



PROTOCOL = DILIN_BIOPSY
 STUDYBOOK = DILIN_BIOPSY

Prospective NO DATA

FORM= HISTORICBIOPSY
 FORM= BIOPSYBASELINE
 FORM= BIOPSY12MONTH
 FORM= BIOPSYAUTOPSY
 FORM= BIOPSYTRANSPLANT
 FORM= BIOPSYOTHER

Case

Liver Biopsy

SUBJNO= INVSITE||-||PATID

DO NOT ENTER

<input type="checkbox"/> Historic biopsy	<input type="checkbox"/> Baseline	<input type="checkbox"/> 12-Month
<input type="checkbox"/> Autopsy	<input type="checkbox"/> Transplant	<input type="checkbox"/> Other

Site Number: _____ Participant ID Number: _____

Biopsy Demographics

1 Date of biopsy:	____ / ____ / ____ / LVBIOPDT	BIOPDEM (TYPE 3)
2 Date of central review:	____ / ____ / ____ / REVIEWDT	Type of Biopsy: BPSYTYPE <V:50>
3 Specimen type (check only one):	<input type="checkbox"/> 1 Needle <input type="checkbox"/> 2 Wedge SPECIMAN <PRSPEC> <input type="checkbox"/> 3 Resection <input type="checkbox"/> 4 Explant <input type="checkbox"/> 5 Autopsy → Specify time interval between death and autopsy: AUTOPHRS <I:3> hours	ALL DAY FIELDS Range 1-31 ALL YEAR FIELDS Range 1900-2020
4 Total portal areas:	TPORTAL <I:3>	FORM= BIOPSYOTHER2 FORM= BIOPSYOTHER3 FORM= BIOPSYOTHER4 FORM= BIOPSYOTHER5
5 Liver weight (explant or autopsy only):	LIVWT <F:9:3> grams	
6 Stains available (check all that apply):	<input type="checkbox"/> H&E <input type="checkbox"/> Masson <input type="checkbox"/> Iron <input type="checkbox"/> PAS with diastase <input type="checkbox"/> Copper <input type="checkbox"/> Other: _____	HE <ZYES> MASON <ZYES> IRON <ZYES> PAS <ZYES> COPPER <ZYES> STAINOTH <ZYES> STAINSP <V:200>

Inflammation

7 Interface hepatitis:	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	INTRFACE <PRINFL>	INFLAMM (TYPE 3)
8 Lobular inflammation:	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	LOBULAR <PRINFL>	
9 Portal inflammation:	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	PORTAL <PRINFL>	
10 Confluent necrosis:	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6	CONNECRO <PRSTGE>	
11 Granulomas:	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Microgranulomas only <input type="checkbox"/> 2 Non-necrotizing epithelioid granulomas <input type="checkbox"/> 3 Necrotizing granulomas	GRANULOM <PRGRAN>	
12 Plasma cells:	<input type="checkbox"/> 0 None to mild <input type="checkbox"/> 1 Noticeably increased	PLASMA <PRNMMI>	
13 Eosinophils:	<input type="checkbox"/> 0 None to mild <input type="checkbox"/> 1 Noticeably increased	EOSINO <PRNMMI>	
14 Neutrophils:	<input type="checkbox"/> 0 None to mild <input type="checkbox"/> 1 Noticeably increased	NEUTRO <PRNMMI>	
15 Lymphoid aggregates:	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Lymphoid aggregates <input type="checkbox"/> 2 Germinal centers	LYMPHOID <PRNLG>	
16 Bridging necrosis:	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Bridging necrosis <input type="checkbox"/> 2 Multiacinar collapse	NECROSIS <PRNBM>	
17 Lipogranulomas:	<input type="checkbox"/> 0 Absent <input type="checkbox"/> 1 Present	LIPOGRAN <PRABPR>	



Drug-Induced Liver Injury Network

Prospective

Case

Liver Biopsy

Site Number: _____ Participant ID Number: _____

Fibrosis

18 Stage: 0 1 2 3 4 5 6 **STAGE <PRSTGE>** FIBROSIS (TYPE 3)

19 Perisinusoidal: 0 None 1 Mild, requiring Masson to see 2 Moderate to marked, visible on H&E **PERISIN <PRPERI>**

Steatosis

20 Character: 0 Absent 1 Predominantly macrovesicular 2 Mixed macro and microvesicular 3 Predominantly microvesicular **CHARACTR <PRCHAR>** STEATOS (TYPE 3)

21 Location: 0 Not applicable 1 Predominantly zone 3 2 Predominantly zone 1 3 Panacinar 4 Azonal **LOCATION <PRLOCA>**

22 Degree: 0 None 1 < 5% of hepatocytes 2 5-33% of hepatocytes 3 33-66% of hepatocytes 4 > 66% of hepatocytes **DEGREE <PRHEPA>**

Cholestasis

23 Cholestasis, degree: 0 No evident cholestasis 1 Cholestasis identified only after careful high magnification search 2 Cholestasis easily demonstrated at high magnification (40x) but not readily apparent at low magnification 3 Cholestasis readily apparent at low magnification **CHOLDGR <PRCHOL>** CHOLEST (TYPE 3)

24 Hepatocellular: 0 Absent 1 Present **HEPACELL <PRABPR>**

25 Canalicular: 0 Absent 1 Present **CANALICU <PRABPR>**

26 Cholangiolar: 0 Absent 1 Present **CHOLANGI <PRABPR>**

27 Ductal: 0 Absent 1 Present **DUCTAL <PRABPR>**

28 Cholate stasis: Update screen name, no space between 0 Absent 1 Present **CHOLESTA <PRABPR>**

29 Ductular reaction: 0 None to mild 1 Prominent **DUCTREAC <PRDURE>**

30 Duct injury: 0 None 1 Single duct 2 Multiple ducts **DUCTINJ <PRDUINJ>**



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Cholestasis (continued)

31 Duct paucity: ₀ None discernible (ducts in > 75% of portal areas)
₁ Mild duct paucity (ducts in 50-75% of portal areas) **DUCTPAUC <PRDUPA>**
₁ Moderate to marked (ducts in < 50% of portal areas)

32 Acute cholangitis: ₀ Absent ₁ Present **ACUTCHOL <PRABPR>**

Hepatocellular Injury

33 Ballooning degeneration: ₀ ₁ ₂ **BALDEGEN <PRBALL>**

HEPAINJ (TYPE 3)

34 Apoptosis: ₀ None to rare
₁ Mild (< 1 per 40x hpf)
₂ Moderate (1-3 per 40x hpf) **APOPTOS <PRAPOP>**
₃ Marked (> 3 per 40x hpf)

35 Coagulative/confluent necrosis location: ₀ None
₁ Zone 1 predominant **COAGLOC <PRCOAG>**
₂ Zone 2 predominant
₃ Zone 3 predominant
₄ Panacinar
₅ Azonal

Update screen name

36 Coagulative/confluent necrosis degree (fraction of parenchyma affected): ₀ None
₁ Minimal (< 5% necrosis) **COAGDGRE <PRNECR>**
₂ Mild (5-33% necrosis)
₃ Moderate (33-66% necrosis)
₄ Marked (> 66% necrosis)

Update screen name

37 Hepatocyte rosettes: ₀ None to rare
₁ More than rare **HEPAROS <PRNRMR>**

38 Lobular disarray: ₀ Absent ₁ Present **LOBDISRY <PRABPR>**

Vascular

39 Veno-occlusive changes in central veins: ₀ Absent ₁ Present **VENOCCLU <PRABPR>**

VASCULAR (TYPE 3)

40 Central vein endophlebitis: ₀ Absent ₁ Present **CNVNENDO <PRABPR>**

41 Portal venopathy: ₀ Absent ₁ Present **PORTVENO <PRABPR>**

42 Hemorrhage: ₀ Absent ₁ Present **HEMORRHG <PRABPR>**

43 Sinusoidal dilation: ₀ None to mild
₁ Moderate to marked **SINUDILA <PRSINU>**
₂ Peliotic

44 Nodular transformation: ₀ Absent ₁ Present **NODUTRAN <PRABPR>**



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Miscellaneous Changes That Do Not Require Special Stains

45 Hepatocyte ground glass change:	<input type="checkbox"/> ₀ None <input type="checkbox"/> ₁ Scattered cells <input type="checkbox"/> ₂ Diffuse	BIOPMISC (TYPE 3) GRNDCHGE <PRCHGE>
46 Hepatocyte globular cytoplasmic inclusions:	<input type="checkbox"/> ₀ Absent <input type="checkbox"/> ₁ Present	GLOBINCL <PRABPR>
47 Mallory bodies:	<input type="checkbox"/> ₀ None to rare <input type="checkbox"/> ₁ Definitely present	MALLORY <PRNRDP>
48 Lipid-laden stellate cells:	<input type="checkbox"/> ₀ None to rare <input type="checkbox"/> ₁ Prominent	STELLATE <PRNRPR>
49 Hepatocellular glycogenosis:	<input type="checkbox"/> ₀ Absent <input type="checkbox"/> ₁ Present	GLYCOGEN <PRABPR>
50 Polarizable talc crystals:	<input type="checkbox"/> ₀ Absent <input type="checkbox"/> ₁ Present	CRYSTALS <PRABPR>

Special Stain Evaluation (Only Performed if Particular Stain Is Available)

51 Iron stain—hepatocellular iron:	<input type="checkbox"/> ₀ <input type="checkbox"/> ₁ <input type="checkbox"/> ₂ <input type="checkbox"/> ₃ <input type="checkbox"/> ₄	STAIN (TYPE 3) HEPAIRON <PRIRON>
52 Iron stain—sinusoidal reticuloendothelial iron:	<input type="checkbox"/> ₀ Absent <input type="checkbox"/> ₁ Rare positive cells <input type="checkbox"/> ₂ Prominent	SINUIRON <PRARP>
53 Copper stain—hepatocellular copper:	<input type="checkbox"/> ₀ None <input type="checkbox"/> ₁ Periportal hepatocytes positive in < 50% of portal areas <input type="checkbox"/> ₂ Periportal hepatocytes positive in > 50% of portal areas	HEPACOPP <PRCOPP>
54 PAS/diastase stain—PAS-positive macrophages:	<input type="checkbox"/> ₀ None <input type="checkbox"/> ₁ Scattered <input type="checkbox"/> ₂ Clusters	PASMACRO <PRPASM>
55 PAS/diastase stain—PAS-positive hepatocellular inclusions:	<input type="checkbox"/> ₀ Absent <input type="checkbox"/> ₁ Present	PASHEPA <PRABPR> PATTERN (TYPE 3)

Pattern

56 Pattern of injury: PATINJUR <PRINJR> <I:3>	<input type="checkbox"/> ₁ Acute hepatic	<input type="checkbox"/> ₇ Steatotic, macrovesicular	<input type="checkbox"/> ₁₃ Hepatocellular alteration
	<input type="checkbox"/> ₂ Chronic hepatic	<input type="checkbox"/> ₈ Steatotic, microvesicular	<input type="checkbox"/> ₁₄ Nodular regenerative hyperplasia
	<input type="checkbox"/> ₃ Acute cholestatic	<input type="checkbox"/> ₉ Steatohepatic	<input type="checkbox"/> ₁₅ Mixed or unclassified patterns
	<input type="checkbox"/> ₄ Chronic cholestatic	<input type="checkbox"/> ₁₀ Coagulative/confluent necrosis, zonal	<input type="checkbox"/> ₁₆ Mild, non-specific changes
	<input type="checkbox"/> ₅ Combined hepatic/cholestatic	<input type="checkbox"/> ₁₁ Coagulative/confluent necrosis, non-zonal	<input type="checkbox"/> ₁₇ Absolutely normal
	<input type="checkbox"/> ₆ Granulomatous	<input type="checkbox"/> ₁₂ Vascular	<input type="checkbox"/> ₁₈ Sub-massive/massive necrosis

Comments

SEQNO = <I:3> COMMENTS <V:200> **BIOPCOMM (TYPE 4) R**
LIMIT to 5 sequences



Drug-Induced Liver Injury Network

Liver Biopsy for Hepatitis Patients

<input type="checkbox"/> ₉₇ Not done OR Date: ___/___/___ <small>day month year</small> / HEPBPD HEPBIOP <ZYES>	Biopsy No.: BIOPNO <V:25> HEPABIOP (TYPE 4)
1 Adequacy of biopsy: ADEQUATE <PRAMI>	Length of specimen: LENGSPEC <F:9:3> cm Number of portal tracts (check only one): <input type="checkbox"/> ₀ Adequate (10 or more portal areas) <input type="checkbox"/> ₁ Marginally adequate (4-9 portal areas) <input type="checkbox"/> ₂ Inadequate (< 4 portal areas)
2 Periportal/inflammation: PERIPORT <PRPORT>	<input type="checkbox"/> ₀ None <input type="checkbox"/> ₁ Mild <input type="checkbox"/> ₂ Mild/moderate <input type="checkbox"/> ₃ Moderate <input type="checkbox"/> ₄ Marked
3 Parenchymal injury: PINJURY <PRPORT>	<input type="checkbox"/> ₀ None <input type="checkbox"/> ₁ Mild <input type="checkbox"/> ₂ Mild/moderate <input type="checkbox"/> ₃ Moderate <input type="checkbox"/> ₄ Marked
4 Portal inflammation: PORTINFL <PRPORT>	<input type="checkbox"/> ₀ None <input type="checkbox"/> ₁ Mild <input type="checkbox"/> ₂ Mild/moderate <input type="checkbox"/> ₃ Moderate <input type="checkbox"/> ₄ Marked
5 Fibrosis (stage): FIBROSIS <PRFIBR>	<input type="checkbox"/> ₀ None <input type="checkbox"/> ₁ Portal fibrosis (some) <input type="checkbox"/> ₂ Portal fibrosis (most) <input type="checkbox"/> ₃ Occasional bridging <input type="checkbox"/> ₄ Marked bridging <input type="checkbox"/> ₅ Incomplete cirrhosis <input type="checkbox"/> ₆ Established or probable cirrhosis
6 Steatosis: STEATOS <PRPORT>	<input type="checkbox"/> ₀ None <input type="checkbox"/> ₁ Mild (< 5%) <input type="checkbox"/> ₂ Mild/moderate (5-33%) <input type="checkbox"/> ₃ Moderate (33-67%) <input type="checkbox"/> ₄ Marked (> 67%)
7 Iron storage: FESTORE <PRFE>	<input type="checkbox"/> ₀ 0 (granules absent or barely discernible × 400) <input type="checkbox"/> ₁ 1 + (barely discernible × 250 or easily confirmed × 400) <input type="checkbox"/> ₂ 2 + (Discrete granules resolved × 100) <input type="checkbox"/> ₃ 3 + (Discrete granules resolved × 25) <input type="checkbox"/> ₄ 4 + (Masses visible × 10, or naked eye)



Drug-Induced Liver Injury Network

Prospective

Case

Baseline Visit

Site Number: _____ Participant ID Number: _____

Liver Biopsy for Hepatitis Patients (continued)

Comments: _____

HEPACOMM (TYPE 4) R

SEQNO= <I:3> HEPCOMNT <V:200>

LIMIT to 5 sequences
