

**DILIN**  
**Annotated Design For Trial: dilindv2**

**Protocol: DILIN PRO**

**Generated By InForm Architect™**

**July 27, 2017 12:27PM**

## Time and Events Schedule For Study: dilindv2

	Assessment	CRF	Screening Visit (PREISV) [ 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 ]	MONTH 36 (M36) [ S/D ]	MONTH 48 (M48) [ S/D ]
1	VISIT STATUS	VISSTAT	1	1	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 2	MEDHX2	5										
6	PAST MEDICAL HISTORY	MEDHX1	6-RF-DF		3-RF-DF			3-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			4-RF-DF	4-RF-DF
8	PAST SURGICAL HISTORY	SURGHX	8-RF-DF		5-RF-DF			5-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			6-RF-DF	6-RF-DF
10	GENERAL MEDICATION COMPLIANCE	RXCOMPLY	10-DF										
11	DRUG SPECIFIC MEDICATION COMPLIANCE	DRUGCOMP	11-RF										
12	QUESTIONNAIRES	QUESTS	12										
13	SOURCE OF RX MEDICATIONS	PHARMACY	13-DF										
14	SOURCE OF RX MEDICATIONS	PHARM1	14-DF										
15	GENERAL SMOKING HISTORY	GENSMOKE	15-DF										
16	SMOKING HISTORY	SMOKEHX	16-RF-DF		33-RF-DF			32-RF-DF	32-RF-DF				
17	SKINNER ALCOHOL CONSUMPTION	SKINNER	17-RF-DF		34-RF-DF			33-RF-DF	33-RF-DF			30-RF-DF	30-RF-DF
18	SYMPTOMS	SAQSYMPT	18-DF		30-DF			29-DF	29-DF				
19	RAND 36 HEALTH SURVEY	RANDHS1	19-DF		35-DF			34-DF	34-DF				
20	RAND 36 HEALTH SURVEY 2	RANDHS2	20-DF		36-DF			35-DF	35-DF				
21	RAND 36 HEALTH SURVEY 3	RANDHS3	21-DF		37-DF			36-DF	36-DF				
22	PEDIATRIC QUALITY OF LIFE INVENTORY	PEDSQL1	22-DF		38-DF			37-DF	37-DF				
23	PEDIATRIC QUALITY OF LIFE INVENTORY 2	PEDSQL2	23-DF		39-DF			38-DF	38-DF				
24	PEDIATRIC QUALITY OF LIFE INVENTORY 3	PEDSQL3	24-DF		40-DF			39-DF	39-DF				
25	PEDIATRIC QUALITY OF LIFE INVENTORY 4	PEDSQL4	25-DF		41-DF			40-DF	40-DF				
26	PEDIATRIC QUALITY OF LIFE INVENTORY 5	PEDSQL5	26-DF		42-DF			41-DF	41-DF				
27	PEDIATRIC QUALITY OF LIFE INVENTORY 6	PEDSQL6	27-DF		43-DF			42-DF	42-DF				
28	PEDIATRIC QUALITY OF LIFE INVENTORY 7	PEDSQL7	28-DF		44-DF			43-DF	43-DF				
29	PEDIATRIC QUALITY OF LIFE INVENTORY 8	PEDSQL8	29-DF		45-DF			44-DF	44-DF				
30	HISTORY OF INJURY	HXINJ1	30-RF										
31	HISTORY OF INJURY 2	HXINJ2	31										
32	HISTORY OF INJURY 3	HXINJ3	32-RF-DF										
33	SIGNS AND SYMPTOMS	SIGN	33-RF-DF										
34	SYMPTOMS AND SIGNS	SYMPSIGN	34-RF-DF										
35	IMPLICATED DILI MEDICATION	DILIMED	35-RF-DF		47-RF-DF			45-RF-DF	45-RF-DF			31-RF-DF	31-RF-DF
36	IMPLICATED CAM PRODUCT/HDS	CAMMED1	36-RF-DF										
37	LIVER TEST FLOW CHART	LABFLOW	37-RF		11-RF-DF			11-RF-DF	11-RF-DF			11-RF-DF	11-RF-DF
38	STANDARD LABS (w/in 4wks prior to ONSET)	STDLABHX	38										
39	STANDARD LAB FLOW CHART	STDFLOW	39-RF										
40	IMAGING STUDIES	IMAGE	40-RF-DF		13-RF-DF			13-RF-DF	13-RF-DF			13-RF-DF	13-RF-DF
41	HEPATITIS STATUS	HEPSTAT	41										
42	HBeAG FLOW CHART	HBeAG	42-RF-DF		16-RF-DF								
43	Anti-HBe FLOW CHART	ANTIHB	43-RF-DF		17-RF-DF								
44	Anti-HDV (total) FLOW CHART	ANTIHDV	44-RF-DF										
45	HBV DNA FLOW CHART	HBVDNA	45-RF-DF		18-RF-DF								
46	HCV RNA FLOW CHART	HCVRNA	46-RF-DF		19-RF-DF								
47	HIV STATUS	HIVSTAT	47										
48	HIV STATUS	HIVSTAT1	48-DF										
49	HIV STATUS 2	HIVSTAT2	49-RF-DF		22-RF-DF			20-RF-DF	20-RF-DF			20-RF-DF	20-RF-DF
50	CD4 FLOW CHART	CD4	50-RF-DF		23-RF-DF			21-RF-DF	21-RF-DF			21-RF-DF	21-RF-DF
51	HIV RNA FLOW CHART	HIVRNA	51-RF-DF		24-RF-DF			22-RF-DF	22-RF-DF			22-RF-DF	22-RF-DF
52	PHYSICAL EXAM	PEX1		2	25			24	24			24	24
53	PHYSICAL EXAM 2	PEX2		3	26			25	25			25	25
54	DIAGNOSTIC LABS 1	DXLAB1		4									
55	DIAGNOSTIC LABS 2	DXLAB2		5									
56	DIAGNOSTIC LABS 3	DXLAB3		6									
57	STANDARD LABS	STDLAB		7	27			26	26			26	26
58	STANDARD LABS	STDLAB2		8	28			27	27			27	27
59	URINALYSIS	URINE		9-DF									
60	RESEARCH SAMPLES	RSAMPLE		10	29			28	28			28	28
61	INTERVAL HISTORY/QUESTIONNAIRES	INTHX			2			2	2			2	2
62	ER/HOSPITAL/MED APPT HISTORY	MEDHX3			7			7	7			7	7
63	EMERGENCY ROOM VISIT	ERRMHX			8-RF-DF			8-RF-DF	8-RF-DF			8-RF-DF	8-RF-DF
64	HOSPITALIZATION VISIT	HOSPHX			9-RF-DF			9-RF-DF	9-RF-DF			9-RF-DF	9-RF-DF
65	MEDICAL APPOINTMENT HISTORY	APPTHIST			10-RF-DF			10-RF-DF	10-RF-DF			10-RF-DF	10-RF-DF
66	IMAGING STUDIES	ABDIMAGE			12			12	12			12	12
67	MAJOR MEDICAL OUTCOMES	MEDOUT			14			23	23			23	23
68	INTERVAL HEPATITIS STATUS	HEPSTATC			15								
69	INTERVAL HIV STATUS	HIVSTATC			20			18	18			18	18

70	INTERVAL HIV STATUS	HIVSTAT3			21-DF			19-DF	19-DF			19-DF	19-DF
71	INTERVAL QUESTIONNAIRES	QUESTS2			31			30	30			29	29
72	INTERVAL GENERAL SMOKING HISTORY	GENSMOK6			32-DF			31-DF	31-DF				
73	CHRONIC INCLUSION/EXCLUSION	CHRONIC			46								
74	CONCOMITANT HISTORY	CONHX				1							
75	CONCOMITANT MEDICATIONS	CONMED				2-RF-DF							
76	CONCOMITANT CAM PRODUCTS	CONCAM				3-RF-DF							
77	HEPATITIS MEDICATIONS LOG	HEPLOG				4-RF-DF							
78	HIV MEDICATION LOG	HIVLOG				5-RF-DF							
79	BIOPSY COLLECTION	COLLECT				6-RF-DF							
80	ADVERSE EVENTS	AE				7							
81	ADVERSE EVENTS	AE1				8-RF-DF							
82	SERIOUS ADVERSE EVENTS	SAE				9-RF-DF							
83	RUCDR DNA	RUCDR				10-RF-DF							
84	Fisher Repository Blooddraw	NIDDKSER				11-RF-DF							
85	FISHER REPOSITORY	NIDDKBPY				12-RF-DF							
86	Serology Flowchart	SEROFLOW				13-RF-DF							
87	Protocol Exemption	PTLEXMPT				14							
88	NARRATIVES	NARR				15							
89	BIOPSY COLLECTION Part 1	BIOPSY1				16-RF-DF							
90	BIOPSY COLLECTION Part 2	BIOPSY2				17-RF-DF							
91	ACUTE DILI CASE	ACUTE				18-DF							
92	Acute LIVER TEST FLOWCHART	ACLABFLW				19-RF-DF							
93	ACUTE RESEARCH SAMPLES	ACSAMP				20-RF-DF							
94	Liver Elastography and Hepatic Steatosis Estimation	FIBRO				21-RF-DF							
95	EARLY WITHDRAWAL and STUDY COMPLETION	PTCOMPL					1						
96	INVESTIGATOR SIGNATURE	SIGNATUR					2						
97	Annual CONCOMITANT HISTORY	ACONHX						14	14			14	14
98	Annual CONCOMITANT MEDICATIONS	ACONMED						15-RF-DF	15-RF-DF			15-RF-DF	15-RF-DF
99	Annual CONCOMITANT CAM PRODUCTS	ACONCAM						16-RF-DF	16-RF-DF			16-RF-DF	16-RF-DF
100	INTERVAL HEPATITIS STATUS 2	HEPSTAT2						17	17			17	17
101	Personal History Questionnaire	APHXQ									1-DF		
102	Personal History Questionnaire	PHXQ1									2-DF		
103	Personal History Questionnaire	PHXQ2									3-RF-DF		
104	Personal History Questionnaire	PHXQ3									4-RF-DF		
105	Personal History Questionnaire	PHXQ8									5-DF		
106	Personal History Questionnaire	PHXQ12									6-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

dilindv2 : Screening (SCR)	
Screening	
1. Birthdate	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (1910-2020) (dillncdd: SCR.SCRDOBDT)
2. Sex	(dillncdd: SCR.SCRSEX) [1] <input type="radio"/> Male [2] <input type="radio"/> Female
3.* PI [read-only]	A3 (dillncdd: SCR.INVSITE)
4. Patient Number	A4 (dillncdd: SCR.PATID)
Inclusion Criteria	
5. Was the patient more than 2 years of age at the time of enrollment?	(dillncdd: 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?	(dillncdd: SCR.INEXC2) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
7. Was the patient/legal guardian willing to sign informed consent?	(dillncdd: 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?	(dillncdd: SCR.INEXC4) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd: 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 (dillncdd: 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 (dillncdd: 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?	(dillncdd: SCR.INEXC5) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd: 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 (dillncdd: 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 (dillncdd: 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?	(dillncdd: SCR.INEX6A) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd: SCR.INEX6A6) If Yes Specify ALT above the ULN [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd: SCR.INEX6A6B) If Yes Specify AST above the ULN [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd: SCR.INEX6A6C) 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
<b>Eligibility</b>		
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) [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) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
18.	Eligibility	(dillncdd: SCR.ELIGIBLE) [1] <input type="radio"/> Satisfied all criteria [2] <input type="radio"/> Did not satisfy all criteria (dillncdd: SCR.PEAPPRV) Protocol Exemption Approved [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, date of approval Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1935-2020) (dillncdd: SCR.PEAP PDT)
* 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
SCRDOB DT	DATE - DDMONYYYY	
INEX6A	NUMERIC	
INEXC5	NUMERIC	
INEXC9	NUMERIC	
INEXC10	NUMERIC	
INEXC5B	NUMERIC	
ELIGIBLE	NUMERIC	
PATID	STRING(4) - A4	
INEXC3	NUMERIC	
PEAP PDT	DATE - DDMONYYYY	
INEXC4C	NUMERIC	
INEXC1	NUMERIC	
INEXC5A	NUMERIC	
INEXC2	NUMERIC	
PEAP PRV	NUMERIC	
INEXA6C	NUMERIC	
INEXB6C	NUMERIC	
INEXC4	NUMERIC	
INEXC8	NUMERIC	
INEXB6B	NUMERIC	
INEXC4B	NUMERIC	
INEX6B	NUMERIC	
INEXC11	NUMERIC	
INEXA6B	NUMERIC	
INEXC7	NUMERIC	
INEXC5C	NUMERIC	
INEXC12	NUMERIC	
INEXC4A	NUMERIC	
INEXB6A	NUMERIC	
INVSITE	STRING(3) - A3	
SCRSEX	NUMERIC	
INEXA6A	NUMERIC	

dilindv2 : Enrollment (ENR)		
•		
1.	Patient Number	A15 (dilncdd: ENR.SUBJNO)
2.	Date of Informed Consent	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dilncdd: ENR.SCRNDT)

CDD: dilncdd	Table: ENR	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
SUBJNO	STRING(15) - A15	
SCRNDT	DATE - DDMYYYYY	

**dilindv2 : VISIT STATUS (VISSTAT)**

VISIT	
1. Date of completed visit or last lab/MD visit	Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (2004-2020) (dillncdd:VISSTAT.SAQDT)
2. Did the patient complete the visit?	(dillncdd:VISSTAT.COMPVST) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If patient withdraws early, died or completes all the expected visits, or is unable to complete last visit, then please complete the Termination Visit
3. * If patient did not complete the visit, indicate any additional details	(dillncdd:VISSTAT.SPCMPVST) [1] <input type="radio"/> Check all that apply (dillncdd:VISSTAT.OUTSIDE) [1] <input type="checkbox"/> Visit date was outside the window (dillncdd:VISSTAT.NOBLDURN) [1] <input type="checkbox"/> Research specimens were not collected (dillncdd:VISSTAT.NOVISIT) [1] <input type="checkbox"/> Patient did not attend clinic visit [96] <input type="radio"/> Not Applicable
4. * If patient did not complete the visit, indicate reason(s) that apply to the details above	(dillncdd:VISSTAT.SPFRSN) [1] <input type="radio"/> Check all that apply (dillncdd:VISSTAT.PTTERM) [1] <input type="checkbox"/> Patient terminated (dillncdd:VISSTAT.TRAVEL) [1] <input type="checkbox"/> Travel (dillncdd:VISSTAT.WRKISSUE) [1] <input type="checkbox"/> Work Issues (dillncdd:VISSTAT.NODRAW) [1] <input type="checkbox"/> Unable to draw blood (dillncdd:VISSTAT.PTREFUSE) [1] <input type="checkbox"/> Patient refused (dillncdd:VISSTAT.NOOTHRR) [1] <input type="checkbox"/> Other Other Specify <input type="text" value="A50"/> (dillncdd:VISSTAT.NOOTHRRSP) [96] <input type="radio"/> Not applicable
5. * Patient enrolled in:	(dillncdd:VISSTAT.DILSTAT) [1] <input type="radio"/> Prospective [2] <input type="radio"/> Acute
6. * Patient enrolled in Retrospective Study: If Yes is checked, do NOT start any Month 6 CRF pages.	(dillncdd:VISSTAT.RETSTAT) [1] <input type="radio"/> Yes [96] <input type="radio"/> NA
7. * REFIRE [hidden]	(dillncdd:VISSTAT.REFIRE) [1] <input type="radio"/> Yes
8. * If this is a Prospective or Acute patient, the FIBROSCAN CRF in the CAS visit must be completed. Please check Yes.	(dillncdd:VISSTAT.FIBROFIR) [1] <input type="radio"/> Yes
* Item is not required	

CDD: dillncdd Table: VISSTAT Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
RETSTAT	NUMERIC	
COMPVST	NUMERIC	
OUTSIDE	NUMERIC	
NOVISIT	NUMERIC	
PTTERM	NUMERIC	
WRKISSUE	NUMERIC	
NODRAW	NUMERIC	
NOOTHRR	NUMERIC	
SAQDT	DATE - DDMYYYYY	
NOOTHRRSP	STRING(50) - A50	
PTREFUSE	NUMERIC	
TRAVEL	NUMERIC	
SPFRSN	NUMERIC	
NOBLDURN	NUMERIC	
SPCMPVST	NUMERIC	
DILSTAT	NUMERIC	
REFIRE	NUMERIC	
FIBROFIR	NUMERIC	

## dilindv2 : 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	(dillncdd: DEMOG.SUBJNO)
2.	Birthdate	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1910-2020)	(dillncdd: DEMOG.DOBTD)
3.	Sex	(dillncdd: DEMOG.SEX) [1] <input type="radio"/> Male [2] <input type="radio"/> Female	

## Demographics

4.	Do you consider yourself Hispanic, Latino, or Latina?	(dillncdd: DEMOG.LATINO) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dillncdd: 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   (dillncdd: DEMOG.ORGINSP)	
5.	What is your race? (Check all that apply)	(dillncdd: DEMOG.WHITE) [1] <input type="checkbox"/> White (dillncdd: DEMOG.BLACK) [1] <input type="checkbox"/> Black or African American (dillncdd: DEMOG.ASIAN) [1] <input type="checkbox"/> Asian (dillncdd: DEMOG.INDIAN) [1] <input type="checkbox"/> American Indian or Alaska Native (dillncdd: DEMOG.NATIVE) [1] <input type="checkbox"/> Native Hawaiian or Other Pacific Islander (dillncdd: DEMOG.RACEOTHR) [1] <input type="checkbox"/> Other Race Other Race (specify)   A50   (dillncdd: DEMOG.RACESP)	
6.	In what country were you born	(dillncdd: DEMOG.BIRTHCTY) [1] <input type="radio"/> Continental U.S., Alaska, or Hawaii [98] <input type="radio"/> Other Specify Other Country   A50   (dillncdd: DEMOG.BRCTRYSP)	
7.	Geographic area of residence State	Pulldown List 1 <input type="text"/> (dillncdd: DEMOG.GEOSTATE) Specify other residence   A50   (dillncdd: DEMOG.GEOSTSP)	
8.*	Geographic area of residence County [hidden]	A50   (dillncdd: DEMOG.GEOCTY)	
9.	Geographic area of residence Zip Code	A10   (dillncdd: DEMOG.GEOZIP)	
10.	Education (highest level completed)	Pulldown List 2 <input type="text"/> (dillncdd: DEMOG.EDUCATE)	
11.	Marital status	(dillncdd: 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	(dillncdd: 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	
13.	Study Consent Date (Date consent form signed)	Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req/Unk <input type="text"/> (2004-2020) (dillncdd: DEMOG.CONSTDT)	
	Agecalc	xxxxxxx   (dillncdd: DEMOG.AGECALC)	
14.*	Data Entry Reviewed (MIGRATION TEAM USE ONLY)	(dillncdd: DEMOG.DEMIGRAT) [1] <input type="radio"/> Yes	
15.*	Queries Reviewed (MIGRATION TEAM USE ONLY)	(dillncdd: DEMOG.DMMIGRAT) [1] <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
MARITAL	NUMERIC	
RACEOTHR	NUMERIC	
LATINORG	NUMERIC	
EDUCATE	NUMERIC - 1, 2, 3, 4, 5, 6, 7	
LATINO	NUMERIC	
NATIVE	NUMERIC	
ORGINSP	STRING(50) - A50	
RACESP	STRING(50) - A50	
GEOCTY	STRING(50) - A50	
WHITE	NUMERIC	
SUBJNO	STRING(15) - A15	
ASIAN	NUMERIC	
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	
AGECALC	FLOAT - F9.0	

INDIAN	NUMERIC	
BLACK	NUMERIC	
DEMIGRAT	NUMERIC	
GEOZIP	STRING(10) - A10	
DMMIGRAT	NUMERIC	
SEX	NUMERIC	
GEOSTSP	STRING(50) - A50	
BIRTHCTY	NUMERIC	
DOBDT	DATE - DDMONYYYY	
INSURANC	NUMERIC	
BRCTRYSP	STRING(50) - A50	
CONSTDT	DATE - DDMONYYYY	

**dilindv2 : 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 <b>[1]</b> <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 <b>[1]</b> <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 <b>[1]</b> <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) <b>[1]</b> <input type="radio"/> xxx (dilincdd: FAMHX1.BRO) [0] <input type="radio"/> None
5.	How many biological sisters do you have?	(dilincdd: FAMHX1.SISNONE) <b>[1]</b> <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) <b>[1]</b> <input type="radio"/> xxx (dilincdd: FAMHX1.SIBALIVE) [0] <input type="radio"/> None
7.	How many biological male children do you have?	(dilincdd: FAMHX1.MCNONE) <b>[1]</b> <input type="radio"/> xxx (dilincdd: FAMHX1.MCHILD) [0] <input type="radio"/> None
8.	How many biological female children do you have?	(dilincdd: FAMHX1.FCNONE) <b>[1]</b> <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) <b>[1]</b> <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

**CDD: dilincdd Table: FAMHX1 Key Type: PATIENTVISIT**

Column Name	Column Data Type	Design Note
MCHILD	NUMERIC - N3	
BRONONE	NUMERIC	
CHILDNA	NUMERIC	
FCHILD	NUMERIC - N3	
TWIN	NUMERIC	
DADPLTH	NUMERIC	
MCNONE	NUMERIC	
BRO	NUMERIC - N3	
DAD	NUMERIC	
SISNONE	NUMERIC	
TWINIDNT	NUMERIC	
MOM	NUMERIC	
FCNONE	NUMERIC	
MOMPLTH	NUMERIC	
SIBNA	NUMERIC	
CHALIVE	NUMERIC - N3	
FALLERGY	NUMERIC	
SIBALIVE	NUMERIC - N3	
SIS	NUMERIC - N3	

dilindv2 : FAMILY HISTORY 2 (FAMHX2) - Repeating Form

#		Biological relative	Drug name	Type of Reaction
1	<div><div></div><div></div></div>			

Family History continued

1. Biological relative	<div>(dilincdd:FAMHX2.RELALLGY) [1] <input type="radio"/> Father [2] <input type="radio"/> Mother [3] <input type="radio"/> Sibling [4] <input type="radio"/> Children</div>
2. Drug name	<div>A80<div>(dilincdd:FAMHX2.FDRGNM)</div></div>
3. Type of Reaction	<div>(dilincdd:FAMHX2.DRGRACT) [1] <input type="radio"/> Allergic [2] <input type="radio"/> Liver Problem [99] <input type="radio"/> Unknown</div>

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

**dilindv2 : PAST MEDICAL HISTORY 2 (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 If yes, please enter MEDHX1 form
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 If yes, please enter LIVHX form
3.	Does the subject have a history of allergies to medications?	(dilincdd: MEDHX2.ALLERGY) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please enter ALLRGYHX form
4.	Does the subject have a history of surgeries within the past 5 years?	(dilincdd: MEDHX2.SURGERY) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please enter SURGHX form
5.	Were any imaging studies performed?	(dilincdd: MEDHX2.IMAGEYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please enter IMAGE form
6. *	Was the Personal Health Questionnaire completed?	(dilincdd: MEDHX2.PHQYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please enter APHXQ form under the AUX visit (dilincdd: MEDHX2.PHQCOMP) PHQ completed by [1] <input type="radio"/> Subject [98] <input type="radio"/> Other
7. *	Does the subject have any signs or symptoms of their liver injury?	(dilincdd: MEDHX2.SYMSGNYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please enter the SYMPSIGN form

\* Item is not required

CDD: dilincdd Table: MEDHX2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SYMSGNYN	NUMERIC	
MEDHXYN	NUMERIC	
PHQCOMP	NUMERIC	
PHQYN	NUMERIC	
ALLERGY	NUMERIC	
LIVHXYN	NUMERIC	
IMAGEYN	NUMERIC	
SURGERY	NUMERIC	

dilindv2 : PAST MEDICAL HISTORY (MEDHX1) - Repeating Form

#		Name of System/Disease	Specify condition	Date of Diagnosis	Active condition	
1	<div><div></div></div>					

Past Medical History

1.	Name of System/Disease	Pulldown List 1 <div></div> (dilincdd:MEDHX1.PASTHX)
2.*	Specify condition	<div>A100</div> (dilincdd:MEDHX1.CONDITN)
3.	Date of Diagnosis	Req/Unk <div></div> / Req/Unk <div></div> (1935-2020) (dilincdd:MEDHX1.PASTHXDT)
4.	Active condition	(dilincdd:MEDHX1.ACTIVE) <div>[0]</div> <div>No</div> <div>[1]</div> <div>Yes</div>

\* 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
ACTIVE	NUMERIC	
PASTHX	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 98	
PASTHXT	DATE - MONYYYY	
CONDITN	STRING(100) - A100	

dilindv2 : PAST ALLERGY HISTORY (ALLRGYHX) - Repeating Form				
#		Agent	Reaction	
1	<div><div></div><div></div><div></div></div>			
Past Allergy History				
1.	Agent	<div>A80</div> <div>(dilincdd: ALLRGYHX.AGENT)</div>		
2.	Reaction	<div>A200</div> <div>(dilincdd: ALLRGYHX.ALLGREAC)</div>		

CDD: dilincdd	Table: ALLRGYHX	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
ALLGREAC	STRING(200) - A200	
AGENT	STRING(80) - A80	

dilindv2 : PAST SURGICAL HISTORY (SURGHX) - Repeating Form

#		Specify surgery	Date of surgery
1	<div><div></div><div></div></div>		

Past Surgical History within past 5 years

1. Specify surgery	A200	(dilincdd: SURGHX.SXTYPE)	
2. Date of surgery	Req/Unk <div></div> / Req/Unk <div></div> / Req/Unk <div></div> (1935-2020)	(dilincdd: SURGHX.SXDT)	

CDD: dilincdd   Table: SURGHX   Key Type: PATIENTVISIT

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



dilindv2 : PAST MEDICAL HISTORY-LIVER SPECIFIC (LIVHX) - Repeating Form

#	Type of Liver Disease	Date of Diagnosis	Active condition
1	<div></div>		

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(dilincdd: LIVHX.MEDLIVHX)  
If Other is checked, please specify condition (dilincdd: LIVHX.LCONDITN)  
A200

2. Date of Diagnosis

Req/Unk / Req/Unk (1935-2020) (dilincdd: LIVHX.LIVHXDT)

3. Active condition

(dilincdd: LIVHX.LACTIVE)  
[0] ☐ No  
[1] ☐ 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	
ieLIVFaM	Family History DO NOT USE	17	
ieOTHER	Other	98	

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, 98	
LIVHXDT	DATE - MONYYYY	
LACTIVE	NUMERIC	
LCONDITN	STRING(200) - A200	

dilindv2 : GENERAL MEDICATION COMPLIANCE (RXCOMPLY)

General Medication Compliance

1.* Surrogate respondent? <i>[hidden]</i>	(dilincdd:RXCOMPLY.SURRO1) [0] <input type="radio"/> No [1] <input checked="" 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? <i>[hidden]</i>	(dilincdd:RXCOMPLY.FOLLOW) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input checked="" 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? <i>[hidden]</i>	(dilincdd:RXCOMPLY.FREQMORE) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input checked="" 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? <i>[hidden]</i>	(dilincdd:RXCOMPLY.FREQLESS) [0] <input type="radio"/> Never [1] <input type="radio"/> Some of the time [2] <input checked="" type="radio"/> Most of the time [3] <input type="radio"/> Always

\* Item is not required

CDD: dilincdd Table: RXCOMPLY Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
FOLLOW	NUMERIC	
FREQLESS	NUMERIC	
SURRO1	NUMERIC	
FREQMORE	NUMERIC	
SURSPEC1	NUMERIC	

dilindv2 : DRUG SPECIFIC MEDICATION COMPLIANCE (DRUGCOMP) - Repeating Form

#		Surrogate respondent	Medication name	Follow medication schedule	More frequently than RX	Less frequently than RX	
1	<div><div></div></div>						

Drug Specific Medication Compliance

1. Surrogate respondent?

(dilincdd: DRUGCOMP.SURRO2)  
[0] ☐ No  
[1] ☐ Yes  
(dilincdd: DRUGCOMP.SURSPEC2)  
Specify Surrogate  
[1] ☐ Relative  
[98] ☐ Other

2. Now, I'd like you to think about your medication schedule with

A80 (dilincdd: DRUGCOMP.RXNAME)

3. How closely did you follow your medication schedule?

(dilincdd: DRUGCOMP.RXFOLLOW)  
[0] ☐ Never  
[1] ☐ Some of the time  
[2] ☐ Most of the time  
[3] ☐ Always

4. Did you ever take this medication more frequently than was prescribed?

(dilincdd: DRUGCOMP.RXMORE)  
[0] ☐ Never  
[1] ☐ Some of the time  
[2] ☐ Most of the time  
[3] ☐ Always

5. Did you ever take this medication less frequently than was prescribed?

(dilincdd: DRUGCOMP.RXLESS)  
[0] ☐ Never  
[1] ☐ Some of the time  
[2] ☐ Most of the time  
[3] ☐ 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? [hidden]

(dilincdd: DRUGCOMP.RXMORTHN)  
[0] ☐ Never  
[1] ☐ Some of the time  
[2] ☐ Most of the time  
[3] ☐ 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? [hidden]

(dilincdd: DRUGCOMP.RXLESTHN)  
[0] ☐ Never  
[1] ☐ Some of the time  
[2] ☐ Most of the time  
[3] ☐ Always

\* Item is not required

CDD: dilincdd Table: DRUGCOMP Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
RXLESS	NUMERIC	
SURRO2	NUMERIC	
RXNAME	STRING(80) - A80	
SURSPEC2	NUMERIC	
RXMORE	NUMERIC	
RXFOLLOW	NUMERIC	
RXMORTHN	NUMERIC	
RXLESTHN	NUMERIC	

dilindv2 : QUESTIONNAIRES (QUESTS)

Questionnaires

1.

Surrogate respondent?

(dilincdd:QUESTS.SURRO3)

[0] ☐ No

[1] ☐ Yes

(dilincdd:QUESTS.SURSPEC3)

Specify Surrogate

[1] ☐ Relative

[98] ☐ Other

2.

During the last 12 months, did you fill a prescription for a medicine that was prescribed for you?

(dilincdd:QUESTS.FILLRX)

[0] ☐ No

[1] ☐ Yes

3.

\* Over the past 5 years, how would you describe your smoking habit? [hidden]

(dilincdd:QUESTS.SMOKE)

[1] ☐ Never smoked

[3] ☐ Current smoker

[2] ☐ 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] ☐ No

[1] ☐ Yes

\* Item is not required

CDD: dilincdd	Table: QUESTS	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
SMOKE	NUMERIC	
QUITSMKE	FLOAT - F9.0	
FILLRX	NUMERIC	
SURRO3	NUMERIC	
SURSPEC3	NUMERIC	
ALCOHOL	NUMERIC	

**dilindv2 : SOURCE OF RX MEDICATIONS (PHARMACY)****Source of Prescription Medications**

1.*	Is there one pharmacy where you usually go to fill most of your prescriptions? <i>[hidden]</i>	(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? <i>[hidden]</i>	A50 (dilincdd: PHARMACY.PHARMNM)
3.*	Pharmacy Address <i>[hidden]</i>	A50 (dilincdd: PHARMACY.PHARMADD)
4.*	Pharmacy City <i>[hidden]</i>	A25 (dilincdd: PHARMACY.PHARMCY)
5.*	Pharmacy State <i>[hidden]</i>	A5 (dilincdd: PHARMACY.PHARMST)
6.*	Pharmacy Zip <i>[hidden]</i>	A10 (dilincdd: PHARMACY.PHARMZIP)
7.*	Pharmacy Telephone Number <i>[hidden]</i>	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)? <i>[hidden]</i>	(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)? <i>[hidden]</i>	(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? <i>[hidden]</i>	(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)

\* Item is not required

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

**dilindv2 : SOURCE OF RX MEDICATIONS (PHARM1)****Source of Prescription Medications**

1.	During the last 12 months, approximately how many different pharmacies filled prescription medications for you (check only one)?	(dilncdd:PHARM1.DIFFPHRX) <input type="radio"/> [1] One - I always go to the same pharmacy <input type="radio"/> [2] Two pharmacies <input type="radio"/> [3] Three pharmacies <input type="radio"/> [4] More than three pharmacies <input type="radio"/> [5] Do not know/unsure If Do not know/unsure is checked, do not complete the rest of the page				
2.*	Is there one pharmacy where you usually go to fill most of your prescriptions?	(dilncdd:PHARM1.FILLPHRX) <input type="radio"/> [0] No <input type="radio"/> [1] Yes				
3.*	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)?	(dilncdd:PHARM1.NATIONLX) <input type="checkbox"/> [1] National pharmacy chain (dilncdd:PHARM1.LOCAL1X) <input type="checkbox"/> [1] Local independently owned pharmacy (dilncdd:PHARM1.CLINICX) <input type="checkbox"/> [1] Hospital or clinic-based pharmacy (dilncdd:PHARM1.MAILX) <input type="checkbox"/> [1] Mail-order pharmacy (dilncdd:PHARM1.OTHRPHRX) <input type="checkbox"/> [1] Other type (dilncdd:PHARM1.UNSUREX) <input type="checkbox"/> [1] Do not know/unsure				
4.*	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?	(dilncdd:PHARM1.SAMPLESX) <input type="radio"/> [0] No <input checked="" type="radio"/> [1] Yes If Yes Please indicate how many times you received samples of prescription medications from your doctors office (dilncdd:PHARM1.PHARMSPX)  xxx				
<b>Name</b>		<b>Addres</b>	<b>City</b>	<b>State</b>	<b>Zip</b>	<b>Phone</b>
5.						

**. Entry**

5.a*	What is the name of the pharmacy you visited most recently to fill or refill a prescription?	A50	(dilncdd: PHARM1A.PHARMNMX)
5.b*	Pharmacy Address	A51	(dilncdd: PHARM1A.PHARMADX)
5.c*	Pharmacy City	A25	(dilncdd: PHARM1A.PHARMCYX)
5.d*	Pharmacy State	A5	(dilncdd: PHARM1A.PHARMSTX)
5.e*	Pharmacy Zip	A10	(dilncdd: PHARM1A.PHARMZPX)
5.f*	Pharmacy Telephone Number	A12	(dilncdd: PHARM1A.PHARMPHX)

\* Item is not required

**CDD: dilncdd Table: PHARM1 Key Type: PATIENTVISIT**

Column Name	Column Data Type	Design Note
OTHRPHRX	NUMERIC	
DIFFPHRX	NUMERIC	
CLINICX	NUMERIC	
PHARMSPX	NUMERIC - N3	
NATIONLX	NUMERIC	
LOCAL1X	NUMERIC	
UNSUREX	NUMERIC	
MAILX	NUMERIC	
SAMPLESX	NUMERIC	
FILLPHRX	NUMERIC	

**CDD: dilncdd Table: PHARM1A Key Type: PATIENTVISIT**

Column Name	Column Data Type	Design Note
PHARMZPX	STRING(10) - A10	
PHARMNMX	STRING(50) - A50	
PHARMSTX	STRING(5) - A5	
PHARMADX	STRING(51) - A51	
PHARMCYX	STRING(25) - A25	
PHARMPHX	STRING(12) - A12	

dilindv2 : GENERAL SMOKING HISTORY (GENSMOKE)

General Smoking History

1.*	How long did you smoke (in years) [hidden]	Pulldown List 1 (dilincdd: GENSMOKE.SMKLNGTH)
2.*	What is/was your smoking preference(s)? [hidden]	(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? [hidden]	(dilincdd: GENSMOKE.SMKINHAL) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

\* Item is not required

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
PIPE	NUMERIC	
CIGARET	NUMERIC	
CIGARS	NUMERIC	
SMKINHAL	NUMERIC	
SMKLNGTH	NUMERIC - 1, 2, 3, 4, 5, 6	

dilindv2 : SMOKING HISTORY (SMOKEHX) - Repeating Form		
#		
1	<div></div>	
Smoking History		
1.* Phase [hidden]		xxx (dillncdd: SMOKEHX.PHASE)
2.* Youngest Age [hidden]		xxx (dillncdd: SMOKEHX.YOUNGAGE)
3.* Oldest Age [hidden]		xxx (dillncdd: SMOKEHX.OLDAGE)
4.* Cigarettes Per Day [hidden]		xxxxxxxx. (dillncdd: SMOKEHX.CIGPDAY)
5.* Cigars Per Week [hidden]		xxxxxxxx. (dillncdd: SMOKEHX.CIGPWK)
6.* Pipes Per Week [hidden]		xxxxxxxx. (dillncdd: SMOKEHX.PIPEPWK)
* Item is not required		

CDD: dillncdd	Table: SMOKEHX	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PIPEPWK	FLOAT - F9.0	
OLDAGE	NUMERIC - N3	
CIGPDAY	FLOAT - F9.0	
PHASE	NUMERIC - N3	
YOUNGAGE	NUMERIC - N3	
CIGPWK	FLOAT - F9.0	



## dilindv2 : 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	<input type="checkbox"/> 1																				
<b>Modified Skinner History of Alcohol Use</b>																					
1.	Phase									xxx   (dilincdd: SKINNER.PHASE2)											
2.	Youngest Age									xxxxxxxxx   (dilincdd: SKINNER.SYNGAGE)											
3.	Oldest Age									xxxxxxxxx   (dilincdd: SKINNER.SOLDAGE)											
4.	Average Quantity of Drinks per day (If Average = 00 Skip to Style)									xxx   (dilincdd: SKINNER.AVERAGE)											
5.*	Maximum Quantity of Drinks per day									xxx   (dilincdd: SKINNER.MAXIMUM)											
6.*	Frequency (Days/month)									xxx   (dilincdd: SKINNER.SKFREQ)											
7.*	Type (check all that apply)									(dilincdd: SKINNER.BEERY) <b>[1]</b> <input type="checkbox"/> Beer % (dilincdd: SKINNER.BEER)   xxx   (dilincdd: SKINNER.LIQUORY) <b>[1]</b> <input type="checkbox"/> Liquor % (dilincdd: SKINNER.LIQUOR)   xxx   (dilincdd: SKINNER.WINEY) <b>[1]</b> <input type="checkbox"/> Wine % (dilincdd: SKINNER.WINE)   xxx											
8.	Style									(dilincdd: SKINNER.STYLE) <b>[1]</b> <input type="radio"/> Abstinent <b>[2]</b> <input type="radio"/> Occasional <b>[3]</b> <input type="radio"/> Weekend <b>[4]</b> <input type="radio"/> Binge <b>[5]</b> <input type="radio"/> Frequent											
9.	Any Life Events that Influenced Drinking? (If No Skip to next phase)									(dilincdd: SKINNER.LIFEVNT) <b>[0]</b> <input type="radio"/> No <b>[1]</b> <input type="radio"/> Yes											
10.*	Perception of Effect on Your Marital / family									(dilincdd: SKINNER.FAM) <b>[1]</b> <input type="radio"/> Positive <b>[2]</b> <input type="radio"/> Negative <b>[3]</b> <input type="radio"/> Neutral <b>[4]</b> <input type="radio"/> Did not occur											
11.*	Perception of Effect on Your Work									(dilincdd: SKINNER.JOB) <b>[1]</b> <input type="radio"/> Positive <b>[2]</b> <input type="radio"/> Negative <b>[3]</b> <input type="radio"/> Neutral <b>[4]</b> <input type="radio"/> Did not occur											
12.*	Perception of Effect on Your School									(dilincdd: SKINNER.SCHOOL) <b>[1]</b> <input type="radio"/> Positive <b>[2]</b> <input type="radio"/> Negative <b>[3]</b> <input type="radio"/> Neutral <b>[4]</b> <input type="radio"/> Did not occur											
13.*	Perception of Effect on Your Medical									(dilincdd: SKINNER.MEDICAL) <b>[1]</b> <input type="radio"/> Positive <b>[2]</b> <input type="radio"/> Negative <b>[3]</b> <input type="radio"/> Neutral <b>[4]</b> <input type="radio"/> Did not occur											
14.*	Perception of Effect on Your Residence									(dilincdd: SKINNER.RESIDENC) <b>[1]</b> <input type="radio"/> Positive <b>[2]</b> <input type="radio"/> Negative <b>[3]</b> <input type="radio"/> Neutral <b>[4]</b> <input type="radio"/> Did not occur											
15.*	Perception of Effect on Your Legal/Jail									(dilincdd: SKINNER.LEGAL) <b>[1]</b> <input type="radio"/> Positive <b>[2]</b> <input type="radio"/> Negative <b>[3]</b> <input type="radio"/> Neutral <b>[4]</b> <input type="radio"/> Did not occur											
16.*	Perception of Effect on Your Financial									(dilincdd: SKINNER.FINANCE) <b>[1]</b> <input type="radio"/> Positive <b>[2]</b> <input type="radio"/> Negative <b>[3]</b> <input type="radio"/> Neutral <b>[4]</b> <input type="radio"/> Did not occur											
17.*	Perception of Effect on Your Peer group									(dilincdd: SKINNER.PEER) <b>[1]</b> <input type="radio"/> Positive <b>[2]</b> <input type="radio"/> Negative <b>[3]</b> <input type="radio"/> Neutral <b>[4]</b> <input type="radio"/> Did not occur											
18.*	Perception of Effect on Your Drug abuse									(dilincdd: SKINNER.DRGABUSE) <b>[1]</b> <input type="radio"/> Positive <b>[2]</b> <input type="radio"/> Negative <b>[3]</b> <input type="radio"/> Neutral <b>[4]</b> <input type="radio"/> Did not occur											
19.*	Perception of Effect on Your Treatment									(dilincdd: SKINNER.TREATMNT) <b>[1]</b> <input type="radio"/> Positive <b>[2]</b> <input type="radio"/> Negative <b>[3]</b> <input type="radio"/> Neutral											

		[4] <input type="radio"/> Did not occur
20.*	Perception of Effect on Your Death	(dlilncdd: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	(dlilncdd: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		

CDD: dlilncdd Table: SKINNER Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
DEATH	NUMERIC	
FAM	NUMERIC	
SOLDAGE	FLOAT - F9.0	
LIQUOR	NUMERIC - N3	
MEDICAL	NUMERIC	
FINANCE	NUMERIC	
LIQUORY	NUMERIC	
SCHOOL	NUMERIC	
WINEY	NUMERIC	
WINE	NUMERIC - N3	
SKFREQ	NUMERIC - N3	
DRGABUSE	NUMERIC	
AVERAGE	NUMERIC - N3	
JOB	NUMERIC	
STYLE	NUMERIC	
EMOTION	NUMERIC	
BEER	NUMERIC - N3	
MAXIMUM	NUMERIC - N3	
RESIDENC	NUMERIC	
LIFEVNT	NUMERIC	
PEER	NUMERIC	
LEGAL	NUMERIC	
PHASE2	NUMERIC - N3	
TREATMNT	NUMERIC	
BEERY	NUMERIC	
SYNGAGE	FLOAT - F9.0	

dilindv2 : SYMPTOMS (SAQSYMPT)

Symptoms

Indicate the score to describe how you felt during the past week:

1.*	Tired or fatigued? <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC1)
2.*	Nausea? <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC2)
3.*	Pain over the liver area? (on the right side under your rib cage) <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC3)
4.*	Poor appetite? <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC4)
5.*	Muscle/joint aches or pains? <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC5)
6.*	Weakness of the arms or legs? <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC6)
7.*	Itching of the skin? <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC7)
8.*	Fever and chills? <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC8)
9.*	Skin rash? <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC9)
10.*	Depressed/sadness? <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC10)
11.*	How you feel overall? <i>[hidden]</i>	xxxxxxxx	(dilincdd:SAQSYMPT.SYMPC11)
* Item is not required			

CDD: dilincdd	Table: SAQSYMPT	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
SYMPC4	FLOAT - F9.0	
SYMPC9	FLOAT - F9.0	
SYMPC2	FLOAT - F9.0	
SYMPC3	FLOAT - F9.0	
SYMPC7	FLOAT - F9.0	
SYMPC11	FLOAT - F9.0	
SYMPC8	FLOAT - F9.0	
SYMPC1	FLOAT - F9.0	
SYMPC5	FLOAT - F9.0	
SYMPC10	FLOAT - F9.0	
SYMPC6	FLOAT - F9.0	

dilindv2 : RAND 36 HEALTH SURVEY (RANDHS1)

RAND 36 Survey Q1-12

1.*	(Q1) In general, would you say your health is: [hidden]	(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? [hidden]	(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 [hidden]	(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 [hidden]	(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. [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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
* Item is not required		

CDD: dilincdd	Table: RANDHS1	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
LIMIT05	NUMERIC	
HLTHNOW	NUMERIC	
LIMIT06	NUMERIC	
LIMIT01	NUMERIC	
LIMIT03	NUMERIC	
LIMIT02	NUMERIC	
HEALTH	NUMERIC	
LIMIT08	NUMERIC	
LIMIT07	NUMERIC	
LIMIT09	NUMERIC	
LIMIT10	NUMERIC	
LIMIT04	NUMERIC	

**dilindv2 : 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 [hidden]	(dilincdd: RANDHS2.WORKANS1) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2.*	(Q14) Accomplished less than you would like [hidden]	(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 [hidden]	(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) [hidden]	(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 [hidden]	(dilincdd: RANDHS2.WORKANS5) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6.*	(Q18) Accomplished less than you would like [hidden]	(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 [hidden]	(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? [hidden]	(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? [hidden]	(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)? [hidden]	(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

\* Item is not required

CDD: dilincdd	Table: RANDHS2	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
WORKANS3	NUMERIC	
BODYPAIN	NUMERIC	
WORKANS4	NUMERIC	
WORKANS6	NUMERIC	
PAINWORK	NUMERIC	
WORKANS1	NUMERIC	
WORKANS2	NUMERIC	
HLTHPROB	NUMERIC	
WORKANS7	NUMERIC	
WORKANS5	NUMERIC	

## dilindv2 : 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? [hidden]	Pulldown List 1	(dilincdd: RANDHS3.FEELANS1)
2.*	(Q24) Have you been a very nervous person? [hidden]	Pulldown List 2	(dilincdd: RANDHS3.FEELANS2)
3.*	(Q25) Have you felt so down in the dumps that nothing could cheer you up? [hidden]	Pulldown List 3	(dilincdd: RANDHS3.FEELANS3)
4.*	(Q26) Have you felt calm and peaceful? [hidden]	Pulldown List 4	(dilincdd: RANDHS3.FEELANS4)
5.*	(Q27) Did you have a lot of energy? [hidden]	Pulldown List 5	(dilincdd: RANDHS3.FEELANS5)
6.*	(Q28) Have you felt downhearted and blue? [hidden]	Pulldown List 6	(dilincdd: RANDHS3.FEELANS6)
7.*	(Q29) Did you feel worn out? [hidden]	Pulldown List 7	(dilincdd: RANDHS3.FEELANS7)
8.*	(Q30) Have you been a happy person? [hidden]	Pulldown List 8	(dilincdd: RANDHS3.FEELANS8)
9.*	(Q31) Did you feel tired? [hidden]	Pulldown List 9	(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.)? [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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. [hidden]	(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	

\* Item is not required

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

ieFEELALLT	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMET	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONET	None of the Time	6	

**Pulldown List 5:**

RefName	Display Text	Value	Design Note
ieFEELALLT	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMET	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONET	None of the Time	6	

**Pulldown List 6:**

RefName	Display Text	Value	Design Note
ieFEELALLT	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMET	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONET	None of the Time	6	

**Pulldown List 7:**

RefName	Display Text	Value	Design Note
ieFEELALLT	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMET	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONET	None of the Time	6	

**Pulldown List 8:**

RefName	Display Text	Value	Design Note
ieFEELALLT	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMET	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONET	None of the Time	6	

**Pulldown List 9:**

RefName	Display Text	Value	Design Note
ieFEELALLT	All of the Time	1	
ieFEELMOST	Most of the Time	2	
ieFEELBIT	A Good Bit of the Time	3	
ieFEELSOMET	Some of the Time	4	
ieFEELLITTLE	A Little of the Time	5	
ieFEELNONET	None of the Time	6	

**CDD: dilincdd Table: RANDHS3 Key Type: PATIENTVISIT**

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

**dilindv2 : 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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(dilincdd: PEDSQL1.PEDS10) [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
11.* (Q3) Feeling angry [hidden]	(dilincdd: PEDSQL1.PEDS11) [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
12.* (Q4) Trouble sleeping [hidden]	(dilincdd: PEDSQL1.PEDS12) [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
13.* (Q5) Worrying [hidden]	(dilincdd: PEDSQL1.PEDS13) [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
* Item is not required	



Column Name	Column Data Type	Design Note
PEDS13	NUMERIC	
PEDS04	NUMERIC	
PEDS05	NUMERIC	
PEDS01	NUMERIC	
PEDS12	NUMERIC	
PEDS02	NUMERIC	
PEDS07	NUMERIC	
PEDS08	NUMERIC	
PEDS11	NUMERIC	
PEDS06	NUMERIC	
PEDS09	NUMERIC	
PEDS10	NUMERIC	
PEDS03	NUMERIC	

**dilindv2 : 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 <i>[hidden]</i>	(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 <i>[hidden]</i>	(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 <i>[hidden]</i>	(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 <i>[hidden]</i>	(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 <i>[hidden]</i>	(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 <i>[hidden]</i>	(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 <i>[hidden]</i>	(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 <i>[hidden]</i>	(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

\* Item is not required

**CDD: dilincdd Table: PEDSQL2 Key Type: PATIENTVISIT**

Column Name	Column Data Type	Design Note
PEDS19	NUMERIC	
PEDS21	NUMERIC	
PEDS16	NUMERIC	
PEDS14	NUMERIC	
PEDS15	NUMERIC	
PEDS20	NUMERIC	
PEDS18	NUMERIC	
PEDS17	NUMERIC	

**dilindv2 : 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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(dilincdd: PEDSQL3.PEDS31) [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
11.* (Q3) Feeling angry [hidden]	(dilincdd: PEDSQL3.PEDS32) [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
12.* (Q4) Trouble sleeping [hidden]	(dilincdd: PEDSQL3.PEDS33) [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
13.* (Q5) Worrying about what will happen to him or her [hidden]	(dilincdd: PEDSQL3.PEDS34) [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
* Item is not required	

CDD: dilincdd Table: PEDSQL3 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PEDS34	NUMERIC	
PEDS29	NUMERIC	
PEDS26	NUMERIC	
PEDS33	NUMERIC	
PEDS30	NUMERIC	
PEDS24	NUMERIC	
PEDS23	NUMERIC	
PEDS25	NUMERIC	
PEDS22	NUMERIC	
PEDS32	NUMERIC	
PEDS27	NUMERIC	
PEDS28	NUMERIC	
PEDS31	NUMERIC	

**dilindv2 : 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 [ <i>hidden</i> ]	(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 [ <i>hidden</i> ]	(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 [ <i>hidden</i> ]	(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 [ <i>hidden</i> ]	(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 [ <i>hidden</i> ]	(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 [ <i>hidden</i> ]	(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 [ <i>hidden</i> ]	(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 [ <i>hidden</i> ]	(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 [ <i>hidden</i> ]	(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 [ <i>hidden</i> ]	(dilincdd: PEDSQL4.PEDS44) [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

\* Item is not required

CDD: dilincdd	Table: PEDSQL4	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PEDS35	NUMERIC	
PEDS40	NUMERIC	
PEDS44	NUMERIC	
PEDS37	NUMERIC	
PEDS42	NUMERIC	
PEDS41	NUMERIC	
PEDS38	NUMERIC	
PEDS36	NUMERIC	
PEDS39	NUMERIC	
PEDS43	NUMERIC	

**dilindv2 : PEDIATRIC QUALITY OF LIFE INVENTORY 5 (PEDSQL5)****PEDSQL 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 [hidden]	(dilincdd: PEDSQL5.PEDS45) [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 [hidden]	(dilincdd: PEDSQL5.PEDS46) [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 [hidden]	(dilincdd: PEDSQL5.PEDS47) [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 [hidden]	(dilincdd: PEDSQL5.PEDS48) [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 [hidden]	(dilincdd: PEDSQL5.PEDS49) [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 [hidden]	(dilincdd: PEDSQL5.PEDS50) [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 [hidden]	(dilincdd: PEDSQL5.PEDS51) [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 [hidden]	(dilincdd: PEDSQL5.PEDS52) [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 [hidden]	(dilincdd: PEDSQL5.PEDS53) [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 [hidden]	(dilincdd: PEDSQL5.PEDS54) [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
11.* (Q3) Feeling angry [hidden]	(dilincdd: PEDSQL5.PEDS55) [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
12.* (Q4) Trouble sleeping [hidden]	(dilincdd: PEDSQL5.PEDS56) [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
13.* (Q5) Worrying about what will happen to him or her [hidden]	(dilincdd: PEDSQL5.PEDS57) [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
* Item is not required	

CDD: dilincdd Table: PEDSQL5 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PEDS55	NUMERIC	
PEDS45	NUMERIC	
PEDS54	NUMERIC	
PEDS57	NUMERIC	
PEDS49	NUMERIC	
PEDS48	NUMERIC	
PEDS50	NUMERIC	
PEDS56	NUMERIC	
PEDS51	NUMERIC	
PEDS52	NUMERIC	
PEDS46	NUMERIC	
PEDS47	NUMERIC	
PEDS53	NUMERIC	

**dilindv2 : 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 [ <i>hidden</i> ]	(dilincdd: 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 [ <i>hidden</i> ]	(dilincdd: 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 [ <i>hidden</i> ]	(dilincdd: 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 [ <i>hidden</i> ]	(dilincdd: 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 [ <i>hidden</i> ]	(dilincdd: 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 [ <i>hidden</i> ]	(dilincdd: 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 [ <i>hidden</i> ]	(dilincdd: 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 [ <i>hidden</i> ]	(dilincdd: 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 [ <i>hidden</i> ]	(dilincdd: 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 [ <i>hidden</i> ]	(dilincdd: PEDSQL6.PEDS67) [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

\* Item is not required

CDD: dilincdd	Table: PEDSQL6	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PEDS67	NUMERIC	
PEDS63	NUMERIC	
PEDS62	NUMERIC	
PEDS65	NUMERIC	
PEDS58	NUMERIC	
PEDS64	NUMERIC	
PEDS60	NUMERIC	
PEDS59	NUMERIC	
PEDS66	NUMERIC	
PEDS61	NUMERIC	



**dilindv2 : PEDIATRIC QUALITY OF LIFE INVENTORY 7 (PEDSQL7)****PEDSQL 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 [hidden]	(dilincdd: PEDSQL7.PEDS68) [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 [hidden]	(dilincdd: PEDSQL7.PEDS69) [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 [hidden]	(dilincdd: PEDSQL7.PEDS70) [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 [hidden]	(dilincdd: PEDSQL7.PEDS71) [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 [hidden]	(dilincdd: PEDSQL7.PEDS72) [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 [hidden]	(dilincdd: PEDSQL7.PEDS73) [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 [hidden]	(dilincdd: PEDSQL7.PEDS74) [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 [hidden]	(dilincdd: PEDSQL7.PEDS75) [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 [hidden]	(dilincdd: PEDSQL7.PEDS76) [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 [hidden]	(dilincdd: PEDSQL7.PEDS77) [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
11.* (Q3) Feeling angry [hidden]	(dilincdd: PEDSQL7.PEDS78) [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
12.* (Q4) Trouble sleeping [hidden]	(dilincdd: PEDSQL7.PEDS79) [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
13.* (Q5) Worrying about what will happen to him or her [hidden]	(dilincdd: PEDSQL7.PEDS80) [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
* Item is not required	

CDD: dilincdd Table: PEDSQL7 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PEDS77	NUMERIC	
PEDS71	NUMERIC	
PEDS78	NUMERIC	
PEDS80	NUMERIC	
PEDS74	NUMERIC	
PEDS70	NUMERIC	
PEDS68	NUMERIC	
PEDS72	NUMERIC	
PEDS75	NUMERIC	
PEDS73	NUMERIC	
PEDS69	NUMERIC	
PEDS79	NUMERIC	
PEDS76	NUMERIC	

**dilindv2 : 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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(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 [hidden]	(dilincdd: PEDSQL8.PEDS90) [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

\* Item is not required

CDD: dilincdd	Table: PEDSQL8	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PEDS83	NUMERIC	
PEDS86	NUMERIC	
PEDS90	NUMERIC	
PEDS81	NUMERIC	
PEDS89	NUMERIC	
PEDS82	NUMERIC	
PEDS87	NUMERIC	
PEDS85	NUMERIC	
PEDS88	NUMERIC	
PEDS84	NUMERIC	

## dilindv2 : 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	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

History of Injury

Did the patient use any other drugs within the same therapeutic class? (USE EOCRATES)

1. Is this a drug or CAM product?

(dilincdd: HXINJ1.DRGCAM)  
[1] ☐ Drug  
[2] ☐ CAM

2. Name of implicated drug/CAM:

A80  (dilincdd: HXINJ1.IMPLDRUG)

3. Name of drug/CAM manufacturer:

A80  (dilincdd: HXINJ1.DRGMANUF)

4. Implicated drug/CAM start date:

Req/Unk  / Req/Unk  / Req/Unk  (1935-2020) (dilincdd: HXINJ1.IMPLSTDT)

5. Implicated drug/CAM stop date:

Req/Unk  / Req/Unk  / Req/Unk  (1935-2020) (dilincdd: HXINJ1.IMPLSPDT)

6. Was the patient rechallenged with the implicated drug/CAM?

(dilincdd: HXINJ1.RECHALL)  
[0] ☐ No  
[1] ☐ Yes-- If Yes: Please provide:  
Start date: Req/Unk  / Req/Unk  / Req/Unk  (1935-2020) (dilincdd: HXINJ1.RECHSTDT)  
(dilincdd: HXINJ1.RECHCONT)  
[2] ☐ Stop Date: Req/Unk  / Req/Unk  / Req/Unk  (1935-2020) (dilincdd: HXINJ1.RECHSPDT)  
[1] ☐ Continuing

7. Did the patient ever take this drug/CAM prior to this episode for any reason?

(dilincdd: HXINJ1.PRIORUSE)  
[0] ☐ No  
[1] ☐ Yes  
[2] ☐ Cannot remember

CDD: dilincdd Table: HXINJ1 Key Type: PATIENTVISIT

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

**dilindv2 : HISTORY OF INJURY 2 (HXINJ2)****History of Injury continued**

1.	Date of onset of qualifying lab abnormalities	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilincdd:HXINJ2.ONSETDT)
2.	Date of first presentation of liver problems to health care provider	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (1935-2020) (dilincdd:HXINJ2.PRESNDT)
3.	Was the patient seen by a gastroenterologist/hepatologist for the DILI event?	(dilincdd: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?	(dilincdd: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?	(dilincdd: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?	(dilincdd: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)?	(dilincdd:HXINJ2.PTSCICK) [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)?	(dilincdd:HXINJ2.DISRUPT) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd:HXINJ2.DISRUPTSP) 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?	(dilincdd:HXINJ2.HEPATIC) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd:HXINJ2.NEUTRPEN) Check all that apply [1] <input type="checkbox"/> Neutropenia (dilincdd:HXINJ2.THRMBPEN) [1] <input type="checkbox"/> Thrombocytopenia (dilincdd:HXINJ2.SJSYNDRM) [1] <input type="checkbox"/> Stevens-Johnson syndrome (dilincdd:HXINJ2.NECROLY) [1] <input type="checkbox"/> Toxic epidermal necrolysis (dilincdd:HXINJ2.HMANEMIA) [1] <input type="checkbox"/> Hemolytic anemia (dilincdd:HXINJ2.SERUMSCK) [1] <input type="checkbox"/> Serum sickness (dilincdd:HXINJ2.HEPAOTHR) [1] <input type="checkbox"/> Other Other (specify) (dilincdd:HXINJ2.HEPASP) A200
10.	Was a liver biopsy performed for this injury?	(dilincdd:HXINJ2.LIVBIOP) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Which Hospital performed liver biopsy? (dilincdd:HXINJ2.BIOPHOSP) A50 Hospital City A25 (dilincdd:HXINJ2.BIOPCITY) Hospital State A5 (dilincdd:HXINJ2.BIOPST) Date liver biopsy performed Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> (1935-2020) (dilincdd:HXINJ2.BIOPDT)
11.	Did the patient receive prednisone or corticosteroids for this injury?	(dilincdd:HXINJ2.STEROIDS) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Please provide first date patient received prednisone or corticosteroids for this injury Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> (1935-2020) (dilincdd:HXINJ2.STERDT) Please record on CONMED form as well
12.	Has the patient taken Ursodeoxycholic acid?	(dilincdd:HXINJ2.URSOACID) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please add to the CONMED page
13.	Has the patient taken Azathioprine or Imuran?	(dilincdd:HXINJ2.IMURAN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please add to the CONMED page
14.	Has the patient taken Celcept (Mycophenolate Mofetil)?	(dilincdd:HXINJ2.CELCEPT) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please add to the CONMED page
15.	Has the patient taken any other immunosuppressive medication(s) ?	(dilincdd:HXINJ2.IMMOTH) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Specify (dilincdd:HXINJ2.IMMOTHSP)

		<div>A200</div>
		If yes, please add to the CONMED page
16.	Was the patient listed for liver transplantation?	<div>(dillncdd:HXINJ2.TRXLIST)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div> <div>Date listing for liver transplant</div> <div>Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> (1935-2020) (dillncdd:HXINJ2.TRXLSTD1)</div> <div>(dillncdd:HXINJ2.TRXLSTS1)</div> <div>Was patient in status 1 at the time of listed for liver transplant?</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div>
17.*	Was a liver transplant performed for this injury (only if patient was listed for liver transplantation)?	<div>(dillncdd:HXINJ2.LIVTRX)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div> <div>Which Hospital performed liver transplant? (dillncdd:HXINJ2.TRXHOSP)</div> <div>A50</div> <div>Hospital City A25 (dillncdd:HXINJ2.TRXCITY)</div> <div>Hospital State A5 (dillncdd:HXINJ2.TRXST)</div> <div>Date liver transplant performed</div> <div>Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> (1935-2020) (dillncdd:HXINJ2.TRXDT)</div> <div>(dillncdd:HXINJ2.TRXSTAT1)</div> <div>Was patient in status 1 when liver transplant was performed?</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div>
18.*	If liver transplant was not performed for this injury, please provide reason	<div>(dillncdd:HXINJ2.NOTRX)</div> <div>[1] <input type="radio"/> Improvement</div> <div>[2] <input type="radio"/> Deterioration (or too sick)</div> <div>[3] <input type="radio"/> Death prior to transplant</div> <div>[98] <input type="radio"/> Other</div> <div>Other Specify A50 (dillncdd:HXINJ2.NOTRXSP)</div>
19.	Was the patient previously diagnosed with a DILI event prior to this injury?	<div>(dillncdd:HXINJ2.PREVDX)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div>

\* Item is not required

CDD: dillncdd	Table: HXINJ2	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
LIVTRX	NUMERIC	
HEPAOTHR	NUMERIC	
HOSPITAL	NUMERIC	
DISRUPT	NUMERIC	
TRXDT	DATE - DDMONYYYY	
PREVDX	NUMERIC	
TRXLSTS1	NUMERIC	
BIOPHOSP	STRING(50) - A50	
STERDT	DATE - DDMONYYYY	
GIHEP	NUMERIC	
THRMBPEN	NUMERIC	
LIVBIOP	NUMERIC	
CELCEPT	NUMERIC	
BIOPDT	DATE - DDMONYYYY	
IMMOTHSP	STRING(200) - A200	
SERUMSCK	NUMERIC	
IMMOTH	NUMERIC	
PREGNANT	NUMERIC	
TRXST	STRING(5) - A5	
SJSYNDRM	NUMERIC	
HEPASP	STRING(200) - A200	
NEUTRPEN	NUMERIC	
PTSICK	NUMERIC	
DISRUPSP	NUMERIC	
TRXLSTD1	DATE - DDMONYYYY	
STEROIDS	NUMERIC	
BIOPCITY	STRING(25) - A25	
NOTRXSP	STRING(50) - A50	
NOTRX	NUMERIC	
IMURAN	NUMERIC	
TRXCITY	STRING(25) - A25	
TRXLIST	NUMERIC	
NECROLY	NUMERIC	
BIOPST	STRING(5) - A5	
TRXSTAT1	NUMERIC	
URSOACID	NUMERIC	
TRXHOSP	STRING(50) - A50	
PRESNDT	DATE - DDMONYYYY	

ONSETDT	DATE - DDMYYYY	
PRLGHOSP	NUMERIC	
HEPATIC	NUMERIC	
HMANEMIA	NUMERIC	

dilindv2 : HISTORY OF INJURY 3 (HXINJ3) - Repeating Form

#		Hospital Name for this liver injury2	Hospital City	Hospital State	Date of admission	Date of discharge	
1	<div><div></div></div>						

History of Injury continued

1.	Hospital Name for this liver injury?	A50	(dilincdd: HXINJ3.HOSPNAME)				
2.	Hospital City	A25	(dilincdd: HXINJ3.HOSPCITY)				
3.	Hospital State	A50	(dilincdd: HXINJ3.HOSPST)				
4.*	Date hospitalized for liver injury {hidden}	Req/Unk <div></div> / Req <div></div>	(1935-2020) (dilincdd: HXINJ3.HOSPHXDT)				
5.	Date of admission	Req/Unk <div></div> / Req/Unk <div></div> / Req/Unk <div></div>	(1935-2020) (dilincdd: HXINJ3.HXADMDT)				
6.	Date of discharge	(dilincdd: HXINJ3.HXCNT) [2] <div></div> Req/Unk <div></div> / Req/Unk <div></div> / Req/Unk <div></div> (1935-2020) (dilincdd: HXINJ3.HXDSCDT) [1] <div></div> Continuing If continuing is checked, update discharge when known					

\* Item is not required

CDD: dilincdd Table: HXINJ3 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
HXADMDT	DATE - DDMONYYYY	
HOSPST	STRING(50) - A50	
HOSPCITY	STRING(25) - A25	
HXDSCDT	DATE - DDMONYYYY	
HXCNT	NUMERIC	
HOSPNAME	STRING(50) - A50	
HOSPHXDT	DATE - MONYYYY	



dilindv2 : SIGNS AND SYMPTOMS (SIGN) - Repeating Form

#

1

Signs & Symptoms

1.\* Signs and Symptoms [hidden]

Pulldown List 1 (dilincdd: SIGN.SGNRES)

Other specify (dilincdd: SIGN.SIGNSP)

A200

2.\* Date of Signs and Symptoms Onset [hidden]

(dilincdd: SIGN.SIGNNA)

[11] ☐ Req/Unk ☐ / ☐ Req/Unk ☐ / ☐ Req ☐ (1935-2020) (dilincdd: SIGN.SGNSYMDT)

[96] ☐ NA

\* Item is not required

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
SGNSYMDT	DATE - DDMONYYYY	
SIGNNA	NUMERIC	
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	

dilindv2 : SYMPTOMS AND SIGNS (SYMPSIGN) - Repeating Form

#	SYMPTOMS	Date of first symptom onset	SIGNS
1	<div><div></div><div></div></div>		

Symptoms of liver injury

1.

SYMPTOMS Entry

1.a\* Symptoms of liver injury

Pulldown List 1

(dilincdd: SYMPSIGN.SYMPINJ)

Specify other

A100

(dilincdd: SYMPSIGN.SYMOTHSP)

Date of onset

2. Date of first symptom onset  
(symptom of liver injury, not pre-existing symptoms)

(dilincdd: SYMPSIGN2.SYMPNA)  
[1] 

Req/Unk

 / 

Req/Unk

 / 

Req/Unk

 (1935-2020)  
(dilincdd: SYMPSIGN2.SYMPDT)  
[96] 

NA

Signs of liver injury

3.

SIGNS Entry

3.a\* Signs of liver injury Injury

Pulldown List 2

(dilincdd: SYMPSIGN3.SIGNINJ)

Specify other

A100

(dilincdd: SYMPSIGN3.SGNOTHSP)

\* Item is not required

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieLiverSYM1	Fatigue	1	
ieLiverSYM2	Nausea	2	
ieLiverSYM3	Vomiting	3	
ieLiverSYM4	Poor appetite	4	
ieLiverSYM5	Abdominal pain	5	
ieLiverSYM6	Dark Urine	6	
ieLiverSYM7	Jaundice	7	
ieLiverSYM8	Light stools	8	
ieLiverSYM9	Itching	9	
ieLiverSYM10	Fever	10	
ieLiverSYM11	Chills	11	
ieLiverSYM12	Rash	12	
ieOTHER	Other	98	
ieNOTAPPL	Not applicable	96	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieLvSYM1	Jaundice	1	
ieLvSYM2A	Fever (temperature > 38° C)	2	
ieLvSYM3	Rash (visible)	3	
ieLvSYM4	Abdominal (liver) tenderness	4	
ieLvSYM5	Hepatomegaly	5	
ieLvSYM6	Splenomegaly	6	
ieLvSYM7	Lymphadenopathy	7	
ieLvSYM8	Facial edema	8	
ieLvSYM9	Ascites	9	
ieLvSYM10	Mental Confusion	10	
ieLvSYM11	Asterixis	11	
ieOTHER	Other	98	
ieNOTAPPL	Not applicable	96	

CDD: dilincdd Table: SYMPSIGN Key Type: PATIENTVISIT			
Column Name	Column Data Type	Design Note	
SYMPINJ	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 98, 96		
SYMOTHSP	STRING(100) - A100		

CDD: dilincdd Table: SYMPSIGN2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SYMPNA	NUMERIC	
SYMPDT	DATE - DDMONYYYY	

CDD: dilincdd Table: SYMPSIGN3 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SIGNINJ	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 98, 96	
SGNOTHSP	STRING(100) - A100	

[illegible]

1. Medication	A80 (dillncdd: DILIMED.DILNAME)
2. Dose	A12 (dillncdd: DILIMED.DOSE)
3. Unit	A8 (dillncdd: DILIMED.UNIT)
4. Frequency	Pulldown List 1 (dillncdd: DILIMED.FREQ) Specify other frequency (dillncdd: DILIMED.FREQSP) A100
5. Route	Pulldown List 2 (dillncdd: DILIMED.ROUTE) Specify other route (dillncdd: DILIMED.RTESP) A100
6. Start Date	Req/Unk /   Req/Unk /   Req/Unk (1935-2020) (dillncdd: DILIMED.DILISTDT)
7. Stop Date	(dillncdd: DILIMED.DILICONT) [2] Req/Unk /   Req/Unk /   Req/Unk (1935-2020) (dillncdd: DILIMED.DILISPDT) [1] Continuing
8. Indication	A200 (dillncdd: DILIMED.DILISPEC)
9.* If drug is within same class, please enter the implicated drug it belongs to	A200 (dillncdd: DILIMED.DIMLPDRG)

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	
ieFREQ8	Once	8	
ieFREQ9	Every Other Day	9	
ieFREQ10	3 x per Week	10	
ieFREQ11	2 x per Week	11	
ieFREQ98	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	
ieROUTE98	Other	98	

CDD: dilncdd	Table: DILIMED	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
RTESP	STRING(100) - A100	
DILINAME	STRING(80) - A80	
ROUTE	NUMERIC - 1, 2, 3, 4, 5, 98	
DIMLPDRG	STRING(200) - A200	
DILISPD	DATE - DDMONYYYY	
DILICONT	NUMERIC	
DILISPEC	STRING(200) - A200	
DILISTDT	DATE - DDMONYYYY	
FREQ	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 98	
FREQSP	STRING(100) - A100	
DOSE	STRING(12) - A12	
UNIT	STRING(8) - A8	

dilindv2 : IMPLICATED CAM PRODUCT/HDS (CAMMED1) - Repeating Form

#	HDS#	Br Product name	Product Line	Lot number	Expiration date	Manufactures name	Manufacturers Address	Manufacturers City	Manufacturers State	Manufacturers ZIP	Manufacturers Phone number	HDS ingredients available	CAMMED2	CAMMED3	Taking this HDS	Taking Medications	Medic doctor aware of HDS	HDS use Information	HfFrom where did you purchase this HDS	CAMMED5 Repeating Section Summary (corresponds with item #16)
1																				

Implicated herbals and dietary suuplements (HDS)

1.	HDS#	.xxx (dilincdd: CAMMED1.CAMSEQNO)
2.	Product name (Brand Name)	A80 (dilincdd: CAMMED1.CAMBRNM)
3.	Product line (Common Name)	A80 (dilincdd: CAMMED1.CAMCOMM)
4.	Lot number	A25 (dilincdd: CAMMED1.LOTNUM)
5.	Expiration date	Req/Unk / Req/Unk / Req/Unk (1935- (dilincdd: CAMMED1.CAMEXPDT) 2020)
6.	Manufacturers name	A80 (dilincdd: CAMMED1.CAMMANUF)
7.	Manufacturers Address	A50 (dilincdd: CAMMED1.CAMADD)
8.	Manufacturers City	A25 (dilincdd: CAMMED1.CAMCITY)
9.	Manufacturers State	A5 (dilincdd: CAMMED1.CAMST)
10.	Manufacturers ZIP	A10 (dilincdd: CAMMED1.CAMZIP)
11.	Manufacturers Phone number	A12 (dilincdd: CAMMED1.CAMPHONE)
12.	Are HDS ingredients available? Complete Section CAMMED2 & CAMMED3	(dilincdd: CAMMED1.CAMINGYN) [0] No [1] Yes
List Each Implicated HDS Ingredient		
13.		

CAMMED2 Entry

13.a	Ingredients	A100 (dilincdd: CAMMED2.CAMINGRD)							
	HDS#	Dose	Unit	Frequency	Route	Start Date	Stop Date	Indication	
14.									[hidden]

CAMMED3 Entry

14.a	HDS#	.xxx (dilincdd: CAMMED3.CAMSEQNO)
14.b	Dose	xxxxxxx (dilincdd: CAMMED3.CDOSE)
14.c	Unit	A10 (dilincdd: CAMMED3.CUNIT)
14.d	Frequency	Pulldown List 1 (dilincdd: CAMMED3.CFREQ) Specify other frequency (dilincdd: CAMMED3.CFREQSP) A100
14.e	Route	Pulldown List 2 (dilincdd: CAMMED3.CROUTE) Specify other route (dilincdd: CAMMED3.CRTESP) A100
14.f	Start Date	Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd: CAMMED3.CAMSTDT)
14.g	Stop Date	(dilincdd: CAMMED3.CAMCONT) [2] Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd: CAMMED3.CAMSPDT) [1] Continuing
14.h	Indication [hidden]	Pulldown List 3 (dilincdd: CAMMED3.CAMIND) Other Indication (specify) (dilincdd: CAMMED3.CAMSP) A200

CAMMED4

Implicated HDS continued

15.	Are you taking this HDS for any of the following reasons (check all that apply)?	(dilincdd: CAMMED1.HRSNA) [1] Not applicable (dilincdd: CAMMED1.HBONE) [1] Arthritis/ Bone/ Joint Disorders (dilincdd: CAMMED1.HBLOOD) [1] Blood Disorder/ Anemia (dilincdd: CAMMED1.HMUSCLE) [1] Bodybuilding/ Muscle Building (dilincdd: CAMMED1.HCANCER) [1] Cancer (dilincdd: CAMMED1.HMENTAL) [1] Depression/ Anxiety/ Mental Health (dilincdd: CAMMED1.HENERGY) [1] Energy booster (dilincdd: CAMMED1.HGASTRO) [1] Gastrointestinal Disorders (dilincdd: CAMMED1.HGENHLTH) [1] General Health/ Disease Prevention (dilincdd: CAMMED1.HCADHTN) [1] Heart Disease/ Hypertension (dilincdd: CAMMED1.HIMMUNE) [1] Immune support
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http://ms46ad01.dcri.int/dilindv2/pts.dll?Z=F0705EBB7D51560A3B005479621C352A&C=TM\_169&FMID=0&FMRV=0&ISID=0&ITID=0&VM=2&TN=dilindv2&SP=6AS-59391&CP=65535&FP=0&RSV=0

7/27/2017

		<div>(dillncdd: CAMMED1.HINFHIV) [1] <input type="checkbox"/> Infections (including HIV) (dillncdd: CAMMED1.HKIDNEY) [1] <input type="checkbox"/> Kidney Disease (dillncdd: CAMMED1.HLIVER) [1] <input type="checkbox"/> Liver Disease (dillncdd: CAMMED1.HLUNG) [1] <input type="checkbox"/> Lung Disease (dillncdd: CAMMED1.HBRAIN) [1] <input type="checkbox"/> Neurological/ Brain Disorders (dillncdd: CAMMED1.HPAIN) [1] <input type="checkbox"/> Pain relief (dillncdd: CAMMED1.HENHANCE) [1] <input type="checkbox"/> Performance Enhancement (dillncdd: CAMMED1.HSLEEP) [1] <input type="checkbox"/> Sedative/ Sleep aid (dillncdd: CAMMED1.HSEXPERF) [1] <input type="checkbox"/> Sexual performance (dillncdd: CAMMED1.HSKIN) [1] <input type="checkbox"/> Skin Disorders (dillncdd: CAMMED1.HTOXIN) [1] <input type="checkbox"/> Toxin removal (dillncdd: CAMMED1.HUROGYN) [1] <input type="checkbox"/> Urological/ Gynecological Disorders (dillncdd: CAMMED1.HWEIGHT) [1] <input type="checkbox"/> Weight Loss (dillncdd: CAMMED1.HOTHR) [1] <input type="checkbox"/> Specific diagnoses: (dillncdd: CAMMED1.HOTHRSP) <div>A200</div></div>
16.	Are you also taking medications prescribed by your doctor for the above reason(s)?	<div>(dillncdd: CAMMED1.HDSMEDYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, complete CAMMED 5</div>
17.	Is/was your medical doctor aware that you were taking this HDS?	<div>(dillncdd: CAMMED1.HMDAWARE) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</div>
18.	From where did you get information on the use of this HDS (check all that apply)?	<div>(dillncdd: CAMMED1.HINFONA) [1] <input type="checkbox"/> Not applicable (dillncdd: CAMMED1.HWORKER) [1] <input type="checkbox"/> Supplement store associate/ worker (dillncdd: CAMMED1.HNET) [1] <input type="checkbox"/> Internet (dillncdd: CAMMED1.HFAM) [1] <input type="checkbox"/> Family/ Friends (dillncdd: CAMMED1.HPERSMD) [1] <input type="checkbox"/> My doctor (dillncdd: CAMMED1.HNATPMD) [1] <input type="checkbox"/> Naturopathic doctor (dillncdd: CAMMED1.HHEALER) [1] <input type="checkbox"/> Traditional medicine practitioner/Healer (dillncdd: CAMMED1.HINFOTH) [1] <input type="checkbox"/> Other (dillncdd: CAMMED1.HINFOTSP) <div>A200</div></div>
19.*	From where did you purchase this HDS (check all that apply)?	<div>(dillncdd: CAMMED1.PURCHNA) [1] <input type="checkbox"/> Not applicable (dillncdd: CAMMED1.PWORKER) [1] <input type="checkbox"/> Supplement store associate/ worker (dillncdd: CAMMED1.PNET) [1] <input type="checkbox"/> Internet (dillncdd: CAMMED1.PFAM) [1] <input type="checkbox"/> Family/ Friends (dillncdd: CAMMED1.PPERSMD) [1] <input type="checkbox"/> My doctor (dillncdd: CAMMED1.PNATPMD) [1] <input type="checkbox"/> Naturopathic doctor (dillncdd: CAMMED1.PHEALER) [1] <input type="checkbox"/> Traditional medicine practitioner/Healer (dillncdd: CAMMED1.PURCHOTH) [1] <input type="checkbox"/> Other (dillncdd: CAMMED1.PURCHSP) <div>A200</div></div>
	Reason	Prescribed Medication
20.		
CAMMED5 Repeating Section Summary (corresponds with item #16) Entry		
20.a	Reason	<div>A100 (dillncdd: CAMMED4.HDSRSNSP)</div>
20.b	Prescribed Medication	<div>A100 (dillncdd: CAMMED4.HDSMED)</div>
* Item is not required		

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	

leFRE07	Monthly	7	
leOther	Other	98	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
leROUTE1	PO	1	
leROUTE2	IV	2	
leROUTE3	SC	3	
leROUTE4	IM	4	
leROUTE5	Topical/transdermal	5	
leOTHER	Other	98	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
leINDCAT1	Liver disease	1	
leINDCAT2	Heart disease	2	
leINDCAT3	Cancer	3	
leINDCAT4	Depression	4	
leINDCAT5	Disease prevention for Indications 1-4	5	
leINDCAT6	General health	6	
leOTHER	Other	98	

CDD: dilincdd Table: CAMMED1 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
CAMZIP	STRING(10) - A10	
CAMSEQNO	NUMERIC - N3	
CAMBRNM	STRING(80) - A80	
CAMPHONE	STRING(12) - A12	
CAMCITY	STRING(25) - A25	
CAMCOMNM	STRING(80) - A80	
HFAM	NUMERIC	
HENERGY	NUMERIC	
CAMST	STRING(5) - A5	
HGASTRO	NUMERIC	
HSEXPERF	NUMERIC	
HGENHLTH	NUMERIC	
CAMEXPDT	DATE - DDMYYYY	
HLUNG	NUMERIC	
HWORKER	NUMERIC	
HINFOTH	NUMERIC	
CAMINGYN	NUMERIC	
CAMMANUF	STRING(80) - A80	
HBRAIN	NUMERIC	
HRSNA	NUMERIC	
HIMMUNE	NUMERIC	
HDSMEDYN	NUMERIC	
HNATPMD	NUMERIC	
HMDAWARE	NUMERIC	
HINFONA	NUMERIC	
HTOXIN	NUMERIC	
LOTNUM	STRING(25) - A25	
HUROGYN	NUMERIC	
HMUSCLE	NUMERIC	
HSKIN	NUMERIC	
HLIVER	NUMERIC	
HMENTAL	NUMERIC	
HPAIN	NUMERIC	
HBONE	NUMERIC	
HINFHIV	NUMERIC	
HOTHRSP	STRING(200) - A200	
HSLEEP	NUMERIC	
HOTHR	NUMERIC	
HWEIGHT	NUMERIC	
HKIDNEY	NUMERIC	
HCADHTN	NUMERIC	
HINFOTSP	STRING(200) - A200	
HNET	NUMERIC	
PURCHOTH	NUMERIC	
PNATPMD	NUMERIC	
PWORKER	NUMERIC	
HBLOOD	NUMERIC	
HPERSMD	NUMERIC	
PURCHNA	NUMERIC	

PNET	NUMERIC	
PPERSMD	NUMERIC	
PFAM	NUMERIC	
PHEALER	NUMERIC	
PURCHSP	STRING(200) - A200	
HHEALER	NUMERIC	
CAMADD	STRING(50) - A50	
HCANCER	NUMERIC	
HENHANCE	NUMERIC	

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

CDD: dilincdd Table: CAMMED3 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CAMSP	STRING(200) - A200	
CAMSEQNO	NUMERIC - N3	
CDOSE	FLOAT - F9.0	
CFREQSP	STRING(100) - A100	
CFREQ	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 98	
CAMSPDT	DATE - DDMONYYYY	
CAMSTDT	DATE - DDMONYYYY	
CRTESP	STRING(100) - A100	
CAMIND	NUMERIC - 1, 2, 3, 4, 5, 6, 98	
CAMCONT	NUMERIC	
CROUTE	NUMERIC - 1, 2, 3, 4, 5, 98	
CUNIT	STRING(10) - A10	

CDD: dilincdd Table: CAMMED4 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
HDSRSNSP	STRING(100) - A100	
HDSMED	STRING(100) - A100	

## dilindv2 : 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	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Liver Test Flowchart-Record all available labs from 8 weeks prior to the start of the implicated drug up to but excluding the day of the baseline visit.												
1.	Lab Date					Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req/Unk <input type="text"/> (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 (IU/L or U/L or mIU/mL) (dilincdd: LABFLOW.ASTVAL)   xxxxxxxx.   AST ULN (IU/L or U/L or mIU/mL) (dilincdd: LABFLOW.ASTULN)   xxxxxxxx.						
3.	ALT results Available?					(dilincdd: LABFLOW.ALT) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes ALT results (IU/L or U/L or mIU/mL) (dilincdd: LABFLOW.ALTVAL)   xxxxxxxx.   ALT ULN (IU/L or U/L or mIU/mL) (dilincdd: LABFLOW.ALTULN)   xxxxxxxx.						
4.	Alkaline Phosphatase results Available?					(dilincdd: LABFLOW.AKP) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Alkaline Phosphatase results (IU/L or U/L or mIU/mL) (dilincdd: LABFLOW.AKPVAL)   xxxxxxxx.   Alkaline Phosphatase ULN (IU/L or U/L or mIU/mL) (dilincdd: LABFLOW.AKPULN)   xxxxxxxx.						
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)						

CDD: dilincdd Table: LABFLOW Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
ALTULN	FLOAT - F9.0	
INR	NUMERIC	
FLWRATIO	FLOAT - F9.0	
ASTVAL	FLOAT - F9.0	
ASTCALC	FLOAT - F9.0	
STBVAL	FLOAT - F9.0	
AST	NUMERIC	
INRRATE	FLOAT - F9.0	
AKPULN	FLOAT - F9.0	
ASTULN	FLOAT - F9.0	
AKPVAL	FLOAT - F9.0	
AKPCALC	FLOAT - F9.0	
ALTVAL	FLOAT - F9.0	
STBULN	FLOAT - F9.0	
STBUNIT	NUMERIC	
ALTCALC	FLOAT - F9.0	
STB	NUMERIC	
FCLABDT	DATE - DDMONYYYY	
ALT	NUMERIC	
AKP	NUMERIC	
STBCALC	FLOAT - F9.0	



**dilindv2 : STANDARD LABS (w/in 4wks prior to ONSET) (STDLABHX)****Standard Labs within 4 weeks prior to date of onset**

1. Lab Date	Req/Unk <input type="radio"/> / Req/Unk <input type="radio"/> / Req/Unk <input type="radio"/> (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 <sup>^</sup> 9 or 10 <sup>^</sup> 3/mm <sup>^</sup> 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 <sup>^</sup> 9 or 10 <sup>^</sup> 3/mm <sup>^</sup> 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 <sup>^</sup> 9/L OR 10 <sup>^</sup> 3/mm <sup>^</sup> 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 <sup>^</sup> 9/L OR 10 <sup>^</sup> 3/mm <sup>^</sup> 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 <sup>^</sup> 9/L OR 10 <sup>^</sup> 3/mm <sup>^</sup> 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?	(dilincdd: STDLABHX.LABHXN11) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Cholesterol results   xxxxxxxx.   (dilincdd: STDLABHX.LABHXV11) (dilincdd: STDLABHX.LABHXU11) Cholesterol unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L
13. Triglycerides results Available?	(dilincdd: STDLABHX.LABHXN12) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Triglycerides results   xxxxxxxx.   (dilincdd: STDLABHX.LABHXV12) (dilincdd: STDLABHX.LABHXU12) Triglycerides unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L
14. Serum total protein results Available?	(dilincdd: STDLABHX.LABHXN13) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum total protein results   xxxxxxxx.   (dilincdd: STDLABHX.LABHXV13) (dilincdd: STDLABHX.LABHXU13) Serum total protein unit [1] <input type="radio"/> g/dL [9] <input type="radio"/> g/L
15. Amylase results Available?	(dilincdd: STDLABHX.LABHXN14) Not done

		<div><div>[97] <input type="radio"/> Yes</div><div>[1] <input type="radio"/> Not done</div><div>Amylase results (U/L)   xxxxxxxx   (dillncdd:STDLABHX.LABHXV14)</div><div>Amylase ULN   xxxxxxxx   (dillncdd:STDLABHX.LABHXL14)</div></div>
16.	Lipase results Available?	<div><div>(dillncdd:STDLABHX.LABHXN15)</div><div>[97] <input type="radio"/> Not done</div><div>[1] <input type="radio"/> Yes</div><div>Lipase results (U/L)   xxxxxxxx   (dillncdd:STDLABHX.LABHXV15)</div><div>Lipase ULN   xxxxxxxx   (dillncdd:STDLABHX.LABHXL15)</div></div>
17.	CPK results Available?	<div><div>(dillncdd:STDLABHX.LABHXN16)</div><div>[97] <input type="radio"/> Not done</div><div>[1] <input type="radio"/> Yes</div><div>CPK results (U/L)   xxxxxxxx   (dillncdd:STDLABHX.LABHXV16)</div><div>CPK ULN   xxxxxxxx   (dillncdd:STDLABHX.LABHXL16)</div></div>
18.	GGTP results Available?	<div><div>(dillncdd:STDLABHX.LABHXN17)</div><div>[97] <input type="radio"/> Not done</div><div>[1] <input type="radio"/> Yes</div><div>GGTP results (U/L)   xxxxxxxx   (dillncdd:STDLABHX.LABHXV17)</div><div>GGTP ULN   xxxxxxxx   (dillncdd:STDLABHX.LABHXL17)</div></div>
19.	LDH results Available?	<div><div>(dillncdd:STDLABHX.LABHXN18)</div><div>[97] <input type="radio"/> Not done</div><div>[1] <input type="radio"/> Yes</div><div>LDH results (U/L)   xxxxxxxx   (dillncdd:STDLABHX.LABHXV18)</div><div>LDH ULN   xxxxxxxx   (dillncdd:STDLABHX.LABHXL18)</div></div>
20.	When blood samples drawn, patient was	<div><div>(dillncdd:STDLABHX.BLDXSTAT)</div><div>[1] <input type="radio"/> Fasting</div><div>[2] <input type="radio"/> Fed</div><div>[99] <input type="radio"/> Unknown</div></div>

CDD: dillncdd Table: STDLABHX Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LABHXL18	FLOAT - F9.0	
LABHXN09	NUMERIC	
LABHXU12	NUMERIC	
LABHXV10	FLOAT - F9.0	
LABHXV15	FLOAT - F9.0	
LABHXV04	FLOAT - F9.0	
LABHXV09	FLOAT - F9.0	
LABHXN03	NUMERIC	
LABHXN12	NUMERIC	
LABHXU11	NUMERIC	
LABHXL16	FLOAT - F9.0	
BLDXSTAT	NUMERIC	
LABHXN16	NUMERIC	
LABHXN15	NUMERIC	
LABHXU06	NUMERIC	
LABHXV02	FLOAT - F9.0	
LABHXN04	NUMERIC	
LABHXV13	FLOAT - F9.0	
LABHXN17	NUMERIC	
LABHXU05	NUMERIC	
LABHXN02	NUMERIC	
LABHXV05	FLOAT - F9.0	
LABHXN10	NUMERIC	
LABHXV01	FLOAT - F9.0	
LABHXV17	FLOAT - F9.0	
LABHXV07	FLOAT - F9.0	
LABHXN08	NUMERIC	
LABHXL17	FLOAT - F9.0	
LABHXU13	NUMERIC	
LABHXN05	NUMERIC	
LABHXV14	FLOAT - F9.0	
LABHXN14	NUMERIC	
LABHXDT	DATE - DDMONYYYY	
LABHXV11	FLOAT - F9.0	
LABHXN11	NUMERIC	
LABHXN07	NUMERIC	
LABHXN18	NUMERIC	
LABHXL15	FLOAT - F9.0	
LABHXN01	NUMERIC	
LABHXU09	NUMERIC	
LABHXV18	FLOAT - F9.0	
LABHXN13	NUMERIC	
LABHXU04	NUMERIC	

LABHXU10	NUMERIC	
LABHXV08	FLOAT - F9.0	
LABHXL14	FLOAT - F9.0	
LABHXV12	FLOAT - F9.0	
LABHXN06	NUMERIC	
LABHXV03	FLOAT - F9.0	
LABHXV06	FLOAT - F9.0	
LABHXV16	FLOAT - F9.0	

## diliIndv2 : 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	<input type="text"/>							

Standard Lab Flowchart-Record all available labs from 8 weeks prior to the start of the implicated drug up to but excluding the day of the baseline visit.

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

CDD: diliIndcdd Table: STDFLOW Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SDBVAL	FLOAT - F9.0	
CREAT	NUMERIC	
HGBVAL	FLOAT - F9.0	
STDULN	FLOAT - F9.0	
EOSINVAL	FLOAT - F9.0	
CRETVALU	NUMERIC	
ALBUNVAL	FLOAT - F9.0	
EOSIVALU	NUMERIC	
STFLABDT	DATE - DDMYYYYY	
EOSIN	NUMERIC	
PLATE	NUMERIC	
ALBUN	NUMERIC	
WBCVAL	FLOAT - F9.0	
WBC	NUMERIC	
SDB	NUMERIC	
HGB	NUMERIC	
CREATVAL	FLOAT - F9.0	
SDBVALU	NUMERIC	
PLATEVAL	FLOAT - F9.0	
ALBUVALU	NUMERIC	

## dilindv2 : IMAGING STUDIES (IMAGE) - Repeating Form

#	Type of Imaging Study	Date of Imaging Study	Imaging Study Results	Spleen Diameter
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Imaging Studies

1. Type of Imaging Study	Pulldown List 1 <input type="button" value="v"/> (dilincdd: IMAGE.IMAGTYPE)
2. Date of Imaging Study	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (1935-2020) (dilincdd: IMAGE.IMAGEDT)
3. Imaging Study Results	<div>Check all that apply (dilincdd: IMAGE.BILIARY) [1] <input type="checkbox"/> Biliary dilation (dilincdd: IMAGE.TUMOR) [1] <input type="checkbox"/> Liver tumor (dilincdd: IMAGE.IMSPLENO) [1] <input type="checkbox"/> Splenomegaly (dilincdd: IMAGE.ASCITES) [1] <input type="checkbox"/> Ascites (dilincdd: IMAGE.GALLSTON) [1] <input type="checkbox"/> Gallstones (dilincdd: IMAGE.IMHEPATO) [1] <input type="checkbox"/> Hepatomegaly (dilincdd: IMAGE.NORMAL1) [1] <input type="checkbox"/> Normal study (dilincdd: IMAGE.NODULAR) [1] <input type="checkbox"/> Nodular contour of liver (dilincdd: IMAGE.VARCIES) [1] <input type="checkbox"/> Intra-abdominal varices (dilincdd: IMAGE.IMGOTH) [1] <input type="checkbox"/> Other Other Specify <input type="text" value="A200"/> (dilincdd: IMAGE.IMGSP) Other Specify continue <input type="text" value="A200"/> (dilincdd: IMAGE.IMGSP2)</div>
4. Spleen Diameter	(dilincdd: IMAGE.IMGSPDNA) [1] <input type="radio"/> xxxxxxxx (dilincdd: IMAGE.IMGSPLN) [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: dilincdd	Table: IMAGE	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
IMGSPDNA	NUMERIC	
IMGOTH	NUMERIC	
BILIARY	NUMERIC	
IMGSP	STRING(200) - A200	
IMGSPLN	FLOAT - F9.0	
IMGSP2	STRING(200) - A200	
IMHEPATO	NUMERIC	
VARCIES	NUMERIC	
NORMAL1	NUMERIC	
TUMOR	NUMERIC	
IMSPLENO	NUMERIC	
ASCITES	NUMERIC	
IMAGEDT	DATE - DDMMYYYY	
IMAGTYPE	NUMERIC - 1, 2, 3, 4, 5, 98	
NODULAR	NUMERIC	
GALLSTON	NUMERIC	

**dilindv2 : 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 If Yes, please complete the HEPLOG under the CAS visit.
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 If Yes, please complete the HBEAG Flowchart.
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 If Yes, please complete the ANTHBE Flowchart.
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 If Yes, please complete the ANTHDV Flowchart.
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 If Yes, please complete the HBVDNA Flowchart.
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 If Yes, please complete the HCVRNA Flowchart.

\* Item is not required

CDD: dilincdd Table: HEPSTAT Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
ANTHDVYN	NUMERIC	
HBEAGYN	NUMERIC	
HCVRNAYN	NUMERIC	
ANTHBEYN	NUMERIC	
HEPMEDYN	NUMERIC	
HEPB	NUMERIC	
HBVDNAYN	NUMERIC	
DELTA	NUMERIC	
HEPC	NUMERIC	

dilindv2 : HBeAG FLOW CHART (HBEAG) - Repeating Form

#		HBeAg Date	HBeAg Result
1	<div><div></div><div></div></div>		

HBeAG Flowchart

For PREISV visit: Please provide labs within 5 years up to prior to date of onset

For all other visits: Please provide labs since last visit

1	HBeAg Date	Req/Unk / Req/Unk / Req/Unk (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

CDD: dilincdd Table: HBEAG Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
HBEAGDT	DATE - DDMONYYYY	
HBEAGRS	NUMERIC	

dilindv2 : Anti-HBe FLOW CHART (ANTI HBE) - Repeating Form				
#		Anti-HBe Date	Anti-HBe Result	
1	<div></div>			
<b>Anti-Hbe Flowchart</b> For PREISV visit: Please provide labs within 5 years up to prior to date of onset For all other visits: Please provide labs since last visit				
1.	Anti-HBe Date	Req/Unk / Req/Unk / Req/Unk (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		

CDD: dilincdd Table: ANTIHBE Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ANTHBGRS	NUMERIC	
ANTHBEDT	DATE - DDMONYYYY	



dilindv2 : Anti-HDV (total) FLOW CHART (ANTIHDV) - Repeating Form

#		Anti-HDV Date	Anti-HDV Result	
1	<div><div></div></div>			

Anti-HDV (total) Flowchart  
For PREISV visit: Please provide labs within 5 years up to prior to date of onset  
For all other visits: Please provide labs since last visit

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

CDD: dilincdd Table: ANTIHDV Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ANTHDVDT	DATE - DDMONYYYY	
ANTHDVRS	NUMERIC	

dilindv2 : HBV DNA FLOW CHART (HBVDNA) - Repeating Form

#	HBV DNA Date	HBV DNA Results
1		

HBV DNA Flowchart

For PREISV visit: Please provide labs within 5 years up to prior to date of onset

For all other visits: Please provide labs since last visit

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

CDD: dilincdd Table: HBVDNA Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
HBVDT	DATE - DDMONYYYY	
HBVVAL	FLOAT - F9.0	
HBVUNIT	NUMERIC	
HBVALNA	NUMERIC	
HBVRSLT	NUMERIC	

dilindv2 : HCV RNA FLOW CHART (HCVRNA) - Repeating Form

#	HCV RNA Date	HCV RNA Results
1		

HCV RNA Flowchart

For PREISV visit: Please provide labs within 5 years up to prior to date of onset

For all other visits: Please provide labs since last visit

1. HCV RNA Date	Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd:HCVRNA.HCVDT)
2. HCV RNA Results	<div>(dilincdd:HCVRNA.HCVRSLT)</div> <div>[96] <input type="radio"/> Not available</div> <div>[0] <input type="radio"/> Negative</div> <div>[1] <input type="radio"/> (dilincdd:HCVRNA.HCVNALNA)</div> <div>Positive</div> <div>[96] <input type="radio"/> Not available</div> <div>[1] <input type="radio"/> HCV RNA Value xxxxxxxx (dilincdd:HCVRNA.HCVVAL)</div> <div>(dilincdd:HCVRNA.HCVUNIT)</div> <div>[1] <input type="radio"/> copies/mL</div> <div>[2] <input type="radio"/> IU/mL</div>

CDD: dilincdd	Table: HCVRNA	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
HCVVAL	Float - F9.0	
HCVNALNA	Numeric	
HCVUNIT	Numeric	
HCVDt	DATE - DDMONYYYY	
HCVRSLT	Numeric	

dilindv2 : HIV STATUS (HIVSTAT)

HIV Status

1. Did the patient have known HIV infection?

(dilincdd:HIVSTAT.HIV)

[0] ☐ No

[1] ☐ Yes

If Yes: What was the date of diagnosis?

Req/Unk  / Req/Unk  / Req/Unk  (1935-2020) (dilincdd: HIVSTAT.HIVDXDT)

CDD: dilincdd	Table: HIVSTAT	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
HIVDXDT	DATE - DDMONYYYY	
HIV	NUMERIC	

**dilindv2 : HIV STATUS (HIVSTAT1)**

<b>HIV Status continued</b>		
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/Unk <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/Unk <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
<b>List all substances for which the test was positive</b>		
3.		
<b>. Entry</b>		
3.a	List all substances for which the test was positive	ABO (dilincdd: HIVSTATA.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/Unk <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/Unk <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/Unk <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/Unk <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/Unk <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 If Yes, please complete the HIVSTAT2 form.
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 If Yes, please complete the HIVLOG under the CAS visit.
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 If Yes, please complete the HIVRNA Flowchart.
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 If Yes, please complete the CD4 Flowchart.

CDD: dilincdd	Table: HIVSTAT1	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
EVIDYN03	NUMERIC	
HIVMEDYN	NUMERIC	
EVIDRS01	NUMERIC	
EVIDUK03	NUMERIC	

EVIDUK01	NUMERIC	
EVIDDT01	DATE - DDMONYYYY	
EVIDUK05	NUMERIC	
AIDS	NUMERIC	
AIDSXDXT	DATE - DDMONYYYY	
EVIDRS02	NUMERIC	
EVIDUK04	NUMERIC	
EVIDDT03	DATE - DDMONYYYY	
EVIDYN02	NUMERIC	
HIVRNAYN	NUMERIC	
EVIDDT05	DATE - DDMONYYYY	
EVIDYN05	NUMERIC	
EVIDRS04	NUMERIC	
EVIDYN04	NUMERIC	
EVIDPOS	FLOAT - F9.0	
URINSCRN	NUMERIC	
URINTOX	NUMERIC	
EVIDYN01	NUMERIC	
EVIDDT04	DATE - DDMONYYYY	
SEROYN	NUMERIC	
EVIDRS03	NUMERIC	
URINDT	DATE - DDMONYYYY	
EVIDRS05	NUMERIC	
EVIDUK02	NUMERIC	
EVIDDT02	DATE - DDMONYYYY	
CD4RYN	NUMERIC	
URINUNK	NUMERIC	

CDD: dilincdd Table: HIVSTATA Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SUBSTANC	STRING(80) - A80	

## dilindv2 : HIV STATUS 2 (HIVSTAT2) - Repeating Form

#	Serology Type	Serology Date	Serology Value	Serology Value Unit	Serology Value ULN	Serology Results
1	<input type="text"/>					
.						
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 checked="" type="checkbox"/> / Req/Unk <input checked="" type="checkbox"/> / Req/Unk <input checked="" 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 checked="" 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
SERUM	NUMERIC	
SERORSLT	STRING(100) - A100	
SERUMULN	FLOAT - F9.0	
SERUMUNT	NUMERIC - 13, 5, 2, 4, 6, 8, 9, 1	
SERUMDT	DATE - DDMYYYY	
SEROTYPE	STRING(80) - A80	
SERUMVAL	STRING(100) - A100	

dilindv2 : CD4 FLOW CHART (CD4) - Repeating Form

#		CD4 Date	CD4 Value (cells/mm^3)
1	<div></div>		

CD4 Flowchart  
For PREISV visit: Please provide labs within 5 years up to prior to date of onset  
For all other visits: Please provide labs since last visit

1.	CD4 Date	Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd: CD4.CD4DT)
2.	CD4 Value (cells/mm^3)	xxxxxxx. (dilincdd: CD4.CD4VAL)

CDD: dilincdd Table: CD4 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CD4VAL	FLOAT - F9.0	
CD4DT	DATE - DDMONYYYY	



dilindv2 : HIV RNA FLOW CHART (HIVRNA) - Repeating Form			
#		HIV RNA Date	HIV RNA Value (copies/mL)
1	<div><div></div><div></div></div>		
HIV RNA Flowchart			
For PREISV visit: Please provide labs within 5 years up to prior to date of onset			
For all other visits: Please provide labs since last visit			
1.	HIV RNA Date	Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilncdd: HIVRNA.HIVRNADT)	
2.	HIV RNA Value (copies/mL)	xxxxxxx. (dilncdd: HIVRNA.HIVRVAL)	

CDD: dilncdd	Table: HIVRNA	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
HIVRVAL	FLOAT - F9.0	
HIVRNADT	DATE - DDMONYYYY	

dilindv2 : PHYSICAL EXAM (PEX1)		
Physical Exam		
1. Date of Physical Examination	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dilincdd: PEX1.PHEXDT)	
2. Weight (required)	xxxxxxx. (dilincdd: PEX1.WT)	
3. Weight Unit	(dilincdd: PEX1.WTUN) [1] <input type="radio"/> kg [2] <input type="radio"/> lbs	
4. Height (required)	xxxxxxx. (dilincdd: PEX1.HT)	
5. Height Unit	(dilincdd: PEX1.HTUN) [1] <input type="radio"/> cm [2] <input type="radio"/> in	
6. Heart rate (bpm)	xxx (dilincdd: PEX1.HRATE)	
7. Blood pressure systolic (mmHg)	xxx (dilincdd: PEX1.BPSYS)	
8. Blood pressure diastolic (mmHg)	xxx (dilincdd: PEX1.BPDIA)	

CDD: dilincdd	Table: PEX1	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PHEXDT	DATE - DDMONYYYY	
HRATE	NUMERIC - N3	
BPDIA	NUMERIC - N3	
HTUN	NUMERIC	
WTUN	NUMERIC	
WT	FLOAT - F9.0	
HT	FLOAT - F9.0	
BPSYS	NUMERIC - N3	

dilindv2 : 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 [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd: PEX2.PXABNL09) A200
10. Extremities	(dilincdd: PEX2.ASSESS10) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd: PEX2.PXABNL10) A200
11. Neurological	(dilincdd: PEX2.ASSESS11) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd: PEX2.PXABNL11) A200
12. Skin	(dilincdd: PEX2.ASSESS12) [97] <input type="radio"/> Not done [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal If Abnormal Provide Pertinent Details (dilincdd: PEX2.PXABNL12) A200
13. Musculoskeletal	(dilincdd: PEX2.ASSESS13)

		<div><div>[97] <input type="radio"/> Not done</div><div>[1] <input type="radio"/> Normal</div><div>[2] <input type="radio"/> Abnormal</div><div>If Abnormal Provide Pertinent Details (dlinccdd: PEX2.PXABNL13)</div><div><div>A200</div></div></div>
14.	Other	<div><div>(dlinccdd: PEX2.ASSESS14)</div><div>[97] <input type="radio"/> Not done</div><div>[1] <input type="radio"/> Normal</div><div>[2] <input type="radio"/> Abnormal</div><div>If Abnormal Provide Pertinent Details (dlinccdd: PEX2.PXABNL14)</div><div><div>A200</div></div></div>

CDD: dlinccdd	Table: PEX2	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PXABNL12	STRING(200) - A200	
PXABNL09	STRING(200) - A200	
ASSESS10	NUMERIC	
PXABNL02	STRING(200) - A200	
PXABNL06	STRING(200) - A200	
PXABNL11	STRING(200) - A200	
PXABNL14	STRING(200) - A200	
ASSESS03	NUMERIC	
PXABNL04	STRING(200) - A200	
ASSESS07	NUMERIC	
PXABNL03	STRING(200) - A200	
ASSESS01	NUMERIC	
PXABNL13	STRING(200) - A200	
PXABNL10	STRING(200) - A200	
PXABNL05	STRING(200) - A200	
ASSESS05	NUMERIC	
ASSESS13	NUMERIC	
ASSESS09	NUMERIC	
PXABNL08	STRING(200) - A200	
ASSESS06	NUMERIC	
ASSESS04	NUMERIC	
ASSESS11	NUMERIC	
ASSESS14	NUMERIC	
ASSESS02	NUMERIC	
ASSESS12	NUMERIC	
PXABNL01	STRING(200) - A200	
PXABNL07	STRING(200) - A200	
ASSESS08	NUMERIC	

**dilindv2 : DIAGNOSTIC LABS 1 (DXLAB1)****Diagnostic Labs-Provide labs collected between date of onset and 7 days post visit**

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 (Total or IgG) 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.	HBeAg available?	(dilincdd: DXLAB1.DLAB08) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes HBeAg Date   Req <input type="text"/> /   Req <input type="text"/> /   Req <input type="text"/> (2004-2020) (dilincdd: DXLAB1.DLABDT08) (dilincdd: DXLAB1.DRSLT08) HBeAg Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown
9.	Anti-HBe available?	(dilincdd: DXLAB1.DLAB09) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Anti-HBe Date   Req <input type="text"/> /   Req <input type="text"/> /   Req <input type="text"/> (2004-2020) (dilincdd: DXLAB1.DLABDT09) (dilincdd: DXLAB1.DRSLT09) Anti-HBe Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown
10.	HBV-DNA available?	(dilincdd: DXLAB1.DLAB10) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes HBV-DNA Date   Req <input type="text"/> /   Req <input type="text"/> /   Req <input type="text"/> (2004-2020) (dilincdd: DXLAB1.DLABDT10) (dilincdd: DXLAB1.DRSLT10) HBV-DNA Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown
11.	Anti-HDV available?	(dilincdd: DXLAB1.DLAB11) Not done

		<p>[97] <input type="radio"/> Yes</p> <p>[1] <input type="radio"/> Yes</p> <p>Anti-HDV Date   Req <input type="checkbox"/> /   Req <input type="checkbox"/> /   Req <input type="checkbox"/> (2004-2020) (dlinccdd: DXLAB1.DLABDT11)</p> <p>(dlinccdd: 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>(dlinccdd: 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="checkbox"/> /   Req <input type="checkbox"/> /   Req <input type="checkbox"/> (2004-2020) (dlinccdd: DXLAB1.DLABDT12)</p> <p>(dlinccdd: 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>(dlinccdd: DXLAB1.DLAB13)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>ANA Date   Req <input type="checkbox"/> /   Req <input type="checkbox"/> /   Req <input type="checkbox"/> (2004-2020) (dlinccdd: DXLAB1.DLABDT13)</p> <p>(dlinccdd: DXLAB1.DLABTP13)</p> <p>Type of test   [1] <input type="radio"/> IF   [2] <input type="radio"/> ELISA</p> <p>(dlinccdd: DXLAB1.DXTITR13)</p> <p>Threshold for positive results   [1] <input type="radio"/> Titer 1:   [2] <input type="radio"/> ULN</p> <p>Threshold Value   xxxxxxxx.   (dlinccdd: DXLAB1.DXULN13)</p> <p>(dlinccdd: 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.   (dlinccdd: DXLAB1.DXVAL13)</p>
14.	ASMA available?	<p>(dlinccdd: DXLAB1.DLAB14)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>ASMA Date   Req <input type="checkbox"/> /   Req <input type="checkbox"/> /   Req <input type="checkbox"/> (2004-2020) (dlinccdd: DXLAB1.DLABDT14)</p> <p>(dlinccdd: DXLAB1.DLABTP14)</p> <p>Type of test   [1] <input type="radio"/> IF   [2] <input type="radio"/> ELISA</p> <p>(dlinccdd: DXLAB1.DXTITR14)</p> <p>Threshold for positive results   [1] <input type="radio"/> Titer 1:   [2] <input type="radio"/> ULN</p> <p>Threshold Value   xxxxxxxx.   (dlinccdd: DXLAB1.DXULN14)</p> <p>(dlinccdd: DXLAB1.DRSLT14)</p> <p>Results   [99] <input type="radio"/> Unknown</p> <p>  [0] <input type="radio"/> Negative</p> <p>  [1] <input type="radio"/> Positive</p> <p>ASMA Value   xxxxxxxx.   (dlinccdd: DXLAB1.DXVAL14)</p>
15.	AMA available?	<p>(dlinccdd: DXLAB1.DLAB15)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>AMA Date   Req <input type="checkbox"/> /   Req <input type="checkbox"/> /   Req <input type="checkbox"/> (2004-2020) (dlinccdd: DXLAB1.DLABDT15)</p> <p>(dlinccdd: DXLAB1.DLABTP15)</p> <p>Type of test   [1] <input type="radio"/> IF   [2] <input type="radio"/> ELISA</p> <p>(dlinccdd: DXLAB1.DXTITR15)</p> <p>Threshold for positive results   [1] <input type="radio"/> Titer 1:   [2] <input type="radio"/> ULN</p> <p>Threshold Value   xxxxxxxx.   (dlinccdd: DXLAB1.DXULN15)</p> <p>(dlinccdd: DXLAB1.DRSLT15)</p> <p>Results   [99] <input type="radio"/> Unknown</p> <p>  [0] <input type="radio"/> Negative</p> <p>  [1] <input type="radio"/> Positive</p> <p>AMA Value   (dlinccdd: DXLAB1.DXVAL15)</p> <p>xxxxxxx.</p>
16.	Heterophile antibody or monospot available?	<p>(dlinccdd: DXLAB1.DLAB16)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>Heterophile antibody Date   Req <input type="checkbox"/> /   Req <input type="checkbox"/> /   Req <input type="checkbox"/> (2004-2020) (dlinccdd: DXLAB1.DLABDT16)</p> <p>(dlinccdd: DXLAB1.DRSLT16)</p> <p>Heterophile antibody Result   [0] <input type="radio"/> Negative</p> <p>  [1] <input type="radio"/> Positive</p> <p>  [99] <input type="radio"/> Unknown</p>
17.*	If Heterophile antibody result was positive, was EBV DNA performed?	<p>(dlinccdd: DXLAB1.EBVDNA)</p> <p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes</p> <p>EBV DNA Value (copies/mL) (dlinccdd: DXLAB1.EBVVAL)</p> <p>xxxxxxx.</p> <p>(dlinccdd: DXLAB1.EBVNA)</p> <p>[96] <input type="radio"/> Not Available</p>
18.	Serum ceruloplasmin (Only if age is less than or equal 50 years) available?	<p>(dlinccdd: DXLAB1.DLAB17)</p> <p>[97] <input type="radio"/> Not done</p> <p>[1] <input type="radio"/> Yes</p> <p>Serum ceruloplasmin Date   Req <input type="checkbox"/> /   Req <input type="checkbox"/> /   Req <input type="checkbox"/> (2004-2020) (dlinccdd: DXLAB1.DLABDT17)</p> <p>Serum ceruloplasmin Value (mg/dL)   xxxxxxxx.   (dlinccdd: DXLAB1.DRSLT17)</p> <p>Serum ceruloplasmin ULN (mg/dL)   xxxxxxxx.   (dlinccdd: DXLAB1.DXULN17)</p>

\* Item is not required

CDD: dlinccdd Table: DXLAB1 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note

DLAB15	NUMERIC	
DLAB12	NUMERIC	
DRSLT13	NUMERIC	
DLAB14	NUMERIC	
DLABDT13	DATE - DDMONYYYY	
DXTITR14	NUMERIC	
DLAB10	NUMERIC	
DRSLT09	NUMERIC	
DLABDT17	DATE - DDMONYYYY	
DLAB11	NUMERIC	
DXULN15	FLOAT - F9.0	
DXVAL14	FLOAT - F9.0	
DLABDT05	DATE - DDMONYYYY	
DRSLT07	NUMERIC	
DRSLT17	FLOAT - F9.0	
DLABDT06	DATE - DDMONYYYY	
DLABDT08	DATE - DDMONYYYY	
DRSLT08	NUMERIC	
DLAB13	NUMERIC	
DLABDT11	DATE - DDMONYYYY	
DRSLT11	NUMERIC	
DLAB08	NUMERIC	
DLABDT07	DATE - DDMONYYYY	
DRSLT16	NUMERIC	
EBVNA	NUMERIC	
DRSLT10	NUMERIC	
DRSLT05	NUMERIC	
DXTITR13	NUMERIC	
DLABDT14	DATE - DDMONYYYY	
DXVAL15	FLOAT - F9.0	
DLAB17	NUMERIC	
DLABDT09	DATE - DDMONYYYY	
DRSLT14	NUMERIC	
DLAB06	NUMERIC	
DLABDT16	DATE - DDMONYYYY	
DLABTP13	NUMERIC	
DXVAL13	FLOAT - F9.0	
DRSLT06	NUMERIC	
DXULN13	FLOAT - F9.0	
DLAB09	NUMERIC	
DXTITR15	NUMERIC	
EBVVAL	FLOAT - F9.0	
DRSLT12	NUMERIC	
DLAB07	NUMERIC	
DRSLT01	NUMERIC	
DLABTP15	NUMERIC	
DLAB16	NUMERIC	
DLABTP14	NUMERIC	
DRSLT02	NUMERIC	
DLAB03	NUMERIC	
DXULN17	FLOAT - F9.0	
DRSLT15	NUMERIC	
DLAB04	NUMERIC	
DLABDT12	DATE - DDMONYYYY	
DLABDT02	DATE - DDMONYYYY	
DRSLT04	NUMERIC	
DLAB05	NUMERIC	
DLABDT15	DATE - DDMONYYYY	
DLAB01	NUMERIC	
DLAB02	NUMERIC	
DLABDT10	DATE - DDMONYYYY	
DRSLT03	NUMERIC	
DLABDT01	DATE - DDMONYYYY	
EBVDNA	NUMERIC	
DXULN14	FLOAT - F9.0	
DLABDT04	DATE - DDMONYYYY	
DLABDT03	DATE - DDMONYYYY	

**dilindv2 : DIAGNOSTIC LABS 2 (DXLAB2)****Diagnostic Labs continued-Provide labs collected between date of onset and 7 days post visit**

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   Req <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   Req <input type="text"/> /   Req <input type="text"/> /   Req <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   Req <input type="text"/> /   Req <input type="text"/> /   Req <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?	(dilincdd: DXLAB2.DLAB26) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Anti HAV Date   Req <input type="text"/> /   Req <input type="text"/> /   Req <input type="text"/> (2004-2020) (dilincdd: DXLAB2.DLABDT26) (dilincdd: DXLAB2.DRSLT26) Anti HAV Result [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive [99] <input type="radio"/> Unknown

**CDD: dilincdd Table: DXLAB2 Key Type: PATIENTVISIT**

Column Name	Column Data Type	Design Note
DXULN21	FLOAT - F9.0	
DLABDT25	DATE - DDMONYYYY	
DXULN18	FLOAT - F9.0	
DXRSLT21	FLOAT - F9.0	
DXULN24	FLOAT - F9.0	
DLABDT19	DATE - DDMONYYYY	
DLAB24	NUMERIC	
DLAB20	NUMERIC	
DXRSLT23	FLOAT - F9.0	
DXULN20	FLOAT - F9.0	
DLAB23	NUMERIC	



DRSLT25	NUMERIC	
DXRSLT19	FLOAT - F9.0	
DXRSLT22	FLOAT - F9.0	
DLABDT18	DATE - DDMONYYYY	
DLABDT26	DATE - DDMONYYYY	
DLAB21	NUMERIC	
DXRSLT24	FLOAT - F9.0	
DLABDT20	DATE - DDMONYYYY	
DLABDT23	DATE - DDMONYYYY	
DLABDT21	DATE - DDMONYYYY	
DXRSLT18	FLOAT - F9.0	
DXULN23	FLOAT - F9.0	
DXULN19	FLOAT - F9.0	
DXULN22	FLOAT - F9.0	
DLAB25	NUMERIC	
DLAB22	NUMERIC	
DLAB18	NUMERIC	
DLAB19	NUMERIC	
DLABDT24	DATE - DDMONYYYY	
DXRSLT20	FLOAT - F9.0	
DRSLT26	NUMERIC	
DLAB26	NUMERIC	
DLABDT22	DATE - DDMONYYYY	

dilindv2 : DIAGNOSTIC LABS 3 (DXLAB3)

Diagnostic Labs continued-Provide labs collected between date of onset and 7 days post visit

1.

Serum protein electrophoresis

(dilincdd: DXLAB3.DXLABSPE)  
[97] ☐ Not done  
[1] ☐ Yes

Serum protein electrophoresis Date | Req ☐ / | Req ☐ / | Req ☐ (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] ☐ No  
[1] ☐ Yes  
If yes, complete SEROFLOW under CAS visit

\* Item is not required

CDD: dilincdd	Table: DXLAB3	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
SPEBETA	FLOAT - F9.0	
SPELABDT	DATE - DDMONYYYY	
SPEGAMMA	FLOAT - F9.0	
SPECOMM	STRING(200) - A200	
SPEALPH1	FLOAT - F9.0	
SPEALPH2	FLOAT - F9.0	
DXLABSPE	NUMERIC	
SPETPRO	FLOAT - F9.0	
SPEALBUN	FLOAT - F9.0	
DXLABSER	NUMERIC	

**dilindv2 : STANDARD LABS (STDLAB)****Standard Labs-Provide labs on or closest to the date of visit.**

1. Lab Date	Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <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) (dilincdd:STDLAB.LABUNT04) % 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 [1] <input type="radio"/> Yes BUN value   xxxxxxxx   (dilincdd:STDLAB.LABVAL10) (dilincdd:STDLAB.LABUNT10) Bun unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L
13. Cholesterol available?	(dilincdd:STDLAB.LABNAM11) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Cholesterol value   xxxxxxxx   (dilincdd:STDLAB.LABVAL11) (dilincdd:STDLAB.LABUNT11) Cholesterol unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L
14. Triglycerides available?	(dilincdd:STDLAB.LABNAM12) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Triglycerides value   xxxxxxxx   (dilincdd:STDLAB.LABVAL12) (dilincdd:STDLAB.LABUNT12) Triglycerides unit [5] <input type="radio"/> mg/dL [6] <input type="radio"/> mmol/L

CDD: dilincdd Table: STDLAB Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LABNAM02	NUMERIC	

LABUNT11	NUMERIC	
LABNAM03	NUMERIC	
LABNAM07	NUMERIC	
LABNAM05	NUMERIC	
LABVAL05	FLOAT - F9.0	
LABVAL04	FLOAT - F9.0	
LABUNT10	NUMERIC	
LABNAM08	NUMERIC	
LABNAM11	NUMERIC	
LABNAM12	NUMERIC	
LABNAM09	NUMERIC	
STDLABDT	DATE - DDMONYYYY	
LABVAL07	FLOAT - F9.0	
LABUNT09	NUMERIC	
LABVAL10	FLOAT - F9.0	
LABUNT06	NUMERIC	
LABVAL11	FLOAT - F9.0	
LABNAM01	NUMERIC	
LABUNT04	NUMERIC	
LABVAL02	FLOAT - F9.0	
LABUNT12	NUMERIC	
LABNAM06	NUMERIC	
LABVAL12	FLOAT - F9.0	
LABNAM04	NUMERIC	
LABVAL06	FLOAT - F9.0	
LABVAL09	FLOAT - F9.0	
LABVAL03	FLOAT - F9.0	
LABNAM10	NUMERIC	
LABUNT05	NUMERIC	
BLDSTATE	NUMERIC	
LABVAL08	FLOAT - F9.0	
LABVAL01	FLOAT - F9.0	

**dilindv2 : STANDARD LABS (STDLAB2)****Standard Labs-Provide labs on or closest to the date of visit.**

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   [1] <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   [1] <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) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Amylase value (U/L)   xxxxxxxx.   (dilincdd: STDLAB2.LABVAL22) Amylase ULN   xxxxxxxx.   (dilincdd: STDLAB2.LABULN22)
11.	Lipase available?	(dilincdd: STDLAB2.LABNAM23) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Lipase value (U/L)   xxxxxxxx.   (dilincdd: STDLAB2.LABVAL23) Lipase ULN   xxxxxxxx.   (dilincdd: STDLAB2.LABULN23)
12.	CPK available?	(dilincdd: STDLAB2.LABNAM24) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes CPK value (U/L)   xxxxxxxx.   (dilincdd: STDLAB2.LABVAL24) CPK ULN   xxxxxxxx.   (dilincdd: STDLAB2.LABULN24)
13.	GGTP available?	(dilincdd: STDLAB2.LABNAM25) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes GGTP value (U/L)   xxxxxxxx.   (dilincdd: STDLAB2.LABVAL25) GGTP ULN   xxxxxxxx.   (dilincdd: STDLAB2.LABULN25)
14.	LDH available?	(dilincdd: STDLAB2.LABNAM26) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes

CDD: dlinccd Table: STDLAB2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LABULN23	FLOAT - F9.0	
LABVAL13	FLOAT - F9.0	
LABULN25	FLOAT - F9.0	
LABNAM22	NUMERIC	
LABVAL26	FLOAT - F9.0	
LABUNT13	NUMERIC	
LABULN26	FLOAT - F9.0	
LABVAL15	FLOAT - F9.0	
LABNAM25	NUMERIC	
LABNAM23	NUMERIC	
LABNAM18	NUMERIC	
LABVAL23	FLOAT - F9.0	
LABULN18	FLOAT - F9.0	
LABNAM26	NUMERIC	
LABNAM21	NUMERIC	
LABNAM15	NUMERIC	
LABVAL18	FLOAT - F9.0	
LABVAL17	FLOAT - F9.0	
LABVAL20	FLOAT - F9.0	
LABNAM13	NUMERIC	
LABULN22	FLOAT - F9.0	
LABNAM17	NUMERIC	
LABULN21	FLOAT - F9.0	
LABULN19	FLOAT - F9.0	
LABUNT18	NUMERIC	
LABUNT17	NUMERIC	
LABUNT14	NUMERIC	
LABVAL19	FLOAT - F9.0	
LABULN20	FLOAT - F9.0	
LABNAM19	NUMERIC	
LABNAM20	NUMERIC	
LABVAL21	FLOAT - F9.0	
LABVAL24	FLOAT - F9.0	
LABVAL14	FLOAT - F9.0	
LABVAL22	FLOAT - F9.0	
LABVAL16	FLOAT - F9.0	
LABNAM14	NUMERIC	
LABVAL25	FLOAT - F9.0	
LABNAM24	NUMERIC	
LABULN17	FLOAT - F9.0	
LABULN24	FLOAT - F9.0	
LABNAM16	NUMERIC	

**dilindv2 : URINALYSIS (URINE)****Urinalysis**

1.*	Labs-Urinalysis Date <i>[hidden]</i>	Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dilincdd: URINE.URINEDT)
2.*	Specific gravity available? <i>[hidden]</i>	(dilincdd: URINE.GRAVTYN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Specific gravity value   xxxxxxxx   (dilincdd: URINE.GRAVITY)
3.*	pH available? <i>[hidden]</i>	(dilincdd: URINE.PHYN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes pH value   xxxxxxxx   (dilincdd: URINE.PH)
4.*	Glucose available? <i>[hidden]</i>	(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? <i>[hidden]</i>	(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? <i>[hidden]</i>	(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? <i>[hidden]</i>	(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? <i>[hidden]</i>	(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? <i>[hidden]</i>	(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 [1] <input type="radio"/> count/HPF [2] <input type="radio"/> uL
10.*	Casts available? <i>[hidden]</i>	(dilincdd: URINE.CASTYN) [97] <input type="radio"/> Not done [2] <input type="radio"/> Not Reported [1] <input type="radio"/> Yes Casts value   A20   (dilincdd: URINE.CASTVAL) (dilincdd: URINE.CASTUNIT) Casts unit [1] <input type="radio"/> count/HPF [2] <input type="radio"/> count/LPF
11.*	Crystals available? <i>[hidden]</i>	(dilincdd: URINE.CRSTYN) [97] <input type="radio"/> Not done [2] <input type="radio"/> Not Reported [1] <input type="radio"/> Yes Crystals value   A20   (dilincdd: URINE.CRSTVAL) (dilincdd: URINE.CRSTUNIT) Crystals unit [1] <input type="radio"/> count/HPF [2] <input type="radio"/> count/LPF
12.*	Bacteria available? <i>[hidden]</i>	(dilincdd: URINE.BACYN) [97] <input type="radio"/> Not done [2] <input type="radio"/> Not Reported [1] <input type="radio"/> Yes Bacteria value   A20   (dilincdd: URINE.BACVAL) (dilincdd: URINE.BACUNIT) Bacteria unit [1] <input type="radio"/> count/HPF

		[2] 
* Item is not required		

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: dilincdd	Table: URINE	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
CRSTUNIT	NUMERIC	
GRAVITY	FLOAT - F9.0	
WBCUNIT	NUMERIC	
BILRUBYN	NUMERIC	
PROTOTH	STRING(50) - A50	
LEUKOCYT	NUMERIC	
BACUNIT	NUMERIC	
BACYN	NUMERIC	
BILIOTH	STRING(50) - A50	
CASTYN	NUMERIC	
GRAVTYN	NUMERIC	
CASTVAL	STRING(20) - A20	
GLUCOSYN	NUMERIC	
PH	FLOAT - F9.0	
URWBCVAL	STRING(20) - A20	
GLUCOSE	NUMERIC - 1, 2, 3, 4, 5, 6, 98	
CRSTVAL	STRING(20) - A20	
WBCYN	NUMERIC	
LEUKOTH	STRING(50) - A50	
PROTEYN	NUMERIC	
RBCYN	NUMERIC	
PROTEIN	NUMERIC - 1, 2, 3, 4, 5, 98	
URINEDT	DATE - DDMONYYYY	
CASTUNIT	NUMERIC	
RBCUNIT	NUMERIC	
BILRUBIN	NUMERIC	
BACVAL	STRING(20) - A20	
CRSTYN	NUMERIC	
RBCVAL	STRING(20) - A20	
GLUCOTH	STRING(50) - A50	
LEUKOCYN	NUMERIC	
PHYN	NUMERIC	



dilindv2 : 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? [hidden]	(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.	When blood samples drawn, patient was?	(dilincdd:RSAMPLE.SAMPSTAT) [1] <input type="radio"/> Fasting [2] <input type="radio"/> Fed [99] <input type="radio"/> Unknown
4.	Did the subject receive a Liver Biopsy?	(dilincdd:RSAMPLE.LVBIOPYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
* Item is not required		

CDD: dilincdd	Table: RSAMPLE	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
URINEDT	DATE - DDMONYYYY	
BLDSAMP	NUMERIC	
LVBIOPYN	NUMERIC	
URNSAMP	NUMERIC	
SAMPSTAT	NUMERIC	
BLOODDT	DATE - DDMONYYYY	

dilindv2 : 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
5.	Has the patient taken suspect drug(s) in the same class? (Check Epocrates)	(dilincdd: INTHX.PDRUGS) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, please enter the DILIMED page
6.	Has the patient taken corticosteroids since the last visit?	(dilincdd: INTHX.PSTEROID) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please add to the CONMED page
7.	Has the patient taken Ursodeoxycholic acid since the last visit?	(dilincdd: INTHX.PURSOACD) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please add to the CONMED page
8.	Has the patient taken Azathioprine or Imuran since the last visit?	(dilincdd: INTHX.PIMURAN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please add to the CONMED page
9.	Has the patient taken Celcept (Mycophenolote Mofetil) since the last visit?	(dilincdd: INTHX.PCELCEPT) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, please add to the CONMED page
10.	Has the patient taken any other immunosuppressive medication(s) since the last visit?	(dilincdd: INTHX.PIMMOTH) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Specify   A200   (dilincdd: INTHX.PIMOTHSP) If yes, please add to the CONMED page

CDD: dilincdd	Table: INTHX	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PCELCEPT	NUMERIC	
PIMURAN	NUMERIC	
PSTEROID	NUMERIC	
PDRUGS	NUMERIC	
PURSOACD	NUMERIC	
PMEDHX	NUMERIC	
PALGYHX	NUMERIC	
PIMOTHSP	STRING(200) - A200	
PLIVHX	NUMERIC	
PIMMOTH	NUMERIC	
PSRGYHX	NUMERIC	

dilindv2 : 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
ERHX	NUMERIC	
PHYSLV	NUMERIC	
HOSHX	NUMERIC	

## diliindv2 : 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	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

ER Visit

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

CDD: diliincdd Table: ERRMHX Key Type: PATIENTVISIT

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

## dilindv2 : 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:	A50 (dilincdd: HOSPHX.HOSPNM)
2.	City:	A25 (dilincdd: HOSPHX.HOSPCY)
3.	State:	A5 (dilincdd: HOSPHX.HOSPSTE)
4.	Date admitted:	Req/Unk / Req/Unk / Req/Unk (2004-2020) (dilincdd: HOSPHX.HOSADMDT)
5.	Date discharged:	(dilincdd: HOSPHX.HOSTYP) [2] Req/Unk / Req/Unk / Req/Unk (2004-2020) (dilincdd: HOSPHX.HOSDISDT) OR [1] Total number of days hospitalized: (dilincdd: HOSPHX.HOSTOTNU) xxxxxxxx.
6.	Admission diagnosis:	A200 (dilincdd: HOSPHX.HOSADMDX)
7.	Was the hospitalization DILI-related?	(dilincdd: HOSPHX.HSDILIRD) [0] No [1] Yes [99] Unknown
8.	Were liver function tests performed?	(dilincdd: HOSPHX.HOSLIVTS) [0] No [1] Yes [99] Unknown
9.	Were abdominal imaging studies performed?	(dilincdd: HOSPHX.HOSABIMG) [0] No [1] Yes [99] Unknown
10.	Discharge diagnosis:	A200 (dilincdd: HOSPHX.HOSDISCH)

CDD: dilincdd Table: HOSPHX Key Type: PATIENTVISIT

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

dilindv2 : 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	<div><div></div></div>									

Medical Appointment Visit

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

CDD: dilincdd	Table: APPTHIST	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PSTE	STRING(5) - A5	
PCITY	STRING(25) - A25	
DILIABIM	NUMERIC	
DILILF	NUMERIC	
PHYSICIA	STRING(25) - A25	
PHYSPEC	STRING(50) - A50	
MEDAP PDT	DATE - DDMYYYY	
REASVT	STRING(200) - A200	
DILIREL	NUMERIC	

dilindv2 : IMAGING STUDIES (ABDIMAGE)

Imaging Studies

1. Were abdominal imaging studies performed since the last visit?

(dilincdd: ABDIMAGE.ABDIMG)  
[0] ☐ No  
[1] ☐ Yes

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

**dilindv2 : 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 If yes: (dilincdd:MEDOUT.LOCTRANS) Document location of transplant: A200 Document date of transplant: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2004-2020) (dilincdd:MEDOUT.TRANSOT) (dilincdd:MEDOUT.MOSTAT1) Was patient in status 1 when liver transplant was performed? [0] <input type="radio"/> No [1] <input type="radio"/> Yes
2.*	If patient did not undergo a liver transplant, please provide reason	(dilincdd:MEDOUT.MONOTRX) [1] <input type="radio"/> Improvement [2] <input type="radio"/> Deterioration (or: too sick) [3] <input type="radio"/> Death prior to transplant [98] <input type="radio"/> Other Other Specify (dilincdd:MEDOUT.MNOTRXSP) A50
3.*	Has the patient expired since the last visit? [hidden]	(dilincdd:MEDOUT.EXLSTVI) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
4.	Was the patient listed for liver transplantation since the last visit?	(dilincdd:MEDOUT.MOTRXLST) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date listing for liver transplant Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1935-2020) (dilincdd:MEDOUT.MOTLSTDT) (dilincdd:MEDOUT.MOLSTS1) Was patient in status 1 at the time of listed for liver transplant? [0] <input type="radio"/> No [1] <input type="radio"/> Yes

\* Item is not required

CDD: dilincdd	Table: MEDOUT	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
MOTRXLST	NUMERIC	
MOSTAT1	NUMERIC	
LIVTRANS	NUMERIC	
MOLSTS1	NUMERIC	
EXLSTVI	NUMERIC	
LOCTRANS	STRING(200) - A200	
MOTLSTDT	DATE - DDMONYYYY	
TRANSOT	DATE - DDMONYYYY	
MNOTRXSP	STRING(50) - A50	
MONOTRX	NUMERIC	



**dilindv2 : 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 If Yes, please complete the HEPLOG under the CAS visit.
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 If Yes, please complete the HBEAG Flowchart.
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 If Yes, please complete the ANTIHBE Flowchart.
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 If Yes, please complete the HBVDNA Flowchart.
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 If Yes, please complete the HCVRNA Flowchart.

\* Item is not required

**CDD: dilincdd Table: HEPSTATC Key Type: PATIENTVISIT**

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

dilindv2 : INTERVAL HIV STATUS (HIVSTATC)

Interval HIV Status

1. Did the patient have HIV infection at the last study visit?

(dilincdd:HIVSTATC.HIVINF)

[0] ☐ No

[1] ☐ Yes (dilincdd:HIVSTATC.AIDSLV)  
If Yes: Has the condition progressed to AIDS since the last visit?  
[0] ☐ No  
[1] ☐ Yes  
If Yes What was the date of this diagnosis?  
Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd:HIVSTATC.AIDSLVDT)

2.\* If Q #1 = No: Was the patient diagnosed with HIV infection since the last visit?

(dilincdd:HIVSTATC.HIVLV)

[0] ☐ No

[1] ☐ Yes  
If Yes, Date of diagnosis  
Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd:HIVSTATC.HIVDIADT)  
(dilincdd:HIVSTATC.AIDSPRO)  
Did the condition progress to AIDS?  
[0] ☐ No  
[1] ☐ Yes  
If Yes What was the date of this diagnosis?  
Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd:HIVSTATC.AIDSDT)

\* Item is not required

CDD: dilincdd	Table: HIVSTATC	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
HIVINF	NUMERIC	
HIVLV	NUMERIC	
AIDSPRO	NUMERIC	
AIDSLVDT	DATE - DDMONYYYY	
AIDSLV	NUMERIC	
AIDSDT	DATE - DDMONYYYY	
HIVDIADT	DATE - DDMONYYYY	

http://ims46ad01.dcri.int/dilindv2/pfts.dll?Z=F0705EBB7D51560A3B005479621C352A&C=TM\_169&FMID=0&FMRV=0&ISID=0&ITID=0&VM=2&TN=dilindv2&SP=&AS=59391&CP=65535&FP=0&RSV=0

7/27/2017

**dilindv2 : INTERVAL HIV STATUS (HIVSTAT3)****Interval HIV Status**

1.	Was a urine toxicology screen done since the last visit?	<div>(dilincdd: HIVSTAT3.URTXYN) [97] <input type="radio"/> Not done</div> <div> <div>[1] <input type="radio"/> Date of result</div> <div> <div>(dilincdd: HIVSTAT3.URTXNK) [1] <input type="radio"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> (1935- (dilincdd: HIVSTAT3.URTXDT) [99] <input type="radio"/> Unknown 2020)</div> <div>(dilincdd: HIVSTAT3.URTXSCR) [0] <input type="radio"/> Negative [1] <input type="radio"/> Positive</div> </div> </div>
List all substances for which the test was positive		
2.		
<b>. Entry</b>		
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?	<div>(dilincdd: HIVSTAT3.EVRTYN01) [97] <input type="radio"/> Not done</div> <div> <div>[1] <input type="radio"/> Date of result</div> <div> <div>(dilincdd: HIVSTAT3.EVRTUK01) [1] <input type="radio"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> (1935- (dilincdd: HIVSTAT3.EVRTDT01) [99] <input type="radio"/> Unknown 2020)</div> <div>(dilincdd: HIVSTAT3.EVIDRT01) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive</div> </div> </div> <div>CMV DNA calue (copies/ml) (dilincdd: HIVSTAT3.EVID1VAL) xxxxxxxxx.</div>
4.	Did the patient have evidence of herpes simplex viral infection (HSV IGM) since the last visit?	<div>(dilincdd: HIVSTAT3.EVRTYN02) [97] <input type="radio"/> Not done</div> <div> <div>[1] <input type="radio"/> Date of result</div> <div> <div>(dilincdd: HIVSTAT3.EVRTUK02) [1] <input type="radio"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> (1935- (dilincdd: HIVSTAT3.EVRTDT02) [99] <input type="radio"/> Unknown 2020)</div> <div>(dilincdd: HIVSTAT3.EVIDRT02) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive</div> </div> </div>
5.	Did the patient have evidence of syphilis by VDRL (Venereal Disease Research Laboratory) since the last visit?	<div>(dilincdd: HIVSTAT3.EVRTYN03) [97] <input type="radio"/> Not done</div> <div> <div>[1] <input type="radio"/> Date of result</div> <div> <div>(dilincdd: HIVSTAT3.EVRTUK03) [1] <input type="radio"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> (1935- (dilincdd: HIVSTAT3.EVRTDT03) [99] <input type="radio"/> Unknown 2020)</div> <div>(dilincdd: HIVSTAT3.EVIDRT03) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive</div> </div> </div>
6.	Did the patient have evidence of syphilis by RPR (Rapid Plasma Reagent) since the last visit?	<div>(dilincdd: HIVSTAT3.EVRTYN04) [97] <input type="radio"/> Not done</div> <div> <div>[1] <input type="radio"/> Date of result</div> <div> <div>(dilincdd: HIVSTAT3.EVRTUK04) [1] <input type="radio"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> (1935- (dilincdd: HIVSTAT3.EVRTDT04) [99] <input type="radio"/> Unknown 2020)</div> <div>(dilincdd: HIVSTAT3.EVIDRT04) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive</div> </div> </div>
7.	Did the patient have evidence of a MAI infection (mycobacterium avium intracellulare) since the last visit?	<div>(dilincdd: HIVSTAT3.EVRTYN05) [97] <input type="radio"/> Not done</div> <div> <div>[1] <input type="radio"/> Date of result</div> <div> <div>(dilincdd: HIVSTAT3.EVRTUK05) [1] <input type="radio"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> / <input type="checkbox"/> Req/Unk <input type="checkbox"/> (1935- (dilincdd: HIVSTAT3.EVRTDT05) [99] <input type="radio"/> Unknown 2020)</div> <div>(dilincdd: HIVSTAT3.EVIDRT05) [2] <input type="radio"/> Undetectable [1] <input type="radio"/> Positive</div> </div> </div>
8.	Did the patient have any pertinent serologies/serum levels performed since the last visit?	<div>(dilincdd: HIVSTAT3.SEROCYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, please complete the HIVSTAT2 form.</div>
9.	Did the patient use any non-implicated anti-retrovirals taken within 5 years of onset of DILI event?	<div>(dilincdd: HIVSTAT3.HVMEDCYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, please complete the HIVLOG under the CAS visit.</div>
10.	Did the patient have any available HIV RNA results since the last visit?	<div>(dilincdd: HIVSTAT3.HVRNACYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, please complete the HIVRNA Flowchart.</div>
11.	Did the patient have any available CD4 results since the last visit?	<div>(dilincdd: HIVSTAT3.CD4RCYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, please complete the CD4 Flowchart.</div>

CDD: dilincdd	Table: HIVSTAT3	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
EVRTUK01	NUMERIC	
EVRTDT02	DATE - DDMONYYYY	
URTXDT	DATE - DDMONYYYY	
EVRTYN01	NUMERIC	
EVRTDT05	DATE - DDMONYYYY	
EVIDRT04	NUMERIC	
EVRTYN02	NUMERIC	
EVRTDT03	DATE - DDMONYYYY	

EVRTUK05	NUMERIC	
EVRTYN05	NUMERIC	
HVRNACYN	NUMERIC	
URTXYN	NUMERIC	
URTXSCR	NUMERIC	
EVRTYN04	NUMERIC	
EVIDRT05	NUMERIC	
EVRTYN03	NUMERIC	
EVRTUK03	NUMERIC	
SEROCYN	NUMERIC	
EVIDRT01	NUMERIC	
EVID1VAL	FLOAT - F9.0	
EVIDRT02	NUMERIC	
CD4RCYN	NUMERIC	
HVMEDCYN	NUMERIC	
EVRTDT01	DATE - DDMONYYYY	
URTXNK	NUMERIC	
EVIDRT03	NUMERIC	
EVRTUK04	NUMERIC	
EVRTDT04	DATE - DDMONYYYY	
EVRTUK02	NUMERIC	

CDD: dilincdd    Table: HIVSTATB    Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PSSBSTNC	STRING(80) - A80	

dilindv2 : INTERVAL QUESTIONNAIRES (QUESTS2)

Interval Questionnaires

1.

Surrogate respondent?

(dilincdd:QUESTS2.SURRO4)

[0] ☐ No

[1] ☐ Yes

(dilincdd:QUESTS2.SURSPEC4)

Specify Surrogate

[1] ☐ Relative

[98] ☐ Other

2.

\* Since the last visit, how would you describe your smoking habit? *[hidden]*

(dilincdd:QUESTS2.SMOKE6)

[1] ☐ Never smoked

[3] ☐ Current smoker

[2] ☐ 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] ☐ No

[1] ☐ Yes

\* Item is not required

CDD: dilincdd	Table: QUESTS2	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
ALCOHOLX	NUMERIC	
SURRO4	NUMERIC	
SURSPEC4	NUMERIC	
SMOKE6	NUMERIC	
QUITSMKM	FLOAT - F9.0	

dilindv2 : INTERVAL GENERAL SMOKING HISTORY (GENSMOK6)

Interval General Smoking History

1. \*

What is/was your smoking preference(s)? [hidden]

(dilincdd:GENSMOK6.CIGARET6)

[1] ☐ Cigarette

(dilincdd:GENSMOK6.CIGARS6)

[1] ☐ Cigar

(dilincdd:GENSMOK6.PIPE6)

[1] ☐ Pipe

2. \*

Do/did you regularly inhale tobacco when smoking? [hidden]

(dilincdd:GENSMOK6.SMKINHA6)

[0] ☐ No

[1] ☐ Yes

\* Item is not required

CDD: dilincdd    Table: GENSMOK6    Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SMKINHA6	NUMERIC	
PIPE6	NUMERIC	
CIGARS6	NUMERIC	
CIGARET6	NUMERIC	

**dilindv2 : 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
<b>Immunosuppressive Therapy</b>		
11.	The participant is/continues on immunosuppressive therapy for their DILI event	(dilincdd: CHRONIC.CINEXC11) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilincdd Table: CHRONIC Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CINEXC6	NUMERIC	
CINEXC2	NUMERIC	
CINEXC1	NUMERIC	
CINEXC5	NUMERIC	
CINEXC7	NUMERIC	
CINEXC10	NUMERIC	
CINEXC8	NUMERIC	
CINEXC9	NUMERIC	
CINEXC3	NUMERIC	
CINEXC4	NUMERIC	
CINEXC11	NUMERIC	

dilindv2 : 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
CONCHXYN	NUMERIC	
CONMHXYN	NUMERIC	



dilindv2 : CONCOMITANT MEDICATIONS (CONMED) - Repeating Form

#	Medication	Start Date	Stop Date
1			

Concomitant Medications

1. Medication

Do not record hepatitis or HIV meds here (dilincdd: CONMED.MEDNAME)  
A80

2. Start Date

Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd: CONMED.MEDSTDT)

3. Stop Date

(dilincdd: CONMED.MEDCONT)  
[2] Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd: CONMED.MEDSPDT)  
[1] Continuing

CDD: dilincdd	Table: CONMED	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
MEDNAME	STRING(80) - A80	
MEDCONT	NUMERIC	
MEDSTDT	DATE - DDMONYYYY	
MEDSPDT	DATE - DDMONYYYY	

dilindv2 : CONCOMITANT CAM PRODUCTS (CONCAM) - Repeating Form

#	Brand or commercial name	Common names	Start Date	Stop Date
1	<div><div></div></div>			

Concomitant CAM Products

1. Brand or commercial name

A80 (dilincdd:CONCAM.CAMBRAND)

2. Common names

A80 (dilincdd:CONCAM.CAMCOMM)

3. Start Date

Req/Unk  / Req/Unk  / Req/Unk  (1935-2020) (dilincdd:CONCAM.CAMLSTDT)

4. Stop Date

(dilincdd:CONCAM.CAMLCONT)  
[2]  Req/Unk  / Req/Unk  / Req/Unk  (1935-2020) (dilincdd:CONCAM.CAMLSPDT)  
[1]  Continuing

CDD: dilincdd	Table: CONCAM	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
CAMBRAND	STRING(80) - A80	
CAMCOMM	STRING(80) - A80	
CAMLSPDT	DATE - DDMONYYYY	
CAMLCONT	NUMERIC	
CAMLSTDT	DATE - DDMONYYYY	

dlilndv2 : HEPATITIS MEDICATIONS LOG (HEPLOG) - Repeating Form

#	Medication	Start Date	Stop Date
1	<div><div></div></div>		

Hepatitis Medications Log

1. Medication	<div>A80</div> <div>(dlilncdd: HEPLOG.HEPMED)</div>
2. Start Date	<div>Req/Unk / Req/Unk / Req/Unk (1935-2020)</div> <div>(dlilncdd: HEPLOG.HEPSTDT)</div>
3. Stop Date	<div>(dlilncdd: HEPLOG.HEPCONT)</div> <div><div>[2]</div> <div>Req/Unk / Req/Unk / Req/Unk (1935-2020)</div> <div>(dlilncdd: HEPLOG.HEPSPDT)</div></div>

[1]

Continuing

CDD: dlilncdd	Table: HEPLOG	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
HEPSPDT	DATE - DDMONYYYY	
HEPSTDT	DATE - DDMONYYYY	
HEPMED	STRING(80) - A80	
HEPCONT	NUMERIC	

## dilindv2 : HIV MEDICATION LOG (HIVLOG) - Repeating Form

#	Medication	Dose	Unit	Frequency	Route	Start Date	Stop Date
1	<input type="text"/>						

  

HIV Medication Log	
1. Medication	<input type="text" value="A80"/> (dilincdd: HIVLOG.HIVMED)
2. Dose	<input type="text" value="A5"/> (dilincdd: HIVLOG.HIVDOSE)
3. Unit	<input type="text" value="A8"/> (dilincdd: HIVLOG.HIVUNIT)
4. Frequency	Pulldown List 1 <input type="text" value="1"/> (dilincdd: HIVLOG.HIVFREQ) Specify Frequency <input type="text" value="A100"/> (dilincdd: HIVLOG.HIVFREQSP)
5. Route	Pulldown List 2 <input type="text" value="1"/> (dilincdd: HIVLOG.HIVROUTE) Specify Route <input type="text" value="A100"/> (dilincdd: HIVLOG.HIVRTESP)
6. Start Date	<input type="text" value="Req/Unk"/> / <input type="text" value="Req/Unk"/> / <input type="text" value="Req/Unk"/> (1935-2020) (dilincdd: HIVLOG.HIVSTDT)
7. Stop Date	(dilincdd: HIVLOG.HIVCONT) <input checked="" type="radio"/> <input type="radio"/> <input type="text" value="Req/Unk"/> / <input type="text" value="Req/Unk"/> / <input type="text" value="Req/Unk"/> (1935-2020) (dilincdd: HIVLOG.HIVSPDT) <input type="radio"/> 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
HIVCONT	NUMERIC	
HIVROUTE	NUMERIC - 1, 2, 3, 4, 5, 98	
HIVMED	STRING(80) - A80	
HIVFREQSP	STRING(100) - A100	
HIVUNIT	STRING(8) - A8	
HIVDOSE	STRING(5) - A5	
HIVRTESP	STRING(100) - A100	
HIVSTDT	DATE - DDMYYYY	
HIVFREQ	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 98	
HIVSPDT	DATE - DDMYYYY	

## dilindv2 : BIOPSY COLLECTION (COLLECT) - Repeating Form

#	Date of biopsy collection	Name of hospital	DILI Biopsy	Autopsy biopsy available?	Explant available?	Date slides were shipped
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**Biopsy Collection**

1.	Date of biopsy collection	Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req/Unk <input type="text"/> (1935-2020) (dillncdd: COLLECT1.LVBIOPDT)
2.	Name of hospital:	A50 (dillncdd: COLLECT1.BIOPSYNM) City: A25 (dillncdd: COLLECT1.BIOPSYCY) State: A50 (dillncdd: COLLECT1.BIOPSYST)
3.	DILI Biopsy	(dillncdd: COLLECT1.DILIBIOP) [96] <input type="radio"/> NA [1] <input type="radio"/> Biopsy at time of injury [2] <input type="radio"/> Biopsy at Baseline Visit [98] <input type="radio"/> Other follow up biopsy Specify A200 (dillncdd: COLLECT1.DILBXSP)
4.*	DILI biopsy [hidden]	Pulldown List 1 <input type="text"/> (dillncdd: COLLECT1.BIOPTYPE) Other Specify A100 (dillncdd: COLLECT1.BIOPSP) Slides from: A10 (dillncdd: COLLECT1.BIOPS1) Slides to: A10 (dillncdd: COLLECT1.BIOPS2) (dillncdd: COLLECT1.CRYO1YN) Is there a Cryovial/Cryomold: [0] <input type="radio"/> No [1] <input type="radio"/> Yes Cryovial/Cryomold: A10 (dillncdd: COLLECT1.CRYO1) (dillncdd: COLLECT1.CRYO2YN) Is there a second Cryovial/Cryomold: [0] <input type="radio"/> No [1] <input type="radio"/> Yes Cryovial/Cryomold: A10 (dillncdd: COLLECT1.CRYO2) (dillncdd: COLLECT1.CRYO3YN) Is there a third Cryovial/Cryomold: [0] <input type="radio"/> No [1] <input type="radio"/> Yes Cryovial/Cryomold: A10 (dillncdd: COLLECT1.CRYO3)
5.*	Other/historic biopsies prior to DILI event available? [hidden]	(dillncdd: COLLECT1.HXBIOP) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Slides from: A10 (dillncdd: COLLECT1.HXBIOP1) Slides to: A10 (dillncdd: COLLECT1.HXBIOP2)
6.*	Autopsy biopsy available?	(dillncdd: COLLECT1.AUTPYBX) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [96] <input type="radio"/> NA
7.*	Explant available?	(dillncdd: COLLECT1.TRXBIOP) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [96] <input type="radio"/> NA
8.	Date slides were shipped:	Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req/Unk <input type="text"/> (2004-2020) (dillncdd: COLLECT1.SHIPDT)

\* Item is not required

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: dillncdd	Table: COLLECT1	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
CRYO3YN	NUMERIC	
CRYO2YN	NUMERIC	
BIOPSP	STRING(100) - A100	
HXBIOP1	STRING(10) - A10	
CRYO3	STRING(10) - A10	
LVBIOPDT	DATE - DDMONYYYY	
BIOPSYST	STRING(50) - A50	
SHIPDT	DATE - DDMONYYYY	
BIOPSYNM	STRING(50) - A50	
CRYO1YN	NUMERIC	
HXBIOP	NUMERIC	

CRYO2	STRING(10) - A10	
DILBXSP	STRING(200) - A200	
BIOPS1	STRING(10) - A10	
HXBIOP2	STRING(10) - A10	
AUTPYBX	NUMERIC	
CRYO1	STRING(10) - A10	
BIOPSYCY	STRING(25) - A25	
BIOPTYPE	NUMERIC - 1, 2, 3, 4, 5, 98	
DILBIOP	NUMERIC	
TRXBIOP	NUMERIC	
BIOPS2	STRING(10) - A10	

dilindv2 : ADVERSE EVENTS (AE)	
Adverse Events	
1. Did the patient have any adverse event(s) specifically related to study procedures?	(dilincdd: AE.AEOCCUR) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: dilincdd	Table: AE	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
AEOCCUR	NUMERIC	

dilindv2 : ADVERSE EVENTS (AE1) - Repeating Form

#	AE#	Adverse Event	Onset Date	Maximum Intensity	Outcome	Was This Event Serious?	End Date
1	<div><div></div><div></div><div></div></div>						

Adverse Events continued

1.	AE#	xxx (dilincdd: AE1.AENUM)					
2.	Adverse Event	A100 (dilincdd: AE1.AENAME)					
3.	Onset Date	Req/Unk <div></div> / Req/Unk <div></div> / Req/Unk <div></div> (2004-2020) (dilincdd: AE1.AEONSTDY)					
4.	Maximum Intensity	(dilincdd: AE1.INTENSE) [1] <div></div> Mild [2] <div></div> Moderate [3] <div></div> Severe					
5.	Outcome	(dilincdd: AE1.OUTCOME) [1] <div></div> Resolved [2] <div></div> Resolved - with sequelae [3] <div></div> Unresolved [4] <div></div> Death					
6.	Was This Event Serious?	(dilincdd: AE1.SERIOUS) [0] <div></div> No [1] <div></div> Yes					
7.*	End Date	(dilincdd: AE1.AECONT) [2] <div></div> Req/Unk <div></div> / Req/Unk <div></div> / Req/Unk <div></div> (2004-2020) (dilincdd: AE1.AESTOPDY) [1] <div></div> Ongoing					

\* Item is not required

Associations For Visit RefName vsCAS	
Visit RefName	Form RefName
vsCAS	frSAE

CDD: dilincdd	Table: AE1	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
SERIOUS	NUMERIC	
AENUM	NUMERIC - N3	
INTENSE	NUMERIC	
AENAME	STRING(100) - A100	
OUTCOME	NUMERIC	
AEONSTDY	DATE - DDMYYYYY	
AESTOPDY	DATE - DDMYYYYY	
AECONT	NUMERIC	



dilindv2 : 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	<div><div></div></div>							

Serious Adverse Events

1. Report type:

(dilincdd: SAE.REPORT)  
[1] ☐ Initial  
[2] ☐ 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/Unk (2004-2020) (dilincdd: SAE.SAETM)  
Req/Unk : Req/Unk 24-hour clock

4. Serious Reporting Criteria

Check all that apply  
(dilincdd: SAE.SAEDEATH)  
[1] ☐ Death  
(dilincdd: SAE.THREATEN)  
[1] ☐ Life-threatening  
(dilincdd: SAE.DISABLE1)  
[1] ☐ Resulted in a persistent or significant disability/incapacity  
(dilincdd: SAE.PROHOSP)  
[1] ☐ Prolonged or required hospitalization  
(dilincdd: SAE.CONGENT)  
[1] ☐ Congenital anomaly or birth defect  
(dilincdd: SAE.OTHSIGEV)  
[1] ☐ Other significant event requiring medical and/or surgical intervention

5. Outcome

(dilincdd: SAE.OUTCME)  
[1] ☐ Patient died  
[2] ☐ Recovered  
[3] ☐ Recovered with Sequelae  
[4] ☐ 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] ☐ Continued  
[2] ☐ Discontinued (dilincdd: SAE.ABATE)  
Did the event abate?  
[0] ☐ No  
[1] ☐ Yes

8. Causal Relationship (Investigator assessment of causal relationship of adverse event to study procedure):

(dilincdd: SAE.RELATION)  
[1] ☐ Possibly  
[2] ☐ Probably  
[3] ☐ 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
DISABLE1	NUMERIC	
OUTCME	NUMERIC	
THREATEN	NUMERIC	
PROHOSP	NUMERIC	
OUTCOMDT	DATE - DDMONYYYY	
ABATE	NUMERIC	
FUNUM	STRING(3) - A3	
RELATION	NUMERIC	
ACTION	NUMERIC	
OTHSIGEV	NUMERIC	
SAETM	DATE - DDMONYYYY HHMM	
SAEVENT	STRING(100) - A100	
CONGENT	NUMERIC	
SAEDEATH	NUMERIC	
REPORT	NUMERIC	

dilindv2 : RUCDR DNA (RUCDR) - Repeating Form

#

1

RUCDR Blooddraw

1.\*

Blooddraw Visit [hidden]

(dilncdd: RUCDR.BLDVST)  
[1] ☐ Baseline  
[2] ☐ 6 Month  
[3] ☐ 12 Month  
[4] ☐ 24 Month

2.\*

Age [hidden]

xxx (dilncdd: RUCDR.PBLDAGE)

3.\*

Sex [hidden]

(dilncdd: RUCDR.PBLDSX)  
[1] ☐ Male  
[2] ☐ Female

4.\*

Alternate ID# [hidden]

A15 (dilncdd: RUCDR.PBLDALT)

5.\*

NIDDK-ID# [hidden]

A10 (dilncdd: RUCDR.PBLDID)

6.\*

# Yellow (ACD) top tubes 3.0 ML [hidden]

xxx (dilncdd: RUCDR.PDYELL)

7.\*

# Yellow (ACD) top tubes 8.5 ML [hidden]

xxx (dilncdd: RUCDR.ADYELL)

8.\*

# Purple (EDTA) top tubes 3.0 ML [hidden]

xxx (dilncdd: RUCDR.PDPURP)

9.\*

# Purple (EDTA) top tubes 10.0 ML [hidden]

xxx (dilncdd: RUCDR.ADPURP)

10.\*

Date and Time Blood Drawn [hidden]

Req/Unk / Req/Unk / Req (2004-2020) (dilncdd: RUCDR.PBLDTM)  
Req/Unk : Req/Unk 24-hour clock

11.\*

Drawn By [hidden]

A25 (dilncdd: RUCDR.PDRAWN)

12.\*

Contact Method [hidden]

(dilncdd: RUCDR.PBLDMETH)  
[1] ☐ Emailed  
[2] ☐ Faxed  
[3] ☐ Call in

13.\*

Call in by [hidden]

A25 (dilncdd: RUCDR.PBLDNM)

14.\*

Call date and time [hidden]

Req/Unk / Req/Unk / Req (2004-2020) (dilncdd: RUCDR.PBLDNMTM)  
Req/Unk : Req/Unk 24-hour clock

15.\*

Package tracking # [hidden]

A25 (dilncdd: RUCDR.PBLDTRK)

\* Item is not required

CDD: dilncdd	Table: RUCDR	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PBLDID	STRING(10) - A10	
PBLDMETH	NUMERIC	
PBLDAGE	NUMERIC - N3	
ADYELL	NUMERIC - N3	
PBLDTRK	STRING(25) - A25	
PBLDSX	NUMERIC	
PBLDNM	STRING(25) - A25	
ADPURP	NUMERIC - N3	
BLDVST	NUMERIC	
PBLDALT	STRING(15) - A15	
PDYELL	NUMERIC - N3	
PDRAWN	STRING(25) - A25	
PDPURP	NUMERIC - N3	
PBLDTM	DATE - DDMONYYYY HHMM	
PBLDNMTM	DATE - DDMONYYYY HHMM	

dilindv2 : Fisher Repository Blooddraw (NIDDKSER) - Repeating Form

#					
1		<div></div>			
Fisher Blooddraw					
1.* Blooddraw Visit [hidden]		(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 [hidden]		A25 (dilincdd:NIDDKSER.REPONM)			
3.* Completion Date [hidden]		Req/Unk <div></div> / Req/Unk <div></div> / Req <div></div> (2004-2020) (dilincdd:NIDDKSER.REPODT)			
4.* Collection Site Name [hidden]		A50 (dilincdd:NIDDKSER.SITENM)			
5.* Collection Site Address [hidden]		A25 (dilincdd:NIDDKSER.SITEADD)			
6.* Collection Site City [hidden]		A25 (dilincdd:NIDDKSER.SITECITY)			
7.* Collection Site State [hidden]		A50 (dilincdd:NIDDKSER.SITEST)			
8.* Collection Site Zip [hidden]		A10 (dilincdd:NIDDKSER.SITEZIP)			
9.* Was a biopsy sample(s) included in this shipment? [hidden]		(dilincdd:NIDDKSER.RBIOOPYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes			
NIDDK ID#		Alternate ID#		Serum collection date	Number of vials of Serum
				Plasma collection date	Number of vials of Plasma
				Urine collection date	Number of vials of Urine
10. [hidden]					
. Entry [hidden]					
10.a* NIDDK ID# [hidden]		A25 (dilincdd:NIDDKSE1.REPOID)			
10.b* Alternate ID#		A25 (dilincdd:NIDDKSE1.REPOALT)			
10.c* Serum collection date		Req/Unk <div></div> / Req/Unk <div></div> / Req <div></div> (2004-2020) (dilincdd:NIDDKSE1.SERCOLDT)			
10.d* Number of vials of Serum		xxxxx (dilincdd:NIDDKSE1.SERVIAL)			
10.e* Plasma collection date		Req/Unk <div></div> / Req/Unk <div></div> / Req <div></div> (2004-2020) (dilincdd:NIDDKSE1.PLSCOLDT)			
10.f* Number of vials of Plasma		xxxxx (dilincdd:NIDDKSE1.PLSVIAL)			
10.g* Urine collection date		Req/Unk <div></div> / Req/Unk <div></div> / Req <div></div> (2004-2020) (dilincdd:NIDDKSE1.URNCOLDT)			
10.h* Number of vials of Urine		xxxxx (dilincdd:NIDDKSE1.URNVIAL)			
* Item is not required					

CDD: dilincdd	Table: NIDDKSE1	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
URNVIAL	NUMERIC - N5	
REPOALT	STRING(25) - A25	
REPOID	STRING(25) - A25	
SERVIAL	NUMERIC - N5	
SERCOLDT	DATE - DDMONYYYY	
PLSCOLDT	DATE - DDMONYYYY	
URNCOLDT	DATE - DDMONYYYY	
PLSVIAL	NUMERIC - N5	

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

dilindv2 : FISHER REPOSITORY (NIDDKBPY) - Repeating Form

#

1

1.\* Biopsy Visit [hidden]

(dilincdd:NIDDKBPY.BIOPVST)  
[1] ☐ Baseline  
[2] ☐ 6 Month  
[3] ☐ 12 Month  
[4] ☐ 24 Month

2.\* Biorepository notified via [hidden]

(dilincdd:NIDDKBPY.NOTIFY)  
[1] ☐ Emailed  
[2] ☐ Faxed

3.\* Biorepository notified by [hidden]

A25 (dilincdd:NIDDKBPY.NOTFYNM)

4.\* Date and time of notification [hidden]

Req/Unk  / Req/Unk  / Req  (2004-2020) (dilincdd:NIDDKBPY.NOTFYDTM)  
Req/Unk  : Req/Unk  24-hour clock

5.\* FedEx Tracking Number [hidden]

A25 (dilincdd:NIDDKBPY.NOTFYTRK)

NIDDK ID#

Alternate ID#

Barcode Number

Collection Date

6. [hidden]

[hidden]

[hidden]

[hidden]

. Entry

6.a.\* NIDDK ID# [hidden]

A25 (dilincdd:NIDDKBP1.BIOPID)

6.b.\* Alternate ID# [hidden]

A25 (dilincdd:NIDDKBP1.BIOPALT)

6.c.\* Barcode Number [hidden]

A25 (dilincdd:NIDDKBP1.BIOPCODE)

6.d.\* Collection Date [hidden]

Req/Unk  / Req/Unk  / Req  (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
NOTFYTRK	STRING(25) - A25	
NOTFYNM	STRING(25) - A25	
NOTIFY	NUMERIC	
BIOPVST	NUMERIC	
NOTFYDTM	DATE - DDMONYYYY HHMM	

dilindv2 : Serology Flowchart (SEROFLOW) - Repeating Form

#		Serology available	Serology type?	Date	
1	<div><div></div></div>				

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="checkbox"/> /   Req/Unk <input type="checkbox"/> /   Req/Unk <input type="checkbox"/> (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)

CDD: dilincdd Table: SEROFLOW Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SEROLAB	NUMERIC	
SERTHVAL	FLOAT - F9.0	
SERTRULN	NUMERIC	
SEROVIS	NUMERIC	
SEROVAL	FLOAT - F9.0	
SERODATE	DATE - DDMYYYY	
SERNPUNK	NUMERIC	
SEROIFEL	NUMERIC	

dilindv2 : Protocol Exemption (PTLEXMPT)	
Protocol Exemption	
1.	Is there a change to the inclusion/exclusion criteria since the enrollment/screening form was completed? <div>(dilncdd:PTLEXMPT.PECHG)</div> <div>[1] <input type="radio"/> Yes</div> <div>[0] <input type="radio"/> No</div>
<b>Inclusion Criteria</b>	
Do not complete the entire form, only record those criterion that need to be changed from the original screening form	
2.*	Was the patient more than 2 years of age at the time of enrollment? <div>(dilncdd:PTLEXMPT.PTEX1)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div>
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? <div>(dilncdd:PTLEXMPT.PTEX2)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div>
4.*	Was the patient/legal guardian willing to sign informed consent? <div>(dilncdd:PTLEXMPT.PTEX3)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div>
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? <div>(dilncdd:PTLEXMPT.PTEX4)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes (dilncdd:PTLEXMPT.PTEX5)            If Yes, was ALT &gt; 5 × ULN on at least 2 consecutive blood draws?  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes            (dilncdd:PTLEXMPT.PTEX6)            If Yes, was AST &gt; 5 × ULN on at least 2 consecutive blood draws?  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes            (dilncdd:PTLEXMPT.PTEX7)            If Yes, was AP &gt; 2 × ULN on at least 2 consecutive blood draws?  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div> </div> </div></div>
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? <div>(dilncdd:PTLEXMPT.PTEX8)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes (dilncdd:PTLEXMPT.PTEX9)            If Yes, was ALT &gt; 5 × pre-drug average on at least 2 consecutive blood draws?  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes            (dilncdd:PTLEXMPT.PTEX10)            If Yes, was AST &gt; 5 × pre-drug average on at least 2 consecutive blood draws?  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes            (dilncdd:PTLEXMPT.PTEX11)            If Yes, was AP &gt; 2 × pre-drug average on at least 2 consecutive blood draws?  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div> </div> </div></div>
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? <div>(dilncdd:PTLEXMPT.PTEX12)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes (dilncdd:PTLEXMPT.PTEX13)            If Yes Specify ALT above the ULN  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes            (dilncdd:PTLEXMPT.PTEX14)            If Yes Specify AST above the ULN  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes            (dilncdd:PTLEXMPT.PTEX15)            If Yes Specify AP above the ULN  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div> </div> </div></div>
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? <div>(dilncdd:PTLEXMPT.PTEX16)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes (dilncdd:PTLEXMPT.PTEX17)            If Yes Specify ALT above the ULN  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes            (dilncdd:PTLEXMPT.PTEX18)            If Yes Specify AST above the ULN  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes            (dilncdd:PTLEXMPT.PTEX19)            If Yes Specify AP above the ULN  <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div> </div> </div></div>
<b>Exclusion Criteria</b>	
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? <div>(dilncdd:PTLEXMPT.PTEX20)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div>
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) <div>(dilncdd:PTLEXMPT.PTEX21)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div>
11.*	Did the patient have acetaminophen hepatotoxicity? <div>(dilncdd:PTLEXMPT.PTEX22)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div>
12.*	Did the patient have a liver/organ transplant prior to development of drug- or CAM-induced injury? <div>(dilncdd:PTLEXMPT.PTEX23)</div> <div>[0] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div>

Eligibility	
13.*	<div>Eligibility</div> <div>(dilinccd: PTLEXMPT.PTEX24) [1] <input type="radio"/> Satisfied all criteria [2] <input type="radio"/> Did not satisfy all criteria (dilinccd: PTLEXMPT.PTEX28) Protocol Exemption Approved [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, date of approval Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1935-2020) (dilinccd: PTLEXMPT.PTEX28DT)</div>
14.*	<div>Was this patient enrolled previously?</div> <div>(dilinccd: PTLEXMPT.PTEX25) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, specify all previous DILIN ID(s): <div>A50 (dilinccd: PTLEXMPT.PTEX25A)</div></div>
15.*	<div>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).</div> <div>(dilinccd: PTLEXMPT.PTEX26) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</div>
16.*	<div>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).</div> <div>(dilinccd: PTLEXMPT.PTEX27) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</div>

\* Item is not required

CDD: dilinccd	Table: PTLEXMPT	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PTEX1	NUMERIC	
PTEX4	NUMERIC	
PTEX19	NUMERIC	
PTEX12	NUMERIC	
PTEX7	NUMERIC	
PTEX8	NUMERIC	
PTEX26	NUMERIC	
PECHG	NUMERIC	
PTEX16	NUMERIC	
PTEX2	NUMERIC	
PTEX10	NUMERIC	
PTEX28	NUMERIC	
PTEX3	NUMERIC	
PTEX21	NUMERIC	
PTEX22	NUMERIC	
PTEX25	NUMERIC	
PTEX13	NUMERIC	
PTEX9	NUMERIC	
PTEX18	NUMERIC	
PTEX20	NUMERIC	
PTEX25A	STRING(50) - A50	
PTEX27	NUMERIC	
PTEX15	NUMERIC	
PTEX14	NUMERIC	
PTEX5	NUMERIC	
PTEX28DT	DATE - DDMONYYYY	
PTEX24	NUMERIC	
PTEX11	NUMERIC	
PTEX6	NUMERIC	
PTEX17	NUMERIC	
PTEX23	NUMERIC	

dilindv2 : NARRATIVES (NARR)	
Clinical Narratives	
1. * Initial Causality Narrative Received	(dilincdd:NARR.CLINNARR) [1] <input type="radio"/> Yes
2. * Death Narrative Received	(dilincdd:NARR.DTHNARR) [1] <input type="radio"/> Yes
3. * EOS Narrative Received	(dilincdd:NARR.EOSNARR) [1] <input type="radio"/> Yes
4. * Biopsy to Kleiner Received	(dilincdd:NARR.BIOPRCVD) [1] <input type="radio"/> Yes
* Item is not required	

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



## dilindv2 : BIOPSY COLLECTION Part 1 (BIOPSY1) - Repeating Form

#	Biopsy Type	Date of biopsy	Date of central review	Specimen Type	Total portal areas	Liver length (mm)	Stains available	Interface hepatitis	Lobular inflammation	Portal inflammation	Confluent necrosis	Granulomas	Plasma cells	Eosinophils	Neutrophils	Lymphoid aggregates	Bridging necrosis	Lipogranulomas	Stage	Perisinusoidal	Character	Location	Degree	Cholestasis, degree	Hepatocellular	Canalicular	Cholangiolar	Ductal	Chol			
1	<input type="radio"/> [1] <input type="radio"/> [2] <input type="radio"/> [3] <input type="radio"/> [4] <input type="radio"/> [98]																															
Biopsy Demographics																																
1.*	Biopsy Type											(dilincdd: BIOPSY1.BIOPYPK) [1] <input type="radio"/> Biopsy at time of injury [2] <input type="radio"/> Biopsy at Baseline Visit [3] <input type="radio"/> Autopsy [4] <input type="radio"/> Explant [98] <input type="radio"/> Other																				
2.*	Date of biopsy											Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (2004-2020) (dilincdd: BIOPSY1.SITEBXDT)																				
3.*	Date of central review											Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (2004-2020) (dilincdd: BIOPSY1.REVIEWDT)																				
4.*	Specimen Type											(dilincdd: BIOPSY1.SPECIMAN) [1] <input type="radio"/> Needle [2] <input type="radio"/> Wedge [3] <input type="radio"/> Resection [4] <input type="radio"/> Explant [5] <input type="radio"/> Autopsy																				
5.*	Total portal areas											xx (dilincdd: BIOPSY1.TPORTAL)																				
6.*	Liver length (mm)											xx (dilincdd: BIOPSY1.LENGTH)																				
7.*	Stains available (check all that apply)											(dilincdd: BIOPSY1.HE) [1] <input type="checkbox"/> H & E (dilincdd: BIOPSY1.MASON) [1] <input type="checkbox"/> Masson (dilincdd: BIOPSY1.IRON) [1] <input type="checkbox"/> Iron (dilincdd: BIOPSY1.PAS) [1] <input type="checkbox"/> PAS with diastase (dilincdd: BIOPSY1.COPPER) [1] <input type="checkbox"/> Copper (dilincdd: BIOPSY1.RETICULN) [1] <input type="checkbox"/> Reticulin (dilincdd: BIOPSY1.CYTOK7) [1] <input type="checkbox"/> Cytokeratin 7 (dilincdd: BIOPSY1.STAINOTH) [1] <input type="checkbox"/> Other Specify A200 (dilincdd: BIOPSY1.STAINSP)																				
Inflammation																																
8.*	Interface hepatitis											(dilincdd: BIOPSY1.INTRFACE) [0] <input type="radio"/> 0 [1] <input type="radio"/> 1 [2] <input type="radio"/> 2 [3] <input type="radio"/> 3 [4] <input type="radio"/> 4																				
9.*	Lobular inflammation											(dilincdd: BIOPSY1.LOBULAR) [0] <input type="radio"/> 0 [1] <input type="radio"/> 1 [2] <input type="radio"/> 2 [3] <input type="radio"/> 3 [4] <input type="radio"/> 4																				
10.*	Portal inflammation											(dilincdd: BIOPSY1.PORTAL) [0] <input type="radio"/> 0 [1] <input type="radio"/> 1 [2] <input type="radio"/> 2 [3] <input type="radio"/> 3 [4] <input type="radio"/> 4																				
11.*	Confluent necrosis											(dilincdd: BIOPSY1.CONNECRO) [0] <input type="radio"/> 0 [1] <input type="radio"/> 1 [2] <input type="radio"/> 2 [3] <input type="radio"/> 3 [4] <input type="radio"/> 4 [5] <input type="radio"/> 5 [6] <input type="radio"/> 6																				
12.*	Granulomas											(dilincdd: BIOPSY1.GRANULOM) [0] <input type="radio"/> None [1] <input type="radio"/> Microgranulomas only [2] <input type="radio"/> Non-necrotizing epithelioid [3] <input type="radio"/> Necrotizing granulomas																				
13.*	Plasma cells											(dilincdd: BIOPSY1.PLASMA) [0] <input type="radio"/> None to mild [1] <input type="radio"/> Noticeably increased																				
14.*	Eosinophils											(dilincdd: BIOPSY1.EOSINO) [0] <input type="radio"/> None to mild [1] <input type="radio"/> Noticeably increased																				
15.*	Neutrophils											(dilincdd: BIOPSY1.NEUTRO) [0] <input type="radio"/> None to mild [1] <input type="radio"/> Noticeably increased																				
16.*	Lymphoid aggregates											(dilincdd: BIOPSY1.LYMPHOID) [0] <input type="radio"/> None Lymphoid aggregate																				

		<div>[1] <input type="radio"/></div> <div>[2] <input type="radio"/> Germinal centers</div>
17.*	Bridging necrosis	(dlinccd: BIOPSY1.NECROSIS) <div>[0] <input type="radio"/> None</div> <div>[1] <input type="radio"/> Bridging necrosis</div> <div>[2] <input type="radio"/> Multinuclear collapse</div>
18.*	Lipogranulomas	(dlinccd: BIOPSY1.LIPOGRAN) <div>[0] <input type="radio"/> Absent</div> <div>[1] <input type="radio"/> Present</div>
<b>Fibrosis</b>		
19.*	Stage	(dlinccd: BIOPSY1.STAGE) <div>[0] <input type="radio"/> 0</div> <div>[1] <input type="radio"/> 1</div> <div>[2] <input type="radio"/> 2</div> <div>[3] <input type="radio"/> 3</div> <div>[4] <input type="radio"/> 4</div> <div>[5] <input type="radio"/> 5</div> <div>[6] <input type="radio"/> 6</div>
20.*	Perisinusoidal	(dlinccd: BIOPSY1.PERISIN) <div>[0] <input type="radio"/> None</div> <div>[1] <input type="radio"/> Mild, requiring Masson to see</div> <div>[2] <input type="radio"/> Moderate to marked, visible on H &amp; E</div>
<b>Steatosis</b>		
21.*	Character	(dlinccd: BIOPSY1.CHARACTR) <div>[0] <input type="radio"/> Not applicable</div> <div>[1] <input type="radio"/> Predominantly macrovesicular</div> <div>[2] <input type="radio"/> Mixed macro and microvesicular</div> <div>[3] <input type="radio"/> Predominantly microvesicular</div>
22.*	Location	(dlinccd: BIOPSY1.LOCATION) <div>[0] <input type="radio"/> Not applicable</div> <div>[1] <input type="radio"/> Predominantly zone 3</div> <div>[2] <input type="radio"/> Predominantly zone 1</div> <div>[3] <input type="radio"/> Panacinar</div> <div>[4] <input type="radio"/> Azonal</div>
23.*	Degree	(dlinccd: BIOPSY1.BPDEGREE) <div>[0] <input type="radio"/> None</div> <div>[1] <input type="radio"/> &lt; 5% of hepatocytes</div> <div>[2] <input type="radio"/> 5-33% of hepatocytes</div> <div>[3] <input type="radio"/> 33-66% of hepatocytes</div> <div>[4] <input type="radio"/> &gt; 66% of hepatocytes</div>
<b>Cholestasis</b>		
24.*	Cholestasis, degree	(dlinccd: BIOPSY1.CHOLDGR) <div>[0] <input type="radio"/> No evident cholestasis</div> <div>[1] <input type="radio"/> Cholestasis identified only after careful high magnification search</div> <div>[2] <input type="radio"/> Cholestasis easily demonstrated at high magnification (40x) but not readily apparent at low magnification</div> <div>[3] <input type="radio"/> Cholestasis readily apparent at low magnification</div>
25.*	Hepatocellular	(dlinccd: BIOPSY1.HEPACELL) <div>[0] <input type="radio"/> Absent</div> <div>[1] <input type="radio"/> Present</div>
26.*	Canalicular	(dlinccd: BIOPSY1.CANALICU) <div>[0] <input type="radio"/> Absent</div> <div>[1] <input type="radio"/> Present</div>
27.*	Cholangiolar	(dlinccd: BIOPSY1.CHOLANGI) <div>[0] <input type="radio"/> Absent</div> <div>[1] <input type="radio"/> Present</div>
28.*	Ductal	(dlinccd: BIOPSY1.DUCTAL) <div>[0] <input type="radio"/> Absent</div> <div>[1] <input type="radio"/> Present</div>
29.*	Cholestasis	(dlinccd: BIOPSY1.CHOLESTA) <div>[0] <input type="radio"/> Absent</div> <div>[1] <input type="radio"/> Present</div>
30.*	Ductal Reaction	(dlinccd: BIOPSY1.DUCTREAC) <div>[0] <input type="radio"/> None to mild</div> <div>[1] <input type="radio"/> Prominent</div>
31.*	Duct Injury	(dlinccd: BIOPSY1.DUCTINJ) <div>[0] <input type="radio"/> None</div> <div>[1] <input type="radio"/> Single Duct</div> <div>[2] <input type="radio"/> Multiple Ducts</div>
32.*	Duct paucity	(dlinccd: BIOPSY1.DUCTPAUC) <div>[0] <input type="radio"/> None discernible (ducts &gt; 75% of portal area)</div> <div>[1] <input type="radio"/> Mild duct paucity (ducts in 50-75% of portal areas)</div> <div>[2] <input type="radio"/> Moderate to marked (ducts &lt; 50% of portal areas)</div>
33.*	Acute cholangitis	(dlinccd: BIOPSY1.ACUTCHOL) <div>[0] <input type="radio"/> Absent</div> <div>[1] <input type="radio"/> Present</div>
* Item is not required		

CDD: dlinccd	Table: BIOPSY1	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
NECROSIS	NUMERIC	
TPORTAL	FLOAT - F3.0	
CYTOK7	NUMERIC	

MASON	NUMERIC	
COPPER	NUMERIC	
LIPOGRAN	NUMERIC	
PAS	NUMERIC	
IRON	NUMERIC	
CHOLANGI	NUMERIC	
BIOPTYK	NUMERIC	
SPECIMAN	NUMERIC	
CANALICU	NUMERIC	
CHARACTR	NUMERIC	
LENGTH	FLOAT - F3.0	
RETICULN	NUMERIC	
STAINSP	STRING(200) - A200	
EOSINO	NUMERIC	
STAGE	NUMERIC	
DUCTPAUC	NUMERIC	
DUCTAL	NUMERIC	
STAINOTH	NUMERIC	
DUCTINJ	NUMERIC	
LYMPHOID	NUMERIC	
CHOLESTA	NUMERIC	
HEPACELL	NUMERIC	
GRANULOM	NUMERIC	
PERISIN	NUMERIC	
ACUTCHOL	NUMERIC	
SITEBXDT	DATE - DDMONYYYY	
HE	NUMERIC	
LOBULAR	NUMERIC	
CHOLDGR	NUMERIC	
INTRFACE	NUMERIC	
CONNECRO	NUMERIC	
REVIEWDT	DATE - DDMONYYYY	
LOCATION	NUMERIC	
PLASMA	NUMERIC	
PORTAL	NUMERIC	
NEUTRO	NUMERIC	
DUCTREAC	NUMERIC	
BPDEGREE	NUMERIC	

## dilindv2 : BIOPSY COLLECTION Part 2 (BIOPSY2) - Repeating Form

#	Date of central review	Ballooning degeneration	Apoptosis	Coag/Conflu necrosis locale	Coag/Conflu necrosis degree	Hepatocyte rosettes	Lobular disarray	Veno-occlusive changes	Central vein endophlebitis	Portal venopathy	Hemorrhage	Sinusoidal dilation	Nodular transformation	Hepatocyte ground glass change	Hepatocyte globular cytoplasmic inclusions	Mallory bodies	Lipid-laden stellate cells	Hepatocellular glycogenosis	Polarizeable talc crystals	Iron stain-hepatocellular iton	Iron stain-sinusoidal reticuloendothelial iron	Copper stain-hepatocellular copper	PAS positive macrophages	PAS positive hepatocellular inclusions
1	<div><div></div><div></div></div>																							
<b>Hepatocellular Injury</b>																								
1.* Date of central review										Req/Unk <div></div> / Req/Unk <div></div> / Req/Unk <div></div> (2004-2020) (dilincdd:BIOPSY2.REVW3DT)														
2.* Ballooning degeneration										(dilincdd:BIOPSY2.BALDEGEN) [0] <div></div> 0 [1] <div></div> 1 [2] <div></div> 2														
3.* Apoptosis										(dilincdd:BIOPSY2.APOPTOS) [0] <div></div> None to rare [1] <div></div> Mild (< 1 per 40x hpf) [2] <div></div> Moderate (1-3 per 40x hpf) [3] <div></div> Marked (>3 per 40x hpf)														
4.* Coagulative/ Confluent necrosis location										(dilincdd:BIOPSY2.COAGLOC) [0] <div></div> None [1] <div></div> Zone 1 predominant [2] <div></div> Zone 2 predominant [3] <div></div> Zone 3 predominant [4] <div></div> Panacinar [5] <div></div> Azonal														
5.* Coagulative/ Confluent necrosis degree (fraction of parenchyma affected)										(dilincdd:BIOPSY2.COAGDGRE) [0] <div></div> None [1] <div></div> Minimal (< 5% necrosis) [2] <div></div> Mild (5-33% necrosis) [3] <div></div> Moderate (33-66% necrosis) [4] <div></div> Marked(>66% necrosis)														
6.* Hepatocyte rosettes										(dilincdd:BIOPSY2.HEPAROS) [0] <div></div> None to rare [1] <div></div> More than rare														
7.* Lobular disarray										(dilincdd:BIOPSY2.LOBDISRY) [0] <div></div> Absent [1] <div></div> Present														
<b>Vascular</b>																								
8.* Veno-occlusive changes in central veins										(dilincdd:BIOPSY2.VENOCCLU) [0] <div></div> Absent [1] <div></div> Present														
9.* Central vein endophlebitis										(dilincdd:BIOPSY2.CNVNENDO) [0] <div></div> Absent [1] <div></div> Present														
10.* Portal venopathy										(dilincdd:BIOPSY2.PORTVENO) [0] <div></div> Absent [1] <div></div> Present														
11.* Hemorrhage										(dilincdd:BIOPSY2.HEMORRHG) [0] <div></div> Absent [1] <div></div> Present														
12.* Sinusoidal dilation										(dilincdd:BIOPSY2.SINUDILA) [0] <div></div> None to mild [1] <div></div> Moderate to marked [2] <div></div> Peliotic														
13.* Nodular transformation										(dilincdd:BIOPSY2.NODUTRAN) [0] <div></div> Absent [1] <div></div> Present														
<b>Miscellaneous Changes That Do Not Require Special Stains</b>																								
14.* Hepatocyte ground glass change										(dilincdd:BIOPSY2.GRNDCHGE) [0] <div></div> None [1] <div></div> Scattered cells [2] <div></div> Diffuse														
15.* Hepatocyte globular cytoplasmic inclusions										(dilincdd:BIOPSY2.GLOBINCL) [0] <div></div> Absent [1] <div></div> Present														
16.* Mallory bodies										(dilincdd:BIOPSY2.MALLORY) [0] <div></div> None to rare [1] <div></div> Definitely present														
17.* Lipid-laden stellate cells										(dilincdd:BIOPSY2.STELLATE) [0] <div></div> None to rare [1] <div></div> Prominent														
18.* Hepatocellular glycogenosis										(dilincdd:BIOPSY2.GLYCOGEN) [0] <div></div> Absent [1] <div></div> Present														
19.* Polarizeable talc crystals										(dilincdd:BIOPSY2.CRYSTALS) [0] <div></div> Absent [1] <div></div> Present														
<b>Special Stain Evaluation</b>																								
20.* Iron stain-hepatocellular iton										(dilincdd:BIOPSY2.HEPAIRON) [0] <div></div> 0 [1] <div></div> 1 [2] <div></div> 2														

		<div>[3] <input type="radio"/> 3</div> <div>[4] <input type="radio"/> 4</div>
21.*	Iron stain- sinusoidal reticuloendothelial iron	(dlinccdd:BIOPSY2.SINUIRON) [0] <input type="radio"/> Absent [1] <input type="radio"/> Rare positive cells [2] <input type="radio"/> Prominent
22.*	Copper stain-hepatocellular copper	(dlinccdd:BIOPSY2.HEPACOPP) [0] <input type="radio"/> None [1] <input type="radio"/> Periportal hepatocytes positive in < 50% of portal areas [2] <input type="radio"/> Periportal hepatocytes positive in > 50% of portal areas
23.*	PAS/ diastase stain- PAS-positive macrophages	(dlinccdd:BIOPSY2.PASMACRO) [0] <input type="radio"/> None [1] <input type="radio"/> Scattered [2] <input type="radio"/> Clusters
24.*	PAS/ diastase stain- PAS-positive hepatocellular inclusions	(dlinccdd:BIOPSY2.PASHEPA) [0] <input type="radio"/> Absent [1] <input type="radio"/> Present
25.*	CK 7 Evaluation Ductular Reaction (judged on worst area)	(dlinccdd:BIOPSY2.CK7EVAL) [0] <input type="radio"/> No ductules/ ductular reaction [1] <input type="radio"/> Isolated ductules [2] <input type="radio"/> Single layer of reactive ductules [3] <input type="radio"/> Multi-layered reactive ductules [4] <input type="radio"/> Ductular reaction extending between portal areas
26.*	CK 7 Hepatocyte Staining	(dlinccdd:BIOPSY2.HEPSTAIN) [0] <input type="radio"/> No hepatocytes positive [1] <input type="radio"/> Rare hepatocytes positive [2] <input type="radio"/> More than rare, but < 5% [3] <input type="radio"/> 5-33% of hepatocytes positive [4] <input type="radio"/> >33% of hepatocytes positive
27.*	Pattern of Injury	Pulldown List 1 <input type="button" value="v"/> (dlinccdd:BIOPSY2.PATINJUR)
28.*	Comments	<div>A200</div> (dlinccdd:BIOPSY2.COMMENTS)

\* Item is not required

Pulldown List 1:			
RefName	Display Text	Value	Design Note
iePATINJ1	Acute hepatic	1	
iePATINJ2	Chronic hepatic	2	
iePATINJ3	Acute cholestatic	3	
iePATINJ4	Chronic cholestatic	4	
iePATINJ5	Combined hepatic/ cholestatic	5	
iePATINJ6	Granulomatous	6	
iePATINJ7	Steatotic, macrovesicular	7	
iePATINJ8	Steatotic, microvesicular	8	
iePATINJ9	Steatohepatic	9	
iePATINJ10	Coagulative /confluent necrosis, zonal	10	
iePATINJ11	Coagulative /confluent necrosis, non-zonal	11	
iePATINJ12	Vascular	12	
iePATINJ13	Hepatocellular alteration	13	
iePATINJ14	Nodular regenerative hyperplasia	14	
iePATINJ15	Mixed or unclassified patterns	15	
iePATINJ16	Mild, non-specific changes	16	
iePATINJ17	Absolutely normal	17	
iePATINJ18	Sub-massive/ massive necrosis	18	

CDD: dlinccdd Table: BIOPSY2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PORTVENO	NUMERIC	
PASHEPA	NUMERIC	
STELLATE	NUMERIC	
CHNVENDO	NUMERIC	
SINUIRON	NUMERIC	
COAGDGRE	NUMERIC	
HEPAROS	NUMERIC	
CRYSTALS	NUMERIC	
LOBDISRY	NUMERIC	
COMMENTS	STRING(200) - A200	
GLYCOGEN	NUMERIC	
PATINJUR	NUMERIC - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18	
HEPSTAIN	NUMERIC	
HEPAIRON	NUMERIC	
GLOBINCL	NUMERIC	
APOPTOS	NUMERIC	
CK7EVAL	NUMERIC	
HEMORRHG	NUMERIC	
VENOCCLU	NUMERIC	

GRNDCHGE	NUMERIC	
NODUTRAN	NUMERIC	
PASMACRO	NUMERIC	
MALLORY	NUMERIC	
SINUDILA	NUMERIC	
BALDEGEN	NUMERIC	
HEPACOPP	NUMERIC	
COAGLOC	NUMERIC	
REVV3DT	DATE - DDMMYYYY	

dilindv2 : ACUTE DILI CASE (ACUTE)	
Acute DILI Case	
1. * Were acute labs drawn?	(dilincdd:ACUTE.ACDILI) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Complete the Acute Liver Test Flowchart form
2. * Were acute blood samples drawn?	(dilincdd:ACUTE.ACLOOD) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Complete the Acute Research Sample form
* Item is not required	

CDD: dilincdd   Table: ACUTE   Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ACBLOOD	NUMERIC	
ACDILI	NUMERIC	

## dilindv2 : Acute LIVER TEST FLOWCHART (ACLABFLW) - Repeating Form

#	Visit	Acute Lab Date	AST results	ALT results	Alkaline Phosphatase results	Serum Total Bilirubin results	Serum Albumin results	INR results
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

  
**Acute Liver Test Flowchart**

1. Visit	(dillncdd: ACLABFLW.ACLVISIT) [1] <input type="radio"/> Initial Study Visit [2] <input type="radio"/> Day 3 [3] <input type="radio"/> Week 4 [4] <input type="radio"/> Week 4 [5] <input type="radio"/> Week 12
2. Acute Lab Date	Req/Unk <input type="text"/> / <input type="text"/> Req/Unk <input type="text"/> / <input type="text"/> (2004-2020) (dillncdd: ACLABFLW.ACLABDTM) Req/Unk <input type="text"/> : <input type="text"/> Req/Unk <input type="text"/> 24-hour clock
3. AST results Available?	(dillncdd: ACLABFLW.ACAST) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes AST results (IU/L or U/L or mIU/mL) (dillncdd: ACLABFLW.ACASTVAL)   xxxxxxxx.   AST ULN (IU/L or U/L or mIU/mL) (dillncdd: ACLABFLW.ACASTULN)   xxxxxxxx.
4. ALT results Available?	(dillncdd: ACLABFLW.ACALT) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes ALT results (IU/L or U/L or mIU/mL) (dillncdd: ACLABFLW.ACALTVAL)   xxxxxxxx.   ALT ULN (IU/L or U/L or mIU/mL) (dillncdd: ACLABFLW.ACALTULN)   xxxxxxxx.
5. Alkaline Phosphatase results Available?	(dillncdd: ACLABFLW.ACAKP) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Alkaline Phosphatase results (IU/L or U/L or mIU/mL) (dillncdd: ACLABFLW.ACAKPVAL)   xxxxxxxx.   Alkaline Phosphatase ULN (IU/L or U/L or mIU/mL) (dillncdd: ACLABFLW.ACAKPULN)   xxxxxxxx.
6. Serum Total Bilirubin results Available?	(dillncdd: ACLABFLW.ACSTB) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum Total Bilirubin results   xxxxxxxx.   (dillncdd: ACLABFLW.ACSTBVAL) (dillncdd: ACLABFLW.ACSTBUNT) Serum Total Bilirubin unit [5] <input type="radio"/> mg/dL [4] <input type="radio"/> µmol/L Serum Total Bilirubin ULN   xxxxxxxx.   (dillncdd: ACLABFLW.ACSTBULN)
7. Serum Albumin results Available?	(dillncdd: ACLABFLW.ACALBUN) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes Serum Albumin results   xxxxxxxx.   (dillncdd: ACLABFLW.ACALBVAL) (dillncdd: ACLABFLW.ACALBUNT) Serum Albumin unit [1] <input type="radio"/> g/dL [9] <input type="radio"/> g/L
8. INR results Available?	(dillncdd: ACLABFLW.ACINR) [97] <input type="radio"/> Not done [1] <input type="radio"/> Yes INR results   xxxxxxxx.   (dillncdd: ACLABFLW.ACINRATE)

CDD: dillncdd	Table: ACLABFLW	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
ACAKP	NUMERIC	
ACSTBULN	FLOAT - F9.0	
ACASTULN	FLOAT - F9.0	
ACINR	NUMERIC	
ACALBVAL	FLOAT - F9.0	
ACALTVAL	FLOAT - F9.0	
ACLABDTM	DATE - DDMONYYYY HHMM	
ACASTVAL	FLOAT - F9.0	
ACSTBVAL	FLOAT - F9.0	
ACALTULN	FLOAT - F9.0	
ACALBUNT	NUMERIC	
ACAKPULN	FLOAT - F9.0	
ACAST	NUMERIC	
ACSTBUNT	NUMERIC	
ACAKPVAL	FLOAT - F9.0	
ACLVISIT	NUMERIC	
ACINRATE	FLOAT - F9.0	
ACALBUN	NUMERIC	
ACALT	NUMERIC	
ACSTB	NUMERIC	



dilindv2 : ACUTE RESEARCH SAMPLES (ACSAMP) - Repeating Form

#	Visit	Date and Time collected	When blood samples drawn, patient was?	Date of admission	Date of discharge	
1	<div><div></div><div></div><div></div></div>					

Research samples

Note: If patient started new medication(s) or HDS product(s), please record on the CONMED and CONCAM logs

1. Visit	(dillncdd: ACSAMP.ACRVISIT) [1] <input type="radio"/> Initial Study Visit [2] <input type="radio"/> Day 3 [3] <input type="radio"/> Week 1 [4] <input type="radio"/> Week 4 [5] <input type="radio"/> Week 12
2. Date and Time collected	Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (2004-2020) (dillncdd: ACSAMP.ACRLBDTM) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock
3. When blood samples drawn, patient was?	(dillncdd: ACSAMP.ACSTATE) [1] <input type="radio"/> Fasting [2] <input type="radio"/> Fed [99] <input type="radio"/> Unknown
4. Date of admission	(dillncdd: ACSAMP.ACRADM) [96] <input type="radio"/> Not Applicable [1] <input type="radio"/> Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (1935-2020) (dillncdd: ACSAMP.ACRADMDT)
5. Date of discharge	(dillncdd: ACSAMP.ACRDSC) [96] <input type="radio"/> Not Applicable [2] <input type="radio"/> Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (1935-2020) (dillncdd: ACSAMP.ACRDSCDT) [1] <input type="radio"/> Continuing If continuing is checked, update discharge on the last record when known

CDD: dillncdd Table: ACSAMP Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ACRADMDT	DATE - DDMONYYYY	
ACSTATE	NUMERIC	
ACRVISIT	NUMERIC	
ACRLBDTM	DATE - DDMONYYYY HHMM	
ACRADM	NUMERIC	
ACRDSC	NUMERIC	
ACRDSCDT	DATE - DDMONYYYY	

## diliindv2 : Liver Elastography and Hepatic Steatosis Estimation (FIBRO) - Repeating Form

#	Visit	Will a FIBROSCAN be performed this visit?	Sex	Implanted electrical devices	Food/drink ingestion date and time	Implanted electrical devices	Weight	Height	Waist Circumference	Hip Circumference	Chest Circumference	Evidence of heart failure	Evidence of Passive congestion of the liver	Evidence of ascites	Fibroscan performed	Fibroscan velocity	Median Fibroscan stiffness score	CAP measurements obtained	
1																			
<b>Screening</b>																			
1.	Visit											(diliincdd: FIBRO.FIBROVIS) [1] <input type="radio"/> Initial Study Visit [2] <input type="radio"/> MTH 6 [3] <input type="radio"/> MTH 12 [4] <input type="radio"/> MTH 24 [5] <input type="radio"/> MTH 36 [6] <input type="radio"/> MTH 48 [7] <input type="radio"/> Unscheduled Visit							
2.*	Date and time of Screening Assessment [hidden]											Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1935-2020) (diliincdd: FIBRO.SCRNDTM) Req <input type="text"/> : Req <input type="text"/> 24-hour clock							
3.	Will a FIBROSCAN be performed this visit?											(diliincdd: FIBRO.FIBPERF1) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: Date and time of Screening Assessment Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1935-2020) (diliincdd: FIBRO.SCRNDTM1) Req <input type="text"/> : Req <input type="text"/> 24-hour clock							
<b>Patient Assessment</b>																			
4.*	Sex [hidden]											(diliincdd: FIBRO.SEX1) [1] <input type="radio"/> Male [2] <input type="radio"/> Female (diliincdd: FIBRO.PREGYN) If female, is the patient pregnant? [0] <input type="radio"/> No [1] <input type="radio"/> Yes [96] <input type="radio"/> Not applicable Date and time of pregnancy test Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1935-2020) (diliincdd: FIBRO.PREGDTM) Req <input type="text"/> : Req <input type="text"/> 24-hour clock							
5.*	Sex											(diliincdd: FIBRO.SEX2) [1] <input type="radio"/> Male [2] <input type="radio"/> Female (diliincdd: FIBRO.PRGPREF) If female, will the pregnancy test be completed? [96] <input type="radio"/> NA [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes: Date and time of pregnancy test Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1935-2020) (diliincdd: FIBRO.PREGDTM1) Req <input type="text"/> : Req <input type="text"/> 24-hour clock (diliincdd: FIBRO.PREGYN1) If female, is the patient pregnant? [0] <input type="radio"/> No [1] <input type="radio"/> Yes							
6.*	Does the patient have any implanted electrical devices such as cardiac pacemakers, AICD or neural stimulator, etc.? If yes, do not do FibroScan testing.											(diliincdd: FIBRO.IMPLYS) [0] <input type="radio"/> No [1] <input type="radio"/> Yes							
7.*	Date and time of patient's last food/drink ingestion?											Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (1935-2020) (diliincdd: FIBRO.FOODDTM) Req <input type="text"/> : Req <input type="text"/> 24-hour clock							
8.*	Did the patient ingest greater than 2 alcoholic beverages per day over the past 2 weeks?											(diliincdd: FIBRO.ALCOHYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes							
9.*	Current Weight [hidden]											xxx.x   (diliincdd: FIBRO.WEIGHT1) (diliincdd: FIBRO.WGUNIT) [1] <input type="radio"/> kg [2] <input type="radio"/> lbs							
10.*	Current Weight											(diliincdd: FIBRO.WGHT) [1] <input type="radio"/> xxx.x   (diliincdd: FIBRO.WEIGHT2) (diliincdd: FIBRO.WGUNIT1) [1] <input type="radio"/> kg [2] <input type="radio"/> lbs [99] <input type="radio"/> Unknown							
11.*	Current Height [hidden]											xxx.x   (diliincdd: FIBRO.HEIGHT1) (diliincdd: FIBRO.HGUNIT) [1] <input type="radio"/> cm [2] <input type="radio"/> in							
12.*	Current Height											(diliincdd: FIBRO.HGHT) [1] <input type="radio"/> xxx.x   (diliincdd: FIBRO.HEIGHT2) (diliincdd: FIBRO.HGUNIT1) [1] <input type="radio"/> cm [2] <input type="radio"/> in [99] <input type="radio"/> Unknown							
13.*	Current Waist Circumference [hidden]											xxx.x   (diliincdd: FIBRO.WAIST1) (diliincdd: FIBRO.WSUNIT) [1] <input type="radio"/> cm [2] <input type="radio"/> in							
14.*	Current Waist Circumference											(diliincdd: FIBRO.WST) [1] <input type="radio"/> xxx.x   (diliincdd: FIBRO.WAIST2) (diliincdd: FIBRO.WSUNIT1) [1] <input type="radio"/> cm [2] <input type="radio"/> in [99] <input type="radio"/> Unknown							
15.*	Current Hip Circumference [hidden]											xxx.x   (diliincdd: FIBRO.HIP1) (diliincdd: FIBRO.HPUNIT) [1] <input type="radio"/> cm [2] <input type="radio"/> in							
16.*	Current Hip Circumference											(diliincdd: FIBRO.HP) [1] <input type="radio"/> xxx.x   (diliincdd: FIBRO.HIP2) (diliincdd: FIBRO.HPUNIT1) [1] <input type="radio"/> cm [2] <input type="radio"/> in [99] <input type="radio"/> Unknown							
	Current Chest Circumference											(diliincdd: FIBRO.CHUNIT)							

17.*	Note: This will indicate which probe to use for children. <i>[hidden]</i>	xxx.x (dillncdd: FIBRO.CHEST1) [1] <input type="radio"/> cm [2] <input type="radio"/> in
18.*	Current Chest Circumference Note: This will indicate which probe to use for children.	(dillncdd: FIBRO.CHST) [1] <input type="radio"/> xxx.x (dillncdd: FIBRO.CHEST2) (dillncdd: FIBRO.CHUNIT1) [1] <input type="radio"/> cm [2] <input type="radio"/> in [99] <input type="radio"/> Unknown
19.*	Does the patient show any evidence of right heart failure?	(dillncdd: FIBRO.HRTFALYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes: ECHO DATE   Req <input type="text"/> /   Req <input type="text"/> /   Req <input type="text"/> (1935-2020) (dillncdd: FIBRO.ECHODT) Cardiac Ejection Fraction (%)   xxx (dillncdd: FIBRO.EJEFRAC) Shortening Fraction (%)   xxx (dillncdd: FIBRO.SHORFRAC)
20.*	Does the patient show any evidence of passive congestion of the liver?	(dillncdd: FIBRO.CONGESYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
21.*	Does the patient show any evidence of ascites on their most recent abdominal imaging?	(dillncdd: FIBRO.ASCITEYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes: IMAGE DATE   Req <input type="text"/> /   Req <input type="text"/> /   Req <input type="text"/> (1935-2020) (dillncdd: FIBRO.IMAGE2DT) (dillncdd: FIBRO.RADINTER) Radiological Interpretation: [1] <input type="radio"/> Trace [2] <input type="radio"/> Mild [3] <input type="radio"/> Moderate [4] <input type="radio"/> Severe
<b>FIBROSCAN</b>		
22.*	Based on this visit's assessment, will the Fibroscan be performed at this visit?	(dillncdd: FIBRO.FIBROYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes: FIBROSCAN date and time   Req <input type="text"/> /   Req <input type="text"/> /   Req <input type="text"/> (1935-2020) (dillncdd: FIBRO.FIBRODTM) Req <input type="text"/> :   Req <input type="text"/> 24-hour clock (dillncdd: FIBRO.PROBE) Probe used: [1] <input type="radio"/> M Probe (Adult) [2] <input type="radio"/> XL Probe (Adult) [3] <input type="radio"/> S1 Probe (Pediatric) [4] <input type="radio"/> S2 Probe (Pediatric)
23.*	Median Fibroscan velocity (Total of 10 consecutive, valid measurements obtained in 10 minute time frame)	xx.xx (meters/second) (dillncdd: FIBRO.MEFIBROV) Lowest Fibroscan Velocity (meters/second)   xx.xx (dillncdd: FIBRO.LOFIBROV) Highest Fibroscan Velocity (meters/second)   xx.xx (dillncdd: FIBRO.HIFIBROV) Interquartile range (%)   xx.x (dillncdd: FIBRO.INTRANV)
24.*	Median Fibroscan stiffness score (Total of 10 consecutive, valid measurements obtained in 10 minute time frame)	xx.x (kPa) (dillncdd: FIBRO.MEDFIBROS) Lowest Fibroscan Stiffness score (kPa)   xx.x (dillncdd: FIBRO.LOFIBROS) Highest Fibroscan Stiffness score (kPa)   xx.x (dillncdd: FIBRO.HIFIBROS) Interquartile range to median ratio (%)   xx (dillncdd: FIBRO.INTRANS)
25.*	Were CAP measurements obtained and recorded?	(dillncdd: FIBRO.CAPYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If yes, provide: Median CAP measurement (db/m)   xxx (dillncdd: FIBRO.MEDCAP) Lowest CAP measurement (db/m)   xxx (dillncdd: FIBRO.LOCAP) Highest CAP measurement (db/m)   xxx (dillncdd: FIBRO.HICAP) Interquartile range to Median ratio (%)   xx (dillncdd: FIBRO.INTRANC)
* Item is not required		

CDD: dillncdd	Table: FIBRO	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
EJEFRAC	NUMERIC - N3	
RADINTER	NUMERIC	
MEDFIBROS	FLOAT - F4.1	
FOODDTM	DATE - DDMONYYYY HHMM	
ALCOHYN	NUMERIC	
HIFIBROS	FLOAT - F4.1	
FIBRODTM	DATE - DDMONYYYY HHMM	
SEX1	NUMERIC	
FIBROVIS	NUMERIC	
CHUNIT	NUMERIC	
SCRNDTM	DATE - DDMONYYYY HHMM	
WAIST1	FLOAT - F5.1	
SHORFRAC	NUMERIC - N3	
IMAGE2DT	DATE - DDMONYYYY	
FIBROYN	NUMERIC	
INTRANS	NUMERIC - N2	
HRTFALYN	NUMERIC	
CAPYN	NUMERIC	

IMPLYS	NUMERIC	
HIP1	FLOAT - F5.1	
LOFIBROV	FLOAT - F5.2	
WGUNIT	NUMERIC	
CONGESYN	NUMERIC	
PROBE	NUMERIC	
PREGYN	NUMERIC	
HEIGHT1	FLOAT - F5.1	
ASCITEYN	NUMERIC	
MEDCAP	NUMERIC - N3	
PREGDTM	DATE - DDMONYYYY HHMM	
HGUNIT	NUMERIC	
ECHODT	DATE - DDMONYYYY	
CHST	NUMERIC	
CHEST2	FLOAT - F5.1	
CHUNIT1	NUMERIC	
HGHT	NUMERIC	
HEIGHT2	FLOAT - F5.1	
HGUNIT1	NUMERIC	
HP	NUMERIC	
HIP2	FLOAT - F5.1	
HPUNIT1	NUMERIC	
WST	NUMERIC	
WAIST2	FLOAT - F5.1	
WSUNIT1	NUMERIC	
WGHT	NUMERIC	
WEIGHT2	FLOAT - F5.1	
WGUNIT1	NUMERIC	
MEFIBROV	FLOAT - F5.2	
LOFIBROS	FLOAT - F4.1	
HICAP	NUMERIC - N3	
FIBPERF1	NUMERIC	
SCRNDTM1	DATE - DDMONYYYY HHMM	
SEX2	NUMERIC	
PRGPERF	NUMERIC	
PREGDTM1	DATE - DDMONYYYY HHMM	
PREGYN1	NUMERIC	
INTRANC	NUMERIC - N2	
LOCAP	NUMERIC - N3	
CHEST1	FLOAT - F5.1	
HIFIBROV	FLOAT - F5.2	
INTRANV	FLOAT - F4.1	
HPUNIT	NUMERIC	
WEIGHT1	FLOAT - F5.1	
WSUNIT	NUMERIC	

**dilindv2 : EARLY WITHDRAWAL and STUDY COMPLETION (PTCOMPL)****Early Withdrawal and Study Completion**

1.	End of study date (Use visit completion date or last known alive date)	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2004-2020) (dilincdd:PTCOMPL.COMPLDT)
2.	Did the participant complete the study? (attended last expected visit)	(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 [98] <input type="radio"/> Other Other Specify (dilincdd:PTCOMPL.REASONSP) A200 [1] <input type="radio"/> Death Date of death: Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req/Unk <input type="checkbox"/> (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

CDD: dilincdd Table: PTCOMPL Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SPLVTX	NUMERIC	
CEREDEMA	NUMERIC	
REASON	NUMERIC	
CAUSE	STRING(200) - A200	
COMPLDT	DATE - DDMONYYYY	
DEATHDT	DATE - DDMONYYYY	
CHRONARR	NUMERIC	
HEPATOCA	NUMERIC	
REASONSP	STRING(200) - A200	
VARCIBLD	NUMERIC	
STUDYCOM	NUMERIC	
DTHOTHSP	STRING(200) - A200	
FALF	NUMERIC	
SEPSIS	NUMERIC	
NLLRDTH	NUMERIC	
NONDILI	NUMERIC	
LRDTHOTH	NUMERIC	
RENLFAIL	NUMERIC	

dilindv2 : 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	

diiindv2 : 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?	(diiincdd: 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?	(diiincdd: ACONHX.ACNCHXYN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes

CDD: diiincdd	Table: ACONHX	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
ACNCHXYN	NUMERIC	
ACNMHXYN	NUMERIC	

dilindv2 : Annual CONCOMITANT MEDICATIONS (ACONMED) - Repeating Form

#	Medication	Start Date	Stop Date
1	<div></div>		

Concomitant Medications taken within 4 week period prior to annual visit

1. Medication	A80 (dilincdd: ACONMED.AMEDNAME)
2. Start Date	Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd: ACONMED.AMEDSTDT)
3. Stop Date	(dilincdd: ACONMED.AMEDCONT) [2] Req/Unk / Req/Unk / Req/Unk (1935-2020) (dilincdd: ACONMED.AMEDSPDT) [1] Continuing

CDD: dilincdd	Table: ACONMED	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
AMEDSTDT	DATE - DDMONYYYY	
AMEDSPDT	DATE - DDMONYYYY	
AMEDNAME	STRING(80) - A80	
AMEDCONT	NUMERIC	



dilindv2 : Annual CONCOMITANT CAM PRODUCTS (ACONCAM) - Repeating Form

#		Brand or Commercial name	Common name	Start Date	Stop Date	
1	<div><div></div><div></div></div>					

Concomitant CAM Products taken within 4 week period prior to annual visit

1. Brand or Commercial name	<div>A80 (dilincdd: ACONCAM.ACMBRNM)</div>
2. Common name	<div>A80 (dilincdd: ACONCAM.ACMCOMNM)</div>
3. Start Date	<div>Req/Unk <div></div> / Req/Unk <div></div> / Req/Unk <div></div> (1935-2020) (dilincdd: ACONCAM.ACMSTDT)</div>
4. Stop Date	<div>(dilincdd: ACONCAM.ACMCONT) [2] <div></div> Req/Unk <div></div> / Req/Unk <div></div> / Req/Unk <div></div> (1935-2020) (dilincdd: ACONCAM.ACMSPDT) [1] <div></div> Continuing</div>

CDD: dilincdd	Table: ACONCAM	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
ACMSPDT	DATE - DDMONYYYY	
ACMCOMNM	STRING(80) - A80	
ACMBRNM	STRING(80) - A80	
ACMCONT	NUMERIC	
ACMSTDT	DATE - DDMONYYYY	

dilindv2 : 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	

## dilindv2 : Personal History Questionnaire (APHXQ)

## Personal History Questionnaire

1. *	Q3 - Did you travel outside of the United States in the 6 months before you became sick with your liver injury?	(dilincdd: APHXQ.APHQTRVL) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes, please indicate below		
	Country	From date	To date	Type of Area
2.				

## Travel Entry

2. a *	Country	A50 (dilincdd: APHXQ2.APHQCTRY)
2. b *	From date	(dilincdd: APHXQ2.APHQ2FUN) [1] <input type="radio"/> Req/Unk <input type="radio"/> / <input type="radio"/> Req/Unk <input type="radio"/> / <input type="radio"/> Req/Unk (1980-2020) (dilincdd: APHXQ2.APHQ2FDT) [99] <input type="radio"/> Unknown
2. c *	To date	(dilincdd: APHXQ2.APHQ2TUN) [1] <input type="radio"/> Req/Unk <input type="radio"/> / <input type="radio"/> Req/Unk <input type="radio"/> / <input type="radio"/> Req/Unk (1980-2020) (dilincdd: APHXQ2.APHQ2TDT) [99] <input type="radio"/> Unknown
2. d *	Type of Area	(dilincdd: APHXQ2.APHQ2TYP) [1] <input type="radio"/> Rural [2] <input type="radio"/> Urban

## Personal History Questionnaire continued

3. *	Q9 - Have you ever received a blood transfusion?	(dilincdd: APHXQ.APHQ3YN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: APHXQ.APHQ3FUN) Year of First Transfusion [1] <input type="radio"/> Req/Unk <input type="radio"/> (1980-2020) (dilincdd: APHXQ.APHQ3FDT) [99] <input type="radio"/> Unknown (dilincdd: APHXQ.APHQ3RUN) Year of Most Recent Transfusion [1] <input type="radio"/> Req/Unk <input type="radio"/> (1980-2020) (dilincdd: APHXQ.APHQ3RDT) [99] <input type="radio"/> Unknown
4. *	Q10 - Have you ever used injection drugs, such as heroin, cocaine or crack?	(dilincdd: APHXQ.APHQ4YN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: APHXQ.APHQ4FUN) Year of First use of Injection drugs [1] <input type="radio"/> Req/Unk <input type="radio"/> (1980-2020) (dilincdd: APHXQ.APHQ4FDT) [99] <input type="radio"/> Unknown (dilincdd: APHXQ.APHQ4RUN) Year of Most Recent Use of Injection Drugs [1] <input type="radio"/> Req/Unk <input type="radio"/> (1980-2020) (dilincdd: APHXQ.APHQ4RDT) [99] <input type="radio"/> Unknown
5. *	Q11 - Have you ever snorted or sniffed cocaine or crack?	(dilincdd: APHXQ.APHQ5YN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: APHXQ.APHQ5FUN) Year of First Exposure [1] <input type="radio"/> Req/Unk <input type="radio"/> (1980-2020) (dilincdd: APHXQ.APHQ5FDT) [99] <input type="radio"/> Unknown (dilincdd: APHXQ.APHQ5RUN) Year of Most Recent Exposure [1] <input type="radio"/> Req/Unk <input type="radio"/> (1980-2020) (dilincdd: APHXQ.APHQ5RDT) [99] <input type="radio"/> Unknown
6. *	Q12 - Are you a health care worker whose job involves direct face-to-face contact with patients?	(dilincdd: APHXQ.APHQ6YN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
7. *	Q12A - Have you ever had any direct contact with patient body fluids/secretions such as blood, urine, feces, etc?	(dilincdd: APHXQ.APHQ7YN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: APHXQ.APHQ7FUN) Year of First Exposure to Patient Body Fluids/secretions [1] <input type="radio"/> Req/Unk <input type="radio"/> (1980-2020) (dilincdd: APHXQ.APHQ7FDT) [99] <input type="radio"/> Unknown (dilincdd: APHXQ.APHQ7RUN) Year of Most Recent Exposure to Patient Body Fluids/secretions [1] <input type="radio"/> Req/Unk <input type="radio"/> (1980-2020) (dilincdd: APHXQ.APHQ7RDT) [99] <input type="radio"/> Unknown
8. *	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.	(dilincdd: APHXQ.APHQ8YN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes (dilincdd: APHXQ.APHQ8FUN) If Yes, Year of First Needle Stick/Injury Exposure [1] <input type="radio"/> Req/Unk <input type="radio"/> (1980-2020) (dilincdd: APHXQ.APHQ8FDT) [99] <input type="radio"/> Unknown (dilincdd: APHXQ.APHQ8RUN) Year of Most Recent Needle Stick/Injury Exposure [1] <input type="radio"/> Req/Unk <input type="radio"/> (1980-2020) (dilincdd: APHXQ.APHQ8RDT) [99] <input type="radio"/> Unknown
9. *	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?	(dilincdd: APHXQ.APHQ9YN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes What was your relationship with that person? (Check all that apply) (dilincdd: APHXQ.APHQ9SPS) [1] <input type="checkbox"/> Spouse or Sexual Partner (dilincdd: APHXQ.APHQ9HSE)

[1] ☐ Household exposure such as to siblings or children  
(dlinccdd: APHXQ.APHQ9WRK)  
[1] ☐ Informal workplace or school exposure  
(dlinccdd: APHXQ.APHQ9OTH)  
[1] ☐ Other Specify  (dlinccdd: APHXQ.APHQ9OSP)

\* Item is not required

CDD: dlinccdd	Table: APHXQ	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
APHQ9HSE	NUMERIC	
APHQ3YN	NUMERIC	
APHQ7FDT	DATE - YYYY	
APHQ4RDT	DATE - YYYY	
APHQ3RDT	DATE - YYYY	
APHQ5RUN	NUMERIC	
APHQ5FUN	NUMERIC	
APHQ8FDT	DATE - YYYY	
APHQ3FDT	DATE - YYYY	
APHQ5FDT	DATE - YYYY	
APHQ7RUN	NUMERIC	
APHQ6YN	NUMERIC	
APHQ7YN	NUMERIC	
APHQ8RUN	NUMERIC	
APHQ9OTH	NUMERIC	
APHQ8FUN	NUMERIC	
APHQ4RUN	NUMERIC	
APHQ3RUN	NUMERIC	
APHQ4FDT	DATE - YYYY	
APHQ5RDT	DATE - YYYY	
APHQ8RDT	DATE - YYYY	
APHQ3FUN	NUMERIC	
APHQ9SPS	NUMERIC	
APHQ9WRK	NUMERIC	
APHQ9YN	NUMERIC	
APHQ4YN	NUMERIC	
APHQ9OSP	STRING(200) - A200	
APHQ5YN	NUMERIC	
APHQ7RDT	DATE - YYYY	
APHQ7FUN	NUMERIC	
APHQ8YN	NUMERIC	
APHQTRVL	NUMERIC	
APHQ4FUN	NUMERIC	

CDD: dlinccdd	Table: APHXQ2	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
APHQ2TUN	NUMERIC	
APHQ2TDT	DATE - DDMONYYYY	
APHQ2FDT	DATE - DDMONYYYY	
APHQ2TYP	NUMERIC	
APHQ2FUN	NUMERIC	
APHQCTRY	STRING(50) - A50	

## dilindv2 : Personal History Questionnaire (PHXQ1)

## Personal History Questionnaire

1.*	Q1 - Do you currently have any pets at home? [hidden]	(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 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? [hidden]	(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? [hidden]	(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? [hidden]	(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 A200 (dillncdd:PHXQ1.PHQ04SP)
5.*	Q5 - Do you ever eat raw or undercooked meats? [hidden]	(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? [hidden]	(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? [hidden]	(dillncdd:PHXQ1.PHQ07) [0] <input type="radio"/> No [1] <input type="radio"/> Yes If Yes Specify 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? [hidden]	(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 / Req/Unk (1980-2020) (dillncdd:PHXQ1.PHQ09FDT) [99] <input type="radio"/> Unknown (dillncdd:PHXQ1.PHQ09R) Month/Year of Most Recent Transfusion [1] <input type="radio"/> Req/Unk / Req/Unk (1980-2020) (dillncdd:PHXQ1.PHQ09RDT) [99] <input type="radio"/> Unknown
9.*	Q10 - Have you ever used injection drugs, such as heroin, cocaine or crack? [hidden]	(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 / Req/Unk (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 / Req/Unk (1980-2020) (dillncdd:PHXQ1.PHQ10RDT) [99] <input type="radio"/> Unknown
10.*	Q11 - Have you ever snorted or sniffed cocaine or crack? [hidden]	(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 / Req/Unk (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 / Req/Unk (1980-2020) (dillncdd:PHXQ1.PHQ11RDT) [99] <input type="radio"/> Unknown
11.*	Q12 - Are you a health care worker whose job involves direct face-to-face contact with patients? [hidden]	(dillncdd:PHXQ1.PHQ12) [0] <input type="radio"/> No

[1] ☐ Yes

NOTE: If Q12 above is answered YES, please answer question 12A and 12B found on form PHXQ12

12.\* Q13 - Have you ever had any direct occupational contact (meat packing factory, slaughterhouse, etc.) with animal body fluid such as blood, intestinal content? [hidden]

(dillncdd: PHXQ1.PHQ13)

[0] ☐ No

[1] ☐ Yes

If Yes

(dillncdd: PHXQ1.PHQ13F)

Month/Year of First Exposure to Animal Body Fluids/secretions

[1] ☐ Req/Unk / Req/Unk (1980-2020) (dillncdd: PHXQ1.PHQ13FDT)

[99] ☐ Unknown

(dillncdd: PHXQ1.PHQ13R)

Month/Year of Most Recent Exposure to Animal Body Fluids/secretions

[1] ☐ Req/Unk / Req/Unk (1980-2020) (dillncdd: PHXQ1.PHQ13RDT)

[99] ☐ Unknown

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? [hidden]

(dillncdd: PHXQ1.PHQ14)

[0] ☐ No

[1] ☐ Yes

(dillncdd: PHXQ1.PHQPART)

[1] ☐ Spouse or Sexual Partner

(dillncdd: PHXQ1.PHQEXP)

[1] ☐ Household exposure such as to siblings or children

(dillncdd: PHXQ1.PHQWKP)

[1] ☐ Informal workplace or school exposure

(dillncdd: PHXQ1.PHQOTHR)

[1] ☐ Other Specify A200 (dillncdd: PHXQ1.PHQOTSP)

\* Item is not required

CDD: dillncdd	Table: PHXQ1	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PHQ12	NUMERIC	
PHQ11FDT	DATE - MONYYYY	
PHQ06S	NUMERIC	
PHQ01	NUMERIC	
PHQ11R	NUMERIC	
PHQCAT	NUMERIC	
PHQWKP	NUMERIC	
PHQ10F	NUMERIC	
PHQ9RDT	DATE - MONYYYY	
PHQOTHR	NUMERIC	
PHQ10RDT	DATE - MONYYYY	
PHQ13	NUMERIC	
PHQ11RDT	DATE - MONYYYY	
PHQ13FDT	DATE - MONYYYY	
PHQ07SP	STRING(200) - A200	
PHQ03	NUMERIC	
PHQ10	NUMERIC	
PHQOTSP	STRING(200) - A200	
PHQ10FDT	DATE - MONYYYY	
PHQ10R	NUMERIC	
PHQ9F	NUMERIC	
PHQ14	NUMERIC	
PHQ05	NUMERIC	
PHQ02	NUMERIC	
PHQ13F	NUMERIC	
PHQBIRD	NUMERIC	
PHQEXP	NUMERIC	
PHQ07	NUMERIC	
PHQ04SP	STRING(200) - A200	
PHQPART	NUMERIC	
PHQOTH	STRING(255)	
PHQSPEC	STRING(200) - A200	
PHQFER	NUMERIC	
PHQ11	NUMERIC	
PHQ13R	NUMERIC	
PHQ06	NUMERIC	
PHQ01PET	NUMERIC - N3	
PHQ9R	NUMERIC	
PHQ04	NUMERIC	
PHQ9FDT	DATE - MONYYYY	
PHQ11F	NUMERIC	
PHQ13RDT	DATE - MONYYYY	
PHQDOG	NUMERIC	
PHQPIG	NUMERIC	
PHQ09	NUMERIC	

http://ms46ad01.dcri.int/dilindv2/pfts.dll?Z=F0705EBB7D51560A3B005479621C352A&C=TM\_169&FMD=0&FMRV=0&ISID=0&ITID=0&VM=2&TN=dilindv2&SP=&AS=59391&CP=65535&FP=0&RSV=0

7/27/2017

dilindv2 : Personal History Questionnaire (PHXQ2) - Repeating Form

#		
1	<div><div></div></div>	
Personal History Questionnaire 2		
1.* Q 2 - Type of Animal [hidden]	<div>Pulldown List 1 (dilincdd:PHXQ2.PHQ02A) If Farm Animals or Wild Animals other is checked, please specify animal (dilincdd:PHXQ2.PHQ02SP) A200</div>	
2.* Most Recent date of Contact [hidden]	<div>(dilincdd:PHXQ2.PHQ02UNK) [11] Req/Unk / Req/Unk (1980-2020) (dilincdd:PHXQ2.PHQ02ADT) [99] Unknown</div>	
* Item is not required		

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

dilindv2 : Personal History Questionnaire (PHXQ3) - Repeating Form

#

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 [hidden]

(dilincdd:PHXQ3.PHQ03AVS)

[1] ☐ US City  (dilincdd:PHXQ3.PHQ3CTY)

State  (dilincdd:PHXQ3.PHQ3ST)

[2] ☐ Country (outside of US)

Country Visited  (dilincdd:PHXQ3.PHQ3CTRY)

2.\* From date [hidden]

(dilincdd:PHXQ3.PHQ3F)

[1] ☐ Req/Unk  / Req/Unk  / Req/Unk  (1980-2020) (dilincdd:PHXQ3.PHQ3FRDT)

[99] ☐ Unknown

3.\* To date [hidden]

(dilincdd:PHXQ3.PHQ3T)

[1] ☐ Req/Unk  / Req/Unk  / Req/Unk  (1980-2020) (dilincdd:PHXQ3.PHQ3TODT)

[99] ☐ Unknown

4.\* Type of Area [hidden]

(dilincdd:PHXQ3.PHQ3TAR)

[1] ☐ Rural

[2] ☐ Urban

\* Item is not required

CDD: dilincdd	Table: PHXQ3	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PHQ3T	NUMERIC	
PHQ3F	NUMERIC	
PHQ3CTY	STRING(25) - A25	
PHQ3TODT	DATE - DDMONYYYY	
PHQ3TAR	NUMERIC	
PHQ03AVS	NUMERIC	
PHQ3CTRY	STRING(50) - A50	
PHQ3ST	STRING(50) - A50	
PHQ3FRDT	DATE - DDMONYYYY	

http://ms46ad01.dcri.int/dilindv2/pfts.dll?Z=F0705EBB7D51560A3B005479621C352A&C=TM\_169&FMID=0&FMRV=0&ISID=0&ITID=0&VM=2&TN=dilindv2&SP=&AS=59391&CP=65535&FP=0&RSV=0

7/27/2017



**dilindv2 : 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 [hidden]	(dilincdd: PHXQ8.PHQ8A) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
2.*	b - Raw or undercooked Shellfish [hidden]	(dilincdd: PHXQ8.PHQ8B) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown If Yes: Specify type of shellfish (dilincdd: PHXQ8.PHQ8BSP) A200
3.*	c - Crabs [hidden]	(dilincdd: PHXQ8.PHQ8C) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
4.*	d - Lobsters [hidden]	(dilincdd: PHXQ8.PHQ8D) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
5.*	e - Other Crustaceans [hidden]	(dilincdd: PHXQ8.PHQ8E) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
6.*	f - Unpasteurized Milk Products [hidden]	(dilincdd: PHXQ8.PHQ8F) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
7.*	g - Innards or offal [hidden]	(dilincdd: PHXQ8.PHQ8G) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
8.*	h - Chicken, raw or rare [hidden]	(dilincdd: PHXQ8.PHQ8H) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
9.*	i - Pork, raw or rare [hidden]	(dilincdd: PHXQ8.PHQ8I) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
10.*	j - Beef, raw or rare [hidden]	(dilincdd: PHXQ8.PHQ8J) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
11.*	k - Lamb, raw or rare [hidden]	(dilincdd: PHXQ8.PHQ8K) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
12.*	l - Goat meat, raw or rare [hidden]	(dilincdd: PHXQ8.PHQ8L) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
13.*	m - Wild Boar [hidden]	(dilincdd: PHXQ8.PHQ8M) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
14.*	n - Other wild meat [hidden]	(dilincdd: PHXQ8.PHQ8N) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
15.*	o - Pig Liver [hidden]	(dilincdd: PHXQ8.PHQ8O) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
16.*	p - Beef Liver [hidden]	(dilincdd: PHXQ8.PHQ8P) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown
17.*	q - Other [hidden]	(dilincdd: PHXQ8.PHQ8Q) [0] <input type="radio"/> No [1] <input type="radio"/> Yes [99] <input type="radio"/> Unknown If Yes: Other Specify (dilincdd: PHXQ8.PHQ8QSP) A200

\* Item is not required

CDD: dilincdd	Table: PHXQ8	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PHQ8G	NUMERIC	
PHQ8M	NUMERIC	

PHQ8J	NUMERIC	
PHQ8C	NUMERIC	
PHQ8I	NUMERIC	
PHQ8K	NUMERIC	
PHQ8E	NUMERIC	
PHQ8N	NUMERIC	
PHQ8B	NUMERIC	
PHQ8O	NUMERIC	
PHQ8F	NUMERIC	
PHQ8H	NUMERIC	
PHQ8P	NUMERIC	
PHQ8D	NUMERIC	
PHQ8BSP	STRING(200) - A200	
PHQ8QSP	STRING(200) - A200	
PHQ8L	NUMERIC	
PHQ8A	NUMERIC	
PHQ8Q	NUMERIC	

dilindv2 : Personal History Questionnaire (PHXQ12)

Personal History Questionnaire 12

1. \*

Q12A - Have you ever had any direct contact with patient body fluids/secretions such as blood, urine, feces, etc? *[hidden]*

(dilincdd:PHXQ12.PHQ12A)

[0] ☐ No

[1] ☐ Yes (dilincdd:PHXQ12.PHQ12F)

If Yes, Month/Year of First Exposure to Patient Body Fluids/secretions

[1] ☐ Req/Unk  /  (1980-2020) (dilincdd:PHXQ12.PHQ12FDT)

[99] ☐ Unknown

(dilincdd:PHXQ12.PHQ12R)

Month/Year of Most Recent Exposure to Patient Body Fluids/secretions

[1] ☐ Req/Unk  /  (1980-2020) (dilincdd:PHXQ12.PHQ12RDT)

[99] ☐ Unknown

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. *[hidden]*

(dilincdd:PHXQ12.PHQ12B)

[0] ☐ No

[1] ☐ Yes (dilincdd:PHXQ12.PHQ12BF)

If Yes, Month/Year of First Needle Stick/Injury Exposure

[1] ☐ Req/Unk  /  (1980-2020) (dilincdd:PHXQ12.PHQ12BDT)

[99] ☐ Unknown

(dilincdd:PHXQ12.PHQ12MR)

Month/Year of Most Recent Needle Stick/Injury Exposure

[1] ☐ Req/Unk  /  (1980-2020) (dilincdd:PHXQ12.PHQ12DT)

[99] ☐ Unknown

\* Item is not required

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

**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.

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