Call for expression of interest to develop the ESOT multi-organ registry

Questions and Answers

What dataset will be collected in the new registry

The first registries that will be created on the platform are the European Kidney Recipient Registry (EKRR), the European pancreas and islets transplant registry (EPITR) and the European Living kidney Donors registry (ELDR). EKKR collects data on about 80 variables in four categories: Donor, Recipient, Transplantation, Follow-up. EPITR collects data on about 130 variables on Donor, Quality of Organ, Recipient, Follow-up.

How will EDITH, ELITA, ELTR, EPITR interact with the new registry?

These registries as well as new ones will be part of the ESOT registry platform which will replace the individual existing (ELTR) of completed projects (EDITH, ELDR).

Do you expect the technical partner to follow up on the technical solutions proposed in the EDITH final report?

No. The technical partner can propose new technical solutions, but they have to accommodate existing ELTR registry and data collected in EDITH and ELDR.

Can you share the technical spec and datasets from already developed EDITH, ELTR, ELDR, EPITR registries in order to understand and prepare appropriate portal to accommodate all in one hub?

Apart from ELTR that will be integrated into the platform at a later stage, all other registries will be built de novo starting from existing datasets, when possible (EKRR and ELDR).

Over the coming 5 years, how many additional registries are you planning to initiate next to those described in the proposal?

This will depend on how quickly the technical provider will deliver the registry platform. New registries may be proposed by other sections of ESOT, but the above ones are likely to be the ones to be developed in the next five years.

Do you have the definition of variables for each organ and transplant type?

ESOT scientific committees are working on the definition of variables for various registries. The technical partner will be provided with this information as soon as the contract is signed. Concerning the registries developed in the EDITH project, please have a look at the final report.

Do you have the input forms available?

ESOT scientific committees are working on the definition of variables for various registries. Some are already developed (for example those part of the EDITH project or current ELTR registry, which will be migrated in the next 3-5 years). The technical partner will be provided with this information as soon as the contract is signed.

Will you also collect the donor/recipient anonymised profiles together with all their laboratory results and history?

Yes. The variables to collect will be defined for each registry by dedicated scientific committees and also considering what currently exists in the data sources from where data will be collected.

Is part of the scope of this project to include ELTR?

Yes, ELTR will eventually be integrated in the ESOT registry platform.

Can you provide more detailed information about EPITR

EPITR is a new registry that is being developed by a dedicated scientific committee.

Should the implementation partner also have the know-how about healthcare outcomes and organ transplant data?

ESOT will develop all scientific/medical content, including variables, with the help of committees dedicated to each registry. The technical partner will be part of the platform Executive Committee and advise ESOT on further (technical) implementation even after delivering the initial platform, but knowledge about healthcare and transplant would assist development and expedite the process.

How the new data will be fed into the registry?

The platform should allow synchronization with existing, local registries, upload of file and manual entry.

Will there be a need to connect with the National databases online.

Yes, this is an option that the platform must offer.

Will you be later expanding into Tissue and Cells area?

The platform should be able to host new registries, including registries on tissue and cell transplantations.

Do you want to also collect info about the cadaveric donors?

Yes. These variables are essential to inform outcomes in each registry.

Is this portal aiming to be also a live system for the organ procurement for surplus organs not allocated nationally?

No

At which interval will data be collected?

The data should be imported in the registries once or twice per year (if fed from existing registries), but should also allow real time input from partners who do not have currently access to local registries.

Will you be happy with the Oracle DBMS?

ESOT has no a priori view preference on the technical solution to be adopted.

Will you be happy with a purely Web based technology?

ESOT has no a priori preference on the technical solution to be adopted.

With which countries will you want to collaborate?

Our first target is the 47 member states of the Council of Europe; other countries of the Mediterranean area will be considered as well.

Which countries do you want to cover in 1, 3 and 5 years?

We do not have a priority list, but can expect that countries of the European Union may join in the early phases of the project.

Will the system be anonymised or dealing with real recipients/donors IDs?

Data will be reported aggregated and anonymised, but raw data imported will require identifiable variables to allow data checks and validations; also some data will be collected directly from hospitals.

How many users do you expect?

We expect different categories of users. Our first target is the 47 member states of the Council of Europe, each of them will be an user. For some registries, users may be hospitals or transplantation centres. In addition, we consider as users, patients that will input data via the dedicated mobile application or directly via the online platform for patient reported outcomes. Finally, the members of the medical and scientific communities that will visit the platform to gather information are considered as users.

Who is an "institutional data provider"?

National/local authorities or individual institutions providing data

Who is an "individual data provider"?

That may be 1) a patient; 2) an hospital/transplantation centre/physician inputting data on individual patients.

Where will be the servers located?

ESOT has no a priori preference on the technical solution to be adopted.

Is there a need for a demilitarised zone (DMZ)?

If the technical partner believes that this is necessary to secure data, they should include it in the proposal.

Is there a need for backups?

Yes. The technical partner should propose a solution for secure, long-term data storage.

Is there a need for audits?

The technical partner should propose a solution to check the quality of imported data; audits will be part of this solution.

Will there be any routine pre-defined reports?

Yes. ESOT Scientific committees will provide the technical partner with standardised reports to implement.

Is there a need to also provide hardware and infrastructure from the technical partner?

The technical partner should state any need for infrastructure in their proposal.

What are the success criteria of this project?

Successful implementation of the platform is the key criteria for success of phase one. Clear milestones should be defined by the technical provided and audited for achievement. Once the platform is established, ESOT expects a proposal for the monitoring of the success of the platform. By success it is meant satisfaction of both the users that input data and the users that visit the platform to retrieve information. Frequency of accesses, number of visualizations of reports, monitoring of errors, bugs and requests for support, interaction, referral to external websites are some parameters that may help evaluate the success of the platform.

Who delivers the first line of operational support when the system is in use?

The technical provider should provide such a service; that will be considered as an added value in the proposal.

What is "centre-specific tableau"?

Users (i.e. transplant centres) should be able to visualize their data.

Can you explain how ESOT intends to collect patient-reported outcomes?

The ESOT platform will collect data reported directly from patients (recipients and living donors). Patients will have the possibility to input data via an online form integrated in the registry platform or via a dedicated mobile application. The technical partner should include in the proposal its capability to build a mobile application dedicated to patients. Alternatively, integration with others apps developed by third parties providing this option to collect data may be considered.

Do you want to collect the data also from dialysis centres?

The focus for the registries is transplant outcomes.

Will hospitals upload directly to the registry or always through a national registry?

Whenever a national registry exists, we will request data directly to national authorities. However, not all transplantations have their own national registries; that is why the option for hospitals and transplantation centres to input data directly should be available on the platform.

Will it be sufficient to export reports in pdf, xml, xls, csv files for deeper analysis or is there a need to do the complicated statistical analysis within the registry?

All options should be available. The extent of statistical analysis will depend on the needs of the users, but registries reports should include advanced statistical analyses of the aggregated data.

On what platform is ESOT website running?

WordPress

What is the overarching objective of the registry?

The aim of the registries is to provide the medical and scientific communities with solid data on patient outcome after transplantation, facilitate benchmarking and scientific analyses. The technical partner should then consider not only how to collect data, but also how to make those data easily searchable for a general user that visits the platform to search for information.

Should PROMS (patient reported outcomes) be part of the offer? Do you expect this from the start?

Yes, PROMS and DROMS (donor reported outcomes) should be part of the offer and developed at the beginning of the project. Patient-reported data will be collected via a mobile application and a dedicated form on the registry platform. The technical partner should include the development of the application in their proposal; partnership with other companies is possible; integration with third parties is essential if own development ability is not possible. A two-step implementation (registry first, mobile app second) may also be considered.

How the evaluators are expecting to take into consideration the level of innovation of the partner?

The main novelty of the ESOT registry platform is that it will allow hosting of various registries and easy addition of new registries in a way that is user friendly. Therefore, we are seeking a proposal that is innovative in the way output is communicated and made available as well as in the way new scientific data can be collected. The innovation culture of the technical partner, not only of the proposal, will be also taken into consideration (e.g. business development, service delivery, product development and technology).

Are data collected from national institutions and third party repository anonymised?

Input data may be anonymised or not depending on the registry; in case of data from national authorities, they will probably be anonymised, but in case of collection directly from transplantation centres (if no national registry exists), anonymisation may not be possible. Output data will be aggregated and anonymised.

Does ESOT require supporting services from the partner for a Data Scientist/Statistician/Data Engineer/Data Analyst?

If the technical partner can offer this service, it is invited to add it to the proposal, which is certainly seen as an added value. The amount of support needed will vary according to the evolution of the registry, therefore quote per working hours are accepted. The technical partner should specify if such service is already in place or will be built ad hoc.

Is the mobile application intended as an alternative to access data or is it intended to acquire data?

The mobile application is intended to collect data from patients (user category: individual data provider).

Would it be acceptable to ESOT to receive the Technical and Financial proposal in one mail and then the statements as attachments in separate emails?

ESOT would appreciate receiving all documents in a single document or downloadable from a single folder.

Should the Financial Proposal include the IT infrastructure required to set up the multi-organ registry as well as its costs? Which types of IT infrastructures are considered acceptable?

The technical partner should mention all costs, including infrastructure if needed. EOST has no a priori view on the technical solutions to be adopted.

Can you please specify if subsets of data are to be shared as Open Data on the ESOT website?

Aggregated reports will be shared as open files, but not the raw data files. Data will be provided on demand and after approval by the Scientific committee.

Does ESOT accept the use of commercial off-the-shelf products or licensed products? Will third party licenses be bought by ESOT or should be included in the financial proposal?

ESOT has no a priori view on the technical solution to be adopted. All costs should be mentioned in the proposal.

Are Open Source products suitable for ESOT, and which are, if any, the appropriate OS licenses can be acceptable?

ESOT has no a priori view on the technical solution to be adopted.

Do you confirm that any further code developed as part of this contract pertain to ESOT?

Yes, ESOT will have ownership of additional codes developed in this project.

What are the types of data required from patient/donor that need to be collected from the mobile App?

Both personal and medical data, in respect to current legislation.

Should the application be available in any specific mobile platform? (e.g. IOS/version, Android/version)?

The application should be eventually available on the most common platforms.

Which will be the available languages for the mobile application?

The aim is to have the app in most European languages.

Will the development of the multi-organ registry be carried out at the ESOT headquarters?

No.

Can you please specify the differences envisioned between individual data provider and institutional data provider in terms of functions and services they are allowed to use?

Both data providers should have the possibility to compare their data easily with the aggregated data collected in the database. Institutional data providers should have the possibility to assign multiple individual users to their profile and access their own data. Users tableaus should provide comparative aggregated anonymised for institutional users vs registry data. Individual data providers, especially patients, should have the possibility to enter detailed personal and medical information, but not access the registry data.

Will English be the language of all interfaces?

English will be used for the online platform; in addition, other European languages will be used for the mobile application.