

LTD1 Data Archive

The LTD1 Data Archive contains the study protocol, manual, procedures, and other descriptive documentation; study forms; data collected by the study; and analysis files.

The files are organized into the following directories:

- Data
- Forms
- Manual of Operations (MOOP)
- SAS files
- Serum study (ancillary study)

The LTD1 study used 41 data collection forms. Each data collection form is designated by a two letter abbreviation (CD through YP). The data files for each data collection form, the manual of operations for each form, documentation of contents of data files, and SAS data files are named using these two letter codes. For example, the “Post-transplant Status Form” is form “PS.” The Manual of Operations (MOOP) for the PS dataset is PSMOOP.DOC, and the SAS data files derived from the PS form are PS.RD and PS.SD2. Table 1, “LTD1 Forms and Data Sets” lists the types of files are available for each data set.

The table “LTD2 Data Sets” lists an additional 14 files contain containing demographic, clinical, and pathology data. There are seven data sets (all_path, clip, correct, cseq_dib, hvc_lt, labs, weston, and sl_read) that were used to create seven SAS contents files and seven SAS bdata files

The LTD1 data set also contains data from Serum Bank hepatitis testing. The LTD Serum Bank contains over 14,000 vials of serum from 907 of the 916 LTD transplant recipients. Blood samples were drawn from the donor and from the recipient before transplantation and at month 4, year 1, and year 2 post-transplant. Each sample was sent to the Serum Bank, aliquoted and stored in up to five 1-ml vials. Because these hepatitis tests have been done at various labs using several different techniques, there may be discrepancies in these data. Table 2, “LTD1 Serum Study” lists the types of files are available for each data set.

1. LTD1 Data Directory

The Data directory contains 3 subdirectories

- LTD1 Data ASC subdirectory contains data in .ASC format in 39 files named using the same 2-letter abbreviations as the corresponding data collection forms.
- LTD1 Data Dictionary subdirectory contains 2 subdirectories. The DIC Data Dictionary subdirectory contains data dictionary files in .DIC format, and the DRP Data Dictionary subdirectory contains data dictionary files in .DRP format.
- The “LTD1 TEXT DATASET text fields of forms” contains data from the CE, CP, and MF forms. The text fields were reviewed and variables were created.

2. LTD1 Forms Directory

The LTD1 Forms directory contains the forms used for data collection. There are 3 subdirectories

- LTD1 Forms VAR subdirectory contains 39 data collection forms in VAR format. These text files show the data variables for each form.
- LTD1 Forms ASC subdirectory contains 41 data collection forms in ASC format. This subdirectory contains two additional files: ES-End of Study Assessment Adults (full follow-up required) and ES-End of Study Assessment Pediatric (full follow-up required).
- The LTD Forms WORD DOC subdirectory contains the 41 data collection forms in Word DOC format.

3. LTD1 MOOP Directory

The LTD1 MOOP directory contains the Manual of Operations (MOOP) for each of the data collection forms.

- The LTD1 MOOP ASC subdirectory contains 39 data collection forms in ASC format. These text files show the data variables for each form.
- LTD1 MOOP WORD subdirectory contains 39 data collection forms in Word DOC format.

4. LTD1 SAS Files Directory

The LTD1 Forms directory contains data analysis files in 3 subdirectories

- LTD1 RD SAS subdirectory contains 39 data dictionary files in RD format.
- LTD1 SAS Format subdirectory contains the LTDFMT.SAS file
- LTD1 SD2 SAS Format subdirectory contains 39 SAS data files in SD2 format

5. LTD1 SAS Serum Study Directory

Various tests for viral hepatitis were performed on Serum Bank samples for various studies. The LTD Serum Bank contains over 14,000 vials of serum from 907 of the 916 LTD transplant recipients. Blood samples were drawn from the donor and recipient before transplantation and at month 4, year 1, and year 2 post-transplant. Each sample was sent to the Serum Bank, aliquoted and stored in up to five 1-ml vials. Because hepatitis tests done were for multiple studies using a variety of methods, these data may contain duplications or discrepancies.

Table 2. "LTD1 Serum Study" shows an overview of the Serum Study files.

The LTD1 SERUM Study directory contains five subdirectories:

- The Serum Documentation subdirectory contains the SERUM.TXT file which describes the serum data sets
- The Serum Forms subdirectory contains ASC and Word DOC version of three data collection forms for use by the Serum Bank.
- The Serum Data subdirectory contains the Serum ASC Data and Serum CNT Contents folders. The Serum ASC Data subdirectory contains eight datasets in ASC format. The Serum CNT Contents subdirectory contains the contents files in CNT format.

- The Serum Data Analysis subdirectory contains the Serum RD and Serum SD2 subdirectories. The Serum SD2 subdirectory contains eight SAS SD2 data files. The Serum RD subdirectory contains eight SAS RD data dictionary files.
- The Serum MOOP subdirectory contains the SSMOOP.ASC and SSMOOP.DOC files, which is the Manual of Operations for the Serum Storage form.

Table 1: LTD1 Forms and Data Sets

Form	Title	Data .ASC	Data Dictionary .DIC .DRP	Forms with variables .ASC	Forms Word .DOC	MOOP .DOC .ASC	SAS Content	SAS sas7bdata	SAS SD2	SAS RD	Part of the TEXT dataset
CD	Change of Diagnosis for Native Liver	+	+	+	+	+			+	+	
CE	Initial Evaluation	+	+	+	+	+			+	+	+
CI	Post-Transplant Short Term Evaluation	+	+	+	+	+			+	+	
CM	CMV Study - Dosage Change Form	+	+	+	+	+			+	+	
CO	Post-Transplant Long-Term Follow-Up	+	+	+	+	+			+	+	+
CP	Immediate Pre-Operative	+	+	+	+	+			+	+	+
CS	Change of Status	+	+	+	+	+			+	+	
CU	CMV Status	+	+	+	+	+			+	+	
DF	Donor Form	+	+	+	+	+			+	+	+
DR	Donor Liver Recovery	+	+	+	+	+			+	+	
DS	Donor Liver Surgeon Assessment	+	+	+	+	+			+	+	
ES	End of Study Assessment Adults (full follow-up not required)	+	+	+	+	+			+	+	
EA	End of Study Assessment Adults (full follow-up required)			+	+						
EP	End of Study Assessments Pediatric (full follow-up required)			+	+						

Form	Title	Data .ASC	Data Dictionary .DIC .DRP	Forms with variables .ASC	Forms Word .DOC	MOOP .DOC .ASC	SAS Content	SAS sas7bdata	SAS SD2	SAS RD	Part of the TEXT dataset
FF	Final Follow-Up	+	+	+	+	+			+	+	
FI	Post Transplant Follow-Up ICP Monitoring Form	+	+	+	+	+			+	+	
FK	FK506 Study Dosage Change Form	+	+	+	+	+			+	+	
FS	Fulminant Form	+	+	+	+	+			+	+	+
IA	Anesthesiology Study	+	+	+	+	+			+	+	
IO	Inter-Operative Procedure	+	+	+	+	+			+	+	
IS	Intra-operative Surgeon Assessment	+	+	+	+	+			+	+	
LC	Living Donor Follow-Up Complications Form	+	+	+	+	+			+	+	
LD	Living Donor Form	+	+	+	+	+			+	+	+
LF	Living Donor Follow-Up Form	+	+	+	+	+			+	+	
MC	CMV Disease	+	+	+	+	+			+	+	
MD	Death Report	+	+	+		+			+	+	
MF	Complications Form	+	+	+	+	+			+	+	+
MP	Post Transplant Follow-Up Short-Term Immunosuppressive Medications and other Medications	+	+	+	+	+			+	+	
MR	Complications - Rejection	+	+	+	+	+			+	+	

Form	Title	Data .ASC	Data Dictionary .DIC .DRP	Forms with variables .ASC	Forms Word .DOC	MOOP .DOC .ASC	SAS Content	SAS sas7bdata	SAS SD2	SAS RD	Part of the TEXT dataset
NR	No Rejection Clinically Diagnosed	+	+	+	+	+			+	+	
PB	Back Table Day 0/1 Histology Findings	+	+	+	+	+			+	+	
PG	Post-Transplant Pathology: Failed Allografts and Autopsies	+	+	+	+	+			+	+	
PO	Pathology for Native Liver	+	+	+	+	+			+	+	
PP	Post-Transplant Pathology: Histology Findings	+	+	+	+	+			+	+	
PS	Post-Transplant Status	+	+	+	+	+			+	+	
QA	Quality of Life: Adults	+	+	+	+	+			+	+	
QP	Quality of Life: Children	+	+	+	+	+			+	+	
RU	Rejection Update	+	+	+	+	+			+	+	
SL	Screening Log	+	+	+	+	+			+	+	
ST	Study Log	+	+	+	+	+			+	+	
YP	Yearly Pre-Transplant Follow-Up	+	+	+	+	+			+	+	

Table 2: LTD1 Serum Study

File	Dataset Name	Form	Description	Data from LTD forms CE, FS, DF, LD, CP, CO	Data .ASC	Forms Word .DOC .ASC	MOOP .ASC .DOC	SAS Content	SAS sas7bdata	SAS SD2	SAS RD
EIA2	SERUM.EIA2		1,467 anti-HCV tests 768 patients and donors who did not have 2nd generation tests recorded on LTD forms	+	+			+		+	+
HGV	SERUM.HGV		320 tests for HGV RNA using RT-PCR in 188 patients and donors (Genelabs)		+			+		+	+
MRKR_HBV	SERUM.MRKR_H BV		566 PCR tests for HBV DNA on 158 patients and donors 1 year post-transplant (NIH)		+			+		+	+
MRKR_PCR	SERUM.MRKR_P CR		374 PCR tests for HCV RNA on 105 patients and donors 1 year post-transplant		+			+		+	+
MT	SERUM.MT	MT	Roche HCV Chiron HCV Genotype		+	+		+		+	+
RIBA	SERUM.RIBA		Retest 430 positive EIA-2 results for 245 patients and donors		+			+		+	+
SSVIAL	SERUM.SSVIAL	SS	Serum Storage inventory of 14,139 vials		+	+	+	+		+	+
VB	SERUM.VB	VB	920 Hep B tests 580 patients and donors who did not have test results on LTD forms	+	+	+		+		+	+