Persons using assistive technology may not be able to fully access information in this file. For assistance, e-mail niddk-cr@imsweb.com. Include the web site and filename in your message.

DILIN

Drug–Induced Liver Injury Network

National Institute of Diabetes, and Digestive, and Kidney Disease (NIDDK)

National Institutes of Health

A Multi-Center Longitudinal Study of Drug- and CAM-Induced Liver Injury (Retrospective)

Interview and Chart Review Case Report Form

Drug-Induced Liver Injury Network

Retrospective

Case Table of Contents

Contact Form

Initial Contact Information 1

Secondary Contact Information 2

Screening Form

Screening 1

Valproic Acid Cases 3

Telephone/Personal Interview

Opening Script T1

Demographics T1

Prior Medical History T1

History of Injury T2

Medical History T4

Concomitant Products T5

Medical History T6

Concomitant Products T7

Family History T8

Blood Draw T11

Medical Chart Review

Medical Chart Review M1

DILI Episode M1

DILI Onset M2

Signs and Symptoms At Onset M2

Treatment M3

Concomitant Prescription Medications M4

Concomitant Non-prescription Medications M5

Concomitant Medical Conditions and Illnesses M6

Lab M8

Serological and Other Assays During DILI Event M13

Imaging Studies M14

Procedures M14

Completion Form

Participant Completion Comp1

DILIN
Drug-Induced Liver Injury Network

Retrospective Case Contact Form

NOT DATABASED

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Initial Contact Information

Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
day month year

This information remains at the site.

1 Participant name: _____
(Last) (First)

2 Address: _____
(Street)

_____
(City) (State) (Zip)

3 Phone number: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___ → Voice mail message can be left? ☐ No ☐ Yes

4 Cell-phone number: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___ → Voice mail message can be left? ☐ No ☐ Yes

5 Fax number: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

6 Email address: _____

7 Spouse's or significant other's name *(if applicable)*: _____

8 Participant's employment information:
☐ Not applicable **OR** Complete information below:

Name of employer: _____

Address: _____
(Street)

_____
(City) (State) (Zip)

Business phone number: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___ → Voice mail message can be left? ☐ No ☐ Yes

Fax number: (___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Business email: _____

9 Preferred method of contact: ☐ Home ☐ Cell ☐ Business ☐ Email

10 What is the participant's Social Security Number *(optional)*: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ **OR** ☐ Declined

DILIN
Drug-Induced Liver Injury Network

Retrospective Case Contact Form

NOT DATABASED

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Secondary Contact Information

1 **Primary alternative contact** *(relative, friend or neighbor NOT living with participant)*:

Name: _____
(Last) (First)

Address: _____
(Street)

_____
(City) (State) (Zip)

Phone number: (__ __ __) __ __ __ - __ __ __ __ Fax number: (__ __ __) __ __ __ - __ __ __ __

Cell-phone number: (__ __ __) __ __ __ - __ __ __ __

Email address: _____

Contact's relationship to participant: _____

2 **Secondary alternative contact** *(relative, friend or neighbor NOT living with participant)*:

Name: _____
(Last) (First)

Address: _____
(Street)

_____
(City) (State) (Zip)

Phone number: (__ __ __) __ __ __ - __ __ __ __ Fax number: (__ __ __) __ __ __ - __ __ __ __

Cell-phone number: (__ __ __) __ __ __ - __ __ __ __

Email address: _____

Contact's relationship to participant: _____

3 **Tertiary alternative contact** *(relative, friend or neighbor NOT living with participant)*:

Name: _____
(Last) (First)

Address: _____
(Street)

_____
(City) (State) (Zip)

Phone number: (__ __ __) __ __ __ - __ __ __ __ Fax number: (__ __ __) __ __ __ - __ __ __ __

Cell-phone number: (__ __ __) __ __ __ - __ __ __ __

Email address: _____

Contact's relationship to participant: _____

PROTOCOL= DILIN_RET
STUDYBOOK = CASE_RET
FORM = SCREENING

ALL DAY FIELDS RANGE 1-31
ALL YEAR FIELDS RANGE 1900-2017
ALL TIME FIELDS RANGE 00-23 HR
00-59 MIN

DILIN
Drug-Induced Liver Injury Network

Retrospective Case Screening

NO DATA

SUBJNO= INVSITE||-||PATID

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Screening

SCREEN (TYPE 1)

Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SCRNDT RTNONDIL<ZYES>

Who experienced this liver problem? ☐ 1 Self ☐ 2 Child ☐ 98 Other (specify): _____ SCREXP <RTEXP> EXPSPEC <V:30>

The following questions refer to the individual who experienced the liver problem.

REFNA <ZYES>

1 What is the name and location of the physician or health care provider who contacted you about participation in this study?

☐ NA (referring physician is site Principal Investigator) **OR** Complete below:

Name: _____ (Last) SCRLAST <V:30> _____ (First) SCRFIRST <V:30>

Address: _____ (Street) SCRSTRT <V:30>

_____ (City) SCRCITY <V:30> _____ (State) SCRST <V:5> _____ (Zip) SCRZIP <V:10>

2 What is your date of birth? ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) DOBDT → What is your current age? ___ ___ years SCRAGE <I:3>

If the participant is under the age of 2 now, he or she is not eligible for this study. Do not proceed with other questions. Thank the contact person for his or her time and interest.
Reminder: An assent form may be required by your IRB for children of certain ages.

3 What month and year did you start having this liver problem? SCRLIVM <ZMONTH> SCRLIVY <I:4>

Provide month and year: ___ ___ / ___ ___ ___ ___ (month / year)

If the event occurred prior to January 1994, do not proceed with other questions. Thank the contact person for his or her time and interest.

4 What is the name of the drug that caused this reaction? *(check all that apply)*

- ☐ Isoniazid *(INH)* INH <ZYES>
- ☐ Phenytoin *(Dilantin)* PHENYT <ZYES>
- ☐ Clavulanic acid/amoxicillin *(Augmentin)* AUGMENT <ZYES>
- ☐ Valproic acid *(Valproate, Depakote)* VALPACID <ZYES>
- ☐ Nitrofurontoin NITROFTN <ZYES>
- ☐ Minocycline MINOCYLN <ZYES>
- ☐ Trimethoprim-Sulfamethoxazole BACTRIM <ZYES> QUINLNE <ZYES>
- ☐ Quinolone antibiotics → Identify specific quinolone antibiotic on page 11 SCRDRGOT <ZYES> SCRDRGSP <V:80>
- ☐ Other (specify): _____ SCRDRGCR <ZYES>
- ☐ Cannot remember

If the participant received more than one of the above medications simultaneously, he or she is not eligible for this study. Do not proceed with other questions. Thank the participant for his or her time and interest.

5 What month and year did you start this medication? ___ ___ ___ / ___ ___ ___ ___ (month / year) SCRMEDM <ZMONTH> SCRMEDY <I:4>

Reminder: Using the date above, please perform calculation on page 6 of Telephone/Personal Interview form prior to conducting that interview.

6 Did your skin or the whites of your eyes turn yellow? SCRCOLOR <RTYNCR>

- ☐ 0 No
- ☐ 1 Yes
- ☐ 2 Cannot remember

Screening (continued)

7 Part of this study will be to collect a blood sample from you. We will attempt to give you a choice of locations so you can choose a place and time convenient for you. Blood will be drawn by a qualified person. Genetic material called DNA will be used to search for genes that may cause or increase the risk of having a liver injury from a drug. The results of these studies will not be put into your health records. The blood sample will be used in future projects to understand why some people have reactions to drugs and others do not.

SCREEN2 (TYPE 1)

Are you willing to provide a blood sample?

☐0 No
☐1 Yes

SCRBLOOD <ZYESNO>

ICF Liver research allowed only ICF1 <ZYESNO>
ICF All research allowed ICF2 <ZYESNO>

If the participant will not provide a blood sample, do not proceed. Thank the contact person for his or her time and interest.

8 Based on the information we just discussed, are you willing to participate in this study?

☐0 No → **If No: Give reason** *(check all that apply)*:

SCRCONT <ZYESNO>

- ☐ Under the age of 2 — UNDERAGE <ZYES>
- ☐ Event occurred before January 1994 — TOOEARLY <ZYES>
- ☐ Received more than one of the implicated medications — OVRDRUG <ZYES>
- ☐ Not interested — NOINTRST <ZYES>
- ☐ Felt study required too much time — TOOLONG <ZYES>
- ☐ Not willing to give a blood sample — NOBLOOD <ZYES>
- ☐ Did not want to be in a genetics study — NOGENE <ZYES>
- ☐ Other *(specify)*: _____ — NOTCONT <ZYES> NOCONTSP <V:200>

☐1 Yes → **If Yes:** You will receive another packet very soon. We would like to review that information with you and answer any questions you might have. I would like to schedule a date and time for that contact.

Next scheduled contact date and time: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SCRAPPDT ___ ___ ___ ___ (00:00 to 23:59) SCRAPPTM

Preferred method: ☐1 Phone ☐2 Clinic visit

SCRMETHD <RTMETH>

Check if this participant is an approved protocol exemption: ☐1 PROTEXMP <ZYES>

SIGNATUR (TYPE 4)

Investigator Signature

SIGNANS <ZYES> SIGDT

I have reviewed and found all data pertaining to this participant to be complete and accurate.

Investigator's signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year)

Affix label here

Reminder: Please go to your screening binder and assign the next available number to this participant.

Valproic Acid Cases

VALNA <ZYES> VALACID (TYPE 1)

Complete the following if *valproic acid* is checked on page 1, question 5. OR ☐ NA

NOTE: For valproic acid, compatible symptomatic clinical presentation that is severe enough for prompt hospitalization or that is associated with significant biochemical liver dysfunction.

For inclusion criteria to be satisfied, at least one of the following questions must be answered Yes.

VALHOSP <ZYESNO>

1 Was this patient hospitalized?* ..... ☐$_0$ No ☐$_1$ Yes
(*A patient is considered hospitalized if he or she is admitted to a hospital as an inpatient. Treatment and release from an emergency department is not considered a hospitalization.)

INRPAT <ZYESNO>

2 Was the INR > 1.5 for this patient? ..... ☐$_0$ No ☐$_1$ Yes

SERPAT <ZYESNO>

3 Was serum AST or ALT > 3 x ULN or 3 x the baseline level, if the baseline level was elevated, for this patient? ..... ☐$_0$ No ☐$_1$ Yes

BILPAT <ZYESNO>

4 Was the bilirubin > 1x ULN or > 1 x the baseline level, if the baseline level was elevated, for this patient? ..... ☐$_0$ No ☐$_1$ Yes

ELEVART <ZYESNO>

5 Did this patient have unexplained elevated arterial or venous NH_3 levels? ..... ☐$_0$ No ☐$_1$ Yes

LIVBPSTE <ZYESNO>

6 Did this patient undergo a liver biopsy indicating "steatosis"? ..... ☐$_0$ No ☐$_1$ Yes

STUDYBOOK = CASE_RET
FORM = INTERVIEW

DILIN
Drug-Induced Liver Injury Network

Retrospective

NO DATA

Case Telephone/Personal Interview

SUBJNO= INVSITE||-||PATID

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Opening Script

I am calling to gather as much information as possible on your liver problem. You may not know or remember the answers to some of the questions. Please try to give me the information as accurately as you can, and remember that all information that you provide us is held strictly confidential. Please feel at ease to answer honestly and as best you can, because this is very important information for the study.

Date of this interview: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) INTDT

ALL DAY FIELDS RANGE 1-31
ALL YEAR FIELDS RANGE 1900-2017
ALL TIME FIELDS RANGE 00-23 HR
00-59 MIN

Demographics

DEMOG (TYPE 1)

1 What is your country of birth? ☐ 1 United States ☐ 98 Other (specify): BRCTRYSP <V:25>
BIRTHCTY <RTCTRY>

2 What is your sex? ☐1 Male ☐2 Female
SEX <RTSEX>

3 What is your ethnicity? ☐1 Hispanic or Latino ☐2 Not Hispanic or Latino
ETHNIC <RTETHN>

4 What is your race? (check all that apply)
☐ American Indian or Alaska Native INDIAN <ZYES>
☐ Asian ASIAN <ZYES>
☐ Black or African American BLACK <ZYES>
☐ Native Hawaiian or other Pacific Islander NATIVE <ZYES>
☐ White or Caucasian WHITE <ZYES>
☐ Other (specify): RACEOTHR <ZYES> RACESP <V:25>

5 What is your highest education level completed? (check only one)
☐1 Not applicable (preschool age)
☐2 Elementary school (0–8th grade)
☐3 9th–11th grade
☐4 12th grade (or GED)
☐5 Some college/Associate's degree
☐6 College
☐7 Postgraduate degree
EDUCATE <RTEDUC>

WHODRUG_B2 = CODING DICTIONARY
WHOCODE <V:32>
WHONAME <V:80>
CONFLVL <V:2>
CODETM <DATETIME>
MATCHES <V:4>
CODER <V:20>
WORKFLOW <V:5

6 What is your current weight? ___ ___ ___ lb WTLB <F9:3>

7 What is your current height? ___ ft ___ ___ in HTFT <F9:3> HTIN <F9:3>

IBMI <F9:3> =
(WTLB / ((HTFT x 12) + HTIN) x (HTFT x 12) + HTIN))) x 703

Prior Medical History

PMEDHX1 (TYPE 1)

Now, I want you to think about your experiences **before** you started taking HXMED <V:80> (Coding specs above).
(drug name (if quinolone antibiotic, record exact drug name))

You started taking the medication in ___ ___/___ ___ ___ ___ (refer to Screening form).
(month / year) HXMEDM <ZMONTH> HXMEDY <I:4>

1 Did you ever take this drug prior to this date for any reason? ☐0 No ☐1 Yes ☐2 Cannot remember
HXDRG <RTYNCR>

2 Were you ever jaundiced or told you were jaundiced for any reason (i.e. skin turned yellow or the whites of your eyes turned yellow)?
☐0 No ☐1 Yes ☐2 Cannot remember
HXJAUND <RTYNCR>

3 Did you have a prior history of liver problems?
☐0 No
☐1 Yes → If Yes: What type of liver problem did you experience? (check all that apply)

ABNLT <ZYES> ☐ Unexplained abnormal liver tests
HEPA <ZYES> ☐ Hepatitis A (infectious)
HEPB <ZYES> ☐ Hepatitis B
HEPC <ZYES> ☐ Hepatitis C
ARLD <ZYES> ☐ Alcohol-related liver disease
FLNRA <ZYES> ☐ Non-alcoholic fatty liver disease (NALFD/NASH)
PBCIRRH <ZYES> ☐ Primary biliary cirrhosis
HEMCHROM <ZYES> ☐ Hemochromatosis
WILSON <ZYES> ☐ Wilson's disease
AATDEF <ZYES> ☐ A1AT deficiency
CIRRHUN <ZYES> ☐ Cirrhosis–unspecified
AIMD <ZYES> ☐ Autoimmune disease
☐ Primary sclerosing cholangitis
☐ Gilbert's syndrome
☐ Ischemic hepatitis
☐ Liver transplantation
☐ Family history of liver disease
☐ Unknown
☐ Other (specify): PROBSP <V:200>

☐2 Cannot remember
HXLIVPRB <RTYNCR>

PSCHLANG <ZYES>
GILBERT <ZYES>
HEPISCHM <ZYES>
LIVERTRX <ZYES>
FAMHXLIV <ZYES>
UNK <ZYES>
OTHER <ZYES>

Prior Medical History (continued)

PMEDHX (TYPE 2)R
Limit to 20 sequences

4 Did you ever suffer a bad reaction *(e.g. rash, fever, swelling or difficulty breathing)* to any drugs *(prescription or over-the-counter)* and herbals that was severe enough to require a visit to a health care professional?

☐0 No
☐1 Yes → If Yes: Please specify all: Drug: SEQNO= <I:3> DRGREACT <V:80> Month/year: DRGRCTM / DRGRCTY (month / year)
Drug: _____ Month/year: <ZMONTH> / <I:4> (month / year)
Drug: _____ Month/year: ___ ___ / ___ ___ ___ ___ (month / year)
☐2 Cannot remember
HXREACT <RTYNCR>

History of Injury

We would like to get the names and addresses of all the physicians who were involved in the care of your liver problem.

SEQNO = <I:3>

LIVERMD (TYPE 2) R
Limit to 5 sequences

1 MD name: HXMDFRST <V:30> HXMDLST <V:30>
City, State: HXMDCITY <V:25> HXMDST <V:5>

2 MD name: _____
City, State: _____

3 MD name: _____
City, State: _____

HXHOSP (TYPE 2) R
Limit to 5 sequences

4 Were you hospitalized for this injury?

☐0 No
☐1 Yes → If Yes: Please provide: SEQNO= <I:3> Hospital #1: HXHOSPNM <V:50>
City, State: HXHOSPCY <V:25> HXHOSPST <V:5>
Month/year: HXHOSPM / HXHOSPY (month / year)
<ZMONTH> <I:4>
Hospital #2: _____
City, State: _____
Month/year: ___ ___ / ___ ___ ___ ___ (month / year)
Hospital #3: _____
City, State: _____
Month/year: ___ ___ / ___ ___ ___ ___ (month / year)
☐2 Cannot remember
HXHOSPI <RTYNCR>

LIVRHX1 (TYPE1)

5 Was a liver biopsy performed?

☐0 No
☐1 Yes → If Yes: Please provide: Hospital: HXBIOPNM <V:50>
City, State: HXBIOPCY <V:25> HXBIOPST <V:5>
Month/year: HXBIOPM / HXBIOPY (month / year)
<ZMONTH> <I:4>
☐2 Cannot remember
HXBIOP <RTYNCR>

History of Injury (continued)

LIVRHX2 (TYPE 1)

6 Was a liver transplant performed?

☐0 No
☐1 Yes → If Yes: Please provide: Hospital: HXTRXNM <V:50>

HXLIVTRX <ZYESNO>

City, State: HXTRXCY <V:25> HXTRXST <V:5>

Month/year: HXTRXM <ZMONTH> / HXTRXY <Y:4>

7 How long were you sick with this injury? *(check only one)*

☐1 A few days
☐2 A week
☐3 2–4 weeks
☐4 Several months

LIVRSICK <RTLGTH>

8 Did you miss work or school because of this injury?

☐0 No
☐1 Yes → If Yes: Please specify length of time:

☐1 A few days LTIME <RTLGTH>
☐2 1 week
☐3 2–4 weeks
☐4 Several months

LIVRWORK <ZYESNO>

9 Did you have any persistent symptoms *(itch, dark urine or fatigue)* or medical problems?

☐0 No
☐1 Yes → If Yes: Please specify: PERSISSP <V:200>

PERSIST <ZYESNO>

10 In general, would you say your current health is *(check only one)*:

☐1 Excellent
☐2 Very good
☐3 Good
☐4 Fair
☐5 Poor

CURRHLTH <ZHLTH>

11 After you stopped taking NOT DATABASED *drug name* the first time, did you ever take NOT DATABASED *drug name* again?

☐0 No
☐1 Yes → If Yes: Did you suffer a bad reaction to it that was severe enough to require a visit to a health care professional?

☐0 No LIVREACT <ZYESNO>
☐1 Yes → If Yes: What type of bad reaction did you experience? *(check all that apply)*

☐ Jaundice	☐ Itching	☐ Chills
☐ Nausea	☐ Changes in mental states	☐ Other *(specify)*:
☐ Anorexia	☐ Ascites	
☐ Difficulty breathing	☐ Edema	☐ Other *(specify)*:
☐ Dark urine	☐ Hepatomegaly	
☐ Fever	☐ Splenomegaly	
☐ Abdominal pain	☐ Lymphadenopathy	
☐ Vomiting	☐ Fatigue	
☐ Rash	☐ Gray stool	

JAUNDICE <ZYES>
NAUSEA <ZYES>
ANOREXIA <ZYES>
BREATH <ZYES>
DRKURINE <ZYES>
FEVERRCH <ZYES>
ABDPAIN <ZYES>
VOMIT <ZYES>
RASHRCH <ZYES>

CHILLS <ZYES>
REACTOTH <ZYES>
OTHER2 <ZYES>
REACTSP <V:200>
OTHER2SP <V:200>

ITCH <ZYES>
MENTAL <ZYES>
ASCITES <ZYES>
EDEMA <ZYES>
HEPTMGLY <ZYES>
SPLNMGLY <ZYES>
LYPMHDPY <ZYES>
FATIGUE <ZYES>
GRYSTOOL <ZYES>

☐2 Cannot remember

HXRECHAL <RTYNCR>

Medical History Phase 1 One Month Prior To Start of Implicated Medication

MEDHX (TYPE4)

For this next part of the interview, I am going to be asking you questions about your medical history. I'd like to start with the one-month period prior to the start of NOT DATABASED (drug name). We will call this Phase 1. Then I will ask you questions about your medical history for the time period before the liver problem occurred. We will call this Phase 2. Please try to give me the information as accurately as you can.

According to the screening interview, you started NOT DATABASED (drug name) in NOT DATABASED (month/year).

1 Now, I'd like you to think about the one-month period prior to starting the medication. Let's say one drink equals 12 oz of beer or a 5 oz glass of wine, or 1.5 oz of liquor. During this time period, how often did you have at least one drink containing alcohol? *(check only one)*

- ☐1 Never
- ☐2 Less than once per week
- ☐3 Several times per week
- ☐4 Daily

DRINK <RTDRNK>

2 On those occasions when you drank, how many drinks on average did you consume? *(check only one)*

- ☐1 1–2 drinks per occasion
- ☐2 3–6 drinks per occasion
- ☐3 7 or more drinks per occasion

AVGDRNK <RTAVG>

3 During this time period, did you smoke?

- ☐0 No
- ☐1 Yes → **If Yes: How many cigarettes did you typically smoke each day?** *(check only one)*

SMOKE <ZYESNO>

- ☐1 1–5
- ☐2 6–10
- ☐3 11–15
- ☐4 16–20
- ☐5 More than 20

SMOKEDAY <RTSMKE>

4 During this time period, did you take any products containing acetaminophen *(Tylenol, Excedrin, Midrin, or NyQuil, etc.)*?

- ☐0 No
- ☐1 Yes
- ☐2 Cannot remember

ACETAMIN <RTYNCR>

5 During this time period, did you take any products containing aspirin?

- ☐0 No
- ☐1 Yes
- ☐2 Cannot remember

ASA <RTYNCR>

6 During this time period, did you take a drug called L-carnitine?

- ☐0 No
- ☐1 Yes
- ☐2 Cannot remember
- ☐3 Not a valproic acid case

LCARNTN <RTLCAR>

DILIN Drug-Induced Liver Injury Network

Retrospective

Case Telephone/Personal Interview

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Concomitant Products Phase 1 Within One Month of Starting Implicated Medication

During this time period, do you remember taking any other prescription drugs, over-the-counter medications, or any herbal medication *(e.g., St. John's wort, echinacea, ginkgo biloba, garlic, ginseng, hawthorn, green tea or evening primrose)*? HXCONMED (TYPE 4)

☐0 No HXCOMED <RTYNCR>
☐1 Yes → **If Yes: Please specify below. Use generic names. Use trade names for combination drugs.**
☐2 Cannot remember

SEQNO <I:3>	Prescription Drug HXRXMED (TYPE 4)R Limit to 25 sequences	Over-The-Counter Medication HXOTCMED (TYPE 4)R Limit to 25 sequences	Herbal Medication HXCAMMED (TYPE 4)R Limit to 25 sequences
1	HXPRMED <V:80>	HXOCMED <V:80>	HXHRBMED <V:80>
2	WHODRUG_B2 = CODING DICTIONARY WHOCODE <V:32> WHONAME <V:80>	WHODRUG_B2 = CODING DICTIONARY WHOCODE <V:32> WHONAME <V:80>	WHODRUG_B2 = CODING DICTIONARY WHOCODE <V:32> WHONAME <V:80>
3	CONFLVL <V:2> CODETM <DATETIME>	CONFLVL <V:2> CODETM <DATETIME>	CONFLVL <V:2> CODETM <DATETIME>
4	MATCHES <V:4> CODER <V:20> WORKFLOW <V:5	MATCHES <V:4> CODER <V:20> WORKFLOW <V:5	MATCHES <V:4> CODER <V:20> WORKFLOW <V:5
5			
6			
7			
8			
9			
10			
11			

Retrospective Telephone/Personal Interview

Drug-Induced Liver Injury Network

SEE ANNOTATION ON PG T4

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Medical History Phase 2 Time Period Prior To Liver Problem

MEDHX (TYPE4)

Reminder: Please calculate prior to conducting the interview:

Date of liver problem: LIV1M (month) / LIV1Y (year) minus 3 months = LIV2M (month) / LIV2Y (year)

From Screening form, start date of medication: SCRM (month) / SCRY (year)

Ask the questions below based on the later date.

Now, I will ask you to think about your medical history from _____ up to the date the liver problem occurred. This is Phase 2. Please try to give me the information as accurately as you can.

1 Let's say one drink equals 12 oz of beer or a 5 oz glass of wine, or 1.5 oz of liquor. During this time period, how often did you have at least one drink containing alcohol? *(check only one)*

- ☐1 Never
- ☐2 Less than once per week
- ☐3 Several times per week
- ☐4 Daily

2 On those occasions when you drank, how many drinks on average did you consume? *(check only one)*

- ☐1 1–2 drinks per occasion
- ☐2 3–6 drinks per occasion
- ☐3 7 or more drinks per occasion

3 During this time period, did you smoke?

- ☐0 No
- ☐1 Yes → **If Yes: How many cigarettes did you typically smoke each day?** *(check only one)*
  - ☐1 1–5
  - ☐2 6–10
  - ☐3 11–15
  - ☐4 16–20
  - ☐5 More than 20

4 During this time period, did you take any products containing acetaminophen *(Tylenol, Excedrin, Midrin, or NyQuil, etc.)*?

- ☐0 No
- ☐1 Yes
- ☐2 Cannot remember

5 During this time period, did you take any products containing aspirin?

- ☐0 No
- ☐1 Yes
- ☐2 Cannot remember

6 During this time period, did you take a drug called L-carnitine? *(check only one)*

- ☐0 No
- ☐1 Yes
- ☐2 Cannot remember
- ☐3 Not a valproic acid case

DILIN
Drug-Induced Liver Injury Network

Retrospective

Case
Telephone/Personal Interview

SEE ANNOTATION ON PG T5

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Concomitant Products Phase 2 Time Period Prior to Liver Problem

During this time period, do you remember taking any other prescription drugs, over-the-counter medications, or any herbal medication *(e.g, St. John's wort, echinacea, ginkgo biloba, garlic, ginseng, hawthorn, green tea or evening primrose)*?

☐0 No
☐1 Yes → If Yes: Please specify below. Use generic names. Use trade names for combination drugs.
☐2 Cannot remember

Prescription Drug	Over-The-Counter Medication	Herbal Medication
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9
10	10	10
11	11	11

Family History

FAMHXP (TYPE 2) PS

Now, I want you to think about your immediate family and possible liver problems, if known.

SEQNO=1
<ZSEQNO>

1 Is your biological mother still living?

☐0 No
☐1 Yes → If Yes: What is her age? ___ ___ ___ OR ☐99 Unknown
HXAGE <I:3>
PAGEUNK <ZYES>

What is her current health status? *(check only one)*
PARENT <ZYNUNK>
☐1 Good ☐3 Poor
☐2 Fair ☐99 Unknown
PHLTH <RTHLTH>

☐99 Unknown

2 What is her race? *(check all that apply)*

INDIAN <ZYES>
ASIAN <ZYES>
BLACK <ZYES>
☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or other Pacific Islander
☐ White or Caucasian
☐ Other *(specify)*: _____

NATIVE <ZYES>
WHITE <ZYES>
RACEOTHR <ZYES> RACESP <V:25>

3 Has your biological mother had any liver problems?

☐0 No
☐1 Yes → If Yes: What type of liver problems did she experience? *(check all that apply)*

ABNLT <ZYES>
HEPA <ZYES>
HEPB <ZYES>
HEPC <ZYES>
ARLD <ZYES>
FLNRA <ZYES>
☐ Unexplained abnormal liver tests
☐ Hepatitis A *(infectious)*
☐ Hepatitis B
☐ Hepatitis C
☐ Alcohol-related liver disease
☐ Non-alcoholic fatty liver disease (NALFD/NASH)

PBCIRRH <ZYES>
HEMCHROM <ZYES>
WILSON <ZYES>
AATDEF <ZYES>
CIRRHUN <ZYES>
AIMD <ZYES>
☐ Primary biliary cirrhosis
☐ Hemochromatosis
☐ Wilson's disease
☐ A1AT deficiency
☐ Cirrhosis–unspecified
☐ Autoimmune disease

☐ Primary sclerosing cholangitis
☐ Gilbert's syndrome
☐ Ischemic hepatitis
☐ Liver transplantation
☐ Family history of liver disease
☐ Unknown
☐ Other *(specify)*: _____

PSCHLANG <ZYES>
GILBERT <ZYES>
HEPISCHM <ZYES>
LIVERTRX <ZYES>
UNK <ZYES>
OTHER <ZYES>
PROBSP <V:200>

LIVPROB <ZYNUNK>

☐99 Unknown

4 Has your biological mother ever suffered a liver problem *(e.g. jaundice, abnormal liver tests)* due to taking any drugs *(prescription or over-the-counter)* that was severe enough to require a visit to a health care professional?

☐0 No
☐1 Yes → If Yes: Please specify all:

LIVDRG <ZYNUNK>

Drug name: _____ DRGNM1 <V:80> _____ Date: DRG1M <ZMONTH> (month) / DRG1Y <I:4> (year)

Drug name: _____ DRGNM2 <V:80> _____ Date: DRG2M <ZMONTH> (month) / DRG2Y <I:4> (year)

Drug name: _____ DRGNM3 <V:80> _____ Date: DRG3M <ZMONTH> (month) / DRG3Y <I:4> (year)

☐99 Unknown

SEQNO=2
<ZSEQNO>

5 Is your biological father still living?

☐0 No
☐1 Yes → If Yes: What is his age? ___ ___ ___ OR ☐99 Unknown

What is his current health status? *(check only one)*
☐1 Good ☐3 Poor
☐2 Fair ☐99 Unknown

☐99 Unknown

Family History (continued)

FAMHXP (TYPE 2) PS

6 What is his race? *(check all that apply)*

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White or Caucasian
- ☐ Other *(specify)*: _____

7 Has your biological father had any liver problems?

- ☐ 0 No
- ☐ 1 Yes → **If Yes: What type of liver problems did he experience?** *(check all that apply)*
  - ☐ Unexplained abnormal liver tests
  - ☐ Hepatitis A *(infectious)*
  - ☐ Hepatitis B
  - ☐ Hepatitis C
  - ☐ Alcohol-related liver disease
  - ☐ Non-alcoholic fatty liver disease (NALFD/NASH)
  - ☐ Primary biliary cirrhosis
  - ☐ Hemochromatosis
  - ☐ Wilson's disease
  - ☐ A_1AT deficiency
  - ☐ Cirrhosis–unspecified
  - ☐ Autoimmune disease
  - ☐ Primary sclerosing cholangitis
  - ☐ Gilbert's syndrome
  - ☐ Ischemic hepatitis
  - ☐ Liver transplantation
  - ☐ Family history of liver disease
  - ☐ Unknown
  - ☐ Other *(specify)*: _____
- ☐ 99 Unknown

8 Has your biological father ever suffered a liver problem *(e.g. jaundice, abnormal liver test)* **due to taking any drugs** *(prescription or over-the-counter)* **that was severe enough to require a visit to a health care professional?**

- ☐ 0 No
- ☐ 1 Yes → **If Yes: Please specify all:**
  - **Drug name:** _____ **Date:** ___ ___ ___ / ___ ___ ___ ___ (month / year)
  - **Drug name:** _____ **Date:** ___ ___ ___ / ___ ___ ___ ___ (month / year)
  - **Drug name:** _____ **Date:** ___ ___ ___ / ___ ___ ___ ___ (month / year)
- ☐ 99 Unknown

FAMHXS (TYPE 1)

Put Q9-Q12 on same pg

9 Are you a twin or one of a multiple birth?

- ☐ 0 No
- ☐ 1 Yes → **If Yes: Are you identical?**
  - ☐ 0 No
  - ☐ 1 Yes
  - ☐ 99 Unknown

TWIN <ZYESNO> TWINIDNT <ZYNUNK>

10 How many biological brothers and sisters do you have? Brothers: ___ ___ Sisters: ___ ___ ☐ 96 NA

BROTHER <I:2> SISTER <I:2> SIBSNA <ZYES>

How many of your biological siblings are still alive? SIBS <I:2> ***Reminder: Biological includes full and half siblings.***

11 Have any of your biological siblings ever had a liver problem?

- ☐ 0 No
- ☐ 1 Yes → **If Yes: What type of liver problems did they experience?** *(check all that apply)*
  - ☐ Unexplained abnormal liver tests
  - ☐ Hepatitis A *(infectious)*
  - ☐ Hepatitis B
  - ☐ Hepatitis C
  - ☐ Alcohol-related liver disease
  - ☐ Non-alcoholic fatty liver disease (NALFD/NASH)
  - ☐ Primary biliary cirrhosis
  - ☐ Hemochromatosis
  - ☐ Wilson's disease
  - ☐ A_1AT deficiency
  - ☐ Cirrhosis–unspecified
  - ☐ Autoimmune disease
  - ☐ Primary sclerosing cholangitis
  - ☐ Gilbert's syndrome
  - ☐ Ischemic hepatitis
  - ☐ Liver transplantation
  - ☐ Family history of liver disease
  - ☐ Unknown
  - ☐ Other *(specify)*: PROBSP <V:200>
- ☐ 99 Unknown
- ☐ 96 NA or Not applicable

ABNLT <ZYES>
HEPA <ZYES>
HEPB <ZYES>
HEPC <ZYES>
ARLD <ZYES>
FLNRA <ZYES>

PBCIRRH <ZYES>
HEMCHROM <ZYES>
WILSON <ZYES>
AATDEF <ZYES>
CIRRHUN <ZYES>
AIMD <ZYES>

LIVPROB <RTANSR>

PSCHLANG <ZYES>
GILBERT <ZYES>
HEPISCHM <ZYES>
LIVERTRX <ZYES>
FAMHXLIV <ZYES>
UNK <ZYES>
OTHER <ZYES>

Family History (continued)

12 Have any of your biological siblings ever suffered a liver problem *(e.g. jaundice, abnormal liver tests)* due to taking any drugs *(prescription or over-the-counter)* that was severe enough to require a visit to a health care professional?

☐0 No
☐1 Yes → If Yes: Please specify all:

Drug name: DRGNM1 <V:80> Date: DRG1M <ZMONTH> / DRG1Y <I:4>
Drug name: DRGNM2 <V:80> Date: DRG2M <ZMONTH> / DRG2Y <I:4>
LIVDRG <RTANSR> Drug name: DRGNM3 <V:80> Date: DRG3M <ZMONTH> / DRG3Y <I:4>

☐99 Unknown
☐96 NA

FAMHXC (TYPE 1)

13 How many biological children do you have? Males: MCHILD <1:2> ___ Females: FCHILD <1:2> ___ ☐96 NA CHILDNA <ZYES>

How many of your biological children are still alive? CHILDREN <1:2> ___ ___

14 Have any of your biological children ever had a liver problem?

☐0 No
☐1 Yes → If Yes: What type of liver problems did they experience? *(check all that apply)*

- ☐ Unexplained abnormal liver tests ABNLT <ZYES>
- ☐ Hepatitis A *(infectious)* HEPA <ZYES>
- ☐ Hepatitis B HEPB <ZYES>
- ☐ Hepatitis C HEPC <ZYES>
- ☐ Alcohol-related liver disease ARLD <ZYES>
- ☐ Non-alcoholic fatty liver disease (NALFD/NASH) FLNRA <ZYES>
- ☐ Primary biliary cirrhosis PBCIRRH <ZYES>
- ☐ Hemochromatosis HEMCHROM <ZYES>
- ☐ Wilson's disease WILSON <ZYES>
- ☐ A_1AT deficiency AATDEF <ZYES>
- ☐ Cirrhosis–unspecified CIRRHUN <ZYES>
- ☐ Autoimmune disease AIMD <ZYES>
- ☐ Primary sclerosing cholangitis PSCHLANG <ZYES>
- ☐ Gilbert's syndrome GILBERT <ZYES>
- ☐ Ischemic hepatitis HEPISCHM <ZYES>
- ☐ Liver transplantation LIVERTRX <ZYES>
- ☐ Family history of liver disease FAMHXLIV <ZYES>
- ☐ Unknown UNK <ZYES>
- ☐ Other *(specify)*: PROBSP <V:200> OTHER <ZYES>

LIVPROB <RTANSR>

☐99 Unknown
☐96 NA

15 Have any of your biological children ever suffered a liver problem *(e.g. jaundice, abnormal liver tests)* due to taking any drugs *(prescription or over-the-counter)* that was severe enough to require a visit to a health care professional?

☐0 No
☐1 Yes → If Yes: Please specify all:

Drug name: DRGNM1 <V:80> Date: DRG1M <ZMONTH> / DRG1Y <I:4>
Drug name: DRGNM2 <V:80> Date: DRG2M <ZMONTH> / DRG2Y <I:4>
LIVDRG <RTANSR> Drug name: DRGNM3 <V:80> Date: DRG3M <ZMONTH> / DRG3Y <I:4>

☐99 Unknown
☐96 NA

Blood Draw

INTDRAW (TYPE 1)

Preferred location: Name: INTBDNM <V:50>

Address: INTBDADD <V:25>

INTBDCTY <V:25> INTBDST <V:5> INTBDZIP<V:10>

Phone: (___ ___ ___) ___ ___ ___ - INTBDPH <V:10> ___ ___ ___ ___

Date and time of blood draw appointment: ___ ___ / ___ ___ ___ / INTBDDT ___ ___ ___ ___ (day / month / year) INTBDTM ___ ___ : ___ ___ (00:00 to 23:59)

This is the end of the interview. Thank you for participating.

Investigator Signature

SIGNATUR (TYPE 4)

I have reviewed and found all data pertaining to this participant to be complete and accurate.

Investigator's signature: SIGNANS <ZYES> _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SIGDT

STUDYBOOK= CASE_RET
FORM= MED CHART

DILIN
Drug-Induced Liver Injury Network

Retrospective

NO DATA

Case Medical Chart Review

SUBJNO= INVSITE||-||PATID

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Medical Chart Review

MCCOMPLT (TYPE 1)

Was the Medical Chart Review completed?

☐0 No → If No: Check only one:
- ☐1 Patient did not qualify as a case
- ☐2 Insufficient patient records/charts available
- ☐3 Patient records/charts not obtained

NOCOMPL <RTCOMP>

REVCOMPL <ZYESNO>

☐1 Yes

ALL DAY FIELDS RANGE 1-31
ALL YEAR FIELDS RANGE 1900-2017
ALL TIME FIELDS RANGE 00-23 HR
00-59 MIN

DILI Episode

DILIEPSD (TYPE 2) R

Check only one:

☐1 Isoniazid ☐3 Clavulanic acid/Amoxicillin ☐5 Nitrofurantoin ☐7 Trimethoprim-Sulfamethoxazole
☐2 Phenytoin ☐4 Valproic acid ☐6 Minocycline ☐8 Quinolone antibiotics

DILIMED <RTDRUG>

SEQNO=<I:3>

	Dose	Unit	Freq[1]	Route[2]	Start Date	Stop Date	Indication (check only one)
1	DOSE <F9.3> _____	UNIT <V:10>	* FREQ	** ROUTE	DRGSTDT __/__/____ (day month year)	DRGSPDT __/__/____ (day month year)	DRGIND <RTINDC> ☐1 Seizures ☐4 Latent TB ☐2 Migraine ☐5 Bacterial infection ☐3 Bipolar ☐98 Other: _____ DRGINDSP <V:200>
2	_____		FREQSP <V:100>	RTESP <V:100>	__/__/____ (day month year)	__/__/____ (day month year)	☐1 Seizures ☐4 Latent TB ☐2 Migraine ☐5 Bacterial infection ☐3 Bipolar ☐98 Other: _____
3	_____				__/__/____ (day month year)	__/__/____ (day month year)	☐1 Seizures ☐4 Latent TB ☐2 Migraine ☐5 Bacterial infection ☐3 Bipolar ☐98 Other: _____
4	_____				__/__/____ (day month year)	__/__/____ (day month year)	☐1 Seizures ☐4 Latent TB ☐2 Migraine ☐5 Bacterial infection ☐3 Bipolar ☐98 Other: _____
5	_____				__/__/____ (day month year)	__/__/____ (day month year)	☐1 Seizures ☐4 Latent TB ☐2 Migraine ☐5 Bacterial infection ☐3 Bipolar ☐98 Other: _____
6	_____				__/__/____ (day month year)	__/__/____ (day month year)	☐1 Seizures ☐4 Latent TB ☐2 Migraine ☐5 Bacterial infection ☐3 Bipolar ☐98 Other: _____
7	_____				__/__/____ (day month year)	__/__/____ (day month year)	☐1 Seizures ☐4 Latent TB ☐2 Migraine ☐5 Bacterial infection ☐3 Bipolar ☐98 Other: _____

[1] **Frequency:** **1** = QD **4** = QID **7** = Monthly
*<RTFREQ> **2** = BID **5** = PRN **8** = Other (specify in column above)
3 = TID **6** = Weekly

[2] **Route:** **1** = PO **4** = IM
<RTRTE> **2 = IV **5** = Topical/transdermal
3 = SC **6** = Other (specify in column above)

DILIN
Drug-Induced Liver Injury Network

Retrospective Case Medical Chart Review

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

DILI Onset

DILIONST (TYPE 2) R

Please provide pertinent information for the implicated DILI medication:

DILIDRUG <RTDLON>

1= **Valproic acid:**

Record the first date of hospitalization following start of the implicated medication: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year)

2= **Isoniazid:** ONSETDT ONSETVAL <F9:3>

Record the first date of Serum Total Bilirubin > 2.5 mg/dL: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) and Value: _____ mg/dL

3= **Phenytoin:**

Record the first date of Serum Total Bilirubin > 2.5 mg/dL: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) and Value: _____ mg/dL

4= **Clavulanic acid/Amoxicillin:**

Record the first date of Serum Total Bilirubin > 2.5 mg/dL: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) and Value: _____ mg/dL

5= **Minocycline:**

Record the first date of Serum Total Bilirubin > 2.5 mg/dL: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) and Value: _____ mg/dL

6= **Trimethoprim-Sulfamethoxazole:**

Record the first date of Serum Total Bilirubin > 2.5 mg/dL: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) and Value: _____ mg/dL

7= **Nitrofurantoin:**

Record the first date of Serum Total Bilirubin > 2.5 mg/dL: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) and Value: _____ mg/dL

8= **Quinolone antibiotics:**

Record the first date of Serum Total Bilirubin > 2.5 mg/dL: ___ ___/___ ___ ___/___ ___ ___ ___ (day / month / year) and Value: _____ mg/dL

Signs and Symptoms At Onset

DILISYMP (TYPE1)

1 Weight: DILIWT <F9:3>1= ___ ___ ___ lb OR 2= ___ ___ ___ . ___ kg DILIWTUN <RTWGHT>

Height: DILIHT <F9:3>1= ___ ___ ___ in OR 2= ___ ___ ___ cm DILIHTUN <ZHGTU>

MBMI <F9:3>=
(DILIWT / (DILIHT x DILIHT)) x 703
where ALL of (DILIWTUN, DILIHTUN) = 1
(DILIWT / (DILIHT x DILIHT)) x 10,000
where ALL of (DILIWTUN, DILIHTUN) = 2

*2 Check all signs and symptoms that apply:

☐ Jaundice	☐ Changes in mental states	JAUNDICE <ZYES>	MENTAL <ZYES>
☐ Nausea	☐ Ascites	NAUSEA <ZYES>	ASCITES <ZYES>
☐ Anorexia	☐ Edema	ANOREXIA <ZYES>	EDEMA <ZYES>
☐ Difficulty breathing	☐ Hepatomegaly	BREATH <ZYES>	HEPATOMG <ZYES>
☐ Dark urine	☐ Splenomegaly	DKURINE <ZYES>	SPLENOMG <ZYES>
☐ Fever	☐ Lymphadenopathy	FEVER <ZYES>	LYMPHADN <ZYES>
☐ Abdominal pain	☐ Fatigue	ABDPAIN <ZYES>	FATIGUE <ZYES>
☐ Vomiting	☐ Gray stool	VOMIT <ZYES>	GRYSTOOL <ZYES>
☐ Rash	☐ Chills	RASH <ZYES>	CHILLS <ZYES>
☐ Itching	☐ Other (specify): _____	ITCH <ZYES>	SYMOTHR <ZYES>

SYMPTSP <V:200>

*HIDE DROWSY, ENCEPHAL

Treatment

DILITX1 (TYPE 1)

1 Was the participant hospitalized for this episode?

☐0 No
☐1 Yes → If Yes: Please provide: Hospital: _____ TXHOSPNM <V:50>
DILIHOSP <ZYESNO>
City, State: _____ TXHOSPCY <V:25> TXHOSPST <V:5>
Date: __ __/__ __ __ __ TXHOSPDT
day month year

2 Did the participant receive prednisone or corticosteroids for this episode?

☐0 No
☐1 Yes → If Yes: Please provide date: __ __/__ __ __ __/__ __ __ __ STERODDT
day month year
STEROIDS <ZYESNO> *Note: Also record on Concomitant Prescription Medications log.*

3 Did the participant have extrahepatic manifestations during DILI episode?

☐0 No
☐1 Yes → If Yes: Please specify *(check all that apply)*:
HEPATIC <ZYESNO>

- ☐ Neutropenia — NEUTRPEN <ZYES>
- ☐ Thrombocytopenia — THRMBPEN <ZYES>
- ☐ Stevens-Johnson syndrome — SJSYNDRM <ZYES>
- ☐ Toxic epidermal necrolysis — NECROLY <ZYES>
- ☐ Hemolytic anemia — HMANEMIA <ZYES>
- ☐ Serum sickness — SERUMSCK <ZYES>
- ☐ Other *(specify)*: _____ — HEPAOTHR <ZYES> HEPASP <V:200>

DILITX2 (TYPE 1)

4 Was a liver biopsy performed for this episode?

☐0 No
☐1 Yes → If Yes: Please provide: Hospital: _____ TXBPHOSP <V:50>
TXBIOP <ZYESNO>
City, State: _____ TXBPCY <V:25> TXBPST <V:5>
Date: __ __/__ __ __ __ TXBPDT
day month year

5 Was a liver transplant performed for this episode?

☐0 No
☐1 Yes → If Yes: Please provide: Hospital: _____ TXTRHOSP <V:50>
TXTRANS <ZYESNO>
City, State: _____ TXTRCY <V:25> TXTRST <V:5>
Date: __ __/__ __ __ __ TXTRDT
day month year

6 Was the participant rechallenged with the implicated drug?

☐0 No
☐1 Yes → If Yes: Please provide: Start date: __ __/__ __ __/__ __ __ __ TXSTDT Stop date: __ __/__ __ __/__ __ __ __ TXSPDT
day month year day month year
TXRECHAL <ZYESNO>

REPEATING PAGE

DILIN
Drug-Induced Liver Injury Network

Retrospective

Case Medical Chart Review

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Concomitant Prescription Medications

	Prescription Medications (RXMED1 (TYPE 4) R) One Month Prior To Start of Implicated Medication		Prescription Medications (RXMED2 (TYPE 4) R) Time Period Prior To Liver Problem
SEQNO= <I:3> 1	RX1MED <V:80>	1	RX2MED <V:80>
2	WHODRUG_B2= CODING DICTIONARY	2	WHODRUG_B2 = CODING DICTIONARY
3	WHOCODE <V:32> WHONAME <V:80>	3	WHOCODE <V:32> WHONAME <V:80>
4	CONFLVL <V:2> CODETM <DATETIME> MATCHES <V:4>	4	CONFLVL <V:2> CODETM <DATETIME> MATCHES <V:4>
5	CODER <V:20> WORKFLOW <V:5>	5	CODER <V:20> WORKFLOW <V:5>
6		6	
7		7	
8		8	
9		9	
10		10	
11		11	
12		12	
13		13	
14		14	
15		15	
16		16	
17		17	
18		18	
19		19	
20		20	

Adding pages: additional pages are provided in your packet. If needed, insert and sequentially number each additional page in the lower right corner, i.e. M4.2, M4.3, etc.

REPEATING PAGE

DILIN
Drug-Induced Liver Injury Network

Retrospective Case Medical Chart Review

SEE ANNOTATION ON PG M4

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Concomitant Non-prescription Medications CAM/OTC

Non-prescription Medications One Month Prior To Start of Implicated Medication	Non-prescription Medications Time Period Prior To Liver Problem
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9
10	10
11	11
12	12
13	13
14	14
15	15
16	16
17	17
18	18
19	19
20	20

Adding pages: additional pages are provided in your packet. If needed, insert and sequentially number each additional page in the lower right corner, i.e. M5.2, M5.3, etc.

DILIN Drug-Induced Liver Injury Network

Retrospective

Case Medical Chart Review

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

ILLNESS1 (TYPE 2) PS

Concomitant Medical Conditions and Illnesses

CONILLN <RTILLN>	One Month Prior MTHPRIOR <ZYESNO>	Time Period Prior TMPRIOR <ZYESNO>
1 HCV:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
2 HBV:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
3 Alcohol-related liver disease:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
4 Non-alcoholic fatty liver disease *(NALFD-NASH)*:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
5 Wilson's disease:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
6 Hemochromatosis:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
7 Primary biliary cirrhosis:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
8 Primary sclerosing cholangitis:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
9 Unexplained abnormal liver tests:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
10 Gilbert's Syndrome:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
11 A_1AT deficiency:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
12 Cirrhosis—unspecified:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
13 Ischemic hepatitis:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
29 = 14 Hepatitis A:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
30 = 15 Autoimmune hepatitis:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
31 = 16 Liver transplantation:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
28 = Already in codelist 17 Hypertension:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
32 = 18 Congestive heart failure:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
33 = 19 Acute congestive heart failure:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
34 = 20 Hypotension:	☐0 No ☐1 Yes	☐0 No ☐1 Yes
35 = 21 Acute hypotension:	☐0 No ☐1 Yes	☐0 No ☐1 Yes

Drug-Induced Liver Injury Network

Retrospective Case Medical Chart Review

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___ ___ ___

ILLNESS2 (TYPE 2) PS

Concomitant Medical Conditions and Illnesses (continued)

CONILLN <RTILLN>	One Month Prior MTHPRIOR<ZYESNO>	Time Period Prior TMPRIOR <ZYESNO>
14 = **22** Chronic liver disease:	☐0 No ☐1 Yes → If Yes: Specify: ILLNSP <V:200>	☐0 No ☐1 Yes → If Yes: Specify: ILLN2SP <V:200>
15 = **23** Organ transplantation:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
16 = **24** Family history of liver disease:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
17 = **25** Diabetes/endocrine disorder:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
18 = **26** Infectious disease:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
19 = **27** Psychiatric disease:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
20 = **28** Neurological disease:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
21 = **29** Heart disease:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
22 = **30** Renal disease:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
23 = **31** Pulmonary disease:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
24 = **32** Gastrointestinal disease:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
25 = **33** Malignancy:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
26 = **34** Autoimmune/collagen vascular disease:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
27 = **35** Allergies to medications:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
= **36** Reproductive issues:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:
= **37** Other:	☐0 No ☐1 Yes → If Yes: Specify:	☐0 No ☐1 Yes → If Yes: Specify:

DILIN
Drug-Induced Liver Injury Network

Retrospective

Case Medical Chart Review

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

LAB1 (Type 4) PS

Lab

LABNAME <RTLAB>	Value at Onset or Within 2 Weeks of Onset	Most Abnormal Value
1 Hemoglobin:	☐1 Not done ONSTND <ZYES> Value: ___ ___ . ___ g/dL ONSTVAL <F9:3> ONSTUNIT <RTUNIT> Date: ___ ___/___ ___ ___/___ ___ ___ ___ ONSTDT (day month year)	☐1 Not done ABNND <ZYES> Value: ___ ___ . ___ g/dL ABNVAL <F9:3> ABNUNIT <RTUNIT> Date: ___ ___/___ ___ ___/___ ___ ___ ___ ABNDT (day month year)
2 WBC:	☐1 Not done Value: ___ ___ ___ ___ . ___ 10^9/L OR 10^3/mm^3 Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done Value: ___ ___ ___ ___ . ___ 10^9/L OR 10^3/mm^3 Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)
3 Blood Platelets:	☐1 Not done Value: ___ ___ ___ ___ . ___ 10^9/L OR 10^3/mm^3 Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done Value: ___ ___ ___ ___ . ___ 10^9/L OR 10^3/mm^3 Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)
4 % Neutrophils:	☐1 Not done Value: ___ ___ . ___ 1 = ☐10 % 8= ☐8 10^9/L OR 10^3/mm^3 Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done Value: ___ ___ . ___ ☐10 % ☐8 10^9/L OR 10^3/mm^3 Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)
5 % Lymphocytes:	☐1 Not done Value: ___ ___ . ___ ☐10 % ☐8 10^9/L OR 10^3/mm^3 Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done Value: ___ ___ . ___ ☐10 % ☐8 10^9/L OR 10^3/mm^3 Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)
6 % Eosinophils:	☐1 Not done Value: ___ ___ . ___ ☐10 % ☐8 10^9/L OR 10^3/mm^3 Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done Value: ___ ___ . ___ ☐10 % ☐8 10^9/L OR 10^3/mm^3 Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)
7 Serum Creatinine: LABNAME <RTLAB>	☐1 Not done ONSTND <ZYES> Value: ___ ___ . ___ ONSTVAL <F9:3> ☐2 µmol/L ONSTUNIT <RTUNIT> ☐3 mg/dL Date: ___ ___/___ ___ ___/___ ___ ___ ___ ONSTDT (day month year)	☐1 Not done ABNND <ZYES> Value: ___ ___ . ___ ABNVAL <F9:3> ☐2 µmol/L ABNUNIT <RTUNIT> ☐3 mg/dL Date: ___ ___/___ ___ ___/___ ___ ___ ___ ABNDT (day month year)
8 BUN:	☐1 Not done Value: ___ ___ ___ . ___ ☐4 mmol/L ☐3 mg/dL Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done Value: ___ ___ ___ . ___ ☐4 mmol/L ☐3 mg/dL Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)
9 Serum Total Protein:	☐1 Not done Value: ___ ___ . ___ ☐6 g/L ☐7 g/dL Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done Value: ___ ___ . ___ ☐6 g/L ☐7 g/dL Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)
10 Serum Albumin:	☐1 Not done Value: ___ ___ . ___ ☐6 g/L ☐7 g/dL Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done Value: ___ ___ . ___ ☐6 g/L ☐7 g/dL Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)

LAB2 (Type 4) PS

DILIN
Drug-Induced Liver Injury Network

Retrospective Case Medical Chart Review

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

LAB1 (Type 4) PS

Lab

LABNAME <RTLAB>	Value at Onset or Within 2 Weeks of Onset	Most Abnormal Value
11 Sodium: 15 =	ONSTND <ZYES> ☐1 Not done ONSTVAL <F9:3> ONSTUNIT <RTUNIT> Value: ___ ___ ___ mmol/L ONSTDT Date: ___/___/___ (day month year)	ABNND <ZYES> ☐1 Not done ABNVAL <F9:3> ABNUNIT <RTUNIT> Value: ___ ___ ___ mmol/L ABNDT Date: ___/___/___ (day month year)
12 Potassium: 16 =	☐1 Not done Value: ___ ___ . ___ mmol/L Date: ___/___/___ (day month year)	☐1 Not done Value: ___ ___ . ___ mmol/L Date: ___/___/___ (day month year)
13 Cholesterol: 17 =	☐1 Not done Value: ___ ___ ___ ___ . ___ ___ ☐4 mmol/L ☐3 mg/dL Date: ___/___/___ (day month year)	☐1 Not done Value: ___ ___ ___ ___ . ___ ___ ☐4 mmol/L ☐3 mg/dL Date: ___/___/___ (day month year)
14 Triglycerides: 18 =	☐1 Not done Value: ___ ___ ___ ___ . ___ ___ ☐4 mmol/L ☐3 mg/dL Date: ___/___/___ (day month year)	☐1 Not done Value: ___ ___ ___ ___ . ___ ___ ☐4 mmol/L ☐3 mg/dL Date: ___/___/___ (day month year)
15 Serum Direct Bilirubin: 19 =	☐1 Not done Value: ___ ___ . ___ 2= ☐2 µmol/L ☐3 mg/dL Date: ___/___/___ (day month year)	☐1 Not done Value: ___ ___ . ___ 2= ☐2 µmol/L ☐3 mg/dL Date: ___/___/___ (day month year)
16 GGTP: 20 =	☐1 Not done ONSTULN <F9:3> Value: ___ ___ . ___ U/L ___ ___ ___ ULN 9 = Date: ___/___/___ (day month year)	☐1 Not done ABNULN <F9:3> Value: ___ ___ . ___ U/L ___ ___ ___ ULN Date: ___/___/___ (day month year)
17 LDH: 11=	☐1 Not done Value: ___ ___ ___ . ___ U/L ___ ___ ___ ULN Date: ___/___/___ (day month year)	☐1 Not done Value: ___ ___ ___ . ___ U/L ___ ___ ___ ULN Date: ___/___/___ (day month year)
18 CPK: 12 =	☐1 Not done Value: ___ ___ ___ U/L ___ ___ ___ ULN Date: ___/___/___ (day month year)	☐1 Not done Value: ___ ___ ___ U/L ___ ___ ___ ULN Date: ___/___/___ (day month year)
19 Amylase: 13 =	☐1 Not done Value: ___ ___ ___ . ___ U/L ___ ___ ___ ULN Date: ___/___/___ (day month year)	☐1 Not done Value: ___ ___ ___ . ___ U/L ___ ___ ___ ULN Date: ___/___/___ (day month year)
20 Lipase: 14 =	☐1 Not done Value: ___ ___ ___ . ___ U/L ___ ___ ___ ULN Date: ___/___/___ (day month year)	☐1 Not done Value: ___ ___ ___ . ___ U/L ___ ___ ___ ULN Date: ___/___/___ (day month year)

DILIN Drug-Induced Liver Injury Network

Retrospective

Case Medical Chart Review

6=PROTHROMBIN TIME WILL NOT BE USED

Site Number: ___ ___ ___ Participant ID Number: ___ LABFLOW (TYPE 4)R

Lab

	AST	ALT	Alkaline Phosphatase	Serum Total Bilirubin	INR
LABFLW <RTFLOW> **1** Prior to onset of symptoms *if available*: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year) LABDT	AST <ZYES> ☐1 Not done; ASTVAL <F9:3> ___ ___ ___ I/U or U/L or mIU/mL; ASTULN <F9:3> ___ ___ ULN	ALT <ZYES> ☐1 Not done; ALTVAL <F9:3> ___ ___ ___ I/U or U/L or mIU/mL; ALTULN <F9:3> ___ ___ ULN	AKP <ZYES> ☐1 Not done; AKPVAL <F9:3> ___ ___ ___ I/U or U/L or mIU/mL; AKPULN <F9:3> ___ ___ ___ ULN	STB <ZYES> ☐1 Not done; STBVAL <F9:3> ☐5 mg/dL ☐4 µmol/L; STBULN <F9:3> ___ . ___ ULN	INR <ZYES> ☐1 Not done; INRRATE <F9:3> ___ ___ . ___ ratio; STBUNIT <RTBUN>
2 First abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN; ASTCALC= ASTVAL/ ASTULN <F9:3>	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN; ALTCALC= ALTVAL/ ALTULN <F9:3>	☐1 Not done; ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ___ ULN; AKPCALC= AKPVAL/ AKPULN <F9:3>	☐1 Not done; ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L; ___ . ___ ULN; STBCALC= STBVAL/ STBULN <F9:3>	☐1 Not done; ___ ___ . ___ ratio; FLWRATIO= (ALTVAL/ ALTULN) /(AKPVAL/KPULN) <F9:3>
3 Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN	☐1 Not done; ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ___ ULN	☐1 Not done; ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L; ___ . ___ ULN; <RTBUN> 5=mg/dL 4=umol/L	☐1 Not done; ___ ___ . ___ ratio
4 Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN	☐1 Not done; ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ___ ULN	☐1 Not done; ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L; ___ . ___ ULN	☐1 Not done; ___ ___ . ___ ratio
5 Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN	☐1 Not done; ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ___ ULN	☐1 Not done; ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L; ___ . ___ ULN	☐1 Not done; ___ ___ . ___ ratio
6 Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN	☐1 Not done; ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ___ ULN	☐1 Not done; ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L; ___ . ___ ULN	☐1 Not done; ___ ___ . ___ ratio
7 Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN	☐1 Not done; ___ ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ULN	☐1 Not done; ___ ___ ___ ___ I/U or U/L or mIU/mL; ___ ___ ___ ULN	☐1 Not done; ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L; ___ . ___ ULN	☐1 Not done; ___ ___ . ___ ratio

DILIN
Drug-Induced Liver Injury Network

Retrospective

Case Medical Chart Review

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

SEE ANNOTATION ON PG M10

REPEATING PAGE

Lab

	AST	ALT	Alkaline Phosphatase	Serum Total Bilirubin	INR
SEQNO= <i:3> ___ Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ___ ULN	☐1 Not done ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L ___ . ___ ULN	☐1 Not done ___ ___ . ___ ratio
___ Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ___ ULN	☐1 Not done ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L ___ . ___ ULN	☐1 Not done ___ ___ . ___ ratio
___ Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ___ ULN	☐1 Not done ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L ___ . ___ ULN	☐1 Not done ___ ___ . ___ ratio
___ Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ___ ULN	☐1 Not done ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L ___ . ___ ULN	☐1 Not done ___ ___ . ___ ratio
___ Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ___ ULN	☐1 Not done ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L ___ . ___ ULN	☐1 Not done ___ ___ . ___ ratio
___ Subsequent abnormal value: Date: ___ ___/___ ___ ___/___ ___ ___ ___ (day month year)	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ULN	☐1 Not done ___ ___ ___ ___ I/U OR U/L OR mIU/mL ___ ___ ___ ULN	☐1 Not done ___ ___ . ___ ☐5 mg/dL ☐4 µmol/L ___ . ___ ULN	☐1 Not done ___ ___ . ___ ratio

Adding pages: Additional pages are provided in your packet. If needed, insert and sequentially number each additional page in the lower right corner, i.e. M11.1, M11.2, M11.3, etc.

Drug-Induced Liver Injury Network

Retrospective Case Medical Chart Review

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Lab Most Recent Value

LABRCT <RTRCNT>	Value and ULN	LABRCNT (Type 2) PS Date
1= AST:	LABVAL <F9:3> ___ ___ ___ ___ ___ IU/L or U/L or mIU/mL LABULN <F9:3> ___ ___ ULN DO NOT ENTER UNITS	___ ___ / ___ ___ ___ / ___ ___ ___ ___ LABDT day month year
2= ALT:	___ ___ ___ ___ ___ IU/L or U/L or mIU/m ___ ___ ULN DO NOT ENTER UNITS	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year
3= Alkaline Phosphatase:	___ ___ ___ ___ IU/L or U/L or mIU/m ___ ___ ___ ULN DO NOT ENTER UNITS	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year
4= Serum Total Bilirubin:	___ ___ . ___ ☐5 mg/dL ☐4 µmol/L ___ . ___ ULN LABUNIT <RTBUN>	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year
5= INR:	___ ___ . ___ ratio DO NOT ENTER ULN or UNITS	___ ___ / ___ ___ ___ / ___ ___ ___ ___ day month year

6=PROTHROMBIN TIME WILL NOT BE USED

LABCALC= LABVAL/LABULN <F9:3>

LABRATIO = <F9:3>
(LABVAL / LABULN) where LABRCT = 2 /
(LABVAL / LABULN) where LABRCT = 3

DILIN
Drug-Induced Liver Injury Network

Retrospective Case Medical Chart Review

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

SEROLOGY (TYPE 2) PS

Serological and Other Assays During DILI Event

SEROL <RTSERO>	Not Done SEROND <ZYES>	Results SERORSLT <RTNPUN>	Value SEROVAL <F9.3>
1 Anti-HAV IgM:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
2 Anti-HCV:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
3 HCV RNA:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
4 HBsAg:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
5 Anti-HBc:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
6 Anti-HBc IgM:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
7 Anti-HBs:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
8 Anti-HIV:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	SEROIFEL <RTIFEL>
9 Anti-nuclear antibodies *(ANA)*:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	☐1 1:_____ IF ☐2 _____ ELISA
10 Anti-smooth muscle antibodies *(ASMA)*:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	☐1 1:_____ IF ☐2 _____ ELISA
11 Anti-mitochondrial antibodies *(AMA)*:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	☐1 1:_____ IF ☐2 _____ ELISA
12 HBeAg: 17= HBeAG	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
13 Anti-HBe: 18= Anti-HBe	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
19= 14 HBV DNA:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
20= 15 Anti-HDV:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
21= 16 Heterophile antibody:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
22= 17 Anti-HAV:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
23= 18 Anti-CMV IgM:	☐1	☐1 Negative ☐2 Positive ☐99 Unknown	
24= 19 Serum IgM:	☐1		___ ___ ___ ___ mg/dL
25= 20 Serum IgG:	☐1		___ ___ ___ ___ mg/dL
26= 21 Serum IgA:	☐1		___ ___ ___ ___ mg/dL
12= 22 Serum Ceruloplasmin*:	☐1		___ ___ ___ ___ mg/dL
13= 23 Serum alpha-1 antitrypsin:	☐1		___ ___ ___ ___ mg/dL
14= 24 Serum iron:	☐1		___ ___ ___ ___ µg/dL
15= 25 Serum transferrin:	☐1		___ ___ ___ ___ mg/dL
16= 26 Serum ferritin:	☐1		___ ___ ___ ___ ng/dL

DO NOT ENTER

DO NOT ENTER

DO NOT ENTER

*Only if age ≤ 50 years

Serological and Other Assays During DILI Event (continued)

	Not Done	Date Drawn	Value
27 Serum protein electrophoresis: SEROSPE <ZYES>	☐97	___ ___/___ ___ ___/___ ___ ___ ___ (day month year) SERSPEDT	
		Total protein:	SEROTPRO <F9:3> ___ ___.___ g/dL
		Albumin:	SEROALB <F9:3> ___ ___.___ g/dL
		Alpha-1:	SEROALP1 <F9:3> ___ ___.___ g/dL
		Alpha-2:	SEROALP2 <F9:3> ___ ___.___ g/dL
		Beta:	SEROBETA <F9:3> ___ ___.___ g/dL
		Gamma:	SEROGAMA <F9:3> ___ ___.___ g/dL
		Interpretation: SEROLINT <V200> _____	

DILIN Drug-Induced Liver Injury Network

Retrospective

Case Medical Chart Review

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Imaging Studies

IMAGING <RTIMGE> IMGND <ZYES> IMGRSLT<RTNABN> ABNRSLT <RTABNR> ABNLSP <V:200> IMAGE (TYPE 2) PS

	Not Done	Results	If Abnormal: Check primary abnormality (check only one):
1 = Liver ultrasound:	☐1	☐1 Normal ☐2 Abnormal →	☐1 Ascites ☐2 Hepatomegaly ☐3 Splenomegaly ☐4 Small shrunken liver ☐5 Biliary dilatation ☐6 Liver tumor ☐7 Gallstones ☐8 Nodular contour of liver ☐9 Intra-abdominal varices ☐98 Other
2 = Abdominal CT scan:	☐1	☐1 Normal ☐2 Abnormal →	☐1 Ascites ☐2 Hepatomegaly ☐3 Splenomegaly ☐4 Small shrunken liver ☐5 Biliary dilatation ☐6 Liver tumor ☐7 Gallstones ☐8 Nodular contour of liver ☐9 Intra-abdominal varices ☐98 Other
3 = Abdominal MRI:	☐1	☐1 Normal ☐2 Abnormal →	☐1 Ascites ☐2 Hepatomegaly ☐3 Splenomegaly ☐4 Small shrunken liver ☐5 Biliary dilatation ☐6 Liver tumor ☐7 Gallstones ☐8 Nodular contour of liver ☐9 Intra-abdominal varices ☐98 Other
6= 4 MRCP:	☐1	☐1 Normal ☐2 Abnormal →	☐1 Ascites ☐2 Hepatomegaly ☐3 Splenomegaly ☐4 Small shrunken liver ☐5 Biliary dilatation ☐6 Liver tumor ☐7 Gallstones ☐8 Nodular contour of liver ☐9 Intra-abdominal varices ☐98 Other
5 = ERCP:	☐1	☐1 Normal ☐2 Abnormal →	☐1 Ascites ☐2 Hepatomegaly ☐3 Splenomegaly ☐4 Small shrunken liver ☐5 Biliary dilatation ☐6 Liver tumor ☐7 Gallstones ☐8 Nodular contour of liver ☐9 Intra-abdominal varices ☐98 Other
4= 6 Other: _____ IMGSP <V:25> SEQNO <I:3> IMGSP2 <V:25> LIMIT to 10 sequences		☐1 Normal ☐2 Abnormal →	☐1 Ascites ☐2 Hepatomegaly ☐3 Splenomegaly ☐4 Small shrunken liver ☐5 Biliary dilatation ☐6 Liver tumor ☐7 Gallstones ☐8 Nodular contour of liver ☐9 Intra-abdominal varices ☐98 Other
7 Spleen diameter:	IMGSPND <ZYES> ☐1	IMGVAL <F9:3> ___ ___ . ___ cm OR ☐96 NA IMGNA <ZYES>	Add other items from IMAGE panel except IMGND IMAGEOTH (TYPE 2) R IMGSPLDM (TYPE 3)

Procedures

PROC (TYPE 1)

	Not Done	Results	Description
1 Biopsy:	BIOPROC <ZYES> ☐1	PROCRSLT<RTNABN> ☐1 Normal ☐2 Abnormal	BIOPDESC<V:200>
2 Transplant:	TRXPROC <ZYES> ☐1		Specify type of transplant: _____ TRXDESCR <V:200>
3 Other: OTH1PRSP<V:25> _____	OTH1PRND<ZYES> ☐1	OTH1PROC <V:25>	OTH1DESC <V:200>
4 Other: OTH2PRSP <V:25> _____	OTH2PRND<ZYES> ☐1	OTH2PROC <V:25>	OTH2DESC <V:200>

Investigator Signature

SIGNATUR (TYPE 4)

I have reviewed and found all data pertaining to this participant to be complete and accurate.

SIGNANS <ZYES>

Investigator's signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (day / month / year) SIGDT

Drug-Induced Liver Injury Network

Retrospective Case Participant Completion Form

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Participant Completion

COMPLETE (TYPE 1)

1 After the participant agreed at the screening contact to participate in this study, did he/she complete the screening, interview, and blood draw?

☐0 No → If No: Go to question #2.
☐1 Yes → If Yes: Please stop here and provide signature below.

COMPALL <ZYESNO>

2 Were you able to re-contact the participant for the interview?

☐0 No → If No: Go to question #6.
☐1 Yes

CONTACT <ZYESNO>

3 After you re-contacted the participant, did he/she complete the telephone interview?

☐0 No → If No: Go to question #6.
☐1 Yes

COMPINT <ZYESNO>

4 After the participant completed the telephone interview, did he/she agree to make an appointment for the blood draw?

☐0 No → If No: Go to question #6.
☐1 Yes

BDAPPT <ZYESNO>

5 After the appointment was made, did the participant provide a blood sample *(including multiple attempts)*?

☐0 No → If No: Total number of unsuccessful appointments made: ____ NOAPPT <I:3>
☐1 Yes

BDSAMP <ZYESNO>

6 Reasons for termination *(check all that apply)*:

☐ No longer interested — NOTINTRS <ZYES>
☐ Felt study required too much time — LENGTH <ZYES>
☐ Felt study was asking for too much *(personal)* information — TOOINFO <ZYES>
☐ Unwilling to have blood drawn — NOBLDRW <ZYES>
☐ Unwilling to participate in genetics study — NOGENEST < ZYES>
☐ Other *(specify)*: _____ REASONOT <ZYES> REASONSP <V:200>

CLINICAL NARRATIVE RECEIVED CLINNARR <ZYES>

Investigator Signature

SIGNATUR (TYPE 4)

I have reviewed and found all data pertaining to this participant to be complete and accurate.

Investigator's signature: _____ SIGNANS <ZYES> _____ Date: ____/____/SIGDT____
day month year

STUDYBOOK= CASE_RET
FORM= MED CHART

ALL DAY FIELDS RANGE 1-31
ALL YEAR FIELDS RANGE 1900-2017
ALL TIME FIELDS RANGE 00-23 HR
00-59 MIN

RUCDR COLLECTION FORM

Ship at room temperature in Safety Mailer
Enclose a copy of this form with Sample Kit.

NO DATA

DR. DOUGLAS FUGMAN/ GENETICS
RUCDR - NELSON LABS
604 ALLISON ROAD. (RM. C120A)
PISCATAWAY, NJ 08854-8082

NOT DATABASED

Form ID
000000824

https://rucdrlims.rutgers.edu
Email:commstaff@biology.rutgers.edu
Phone: (732) 445-1498
Fax: (732) 445-1149

SUBJNO= INVSITE||-||PATID

To Be Completed at Collection Site:

Subject Code: The patient's unique ID number _____

Sub-Study _____ NIDDK Site # _____

Alternat Same as previous form _____

☐Male ☐Female Age: _____

Inventory ID or Subject Code for:
(pre-labeled barcode from tube) (code from above)

TU Barcode from tube _____ T Barcode from tube _____

TU Barcode from tube _____ T Barcode from tube _____

Family ID: _____

Pedigree (If Applicable):
☐Mother ☐Father
☐Proband ☐Sibling

Collection Date sample was drawn _____

Tracking number _____

Contact the Rutgers Cell & DNA Repository through StarLIMS (https://rucdrlims.rutgers.edu) or at commstaff@biology.rutgers.edu to convey package Tracking Number/Subject ID. If sample is shipped on a Friday for Saturday delivery, notify Rutgers and check FedEx form for Saturday delivery.

To be Completed by Rutgers University Cell & DNA Repository

For RUCDR use only

Initial: ___

Tube 1 Vol: ___ ☐ACD ☐EDTA ☐NaHep ☐PEDI ☐SP ☐S ☐PAX

Tube 2 Vol: ___ ☐ACD ☐EDTA ☐NaHep ☐PEDI ☐SP ☐S ☐PAX

Tube 3 Vol: ___ ☐ACD ☐EDTA ☐NaHep ☐PEDI ☐SP ☐S ☐PAX

Tube 4 Vol: ___ ☐ACD ☐EDTA ☐NaHep ☐PEDI ☐SP ☐S ☐PAX

DATE SAMPLE RECEIVED:

Deviation Code: