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

March 2021

Confidentiality and Disclaimer

This call contains proprietary information and is confidential to the European Society for Organ Transplantation. No part of this call or its attachments may be reproduced or shared, in whole or in part, unless specifically required for the vendor's internal use in responding to the inquiry. No representations or warranties are made concerning the completeness or accuracy of information contained in the call.

All proposals, presentations and supporting materials submitted to this call will be treated with confidentiality and used for the purpose of selecting a company or companies to provide services for the European Society for Organ Transplantation.
## Table of Contents

Executive Summary ....................................................................................................................... 4

Section 1 – Background and objectives .......................................................................................... 5
  1.1. Purpose of the call .................................................................................................................. 5
  1.2. The European Society for Organ Transplantation (ESOT) ...................................................... 5
  1.3. ESOT registries ...................................................................................................................... 5
  1.4. Existing ESOT registries ....................................................................................................... 6
  1.5. Objectives ............................................................................................................................ 6

Section 2 – Call process and administrative information ................................................................. 8
  2.1. Proposal conditions .............................................................................................................. 8
  2.2. Schedule .............................................................................................................................. 8
  2.3. Response format .................................................................................................................. 8
  2.4. Proposal submissions .......................................................................................................... 9
  2.5. Queries about the call ......................................................................................................... 9
  2.6. Selection criteria .................................................................................................................. 9
  2.7. Acceptance of offers .......................................................................................................... 9
  2.8. Agreement finalisation ........................................................................................................ 9
  2.9. Term of contract .................................................................................................................. 10
  2.10. Company conducts .......................................................................................................... 10
  2.11. Disclaimer ......................................................................................................................... 10

Section 3 – Call requirements ........................................................................................................ 11
  3.1. Executive summary ............................................................................................................. 11
  3.2. Services ............................................................................................................................... 11
  3.3. Capability and expertise of the technical provider ............................................................... 11
  3.4. Financial offer and viability of the proposal ........................................................................ 11
  3.5. Ethical values of the technical partner .............................................................................. 12
  3.6. Implementation plan .......................................................................................................... 12
  3.7. Capability Statement ......................................................................................................... 12
3.8. References ..........................................................................................................................12
3.9. Project team and account management .............................................................................13
3.10. Reporting ..........................................................................................................................13
3.11. Innovation .........................................................................................................................13
Executive Summary

The European Society for Organ Transplantation (ESOT) is seeking a technical partner to build and maintain an online platform aimed at hosting several registries on organ transplantation. The platform will be modular and scalable, and partially connected to a mobile application.

ESOT is looking for a reliable, trusted and knowledgeable technical partner to develop a modern and future-proof platform for collecting and storing transplant recipient and living donor data. The technical partner shall be able to present a concept for a platform that will grow continuously with the addition of new registries to the existing ones. Moreover, the platform shall feature powerful means to automatically analyse data and prepare reports in a customised and ready-to-publish format. User friendliness is of extreme importance: different user roles shall be supported, different options for data entry should be facilitated, including automatically import from existing national and local registries. Import of data from existing registries shall be possible as well as easy and autonomous creation of variables. Parts of the registry may be linked to a mobile application: the technical partner shall specify if it is able to offer this service.

Proposals must be submitted by 11 April 2021 by email to Daniele Roppolo (Scientific Advisor, daniele.ropollo@esot.org), copy to Vassilios Papalois (ESOT Board Chair, vassilios.papalois@nhs.net), Gabriel Oniscu (ESOT Board secretary, gabriel.oniscu@ed.ac.uk) and Luca Segantini (CEO, luca.segantini@esot.org).
Section 1 – Background and objectives

1.1. Purpose of the call

The purpose of this call is to solicit proposals from suitable technical partners for building the ESOT multi-organ registry. This registry will collect medical information on patients who have received an organ transplant and on living donors that have donated an organ. It has the aim to collect transplant relevant data, to analyse them and to report openly to the medical community. The registry will have different organ specific modules; the variables, i.e. parameters to collect, will be specific to each type of transplant.

1.2. The European Society for Organ Transplantation (ESOT)

The European Society for Organ Transplantation (ESOT) was founded over 30 years ago and is dedicated to the pursuit of excellence in organ transplantation. Facilitating a wealth of international clinical trials and research collaborations over the years, ESOT remains committed to its primary aim of improving patient outcomes in transplantation.

With a community of over 8,000 members from around the world, ESOT is an influential international organisation and the facilitator of the biennial congress which hosts approximately 3,500 experts who come to meet to explore and discuss the latest scientific research. ESOT attracts the foremost transplantation experts to work in its committees and sections, and has an impressive track record in supporting research, supporting extensive education, and promoting changes in European policy. ESOT reaches out to close to 30,000 transplantation professionals and patients. In addition, ESOT closely collaborates with national and regional transplantation societies around the world and with national and international authorities, including the European Commission.

1.3. ESOT registries

Strong international effort has resulted in the creation of single-organ registries and establishment of international networks supported by national authorities, the EU commission, patient organisations and the medical community. ESOT will build on this effort to provide a high-quality service to the transplant community. In particular, ESOT will follow up on the achievements of the EDITH project, which concluded in December 2020 and has laid the foundations for the establishment of a living donor registry and a kidney recipient registry. In addition, ESOT will also bring together the work of its sections ELITA and EPITA, which have successfully coordinated the European Liver Transplant Registry (ELTR) and worked on the development of a pancreas and islets transplant registry (EPITR).
1.4. Existing ESOT registries

The European Liver Transplantation Registry (ELTR) is one of the oldest European wide registries. It includes data on 170,000 liver transplants undertaken in 153,000 patients from 171 centres in 32 countries over a period of more than 30 years. A large part of those data (>75% of liver transplants) is being derived from Organ Sharing Organizations (OSOs) and the remainder are directly retrieved from the liver transplant centres through electronic data capture.

The European pancreas and islets transplant registry (EPITR) is a project of the European Pancreas and Islets Transplant Association (ELITA), a section of ESOT. The EPITR scientific committee is working on the definition of the variables to be captured in the registry.

The European Living Donor Registry (ELDR) has been developed in the context of the EDITH project. Living donor follow-up registries that support lifelong data collection are considered necessary to understand the long-term effects of living donation on the life of the donor.

The European Kidney Recipient Registry (EKRR) has also been developed in the context of the EDITH project. EKRR gathered necessary information on transplant outcome that can be used for example to improve the process of organ donation and transplantation, for instance in donor and patient selection and kidney allocation.

1.5. Objectives

The purpose of this tender is to find a long-term partner to build, maintain, update, and further develop an online platform to support the ESOT multi-organ registry. Associated product is a mobile application that collects data directly from patients/donors. ESOT is seeking a technical partner capable of covering the following services:

1. **Building a modular platform.** Each registry is a module with its own variables; modules may have sub-modules, for example a living donor registry and a recipient registry. The platform should be built so that adding a new module does not need further re-development and can be done by an administrator.

2. **Building a user-friendly platform.** Users of the platform may have different roles including 1) general administrator; 2) institutional data provider; 3) scientific committee member; 4) individual data provider. Each user type may have different rights and access to one or more modules. Institutional data providers shall be able to grant access to multiple users. Data entry should be possible manually, via file upload as well as synchronisation with existing registries. The platform should be able to import data from a wide range of existing systems and interfaces. The platform should be able to collect patient-reported outcomes via a mobile application and the online platform; data should converge into the online platform only. Users log in with the credentials of their ESOT account.

3. **Building an analytical platform.** The platform should be able to create automatically reports as datasets (e.g. excel), but also in a ready-to-publish format (e.g. pdf). Standard templates will be agreed by the scientific committees; however, the platform should be flexible enough to allow adding/removing
figures to the reports. The ready-to-publish reports should allow customisation, e.g. applying logos, headers. In addition, the platform should allow institutional data providers to compare their own dataset with the general dataset. Institutional data providers should be able to access their own data in tableau format and also be able to compare their data with the entire registry in real time format.

4. **Building an open platform.** The proposed platform and its own software should have a members-only access and should be interlinked with a public interface, that is easy to consult and could be framed within the ESOT website. For example, activity reports issued from the platform will be published regularly on the associated website; the scientific committee members and institutional data providers will be listed on the website. The website is the public interface of the registry and should feature state-of-the-art communication tools (e.g. social media threads).

5. **Building an evolutive platform.** It is essential that the platform can keep adding new registries and that the general administrator can achieve that with only minor assistance from the technical partner.

6. **Building a secure platform.** It is essential that the platform complies with GDPR and that measures are taken to anonymise provided data. The technical partner should propose a plan for data storage and details the security plans and verifications for data access by users.

In addition, ESOT is looking to appoint a technical partner that can assign one or more dedicated project managers to this project and deliver the project in the agreed (short) timeline.
Section 2 – Call process and administrative information

2.1. Proposal conditions

Submission of a proposal does not commit ESOT to award a contract. Each respondent assumes all risks for resource commitment and expenses in respect of preparing the call response, and participation throughout the inquiry process. Only the complete execution of a written contract by both parties will obligate ESOT in accordance with the terms and conditions therein. ESOT reserves the right to modify these and other call requirements and/or to invite additional respondents to submit responses and proposals. ESOT will maintain strict confidentiality in receipt of and possession of call responses including clarifications and other submissions during the process.

2.2. Schedule

All dates are subject to revision with notice by ESOT; any changes to the dates will be communicated to all parties. Respondents should express their interest in submitting a proposal as soon as possible and no later than 26 March 2021. Between 11 and 30 April, ESOT will contact the respondents to obtain further information on their proposal.

Suggested timeline:

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Launch of the call</td>
<td>5 March 2021</td>
</tr>
<tr>
<td>Expression of interest by</td>
<td>26 March 2021</td>
</tr>
<tr>
<td>Final date for technical partners to ask questions or request additional information</td>
<td>2 April 2021</td>
</tr>
<tr>
<td>Deadline for submission of proposals</td>
<td>11 April 2021</td>
</tr>
<tr>
<td>Evaluation and shortlisting by</td>
<td>30 April 2021</td>
</tr>
<tr>
<td>Shortlisted technical partner presentations, week commencing</td>
<td>10 May 2021</td>
</tr>
<tr>
<td>Technical partner selection by</td>
<td>15 May 2021</td>
</tr>
<tr>
<td>Contract signed</td>
<td>30 June 2021</td>
</tr>
</tbody>
</table>

2.3. Response format

Proposals are to follow the format and sequence set out in Section 3 of this call and should include a table of contents and pages numbered in sequence for convenient reference. All attachments are to be clearly cross-referenced in the main body of the response. All offers must be submitted in Euros.
2.4. Proposal submissions

ESOT would appreciate early notification of your intention to respond, ideally by 7 March 2021, to daniele.roppolo@esot.org. Please place in copy: vassilios.papalois@nhs.net, gabriel.oniscu@ed.ac.uk and luca.segantini@esot.org.

Proposals are to be submitted in electronic form. Proposals are to be clearly labeled and delivered to the email addresses above no later than 11 April 2021, noon (Brussels time). If size is too large for email, please provide a Dropbox download link or equivalent. Late proposals may not be accepted.

2.5. Queries about the call

All requests for clarification or further information in respect of this call should be addressed to ESOT’s named point of contact: Daniele Roppolo, Scientific Advisor - Registries, ESOT – daniele.roppolo@esot.org - Telephone: +41 77 253 22 14.

2.6. Selection criteria

The selection criteria to be used in the evaluation of proposals will include:

- Compliance with the objectives listed in point 1.5. The technical partner must present convincing arguments to show that they can meet the technical details.
- Capability and expertise of the technical partner, with particular attention to personnel resources.
- Financial offer and the viability of the proposal.
- Ethical values and cultural fit of the technical partner.
- Implementation plan

2.7. Acceptance of offers

ESOT reserves the right not to accept the most financially advantageous, or any proposal.

2.8. Agreement finalisation

The recommended respondent(s) will be notified that ESOT wishes to enter into negotiations to finalise the terms and conditions of the proposed agreement. The agreement will be negotiated between both parties on the basis of the call, the company’s response to the call, and subsequent discussions and correspondence.
ESOT reserves the right to commence negotiations with any other party should it be unable to reach mutual agreement with the selected company.

2.9. Term of contract

The contract to be awarded on the basis of this call shall be for an initial term of 5 years commencing on 1st July 2021 and ending on 30th June 2026. ESOT is the only owner of the platform: all developments and implementation belong to ESOT.

ESOT reserves the right to perform an in-depth evaluation of the technical partner’s performance and have a clause entitling ESOT to rescind the contract after 3 years, if certain key performance indicators (to be previously agreed with the publishers) are not reached.

Extension of the contract would be subject to the appointed technical partner’s satisfactory performance and the negotiation of terms and conditions acceptable to ESOT for the period of extension. ESOT does not bind itself to extend the contract. In case of non-extension, the technical partner must make available all information needed for a new technical partner to take over, including source code.

2.10. Company conducts

Each respondent shall nominate a person for the purpose of answering queries that may arise during the proposal phase. The name, title, address, email address and telephone number of that person should be included in the proposal.

2.11. Disclaimer

All reasonable care has been taken in compiling this call document and the figures, documents and details presented in good faith and no warranty or guarantee (express or implied) is given by ESOT as to the completeness or accuracy of the document, or any information provided in connection with it.
Section 3 – Call requirements

3.1. Executive summary

Your proposal should begin with an overall executive summary, outlining the major points of the proposal and identifying any innovative service offerings. Include compelling reasons why ESOT should select your company. Be specific about unique service offerings, with particular emphasis on those services that will have an impact on institutional data providers and reporting.

3.2. Services

Respondents are asked to detail their services based on the objectives mentioned in point 1.5:

1. Building a modular platform.
2. Building a user-friendly platform.
3. Building an analytical platform.
4. Building an open platform.
5. Building an evolutive platform.
6. Building a secure platform

3.3. Capability and expertise of the technical provider

ESOT is seeking a technical partner that can help establish, maintain and continuously develop the platform. Please provide evidence of previous experience with registries or other platforms built to create and analyse datasets. Please provide information on competences and expertise of personnel, in particular in terms of project management and statistical analysis in addition to technical development. Please specify if you have the capability to build a mobile application on your own or in association with other companies.

3.4. Financial offer and viability of the proposal

ESOT must be able to differentiate between the proposed offerings from different technical partners. The society values both financial return and service provision; the ultimate decision will not be based solely on proposed revenue. Please provide a detailed breakdown of cost projections for the term of the contract and for each phase of the process (creation, maintenance, updating, additional developments). Please detail the financial arrangements proposed to ESOT and confirm whether these arrangements are to be fixed throughout the duration of the contract and if not, on what basis you envisage that they will be reviewed. All financial statements must be submitted in Euros.
3.5. Ethical values of the technical partner

ESOT is an international society with values that do not tolerate discrimination and work conditions that prevent employees' happiness. ESOT collaborates only with companies that share the same values and actively take measures to prevent discrimination, promote diversity and encourage employees' welfare. The respondent shall provide an ethical statement.

3.6. Implementation plan

Respondents are required to provide a detailed implementation plan to include specific tasks, resources, responsibilities and period of time needed from proposed contract signing date of 31 June 2021. Specifically, the proposal should include details of how the technical partner will deal with the following issues:

- Building the platform as modular and scalable.
- Creating different user profiles connected to ESOT database.
- Creating and editing variables.
- Creating and customising reports and centre-specific tableau.
- Supporting manual data entry as well file upload.
- Supporting synchronisation with existing database and different platforms and interfaces.
- Adding new registries.
- Linking the platform to the ESOT website.
- Making ESOT autonomous in the management of the platform.

3.7. Capability Statement

- Respondents are to provide a capability statement incorporating:
  - Audited copies of the previous three financial years’ accounts.
  - Company ownership structure.
  - Information on similar platforms developed by the respondent. Please specify if any of these platforms can be tested by ESOT.
  - Details of your professional indemnity and other relevant insurance.

3.8. References

Please provide references or statements from clients (names, websites, email addresses and telephone numbers) of similar platforms developed by your company.
3.9. Project team and account management

Please provide a summary of the names, roles, capabilities and previous experience of the individuals who would be assigned to work with ESOT. Please also provide a staff and organisation chart for the relevant division of your company.

3.10. Reporting

Please provide details of the full range of reports, including frequency of reporting, that you will provide to ESOT to monitor the success of the platform.

3.11. Innovation

ESOT is seeking an innovative partner offering innovation across business development, service delivery, user experience, product development and technology. Explain how you can offer this innovative partnership.