Governance of the ESOT registries platform

ESOT is dedicated to the pursuit of clinical and research excellence and improving patient outcomes. Its core mission is to promote sharing of scientific information and building of evidence-based international practice, policies and medical guidelines.

To this aim, ESOT has decided to strengthen its engagement in the collection of data on organ transplantation and has launched a platform to host pan-European registries on transplant recipients and living donors. The aim of this document is to present the governance of this project owned by ESOT.

Principles

The purpose of the ESOT registries platform is to gain and increase knowledge about the outcomes of living donation and the outcomes of transplantation. Each registry hosted on the platform must adhere to the following principles:

- All partners must be represented.
- All partners adhere to the agreed upon rules and regulations.
- All partners respect the interests of other participants.
- Data quality and scientific integrity must be ensured.
- Interests of all participants must be respected.

Audience

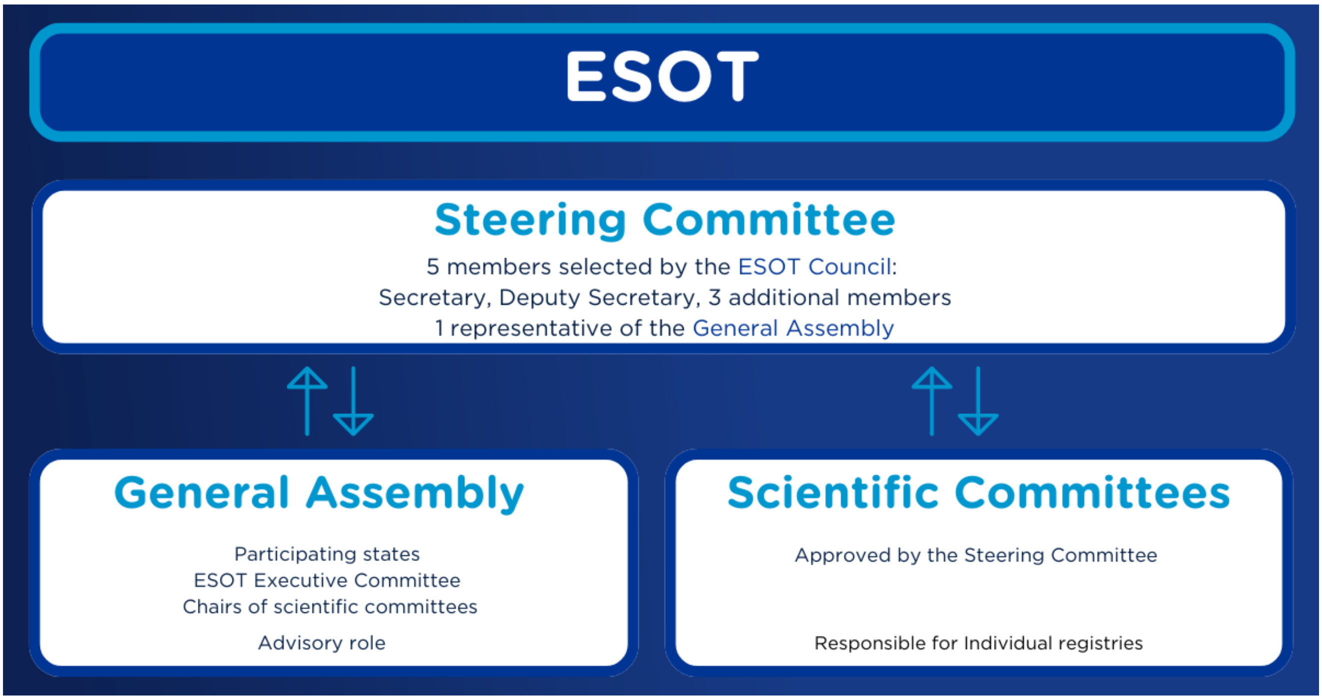
The ESOT registries platform will serve a variety of stakeholders, including:

- National Competent Authorities (CA) of the countries of the Council of Europe
- National, regional and local transplant registries.
- National and international scientific review committees.
- Transplant centres and individual professionals.
- Patients and donor (families).
- The general public.

Structure

A two-layered governance:

- A General Assembly.
- A Steering Committee that develops the strategy of the registries platform and that coordinates, oversees and liaises with Scientific Committees.



The **General Assembly** acts as an advisory body of the ESOT registries platform.

- Ensures that the registries can function in compliance with the existing legal, scientific and ethical regulations.
- Advises the Steering Committee on the development of the strategy.
- Advises on new registries.
- May mandate the Steering Committee to propose strategic solutions to specific issues.

The General Assembly is composed of:

- One representative of each participating state contributing data to the ESOT registries platform; representatives are typically in charge of policy for transplantation in their country. Competent authorities, transplantation centres, organ sharing organisations, national societies and other stakeholders involved in transplantation in the same country should agree on one representative. The mandate of a participating state representative lasts 2 years; it can be renewed once. If a representative leaves the General Assembly, their replacement is in office until the end of the current mandate.
- The ESOT executive committee.
- Chairs of the scientific committee of individual ESOT registries.

- Observers with no voting rights (eg. Representatives of European patient associations, the European Commission, incoming member states).

Participating states are the member states of the Council of Europe that provide data to the Registries. Other states/regions/individual centres may request to join the General Assembly as participating, incoming or observer state.

The General Assembly meets annually, virtually or face-to-face; meetings are called by the ESOT secretariat 6 months in advance; decisions can be taken if a quorum of 25% is reached; decisions are considered final if approved by 50% +1 of attending members. Additional meetings may be held during the year and called with a shorter notice as required. The General Assembly elects a Chair and a Vice-Chair, whose mandate lasts 2 years and cannot be renewed.

The **Steering Committee**:

- Is responsible for developing the strategy of the ESOT registries platform and submitting it to the General Assembly.
- Is responsible for addressing any issues raised by the General Assembly.
- Promotes the registries platform and invites new registries contributing members to the General Assembly.
- Establishes and supervises the scientific committees responsible for the definition, update of the datasets and analyses in each individual registry.
- Liaises with the scientific committees for the production of annual reports.
- Reviews (and grants) requests for data or non-standardized reports.
- Supervises budget and finances, and reports to the General Assembly.

The Steering Committee is composed of:

1) The following members selected by the ESOT Council for a mandate of 3 years, renewable:
    - A Secretary.
    - A Deputy Secretary. The Deputy Secretary may be a patient, for example the chair or the vice-chair of the scientific committee responsible for the Patient Portal.
    - Three additional members selected on the basis of their scientific expertise and previous experience with registries. These persons may be members of scientific committees responsible for individual registries.
2) A representative of the General Assembly, elected by the General Assembly for a mandate of 1 year.
3) Observers and guests:
    - ESOT employees as observers, for example registry data managers.
    - Representatives of the technical partner, as observers.
    - Guests with no voting rights (invited as needed for specific projects).

The Steering Committee meets at least every 4 months, virtually or face-to-face; meetings are called by the ESOT secretariat; decisions can be made if a quorum of 80% is reached; decisions are considered final if approved by 50% of members +1.

The **Scientific Committees** are composed of renowned professionals in the field of transplantation; current and past members of the ESOT Council can be appointed to Scientific Committees. They are responsible for:

- Defining the set of variables to collect.
- Promoting the registry and participation of potential data contributors.
- Defining the expected outcomes of the registry.
- Preparing annual reports with the support of the data manager.
- Evaluating requests for using registry data and providing advice to the Steering Committee on this matter.
- Considering updates of the set of variables every second year.
- A scientific committee is created as soon as the proposal for a new registry is approved by the Steering Committee.
- The mandate of Scientific Committee members lasts 4 years and is not renewable unless decided differently by the Steering Committee.

Proposals for new registries:

- Are initially discussed by the proposer with the ESOT Executive Committee.
- Should follow an application procedure defined by the Steering Committee.
- Are reviewed by the Steering Committee, with the help of external reviewers, if needed.
- Are approved by the Steering Committee and endorsed by the General Assembly.

The proposal should contain a list of people willing to join the new registry and its Scientific Committee; ESOT may establish criteria for the composition of the Scientific Committee in terms of wider representation. The Steering Committee sanctions the composition of the Scientific Committee and the leadership structure of new approved registries.

Contractual arrangements

The ESOT registries platform is an ESOT initiative. ESOT raises funds according to the strategy agreed by the Steering Committee. ESOT is responsible for the implementation of the strategy developed by the Steering Committee, in particular:

- Providing and maintaining the technical infrastructure.
- Providing technical support for users of the registries.
- Maintaining and widening contacts with participating or interested parties.
- Maintaining, intensifying, and expanding contacts with the industry or other scientific consortia.
- Preparing an Annual Report and basic descriptive statistical analyses.
- Preparing a financial plan for the Steering Committee, and reporting on finances.

ESOT establishes agreements with organizations that wish to support the platform. In particular:

- The participating states, national, regional or individual organizations that wish to provide data and join the General Assembly via their national representatives.
- Patient associations that wish to be represented in the Patient Portal Committee and wish to contribute patient specific data.

- National scientific societies that wish to join the General Assembly via their national representatives.
- The EU.
- The technical partner.
- Entities wishing to fund the platform, including industry.
- Entities wishing to exploit the data of the registry, including industry.

Approved by the ESOT Council, 1st April 2022.
Modified on 8 December 2022[1].

To be revised by the ESOT Council within three years after first approval.

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[1] Addition of a representative of the General Assembly in the Steering Committee; removed list of countries of the Council of Europe.