Introduction

Previous EU funded projects, particularly EFRETOS (European Framework for Evaluation of Organ Transplants) and ACCORD (Achieving Comprehensive Coordination in Organ Donation throughout the European Union), have described how a (supra)national registry of follow-up data from both transplant recipients (EFRETOS) and living donors (ACCORD) can advance European transplant practice. Part of WP 6 of the EDITH project is the establishment of a European follow-up registry. The European follow-up registry will be a central database that contains data of the participating national registries. For those countries that haven't established a national registry yet, the project will offer a data entry solution for national authorities.

Functional design

Work package 6 offers both a reference design for national follow-up registries and a functional design of the European follow-up registry.

National registry

Please be advised that the following chapter is a reference design for a national follow-up registry. Individual countries may have different implementations of their national follow-up registry. The design is from the perspective of the European follow-up registry as will be established by the EDITH project and doesn't account for national specific requirements.

Architecture

Business architecture

Actors

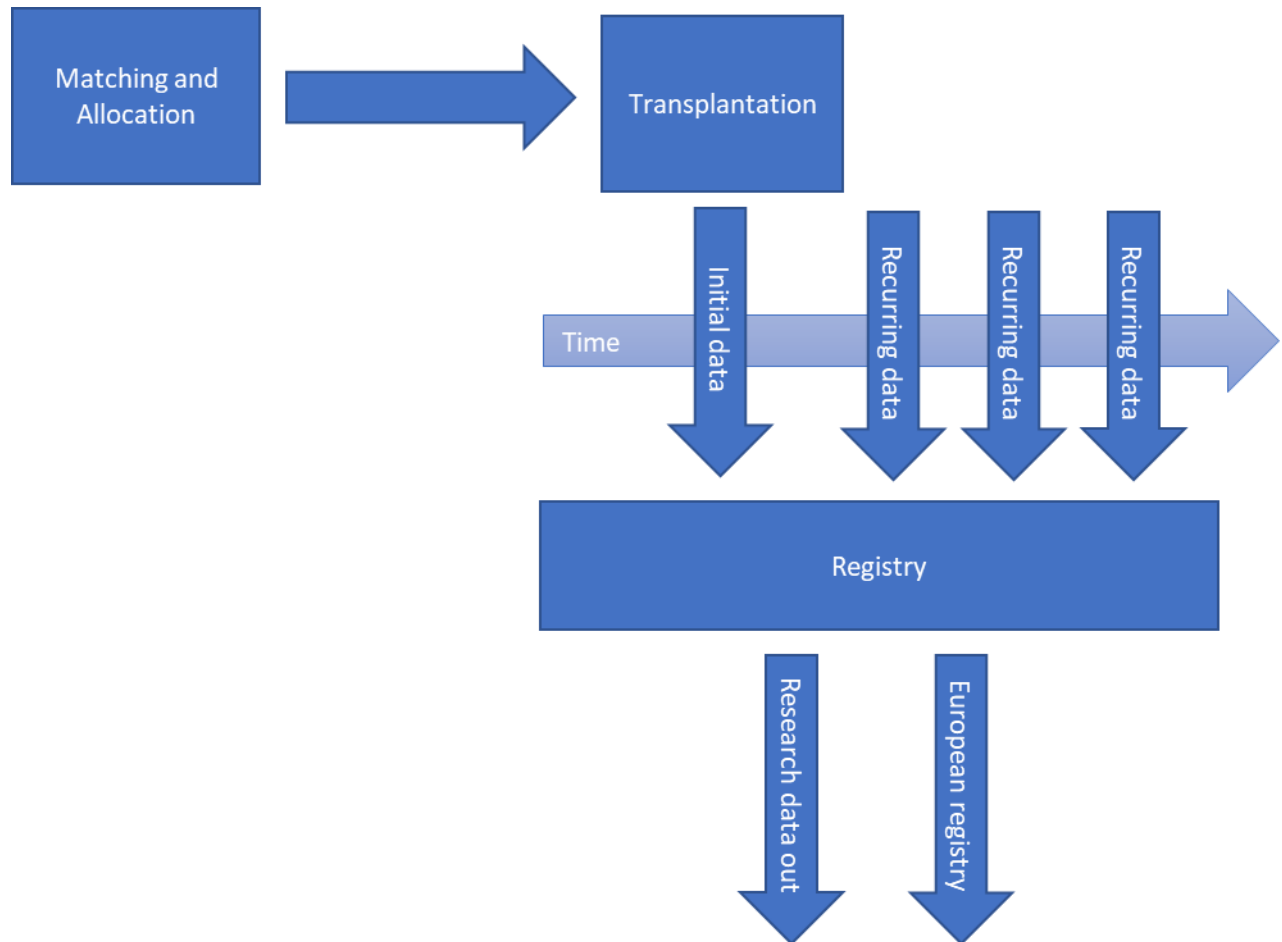A national follow-up registry has the following actors:

- Transplantation center staff
    - Transplantation center staff enter patient data into the national follow-up registry
- National follow-up registry staff
    - Registry staff administrates the follow-up data and executes occasional data entry/editing
- Data manager(s)
    - Manages imports and extracts
- Application manager
    - Manages the application
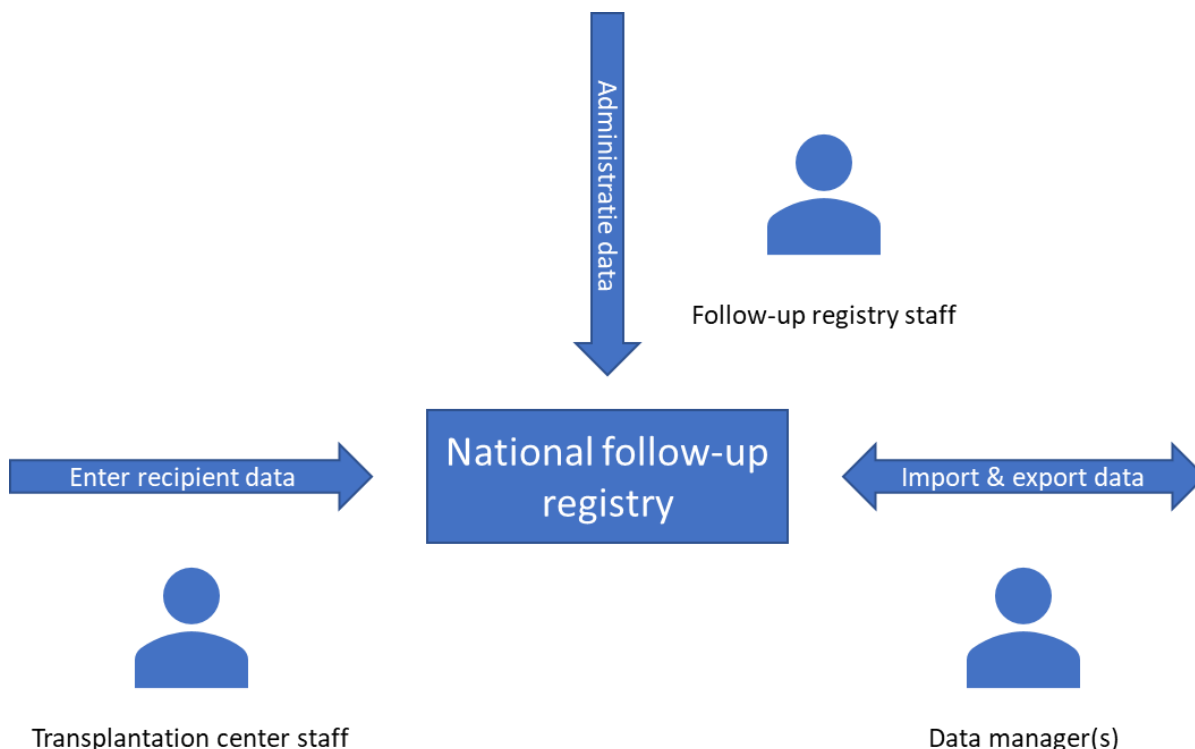
Process

The follow-up registry process starts after a transplantation. First the transplantation center staff will need to fill out initial follow up data on a recipient. After that at set interval in time, the center staff will be asked to fill out recurring follow up data.

The data can then be used for research and analysis & can be uploaded to the European follow-up registry and other registries.

Requirements

Non-functional requirements

Non-functional requirements of national follow-up registries will vary greatly based on country specific law and ambitions. Therefore this paragraph will only outline a set of non-functional requirements that need to be further specified by national implementations.

- Performance
  - Specifications on how fast the system should perform under various loads
- Availability & recoverability
  - Specifications on how often the system should be available and what kind of downtime is acceptable.
- Data integrity
  - Specifications on data integrity, this can include country specific privacy requirements.
- Security
  - Specifications on system security such as encryption requirements and access restriction.
- Usability
  - Specifications on system usability.
- Documentation
  - Specifications on required system documentation.
- Integration
  - Requirements on integration with existing systems such as login systems and existing software in transplantation centres.

Functional requirements

The national registry should provide the following functionality:

Access management

The system needs some kind of provision to protect user data. Usually this is done with user accounts that are administrated by a central body.

Collect initial follow-up data

The users need to be able to enter initial follow-up data as specified in the next subchapter 'Dataset'.

Collect recurring follow-up data

The users need to be able to enter recurring follow-up data as specified in the next subchapter 'Dataset' at a set interval.

Administrate follow-up data

The central administration body needs functionality to administrate the follow-up data. The administrator(s) need to be able to enter, edit and delete both initial and recurring follow-up records.

Export follow-up data

In order to provide the European registry with data the national registry needs functionality to export both initial and recurring follow-up records according to specifications by the European registry.

Collect audit log information

The system needs to log all interactions with the system in order to analyse and detect unauthorized access.

Dataset

See Appendix

European registry

Architecture

Business architecture

Actors

The European follow-up registry has the following actors:

- National follow-up registry staff
    - National registry staff upload their nations follow-up data
    - National registry staff can enter follow-up data through form(s)
    - National registry staff can download data
    - National registry staff corrects
- European follow-up registry staff
    - European follow-up registry staff administrates the follow-up data
    - Assists national follow-up registry staff in follow-up record management
- Data manager
    - Manages extracts
- Application manager
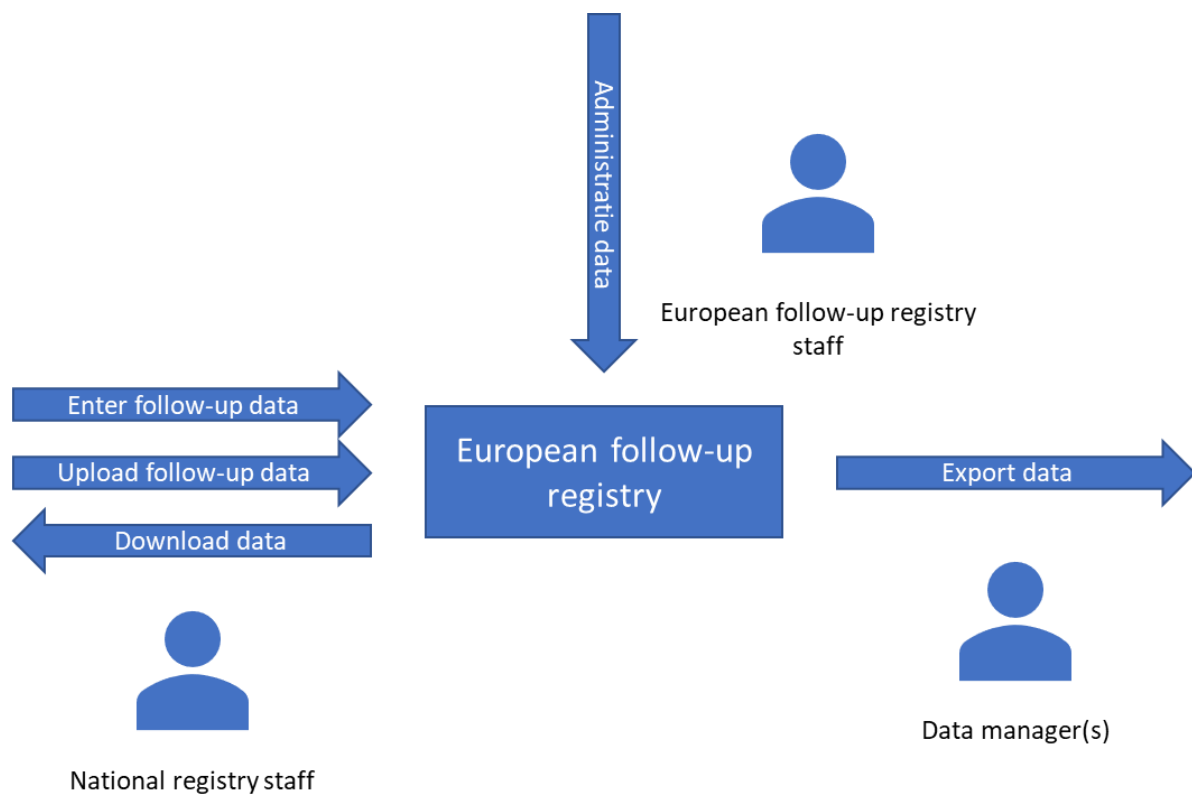
Process

National follow-up registries upload or enter recipient data of their country to the European registry at a (to be determined) set interval. They also have the ability to download their data and potentially aggregated data of all countries.

The European registry central database can then be used to fulfil (approved) research requests and offer reports to all parties.
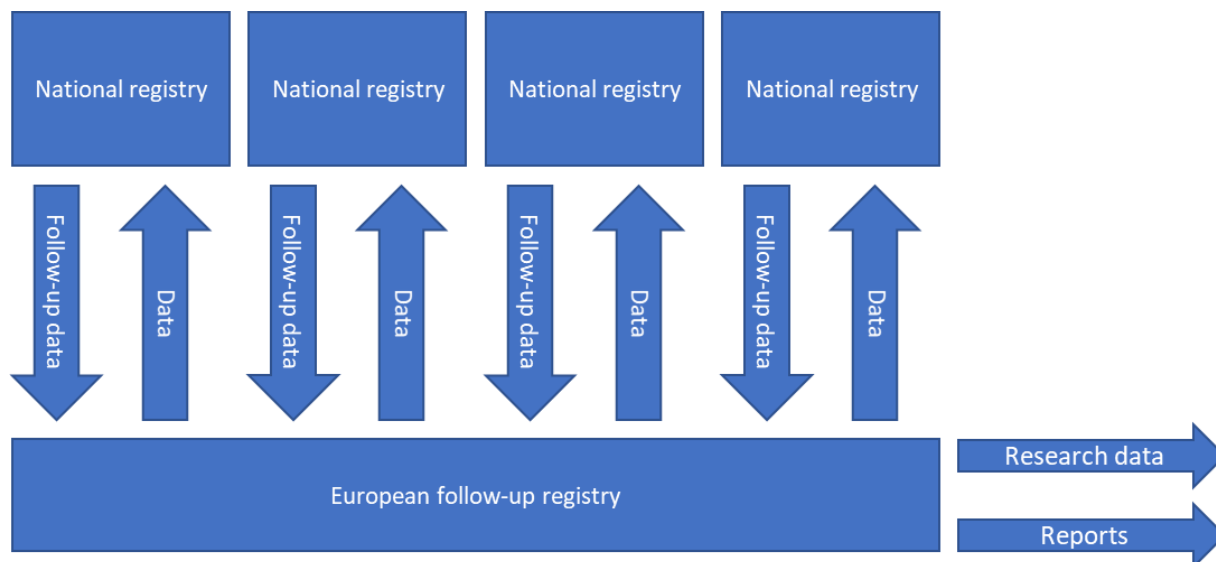
Requirements

Non-functional requirements

Browser support

Since we have limited control over the browsers being used by the various users, the proposed solution should work with recent versions of Chrome, Internet Explorer, Firefox & Safari.

Integration

National follow-up registries

The system should offer an interface for bulk upload of national follow-up records.

Other registries

The system should be prepared for automatic exchange with other registries in the future.

Performance

All non-report pages should load within 2 seconds.

Availability & Recoverability

Availability isn't a crucial part of the system, limited downtime is acceptable. The proposed solution should be recoverable within 24 hours.

Data integrity

The proposed solution should include input validation on data entering the system as specified by the EFRETOS standard in the Appendices.

Security

The proposed solution will contain personal and medical data. As such the proposed solution should be secure and (parts of) the database will need to be encrypted.

All application interactions must be logged for auditing purposes.

Usability

The usability of the proposed solution should be such that end-users won't need a manual to use the system. A one sheet quick reference is acceptable.

Documentation

Technical documentation for the system should be provided. Preferable are:

- Logical solution architecture document
- Technical solution architecture document
- Generated documentation based on code (API / classes)

Functional requirements

The functional requirements in this subchapter are written in the form of Agile epics and stories.

EPIC01 Logging in

STORY01 User log in

As a national follow-up registry staff member,
I want to login to the system,
so that I can enter or upload records

STORY02 Staff log in

As a European follow-up registry staff member,
I want to login to the system,
So that I can administrate the system

EPIC02 Import & enter records

STORY03 Upload CSV file

As a national follow-up registry staff member,
I want to upload a CSV file of predetermined format*,
so that I can fill the registry with my countries follow-up data

*Containing the fields as described in appendix

STORY04 Create initial follow-up record

As a national follow-up registry staff member,
I want to create an initial follow-up record for a recipient*,
so that I can fill the registry with my countries follow-up data

*Containing the fields as described in appendix

STORY05 Look up existing recipient

As a national follow-up registry staff member,
I want to look up an existing recipient,
so that I can create a recurring follow-up record

STORY06 Create recurring follow-up record

As a national follow-up registry staff member,
I want to create a recurring follow-up record for an existing recipient*,
so that I can fill the registry with my countries follow-up data

*Containing the fields as described in appendix

STORY07 Edit follow-up record

As a national follow-up registry staff member,
I want to edit an existing initial or recurring follow-up record,
so that I can correct mistakes

STORY08 Delete follow-up record

As a functional admin,
I want to delete an existing initial or recurring follow-up record,
so that I can correct mistakes

EPIC04 Download data

STORY09 Download country data

As a national follow-up registry staff member,
I want to be able to download my countries data in a CSV file,
so that I analyse data

EPIC03 Administration

STORY10 Follow-up data administration

As a European follow-up registry staff member,
I want to be able to manually add, edit and delete initial or recurring follow-up data for all countries,
so that I can assist the national transplantation registry staff with data entry

STORY11 Data modification logging

As an application manager,
I want the system to log transaction (meta) data on data entry & modification,
so that incidents can be analysed

STORY12 View application logging

As an application manager,
I want to view logging,
so that I can analyse incidents

Appendix I: Dataset National registry

Appendix II: Dataset European registry

Appendix III: Format CSV file