WP 4 'LIVING DONOR REGISTRIES'

MILESTONE 3:
Technical, organisational and governance requirements

K.M. Ooms-de Vries MSc
Prof. A.J. Hoitsma MD PhD

1. GENERAL BACKGROUND

1.1 INTRODUCTION

Scientific research gives insight into the consequences of procedures and into the results of different approaches and techniques. The information helps to improve the effectiveness of the corresponding procedure and its safety and quality. Different partners can identify a 'best practice' and learn from this practice's experience. As described in the first deliverable of ACCORD Work Package (WP) 4, the 'Report on the current experience with living donation and living donor registries', there are differences in the experience with living donation within the European Union (EU) Member States (MS). Some countries have had years of experience with a great number of living donors and have a digital follow-up registry. Others have only just started with very few donors and have no organised or digitalised follow-up system.

By joining forces in a supranational Registry of Registries (RoR) between the MS it is possible to obtain a large amount of data in order to achieve a better understanding of the impact of living donation on the donor, particularly in the long run. This understanding will provide the MS with new insights or can lead to new scientific evidence on the aspect of living donation. The access to so much (inter)national data makes it possible for countries, but also for individual centres, to compare their results with other centres and/or MS. Structural feedback is also an aspect that can help centres and countries to anticipate or influence trends and also to improve clinical practice. ACCORD WP 4 will be of great value to achieve this. The more data we can collect, the better research is possible on the long term follow-up of living donors. This research may lead to improving the existing programmes and in possible implementation of living donation programmes in MS without a living donor (LD) programme yet.

An active international European registry, where MS periodically send in their follow-up data of *living* donors to expand the amount of collected data, is lacking so far. ACCORD WP4 aims to develop the basis for such a RoR.

1.2 WORK PACKAGE 4

The objective of ACCORD WP 4 is to present a set of recommendations for the development of a European Living Donor Registry and to present recommendations for MS to set up a national Living Donor Registry. In articles 15.3 and 15.4 of the EU Directive 2010/53/EU[1], the following provisions are set down:

[1] *Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. European Commission website. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010L0053:EN:NOT. Last access: July 2013.*

Article 15: Quality and safety aspects of living donation

3. *Member States shall ensure that a register or record of the living donors is kept, in accordance with Union and national provisions on the protection of the personal data and statistical confidentiality.*
4. *Member States shall endeavour to carry out the follow-up of living donors and shall have a system in place in accordance with national provisions, in order to identify, report and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.*

Collection of follow-up data after living donation will help to achieve a better understanding of the impact of donation on both short and long term outcomes for the living donor. The great advantage of a supranational RoR is that a greater number of patients will be included and different techniques, (national) policies and approaches can be analysed. The outcome of these analyses will help the MS to optimise the procedures, to improve the safety for the donors and to give complete and specific information about the short and long term risks of living donation. This helps to provide the potential donors with sufficient information to make an informed decision.

The eventual recommendations will be achieved through intensive collaboration of the MS and partners that are working together within WP4. Several meetings led to the agreement on a dataset, data definitions, and data dictionary. After this accomplishment, the next focus will be on setting down the technical and management aspects that are necessary to make a national registry and supranational RoR work. This project offers the opportunity to build an automated system that supports MS with the collection of both mandatory and optional information and to co-operate together in a RoR. Finalising the description of the technical and management aspects as described in this document is the third milestone of ACCORD WP4.

2. TECHNICAL REQUIREMENTS

2.1 INTRODUCTION

The following chapter focuses on the technical design of a supranational living donor follow-up RoR. Also the technical aspects of a national living donor registry will be discussed. Cooperation between different countries with different standards, different experience but also different budgets emphasises the need for a clear description of the technical design of a living donor follow-up registry. Because international data exchange is an absolute necessity, there should be no doubt about the design of the registries. Miscommunication or failure in the design of different registries could be disastrous for the concept of international data collection and data comparison. Besides an extensive description of the technical requirements, every paragraph also gives the requirements in a clear enumeration.

2.2 SUPRANATIONAL REGISTRY OF REGISTRIES (ROR)

2.2.1 General remarks

The new RoR should be designed using the currently available technology. Solutions that will be available in the coming months (or years) are ignored. The standard nowadays for a follow-up database is a **relational database**, which makes it possible to have an infinite number of follow-up records. Moreover this type of database fits best with the databases that already exist in some countries[2].

Another standard for a follow-up database is that it should be **web based**. One of the great advantages of a web based database is that maintenance is only necessary at one place. All other possible solutions will need maintenance at several places, which is not manageable easily for a supranational database. Therefore, the easiest way of building a European RoR is by creating a web based relational database. This database can be accessed by a special website. The webpage as well as the web based database should be approachable by the most common internet surfing programmes (Microsoft internet explorer, Apple safari, Google chrome, Firefox, et cetera). The language used for both the web based database and the website will be English. An option could be that on the basis of login information the screens in the web based application can change to another language. However, the free text that is entered in the database should always be English. In this web based database data can be entered either

[2] *ACCORD WP4 Deliverable 1: A report on the current experience with living donation and living donor registries ref: 19736_kol*

directly by key entry or by file upload from national registries. Both possibilities will be discussed in the following paragraphs.

2.2.2 Direct data entry

The registry will provide the possibility to enter a living donor´s follow-up information directly into the registry by direct key entry. The application will have clear screens with all of the items that need to be collected. Some of the items will have drop-down lists to choose from, others will provide the possibility to enter free text. Whether an item is mandatory or optional will be made visible. The application will be easy to use and will have an attractive feature.

The possibility of direct data entry will be especially attractive for those countries with a small number of transplant centres or a small number of living donors. Using the RoR for the collection of national data will be described in paragraph 2.3.2. Those MS that already have a well-functioning living donor follow-up registry will probably use the file upload module to upload the data from the existing registry into the RoR.

2.2.3 File upload module

If countries already have a living donor registry, data can be uploaded to the RoR, but data items and data definitions should be in accordance with the data items and data definitions of the RoR. There are two ways to achieve this.

1. By changing the items and definitions in the national database for living donors. This adjustment has as a consequence that countries with an already existing registry have to change a lot of their items and definitions before the data can be entered into the RoR. Moreover, the upload file should have the correct format, so it can be well received by the RoR. Upload possibilities are for instance CSV-files (comma separated value), XML files or Excel-files.

   From the questionnaire that was sent to every WP4 partner in 2012, we found that different kinds of databases are used by MS and collaborative partners. For example Access, Oracle, SQL Server and FileMakerPro were mentioned. Of course the MS are free to choose the database platform, as long as data can be uploaded in the predefined format to the RoR.

2. Another possibility to upload data from an existing living donor follow-up registry is by performing a conversion of the collected data into the ACCORD standards. In this conversion, the data from the existing database will be translated in such a way that it meets the definitions that were agreed upon in ACCORD WP4. Without this conversion it wouldn't be possible to compare the data from different MS and living donor follow-up registries.

The RoR must not only have the possibility to upload current data, but also data from earlier donors. For these data, a conversion of the older data should be performed to meet the required ACCORD items and ACCORD definitions. The conversion of data from an existing registry has to be done by the MS themselves. The upload of the older data into the RoR must be a possibility.

2.2.4 Data download possibility

An important feature of the web based database is that data from the RoR will be available for the Competent Authorities (CA) of a country at all times. Crucial in this respect is of course the question who is responsible for the data and who is allowed to see which data. This important issue will be described in the "Governance" section in chapter 3. The minimum technical requirement for the availability of the data is a download possibility for the CA of a country (irrespective of whether data is immediately filled in or sent to the RoR by file upload). Only 'own' national data can be downloaded in this way. Also local centres should have the possibility to download their own centre data at any time. With this feature centres can do statistical analyses on their own data as often as desired. Apart from this download facility, standard (fixed) reports should also be available. Depending on the user's rights, the reports will be more or less detailed (see also the "Governance" section). These reports will be fixed reports

Requirements for Registry of Registries:

- ACCORD items and ACCORD definitions
- Relational database
- Web based application
- Approachable by common Internet surfing programs
- Official language: English
- Direct data entry possibility
- File upload possibility (from national databases)
- Data download possibility
- Standard report function

2.2.5 Data safety and security

Lacking good data safety and security techniques and policies is fatal for a registry. Making sure that no unauthorised person has access to the data in the RoR, that no one abuses the data or uses it incorrectly and that the data cannot be lost, are examples of data safety and security. The human factor in data safety and security can be managed by defining proper authorisation policies (paragraph 3.4.4). Access is only granted if the user's profile allows this access. The possibility to change or delete data is only reserved for a limited number of users, also depending on their user's profile. The application will log every modification in the data, including time of the modification and the name of the moderator (the user that was logged-in).

The registry should be protected against any spyware or viral software which can lead to the damage or loss of data. Also technical defects or power failure may have no influence on the collected data. Regular back-ups (daily) have to be made to facilitate data safety and security. A separate server, hosted on a different location (possibly in a different country) should be kept, preventing physical damage to be the cause of destroying or losing data. Data that could lead to the identification of an individual should be stored separately from the corresponding data. Only a special key or module can lead to the combination of these data, enabling the identification of the individual. Of course, this key or module is only available for a restricted number of people. For all data in the database (from every country involved) only the co-workers of the RoR have such an access possibility. For each country that has delivered data, only one key is provided to give access to identifiable data of their own country. In case individual centres have entered their data directly in the RoR, these centres should also have one key to have access to the identifiable data of their own centre. Data entry and data transfer (using the upload facility) should take place in a secure environment, using cryptographic protocols such as SSL (Secure Sockets Layer) or TLS (Transport Layer Security). The international standard ISO/IEC 17799 covers data security under the topic of information security. It is recommended that this standard will be followed for setting up the RoR.

2.3 NATIONAL DATABASE

2.3.1 Countries with an existing living donor registry

Countries with an already existing living donor follow-up database that want to participate in the RoR, will meet some difficulties when joining the RoR. From the questionnaire that was sent to every WP4 partner in 2012, it was clear that none of the countries with an existing living donor registry had the same items and definitions as defined for the RoR. Either the existing database has to be rebuilt including the ACCORD items and definitions or the upload file to the RoR has to be constructed in such a way that the correct items and definitions are sent to the RoR in the correct format. This last possibility has certainly limitations, and at least some items and definitions will have to be changed. Countries are of course free in the way they proceed, as

long as the final outcome is that the file uploads from the national follow-up databases are delivered in the predefined format according to the definitions from the ACCORD project.

Countries with an existing follow-up database on follow-up of living donors have two possibilities. Either they can change the data input to direct key entry into the new web based RoR, or they maintain their national registry under the above-mentioned conditions and upload data from their national registry into the RoR. Good possibilities for file upload are CSV-files (comma separated value), XML-files or Excel-files. Which choice is made by countries with an already existing registry is of course completely free.

2.3.2 Countries without a living donor registry

Countries that currently do not have a national follow-up database, but want to participate in the RoR, can put in data in the RoR by direct key entry. Direct key entry has some advantages. There is no need to build an own national database to meet the EU Directive. Besides the practical advantages, this is also a very cost effective approach. But countries can decide to build an own national database and send data to the RoR by file upload. A good possibility for a new database is a web based database with exact the same structure as the RoR, to make communication with the RoR easy (both upload and download). Of course, the ACCORD dataset and definitions should be followed. This database should be a relational database, and have the possibility to upload files to the RoR (for instance CSV-files or Excel-files) according to a format that is readable by the RoR. Where there are local databases in the country, the new national database should also have the possibility of receiving bulk data from the databases of the different donor centres.

Requirements for National database:

- Conversion to ACCORD items and ACCORD definitions
- Direct data entry or file upload possibility (from local databases)
- Data download possibility

Recommendations for National database:

- Relational database
- Web based application
- Approachable by common Internet surfing programs
- Direct data entry and file upload possibility (from local databases)

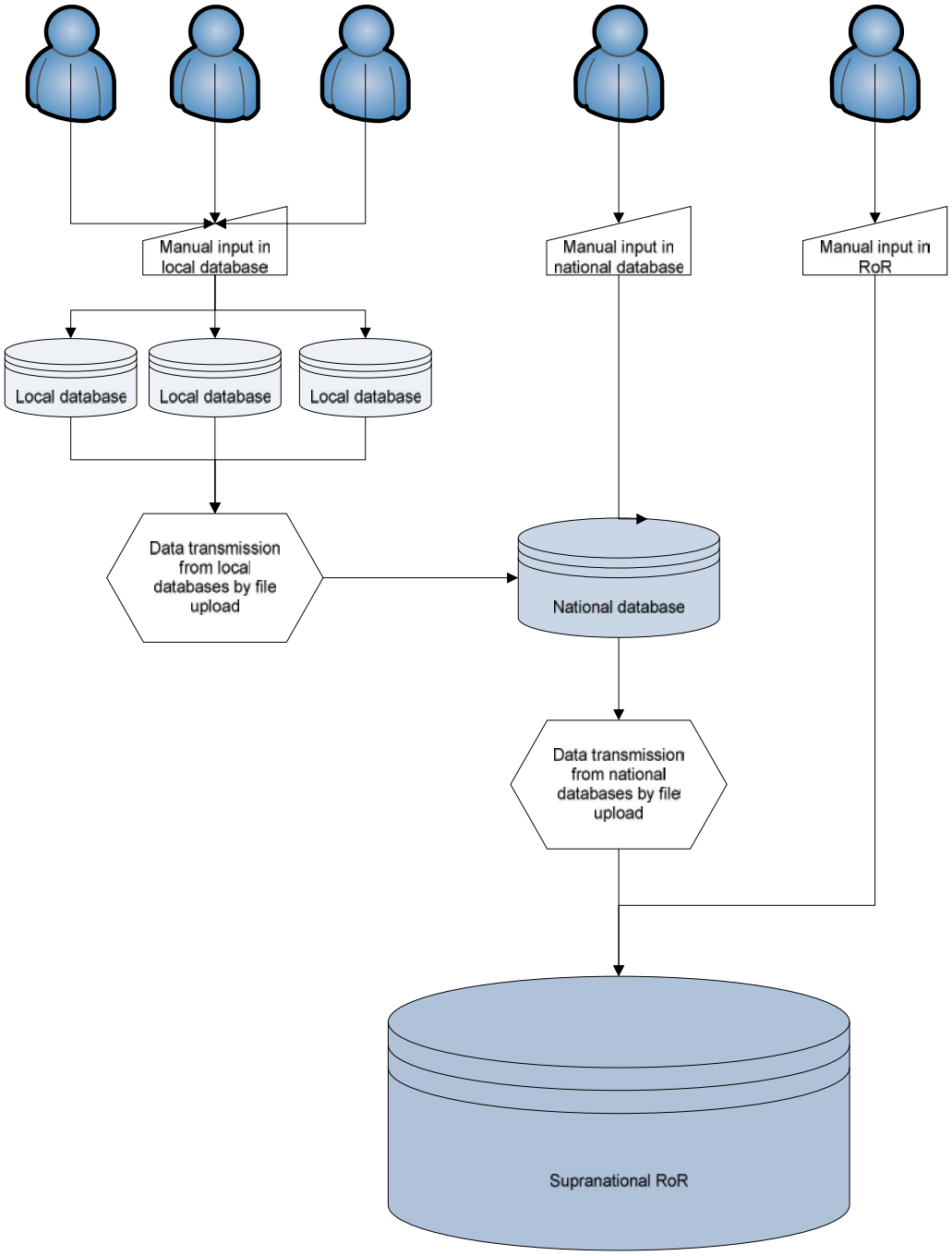

Figure 1. Graphic of the structure of the different databases

3. GOVERNANCE AND ORGANISATION

3.1 INTRODUCTION

Collecting follow-up information from living kidney or living liver donors will help to gain a better understanding of the short and long term consequences of living donation for the donor's health. Comparing data from EU MS or data of donors with different characteristics will give more insight in differences in outcome. Learning from best practices will help to improve the procedure and to decrease the risks that are related to living organ donation.

The follow-up data of living donors from every MS is of enormous value. Without these data we are unable to make a thorough analysis and draw conclusions. To ensure the completeness of the data, the integrity of the data and also the availability of the data it is absolutely necessary to create an effective governance strategy. This governance strategy applies to numerous elements that are involved in the (supra) national database.

3.2 GOVERNANCE STRATEGY

Governance means that one is working towards a situation that is 'under control'. The easier the situation, the easier to keep it under control. In the case of a living donor follow-up registry and especially in the case of a *supranational* living donor follow-up RoR we cannot speak of a simple situation. Different donor centres will be entering their donor's follow-up information into a national system and different EU MS will be collaborating in the RoR. Therefore, a solid governance strategy should be worked out.

First of all, the database **architecture** should be in order. This means that the technical requirements are met and that the system is reliable. The previous chapter has described the design of the database and the technical requirements concerning, for example, state of the art functionalities and applications, security control and safe back-up systems.

Secondly, the **organisation** of the registry and the way the processes are managed should be in place to govern a database. This means that the people that are involved with the daily support, maintenance and control need to be united in an organisational structure. Process management will focus on improving and developing the possibilities of the application to collect the information in the database. Taking care of authorising people (according to the authorisation rules that are described in policies, paragraph 3.4.4) is a task that needs to be fulfilled on a daily (or weekly) basis.

Requests for research, data downloads or national reports should be managed as well. This will be done by a steering committee. Governance of the RoR from the point of view of the MS involved should be applied by an Assembly. The tasks and the consistence of the Assembly and committee will be defined in paragraph 3.3.3 and 3.3.4

In third instance, rules, regulation and **policies** should be developed. Of course, the legal prescriptions in the MS concerning data collection should be met, but also specific questions should be answered. What is the aim of the data collection? Who owns the data? Who will use the data? The answers to these questions should lead to a clear set of rules that can be applied in the management of the processes.

Eventually the database needs to be filled with data. These data will be entered into the database by doctors, nurses or data collection employees in the donor hospitals. The **human factor** is the fourth and last element. Without this element, the previous three are useless. On the other hand, the human factor would not be able to collect living donor follow-up data in an organised manner without a system, policies and management.

The technical design and architecture of the registries is extensively discussed in the previous chapter. The next paragraphs will focus on the elements ‘organisation’, ‘policies’ and ‘human factor’.

3.3 ORGANISATION

3.3.1 Introduction

Different people are involved in the RoR. First of all, the people from the donation centres who fill in the data, either in their own local database or in their national database or directly by key entry in the RoR. Secondly, the people that are involved in the national database, who are responsible for the data entry in the national database, but also for the upload of the national data into the RoR. They also will be responsible for the authorisation of people for the RoR in their own country. Thirdly, people working directly with the RoR, who are responsible for the daily routine (further referred to as ‘RoR staff members’). Fourthly, there should be a body that

is responsible for the overall management of the RoR, including also the responsibilities for major decisions concerning the RoR. All participating MS should be represented in this body (further referred to as 'Assembly'). To make things more practical, a fifth group should be defined, which is a small group with the direct daily supervision of the RoR (further referred to as 'steering committee'). Tasks and responsibilities of each group are given in table 1.

Responsibility	Responsible party
Data entry, review and correction	MS (local professionals that enter the data, co-workers of the national database)
Data integrity	MS (local professionals that enter the data, co-workers of the national database)
Data completeness	MS (local professionals that enter the data, co-workers of the national database)
Conversion of data from an existing living donor registry to ACCORD dataset and dictionary	MS (local professionals that enter the data, co-workers of the national database)
Authorisation for access to the RoR for national co-workers	MS (co-workers of the national database)
Daily support, helpdesk, database management, (technical) development and improvements, releases, etc	RoR staff members
Authorisation of MS	RoR staff members
Data safety and security	Steering committee.
Management of RoR staff members	Steering committee. Depending on the further structure this can be delegated to a Host company
Major changes in the RoR (proposals for extra or other items, proposals for other definitions etc)	Proposed by Steering committee, approved by Assembly
Evaluation of requests for data	Steering committee
Communication concerning requests for data	Steering committee (delegated to secretarial staff RoR)
Finance and budget control	Steering committee
Appointment of the steering committee	Assembly
Monitor and control of steering committee	Assembly
Appointment of Assembly	MS

Table 1. Tasks and responsibilities in the organisation

3.3.2 RoR staff members

A web based database is a solution with a minimum work load for people who manage the database, but still a lot of work has to be done. It can be expected that many different people will fill in data in the RoR and many people are involved in the upload and download of data. All these people need access to the data on different levels. **The management of user names and passwords** will need continuous attention. This can best be organised on a national level by the appointment of an administrative application owner. The national 'administrative application owner' will communicate with an overall functional application manager. This functional application manager is also responsible for **data entry and data management** at the RoR. This co-worker is also responsible for authorisation of MS as a country.

The functional application manager is part of the RoR staff and also plays a role in optimising the registry and in the development of the registry to improve the possibilities, functionalities and features. Suggestions for improvements can come from (daily) contact with users, but also from formal national representatives or CA. The steering committee is the body that decides whether such a change in the system is allowed. Once a year, the Assembly will check all activities of the steering committee. The functional application manager will consult an (external) ICT developer for the technical adjustments and improvements. Besides taking care of the database, also a website has to be built and maintained. An important part of the website will be the reports, which will be renewed every year. These items will be described in paragraph 3.4.1.

For the entire task of **daily support and (functional) application management** it is expected that three employees are necessary. One employee is responsible for data management and functional application management, one for bio statistical analysis and one for secretary work. These three functions are not full time equivalents. An ICT developer can be hired (subcontracting).

3.3.3 Assembly

Due to the complexity of the registry and the fact that many MS are involved, it is necessary to have tasks and responsibilities appointed to an (international) committee and / or Assembly. In the Assembly all countries that participate in the RoR should be represented. The main tasks of the Assembly are: the appointment of the members of the steering committee and the governance of the steering committee. Important decisions concerning the structure of the RoR, the items in the RoR with their definitions will be the responsibility of the steering committee, but the Assembly will check all these activities and judge whether the policies of the RoR are carried out correctly.

All MS that participate in the RoR will depute one representative. This representative is either involved in living kidney donation, or in living liver donation. The representative will be appointed by the CA of their country and should be a specialist in the field of living donor registries and

collection of living donor follow-up data. All of the representatives together, form the 'European Living Donor Registry Assembly' (ELDRA). Given the fact that 28 countries are currently members of the EU, the ELDRA could theoretically consist of 28 persons (in the case that all MS participate in the RoR). The Chairman of the ELDRA needs to have a broad understanding of clinical, technical and regulatory issues, and it is suggested that the CA committee nominates an independent Chairman. This way, the ELDRA is firmly linked to the CA. The role of Chairman of the ELDRA will be fulfilled for three years. The Chairman can be re-elected once. Therefore, the same person can be Chair of the ELDRA for a period of six years. The ELDRA will meet once a year. It could be a possibility to link the meeting of the ELDRA to an annual congress, for instance the ERA-EDTA (European Renal Association – European Dialysis and Transplantation Association), or to a CA meeting.

The ELDRA is quite large and only meets yearly which makes it difficult to make easy and fast decisions. A smaller group from the ELDRA will be appointed to form the steering committee. The ELDRA will monitor and control the steering committee on a yearly basis. The Chairman of the ELDRA cannot be a member of the steering committee.

3.3.4 Steering committee

The steering committee is responsible for reviewing (and granting) requests for data or non-standardised reports. A request for data should be answered within a few days. The final decision as to whether a request will be granted will be sent within two weeks. The steering committee should therefore discuss requests with each other by e-mail or telephone. The steering committee keeps close contact with the RoR staff members. The committee receives administrative and secretarial support from the RoR staff. In case of (large) financial investments, the RoR staff have to ask the steering committee for approval. The steering committee will meet in person frequently, preferably three times a year. The steering committee keeps a record of the requests that were discussed and the grants that were given and reports to the ELDRA.

The steering committee consists of 5 people. These people will be chosen from the ELDRA. Members of the ELDRA can nominate themselves to take part in the steering committee. By taking a vote, the other members of the ELDRA will determine who will participate in the steering committee. The steering committee includes 4 members involved in living kidney donations and 1 in living liver donation. Since a technical (database) expert and a (bio) statistical expert are foreseen in the staffing plan, they can be consulted if and when necessary. The composition of the Steering Committee will rotate every three years on a rolling basis (so that all committee members are not retiring at the same time). Each member represents another country. The ELDRA should ensure that at least one of the top 3 countries is represented in the steering committee. The definition of this ´top 3´ is: ´countries that have included the highest

number of donors yearly in the RoR´. The benchmark should be performed the year before the election.

3.3.5 Host company

The RoR is a small organisation, which is too small to be a self-supporting organisation. Therefore the RoR is preferably hosted in an already existing organisation, which is familiar with transplantation and/or donation and has several possibilities for data management. The host company should also have all functionalities and applications for security control and back-up systems. In this structure the (overhead) costs can be kept as low as possible. Personnel should be employed in the host organisation (shared services personnel), which makes daily (hierarchical) control and continuous support possible. The steering committee remains responsible for the RoR staff members, but can delegate the practical responsibility for working conditions, wages, et cetera to the host company. The staff of the RoR are accountable to the steering committee and will be required to attend their meetings. The employment of the RoR staff will not be a full time job.

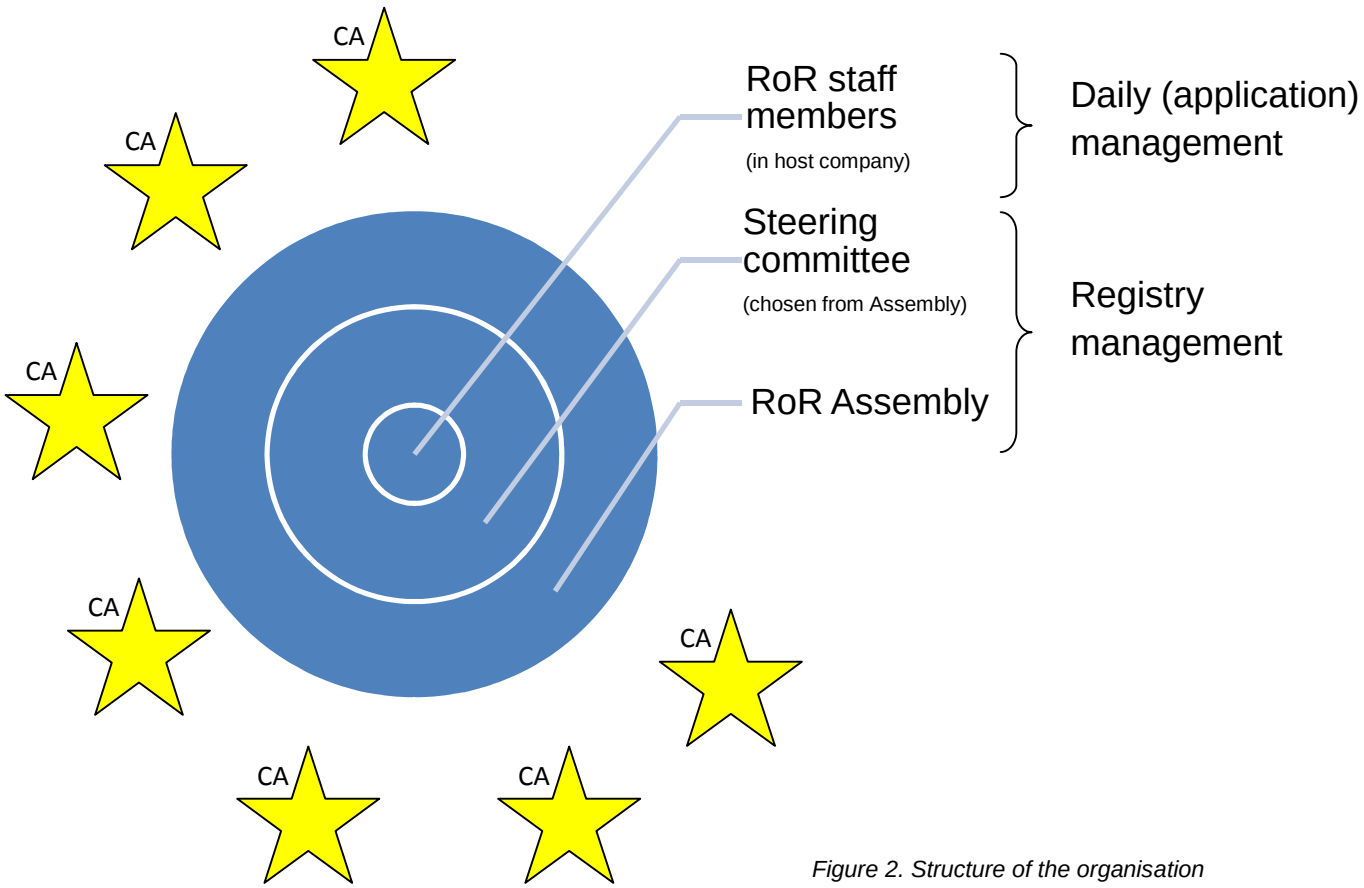

Figure 2. Structure of the organisation

3.4 POLICIES

A supranational RoR will serve different MS, each with its own national rules and regulations. Besides rules and regulations, the different stakeholders each have their own interests and goals. It is too optimistic but also unnecessary to summarise the different (national) rules, policies, interests and goals. The EU Directive 2010/53/EU[3] which applies to every EU MS states that MS need to have a 'register of record' of living donors and a system for the collection of follow-up information from the donor in order to 'identify, report and manage any event relating to the quality and safety of the donated organ'. It does not describe the exact design or the obligation that this should be a digital system.

3.4.1 Standard (fixed) reports and graphs

As mentioned in paragraph 2.2.4, the RoR application will have a data download possibility. This feature enables CA to download their 'own' national data either as an extract from the database (Excel) or in a predefined format (graphs and / or tables). These reports will be fixed reports, which means the format of the report is standardised and the data will be refreshed once a year.

The extent of details in the reports depends on the authorisations. For example, a general report or graph concerning the completeness of the whole registry, a general overview of the average age of a living kidney or liver donor, the distribution of male and female among donors are standard items that will be public information on the website in fixed reports. When the information concerns a specific country or even centre, of course this information is only available for those people that have the rights to receive this, considering their authorisation. A representative of the CA of a MS will be authorised to see information from the whole MS. Paragraph 3.4.2 will focus on the ownership of the data and paragraph 3.4.4 handles the authorisation policies.

3.4.2 Ownership and data requests

One of the items to handle is 'ownership of the data'. This item needs clear policies as to who is allowed to see or retrieve the data from the database. There are several ways of considering the ownership of the data. Whose data are they? What is the aim of the data collection? Who will use the data and with what purpose? Who is allowed to use the data and are there any restrictions (by law)? The answers to these questions lead to appropriate policies. The donation centres are the primary owners of the data. Therefore, requests for an extract of their 'own' data by a donation centre should be granted without restriction. The CA in those MS with an existing national follow-up database can be granted permission to receive an extract of their 'own' national data without restriction as well. It is a greater challenge to set rules for requests for data

[3] *Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. European Commission website. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010L0053:EN:NOT. Last access: July 2013.*

from other centres, MS or organisations. It is recommended to distinguish three categories of requests:

1. The first type of request is for data that are simple and should be made available for the greater public. These data are always general data, for example the number of donors in 2013 in Europe, how many of these are women, et cetera. The first task of the steering committee is to define which data will be categorised under this type of request. The EDLRA has to approve eventual proposals of the steering committee. If this is defined, these kinds of requests can be granted in all occasions without consulting the steering committee. Most of these data will also be available via standard (fixed) reports on the website of the RoR.
2. The second type of request is for data (mostly by one of the participating centres), not only from their own centre, but for data from more (or all) centres. Such a request can only be granted if none of the centres can be identified in the data file. The steering committee has to check this. It is essential that with this type of request individual patients cannot be identified and the data should be anonymised. All requests of this type should be considered by the steering committee.
3. The third type of request is for data with identifiable centres and/or identifiable individual donors. In principle this should be difficult or not even possible at all, since the data in the registry is collected anonymously, but the steering committee must identify such a request. If, for example, the donor centre is known, as well as the date of birth and / or initials, the identity could be recognised. In case of a request of this type, all centres that can be recognised should be asked for permission to deliver these data. In case of one or more identifiable donors the donor centre should also be asked for permission. Whether or not the individual patient has to be asked for permission to use their data is the responsibility of the donor centre according to the national legislation.

It will be necessary to develop more detailed and explicit criteria and principles against which request for data can be assessed. Describing these detailed criteria and principles is a role for the steering committee.

3.4.3 Anonymity

The anonymity of a donor's information should be assured. There should be no fear for a donor that personal information will be made public at any time, identifying him or her. Therefore, a donor's name will never be provided in requested files. Nevertheless, especially at a local level, a combination of items could lead to the identification of an individual. Of course for scientific research on a large scale, it is of no significance to the researcher to know a donor's identity. If there is any possibility that a donor could be identified, the local donor centre has the responsibility to ensure that no one objects to using the data.

Not only should the anonymity of a donor be considered. Also a local centre should not be recognised on a supranational level. Of course, at a national level, each CA probably wants to know the similarities and differences between multiple donor or transplant centres. On a supranational level however, this should not be visible. It is of no importance for other MS to know the differences between local centres. Therefore, on a supranational level, the local centre name will not be visible. If it turns out that for a supranational study, local centre names will be visible or identifiable; the committee has to make sure that the centres give permission for granting the request of this type of data.

3.4.4 Authorisation policies

Different people living in different countries and working in different institutes in different types of functions will be working with the (supra)national RoR. Some people will be entering data, while others will be extracting data from the registry. Different user-profiles will be identified. Depending on the function and tasks, a certain profile will be assigned to a person. The profile determines which authority is granted, for example the right to enter data, the right to change data, the right to extract data on a centre level, the right to extract data on a national level, the right to view general information or the right to see detailed information. On a national level, the national application owners will be responsible for applying the authorisation policies. A person can send a request for access to the (supra)national Registry (of Registries) using a special link on the website. Information concerning the function and associated tasks will determine the profile and corresponding rights.

The application will have the possibility to set the language for direct data entry. This setting will be profile-driven. The national application owner can set the language for users in his / her own country. Of course, users are free to change the standard-language at any time. Free text data entry, however, must be in English. The standard language of reports will also be English.
In the next table the different rights are given. One person can have one or more of these rights.

Rights for the RoR	Co-worker*	Granted by
To view centre specific reports	Donation centre	National application manager
To view own data of a donation centre	Donation centre	National application manager
To enter own data in the RoR by key entry	Donation centre	National application manager
To change own data in the RoR	Donation centre	National application manager
To extract own data from the RoR	Donation centre	National application manager
To grant rights to individual national co-workers of donation centres	National application manager	Functional application manager at the RoR

To view national specific reports	National application manager	Functional application manager at the RoR
To view national data	National application manager	Functional application manager at the RoR
To enter national data in the RoR by key entry	National application manager	Functional application manager at the RoR
To change national data in the RoR	National application manager	Functional application manager at the RoR
To upload national data from the national registry	National application manager	Functional application manager at the RoR
To extract national data from the RoR	National application manager	Functional application manager at the RoR
To view all reports	Functional application manager at the RoR	Steering committee
To construct all reports	Functional application manager at the RoR	Steering committee
To change all reports	Functional application manager at the RoR	Steering committee
To view all data –(anonymised)	Functional application manager at the RoR	Steering committee
To change all data	Functional application manager at the RoR	Steering committee
To make extracts of all data	Functional application manager at the RoR	Steering committee

Table 2. Rights of co-workers

* The co-workers listed in this column are only examples.

3.5 HUMAN FACTOR

As stated earlier, the human factor is essential in the collection of living donor follow-up information. The donor will visit the doctor for a periodic consultation. The (medical) follow-up information after having donated his/her organ needs to be entered into the database. The doctor or assistant who collects the follow-up information has a responsibility in collecting the items that were predefined in the ACCORD working group. The way these items are interpreted and the definition that is used should also correspond with the definitions that were agreed upon within the ACCORD WP4 group. The person that enters the data into the database has the same responsibility and is also responsible for the correctness of the data. Therefore, data accuracy and data integrity are aspects that rely on the precision of the person who collects the data and the person that enters the data into the registry.

Rules should be developed in which the consequences of incompleteness and incorrectness are described. If it turns out that the items and definitions that are used in a local and/or national

database are different from the ACCORD dataset and definitions, then a conversion of the data should take place. Otherwise, the data cannot be compared to the data from other centres / MS. This is described in the technical requirements, chapter 2.

3.5.1 Integrity of the data

To maintain the integrity of the database a system of regular audits should be organised by the CA of EU MS. Sample data taken at random should then be checked by an audit committee. The CA of the EU MS will be advised to install a national audit committee and to develop an audit system to ensure the validity and accuracy of the data collected in the registry. The national audit committee sends an annual report to the ELDRA.

4. FINANCIAL ASPECTS

4.1 ESTIMATED BUDGET FOR SETTING UP AND SUSTAINING A RoR.

Based on the proposal in the EFRETOS project[4], an estimated budget can be made on the required resources and manpower necessary for setting up and sustaining a RoR. For this calculation several assumptions are made.

4.1.1 Functional and structural assumptions used for the cost calculation

A major point for making these assumptions is to keep costs of the RoR as low as possible.

The RoR will:

- be hosted by a contracted well-established organisation, experienced in running a registry in the field of transplantation;
- sustain running costs that are appropriate in relation to the number of participating national registries;
- have outsourced personnel from the host organisation for setting up and maintaining the RoR, in order to keep the costs as low as possible. Have clear reporting relationships and accountability for the RoR function.

The RoR will include:

- web service enabling importing of data from other registries;
- web based application for direct data entry, data cleaning, data storage, and data removal;
- storage in a central relational database management system (Oracle or other) with high security level (authorisation);
- export functionality to registries;
- business intelligence software;
- online analysis tools;
- website for general information and dissemination.
- Publish annual report and accounts

4.1.2 Cost estimate for the RoR

Different phases can be distinguished in the evolution of the RoR. These phases will have an impact on the costs. During the first year (start-up period) extra personnel has to be hired, policies have to be developed, processes have to be organised, hardware investments have to be made and quality checks will be performed to evaluate and optimise the policies and processes. Most importantly the core applications have to be built and tested. This results in

[4] *EFRETOS Report on the use of the European Registry of Registries, 2011; page 56-59*

higher costs in the first year. After the first year, the yearly costs are stable. De cost estimate in the following table is expressed in euro 1000.

Cost estimate	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Personnel						
IT support for hardware and software*	50	20	20	20	20	20
Data entry/data management*	40	40	40	40	40	40
Biostatician*	10	10	10	10	10	10
Secretary*	50	40	40	40	40	40
Book keeping/accountancy*	10	10	10	10	10	10
Housing / accommodation	10	10	10	10	10	10
Total personnel costs	170	130	130	130	130	130
IT infrastructure costs						
Initial development of the IT system/maintenance*	100	10	10	10	10	10
Software licenses*	20	10	10	10	10	10
Other costs						
Expenses for Assembly	10	10	10	10	10	10
Expenses for steering committee	10	10	10	10	10	10
Sundries	30	20	20	20	20	20
Total annual costs	340	190	190	190	190	190

Table 3. Cost estimation for the RoR

* Shared services personnel.

4.1.3 Possibilities for financing

Financing a project as described above is a real challenge. To start up a RoR but also to ensure a sustainable RoR, money is essential. Availability of an EU-fund, particularly for the first three years will help to start the whole system. After these three years, an evaluation of the possibilities for financing will take place. Different possibilities for financing are given in the section below.

EU MS with a large number of living donors already have a national living donor follow-up application. This way, they already meet the requirements as written in the EU Directive 2010/53/EU. It is therefore not in their interest to participate in a supranational RoR. If participating in a supranational RoR also means that they have to pay for their participation, it becomes even less interesting. The most important incentive to participate in a RoR is to be able to compare national results with other MS and to have a larger database for possible research. Smaller countries with a smaller number of living donors may not have a living donor follow-up system yet. The RoR will provide them with a system for (digital) follow-up data collection. If they have to pay the costs for the RoR on their own, it will be too expensive. Also, the number of living donors included in the RoR will be small if the MS with an existing living donor registry will not participate. This makes a RoR less valuable for research. A sustainable way of financing the RoR on the long run, which makes participating and contributing attractive for every EU MS is what should be aimed at. A possible solution could be that each participating country pays a sort of contribution. This could be based on the number of donors included, or according to the number of inhabitants per country. Another possibility is to base the contribution on the type of data entry, this means different contributions for direct key entry and for file upload. A combination of these two options is another possibility: the type of data entry in combination with the number of donors included. Coming up with a sustainable plan for financing will be a task of the steering committee. The ELDRA will make the final decision.