio"/> ELISA</p>

		<p>(dillncdd: DXLAB1.DXTITR14) Threshold for positive results [1] <input type="radio"/> Titer 1: [2] <input type="radio"/> ULN Threshold Value xxxxxxxx. (dillncdd: DXLAB1.DXULN14) (dillncdd: DXLAB1.DRSLT14) Results [99] <input type="radio"/> Unknown [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive ASMA Value xxxxxxxx. (dillncdd: DXLAB1.DXVAL14)</p>
15.	AMA available?	<p>(dillncdd: DXLAB1.DLAB15) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes AMA Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dillncdd: DXLAB1.DLABDT15) (dillncdd: DXLAB1.DLABTP15) Type of test [1] <input type="radio"/> IF [2] <input type="radio"/> ELISA (dillncdd: DXLAB1.DXTITR15) Threshold for positive results [1] <input type="radio"/> Titer 1: [2] <input type="radio"/> ULN Threshold Value xxxxxxxx. (dillncdd: DXLAB1.DXULN15) (dillncdd: DXLAB1.DRSLT15) Results [99] <input type="radio"/> Unknown [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive AMA Value (dillncdd: DXLAB1.DXVAL15) xxxxxxxx. </p>
16.	Heterophile antibody available?	<p>(dillncdd: DXLAB1.DLAB16) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Heterophile antibody Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dillncdd: DXLAB1.DLABDT16) (dillncdd: DXLAB1.DRSLT16) Heterophile antibody Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown</p>
17.	Serum ceruloplasmin (Only if age is less than or equal 50 years) available?	<p>(dillncdd: DXLAB1.DLAB17) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum ceruloplasmin (Only if age is less than or equal 50 years) Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dillncdd: DXLAB1.DLABDT17) Serum ceruloplasmin Value (mg/dL) xxxxxxxx. (dillncdd: DXLAB1.DRSLT17) Serum ceruloplasmin ULN xxxxxxxx. (dillncdd: DXLAB1.DXULN17)</p>

CDD: dillncdd	Table: DXLAB1	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
DXVAL14	FLOAT - F9.0	
DRSLT14	NUMERIC	
DRSLT11	NUMERIC	
DRSLT13	NUMERIC	
DLABDT10	DATE - DDMONYYYY	
DLABDT13	DATE - DDMONYYYY	
DRSLT07	NUMERIC	
DLABDT07	DATE - DDMONYYYY	
DLAB06	NUMERIC	
DLABTP14	NUMERIC	
DLAB13	NUMERIC	
DXULN15	FLOAT - F9.0	
DLAB15	NUMERIC	
DLABDT05	DATE - DDMONYYYY	
DLAB12	NUMERIC	

DRSLT08	NUMERIC	
DLAB08	NUMERIC	
DLABDT06	DATE - DDMONYYYY	
DRSLT06	NUMERIC	
DRSLT04	NUMERIC	
DXULN13	FLOAT - F9.0	
DXVAL15	FLOAT - F9.0	
DLAB10	NUMERIC	
DRSLT10	NUMERIC	
DLABDT08	DATE - DDMONYYYY	
DXULN17	FLOAT - F9.0	
DXVAL13	FLOAT - F9.0	
DXTITR14	NUMERIC	
DLABDT17	DATE - DDMONYYYY	
DRSLT12	NUMERIC	
DLABDT02	DATE - DDMONYYYY	
DXULN14	FLOAT - F9.0	
DLAB11	NUMERIC	
DLAB17	NUMERIC	
DRSLT09	NUMERIC	
DRSLT15	NUMERIC	
DLAB14	NUMERIC	
DLAB07	NUMERIC	
DLAB05	NUMERIC	
DLABDT01	DATE - DDMONYYYY	
DLABDT11	DATE - DDMONYYYY	
DRSLT05	NUMERIC	
DLABDT09	DATE - DDMONYYYY	
DXTITR15	NUMERIC	
DRSLT17	FLOAT - F9.0	
DLABTP13	NUMERIC	
DLAB16	NUMERIC	
DRSLT16	NUMERIC	
DLAB01	NUMERIC	
DLABTP15	NUMERIC	
DRSLT01	NUMERIC	
DLAB09	NUMERIC	
DLABDT12	DATE - DDMONYYYY	
DXTITR13	NUMERIC	
DLABDT16	DATE - DDMONYYYY	
DLABDT04	DATE - DDMONYYYY	
DLABDT14	DATE - DDMONYYYY	
DLABDT15	DATE - DDMONYYYY	
DRSLT03	NUMERIC	
DLABDT03	DATE - DDMONYYYY	
DLAB02	NUMERIC	
DLAB04	NUMERIC	
DRSLT02	NUMERIC	
DLAB03	NUMERIC	

dilin : DIAGNOSTIC LABS 2 (DXLAB2)	
Diagnostic Labs continued	
1. Serum alpha-1 antitrypsin available?	(dilincdd: DXLAB2.DLAB18) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum alpha-1 antitrypsin Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB2.DLABDT18) Serum alpha-1 antitrypsin Value (mg/dL) xxxxxxxx. (dilincdd: DXLAB2.DXRSLT18) Serum alpha-1 antitrypsin ULN xxxxxxxx. (dilincdd: DXLAB2.DXULN18)
2. Serum iron available?	(dilincdd: DXLAB2.DLAB19) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum iron Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB2.DLABDT19) Serum iron Value (µg/dL) xxxxxxxx. (dilincdd: DXLAB2.DXRSLT19) Serum iron ULN xxxxxxxx. (dilincdd: DXLAB2.DXULN19)
3. Serum transferrin available?	(dilincdd: DXLAB2.DLAB20) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum transferrin Date NReq <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB2.DLABDT20) Serum transferrin Value (mg/dL) xxxxxxxx. (dilincdd: DXLAB2.DXRSLT20) Serum transferrin ULN xxxxxxxx. (dilincdd: DXLAB2.DXULN20)
4. Serum ferritin available?	(dilincdd: DXLAB2.DLAB21) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum ferritin Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB2.DLABDT21) Serum ferritin Value (ng/mL) xxxxxxxx. (dilincdd: DXLAB2.DXRSLT21) Serum ferritin ULN xxxxxxxx. (dilincdd: DXLAB2.DXULN21)
5. Serum IgM available?	(dilincdd: DXLAB2.DLAB22) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum IgM Date NReq <input type="text"/> / NReq <input type="text"/> / NReq <input type="text"/> (2004-2020) (dilincdd: DXLAB2.DLABDT22) Serum IgM Value (mg/dL) xxxxxxxx. (dilincdd: DXLAB2.DXRSLT22) Serum IgM ULN xxxxxxxx. (dilincdd: DXLAB2.DXULN22)
6. Serum IgG available?	(dilincdd: DXLAB2.DLAB23) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum IgG Date NReq <input type="text"/> / NReq <input type="text"/> / NReq <input type="text"/> (2004-2020) (dilincdd: DXLAB2.DLABDT23) Serum IgG Value (mg/dL) xxxxxxxx. (dilincdd: DXLAB2.DXRSLT23) Serum IgG ULN xxxxxxxx. (dilincdd: DXLAB2.DXULN23)
7. Serum IgA available?	(dilincdd: DXLAB2.DLAB24) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum IgA Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB2.DLABDT24) Serum IgA Value (mg/dL) xxxxxxxx. (dilincdd: DXLAB2.DXRSLT24) Serum IgA ULN xxxxxxxx. (dilincdd: DXLAB2.DXULN24)
8. Anti CMV IgM available?	(dilincdd: DXLAB2.DLAB25) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Anti CMV IgM Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: DXLAB2.DLABDT25) (dilincdd: DXLAB2.DRSLT25) Anti CMV IgM Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown

9. Anti HAV (total) available?

(dillncdd: DXLAB2.DLAB26)
 [97] Not done
 [1] Yes
 Anti HAV Date | Req / | Req / | Req (2004-2020) (dillncdd: DXLAB2.DLABDT26)
 (dillncdd: DXLAB2.DRSLT26)
 Anti HAV Result
 [0] Negative
 [1] Positive
 [99] Unknown

CDD: dillncdd Table: DXLAB2 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
DLABDT19	DATE - DDMONYYYY	
DXRSLT22	FLOAT - F9.0	
DLABDT21	DATE - DDMONYYYY	
DXRSLT18	FLOAT - F9.0	
DLAB26	NUMERIC	
DXRSLT23	FLOAT - F9.0	
DLAB21	NUMERIC	
DXULN24	FLOAT - F9.0	
DXRSLT24	FLOAT - F9.0	
DXULN21	FLOAT - F9.0	
DXULN18	FLOAT - F9.0	
DXRSLT20	FLOAT - F9.0	
DXULN22	FLOAT - F9.0	
DLAB24	NUMERIC	
DLAB20	NUMERIC	
DLAB22	NUMERIC	
DLAB18	NUMERIC	
DXRSLT19	FLOAT - F9.0	
DLABDT25	DATE - DDMONYYYY	
DLABDT18	DATE - DDMONYYYY	
DXRSLT21	FLOAT - F9.0	
DXULN20	FLOAT - F9.0	
DRSLT26	NUMERIC	
DLABDT26	DATE - DDMONYYYY	
DRSLT25	NUMERIC	
DLAB19	NUMERIC	
DLAB25	NUMERIC	
DLAB23	NUMERIC	
DXULN19	FLOAT - F9.0	
DXULN23	FLOAT - F9.0	
DLABDT24	DATE - DDMONYYYY	
DLABDT22	DATE - DDMONYYYY	
DLABDT23	DATE - DDMONYYYY	
DLABDT20	DATE - DDMONYYYY	

dilin : DIAGNOSTIC LABS 3 (DXLAB3)		
Diagnostic Labs continued		
1.	Serum protein electrophoresis	(dilincdd:DXLAB3.DXLABSPE) [97] <input type="radio"/> Not done [1] <input checked="" type="radio"/> Yes Serum protein electrophoresis Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd:DXLAB3.SPELABDT) Total protein Result (g/dL) xxxxxxxx. (dilincdd:DXLAB3.SPETPRO) Albumin Result (g/dL) xxxxxxxx. (dilincdd:DXLAB3.SPEALBUN) Alpha-1 Result (g/dL) xxxxxxxx. (dilincdd:DXLAB3.SPEALPH1) Alpha-2 Result (g/dL) xxxxxxxx. (dilincdd:DXLAB3.SPEALPH2) Beta Result (g/dL) xxxxxxxx. (dilincdd:DXLAB3.SPEBETA) Gamma Result (g/dL) xxxxxxxx. (dilincdd:DXLAB3.SPEGAMMA) Interpretation A200 (dilincdd:DXLAB3.SPECOMM)
2.*	Were there any additional ANA or ASMA results?	(dilincdd:DXLAB3.DXLABSER) [0] <input type="radio"/> No [1] <input checked="" type="radio"/> Yes If yes, complete SEROFLOW under CAS visit
* Item is not required		

Column Name	Column Data Type	Design Note
SPEBETA	FLOAT - F9.0	
SPECOMM	STRING(200) - A200	
SPEALPH1	FLOAT - F9.0	
SPEALPH2	FLOAT - F9.0	
DXLABSPE	NUMERIC	
SPEALBUN	FLOAT - F9.0	
SPEGAMMA	FLOAT - F9.0	
SPETPRO	FLOAT - F9.0	
SPELABDT	DATE - DDMONYYYY	
DXLABSER	NUMERIC	

dilin : STANDARD LABS (STDLAB)	
Standard Labs	
1. Lab Date	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dilincdd:STDLAB.STDLABDT)
2. When blood samples drawn, patient was?	(dilincdd:STDLAB.BLDSTATE) [1] <input type="radio"/> Fasting [2] <input type="radio"/> Fed [99] <input type="radio"/> Unknown
3. Hemoglobin available?	(dilincdd:STDLAB.LABNAM01) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Hemoglobin value (g/dL) xxxxxxxx. (dilincdd:STDLAB.LABVAL01)
4. WBC available?	(dilincdd:STDLAB.LABNAM02) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes WBC value (10^9 or $10^3/\text{mm}^3$) xxxxxxxx. (dilincdd:STDLAB.LABVAL02)
5. Blood platelets available?	(dilincdd:STDLAB.LABNAM03) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Blood platelets value (10^9 or $10^3/\text{mm}^3$) xxxxxxxx. (dilincdd:STDLAB.LABVAL03)
6. % Neutrophils available?	(dilincdd:STDLAB.LABNAM04) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes % Neutrophils value xxxxxxxx. (dilincdd:STDLAB.LABVAL04) % Neutrophils unit [2] <input type="radio"/> $10^9/\text{L}$ OR $10^3/\text{mm}^3$ [3] <input type="radio"/> %
7. % Lymphocytes available?	(dilincdd:STDLAB.LABNAM05) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes % Lymphocytes value xxxxxxxx. (dilincdd:STDLAB.LABVAL05) (dilincdd:STDLAB.LABUNT05) % Lymphocytes unit [2] <input type="radio"/> $10^9/\text{L}$ OR $10^3/\text{mm}^3$ [3] <input type="radio"/> %
8. % Eosinophils available?	(dilincdd:STDLAB.LABNAM06) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes % Eosinophils value xxxxxxxx. (dilincdd:STDLAB.LABVAL06) (dilincdd:STDLAB.LABUNT06) % Eosinophils unit [2] <input type="radio"/> $10^9/\text{L}$ OR $10^3/\text{mm}^3$ [3] <input type="radio"/> %
9. Sodium available?	(dilincdd:STDLAB.LABNAM07) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Sodium value (mmol/L) xxxxxxxx. (dilincdd:STDLAB.LABVAL07)
10. Potassium available?	(dilincdd:STDLAB.LABNAM08) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Potassium value (mmol/L) xxxxxxxx. (dilincdd:STDLAB.LABVAL08)
11. Serum creatinine available?	(dilincdd:STDLAB.LABNAM09) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum creatinine value xxxxxxxx. (dilincdd:STDLAB.LABVAL09) (dilincdd:STDLAB.LABUNT09) Serum creatinine unit [5] <input type="radio"/> mg/dL [4] <input type="radio"/> $\mu\text{mol/L}$
12. BUN available?	(dilincdd:STDLAB.LABNAM10) [97] <input type="radio"/> Not done

		<p>[1] <input type="radio"/> Yes BUN value xxxxxxxx. (dillncdd:STDLAB.LABVAL10) (dillncdd:STDLAB.LABUNT10) Bun unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L</p>
13.	Cholesterol available?	<p>(dillncdd:STDLAB.LABNAM11) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Cholesterol value xxxxxxxx. (dillncdd:STDLAB.LABVAL11) (dillncdd:STDLAB.LABUNT11) Cholesterol unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L</p>
14.	Triglycerides available?	<p>(dillncdd:STDLAB.LABNAM12) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Triglycerides value xxxxxxxx. (dillncdd:STDLAB.LABVAL12) (dillncdd:STDLAB.LABUNT12) Triglycerides unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L</p>

CDD: dillncdd Table: STDLAB Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
LABVAL04	FLOAT - F9.0	
LABVAL03	FLOAT - F9.0	
LABUNTO9	NUMERIC	
LABNAM02	NUMERIC	
LABVAL11	FLOAT - F9.0	
LABNAM05	NUMERIC	
LABVAL09	FLOAT - F9.0	
LABVAL10	FLOAT - F9.0	
BLDSTATE	NUMERIC	
LABNAM07	NUMERIC	
LABNAM11	NUMERIC	
LABVAL05	FLOAT - F9.0	
LABNAM04	NUMERIC	
LABNAM03	NUMERIC	
LABVAL02	FLOAT - F9.0	
LABVAL12	FLOAT - F9.0	
LABVAL01	FLOAT - F9.0	
LABVAL07	FLOAT - F9.0	
LABVAL08	FLOAT - F9.0	
LABNAM09	NUMERIC	
LABNAM01	NUMERIC	
LABUNT10	NUMERIC	
LABNAM06	NUMERIC	
STDLABDT	DATE - DDMONYYYY	
LABVAL06	FLOAT - F9.0	
LABNAM10	NUMERIC	
LABUNT11	NUMERIC	
LABUNT12	NUMERIC	
LABUNTO5	NUMERIC	
LABUNTO6	NUMERIC	
LABNAM12	NUMERIC	

LABNAM08	NUMERIC	
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dilin : STANDARD LABS (STDLAB2)	
Standard Labs con't	
1. Serum total protein available?	(dilincdd:STDLAB2.LABNAM13) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum total protein value xxxxxxxx. (dilincdd:STDLAB2.LABVAL13) (dilincdd:STDLAB2.LABUNT13) Serum total protein unit [7] <input type="radio"/> g/dL [9] <input type="radio"/> g/L
2. Serum albumin	(dilincdd:STDLAB2.LABNAM14) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum albumin value xxxxxxxx. (dilincdd:STDLAB2.LABVAL14) (dilincdd:STDLAB2.LABUNT14) Serum albumin unit [7] <input type="radio"/> g/dL [9] <input type="radio"/> g/L
3. INR available?	(dilincdd:STDLAB2.LABNAM15) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes INR value (ratio) xxxxxxxx. (dilincdd:STDLAB2.LABVAL15)
4. Prothrombin time available?	(dilincdd:STDLAB2.LABNAM16) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Prothrombin time value (secs) xxxxxxxx. (dilincdd:STDLAB2.LABVAL16)
5. Serum total bilirubin available?	(dilincdd:STDLAB2.LABNAM17) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum total bilirubin value xxxxxxxx. (dilincdd:STDLAB2.LABVAL17) (dilincdd:STDLAB2.LABUNT17) Serum total bilirubin unit [5] <input type="radio"/> mg/dL [4] <input type="radio"/> μmol/L Serum total bilirubin ULN xxxxxxxx. (dilincdd:STDLAB2.LABULN17)
6. Serum direct bilirubin available?	(dilincdd:STDLAB2.LABNAM18) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum direct bilirubin value xxxxxxxx. (dilincdd:STDLAB2.LABVAL18) (dilincdd:STDLAB2.LABUNT18) Serum direct bilirubin unit [5] <input type="radio"/> mg/dL [4] <input type="radio"/> μmol/L Serum direct bilirubin ULN xxxxxxxx. (dilincdd:STDLAB2.LABULN18)
7. AST available?	(dilincdd:STDLAB2.LABNAM19) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes AST value (IU/L or U/L or mIU/mL) xxxxxxxx. (dilincdd:STDLAB2.LABVAL19) AST ULN xxxxxxxx. (dilincdd:STDLAB2.LABULN19)
8. ALT available?	(dilincdd:STDLAB2.LABNAM20) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes ALT value (IU/L or U/L or mIU/mL) xxxxxxxx. (dilincdd:STDLAB2.LABVAL20) ALT ULN xxxxxxxx. (dilincdd:STDLAB2.LABULN20)
9. Alkaline phosphatase available?	(dilincdd:STDLAB2.LABNAM21) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Alkaline phosphatase value (IU/L or U/L or mIU/mL) xxxxxxxx. (dilincdd:STDLAB2.LABVAL21) Alkaline phosphatase ULN xxxxxxxx. (dilincdd:STDLAB2.LABULN21)
10. Amylase available?	(dilincdd:STDLAB2.LABNAM22)

		<p>[97] <input type="radio"/> Not done</p> <p>[11] <input type="radio"/> Yes</p> <p>Amylase value (U/L) xxxxxxxx. (dilincdd:STDLAB2.LABVAL22)</p> <p>Amylase ULN xxxxxxxx. (dilincdd:STDLAB2.LABULN22)</p>
11.	Lipase available?	<p>(dilincdd:STDLAB2.LABNAM23)</p> <p>[97] <input type="radio"/> Not done</p> <p>[11] <input type="radio"/> Yes</p> <p>Lipase value (U/L) xxxxxxxx. (dilincdd:STDLAB2.LABVAL23)</p> <p>Lipase ULN xxxxxxxx. (dilincdd:STDLAB2.LABULN23)</p>
12.	CPK available?	<p>(dilincdd:STDLAB2.LABNAM24)</p> <p>[97] <input type="radio"/> Not done</p> <p>[11] <input type="radio"/> Yes</p> <p>CPK value (U/L) xxxxxxxx. (dilincdd:STDLAB2.LABVAL24)</p> <p>CPK ULN xxxxxxxx. (dilincdd:STDLAB2.LABULN24)</p>
13.	GGTP available?	<p>(dilincdd:STDLAB2.LABNAM25)</p> <p>[97] <input type="radio"/> Not done</p> <p>[11] <input type="radio"/> Yes</p> <p>GGTP value (U/L) xxxxxxxx. (dilincdd:STDLAB2.LABVAL25)</p> <p>GGTP ULN xxxxxxxx. (dilincdd:STDLAB2.LABULN25)</p>
14.	LDH available?	<p>(dilincdd:STDLAB2.LABNAM26)</p> <p>[97] <input type="radio"/> Not done</p> <p>[11] <input type="radio"/> Yes</p> <p>LDH value (U/L) xxxxxxxx. (dilincdd:STDLAB2.LABVAL26)</p> <p>LDH ULN xxxxxxxx. (dilincdd:STDLAB2.LABULN26)</p>

CDD: dilincdd Table: STDLAB2 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
LABULN21	FLOAT - F9.0	
LABVAL15	FLOAT - F9.0	
LABUNT18	NUMERIC	
LABULN23	FLOAT - F9.0	
LABVAL13	FLOAT - F9.0	
LABULN25	FLOAT - F9.0	
LABVAL20	FLOAT - F9.0	
LABNAM18	NUMERIC	
LABVAL21	FLOAT - F9.0	
LABULN24	FLOAT - F9.0	
LABVAL26	FLOAT - F9.0	
LABULN20	FLOAT - F9.0	
LABVAL24	FLOAT - F9.0	
LABUNT17	NUMERIC	
LABNAM19	NUMERIC	
LABUNT13	NUMERIC	
LABULN19	FLOAT - F9.0	
LABNAM16	NUMERIC	
LABVAL25	FLOAT - F9.0	
LABVAL17	FLOAT - F9.0	
LABVAL23	FLOAT - F9.0	
LABNAM25	NUMERIC	
LABULN22	FLOAT - F9.0	
LABNAM17	NUMERIC	
LABNAM26	NUMERIC	

LABNAM15	NUMERIC	
LABNAM20	NUMERIC	
LABVAL18	FLOAT - F9.0	
LABULN26	FLOAT - F9.0	
LABNAM21	NUMERIC	
LABUNT14	NUMERIC	
LABVAL14	FLOAT - F9.0	
LABULN17	FLOAT - F9.0	
LABNAM13	NUMERIC	
LABVAL22	FLOAT - F9.0	
LABNAM24	NUMERIC	
LABVAL16	FLOAT - F9.0	
LABNAM23	NUMERIC	
LABNAM14	NUMERIC	
LABULN18	FLOAT - F9.0	
LABNAM22	NUMERIC	
LABVAL19	FLOAT - F9.0	

dilin : URINALYSIS (URINE)	
Urinalysis	
1. Labs-Urinalysis Date	Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dilincdd: URINE.URINEDT)
2. Specific gravity available?	(dilincdd: URINE.GRAVTYN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Specific gravity value xxxxxxxx. (dilincdd: URINE.GRAVITY)
3. pH available?	(dilincdd: URINE.PHYN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes pH value xxxxxxxx. (dilincdd: URINE.PH)
4. Glucose available?	(dilincdd: URINE.GLUCOSYN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Glucose value Pulldown List 1 <input type="checkbox"/> (dilincdd: URINE.GLUCOSE) Other Specify A50 (dilincdd: URINE.GLUCOTH)
5. Bilirubin available?	(dilincdd: URINE.BILRUBYN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes (dilincdd: URINE.BILRUBIN) Bilirubin value [1] <input type="radio"/> Negative [3] <input type="radio"/> (+)1 [4] <input type="radio"/> (+)2 [5] <input type="radio"/> (+)3 [98] <input type="radio"/> Other Other Specify A50 (dilincdd: URINE.BILIOTH)
6. Protein/albumin available?	(dilincdd: URINE.PROTEYN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Protein/albumin value Pulldown List 2 <input type="checkbox"/> (dilincdd: URINE.PROTEIN) Other Specify A50 (dilincdd: URINE.PROTOTH)
7. Leukocyte esterase available?	(dilincdd: URINE.LEUKOCYN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes (dilincdd: URINE.LEUKOCYT) Leukocyte esterase value [1] <input type="radio"/> Negative [2] <input type="radio"/> Trace [3] <input type="radio"/> (+)1 [4] <input type="radio"/> (+)2 [98] <input type="radio"/> Other Other Specify A50 (dilincdd: URINE.LEUKOTH)
Microscopic Exam	
8. WBC available?	(dilincdd: URINE.WBCYN) [97] <input type="radio"/> Not done [2] <input type="radio"/> Not Reported [1] <input type="radio"/> Yes WBC value A20 (dilincdd: URINE.URWBCVAL) (dilincdd: URINE.WBCUNIT) WBC unit [1] <input type="radio"/> count/HPF [2] <input type="radio"/> uL
9. RBC available?	(dilincdd: URINE.RBCYN) [97] <input type="radio"/> Not done [2] <input type="radio"/> Not Reported [1] <input type="radio"/> Yes RBC value A20 (dilincdd: URINE.RBCVAL) (dilincdd: URINE.RBCUNIT) RBC unit count/HPF

		<p>[1] <input type="radio"/> uL</p> <p>[2] <input type="radio"/> uL</p>
10.	Casts available?	<p>(dillncdd: URINE.CASTYN)</p> <p>[97] <input type="radio"/> Not done</p> <p>[2] <input type="radio"/> Not Reported</p> <p>[1] <input type="radio"/> Yes</p> <p>Casts value A20 (dillncdd: URINE.CASTVAL)</p> <p>(dillncdd: URINE.CASTUNIT)</p> <p>Casts unit [1] <input type="radio"/> count/HPF</p> <p>[2] <input type="radio"/> count/LPF</p>
11.	Crystals available?	<p>(dillncdd: URINE.CRSTYN)</p> <p>[97] <input type="radio"/> Not done</p> <p>[2] <input type="radio"/> Not Reported</p> <p>[1] <input type="radio"/> Yes</p> <p>Crystals value A20 (dillncdd: URINE.CRSTVAL)</p> <p>(dillncdd: URINE.CRSTUNIT)</p> <p>Crystals unit [1] <input type="radio"/> count/HPF</p> <p>[2] <input type="radio"/> count/LPF</p>
12.	Bacteria available?	<p>(dillncdd: URINE.BACYN)</p> <p>[97] <input type="radio"/> Not done</p> <p>[2] <input type="radio"/> Not Reported</p> <p>[1] <input type="radio"/> Yes</p> <p>Bacteria value A20 (dillncdd: URINE.BACVAL)</p> <p>(dillncdd: URINE.BACUNIT)</p> <p>Bacteria unit [1] <input type="radio"/> count/HPF</p> <p>[2] <input type="radio"/> uL</p>

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieURINEG	Negative	1	
ieURINTRA	Trace	2	
ieURIN1	(+)1	3	
ieURIN2	(+)2	4	
ieURIN3	(+)3	5	
ieURIN4	(+)4	6	
ieOTHER	Other	98	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieURINEG	Negative	1	
ieURINTRA	Trace	2	
ieURIN1	(+)1	3	
ieURIN2	(+)2	4	
ieURIN3	(+)3	5	
ieOTHER	Other	98	

CDD: dillncdd Table: URINE Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PROTEIN	NUMERIC - 1, 2, 3, 4, 5, 98	
BACYN	NUMERIC	
RBCYN	NUMERIC	
URINEDT	DATE - DDMONYYYY	
PHYN	NUMERIC	
LEUKOCYT	NUMERIC	

URWBCVAL	STRING(20) - A20	
GRAVTYN	NUMERIC	
BILRUBIN	NUMERIC	
LEUKOTH	STRING(50) - A50	
BILLOTH	STRING(50) - A50	
BACVAL	STRING(20) - A20	
GLUCOSE	NUMERIC - 1, 2, 3, 4, 5, 6, 98	
GRAVITY	FLOAT - F9.0	
GLUCOSYN	NUMERIC	
PROTOTH	STRING(50) - A50	
CASTVAL	STRING(20) - A20	
CRSTUNIT	NUMERIC	
PROTEYN	NUMERIC	
WBCUNIT	NUMERIC	
BACUNIT	NUMERIC	
RBCUNIT	NUMERIC	
BILRUBYN	NUMERIC	
CASTUNIT	NUMERIC	
LEUKOCYN	NUMERIC	
GLUCOTH	STRING(50) - A50	
CRSTVAL	STRING(20) - A20	
CASTYN	NUMERIC	
PH	FLOAT - F9.0	
RBCVAL	STRING(20) - A20	
CRSTYN	NUMERIC	
WBCYN	NUMERIC	

dilin : RESEARCH SAMPLES (RSAMPLE)	
Research Samples	
1. Blood sample provided?	(dilincdd:RSAMPLE.BLDSAMP) [0] <input type="radio"/> No [1] <input type="radio"/> If Yes: Date of collection Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd:RSAMPLE.BLOODDT)
2. Urine sample provided?	(dilincdd:RSAMPLE.URNSAMP) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: Date of collection Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd:RSAMPLE.URINEDT)
3. Did the subject receive a Liver Biopsy?	(dilincdd:RSAMPLE.LVBIOPYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilincdd Table: RSAMPLE Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
BLOODDT	DATE - DDMONYYYY	
URINEDT	DATE - DDMONYYYY	
URNSAMP	NUMERIC	
BLDSAMP	NUMERIC	
LVBIOPYN	NUMERIC	

dilin : INTERVAL HISTORY/QUESTIONNAIRES (INTHX)	
Interval History/Questionnaires	
1. Has the patient's medical history changed since the last visit?	(dilincdd: INTHX.PMEDHX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2. Has the patient's liver-specific medical history changed since the last visit?	(dilincdd: INTHX.PLIVHX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
3. Has the patients allergy history changed since the last visit?	(dilincdd: INTHX.PALGYHX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4. Has the patients surgical history changed since the last visit?	(dilincdd: INTHX.PSRGYHX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilincdd Table: INTHX Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PMEDHX	NUMERIC	
PSRGYHX	NUMERIC	
PALGYHX	NUMERIC	
PLIVHX	NUMERIC	

dilin : ER/HOSPITAL/MED APPT HISTORY (MEDHX3)	
ER/HOSPITAL/MED APPT HISTORY	
1. Was the patient admitted to any emergency room since the last visit?	(dilincdd: MEDHX3.ERHX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
2. Was the patient admitted to any hospital since the last visit?	(dilincdd: MEDHX3.HOSHX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [3] <input type="radio"/> Continuation [99] <input type="radio"/> Unknown
3. Was the patient seen by any other physician/healthcare practitioner since the last visit?	(dilincdd: MEDHX3.PHYSLV) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [3] <input type="radio"/> Lab blood draw visit only [99] <input type="radio"/> Unknown

CDD: dilincdd Table: MEDHX3 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PHYSLV	NUMERIC	
ERHX	NUMERIC	
HOSHX	NUMERIC	

dilin : EMERGENCY ROOM VISIT (ERRMHX) - Repeating Form											
#	Name of hospital:	City:	State:	Date admitted:	Date discharged:	Admission diagnosis:	Was the patient admitted to the ER for > 24 hours?	Was the emergency room visit DILI-related?	Were liver function tests performed?	Were abdominal imaging studies performed?	Discharge diagnosis:
1											

ER Visit	
1. Name of hospital:	A50 (dilincdd: ERRMHX.ERHOSP)
2. City:	A25 (dilincdd: ERRMHX.ERCITY)
3. State:	A5 (dilincdd: ERRMHX.ERSTE)
4. Date admitted:	Req/Unk / Req/Unk / Req (2004-2020) (dilincdd: ERRMHX.ERADMDT)
5. Date discharged:	(dilincdd: ERRMHX.ERDTYP) [2] Req/Unk / Req/Unk / Req (2004-2020) (dilincdd: ERRMHX.ERDISCDT) OR [1] Total number of days in the hospitalized: (dilincdd: ERRMHX.TOTNU) xxxxxxxx.
6. Admission diagnosis:	A200 (dilincdd: ERRMHX.ADMINDIA)
7. Was the patient admitted to the ER for > 24 hours?	(dilincdd: ERRMHX.PHOSHR) [0] No [1] Yes
8. Was the emergency room visit DILI-related?	(dilincdd: ERRMHX.ERDILIRD) [0] No [1] Yes [99] Unknown
9. Were liver function tests performed?	(dilincdd: ERRMHX.LIVTEST) [0] No [1] Yes [99] Unknown
10. Were abdominal imaging studies performed?	(dilincdd: ERRMHX.ABNORIMA) [0] No [1] Yes [99] Unknown
11. Discharge diagnosis:	A200 (dilincdd: ERRMHX.ERDISCH)

Column Name	Column Data Type	Design Note
ERSTE	STRING(5) - A5	
LIVTEST	NUMERIC	
ERCITY	STRING(25) - A25	
TOTNU	FLOAT - F9.0	
ERADMDT	DATE - DDMONYYYY	
ERDTYP	NUMERIC	
ERDISCDT	DATE - DDMONYYYY	
ABNORIMA	NUMERIC	
PHOSHR	NUMERIC	
ERHOSP	STRING(50) - A50	
ERDILIRD	NUMERIC	
ERDISCH	STRING(200) - A200	
ADMINDIA	STRING(200) - A200	

dilin : HOSPITALIZATION VISIT (HOSPHX) - Repeating Form										
#	Name of hospital:	City:	State:	Date admitted:	Date discharged:	Admission diagnosis:	Was the hospitalization DILI-related?	Were liver function tests performed?	Were abdominal imaging studies performed?	Discharge diagnosis:
1										

Hospital Visit	
1.	Name of hospital: <input type="text" value="A50"/> (dilinccd: HOSPHX.HOSPNM)
2.	City: <input type="text" value="A25"/> (dilinccd: HOSPHX.HOSPCY)
3.	State: <input type="text" value="A5"/> (dilinccd: HOSPHX.HOSPSTE)
4.	Date admitted: <input type="text" value="Req/Unk"/> / <input type="text" value="Req/Unk"/> / <input type="text" value="Req"/> (2004-2020) (dilinccd: HOSPHX.HOSADMDT)
5.	Date discharged: (dilinccd: HOSPHX.HOSTYP) [2] <input type="radio"/> Req/Unk <input type="text" value="Req/Unk"/> / <input type="text" value="Req/Unk"/> / <input type="text" value="Req"/> (2004-2020) (dilinccd: HOSPHX.HOSDISDT) OR [1] <input type="radio"/> Total number of days hospitalized: (dilinccd: HOSPHX.HOSTOTNU) <input type="text" value="xxxxxxx"/>
6.	Admission diagnosis: <input type="text" value="A200"/> (dilinccd: HOSPHX.HOSADMDX)
7.	Was the hospitalization DILI-related? (dilinccd: HOSPHX.HSDILIRD) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
8.	Were liver function tests performed? (dilinccd: HOSPHX.HOSLIVTS) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
9.	Were abdominal imaging studies performed? (dilinccd: HOSPHX.HOSABIMG) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
10.	Discharge diagnosis: <input type="text" value="A200"/> (dilinccd: HOSPHX.HOSDISCH)

Column Name	Column Data Type	Design Note
HOSDISCH	STRING(200) - A200	
HOSPSTE	STRING(5) - A5	
HOSPNM	STRING(50) - A50	
HOSADMDT	DATE - DDMONYYYY	
HOSABIMG	NUMERIC	
HOSDISDT	DATE - DDMONYYYY	
HOSTYP	NUMERIC	
HOSPCY	STRING(25) - A25	
HOSLIVTS	NUMERIC	
HOSADMDX	STRING(200) - A200	
HSDILIRD	NUMERIC	
HOSTOTNU	FLOAT - F9.0	

dilin : MEDICAL APPOINTMENT HISTORY (APPTHIST) - Repeating Form										
#	Physician specialty:	Physician:	City:	State:	Date:	Reason for visit:	Was the visit DILI-related?	Were liver function tests performed?	Were abdominal imaging studies performed?	
1										

Medical Appointment Visit	
1. Physician specialty:	A50 (dilinccd: APPTHIST.PHYSPEC)
2. Physician:	A25 (dilinccd: APPTHIST.PHYSICIA)
3. City:	A25 (dilinccd: APPTHIST.PCITY)
4. State:	A5 (dilinccd: APPTHIST.PSTE)
5. Date:	Req/Unk / Req/Unk / Req (2004-2020) (dilinccd: APPTHIST.MEDAP PDT)
6. Reason for visit:	A200 (dilinccd: APPTHIST.REASVT)
7. Was the visit DILI-related?	(dilinccd: APPTHIST.DILIREL) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
8. Were liver function tests performed?	(dilinccd: APPTHIST.DILILF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
9. Were abdominal imaging studies performed?	(dilinccd: APPTHIST.DILIABIM) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown

Column Name	Column Data Type	Design Note
PSTE	STRING(5) - A5	
PCITY	STRING(25) - A25	
MEDAP PDT	DATE - DDMONYYYY	
PHYSICIA	STRING(25) - A25	
DILILF	NUMERIC	
PHYSPEC	STRING(50) - A50	
DILIREL	NUMERIC	
REASVT	STRING(200) - A200	
DILIABIM	NUMERIC	

dilin : IMAGING STUDIES (ABDIMAGE)	
IMAGING STUDIES	
1. Were abdominal imaging studies performed since the last visit?	(dilincdd: ABDIMAGE.ABDIMG) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilincdd Table: ABDIMAGE Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ABDIMG	NUMERIC	

dilin : MAJOR MEDICAL OUTCOMES (MEDOUT)	
Medical Outcomes	
1. Has the patient undergone a liver transplant since the last visit?	(dilincdd:MEDOUT.LIVTRANS) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Document location of transplant: (dilincdd:MEDOUT.LOCTRANS) A200 Document date of transplant: Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2004-2020) (dilincdd:MEDOUT.TRANSDT)
2. Has the patient expired since the last visit?	(dilincdd:MEDOUT.EXLSTVI) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

Column Name	Column Data Type	Design Note
LIVTRANS	NUMERIC	
TRANSDT	DATE - DDMONYYYY	
EXLSTVI	NUMERIC	
LOCTRANS	STRING(200) - A200	

dilin : INTERVAL HEPATITIS STATUS (HEPSTATC)	
Interval Hepatitis Status	
1. Was the patient diagnosed with hepatitis B infection (detectable HBsAg) since the last visit?	(dilincdd: HEPSTATC.HEPAB) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2. Was the patient diagnosed with hepatitis C infection (detectable HCV RNA) since the last visit?	(dilincdd: HEPSTATC.HEPAC) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
3. Did the patient use any non-implicated hepatitis medications taken since the last visit?	(dilincdd: HEPSTATC.HPMEDCYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4. Did the patient have any available HBeAg results since the last visit?	(dilincdd: HEPSTATC.HBAGCYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
5. Did the patient have any available anti-HBe results since the last visit?	(dilincdd: HEPSTATC.ATHBECYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6. Did the patient have any available HBV DNA results since the last visit?	(dilincdd: HEPSTATC.HBDNACYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
7. Did the patient have any available HCV RNA results since the last visit?	(dilincdd: HEPSTATC.HCRNACYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilincdd Table: HEPSTATC Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
HPMEDCYN	NUMERIC	
HEPAC	NUMERIC	
HEPAB	NUMERIC	
HBDNACYN	NUMERIC	
HCRNACYN	NUMERIC	
HBAGCYN	NUMERIC	
ATHBECYN	NUMERIC	

dilin : INTERVAL HIV STATUS (HIVSTATC)	
Interval HIV Status	
1.	<p>Did the patient have HIV infection at the last study visit?</p> <p>(dilincdd:HIVSTATC.HIVINF) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd:HIVSTATC.AIDSLV) If Yes: Has the condition progressed to AIDS since the last visit? [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes What was the date of this diagnosis? Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTATC.AIDSLVDT)</p>
2.*	<p>If Q #1 = No: Was the patient diagnosed with HIV infection since the last visit?</p> <p>(dilincdd:HIVSTATC.HIVLV) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, Date of diagnosis Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTATC.HIVDIADT) (dilincdd:HIVSTATC.AIDSPRO) Did the condition progress to AIDS? [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes What was the date of this diagnosis? Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:HIVSTATC.AIDSDT)</p>
* Item is not required	

Column Name	Column Data Type	Design Note
AIDSLV	NUMERIC	
HIVINF	NUMERIC	
AIDSPRO	NUMERIC	
AIDSLVDT	DATE - DDMONYYYY	
AIDSDT	DATE - DDMONYYYY	
HIVLV	NUMERIC	
HIVDIADT	DATE - DDMONYYYY	

dilin : INTERVAL HIV STATUS (HIVSTAT3)	
Interval HIV Status	
1. Was a urine toxicology screen done since the last visit?	(dilincdd:HIVSTAT3.URTXYN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT3.URTXNK) [1] <input type="radio"/> Req/Unk / <input type="radio"/> Req/Unk / <input type="radio"/> Req (1935- (dilincdd:HIVSTAT3.URTXDT) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT3.URTXSCR) [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive
List all substances for which the test was positive	
2.	
. Entry	
2.a List all substances for which the test was positive	A80 (dilincdd:HIVSTATB.PSSBSTNC)
.	
3. Did the patient have evidence of active CMV infection (CMV DNA by RT-PCR) since the last visit?	(dilincdd:HIVSTAT3.EVRTYN01) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT3.EVRTUK01) [1] <input type="radio"/> Req/Unk / <input type="radio"/> Req/Unk / <input type="radio"/> Req (1935- (dilincdd:HIVSTAT3.EVRTDT01) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT3.EVIDRT01) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive CMV DNA calue (copies/ml) (dilincdd:HIVSTAT3.EVID1VAL) xxxxxxxx.
4. Did the patient have evidence of herpes simplex viral infection (HSV IGM) since the last visit?	(dilincdd:HIVSTAT3.EVRTYN02) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT3.EVRTUK02) [1] <input type="radio"/> Req/Unk / <input type="radio"/> Req/Unk / <input type="radio"/> Req (1935- (dilincdd:HIVSTAT3.EVRTDT02) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT3.EVIDRT02) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive
5. Did the patient have evidence of syphilis by VDRL (Venereal Disease Research Laboratory)since the last visit?	(dilincdd:HIVSTAT3.EVRTYN03) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT3.EVRTUK03) [1] <input type="radio"/> Req/Unk / <input type="radio"/> Req/Unk / <input type="radio"/> Req (1935- (dilincdd:HIVSTAT3.EVRTDT03) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT3.EVIDRT03) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive
6. Did the patient have evidence of syphilis by RPR (Rapid Plasma Reagent) since the last visit?	(dilincdd:HIVSTAT3.EVRTYN04) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT3.EVRTUK04) [1] <input type="radio"/> Req/Unk / <input type="radio"/> Req/Unk / <input type="radio"/> Req (1935- (dilincdd:HIVSTAT3.EVRTDT04) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT3.EVIDRT04) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive
7. Did the patient have evidence of a MAI infection (mycobacterium avium intracellulare) since the last visit?	(dilincdd:HIVSTAT3.EVRTYN05) [97] <input type="radio"/> Not done [1] <input type="radio"/> Date of result (dilincdd:HIVSTAT3.EVRTUK05) [1] <input type="radio"/> Req/Unk / <input type="radio"/> Req/Unk / <input type="radio"/> Req (1935- (dilincdd:HIVSTAT3.EVRTDT05) [99] <input type="radio"/> Unknown (dilincdd:HIVSTAT3.EVIDRT05) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive
8. Did the patient have any pertinent serologies/serum levels performed since the last visit?	(dilincdd:HIVSTAT3.SEROCYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
9. Did the patient use any non-implicated anti-retrovirals taken within 5 years of onset of DILI event?	(dilincdd:HIVSTAT3.HVMEDCYN) [0] <input type="radio"/> No

		[1] <input type="radio"/> Yes
10.	Did the patient have any available HIV RNA results since the last visit?	(dillncdd: HIVSTAT3.HVRNACYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
11.	Did the patient have any available CD4 results since the last visit?	(dillncdd: HIVSTAT3.CD4RCYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dillncdd Table: HIVSTAT3 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
EVRTYN03	NUMERIC	
EVRTUK04	NUMERIC	
EVRTDT01	DATE - DDMONYYYY	
EVRTDT03	DATE - DDMONYYYY	
EVID1VAL	FLOAT - F9.0	
EVRTDT02	DATE - DDMONYYYY	
URTXSCR	NUMERIC	
EVRTUK05	NUMERIC	
HVRNACYN	NUMERIC	
EVIDRT04	NUMERIC	
EVRTUK01	NUMERIC	
EVRTUK03	NUMERIC	
EVIDRT05	NUMERIC	
SEROCYN	NUMERIC	
EVIDRT02	NUMERIC	
EVRTDT04	DATE - DDMONYYYY	
EVRTDT05	DATE - DDMONYYYY	
EVRTYN05	NUMERIC	
URTXNK	NUMERIC	
EVRTYN02	NUMERIC	
HVMEDCYN	NUMERIC	
EVRTYN04	NUMERIC	
CD4RCYN	NUMERIC	
URTXDT	DATE - DDMONYYYY	
EVIDRT01	NUMERIC	
EVIDRT03	NUMERIC	
EVRTYN01	NUMERIC	
EVRTUK02	NUMERIC	
URTXYN	NUMERIC	

CDD: dillncdd Table: HIVSTATB Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PSSBSTNC	STRING(80) - A80	

dilin : INTERVAL QUESTIONNAIRES (QUESTS2)	
Interval Questionnaires	
1. Surrogate respondent?	(dilincdd:QUESTS2.SURRO4) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd:QUESTS2.SURSPEC4) Specify Surrogate [1] <input type="radio"/> Relative [98] <input type="radio"/> Other
2. Since the last visit, how would you describe your smoking habit?	(dilincdd:QUESTS2.SMOKE6) [1] <input type="radio"/> Never smoked [3] <input type="radio"/> Current smoker [2] <input type="radio"/> Ex-smoker How many months since you quit smoking? xxxxxxxx. (dilincdd:QUESTS2.QUITSMKM)
3. Since the last visit, have you ever had at least one drink of alcohol, beer, liquor, wine, or wine coolers, per month during a 12-month time period, or at least three drinks per day for at least three consecutive days (over a regular period of time)?	(dilincdd:QUESTS2.ALCOHOLX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

Column Name	Column Data Type	Design Note
ALCOHOLX	NUMERIC	
SURSPEC4	NUMERIC	
SURRO4	NUMERIC	
QUITSMKM	FLOAT - F9.0	
SMOKE6	NUMERIC	

dilin : INTERVAL GENERAL SMOKING HISTORY (GENSMOK6)	
Interval General Smoking History	
1. What is/was your smoking preference(s)?	(dilincdd:GENSMOK6.CIGARET6) [1] <input type="checkbox"/> Cigarette (dilincdd:GENSMOK6.CIGARS6) [1] <input type="checkbox"/> Cigar (dilincdd:GENSMOK6.PIPE6) [1] <input type="checkbox"/> Pipe
2. Do/did you regularly inhale tobacco when smoking?	(dilincdd:GENSMOK6.SMKINHA6) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilincdd Table: GENSMOK6 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SMKINHA6	NUMERIC	
PIPE6	NUMERIC	
CIGARET6	NUMERIC	
CIGARS6	NUMERIC	

dilin : CHRONIC INCLUSION/EXCLUSION (CHRONIC)		
CHRONIC DILI Inclusion/Exclusion Criteria		
1.	The participant had normal or unknown baseline values prior to initiation of the suspect medication and now, at least 6 months after the date of onset of the DILI episode, has a serum AST, ALT, alkaline phosphatase, INR (in the absence of coumadin therapy or vitamin K deficiency) or total bilirubin level (in the absence of hemolysis or known Gilberts syndrome), that is persistently elevated (i.e. above the upper limit of normal), as measured on 2 separate occasions.	(dilincdd: CHRONIC.CINEXC1) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2.	The participant had abnormal baseline values prior to initiation of suspect medication and now, at least 6 months after the date of onset of the DILI episode, has a serum AST, ALT, alkaline phosphatase, INR (in the absence of coumadin therapy or vitamin K deficiency) or total bilirubin level (in the absence of emolysis or known Gilberts syndrome), that exceeds 1.25 times the baseline value, as measured on 2 separate occasions.	(dilincdd: CHRONIC.CINEXC2) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
3.	The participant shows clinical evidence of portal hypertension such as ascites (fluid in the abdomen by imaging), esophageal or gastric varices on endoscopy, or hepatic encephalopathy, at least 6 months after the date of onset of the DILI episode.	(dilincdd: CHRONIC.CINEXC3) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4.	The participant shows histological evidence of liver injury on a liver biopsy obtained at least 6 months after the date of onset of the DILI episode (i.e. laboratory onset of DILI).	(dilincdd: CHRONIC.CINEXC4) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
5.	The participant shows radiological evidence of chronic liver disease such as ascites, hepatomegaly, splenomegaly, nodular contour of the liver, or intra-abdominal varices obtained at least 6 months after the date of onset of the DILI episode (i.e. laboratory onset of DILI).	(dilincdd: CHRONIC.CINEXC5) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6.	There is a medically reasonable explanation for declaring this a case of chronic DILI.	(dilincdd: CHRONIC.CINEXC9) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
7.	The participant had known chronic HBV or chronic HCV prior to initiation of the suspect medication.	(dilincdd: CHRONIC.CINEXC6) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
8.	The participant has undergone liver transplantation by the time of the 6-month study visit.	(dilincdd: CHRONIC.CINEXC7) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
9.	The participant has biopsy-proven cirrhosis or clinical evidence of portal hypertension due to any chronic liver disease (i.e. ascites, esophageal or gastric varices, hepatic encephalopathy) prior to initiation of the suspect medication.	(dilincdd: CHRONIC.CINEXC8) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
10.	There is a plausible alternative explanation for the laboratory, clinical, radiological, or histological abnormalities.	(dilincdd: CHRONIC.CINEXC10) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

Column Name	Column Data Type	Design Note
CINEXC2	NUMERIC	
CINEXC1	NUMERIC	
CINEXC8	NUMERIC	
CINEXC5	NUMERIC	
CINEXC6	NUMERIC	
CINEXC10	NUMERIC	
CINEXC7	NUMERIC	
CINEXC9	NUMERIC	
CINEXC3	NUMERIC	
CINEXC4	NUMERIC	

dilin : CONCOMITANT HISTORY (CONHX)	
Concomitant History	
1. Has the subject take any medications, including OTC, during the course of this study? This includes any medications taken 8 weeks prior to the initial administration of the implicated drug(s) or CAM product(s).	(dilincdd: CONHX.CONMHXYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2. Has the subject take any CAM products, during the course of this study? This includes any medications taken 8 weeks prior to the initial administration of the implicated drug(s) or CAM product(s).	(dilincdd: CONHX.CONCHXYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilincdd Table: CONHX Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CONMHXYN	NUMERIC	
CONCHXYN	NUMERIC	

dilin : CONCOMITANT MEDICATIONS (CONMED) - Repeating Form				
#		Medication	Start Date	Stop Date
1	<input type="text"/>			

Concomitant Medications	
1. Medication	Do not record hepatitis or HIV meds here (dilincdd:CONMED.MEDNAME) A80
2. Start Date	Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:CONMED.MEDSTDT)
3. Stop Date	(dilincdd:CONMED.MEDCONT) <input checked="" type="radio"/> Req/Unk <input type="text"/> / <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:CONMED.MEDSPDT) <input type="radio"/> Continuing

Column Name	Column Data Type	Design Note
MEDNAME	STRING(80) - A80	
MEDCONT	NUMERIC	
MEDSTDT	DATE - DDMONYYYY	
MEDSPDT	DATE - DDMONYYYY	

dilin : CONCOMITANT CAM PRODUCTS (CONCAM) - Repeating Form					
#		Brand or commercial name	Common names	Start Date	Stop Date
1	<input type="checkbox"/>				

Concomitant CAM Products	
1. Brand or commercial name	<input type="text" value="A80"/> (dilincdd:CONCAM.CAMBRAND)
2. Common names	<input type="text" value="A80"/> (dilincdd:CONCAM.CAMCOMM)
3. Start Date	Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilincdd:CONCAM.CAMLSTDT)
4. Stop Date	(dilincdd:CONCAM.CAMLCONT) <input checked="" type="radio"/> Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilincdd:CONCAM.CAMLSPDT) <input type="radio"/> Continuing

Column Name	Column Data Type	Design Note
CAMBRAND	STRING(80) - A80	
CAMCOMM	STRING(80) - A80	
CAMLSPDT	DATE - DDMONYYYY	
CAMLCONT	NUMERIC	
CAMLSTDT	DATE - DDMONYYYY	

dilin : HEPATITIS MEDICATIONS LOG (HEPLOG) - Repeating Form				
#		Medication	Start Date	Stop Date
1				

Hepatitis Medications Log	
1. Medication	<input type="text" value="A80"/> (dilinccd: HEPLOG.HEPMED)
2. Start Date	Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dilinccd: HEPLOG.HEPSTDT)
3. Stop Date	(dilinccd: HEPLOG.HEPCONT) <input type="radio"/> Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dilinccd: HEPLOG.HEPSPDT) <input type="radio"/> [1] Continuing

Column Name	Column Data Type	Design Note
HEPMED	STRING(80) - A80	
HEPSTDT	DATE - DDMONYYYY	
HEPSPDT	DATE - DDMONYYYY	
HEPCONT	NUMERIC	

dilin : HIV MEDICATION LOG (HIVLOG) - Repeating Form								
#	Medication	Dose	Unit	Frequency	Route	Start Date	Stop Date	
1								
HIV Medication Log								
1.	Medication	A80 (dilincdd:HIVLOG.HIVMED)						
2.	Dose	A5 (dilincdd:HIVLOG.HIVDOSE)						
3.	Unit	A8 (dilincdd:HIVLOG.HIVUNIT)						
4.	Frequency	Pulldown List 1 (dilincdd:HIVLOG.HIVFREQ) Specify Frequency A100 (dilincdd:HIVLOG.HIVFRQSP)						
5.	Route	Pulldown List 2 (dilincdd:HIVLOG.HIVROUTE) Specify Route A100 (dilincdd:HIVLOG.HIVRTESP)						
6.	Start Date	Req/Unk / Req/Unk / Req (1935-2020) (dilincdd:HIVLOG.HIVSTDT)						
7.	Stop Date	(dilincdd:HIVLOG.HIVCONT) [2] Req/Unk / Req/Unk / Req (1935-2020) (dilincdd:HIVLOG.HIVSPDT) [1] Continuing						

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieFREQ1	QD	1	
ieFREQ2	BID	2	
ieFREQ3	TID	3	
ieFREQ4	QID	4	
ieFREQ5	PRN	5	
ieFREQ6	Weekly	6	
ieFREQ7	Monthly	7	
ieOther	Other	98	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieROUTE1	PO	1	
ieROUTE2	IV	2	
ieROUTE3	SC	3	
ieROUTE4	IM	4	
ieROUTE5	Topical/transdermal	5	
ieOther	Other	98	

CDD: dilincdd	Table: HIVLOG	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
HIVSPDT	DATE - DDMONYYYY	
HIVROUTE	NUMERIC - 1, 2, 3, 4, 5, 98	
HIVDOSE	STRING(5) - A5	
HIVCONT	NUMERIC	
HIVUNIT	STRING(8) - A8	
HIVMED	STRING(80) - A80	
HIVFREQ	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 98	
HIVRTESP	STRING(100) - A100	

HIVSTDT	DATE - DDMONYYYY	
HIVFRQSP	STRING(100) - A100	

dilin : BIOPSY COLLECTION (COLLECT) - Repeating Form						
#		Date of biopsy collection	Name of hospital	DILI biopsy	Other/historic biopsies prior to DILI event	Date slides were shipped
1						

Biopsy Collection	
1. Date of biopsy collection	Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilincdd: COLLECT1.LVBIOPDT)
2. Name of hospital:	A50 (dilincdd: COLLECT1.BIOPSYNM) City: A25 (dilincdd: COLLECT1.BIOPSYCY) State: A50 (dilincdd: COLLECT1.BIOPSYST)
3. DILI biopsy	Pulldown List 1 <input type="checkbox"/> (dilincdd: COLLECT1.BIOPTYPE) Other Specify A100 (dilincdd: COLLECT1.BIOPSP) Slides from: A10 (dilincdd: COLLECT1.BIOPS1) Slides to: A10 (dilincdd: COLLECT1.BIOPS2) (dilincdd: COLLECT1.CRYO1YN) Is there a Cryovial/Cryomold: [0] <input type="radio"/> No [1] <input checked="" type="radio"/> Yes Cryovial/Cryomold: A10 (dilincdd: COLLECT1.CRYO1) (dilincdd: COLLECT1.CRYO2YN) Is there a second Cryovial/Cryomold: [0] <input type="radio"/> No [1] <input checked="" type="radio"/> Yes Cryovial/Cryomold: A10 (dilincdd: COLLECT1.CRYO2) (dilincdd: COLLECT1.CRYO3YN) Is there a third Cryovial/Cryomold: [0] <input type="radio"/> No [1] <input checked="" type="radio"/> Yes Cryovial/Cryomold: A10 (dilincdd: COLLECT1.CRYO3)
4. Other/historic biopsies prior to DILI event available?	(dilincdd: COLLECT1.HXBIOP) [0] <input type="radio"/> No [1] <input checked="" type="radio"/> Yes Slides from: A10 (dilincdd: COLLECT1.HXBIOP1) Slides to: A10 (dilincdd: COLLECT1.HXBIOP2)
5. Date slides were shipped:	Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> (2004-2020) (dilincdd: COLLECT1.SHIPDT)

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieBIOPTY	DILI event - historic biopsy	1	
ieBIOPTY02	Baseline	2	
ieBIOPTY03	12 Month	3	
ieBIOPTY04	Autopsy	4	
ieBIOPTY05	Transplant biopsy	5	
ieOTHER	Other	98	

CDD: dilincdd Table: COLLECT1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
BIOPS1	STRING(10) - A10	
LVBIOPDT	DATE - DDMONYYYY	
CRYO3YN	NUMERIC	
HXBIOP1	STRING(10) - A10	

BIOPSP	STRING(100) - A100	
BIOPSYCY	STRING(25) - A25	
CRYO2YN	NUMERIC	
CRYO1YN	NUMERIC	
CRYO2	STRING(10) - A10	
SHIPDT	DATE - DDMONYYYY	
HXBIOP2	STRING(10) - A10	
HXBIOP	NUMERIC	
CRYO1	STRING(10) - A10	
BIOPSYST	STRING(50) - A50	
CRYO3	STRING(10) - A10	
BIOPS2	STRING(10) - A10	
BIOPSYNM	STRING(50) - A50	
BIOPTYPE	NUMERIC - 1, 2, 3, 4, 5, 98	

dilin : ADVERSE EVENTS (AE)**Adverse Events**

1. Did the patient have any adverse event(s) specifically related to study procedures?

(dilincdd:AE.AEOCCUR)

[0] No[1] Yes**CDD: dilincdd Table: AE Key Type: PATIENTVISIT**

Column Name	Column Data Type	Design Note
AEOCCUR	NUMERIC	

dilin : ADVERSE EVENTS (AE1) - Repeating Form							
#	AE#	Adverse Event	Onset Date	Maximum Intensity	Outcome	Was This Event Serious?	End Date
1							
Adverse Events continued							
1.	AE#	xxx (dillncdd: AE1.AENUM)					
2.	Adverse Event	A100 (dillncdd: AE1.AENAME)					
3.	Onset Date	Req/Unk / Req/Unk / Req (2004-2020) (dillncdd: AE1.AEONSTDT)					
4.	Maximum Intensity	(dillncdd: AE1.INTENSE) [1] <input type="radio"/> Mild [2] <input type="radio"/> Moderate [3] <input type="radio"/> Severe					
5.	Outcome	(dillncdd: AE1.OUTCOME) [1] <input type="radio"/> Resolved [2] <input type="radio"/> Resolved - with sequelae [3] <input type="radio"/> Unresolved [4] <input type="radio"/> Death					
6.	Was This Event Serious?	(dillncdd: AE1.SERIOUS) [0] <input type="radio"/> No [1] <input type="radio"/> Yes					
7.*	End Date	(dillncdd: AE1.AECONT) [2] <input type="radio"/> Req/Unk / Req/Unk / Req (2004-2020) (dillncdd: AE1.AESTOPDT) [1] <input type="radio"/> Ongoing					
* Item is not required							

Associations For Visit RefName vsCAS	
Visit RefName	Form RefName
vsCAS	frSAE

CDD: dillncdd	Table: AE1	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
SERIOUS	NUMERIC	
AESTOPDT	DATE - DDMONYYYY	
AENUM	NUMERIC - N3	
AENAME	STRING(100) - A100	
AEONSTDT	DATE - DDMONYYYY	
AECONT	NUMERIC	
INTENSE	NUMERIC	
OUTCOME	NUMERIC	

dilin : SERIOUS ADVERSE EVENTS (SAE) - Repeating Form								
#	Report type:	Serious Adverse Event (medical diagnosis/primary symptom):	Serious Adverse Event onset date and time:	Serious Reporting Criteria	Outcome	Date of final outcome:	Action Taken with respect to Study Participation:	Causal Relationship (Investigator assessment of causal relationship of adverse event to study procedure):
1								
Serious Adverse Events								
1.	Report type:					(dilincdd: SAE.REPORT) [1] <input type="radio"/> Initial [2] <input type="radio"/> Follow-up Follow-up #: A3 (dilincdd: SAE.FUNUM)		
2.	Serious Adverse Event (medical diagnosis/primary symptom):	A100				(dilincdd: SAE.SAEVENT)		
3.	Serious Adverse Event onset date and time:	Req/Unk / / Req/Unk / / Req (2004-2020) (dilincdd: SAE.SAETM) Req/Unk : Req/Unk 24-hour clock						
4.	Serious Reporting Criteria	Check all that apply (dilincdd: SAE.SAEDEATH) [1] <input type="checkbox"/> Death (dilincdd: SAE.THREATEN) [1] <input type="checkbox"/> Life-threatening (dilincdd: SAE.DISABLE1) [1] <input type="checkbox"/> Resulted in a persistent or significant disability/incapacity (dilincdd: SAE.PROHOSP) [1] <input type="checkbox"/> Prolonged or required hospitalization (dilincdd: SAE.CONGENT) [1] <input type="checkbox"/> Congenital anomaly or birth defect (dilincdd: SAE.OTHSIGEV) [1] <input type="checkbox"/> Other significant event requiring medical and/or surgical intervention						
5.	Outcome					(dilincdd: SAE.OUTCME) [1] <input type="radio"/> Patient died [2] <input type="radio"/> Recovered [3] <input type="radio"/> Recovered with Sequelae [4] <input type="radio"/> Condition still present		
6.	Date of final outcome:	Req/Unk / / Req/Unk / / Req (2004-2020) (dilincdd: SAE.OUTCOMDT)						
7.	Action Taken with respect to Study Participation:					(dilincdd: SAE.ACTION) [1] <input type="radio"/> Continued [2] <input type="radio"/> Discontinued (dilincdd: SAE.ABATE) Did the event abate? [0] <input type="radio"/> No [1] <input type="radio"/> Yes		
8.	Causal Relationship (Investigator assessment of causal relationship of adverse event to study procedure):					(dilincdd: SAE.RELATION) [1] <input type="radio"/> Possibly [2] <input type="radio"/> Probably [3] <input type="radio"/> Definitely		

Associations For Visit RefName vsCAS	
Visit RefName	Form RefName
vsCAS	frAE1

CDD: dilincdd	Table: SAE	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
SAEDEATH	NUMERIC	
OUTCME	NUMERIC	
DISABLE1	NUMERIC	
THREATEN	NUMERIC	
PROHOSP	NUMERIC	
OUTCOMDT	DATE - DDMONYYYY	

CONGENT	NUMERIC	
SAEVENT	STRING(100) - A100	
RELATION	NUMERIC	
REPORT	NUMERIC	
OTHSIGEV	NUMERIC	
FUNUM	STRING(3) - A3	
SAETM	DATE - DDMONYYYY HHMM	
ABATE	NUMERIC	
ACTION	NUMERIC	

dilin : RUCDR DNA (RUCDR) - Repeating Form		
#		
1		
RUCDR Blooddraw		
1.*	Blooddraw Visit [<i>hidden</i>]	(dilincdd: RUCDR.BLDVST) [1] <input type="radio"/> Baseline [2] <input type="radio"/> 6 Month [3] <input type="radio"/> 12 Month [4] <input type="radio"/> 24 Month
2.*	Age [<i>hidden</i>]	xxx (dilincdd: RUCDR.PBLDAGE)
3.*	Sex [<i>hidden</i>]	(dilincdd: RUCDR.PBLDSX) [1] <input type="radio"/> Male [2] <input type="radio"/> Female
4.*	Alternate ID# [<i>hidden</i>]	A15 (dilincdd: RUCDR.PBLDALT)
5.*	NIDDK-ID# [<i>hidden</i>]	A10 (dilincdd: RUCDR.PBLDID)
6.*	# Yellow (ACD) top tubes 3.0 ML [<i>hidden</i>]	xxx (dilincdd: RUCDR.PDYELL)
7.*	# Yellow (ACD) top tubes 8.5 ML [<i>hidden</i>]	xxx (dilincdd: RUCDR.ADYELL)
8.*	# Purple (EDTA) top tubes 3.0 ML [<i>hidden</i>]	xxx (dilincdd: RUCDR.PDPURP)
9.*	# Purple (EDTA) top tubes 10.0 ML [<i>hidden</i>]	xxx (dilincdd: RUCDR.ADPURP)
10.*	Date and Time Blood Drawn [<i>hidden</i>]	Req/Unk ▾ / Req/Unk ▾ / Req ▾ (2004-2020) (dilincdd: RUCDR.PBLDTM) Req/Unk ▾ : Req/Unk ▾ 24-hour clock
11.*	Drawn By [<i>hidden</i>]	A25 (dilincdd: RUCDR.PDRAWN)
12.*	Contact Method [<i>hidden</i>]	(dilincdd: RUCDR.PBLDMETH) [1] <input type="radio"/> Emailed [2] <input type="radio"/> Faxed [3] <input type="radio"/> Call in
13.*	Call in by [<i>hidden</i>]	A25 (dilincdd: RUCDR.PBLDNM)
14.*	Call date and time [<i>hidden</i>]	Req/Unk ▾ / Req/Unk ▾ / Req ▾ (2004-2020) (dilincdd: RUCDR.PBLDNMTM) Req/Unk ▾ : Req/Unk ▾ 24-hour clock
15.*	Package tracking # [<i>hidden</i>]	A25 (dilincdd: RUCDR.PBLDTRK)
* Item is not required		

Column Name	Column Data Type	Design Note
PBLDTRK	STRING(25) - A25	
ADYELL	NUMERIC - N3	
PBLDMETH	NUMERIC	
PBLDAGE	NUMERIC - N3	
PBLDALT	STRING(15) - A15	
PDRAWN	STRING(25) - A25	
ADPURP	NUMERIC - N3	
PBLDTM	DATE - DDMONYYYY HHMM	
PBLDNMTM	DATE - DDMONYYYY HHMM	
PBLDID	STRING(10) - A10	
BLDVST	NUMERIC	
PDPURP	NUMERIC - N3	

PBLDNM	STRING(25) - A25	
PBLDSX	NUMERIC	
PDYELL	NUMERIC - N3	

dilin : Fisher Repository Blooddraw (NIDDKSER) - Repeating Form									
#	Blooddraw Visit	Shipment Form completed by	Completion Date	Collection Site Name	Collection Site Address	Collection Site City	Collection Site State	Collection Site Zip	Was a biopsy sample(s) included in this shipment
1									

Fisher Blooddraw						
1.	Blooddraw Visit	(dilincdd: NIDDKSER.REPOVST) [1] <input type="radio"/> Baseline [2] <input type="radio"/> 6 Month [3] <input type="radio"/> 12 Month [4] <input type="radio"/> 24 Month				
2.	Shipment Form completed by	A25	(dilincdd: NIDDKSER.REPONM)			
3.	Completion Date	Req/Unk ▾ / Req/Unk ▾ / Req ▾	(2004-2020) (dilincdd: NIDDKSER.REPODT)			
4.	Collection Site Name	A50	(dilincdd: NIDDKSER.SITENM)			
5.*	Collection Site Address	A25	(dilincdd: NIDDKSER.SITEADD)			
6.*	Collection Site City	A25	(dilincdd: NIDDKSER.SITECITY)			
7.*	Collection Site State	A50	(dilincdd: NIDDKSER.SITEST)			
8.*	Collection Site Zip	A10	(dilincdd: NIDDKSER.SITEZIP)			
9.*	Was a biopsy sample(s) included in this shipment?	(dilincdd: NIDDKSER.RBIOPYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes				
	NIDDK ID#	Alternate ID#				Serum collection date
10.						Number of vials of Serum
						Plasma collection date
						Number of vials of Plasma
						Urine collection date
						Number of vials of Urine

- Entry						
10.a	NIDDK ID#	A25	(dilincdd: NIDDKSE1.REPOID)			
10.b	Alternate ID#	A25	(dilincdd: NIDDKSE1.REPOALT)			
10.c*	Serum collection date	Req/Unk ▾ / Req/Unk ▾ / Req ▾	(2004-2020) (dilincdd: NIDDKSE1.SERCOLDT)			
10.d*	Number of vials of Serum	xxxxx	(dilincdd: NIDDKSE1.SERVIAL)			
10.e*	Plasma collection date	Req/Unk ▾ / Req/Unk ▾ / Req ▾	(2004-2020) (dilincdd: NIDDKSE1.PLSCOLDT)			
10.f*	Number of vials of Plasma	xxxxx	(dilincdd: NIDDKSE1.PLSVIAL)			
10.g*	Urine collection date	Req/Unk ▾ / Req/Unk ▾ / Req ▾	(2004-2020) (dilincdd: NIDDKSE1.URNCOLDT)			
10.h*	Number of vials of Urine	xxxxx	(dilincdd: NIDDKSE1.URNVIAL)			

* Item is not required

Column Name	Column Data Type	Design Note
PLSVIAL	NUMERIC - N5	
REPOID	STRING(25) - A25	
URNVIAL	NUMERIC - N5	
PLSCOLDT	DATE - DDMONYYYY	
SERVIAL	NUMERIC - N5	
URNCOLDT	DATE - DDMONYYYY	
REPOALT	STRING(25) - A25	
SERCOLDT	DATE - DDMONYYYY	

CDD: dilincdd Table: NIDDKSER Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SITECITY	STRING(25) - A25	
SITEZIP	STRING(10) - A10	
SITEST	STRING(50) - A50	
REPOVST	NUMERIC	
REPODT	DATE - DDMONYYYY	
REPONM	STRING(25) - A25	
SITENM	STRING(50) - A50	
RBIOPYN	NUMERIC	
SITEADD	STRING(25) - A25	

dilin : FISHER REPOSITORY (NIDDKBPY) - Repeating Form						
#	Biopsy_Visit	Biorepository_notified_via	Biorepository_notified_by	Date_and_time_of_notification	FedEx_Tracking_Number	
1	<input type="text"/>					
.						
1.*	Biopsy_Visit	(dilincdd: NIDDKBPY.BIOPVST) [1] <input type="radio"/> Baseline [2] <input type="radio"/> 6 Month [3] <input type="radio"/> 12 Month [4] <input type="radio"/> 24 Month				
2.*	Biorepository_notified_via	(dilincdd: NIDDKBPY.NOTIFY) [1] <input type="radio"/> Emailed [2] <input type="radio"/> Faxed				
3.*	Biorepository_notified_by	A25 (dilincdd: NIDDKBPY.NOTFYNM)				
4.*	Date_and_time_of_notification	Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: NIDDKBPY.NOTFYDTM) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock				
5.*	FedEx_Tracking_Number	A25 (dilincdd: NIDDKBPY.NOTFYTRK)				
	NIDDK ID#	Alternate ID#			Barcode Number	Collection Date
6.						
. Entry						
6.a*	NIDDK ID#	A25 (dilincdd: NIDDKBP1.BIOPID)				
6.b*	Alternate ID#	A25 (dilincdd: NIDDKBP1.BIOPALT)				
6.c*	Barcode Number	A25 (dilincdd: NIDDKBP1.BIOPCODE)				
6.d*	Collection Date	Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd: NIDDKBP1.BPCOLLDT)				
* Item is not required						

CDD: dilincdd Table: NIDDKBP1 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
BIOPALT	STRING(25) - A25	
BIOPID	STRING(25) - A25	
BPCOLLDT	DATE - DDMONYYYY	
BIOPCODE	STRING(25) - A25	

CDD: dilincdd Table: NIDDKBPY Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
BIOPVST	NUMERIC	
NOTIFY	NUMERIC	
NOTFYDTM	DATE - DDMONYYYY HHMM	
NOTFYTRK	STRING(25) - A25	
NOTFYNM	STRING(25) - A25	

dilin : Serology Flowchart (SEROFLOW) - Repeating Form				
#		Serology available	Serology type?	Date
1	<input type="text"/>			
Serology Labs				
1.	Serology available?	(dilincdd: SEROFLOW.SEROVIS) [1] <input type="radio"/> BASELINE [2] <input type="radio"/> Month 6		
2.	Serology type?	(dilincdd: SEROFLOW.SEROLAB) [1] <input type="radio"/> ANA [2] <input type="radio"/> ASMA		
3.	Date	Date Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req/Unk <input type="text"/> (2004-2020) (dilincdd: SEROFLOW.SERODATE) (dilincdd: SEROFLOW.SERNPUNK) Results [99] <input type="radio"/> Unknown [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive If IF, provide Titer 1: If ELISA, provide value Serology Value xxxxxxxx. (dilincdd: SEROFLOW.SEROVAL) (dilincdd: SEROFLOW.SEROIFEL) Type of test [1] <input type="radio"/> IF [2] <input type="radio"/> ELISA (dilincdd: SEROFLOW.SERTRULN) Threshold for positive results [1] <input type="radio"/> Titer 1: [2] <input type="radio"/> ULN Threshold Value xxxxxxxx. (dilincdd: SEROFLOW.SERTHVAL)		

Column Name	Column Data Type	Design Note
SEROLAB	NUMERIC	
SEROIFEL	NUMERIC	
SERTRULN	NUMERIC	
SERODATE	DATE - DDMONYYYY	
SERTHVAL	FLOAT - F9.0	
SEROVAL	FLOAT - F9.0	
SEROVIS	NUMERIC	
SERNPUNK	NUMERIC	

dilin : Protocol Exemption (PTLEXMPT)	
Protocol Exemption	
1.*	Did the inclusion/exclusion criteria change since enrollment? (dillncdd:PTLEXMPT.PECHG) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
Inclusion Criteria	
2.*	Was the patient more than 2 years of age at the time of enrollment? (dillncdd:PTLEXMPT.PTEX1) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
3.*	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? (dillncdd:PTLEXMPT.PTEX2) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4.*	Was the patient/legal guardian willing to sign informed consent? (dillncdd:PTLEXMPT.PTEX3) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
5.*	If ALT, AST, or AP was normal prior to the implicated drug start date, was ALT or AST > 5 × ULN or AP > 2 × ULN on at least 2 consecutive blood draws? (dillncdd:PTLEXMPT.PTEX4) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX5) If Yes, was ALT > 5 × ULN on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX6) If Yes, was AST > 5 × ULN on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX7) If Yes, was AP > 2 × ULN on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6.*	If ALT, AST, or AP was elevated prior to the implicated drug start date, was ALT or AST > 5 × pre-drug average or AP > 2 × pre-drug average on at least 2 consecutive blood draws? (dillncdd:PTLEXMPT.PTEX8) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX9) If Yes, was ALT > 5 × pre-drug average on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX10) If Yes, was AST > 5 × pre-drug average on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX11) If Yes, was AP > 2 × pre-drug average on at least 2 consecutive blood draws? [0] <input type="radio"/> No [1] <input type="radio"/> Yes
7.*	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, or evidence of hemolysis? (dillncdd:PTLEXMPT.PTEX12) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX13) If Yes Specify ALT above the ULN [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX14) If Yes Specify AST above the ULN [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX15) If Yes Specify AP above the ULN [0] <input type="radio"/> No [1] <input type="radio"/> Yes
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? (dillncdd:PTLEXMPT.PTEX16) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX17) If Yes Specify ALT above the ULN

		<p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX18) If Yes Specify AST above the ULN</p> <p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PTLEXMPT.PTEX19) If Yes Specify AP above the ULN</p> <p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes</p>
Exclusion Criteria		
9.*	Did the patient have a competing identifiable cause of acute liver injury (e.g., hepatic ischemia) that was felt to be the primary reason for the observed liver injury, supported by laboratory test, serologies, liver biopsy, or radiology?	(dillncdd:PTLEXMPT.PTEX20) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
10.*	Did the patient have a known, pre-existing liver problem that may confound the ability to make a diagnosis of DILI? (e.g. autoimmune hepatitis, primary biliary cirrhosis, primary sclerosing cholangitis, other chronic biliary tract disease)	(dillncdd:PTLEXMPT.PTEX21) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
11.*	Did the patient have acetaminophen hepatotoxicity?	(dillncdd:PTLEXMPT.PTEX22) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
12.*	Did the patient have a liver/organ transplant prior to development of drug- or CAM-induced injury?	(dillncdd:PTLEXMPT.PTEX23) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
Eligibility		
13.*	Eligibility	(dillncdd:PTLEXMPT.PTEX24) [1] <input type="radio"/> Satisfied all criteria [2] <input type="radio"/> Entered per protocol exemption
14.*	Was this patient enrolled previously?	(dillncdd:PTLEXMPT.PTEX25) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, specify all previous DILIN ID(s): <input type="text" value="A50"/> (dillncdd:PTLEXMPT.PTEX25A)
15.*	ICF: Patient agrees to contribute biological samples and associated data and allow medical information to be used in this study and for future research related to liver injury or liver disease (genetic research included).	(dillncdd:PTLEXMPT.PTEX26) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
16.*	ICF: In addition, patient agrees that biological specimens and associated data collected can be used for future research for conditions including but not limited to heart disease, cancer or mental illness (genetic research included).	(dillncdd:PTLEXMPT.PTEX27) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
* Item is not required		

Column Name	Column Data Type	Design Note
PTEX16	NUMERIC	
PTEX24	NUMERIC	
PTEX18	NUMERIC	
PTEX7	NUMERIC	
PTEX6	NUMERIC	
PTEX22	NUMERIC	
PTEX2	NUMERIC	
PTEX12	NUMERIC	
PTEX4	NUMERIC	
PTEX9	NUMERIC	
PTEX13	NUMERIC	
PTEX20	NUMERIC	
PTEX21	NUMERIC	

PTEX17	NUMERIC	
PTEX8	NUMERIC	
PTEX3	NUMERIC	
PTEX25A	STRING(50) - A50	
PTEX23	NUMERIC	
PECHG	NUMERIC	
PTEX11	NUMERIC	
PTEX1	NUMERIC	
PTEX19	NUMERIC	
PTEX15	NUMERIC	
PTEX10	NUMERIC	
PTEX25	NUMERIC	
PTEX27	NUMERIC	
PTEX14	NUMERIC	
PTEX5	NUMERIC	
PTEX26	NUMERIC	

dilin : NARRATIVES (NARR)		
Clinical Narratives		
1.*	Initial Causality Narrative Received [<i>hidden</i>]	(dilincdd:NARR.CLINNARR) [1] <input type="radio"/> Yes
2.*	Death Narrative Received [<i>hidden</i>]	(dilincdd:NARR.DTHNARR) [1] <input type="radio"/> Yes
3.*	EOS Narrative Received [<i>hidden</i>]	(dilincdd:NARR.EOSNARR) [1] <input type="radio"/> Yes
* Item is not required		

CDD: dilincdd Table: NARR Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CLINNARR	NUMERIC	
DTHNARR	NUMERIC	
EOSNARR	NUMERIC	

dilin : EARLY WITHDRAWAL and STUDY COMPLETION (PTCOMPL)	
Early Withdrawal and Study Completion	
1. End of study date	Req [v] / Req [v] / Req [v] (2004-2020) (dilincdd:PTCOMPL.COMPLDT)
2. Did the participant complete the study?	(dilincdd:PTCOMPL.STUDYCOM) [1] <input type="radio"/> Yes [0] <input type="radio"/> No (dilincdd:PTCOMPL.REASON) Choose primary reason [2] <input type="radio"/> Adverse Event [3] <input type="radio"/> Consent withdrawn [4] <input type="radio"/> Lost to follow-up [5] <input type="radio"/> No longer interested [6] <input type="radio"/> Felt study required too much time [7] <input type="radio"/> Felt study was asking for too much information [8] <input type="radio"/> Unwilling to have blood drawn [98] <input type="radio"/> Other Other Specify (dilincdd:PTCOMPL.REASONSP) A200 [1] <input type="radio"/> Death Date of death: Req/Unk [v] / Req/Unk [v] / Req [v] (2004-2020) (dilincdd:PTCOMPL.DEATHDT)
3.* Liver-related death?	(dilincdd:PTCOMPL.NLLRDTH) [1] <input type="radio"/> Non liver-related death Cause of death: (dilincdd:PTCOMPL.CAUSE) A200 [2] <input type="radio"/> Liver-related death (check all that apply) (dilincdd:PTCOMPL.SEPSIS) [1] <input type="checkbox"/> Sepsis (dilincdd:PTCOMPL.VARCIBLD) [1] <input type="checkbox"/> Variceal bleeding (dilincdd:PTCOMPL.RENLFAIL) [1] <input type="checkbox"/> Renal failure (dilincdd:PTCOMPL.CEREDEMA) [1] <input type="checkbox"/> Cerebral edema (dilincdd:PTCOMPL.FALF) [1] <input type="checkbox"/> Fulminant/acute liver failure (within 8 weeks of liver disease onset) (dilincdd:PTCOMPL.HEPATOCA) [1] <input type="checkbox"/> Hepatocellular carcinoma (dilincdd:PTCOMPL.SPLVTX) [1] <input type="checkbox"/> Post liver transplant complications (dilincdd:PTCOMPL.LRDTHOTH) [1] <input type="checkbox"/> Other Specify (dilincdd:PTCOMPL.DTHOTHSP) A200
4. For chronic DILI participants, was the End of Study Clinical Narrative sent to the DCC?	(dilincdd:PTCOMPL.CHRONARR) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [96] <input type="radio"/> NA
5.* Is this person deemed a NON-DILI case?	(dilincdd:PTCOMPL.NONDILI) [1] <input type="radio"/> Yes
* Item is not required	

Column Name	Column Data Type	Design Note
CEREDEMA	NUMERIC	
RENLFAIL	NUMERIC	
REASONSP	STRING(200) - A200	

HEPATOCA	NUMERIC	
FALF	NUMERIC	
DTHOTHSP	STRING(200) - A200	
DEATHDT	DATE - DDMONYYYY	
SEPSIS	NUMERIC	
SPLVTX	NUMERIC	
CHRONARR	NUMERIC	
LRDTHOTH	NUMERIC	
NONDILI	NUMERIC	
COMPLDT	DATE - DDMONYYYY	
REASON	NUMERIC	
CAUSE	STRING(200) - A200	
NLLRDTH	NUMERIC	
VARCIBLD	NUMERIC	
STUDYCOM	NUMERIC	

dilin : INVESTIGATOR SIGNATURE (SIGNATUR)	
Investigator Signature	
1. Casebook ready for Signature	(dilincdd:SIGNATUR.SIGNANS) [1] <input type="radio"/> Yes

CDD: dilincdd Table: SIGNATUR Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SIGNANS	NUMERIC	

dilin : Annual CONCOMITANT HISTORY (ACONHX)**Annual Concomitant History**

1.	Did the subject take any medications, including OTC, at any point in the 4 week period up to and including the annual visit?	(dillncdd:ACONHX.ACNMHXYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2.	Did the subject take any CAM products, at any point in the 4 week period up to and including the annual visit?	(dillncdd:ACONHX.ACNCXHYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilncdd Table: ACONHX Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
ACNCXHYN	NUMERIC	
ACNMHXYN	NUMERIC	

dilin : Annual CONCOMITANT MEDICATIONS (ACONMED) - Repeating Form				
#		Medication	Start Date	Stop Date
1				

Concomitant Medications taken within 4 week period prior to annual visit	
1. Medication	A80 (dilincdd: ACONMED.AMEDNAME)
2. Start Date	NRReq/Unk <input type="checkbox"/> / NRReq/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilincdd: ACONMED.AMEDSTDT)
3. Stop Date	(dilincdd: ACONMED.AMEDCONT) <input checked="" type="radio"/> Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilincdd: ACONMED.AMEDSPDT) <input type="radio"/> Continuing [1]

Column Name	Column Data Type	Design Note
AMEDNAME	STRING(80) - A80	
AMEDSTDT	DATE - DDMONYYYY	
AMEDCONT	NUMERIC	
AMEDSPDT	DATE - DDMONYYYY	

dilin : Annual CONCOMITANT CAM PRODUCTS (ACONCAM) - Repeating Form					
#		Brand or Commercial name	Common name	Start Date	Stop Date
1					

Concomitant CAM Products taken within 4 week period prior to annual visit	
1. Brand or Commercial name	A80 (dilincdd: ACONCAM.ACMBRNM)
2. Common name	A80 (dilincdd: ACONCAM.ACMCOMNM)
3. Start Date	Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilincdd: ACONCAM.ACMSTDT)
4. Stop Date	(dilincdd: ACONCAM.ACMCONT) <input checked="" type="radio"/> Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilincdd: ACONCAM.ACMSPDT) <input type="radio"/> Continuing

Column Name	Column Data Type	Design Note
ACMCOMNM	STRING(80) - A80	
ACMBRNM	STRING(80) - A80	
ACMSTDT	DATE - DDMONYYYY	
ACMSPDT	DATE - DDMONYYYY	
ACMCONT	NUMERIC	

dilin : INTERVAL HEPATITIS STATUS 2 (HEPSTAT2)**Interval Hepatitis Status**

1. Did the patient use any non-implicated hepatitis medications taken since the last visit?

(dilincdd: HEPSTAT2.HPMED2YN)

[0] No[1] Yes**CDD: dilincdd Table: HEPSTAT2 Key Type: PATIENTVISIT**

Column Name	Column Data Type	Design Note
HPMED2YN	NUMERIC	

dilin : Personal History Questionnaire (PHXQ1)		
Personal History Questionnaire		
1.	Q1 - Do you currently have any pets at home?	(dillncdd:PHXQ1.PHQ01) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: How many pets? xxx (dillncdd:PHXQ1.PHQ01PET) (dillncdd:PHXQ1.PHQ01BIRD) What type of pets: (check all that apply) [1] <input type="checkbox"/> Bird (dillncdd:PHXQ1.PHQ01CAT) [1] <input type="checkbox"/> Cat (dillncdd:PHXQ1.PHQ01DOG) [1] <input type="checkbox"/> Dog (dillncdd:PHXQ1.PHQ01FERRET) [1] <input type="checkbox"/> Ferret (dillncdd:PHXQ1.PHQ01PIG) [1] <input type="checkbox"/> Pig (dillncdd:PHXQ1.PHQ01OTHER) [1] <input type="checkbox"/> Other Other Specify <input type="text" value="A200"/> (dillncdd:PHXQ1.PHQ01SPEC)
2.	Q2 - During the 6 months before you became sick with your liver injury, did you have any direct contact with farm or wild animals?	(dillncdd:PHXQ1.PHQ02) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, please indicate animals on form PHXQ2
3.	Q3 - Did you travel and stay overnight anywhere outside of your home town, city or community in the 6 months before you became sick with your liver injury?	(dillncdd:PHXQ1.PHQ03) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, please indicate travel on form PHXQ3
4.	Q4 - What is your main source of drinking water?	(dillncdd:PHXQ1.PHQ04) [1] <input type="radio"/> City or County Water [2] <input type="radio"/> Well Water [3] <input type="radio"/> Outdoor water from a lake or stream [4] <input type="radio"/> Bottled Water [5] <input type="radio"/> Other <input type="text" value="A200"/> (dillncdd:PHXQ1.PHQ04SP)
5.	Q5 - Do you ever eat raw or undercooked meats?	(dillncdd:PHXQ1.PHQ05) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6.	Q6 - Do you ever eat the internal organs of animals such as heart, liver, lungs, intestines or brains?	(dillncdd:PHXQ1.PHQ06) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PHXQ1.PHQ06S) Is the meat usually well cooked? [0] <input type="radio"/> No [1] <input type="radio"/> Yes
7.	Q7 - Do you ever eat meat that you or others have hunted?	(dillncdd:PHXQ1.PHQ07) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes Specify <input type="text" value="A200"/> (dillncdd:PHXQ1.PHQ07SP)
NOTE: IF the response is 'YES' to any or all of Questions 5,6,7 - Please answer Q8 on the PHXQ8 tab		
8.	Q9 - Have you ever received a blood transfusion?	(dillncdd:PHXQ1.PHQ09) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PHXQ1.PHQ09F) If Yes, Month/Year of First Transfusion [1] <input type="radio"/> Req/Unk <input type="text" value=""/> / <input type="text" value=""/> (1980-2020) (dillncdd:PHXQ1.PHQ09FDT) [99] <input type="radio"/> Unknown (dillncdd:PHXQ1.PHQ09R) Month/Year of Most Recent Transfusion

		<p>[1] <input type="radio"/> Req/Unk <input type="text" value=""/> / Req/Unk <input type="text" value=""/> (1980-2020) (dillncdd:PHXQ1.PHQ9RDT) [99] <input type="radio"/> Unknown</p>
9.	Q10 - Have you ever used injection drugs, such as heroin, cocaine or crack?	<p>(dillncdd:PHXQ1.PHQ10) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PHXQ1.PHQ10F) If Yes, Month/Year of First use of Injection drugs [1] <input type="radio"/> Req/Unk <input type="text" value=""/> / Req/Unk <input type="text" value=""/> (1980-2020) (dillncdd:PHXQ1.PHQ10FDT) [99] <input type="radio"/> Unknown (dillncdd:PHXQ1.PHQ10R) Month/Year of Most Recent Use of Injection Drugs [1] <input type="radio"/> Req/Unk <input type="text" value=""/> / Req/Unk <input type="text" value=""/> (1980-2020) (dillncdd:PHXQ1.PHQ10RDT) [99] <input type="radio"/> Unknown</p>
10.	Q11 - Have you ever snorted or sniffed cocaine or crack?	<p>(dillncdd:PHXQ1.PHQ11) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PHXQ1.PHQ11F) If Yes, Month/Year of First Exposure [1] <input type="radio"/> Req/Unk <input type="text" value=""/> / Req/Unk <input type="text" value=""/> (1980-2020) (dillncdd:PHXQ1.PHQ11FDT) [99] <input type="radio"/> Unknown (dillncdd:PHXQ1.PHQ11R) Month/Year of Most Recent Exposure [1] <input type="radio"/> Req/Unk <input type="text" value=""/> / Req/Unk <input type="text" value=""/> (1980-2020) (dillncdd:PHXQ1.PHQ11RDT) [99] <input type="radio"/> Unknown</p>
11.	Q12 - Are you a health care worker whose job involves direct face-to-face contact with patients?	<p>(dillncdd:PHXQ1.PHQ12) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</p>
<p>NOTE: If Q12 above is answered YES, please answer question 12A and 12B found on form PHXQ12</p>		
12.	Q13 - Have you ever had any direct occupational contact (meat packing factory, slaughterhouse, etc.) with animal body fluid such as blood, intestinal content?	<p>(dillncdd:PHXQ1.PHQ13) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes (dillncdd:PHXQ1.PHQ13F) Month/Year of First Exposure to Animal Body Fluids/secretions [1] <input type="radio"/> Req/Unk <input type="text" value=""/> / Req/Unk <input type="text" value=""/> (1980-2020) (dillncdd:PHXQ1.PHQ13FDT) [99] <input type="radio"/> Unknown (dillncdd:PHXQ1.PHQ13R) Month/Year of Most Recent Exposure to Animal Body Fluids/secretions [1] <input type="radio"/> Req/Unk <input type="text" value=""/> / Req/Unk <input type="text" value=""/> (1980-2020) (dillncdd:PHXQ1.PHQ13RDT) [99] <input type="radio"/> Unknown</p>
13.	Q14 - Have you ever been exposed to someone with hepatitis or someone who was jaundiced in the six months before you became sick with your liver problems?	<p>(dillncdd:PHXQ1.PHQ14) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PHXQ1.PHQPART) [1] <input type="checkbox"/> Spouse or Sexual Partner (dillncdd:PHXQ1.PHQEXP) [1] <input type="checkbox"/> Household exposure such as to siblings or children (dillncdd:PHXQ1.PHQWKP) [1] <input type="checkbox"/> Informal workplace or school exposure (dillncdd:PHXQ1.PHQOTHR) [1] <input type="checkbox"/> Other Specify <input type="text" value="A200"/> (dillncdd:PHXQ1.PHQOTSP)</p>

Column Name	Column Data Type	Design Note
PHQWKP	NUMERIC	
PHQ07SP	STRING(200) - A200	
PHQCAT	NUMERIC	
PHQ01PET	NUMERIC - N3	
PHQ10R	NUMERIC	
PHQ05	NUMERIC	
PHQ06S	NUMERIC	

PHQ04SP	STRING(200) - A200	
PHQ13FDT	DATE - MONYYYY	
PHQ13F	NUMERIC	
PHQ13R	NUMERIC	
PHQ04	NUMERIC	
PHQ9FDT	DATE - MONYYYY	
PHQ03	NUMERIC	
PHQ11	NUMERIC	
PHQ10	NUMERIC	
PHQ12	NUMERIC	
PHQEXP	NUMERIC	
PHQ14	NUMERIC	
PHQ9F	NUMERIC	
PHQ11R	NUMERIC	
PHQ10F	NUMERIC	
PHQ11RDT	DATE - MONYYYY	
PHQFER	NUMERIC	
PHQ13RDT	DATE - MONYYYY	
PHQ10FDT	DATE - MONYYYY	
PHQ11F	NUMERIC	
PHQDOG	NUMERIC	
PHQPART	NUMERIC	
PHQOTHR	NUMERIC	
PHQBIRD	NUMERIC	
PHQPIG	NUMERIC	
PHQ13	NUMERIC	
PHQ10RDT	DATE - MONYYYY	
PHQ09	NUMERIC	
PHQSPEC	STRING(200) - A200	
PHQOTSP	STRING(200) - A200	
PHQ06	NUMERIC	
PHQ11FDT	DATE - MONYYYY	
PHQ9RDT	DATE - MONYYYY	
PHQOTH	STRING(255)	
PHQ01	NUMERIC	
PHQ02	NUMERIC	
PHQ07	NUMERIC	
PHQ9R	NUMERIC	

dilin : Personal History Questionnaire (PHXQ2) - Repeating Form			
#		Q 2 - Type of Animal	Most Recent date of Contact
1	<input type="text"/>		

Personal History Questionnaire 2	
1. Q 2 - Type of Animal	Pulldown List 1 <input type="text"/> (dilinccd:PHXQ2.PHQ02A) If Farm Animals or Wild Animals other is checked, please specify animal (dilinccd:PHXQ2.PHQ02SP) <input type="text" value="A200"/>
2. Most Recent date of Contact	(dilinccd:PHXQ2.PHQ02UNK) [1] <input type="radio"/> Req/Unk <input type="text"/> / <input type="radio"/> Req/Unk <input type="text"/> (1980-2020) (dilinccd:PHXQ2.PHQ02ADT) [99] <input type="radio"/> Unknown

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieTYPANMA1	Alpacas	1	
ieTYPANMA2	Chicken/duck/geese/turkeys	2	
ieTYPANMA3	Cows	3	
ieTYPANMA4	Goats	4	
ieTYPANMA5	Horses	5	
ieTYPANMA6	Ostriches	6	
ieTYPANMA7	Pigs	7	
ieTYPANMA8	Sheep	8	
ieTYPANMA9	Farm Animals Other	9	
ieTYPANMA10	Bats	10	
ieTYPANMA11	Deer	11	
ieTYPANMA12	Iguanas	12	
ieTYPANMA14	Peacocks	14	
ieTYPANMA13	Monkeys	13	
ieTYPANMA15	Possums	15	
ieTYPANMA16	Raccoons	16	
ieTYPANMA17	Skunks	17	
ieTYPANMA18	Snakes	18	
ieTYPANMA19	Squirrels	19	
ieTYPANMA20	Wild geese/ducks/turkeys	20	
ieTYPANMA21	Wild Pigs/Wild Boars	21	
ieTYPANMA22	Wild Animals Other	22	

CDD: dilinccd Table: PHXQ2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PHQ02ADT	DATE - MONYYYY	
PHQ02A	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 13, 15, 16, 17, 18, 19, 20, 21, 22	
PHQ02SP	STRING(200) - A200	
PHQ02UNK	NUMERIC	

dilin : Personal History Questionnaire (PHXQ3) - Repeating Form					
#		Q3 - Area Visited	From date	To date	Type of Area
1					

Personal History Questionnaire 3

Tell us where you visited and the dates you spent in these places during the 6 months before you became sick.

1.	Q3 - Area Visited	(dillncdd:PHXQ3.PHQ03AVS) [1] <input type="radio"/> US City <input type="text" value="A25"/> (dillncdd:PHXQ3.PHQ3CTY) State <input type="text" value="A50"/> (dillncdd:PHXQ3.PHQ3ST) [2] <input type="radio"/> Country (outside of US) Country Visited <input type="text" value="A50"/> (dillncdd:PHXQ3.PHQ3CTRY)
2.	From date	(dillncdd:PHXQ3.PHQ3F) [1] <input type="radio"/> Req/Unk <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> (1980-2020) (dillncdd:PHXQ3.PHQ3FRDT) [99] <input type="radio"/> Unknown
3.	To date	(dillncdd:PHXQ3.PHQ3T) [1] <input type="radio"/> Req/Unk <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> (1980-2020) (dillncdd:PHXQ3.PHQ3TODT) [99] <input type="radio"/> Unknown
4.	Type of Area	(dillncdd:PHXQ3.PHQ3TAR) [1] <input type="radio"/> Rural [2] <input type="radio"/> Urban

Column Name	Column Data Type	Design Note
PHQ3TAR	NUMERIC	
PHQ3TODT	DATE - DDMYYYY	
PHQ03AVS	NUMERIC	
PHQ3F	NUMERIC	
PHQ3CTRY	STRING(50) - A50	
PHQ3CTY	STRING(25) - A25	
PHQ3T	NUMERIC	
PHQ3ST	STRING(50) - A50	
PHQ3FRDT	DATE - DDMYYYY	

dilin : Personal History Questionnaire (PHXQ8)		
Personal History Questionnaire 8		
Q8 - In the 6 months before you became sick with your liver injury, did you eat any of the following foods?		
1.	a - Raw Eggs	(dilincdd:PHXQ8.PHO8A) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
2.	b - Raw or undercooked Shellfish	(dilincdd:PHXQ8.PHO8B) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown If Yes: Specify type of shellfish (dilincdd:PHXQ8.PHO8BSP) A200
3.	c - Crabs	(dilincdd:PHXQ8.PHO8C) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
4.	d - Lobsters	(dilincdd:PHXQ8.PHO8D) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
5.	e - Other Crustaceans	(dilincdd:PHXQ8.PHO8E) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
6.	f - Unpasteurized Milk Products	(dilincdd:PHXQ8.PHO8F) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
7.	g - Innards or offal	(dilincdd:PHXQ8.PHO8G) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
8.	h - Chicken, raw or rare	(dilincdd:PHXQ8.PHO8H) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
9.	i - Pork, raw or rare	(dilincdd:PHXQ8.PHO8I) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
10.	j - Beef, raw or rare	(dilincdd:PHXQ8.PHO8J) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
11.	k - Lamb, raw or rare	(dilincdd:PHXQ8.PHO8K) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
12.	l - Goat meat, raw or rare	(dilincdd:PHXQ8.PHO8L) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
13.	m - Wild Boar	(dilincdd:PHXQ8.PHO8M) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
14.	n - Other wild meat	(dilincdd:PHXQ8.PHO8N) No

		<input type="radio"/> [0] <input type="radio"/> [1] Yes <input type="radio"/> [99] Unknown
15.	o - Pig Liver	(dillncdd:PHXQ8.PHQ8O) <input type="radio"/> [0] No <input type="radio"/> [1] Yes <input type="radio"/> [99] Unknown
16.	p - Beef Liver	(dillncdd:PHXQ8.PHQ8P) <input type="radio"/> [0] No <input type="radio"/> [1] Yes <input type="radio"/> [99] Unknown
17.	q - Other	(dillncdd:PHXQ8.PHQ8Q) <input type="radio"/> [0] No <input type="radio"/> [1] Yes <input type="radio"/> [99] Unknown If Yes: Other Specify (dillncdd:PHXQ8.PHQ8QSP) <input type="text" value="A200"/>

CDD: dillncdd Table: PHXQ8 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PHQ8C	NUMERIC	
PHQ8E	NUMERIC	
PHQ8A	NUMERIC	
PHQ8J	NUMERIC	
PHQ8D	NUMERIC	
PHQ8G	NUMERIC	
PHQ8L	NUMERIC	
PHQ8N	NUMERIC	
PHQ8QSP	STRING(200) - A200	
PHQ8Q	NUMERIC	
PHQ8I	NUMERIC	
PHQ8H	NUMERIC	
PHQ8B	NUMERIC	
PHQ8F	NUMERIC	
PHQ8BSP	STRING(200) - A200	
PHQ8O	NUMERIC	
PHQ8P	NUMERIC	
PHQ8K	NUMERIC	
PHQ8M	NUMERIC	

dilin : Personal History Questionnaire (PHXQ12)	
Personal History Questionnaire 12	
<p>1. Q12A - Have you ever had any direct contact with patient body fluids/secretions such as blood, urine, feces, etc?</p>	<p>(dillncdd:PHXQ12.PHQ12A) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PHXQ12.PHQ12F) If Yes, Month/Year of First Exposure to Patient Body Fluids/secretions [1] <input type="radio"/> Req/Unk <input type="button" value="v"/> / <input type="button" value="v"/> (1980-2020) (dillncdd:PHXQ12.PHQ12FDT) [99] <input type="radio"/> Unknown (dillncdd:PHXQ12.PHQ12R) Month/Year of Most Recent Exposure to Patient Body Fluids/secretions [1] <input type="radio"/> Req/Unk <input type="button" value="v"/> / <input type="button" value="v"/> (1980-2020) (dillncdd:PHXQ12.PHQ12RDT) [99] <input type="radio"/> Unknown</p>
<p>2. Q12B - Have you ever had any history of needle stick exposure or injury at work with potential direct contact with patient body fluids/secretions such as blood, urine, feces, etc.</p>	<p>(dillncdd:PHXQ12.PHQ12B) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd:PHXQ12.PHQ12BF) If Yes, Month/Year of First Needle Stick/Injury Exposure [1] <input type="radio"/> Req/Unk <input type="button" value="v"/> / <input type="button" value="v"/> (1980-2020) (dillncdd:PHXQ12.PHQ12BDT) [99] <input type="radio"/> Unknown (dillncdd:PHXQ12.PHQ12MR) Month/Year of Most Recent Needle Stick/Injury Exposure [1] <input type="radio"/> Req/Unk <input type="button" value="v"/> / <input type="button" value="v"/> (1980-2020) (dillncdd:PHXQ12.PHQ12DT) [99] <input type="radio"/> Unknown</p>

CDD: dillncdd Table: PHXQ12 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PHQ12A	NUMERIC	
PHQ12R	NUMERIC	
PHQ12BF	NUMERIC	
PHQ12DT	DATE - MONYYYY	
PHQ12BDT	DATE - MONYYYY	
PHQ12MR	NUMERIC	
PHQ12B	NUMERIC	
PHQ12F	NUMERIC	
PHQ12RDT	DATE - MONYYYY	
PHQ12FDT	DATE - MONYYYY	

CRB Electronic Signature Affidavit

By my dated signature below, I, [**First Name**] [**Last Name**], verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this patient.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked **Submit** below.

CRF Electronic Signature Affidavit

By my dated signature below, I, [**First Name**] [**Last Name**], verify that this case report form accurately displays the results of the examinations, tests, evaluations and treatments noted within.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

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