



# European Liver Transplant Registry

A service of the European Liver and Intestine Transplant Association (E.L.I.T.A) [www.elita.org](http://www.elita.org)  
 A section of the European Society of Transplantation (E.S.O.T) [www.esot.org](http://www.esot.org)

## History and Aim

The idea of a European Liver Transplant Registry (ELTR) was brought up at the meeting of the European Society for Organ Transplantation (ESOT) [www.esot.org](http://www.esot.org) in Munich, 1985. Further to the proposition of Prof. Henri Bismuth, a group including the main liver transplant Centers (Henri Bismuth - Villejuif, Roy Calne - Cambridge and Rudolf Pichlmayr - Hannover) decided to create the ELTR with the following objectives:

- Registry of all adult and pediatric liver transplantation (LT) procedures in Europe
- Link between European LT Centers
- Scientific use and publications.



Roy Calne  
U.K.



Henri Bismuth  
France



Rudolph Pichlmayr  
Germany

Paul Brousse Hospital (Villejuif, France) was designated to manage and analyze the data of ELTR since its creation in 1985. Two years later, ELTR had collected information on all LT recipients from 32 European centres (Lancet, 2: 674, 1987) and since 1991 from 67 centres (Transplant Proc, 21: 2383, 1991). In 1993, the ELTR has become a service of the European Liver and Intestine Transplant Association (ELITA) [www.elita.org](http://www.elita.org). Between 1968 and December 2018, the ELTR has collected data regarding 164,700 LTs performed in 175 centres from 33 European countries. The ELTR have a truly global representation of European countries with clear prerequisites for contribution to ensure quality, validity, and reliability.



## Coordinating Committee

A standardized and computerized method for data entry has been developed by the ELTR coordination Committee (ELTR-CC) to collect accurate and uniform data in all liver transplants across the European participating centres.

Each Centre participates by collecting the requested data of all the LTs and the follow-up of the recipients and living donors.

The ELTR-CC is responsible for maintaining the data collection system, monitoring the quality of the data, and for statistical data analysis. Data Analysis with adult and pediatric figures are then published and transmitted to all the participating centers. A set of updated pdf slides is put on the website at the disposal of the authorized users (cf. "Data communication and Publication"). Periodical meetings are organized by the ELTR-CC to review the data and to discuss topics of scientific and clinical interest. The ELTR Coordinating Committee is composed of:



René Adam  
Custodian



Vincent H. Karam  
Manager



Valérie Delvart  
Biostatistician

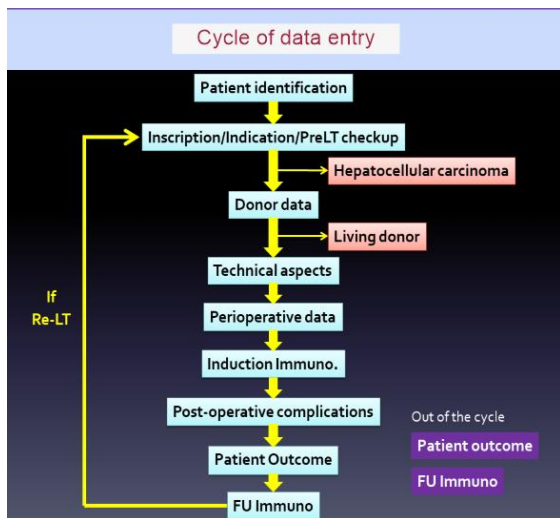


Anne-Marie Lamerant  
Secretary

## Data Management and quality Control

### 1. Questionnaire, Database and Data transfer

The questionnaire includes data on LT indication, donor and recipient, technical aspects of LT (live donation, split liver, domino transplant, Non heart beating donors...), immunosuppression, patient follow-up and contains questions on the cause of death or graft failure. The ELTR has developed an online application (Electronic Data Capture – EDC) for collecting data according to the cycle below.



To encourage completion, the questionnaire was intentionally limited to the main items. The ELTR Web-based module "ELTRweb platform" was developed to allow for real-time data capture. Software, questionnaires, validation routines and statistics are located on a central server, which can be accessed from participating transplant centers with a standard internet browser.

This web-based approach enhances participation and avoids time-consuming installation of software in many different centres. The ELTRweb platform was built by the ELTR Data Manager and Biostatistician with innovative techniques of FileMaker® Server technology for collection and analysis of electronic clinical data. It was tailored to meet the needs of LT centers looking to run registry studies.

## 2. Data validation

The data-entry process is dynamically controlled. A logic control procedure has been developed. The data are subjected to checks for completeness, consistency, and range. Comprehensive logical intra- and inter-updates are performed. A list of the queries are communicated to the Centre's personnel in charge of data management each time a new update comparison is performed. The Centre performs the corrections before the data validation for analysis.





In addition, the ELTR has established a data sharing collaboration with the key European Organizations:


Done:

 United Kingdom Blood and Transplant Authority (NHSBT) [www.nhsbt.nhs.uk](http://www.nhsbt.nhs.uk)

 Spanish "Organización Nacional de Transplantes" (ONT) [www.ont.es](http://www.ont.es)

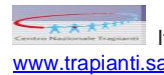
 French "Agence de la Biomédecine" (ABM) [www.agence-biomedecine.fr](http://www.agence-biomedecine.fr)

 Deutch "Nederlandse Transplantatie Stichting" (NTS) [www.transplantatiestichting.nl](http://www.transplantatiestichting.nl)

 Eurotransplant International Foundation (Austria, Belgium, Croatia, Germany, Luxembourg, Netherlands and Slovenia) [www.eurotransplant.org](http://www.eurotransplant.org)

 ScandiTransplant (Denmark, Finland, Norway and Sweden) [www.scandiTransplant.org](http://www.scandiTransplant.org)

In process:

 Italian Centro Nazionali Trapianti (CNT) [www.trapianti.salute.gov.it](http://www.trapianti.salute.gov.it)

The purpose of these agreements was to exchange and cross-check data collected from European Centers. The harmonization of questionnaires and classifications, sential step, was conducted prior to the start of collaboration.

ELTR also established collaboration with the Liver Intensive Care Group of Europe (LICAGE). Main perioperative variables were added to the ELTR questionnaire. The aim of this scientific collaboration is to bring together from throughout Europe specialists of all disciplines involved in the perioperative and long-term care of liver transplant recipients.

## 3. Data analysis

Data are analyzed with Statistical Analysis System (SAS). The dynamics of data control are continued during the statistical analyzes. Editing and referral to clinical records are used when necessary, to resolve any inconsistencies that are detected during the analysis. Most of the studies in which ELTR data is analyzed require calculation of graft

and patient survival rates. These are determined by actuarial methods and the statistical significance is determined by the Log rank test to compare survival curves. Regression methods are also used to identify risk factors associated with LT.

The ELTR is also a pediatric database, and a specific routine data analysis concerns this population of patients.



#### 4. Experts Scientific Committee, Workshops and Congresses

Periodic meetings are organized by the ELTR Expert Committee to review the questionnaire and to discuss topics of scientific and clinical interest. The expert Committee is composed of hepatologists and surgeons, which discuss each item of the questionnaire and validate the data entry masks and the instruction handbook. Periodic workshops are also organized each two years and all of the persons in charge of the updating of ELTR data (Transplant Coordinators, Data Managers, OSO representatives) who are invited to give their comments and to report problems.



The ELTR-EC and the workshops permit to adapt the questionnaire and the data management procedures to the evolution of LT, to provide an updated evaluation of LT results.

Traditionally, ELITA/ELTR organizes a Specialty Update Symposium at each ESOT Congresses. Moreover, The ELITA/ELTR organizes frequently joint meetings with other societies and registries with topics of common interest:



the European Society of Transplantation (E.S.O.T) [www.esot.org](http://www.esot.org)



the European Association for the Study of the Liver (EASL) <https://easl.eu>



the International Liver Transplantation Society (ILTS) [www.ilts.org](http://www.ilts.org)



The European Association for the Study of the Liver (AASLD) [www.aasld.org](http://www.aasld.org)



The Liver Intensive Care Group of Europe (LICAGE) [www.licage.org](http://www.licage.org)



The European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) [www.espgan.med.up.pt](http://www.espgan.med.up.pt)



Familial Amyloidotic Polyneuropathy World Transplant Registry and Domino Liver Transplant Registry (FAPWTR) [www.fapwtr.org](http://www.fapwtr.org)



The International Liver Cancer Association (ILCA) [www.ilca-online.org](http://www.ilca-online.org)



European Foundation for the study of chronic liver failure <https://efclif.com>

#### 5. Audit visits

To compare information contained in the report with original source documents or database, additional measures have been taken and include site visits to the Centers. In 1997, the ELTR coordinating team appointed an independent committee:

- Vincent KARAM, France
- Bridget GUNSON, UK
- Chantal DE REYCK, Belgium
- Wolfgang WANNOFF, Germany
- Baltasar PEREZ SOBREDO, Spain



to perform the audits according to a predetermined standard methodology. Five randomly selected centers are visited per year. The audit visits also allow resolution of any center-specific problems that may have arisen and define guidelines to prevent further errors. A confidential audit report is sent to the head of the Centre with the list of inconsistencies.

TRANSPLANTATION has published a forum with our manuscript describing the ELTR auditing procedure as the lead article (cf. Publications).

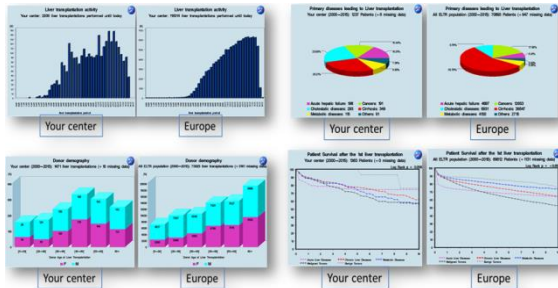
#### Data Communication and Publications

The ELTR Centers have access to their real-time center's specific and European data analysis totalizing more than 750 statistical figures and tables each 6-month period. The figures are distributed in 5 booklets: Overall data, last 10-yr data, adults' data, pediatric data and LDLT data. These





data are available in the password protected professional part of the website <https://eltr.fmdata.fr/eltr-form>



Registry thematic studies are also conducted but only when the project was accepted by the ELITA SC. The ELTR-ELITA rules for studies are available in <http://www.eltr.org/ELTR-publications-rules.html>.

The ELTR is increasingly present in scientific congresses with more than 10 communications per year (lectures and abstracts). The ELTR has also published 73 peer-reviewed papers in the main scientific journals. The list of publications is available in the appendix.



ELTR created in 1997 a website [www.eltr.org](http://www.eltr.org) that is continuously updated. The ELTR public website contains the following information:

- News (Audit visits, ongoing studies, ELTR events...)
- ELTR purpose and description of the procedures
- Updated list of contributing centres
- Data analysis results (52 figures and slides)
- Biannual center Specific analysis (protected pdf)
- ELTR conventional slides (pw protected)
- Online data request form
- List of publications
- Links



Home Page of [www.eltr.org](http://www.eltr.org)

Once a year, ELTR send a Newsletter to all the contributing centers and ELITA members. Purpose of the newsletter is to inform members about new developments within the Registry, such as enrolment of new centers, updated numbers, collaborations, future meetings, and publications of ELTR-studies. In addition, it contains an overview of activities during the previous year.

## Funding

From its inception the ELTR has been supported by funding raised by the biomedical companies. The size, completeness and continuous validation of the database now warrant an improved financial structure. The ELTR thanks very much the following sponsors:



[www.astellas.com](http://www.astellas.com)



[www.novartis.com](http://www.novartis.com)



<https://groupe-igl.com/fr>



[www.sandoz.com](http://www.sandoz.com)



<https://www.chiesi.com/en>



[www.aphp.fr](http://www.aphp.fr)

Both ELTR and ELITA officers with the backing of ESOT council are seeking funding structures to maintain, continue and expand the ELTR – the only pan European database on liver transplantation in Europe. It is a European resource of very great importance for scientific research, patient safety, professional audit, and for information on results of donation.



*... Both the rate of completeness of data and the rate of consistency between charts and the registry data were excellent. This does indicate that the scientific data held in the European Liver Transplant Registry is of a high quality and therefore of very considerable value in analyzing the indications for and outcomes of liver transplantation in Europe...*

Peter J. Morris and Anthony P. Monaco  
Transplantation. Vol. 75, No. 12, June 27, 2003

*... Theodore Roosevelt once said, "Do what you can, with what you have, where you are." Today we can no longer afford to undertake randomized effectiveness trials that cost tens or hundreds of millions of dollars. But today we also have registries and other powerful digital platforms...*

Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.  
N Engl J Med 369;17 October 24, 2013



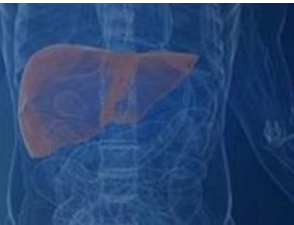
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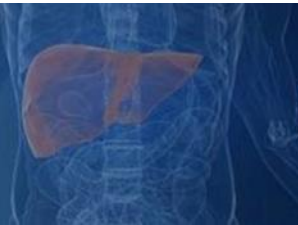


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