

# **EDITH Project**

## **WP6: Follow up Registry for Transplant Recipients**

# Workpackage 6

Led by ET and NHSBT



# Establishment of European Registry

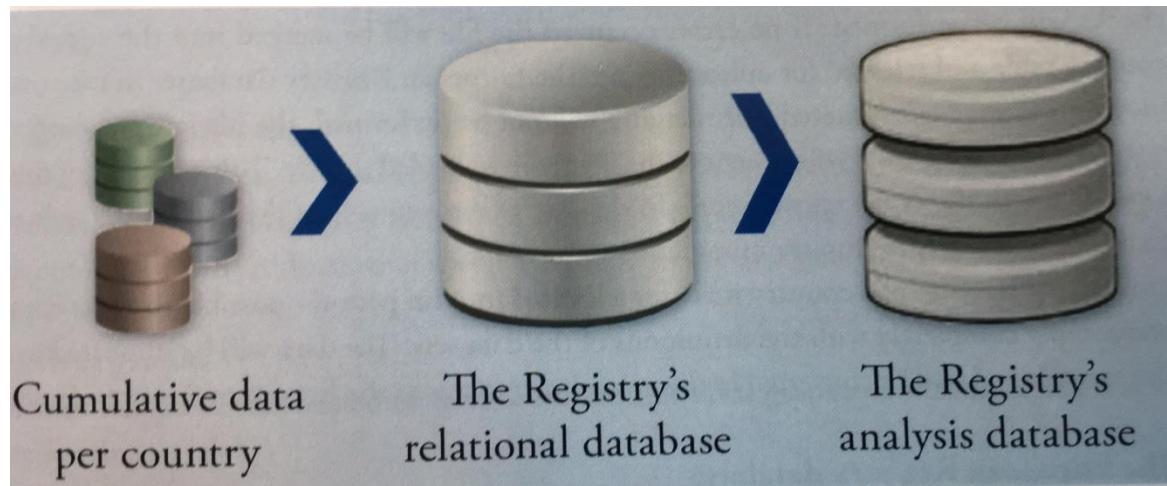
- Input: EFRETOS Functional and Technical requirement recommendations
- Input: Functional design
- Input: Technical requirements

# Functional requirements (EFRETOS)

- Data format
- Types of data sets
- Data submission time points
- Record identification
- Interaction with editorial tables
- European Registry database
  - Central database with internet access
  - Access to “your own” data
  - General overviews available to all participants

# Technical requirements (EFRETOS)

- National registries in participating countries
- Upload facilities to European Registry database
- Analysis tools and predefined reports



## Technical requirements (EFRETOS)

- Open Source development environment preferred
- Easy and simple upload tools
- Data check, validation, etc
- Analysis and reporting tools (?)
- Authorization and security measures
- Hosting party (Cloud-based?)
- Helpdesk in place

## WP5 and WP6 collaboration

- Governance
- Legal and ethical requirements
- Quality assurance
- Authorization and Security
- Person ID methodology (Donor and recipient)
- (Pseudo) anonymisation strategy
- Build on Open Source philosophy (TBD)

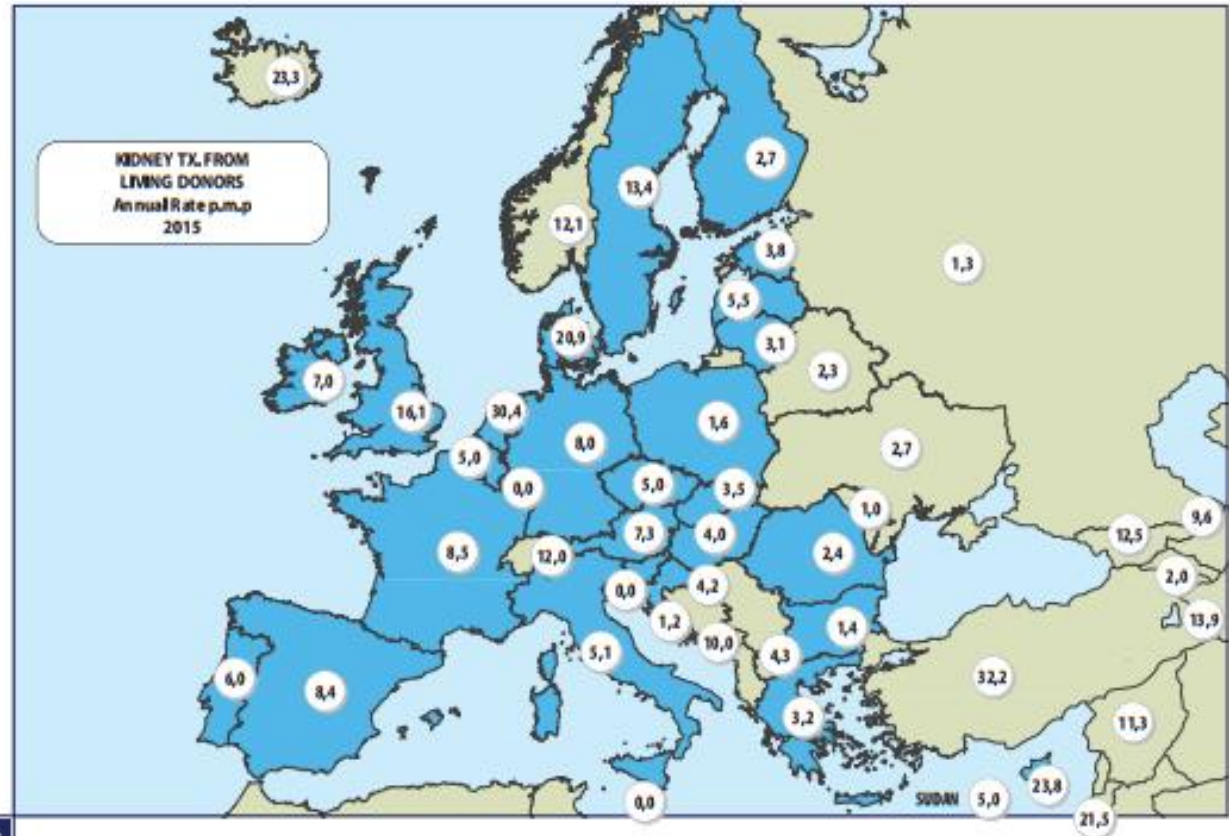
# Objectives of WP6 (year 1)

- Review national arrangements for collection of kidney transplant recipient data
  - identify MS who may contribute to European Registry
- Identify support needed by MS for data collection
  - identify and help overcome obstacles
- Define data set to be used as basis for the registry
  - specify variables and provide data dictionary
- Specify technical needs of database
  - arrangements for governance, reporting, consent
  - requirements for data entry, file upload, data storage, validation, security



# WP6

## International figures on donation and transplantation 2015



# WP6

## Review national arrangements for collection of kidney transplant recipient data

- identify MS who may contribute to European Registry

### QUESTIONNAIRE WP4

#### A. General information

Participating partner (country) or Collaborating partner	
Name of representative (person who filled in this questionnaire + email address)	



#### B. Current experience with living donation and living donor follow-up

1. Does your country have experience with living donation? <input type="radio"/> YES, kidney only <input type="radio"/> YES, both kidney and liver <input type="radio"/> NO
2. Does your country systematically gather information on living donor follow-up? <input type="radio"/> YES, kidney only <input type="radio"/> YES, both kidney and liver <input type="radio"/> NO
3. Is this information collected in a digital registry? <input type="radio"/> YES → if yes, please skip question 4. <input type="radio"/> NO → if no, please answer question 4.
4. If your country does not yet collect data in a digital registry, does your country want to have such a registry? <input type="radio"/> YES → if yes, please fill out the questions in this questionnaire with a <u>preferred situation in mind</u>

# WP6

## Review national arrangements for collection of kidney transplant recipient data

- identify MS who may contribute to European Registry



EUROPEAN COMMISSION

Brussels, 4.1.2017

### *3.2.6. The selection and protection of living donors*

For some organs such as kidneys and livers (and very experimentally lungs), living donation is possible. This allows for a complementary source of organs. However, removing an organ from a healthy person is an invasive measure and can have medical, psychological, social and economic consequences. Hence, living donors must be carefully screened, selected and followed up, as laid down in Article 15 of the Directive.

Most countries have introduced registers or records for living donors (23/29). 17 countries reported having already initiated a register before the adoption of the Directive, while others have launched such records in 2014 or 2015. In most of these Member States, record keeping is set at national level (16/23). Four Member States reported that a record is kept at the international level, their national data on living donors being included in the relevant record hosted by their EOEO (Belgium with Eurotransplant; Denmark, Sweden and Norway with Scandiatransplant). A few Member States specified that a record is locally kept by each transplantation centre. Significant differences are noted between Member States in the content and type of data captured in the register. Six countries reported not to have a register in place, but three of them plan to establish one soon (Croatia, Portugal, Slovenia).



### 4.2.3. Detailed specification on the content of the database

This inventory has some bias, since some countries decided not to answer (all) of the questions concerning the specification of the items because they do not apply a digital data collection yet. They've given some answers to the questions with a preferred situation in mind, but some answers were kept blank. This hasn't influenced the overall impression of the current situation within the participating MS.

The definitions that were given by the respondents for each predefined item differ in some cases. It is suggested that internationally accepted definitions should be discussed and agreed upon by ACCORD WP4 in the further development of a registry of registries.

#### a. Data for evaluation of the donor

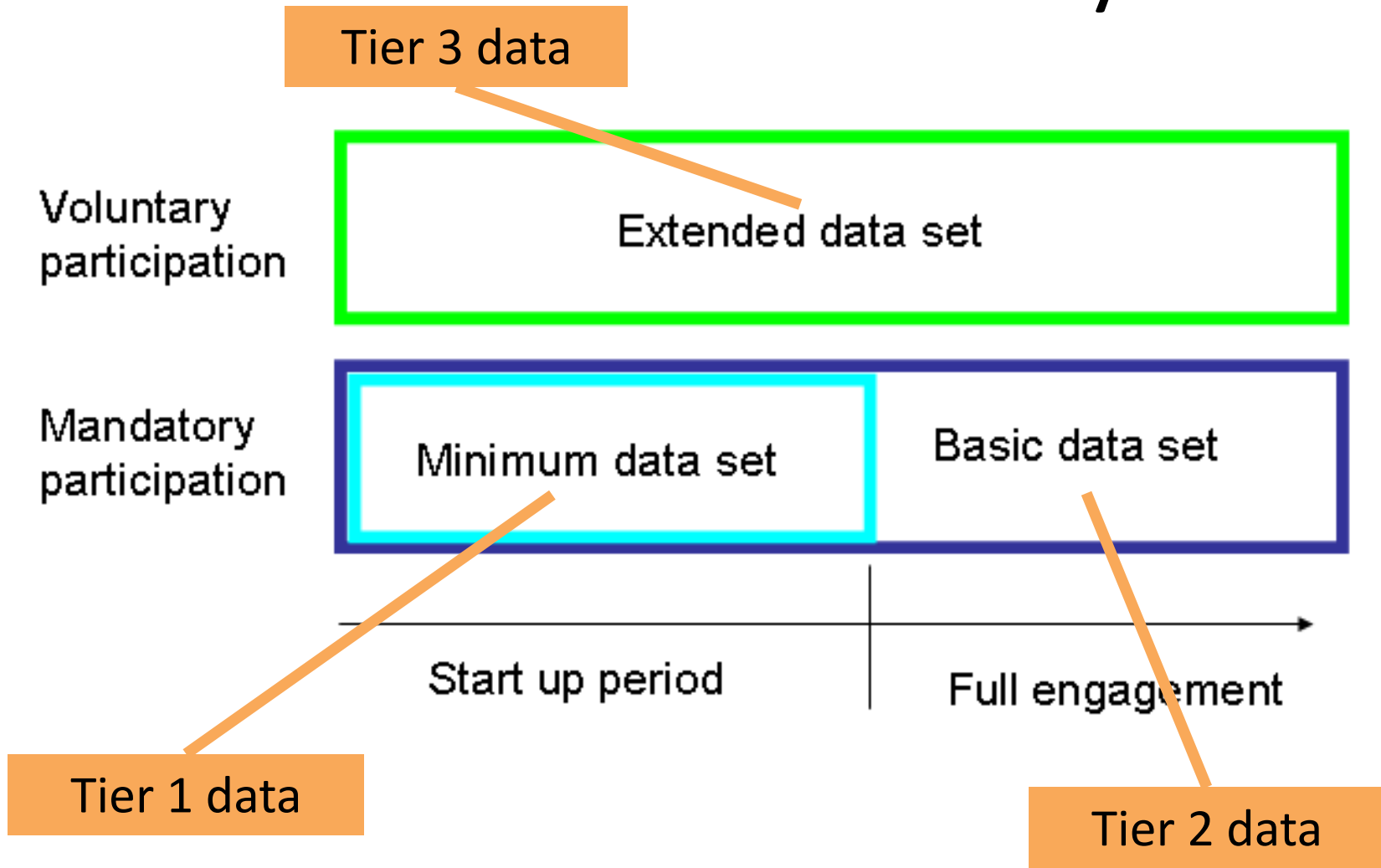
The following items were predefined and partners were asked to answer whether the items are collected in their database or registry, whether the items are mandatory and what definitions are used. One country without a registry has not answered the questions.

Item	Definition	Mandatory Yes	Mandatory No	Not collected
Age	Age in years at the moment of transplant	12	0	0
	Date of birth			

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  - **specify variables and provide data dictionary**
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# 3 Tiers data collection system



# Kidney Tier 1 variables



Donor	Recipient	Transplant	Follow-up
gender	gender	Date transplant	Date follow-up
ABO blood group	ABO blood group	Previous transplant	Lost to follow-up
Age	age	Country	Fail date +cause
Height	Diagnose	Height	Death date+cause
Weight	Date listing	Weight	Weight
cause of death	Date start dialysis	Total ischemic time	Serum creatinine
HLA –A-B-DR antigens	Country residence	Organ type	
Malignancy	HLA-A-B-DR antigens	Induction therapy	
Donor type		Initial IS therapy	
		Fail date+cause	
		Death date+cause	
		DGF	
		Date last dialysis	

# Timeline



## Prerequisite

Address list:

- Main contact person
- Technical contact person
- Data manager
- Legal advisor