

# HBRN Pediatric Immune Tolerant Manuscript Data

## The CONTENTS Procedure

<b>Data Set Name</b>	P_IT.ITP_ENRCRIT	<b>Observations</b>	77
<b>Member Type</b>	DATA	<b>Variables</b>	95
<b>Engine</b>	V9	<b>Indexes</b>	0
<b>Created</b>	10/16/2019 16:57:17	<b>Observation Length</b>	824
<b>Last Modified</b>	10/16/2019 16:57:17	<b>Deleted Observations</b>	0
<b>Protection</b>		<b>Compressed</b>	NO
<b>Data Set Type</b>		<b>Sorted</b>	NO
<b>Label</b>			
<b>Data Representation</b>	WINDOWS_32		
<b>Encoding</b>	wlatin1 Western (Windows)		

Engine/Host Dependent Information	
<b>Data Set Page Size</b>	69632
<b>Number of Data Set Pages</b>	2
<b>First Data Page</b>	1
<b>Max Obs per Page</b>	84
<b>Obs in First Data Page</b>	68
<b>Number of Data Set Repairs</b>	0
<b>ExtendObsCounter</b>	YES
<b>Filename</b>	L:\HepB\NIDDK Repository Data Archive\Pediatric Immune Tolerant\SAS Datasets\Analytic Datasets\itp_enrcrit.sas7bdat
<b>Release Created</b>	9.0401M2
<b>Host Created</b>	W32_7PRO
<b>Owner Name</b>	PITT\HSL26
<b>File Size</b>	204KB
<b>File Size (bytes)</b>	208896

Alphabetic List of Variables and Attributes						
#	Variable	Type	Len	Format	Informat	Label
40	ACYTX	Num	8	YN.	6.	Treatment with systemic acyclovir
70	ALT1	Num	8	32.10	32.10	ALT Result (IU/L) 1
71	ALT2	Num	8	32.10	32.10	ALT Result (IU/L) 2
73	ALT1D	Num	8	6.	6.	ALT Sample Day 1

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#	Variable	Type	Len	Format	Informat	Label
93	ALT1DATE	Num	8	MMDDYY8.		ALT Sample Date 1
72	ALT1M	Num	8	6.	6.	ALT Sample Month 1
74	ALT1Y	Num	8	6.	6.	ALT Sample Year 1
76	ALT2D	Num	8	6.	6.	ALT Sample Day 2
94	ALT2DATE	Num	8	MMDDYY8.		ALT Sample Date 2
75	ALT2M	Num	8	6.	6.	ALT Sample Month 2
77	ALT2Y	Num	8	6.	6.	ALT Sample Year 2
41	ANTIVTX	Num	8	YN.	6.	Ongoing use of any antivirals
60	BDNA1	Num	8			HBV DNA level result (IU/mL) 1
61	BDNA2	Num	8			HBV DNA level result (IU/mL) 2
63	BDNA1D	Num	8	6.	6.	HBV DNA Sample Day 1
91	BDNA1DATE	Num	8	MMDDYY8.		HBV DNA Sample Date 1
62	BDNA1M	Num	8	6.	6.	HBV DNA Sample Month 1
64	BDNA1Y	Num	8	6.	6.	HBV DNA Sample Year 1
66	BDNA2D	Num	8	6.	6.	HBV DNA Sample Day 2
92	BDNA2DATE	Num	8	MMDDYY8.		HBV DNA Sample Date 2
65	BDNA2M	Num	8	6.	6.	HBV DNA Sample Month 2
67	BDNA2Y	Num	8	6.	6.	HBV DNA Sample Year 2
68	BDNALL1	Num	8	32.10	32.10	HBV DNA Lower Level of Detection 1
69	BDNALL2	Num	8	32.10	32.10	HBV DNA Lower Level of Detection 2
23	BLD	Num	8	YN.	6.	No consent reason: Blood draw freq or volume
10	CVERSION	Num	8	5.1	5.1	Form Version
58	DCD	Num	8	6.	6.	Data Collection Completed Day
90	DCDATE	Num	8	MMDDYY8.		Date Data Collection Completed
56	DCID	Char	3	\$3.	\$3.	Data collector initials
57	DCM	Num	8	6.	6.	Data Collection Completed Month
59	DCY	Num	8	6.	6.	Data Collection Completed Year
89	EDT_DATE	Num	8	MMDDYY8.		Edit Date
55	ENROLLIT	Num	8	YN.	6.	Eligible to participate in Immune-tolerant trial
21	ENTSE	Num	8	YN.	6.	No consent reason: Entecavir side effects
7	ERLDATE	Num	8	MMDDYY8.	DATETIME22.3	Date of Determination
42	EXALC	Num	8	YN.	6.	Any use of illegal drugs
39	EXALGY	Num	8	YN.	6.	Allergy to study drugs

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#	Variable	Type	Len	Format	Informat	Label
35	EXBRF	Num	8	YN.	6.	Children currently breastfeeding
46	EXCARDV	Num	8	YN.	6.	History of significant cardiovascular disease
32	EXCHLIV	Num	8	YN.	6.	Chronic liver disease
34	EXCONT	Num	8	YN.	6.	Female patient unable or unwilling to use contraception
43	EXIMMDX	Num	8	YN.	6.	History of immunologically mediated disease
38	EXLAB	Num	8	YN.	6.	Hematological abnormalities during the screening
36	EXMEDDX	Num	8	YN.	6.	Malignancy or other significant medical or psychiatric illness
33	EXPRG	Num	8	YN.	6.	Pregnant or breastfeeding
45	EXPULM	Num	8	YN.	6.	Evidence of chronic pulmonary disease
48	EXRTN	Num	8	YN.	6.	Sever retinopathy
47	EXSZR	Num	8	YN.	6.	Severe seizure disorder
49	EXTHY	Num	8	YN.	6.	Thyroid disease poorly controlled on prescribed medication
44	EXVARC	Num	8	YN.	6.	Evidence of bleeding from esophageal varices
2	FORMID	Char	10	\$10.	\$10.	Form Name
51	HERBAL	Num	8	YN.	6.	Concomitant use of complementary or alternative medications
79	IMAGD	Num	8	6.	6.	Liver ultrasound imaging day
95	IMAGDATE	Num	8	MMDDYY8.		Liver Ultrasound Imaging Date
78	IMAGM	Num	8	6.	6.	Liver ultrasound imaging month
80	IMAGY	Num	8	6.	6.	Liver ultrasound imaging year
50	IMMTX	Num	8	YN.	6.	Concomitant use of anti-neoplastic, or other medications
12	INAGEIT	Num	8	YN.	6.	Age 3 to less than 18 years
16	INALT	Num	8	YN.	6.	ALT levels
17	INBILI	Num	8	YN.	6.	Compensated liver disease
13	INCHB	Num	8	YN.	6.	Chronic HBV infection
11	INCOHORT	Num	8	YN.	6.	Enrolled in cohort study or equivalent
18	INCRCL	Num	8	YN.	6.	Creatinine clearance $\geq 90$ ml/min
15	INDNA	Num	8	YN.	6.	HBV DNA level
14	INHBE	Num	8	YN.	6.	Presence of HBeAg in serum
52	INVRX	Num	8	YN.	6.	A participant may not be co-enrolled in another clinical trial
20	ITCONS	Num	8	YN.	6.	Parent/gardian has provided written consent
31	ITHDC	Num	8	YN.	6.	Evidence of decompensated liver disease
25	MOVE	Num	8	YN.	6.	No consent reason: Patient moved
26	NCOTH	Num	8	YN.	6.	No consent reason: Other

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#	Variable	Type	Len	Format	Informat	Label
27	NCOTHS	Char	30	\$30.	\$30.	No consent reason: Other specify
19	NEGUS	Num	8	YN.	6.	Absence of hepatocellular carcinoma
30	NOCHILD	Num	8	YN.	6.	Female not of child bearing potential
37	ORGANTX	Num	8	YN.	6.	Liver or other organ transplant
29	OTHLVDX	Num	8	YN.	6.	Presence of liver disease or HCC
28	OTHVIRDX	Num	8	YN.	6.	Presence of infection at screening
9	OVERSION	Num	8	5.1	5.1	Old Form Version
22	PEGSE	Num	8	YN.	6.	No consent reason: Pegylated interferon side effects
53	PIOTH	Num	8	YN.	6.	Unsuitable in investigators opinion
54	PIOTHS	Char	50	\$50.	\$50.	Reason unsuitable in investigators opinion
8	RSC	Num	8	YN.	6.	Rescreen
1	STUDYID	Num	8	STUDYID.	11.	Current Study
85	UCALT1	Num	8	32.10	32.10	UCALT1
87	UCALT2	Num	8	32.10	32.10	UCALT2
81	UCBDNALL1	Num	8	32.10	32.10	UCBDNALL1
83	UCBDNALL2	Num	8	32.10	32.10	UCBDNALL2
86	UNALT1	Num	8	6.	6.	UNALT1
88	UNALT2	Num	8	6.	6.	UNALT2
82	UNBDNALL1	Num	8	6.	6.	UNBDNALL1
84	UNBDNALL2	Num	8	6.	6.	UNBDNALL2
24	VISIT	Num	8	YN.	6.	No consent reason: Frequency of visits
4	enrit	Num	8	YN.		Enrolled IT
5	orig_id	Char	9	\$9.	\$9.	ID at enrollment site
3	screenit	Num	8	YN.		Assessed for eligibility
6	siteid	Num	8	SITE.		Site