Frequently Asked Question (FAQ)

What is LDLTregistry.org?

- The **International Living Donor Liver Transplant (LDLT) Registry | LDLTregistry.org** is a multidisciplinary collaborative of international physicians to study the outcomes of Living Donor Liver Transplantation (LDLT).
- The goal of LDLTregistry.org is to improve the practice of LDLT by sharing of research and innovation.

What is a Patient Registry?

Patient registries are organized systems that use observational methods to collect uniform data on a population. A patient registry is a powerful tool to observe:

- The course of disease
- Understand variations in treatment and outcomes
- Examine factors that influence prognosis
- Describe care patterns
- Assess effectiveness
- Monitor safety and harm
- Measure quality of care
- Assess costs

Why participate?

- Provide a verified record of true morbidity and mortality in consecutive unselected patients.
- Help identify relevant, modifiable risk factors for outcome after LDLT.
- Become part of a growing global surgical research and audit network.
- Obtain PubMed citable co-authorship from all publications derived from LDLTregistry.org.
- Access the raw data for future studies.

Who can participate?

- Any surgeon, anesthesiologist, hepatologist, critical care physician or other member of any grade involved in LDLT is eligible and welcome to participate.
- Each participant may form a team of 3 members in total.

Which patients should we include in the registry?

- Both donors and recipients will be included in the registry, including adult and pediatric, as well as two stage LDLT, (e.g. Auxilary, RAPID, APOLT, ASPIRE, RAVAS)
- All consecutive, unselected cases should be included from the time the first case is submitted.

Which patients should we exclude from the study?

- Domino and dual graft cases will be excluded.

How can I get involved?

- Form a team of up to 3 people per surgical team to collect data and obtain appropriate approvals.
- It is up to the local primary investigator/collaborator to decide whom to include in their team of 3.
- Identify an additional Auditor (data monitor) at your institution. Auditors will be assigned to monitor the adherence to the registry protocol as well as auditing the quality of data collection of the participating centers. Auditors should be non-surgeon physicians not directly involved in LDLT.
- Register your participation at https://LDLTregistry.org/user/register including the details of your 2 additional colleagues that will form your local team.
- After submitting your registration form, we will review the information and provide you with an account for the LDLTregistry.org platform within 48 hours upon receival.
- Obtain necessary local approvals if required. Note that our NHS (UK) Audit Committee has approved this project as an audit.

How should data be collected?

- We strongly recommend to first extract and record the data for each case on our paper Case Report Form (CRF) version and then submit them online using our electronic CRF. This will be very useful to record all data prospectively and submit them only when all mandatory data are available (e.g. 90-day morbidity and mortality).
- The paper and electronic CRFs are available at: https://LDLTregistry.org/CRF
- The electronic CRF was specially designed to support the online data collection of the LDLTregistry.org. This CRF is an online data collection form where you can submit your cases.
- Note that all field names (e.g. “Age”) followed by an asterisk (*) are mandatory for case submissions. If you miss to fill out a mandatory field, the platform will point out which one it is.
- There are some fields that may not be applicable or data not available. In such cases, please leave them blank.
- Links to classifications, definitions, online lab value converters and other calculators are available in the LDLTregistry.org platform after you login to the website.
- The following link provides detailed information on how to use the LDLTregistry.org platform and the electronic CRF for submitting cases: https://LDLTregistry.org/instructions
- The LDLTregistry.org platform was designed to adapt to all different screen sizes, browsers and devices currently available.
- You may use your desktop computer, laptop, tablet or even smartphone to navigate the website, read the protocol or even submit cases through the electronic CRF.
- Note that the “Case number” in the CRF for each case should be a unique ID without including any patient identifier such as the hospital number, initials, year of birth or other such combinations.
- Please keep a separate list of anonymized case numbers linking to the patient hospital number somewhere safe at your institution. This will help you identify patients in the CRF for further editing if needed.

Will my work be recognized?

- Yes. All LDLTregistry.org members, including auditors, country leaders, administration, management, scientific committee, and founding members will be publicly listed on the website.
- All LDLTregistry.org publications will be published on behalf of the LDLTregistry.org Collaborative which means all LDLTregistry.org members can include these in their curriculum vitae.
- All LDLTregistry.org members will obtain PubMed citable group authorship.

Who owns the data?

- The study Chief Investigators and Founders will act as the custodians of the data.
- The data however belong to all collaborators.
- The scientific and management committees together will decide after the publication of the main report about requests regarding secondary analysis and will consider all such requests based on quality and the validity of the proposed project and decide by majority decision.

How are the data protected?

- All data collected, processed and stored for the purpose of the project will remain confidential and comply with Good Clinical Practice for research (GCP) guidelines and the principles of the Data Protection Act 1998 (UK).
- Data submitted are anonymized prior to submission to the LDLTregistry.org data entry system.
- Access to the data entry system will be protected by username and password during the registration process for individual local investigators.
- All electronic data transfer between participating centers and the coordinating centers will be encrypted using SSL/TLS protocol (HTTPS).
- The LDLTregistry.org platform is protected by additional web security software that monitors, identified and fixes threats, prevents attacks, accelerates website performance and meets international compliance standards.

How will you ensure the validity of the submitted data?

- The Auditor (data Monitor) that you have assigned at your institution will conduct regular checks of the consecutivity and completeness of outcome data entered on a regular monthly basis.
- Auditors will be acknowledged at LDLTregistry.org and in all publications (PubMed cited).

Do we need to submit the protocol to our local institution or regional ethics committee?

- Each country, state or region may have differing regulations for gaining ethics permission.
- LDLTregistry.org is an observational study without affecting the patient management.
- The raw data collection is fully anonymized without containing any patient identifiers.
- In many countries, such as in the UK, this study is considered as an audit, without necessitating a formal ethics approval. In the US it may registered as a Quality Improvement Project.
- The local investigators should seek advice from their own Ethics Committee or Institutional Review Board.
- If your Ethics Committee requires you to provide patient information and obtained informed consent, you will be able to download these template documents from our website (instructions page).

What is the role of the country leader?

- Country leaders recruit and co-ordinate collaborators in their own country or region.
- They may provide additional scientific and administrative support to the local collaborators.
- Country leaders will also obtain PubMed citable group authorship and accreditation for leadership.
- To become a country leader, register your participation and indicate in the form that you would like to become a country leader: https://LDLTregistry.org/user/register.

How are surgical complications defined and graded in this study?

- Postoperative surgical complications are defined as any deviation from the normal postoperative course and their severity is graded according to the way they are treated (according to the Clavien-Dindo Classification of surgical complications). For more information, please visit the official website: https://www.assessurgery.com
- Our detailed illustrated instructions with examples are available at: https://LDLTregistry.org/sites/default/files/Instructions_LDLTregistry.org_v1.pdf