University of California San Francisco The ITS Academic Research Systems

## **AASLD Autoimmune Pilot**



## Data Dictionary Codebook

10/15/2018 9:39am

#	Variable / Field Name	Field Label Field Note	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Ins	strument: <b>Demograp</b>	<b>hics</b> (demographics)	
1	aasld_id	AASLD ID	text
2	ind_id	Indiana sample ID	text
3	case_hl_du	ls this a Case (AlH) , a Control (Healthy) or a Duplicate?	radio  1 Case (AIH)  2 Control (Healthy)  3 Duplicate
4	du Show the field ONLY if: [case_hl_du] = '3'	Enter here the duplicate associated with this ID  Enter Indiana ID. If other entry for this patient is complete, then OK to stop here.	text
5	du_stop Show the field ONLY if: [case_hl_du] = '3'	IF THE DUPLICATE FORMS ARE ALREADY COMPLETED, YOU CAN STOP NOW!	descriptive
6	sex	Sex	radio 1 Male 2 Female 3 Other
7	other_sex  Show the field ONLY  if:  [sex] = '3'	Specify e.g. male to female transgender	text

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8	race	Race	dropdown  1 White  2 Black  3 Asian  4 Other
9	other_race Show the field ONLY if: [race] = '4'	Specify	text
10	ethn	Ethnicity	dropdown  1 Hispanic or Latino  2 Not Hispanic or Latino
11	notes	General Notes General comments on case	notes
12	demographics_compl ete	Section Header: Form Status Complete?	dropdown  0 Incomplete  1 Unverified  2 Complete
		ne (data around the time of diagnosis nd_the_time_of_diagnosis)	)
13	mo_yr_dx	Month and Year of AIH diagnosis month&year only, enter 1 for day	text (date_dmy)
14	aih_type	Type of AIH	radio  0 Unknown  1 Type I  2 Type 2  3 Drug-induced  4 Other (please specify)
15	susp_med Show the field ONLY if: [aih_type] = '3'	Suspected Medication which med possibly caused AIH	text
16	other_spec Show the field ONLY if: [aih_type] = '4'	Other Type of AIH  Please comment on type of AIH if not Type I, II, or DILI	notes

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17	ai_dz	Does the patient have a concomitant autoimmune disorder?	radio 1 Yes 2 No 3 Unknown
18	ai_dz_lis  Show the field ONLY  if:  [ai_dz] = '1'	If yes, then please list	notes
19	igg_bl	Total IgG titer before treatment initiation (mg/dl) 700 to 1500 mg/dL	text
20	ast_bl	AST before treatment initiation (U/L) 13 to 39 U/L	text
21	alt_bl	ALT before treatment initiation (U/L) 7 to 52 U/L	text
22	alp_bl	AlkPhos before treatment initiation (U/L) 15 to 125 U/L	text
23	tbili_bl	Total Bilirubin before treatment initiation (mg/dL) 0.0 to 1.0 mg/dL	text
24	inr_bl	INR (ratio - no units) < 1 PT 9.3 - 13.5	text
25	cr_bl	Creatinine (mg/dL) 0.80 to 1.40 mg/dL	text
26	alb_bl	Albumin (g/dL) 3.5 to 5.0 g/dL	text
27	plt_bl	Platelets (k - or 1,000/uL) 150 to 450	text
28	ana_bl	ANA Titer (Ratio) < 1: 40	text
29	actin_bl	Actin (Smooth Muscle) IgG Antibody (Units) < 1: 20	text
30	lkm_bl	Anti Liver Kidney Microsome 1 (ALKM1)  < 20 U (performed at Mayo Clinic as a send out)  20.1 - 24.9 Equivocal  > 25 Units Positive	text
31	sla	Anti-SLA anti-SLA titer, if available	text
32	ama_bl	AMA titer < 1: 20	text

33	bx_bl	Liver Biopsy Performed?	yesno 1 Yes 0 No
34	bx_bl_rpt Show the field ONLY if: [bx_bl] = '1'	Liver biopsy report (redacted, if available) Redacted, if available	file
35	bx_infl_bl  Show the field ONLY if: [bx_bl] = '1'	Liver Biopsy Inflammation Grade	text
36	bx_fib_bl Show the field ONLY if: [bx_bl] = '1'	Liver Biopsy Fibrosis Stage	text (number)
37	bx_sys_bl Show the field ONLY if: [bx_bl] = '1'	Liver Biopsy Scoring System e.g. Ishak, Bhatts Ludwig, etc.	text
38	te_bl	TE (Fibroscan) kPa 6 mos before or after diagnosis	text (number)
39	imag_bl	Imaging Report (redacted, if available)	file
40	ov_fib_bl	Overall Fibrosis Staging at time of AIH diagnosis (scale 0-4, use 1.5 for stage 1-2) +/- 6 months from diagnosis	text
41	comm_fib_bl	Comments about Fibrosis Stage around Diagnosis e.g., collapse, outside hospital	notes
42	viral	Viral Hepatitis  Does the patient have viral hepatitis?	radio  0 Absence of Viral Hepatitis  1 Presence of Viral Hepatitis
43	etoh	Alcohol Intake 14 g alcohol = 12 oz beer, 5 oz wine, 1.5 oz spirits	radio  0 < 25 g daily  1 25-60 g daily  2 >60 g daily  3 Unknown
44	toxin	Is there exposure to hepatotoxic drugs? for IAIHG score	radio 0 No 1 Yes 2 Unknown

45	diag_sys	Diagnostic Score	radio  0 Revised Original IAIHG Score 1999  1 Simplified IAIHG Score 2008  2 Other
46	revorig  Show the field ONLY  if: [diag_sys] = '0'	Revised Original IAIHG Score 1999 J Hep Nov 1999	text (number)
47	simpl Show the field ONLY if: [diag_sys] = '1'	Simplified IAIHG Score 2008 Hepatology July 2008, PMID 18537184	text (integer)
48	oth_diag_sys  Show the field ONLY  if: [diag_sys] = '2'	Specify the Scoring System and Diagnostic Score	notes
49	aih_baseline_data_ar ound_the_time_of_di agnosis_complete	Section Header: Form Status  Complete?	dropdown  0 Incomplete  1 Unverified  2 Complete
Ins	trument: AIH at Sam	nple Collection (aih_at_sample_collection)	
50	age_coll	Age at sample collection Age in years	text
51	date_coll	Date of sample collection	text (date_dmy)
52	on_tx	Was the patient on an AIH medication regimen at the time of sample collection?	yesno 1 Yes 0 No
53	igg_coll	Section Header: Labs at time of sample collection. If different from date of research specimen collection, please note date in comments for each lab result.  Total IgG Titer (mg/dL) 700 to 1500 mg/dL	text
54	ast_coll	AST (U/L) 13 to 39 U/L	text
55	alt_coll	ALT (U/L) 7 to 52 U/L	text
56	alp_coll	AlkPhos (U/L) 15 to 125 U/L	text
57	tbili_coll	Total Bilirubin (mg/dL) 0.0 to 1.0 mg/dL	text

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58	inr_coll	INR (ratio - no units) < 1 PT 9.3 - 13.5	text
59	cr_coll	Creatinine (mg/dL) 0.80 to 1.40 mg/dL	text
60	alb_coll	Albumin (g/dL) 3.5 to 5.0 g/dL	text
61	wbc_coll	WBC	text
62	neut_coll	Absolute Neutrophils (k/uL) normal range 1.7-7.5	text
63	lymph_coll	Absolute Lymphocytes (k/uL) normal range 1.0-3.2	text
64	mono_coll	Absolute Monocytes (k/uL) normal range 0.1-1.3	text
65	eos_coll	Absolute Eosinophils (k/uL) normal range 0-0.3	text
66	baso_coll	Absolute Basophils (k/uL) normal range 0-0.2	text
67	hb_coll	Hemoglobin	text
68	plt_coll	Platelets (k - or 1,000/uL) 150 to 450	text
69	imag_coll	Section Header: Fibrosis Assessment Around Time of Specimen Collection Imaging Report	file
		(redacted, if available)	
70	te_coll	Transient Elastography (Fibroscan) Score sample date +- 6 months	text (number)
71	bx_bl_coll	Liver Biopsy Performed at time of Biospecimen Collection? +- 6 months	yesno 1 Yes 0 No
72	bx_coll	Liver biopsy report (redacted, if available)	file
	Show the field ONLY		
	if:  [bx_bl_coll] = '1'		
73	bx_infl_coll	Biopsy Inflammation Grade	text
	Show the field ONLY		
	if: [bx_bl_coll] = '1'		
74	bx_fib_coll	Biopsy Fibrosis Stage	text
	Show the field ONLY		
	if: [bx_bl_coll] = '1'		
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75	bx_sys_coll  Show the field ONLY  if: [bx_bl_coll] = '1'	Liver Biopsy Scoring System e.g. Ishak, Bhatts Ludwig, etc.	text
76	ov_fib_coll	Overall Fibrosis Stage at Sample Collection (0-4, use 2.5 for stage 2-3) +/- 6 months from specimen collection date	text
77	comm_fib_coll	Comments about Fibrosis Assessment Around Time of Sample Collection e.g. not done, unreliable in setting of inflammation, etc.	notes
78	aih_at_sample_collect ion_complete	Section Header: Form Status  Complete?	dropdown  0 Incomplete  1 Unverified  2 Complete
Ins	trument: <b>AIH Treatn</b>	nent Regimens (aih_treatment_regimens)	
<ul><li>79</li><li>80</li></ul>	reg_coll  aza_dose  Show the field ONLY if: [reg_coll(2)] = '1'	AlH medications at the time of sample collection (check ALL that apply) regimen@collection  If on Azathioprine, please enter the dose in mg mg	checkbox  1 reg_coll1 Prednisone  2 reg_coll2 Azathioprine  3 reg_coll3 6-Mercaptopurine  4 reg_coll4 Budesonide  5 reg_coll5 Mycophenolate (MMF)  6 reg_coll6 Tacrolimus  7 reg_coll7 Prednisolone  8 reg_coll8 Other  text
81	other_meds  Show the field ONLY  if:  [reg_coll(8)] = '1'	Other medications at time of sample collection:  Please indicate names	notes
82	pred_dose	If on prednisone or prednisolone, what dose? dose of systemic corticosteroids	radio  0 unknown  1 < 30mg predniso(lo)ne daily  2 >=30mg predniso(lo)ne daily
83	durn_reg	How long (in months) has the patient been on regimen as of time of sample collection? in months	notes

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84	date_resp	Section Header: Response to Regimen@Collection (usually 6-12 months after initiation)	text (date_dmy)
		Date treatment response was assessed date of labs, usually 6-12 months after treatment initiation	
85	ast_resp	AST (U/L) 13-39 U/L	text
86	alt_resp	ALT (U/L) 7- 52 U/L	text
87	tbili_resp	Total Bilirubin (mg/dL) 0.0-1.0 mg/dL	text
88	alp_resp	AlkPhos (U/L) 15-125 U/L	text
89	igg_resp	IgG Titer (mg/dL) 700- 1500 mg/dL	text
90	other_resp	Other Ways Treatment Response was Assessed Please specify test and results	notes
91	response	Response to regimen@collection	radio
		p 6-12mo tx	1 Complete (ALT < 20 for women, <
			31 men)
			2 Partial (20 for women or 31 for
			men up to 2xULN)
			3 Non-Responder (above 2xULN)
92	relapse	Did this patient experience a relapse while on	yesno
		the AlHregimen@collection (e.g. AST > 3x upper limit of normal)?	1 Yes
		e.g. requiring dose adjustment or steroid burst	0 No
93	prior_reg	Section Header: Prior AIH Regimens	yesno
		Was pt on a different regimen(s) prior to the	1 Yes
		regimen@collection?	0 No
94	prior_aihmeds	Please specify prior regimen(s)	notes
	Show the field ONLY	Please indicate med name(s)	
	if:		
	[prior_reg] = '1'		
95	diff_treat	Did this patient ever require a change in AIH meds due to inadequate treatment response?	yesno 1 Vos
		i.e. require 2nd or 3rd line therapy	1 Yes
			0 No
96	aih_treatment_regim	Section Header: Form Status	dropdown
	ens_complete	Complete?	0 Incomplete
			1 Unverified
			2 Complete

Ins	Instrument: AIH Outcomes (aih_outcomes)			
97	decomp	Experienced decompensation?	yesno 1 Yes 0 No	
98	date_decomp  Show the field ONLY if: [decomp] = '1'	Approximate date of decompensation	text (date_dmy)	
99	type_decomp  Show the field ONLY  if: [decomp] = '1'	Type of decompensation developed	checkbox  1 type_decomp1 Variceal Bleeding	
	[decomp]		2 type_decomp2 Ascites 3 type_decomp3 Encephalopathy 4 type_decomp4 HCC 5 type_decomp5 Other	
100	other_decomp  Show the field ONLY  if:  [type_decomp(5)] =  '1'	Specify other decompensation?	text	
101	lt	Did the patient undergo liver transplant?	yesno 1 Yes 0 No	
102	date_lt Show the field ONLY if: [lt] = '1'	Approximate date of liver transplant	text (date_dmy)	
103	last_contact	Month & Year of Last Contact enter 1 for day	text (date_dmy)	
104	alive_dead	At the last time of contact, was the patient alive or dead?	radio 0 alive/censored 1 dead	
105	liver_death  Show the field ONLY  if:  [alive_dead] = '1'	Liver-related death?	yesno 1 Yes 0 No	

106	aih_outcomes_compl ete	Section Header: Form Status Complete?	dropdown  0 Incomplete  1 Unverified  2 Complete
Ins	trument: <b>Healthy Co</b>	ontrol Information (healthy_control_infor	mation)
107	date_hc	Date of blood collection	text (date_dmy)
108	age_hc	Age of Healthy Control at Time of Sample Collection	text
109	ast_hc	AST (U/L) 13 to 39	text
110	alt_hc	ALT (U/L) 7 to 52	text
111	alkphos_hc	AlkPhos (U/L) 15 to 125	text
112	tbili_hc	Total Bilirubin (mg/dL) 0.0 to 1.0	text
113	alb_hc	Albumin (g/dL) 3.5 to 5.0	text
114	bmi_hc	BMI (if available)	text
115	healthy_control_infor mation_complete	Section Header: Form Status  Complete?	dropdown  0 Incomplete  1 Unverified  2 Complete
Ins	trument: Sample Inf	formation (sample_information)	
116	bl_coll_dt	Blood Collection Date:	text (date_dmy)
117	spl_plate	Sample Assigned Plate:	radio 1 AASLD- P01 2 AASLD- P02
118	spl_posit	Sample Assigned Position:	text
119	splt_type	Sample Type:	text
120	dt_isl	Date RNA Isolated date of rna isolation	text (date_dmy)
121	spl_vl	Sample Volume: μL	text
122	sample_information_ complete	Section Header: Form Status  Complete?	dropdown  0 Incomplete  1 Unverified  2 Complete

Ins	Instrument: Results (results)			
123	3 aws	Link to AWS Raw data RNA Seq Results	notes	
124	results_complete	Section Header: Form Status  Complete?	dropdown  0 Incomplete  1 Unverified  2 Complete	