



Accord

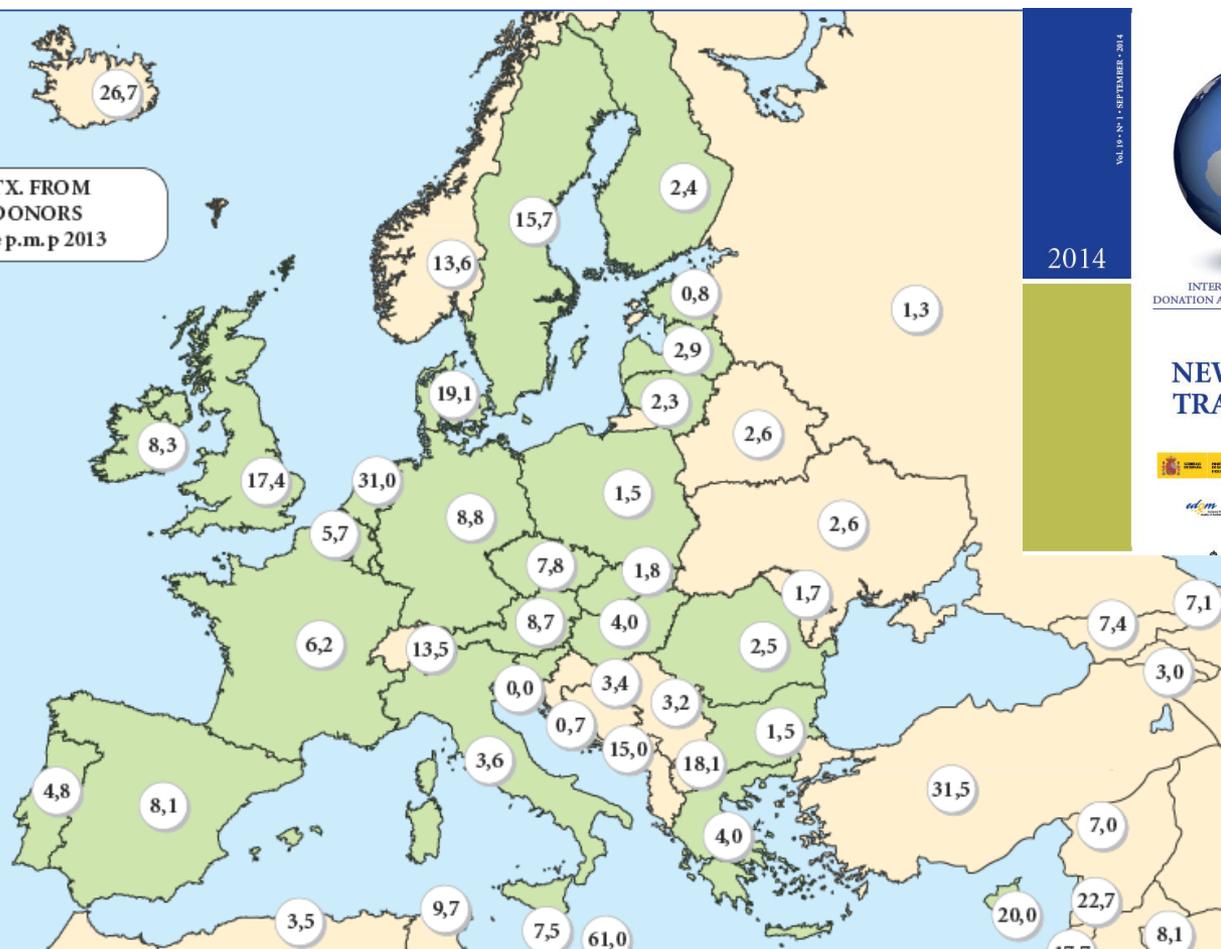
Achieving Comprehensive
Coordination in Organ Donation

Recommendations for Living Donor Registries and for a European Registry of Living Donor Registries

**Maria Valentin on behalf of the ACCORD
consortium**



KIDNEY TX. FROM LIVING DONORS
Annual Rate p.m.p 2013



WORLD N°1 - SEPTEMBER - 2014
2014



INTERNATIONAL FIGURES ON DONATION AND TRANSPLANTATION - 2013

NEWSLETTER TRANSPLANT



2013 data: 260 living donor **liver** transplants performed within the EU

Background

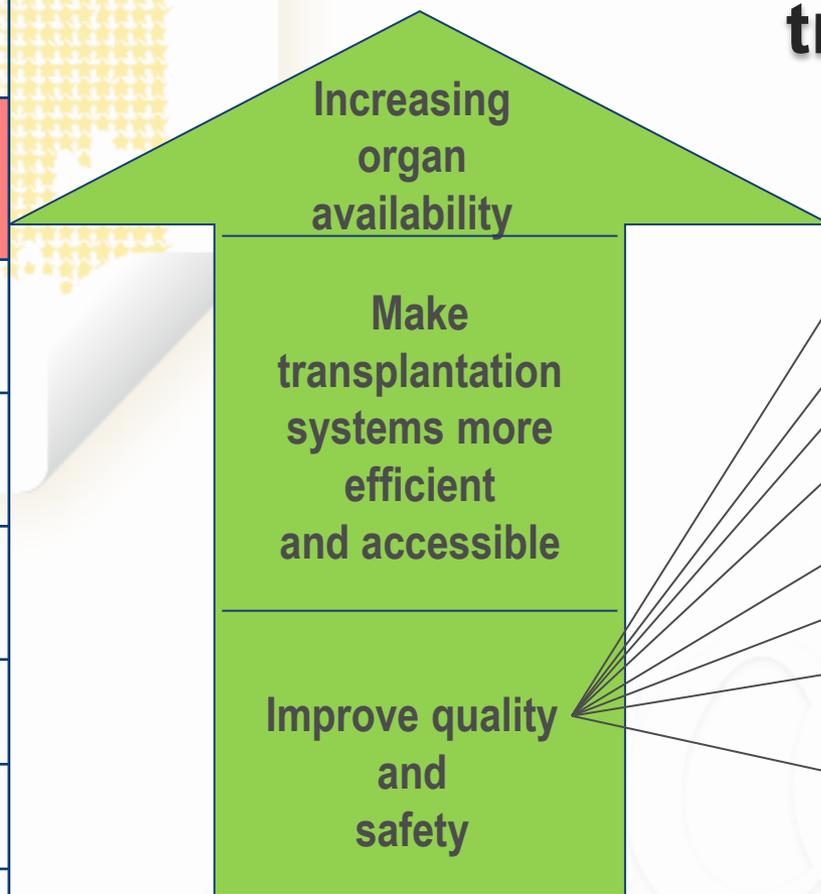
- Which donors are eligible?
- Is the operation procedure safe?
- Which is the impact on the health of the donor and his/her quality of life in the short and long term?



Adequate information
Risk balance
Donor protection

EU initiatives in the field of organ donation and transplantation

- Priority action 1: Promote the role of transplant donor coordinators in every hospital where there is a potential for organ donation
- Priority action 2: Promote Quality Improvement Programmes in every hospital where there is a potential for organ donation
- Priority Action 3 : Exchange of best practices on organ living donation programmes among EU Member States: Support registers of living donors
- Priority Action 4: Improve knowledge and communication skills of health professionals and patients support groups on organ transplantation
- Priority Action 5. Facilitate the identification of organ donors across Europe and cross border donation in Europe
- Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU member states
- Priority Action 7: Promote EU-Wide agreements on aspects of transplantation medicine
- Priority Action 8: Facilitate the interchange of organs between national authorities
- Priority Action 9: Evaluation of post transplant results
- Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes



DIRECTIVE

The establishment of national oversight authority or authorities
Authorization of activities
Ensure traceability
Reporting of serious adverse events and reactions
Establishment of Quality and Safety Framework
Protection of the donor
Establishment of registers
Ensure a complete characterisation of the organ, in order that the transplant team could undertake the appropriate risk assessment

ACTION PLAN



OBJECTIVE WP4:

To state recommendations for MS to set up a National Living Donor Registry and the development of a European Living Donor Registry

Directive 2010/53/EU OF THE European Parliament and the Council on standards of quality and safety of human organs intended for transplantation:

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 endeavor 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.

WP 4 partners



Croatia
France
Germany
Ireland
Italy
Latvia
Lithuania
Netherlands
Norway
Poland
Portugal
Romania
Slovak Republic
Spain
United Kingdom

Collaborating partners:

Eurotransplant;
ScandiaTransplant,
H. Clinic from Barcelona
Belgium

Questionnaire on live donor practices was sent to the partners :
70% of them collect their data on a registry



Accord

Achieving Comprehensive
Coordination in Organ Donation

WP4: Living donor registries Workplan

Step 1:
Description of
existing LDR

Step 2:
Recommendations
for LDR – minimum
& expanded data set,
governing rules

Step 3:
Recommendations
(PILOTED) for a
European registry of
LDR

Milestones and Deliverables:

- Description of the variables considered necessary and feasible to collect in a living donor registry whether the registry is National or Supranational.
- Recommendations to build a Registry of Registries (RoR).



Accord

Achieving Comprehensive
Coordination in Organ Donation

Data set & Data dictionary for Living Donor Registries

KIDNEY

Donor demographic
information

Identification (M)

Necessary for traceability but ID
code to guarantee anonymity

Date of birth (O)

Age (M)

Gender (M)

Weight (M)

Height (M)

Blood group (M)

Address (O)

Only national

Country of residence (M)

Nationality (M)

Ethnicity (O)

Pre-donation
data

Relation (M)

Blood pressure (O)

Hypertension (O)

Antihypertensive treatment (M)

Creatinine (M)

Proteinuria (M)

Any significant co-morbidity (M)



WP 4 'LIVING DONOR REGISTRIES'

DATA SET AND DATA DICTIONARY

NATIONAL REGISTRY
AND

SUPRANATIONAL REGISTRY OF REGISTRIES

(including glossary of terms)

www.accord-ja.eu



Accord

Achieving Comprehensive
Coordination in Organ Donation

Data set & Data dictionary for Living Donor Registries

KIDNEY

Peri-and
post-operative
data

Donor hospital (center) name (M) Only national
 Country of donor hospital (M)
 Date of donation (M)
 Left or right kidney (M)
 Operation technique (M)
 Complications during operation (M)
 Complications after operation (until first discharge)
 (M)
 Length of hospital stay (O)
 Number of days in ICU (O).

Follow-up data

Follow-up center (M) Only national
 Date of follow-up (M)
 Donor lost to follow-up (M)
 Death (M)
 Cause of death (M)
 Date of death (M)
 Weight (M)
 Blood pressure (O)
 Hypertension (O)
 Antihypertensive treatment (M)
 Creatinine (M)
 Proteinuria (M)



Accord
Achieving Comprehensive
Coordination in Organ Donation



WP 4 'LIVING DONOR REGISTRIES'

DATA SET AND DATA DICTIONARY

NATIONAL REGISTRY
AND

SUPRANATIONAL REGISTRY OF REGISTRIES
(including glossary of terms)

www.accord-ja.eu



Accord

Achieving Comprehensive
Coordination in Organ Donation

Data set & Data dictionary for Living Donor Registries

LIVER

Donor demographic
information

Identification (M)

Necessary for traceability but ID
code to guarantee anonymity

Date of birth (O)

Age (M)

Gender (M)

Weight (M)

Height (M)

Blood group (M)

Address (O)

Only national

Country of residence (M)

Nationality (M)

Ethnicity (O)

Pre-donation data

Relation type (M)

Any significant co-morbidity (M)



Accord

Achieving Comprehensive
Coordination in Organ Donation



WP 4 'LIVING DONOR REGISTRIES'

DATA SET AND DATA DICTIONARY

NATIONAL REGISTRY

AND

SUPRANATIONAL REGISTRY OF REGISTRIES

(including glossary of terms)

www.accord-ja.eu

M: Mandatory; O: Optional



Accord

Achieving Comprehensive
Coordination in Organ Donation

Data set & Data dictionary for Living Donor Registries

LIVER

Peri-and
post-operative data

Donor hospital (center) name (M) Only national
 Country of donor hospital (M)
 Date of donation (M)
 Segment donated (M)
 Percentage of remnant donor liver (M)
 Complications during operation (M)
 Complications after operation (until first discharge) (M)
 Length of hospital stay (O)
 Number of days in ICU (O)

Follow-up data

Follow-up center (M) Only national
 Date of follow-up (M)
 Donor lost to follow-up (M)
 Death (M)
 Cause of death (M)
 Date of death (M)
 Weight (M)
 Max. bilirubin (M), Max. INR (M), AST (M), ALT (M), GGT (M), Platelets (M)
 Complication (within the first 12 months) (M)
 Readmission (within the first 12 months) (M)
 Health issues (M)
 Return to previous activity level (O)



Accord

Achieving Comprehensive
Coordination in Organ Donation



WP 4 'LIVING DONOR REGISTRIES'

DATA SET AND DATA DICTIONARY

NATIONAL REGISTRY
AND

SUPRANATIONAL REGISTRY OF REGISTRIES

(including glossary of terms)

www.accord-ja.eu



Accord

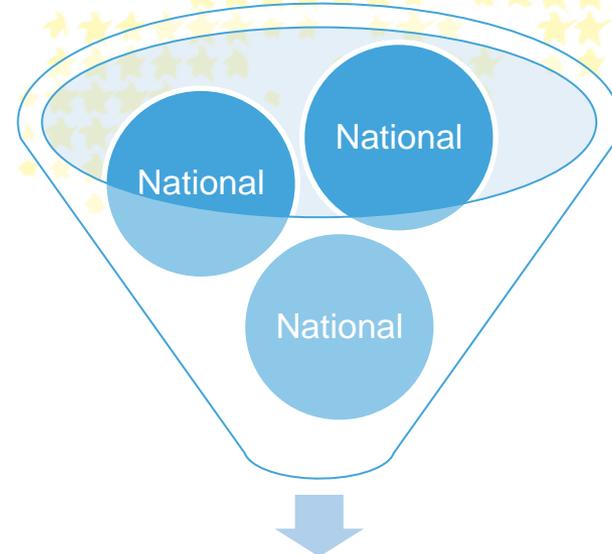
Achieving Comprehensive
Coordination in Organ Donation

Building up a Registry of Registries (RoR)

Key elements:

- Technical requirements
- People involved in the registry
- Governance rules
- Policies
- Financial aspects

The image shows the cover of a report. At the top left is the European Commission logo. At the top right is the Accord logo. In the center is a large version of the Accord logo. Below it are logos for the European Union, the French Republic, and the German Republic. The main title is 'WP 4 'LIVING DONOR REGISTRIES'' and the subtitle is 'MILESTONE 3: Technical, organisational and governance requirements'. At the bottom left, the authors are listed as 'K.M. Coms-de Vries MSc' and 'Prof. A.J. Holtzma MD PhD'. At the bottom right, the page number is '1 / 23'.



Registry of registries



Accord

Achieving Comprehensive
Coordination in Organ Donation

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:

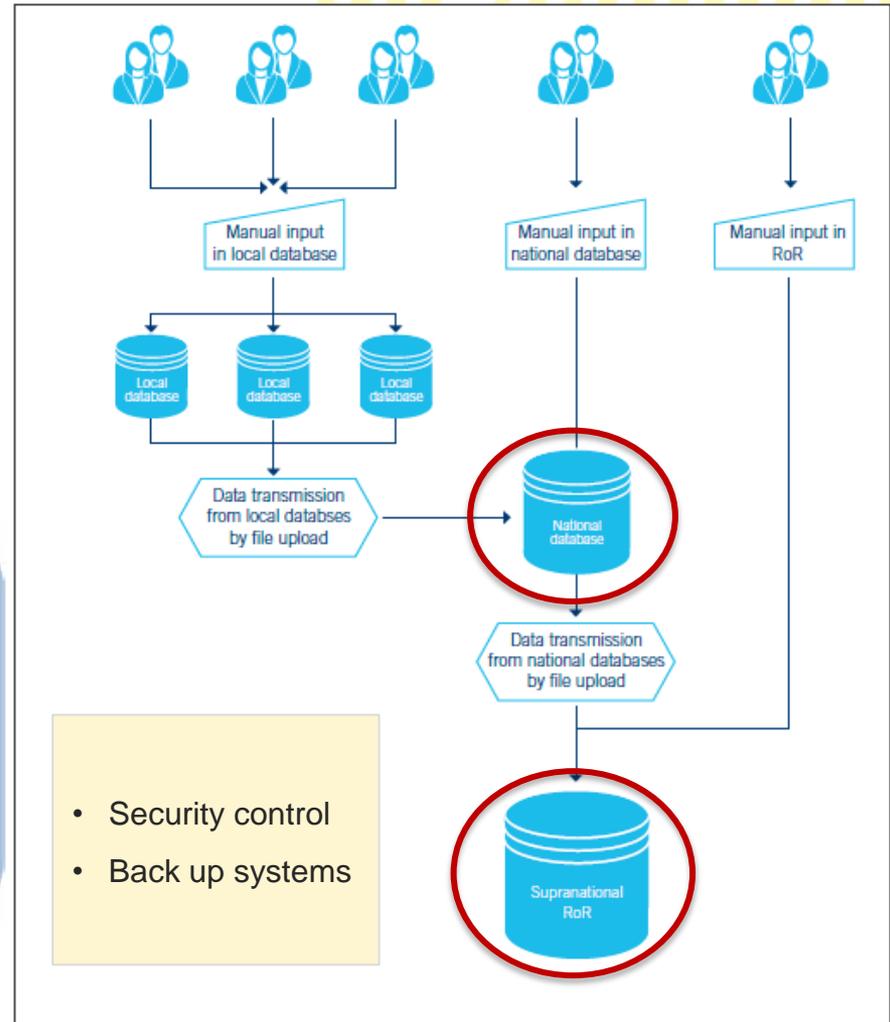
- > Relational database
- > Web based application
- > Approachable by common Internet surfing programs
- > Direct data entry and file upload possibility (from local databases)

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

Building up a RoR

TECHNICAL REQUIREMENTS



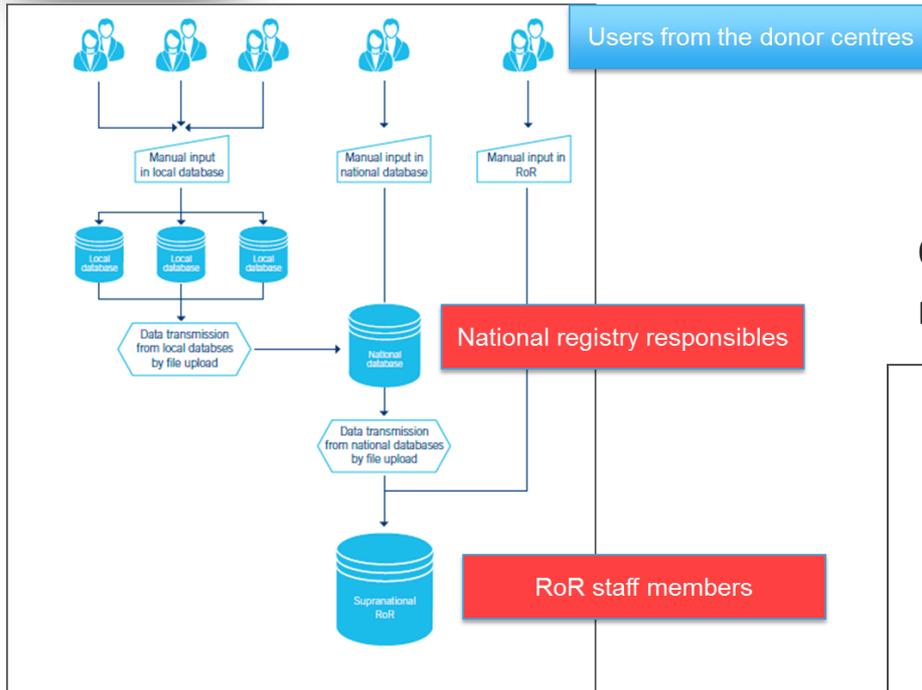


Accord

Achieving Comprehensive
Coordination in Organ Donation

Building up a RoR

GOVERNANCE STRATEGY



Organization responsible for the overall management

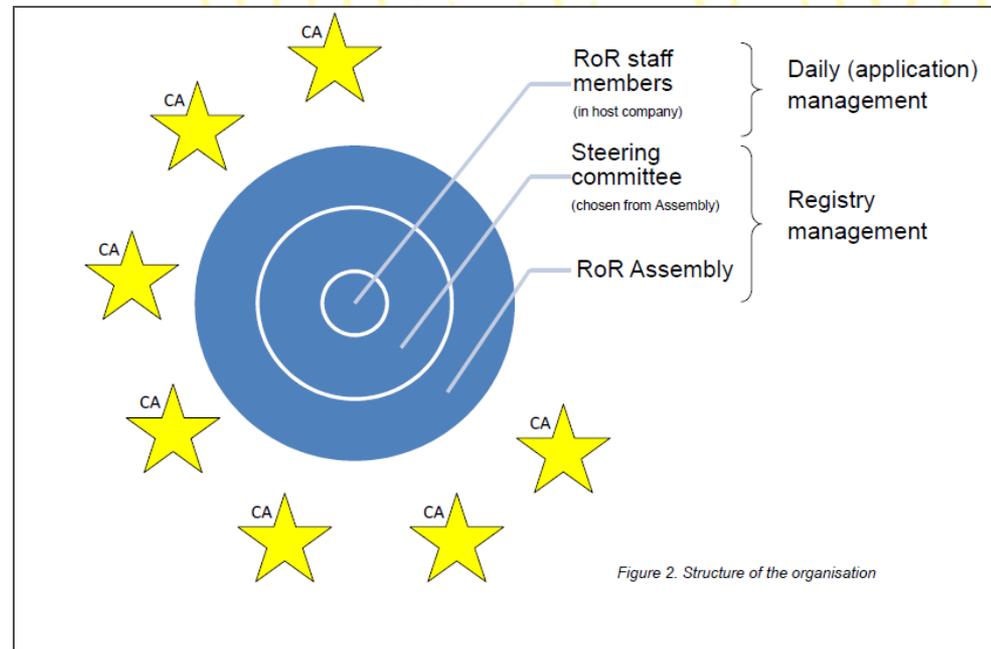
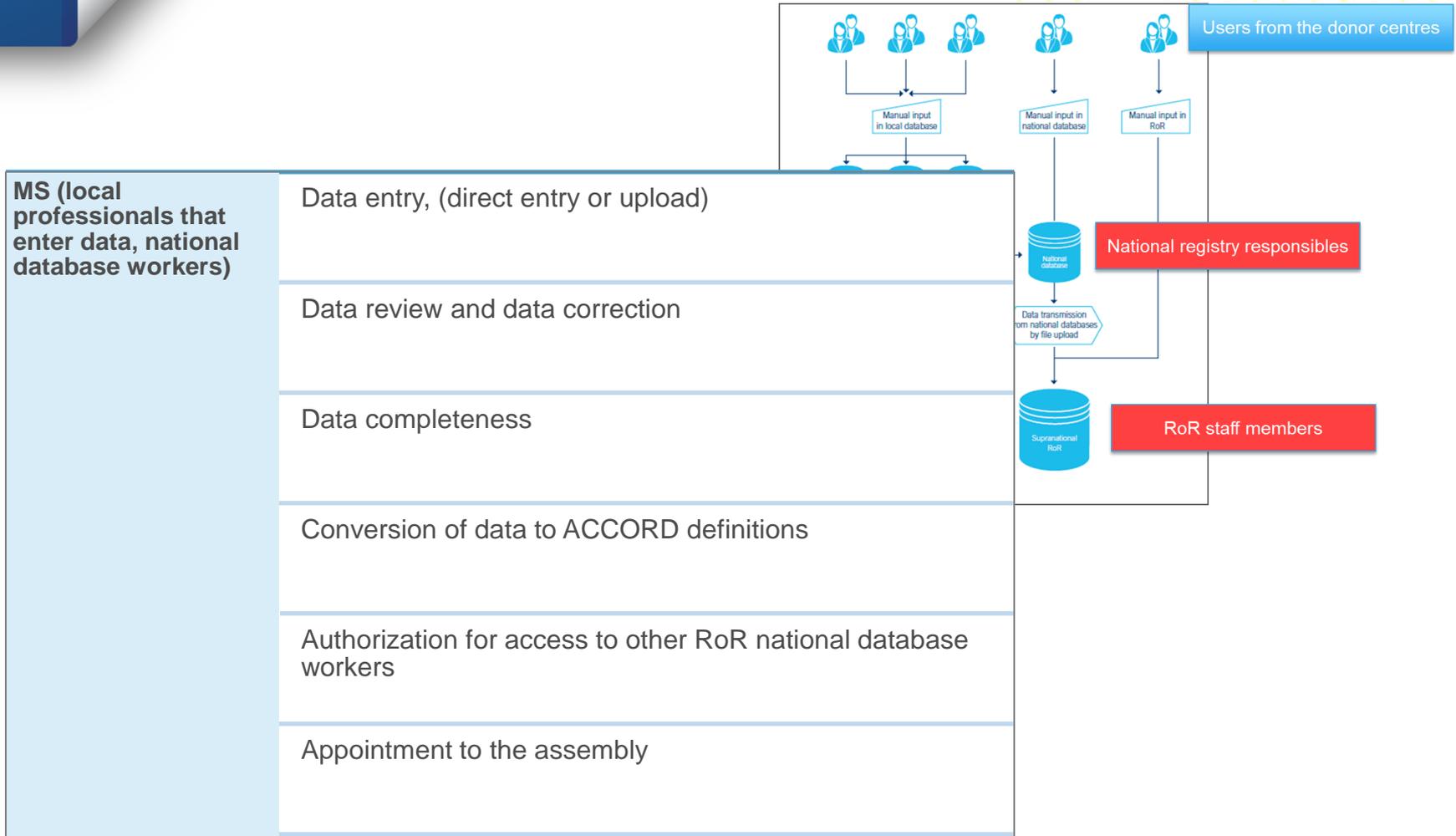


Figure 2. Structure of the organisation

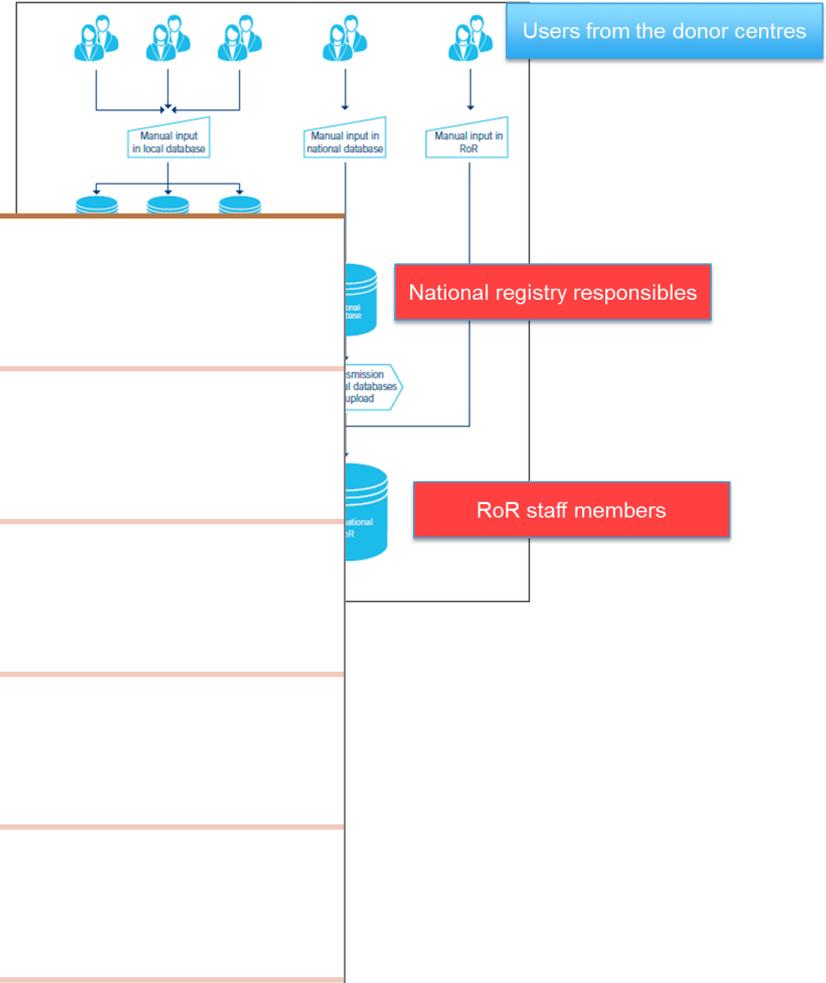


Tasks and responsibilities of the participants in a Supranational Living Donor Registry





Tasks and responsibilities of the participants in a Supranational Living Donor Registry





Tasks and responsibilities of the participants in a Supranational Living Donor Registry

Assembly
(ELDRA)

Appointment of the steering committee

Monitor and control of the steering committee

Steering committee

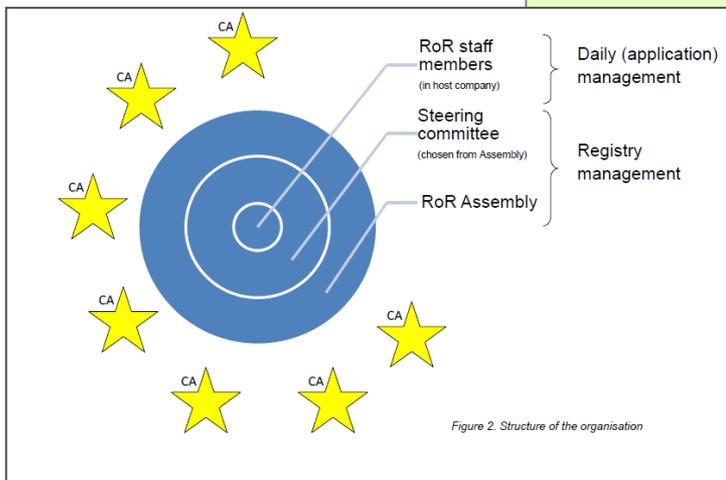
Data safety and security

Management of RoR staff members

Major changes

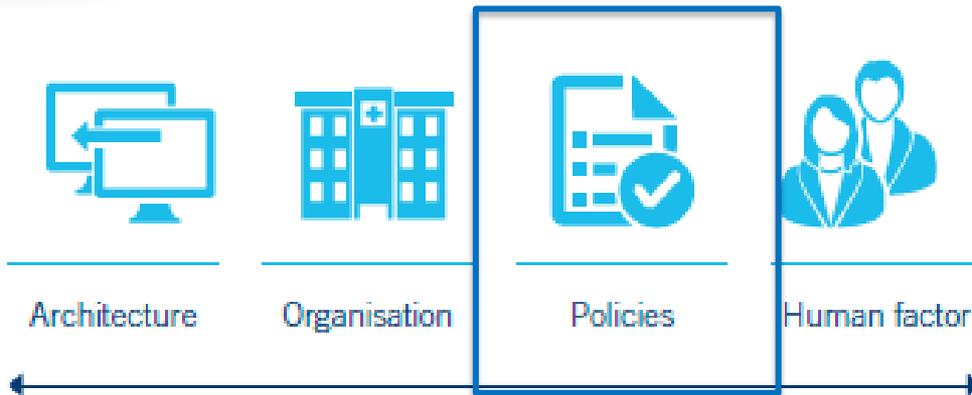
Evaluation of request of data and communication of the decisions

Finances and budget control





Organizing a Supranational Registry of Living Donor Registries Policies



Regulations:

EU directive
Data protection...

Protocols:

Data integrity
Anonymity
Data access

Dissemination:

Reports...

9.2 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. Different possibilities for financing are:

1. EU grant, this would be particularly useful in the first three years of the RoR. After three years the financial position could be evaluated with continuation of the EU grant or choosing one or more of the below mentioned items,
2. The country that hosts the RoR will also pay everything that is necessary to sustain the database. A rotation scheme could be made for hosting the database.
3. Finance based on contribution from MS:
 - a. based on the number of donors included,
 - b. based on the number of inhabitants per country,
 - c. based on the type of data entry (direct data entry or file upload),
 - d. based on the gross national product
 - e. each country that participates in the RoR pays the same amount of money.
4. A combination of two or more of the abovementioned items.

9.3 Summary

The great majority of respondents wanted to participate in a future RoR, were willing to adapt their existing database, and were in favour of a financing system in the starting years by an EU fund. Two organisations indicated that they wanted to host a future RoR. Decisions about a future RoR, a financing system, and hosting the RoR have to be taken by the CA's of the participating countries in the RoR and the EU.



Accord

Achieving Comprehensive
Coordination in Organ Donation

Summary:

The WP 4 has settled the basis to share practices on living donation in Europe. The recommendations agreed upon will help us to gain knowledge, improve practices and increase the protection of the donors

Thank you!