



FACILITATING EXCHANGE OF ORGANS DONATED IN EU MEMBER STATES

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## FOREWORD

**Dr. Alessandro Nanni Costa**

*Project leader: Centro Nazionale Trapianti-CNT*

“Facilitating the Exchange of Organs Donated in EU member States” is the aim of FOEDUS Joint Action (JA) which is a three-year Action receiving funding by the European Commission under the Health Program 2009-2013. Since May 1st 2013 the Italian National Transplant Centre – Italian National Institute of Health has been coordinating the Joint Action FOEDUS which involves 25 European partners (18 associated and 7 collaborating partners). FOEDUS is the result of a former EU funded project, called COORENOR (Grant Agreement 20091103) and of the joint efforts of 11 organizations from 10 different countries which established the first European tool for international organ exchange, freely accessible for national Competent Authorities. The IT platform for organ exchange was launched in July 2012 and thanks to it, all EU countries were able to receive communication of an organ offer at the same time. The system is quick and user friendly and since the very beginning of its operation, 10 national coordinators were able to access the platform with username and password.

The overcome of communication difficulties in the reporting of surplus organs between European Union countries was a great value of the COORENOR project which, however, has given room to reflection and analysis of deeper problems. FOEDUS is its natural continuation with the main goal of finding an answer to the unresolved key issues arising in cross-border organ exchange. One of the main objectives of the action is identifying a common methodology for the international cross border organ exchanged to be performed at European level.

In the framework of FOEDUS activities, a common donor form which could easily replace the old EOEO form for organ exchange has been agreed upon (work package - WP5) and the preparation of guidelines for cross-border organ exchange as well as models of bilateral and multilateral agreement are going to be prepared in the future ahead (WP4).

The second relevant aim of the Action is to create a **common communication strategy** in order to approach general public once dealing with the topic of organ transplantation in general and of organ exchange in particular.

WP7 leader, in cooperation with other associated partners, will answer to the question ‘How to communicate with media on the field of organ donation and transplantation at national and international level?’ with a special emphasis on cross-border exchange. The result will be a manual addressed to all the European Competent Authorities in charge of organ donation and transplantation as well as transnational organizations.

FOEDUS is halfway and there is still a long road to go, here below there is a general update of our ongoing activities, please follow our progresses in the future ahead!

## EVALUATION OF THE PROJECT

*WP leader: Hellenic Transplant Organization – EOM*

The **general objective** of this WP is to assure and improve the quality of the project and the project outcomes, relieve on time weaknesses and obstacles to progress and propose recommendations to continue, modify, and/or delete in a context of open discussion on the project.

In accordance with the **specific objectives** of the project and their quantitative and time framed performances/aspects, WP3 has to evaluate:

1. the processes of the project and action effectiveness
2. the outputs of the project in the objectives achievement
3. the outcomes of the project and their outcome impact

The **Milestones** of WP3 until the end of 2014, are presented on the FOEDUS GANTT chart as follow:

1. **Setting up of Advisory Board:** The Advisory Board is composed by recognized experts and its role is to oversee the project by reviewing the progress of the consortium on issues of technical priorities and relevance, with a view to achieving impacts. The AB is respectively composed by: Rafael Matesanz, ONT; Bernadette Haase, Dutch Transplant Foundation; Jórlaug Heimisdóttir, Iceland Directorate of Health; Pål Foyn Jørgensen Norwegian directorate of Health; Olga Kalakouta, Cyprus Transplant Council; Igor Codreanu, Renal Foundation of Moldova; Tanel Laisaar, Estonian Ministry of Health. Martin Häfliger from Swisstransplant was

also nominated as external member of the Board due to the previous cooperation with some EU countries in the field of organ exchanges. The AB is asked to evaluate project deliverables and also to assure and improve the quality of the results of the JA.

2. **Developing a Project Evaluation System** which includes tools for Monitoring and Evaluation and tracks outputs by collecting information on results of project activities using participant tracking forms and meeting evaluation forms.
3. **Evaluation questionnaire** circulated during general and technical meeting.

#### **Further activities of WP3:**

WP3 is presently finalizing the Interim Progress Analysis and Evaluation Report, which is a Milestone . The report is focused on the project progress, the arisen difficulties and suggestions for improvement.

## **DEFINITION OF GUIDELINES IN CROSS-BORDER ORGAN EXCHANGE AND ANALYSIS OF BARRIERS AND OBSTACLES**

*WP leader: Eurotransplant International Foundation*

The FOEDUS project is set up in order to improve the exchange of organs donated in EU member states. The main objective of FOEDUS WP 4, is to compare and analyze the existing practice of organ exchange procedures within Europe, objectify the current obstacles and barriers that hinder the cross border exchange of donated organs and based on these results, develop standards for the cross border exchange of donor organs.

#### **Analysis existing practice**

In order to reach the objective to analyze the existing practice of cross border organ exchange procedures and objectify the current obstacles and barriers, an extensive questionnaire was developed. This online questionnaire comprised of 56 questions on 11 relevant topics within the field of cross border exchange of donated organs, including legal, logistical and financial items. This questionnaire was circulated in May 2014. Out of the 35 participating FOEDUS member countries and/or organizations, 24 members completed and returned the questionnaire, resulting in a 67% return rate.

#### **Standards and common practices**

The questionnaire has been of great value in identifying areas that form no barriers, as common standards and/or practices in participating FOEDUS member countries are applied. From the survey it can be concluded that although different organizational structures occur in various FOEDUS member states (MS), these form no barriers in facilitating international organ exchange. Looking into contra indications (such as HIV and Malignancy), the survey learned that these are identified and treated in similar ways and do not block the exchange of organs between countries. Organ procurement in FOEDUS MS is based on EU Directive 2010/53 and although differences exist on national levels, these form no barriers for international organ exchange. Also in the area of procurement, the composition of procurement teams is overall similar and forms no obstacle. The replies received on the questions on transport and logistics, learned that organization of cross border transport of donor organs is no obstacle.

#### **Existing contracts and agreements**

Multiple countries/organizations indicated they have agreements and/or contracts with other EU member states for the following reasons:

- General agreement for possible exchange of all non allocated organs.
- Definition of allocation rules and arrangements to ensure national balances
- Supporting transplant activities and improve level of assistance of patients on waiting list.
- Arrangements for quality, safety, traceability and transparency in organ exchange.
- Contract for organ exchange with Eurotransplant member states

#### **Areas requiring attention**

From the survey, it was concluded that there are some areas that form no real 'obstacle' for international organ exchange, but that have to be taken into account. For example, in Germany the national regulations prevent accepting organs from DCD donors.

## Obstacles and barriers

The survey results highlighted the following areas where potentially obstacles or barriers for international donor organ exchange may arise:

**Quality standards:** respondents identified that there is a lack of information on quality standards that are applied by the organizations to make sure donor characterizations is performed adequately. For countries to facilitate and contribute to international organ exchange, more information on quality standards is necessary, such as up-to-date information on certification of laboratories and hospitals to perform certain tasks.

**Cost models:** from the responses it became clear that there is a demand for a clear overview and agreement of handling of costs, related to international organ exchange. Additional costs are made for procurement teams, transport and logistics etc and currently, it is unclear who is paying for these costs and/or where to send the declaration of costs in a country.

**Common language:** approximately 50% of the respondents identified language issues as a potential barrier for international organ exchange. Common language to facilitate verbal and written communication, which is essential in international cooperation in cross border exchange of donor organs, has to improve.

## Preliminary and final reports

The preliminary data of the sub report containing the identification of all obstacles and barriers – as highlighted above - was presented in the intermediate technical meetings in Rome on June 24 and 25, 2014. The final summarizing sub report on these obstacles will be circulated for approval by all countries in October 2014. This will consist of two sub reports;

1. Current obstacles and barriers that hinder the cross border exchange of donated organs (based on the questionnaire)
2. Inventory of all collected current bi- and multilateral agreements between member states and/or European Organ Exchange Organizations.

## Next steps

After the circulation of the final report, a technical meeting will be held in the first quarter of 2015. In this meeting, guidelines and/or recommendations according to obstacles and barriers as mentioned in the final report will be formulated. In addition, a standard agreement for the cross border exchange of donated organs will be formulated for the general use of all member states and/or European Organ Exchange Organizations.

## DONOR MEDICAL INFORMATION FOR CROSS-BORDER ORGAN EXCHANGES

*WP leader: Agence de la biomédecine*

The Agence de la biomédecine is the only Agency in Europe covering the four areas of transplantation, procreation, embryology and genetics. It has forged close links with Transplant medical teams and patients, thanks to its 24/7 operational role of managing transplants waiting list and the non-donor registry, and allocating transplantable organs.

Drawing on the skills of medical and scientific experts, the Agency works together with professionals to develop guidelines for harmonizing and developing best medical practices, contributes to the development of homogeneous quality and safety treatments accessible to all, issues recommendations, approvals and authorizations, and ensures their application and the respect of legal provisions notably regarding consent, anonymity and donation criteria for organs, tissues, cells, gametes and embryos. The Agency guarantees that patients throughout France benefit from the highest levels of safety and quality care. In this regard, the Agency also evaluates medical activities and makes such evaluations available to the government, professionals and to the public at large.

A few years ago, in the absence of a suitable national recipient, a national form containing medical information on the donor and on the organ was faxed to organ allocation platform of other countries. Forms could be very different from one country to another and was even sometimes sent in national languages. Additionally, to mention but a few problematic aspect we encountered, most of the time medical information was too scarce to assess suitability, units measures ( $\mu\text{M}$ ;  $\mu\text{g}/\text{ml}$  etc.) were disparate, it was really difficult to get further information by phone (language differences, availability etc.), the offering country had very little feedback on organ utilization when indeed an organ was accepted abroad and poor feedback on potential technical problems like organ conditioning. Notwithstanding obviously that the fax system was time consuming and outdated to nowadays practices and needs. During the COORENOR project co-funded by the European Commission under the 2008 – 2013 Health Programme, the former fax system was then replaced by a dedicated Information Technology (IT) portal (web access).



The IT portal was set up in the end of the projet as an outcome of the working group, but with very basic information: gender, organ, age and blood group.

*As expected, we experienced the same problems as with the former fax system, but of course a plan for a continuation with a broader Joint Action FOEDUS was set so as to notably fulfill this gap.*

Consequently, the aim of this section (WP5) – led by the Agency of Biomedicine – was to prepare a common form to be used to offer an organ abroad, in the absence of a suitable national recipient. This form had to contain medical information regarding the donor and also key criteria characterizing each organ offered, so as to allow rapid search (running of the allocation system to select potential recipients) for the selection of matching potential recipients on the waiting list and also facilitate decision making (assessment in turn by the transplant team of organ suitability for the selected patient to be transplanted in regards to some potential specific needs).



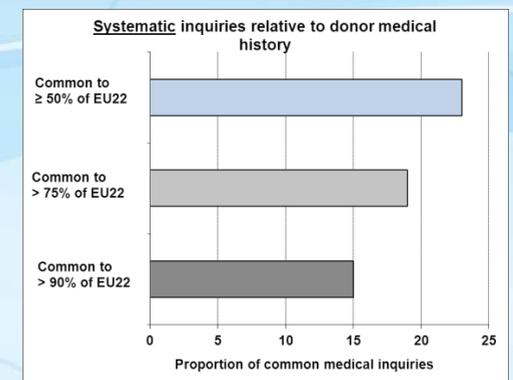
(Photos of the French organ packaging and partial transport system, ©Benoit Rajau for the Agency of Biomedicine).

As a first step, participants to the WP5 working group were invited to provide an English copy of the form they used with the former fax system for international organ exchanges. A transversal analysis of the different existing national forms was performed and the results of the Agency of Biomedicine previous COORENOR survey regarding systematic donor and organ characterization criteria used by 22 Member States (see illustration below), were gathered to propose the first version of the form that was discussed by experts notably during a dedicated meeting.

### Donor Evaluation (22 Member States): COORENOR project

Systematic inquiries	Out of 22 MS
1) Anamnestic information available	21
2) Risk factors for HIV/hepatitis	21
3) Previous Infectious Diseases	20
4) Illicit substance abuse	21
5) Neoplastic Diseases	21
6) Familiar history of malignancies	16
7) Surgical interventions	21
8) Pregnancy tests	9
9) βHCG	7
10) History of recent miscarriages	7
11) Cardiovascular diseases	21
12) Pulmonary diseases	20
13) Liver diseases	21
14) Renal disorders	21
15) Diabetes	21
16) Autoimmune disorders	19
17) Hypertension	21
18) PSA	8
19) Dyslipidemia	12
20) Alcohol consumption	20
21) Smoking status	20
22) Diseases of unknown etiology	17
23) Radiation exposure	8
24) Recent history of immunisation with live vaccines	14
25) History of blood transfusion	20
26) Congenital/inherited disorder	19
27) Risk of transmitting prion disease	14
28) Neurodegenerative diseases	18

### Donor Medical History



15 criteria common > 90% EU 22  
 19 criteria common > 75% EU 22  
 23 criteria common ≥ 50% EU 22

## Morphological tests performed

Morphological tests performed	Yes systematically	Yes, under specific conditions	No
1) ECG	21	1	0
2) Chest radiography	22	0	0
3) CT scan/ body scan	8	13	0
4) Echocardiography	10	12	0
5) Coronarography	0	18	4
6) Abdominal and pelvic ultrasonographic examination	15	7	0

Figure 10 : table listing additional morphological tests that could be performed.

- ECG and chest radiography are almost systematically performed by all 22MS
- Abdominal and pelvic ultrasonic examination are performed by 68% of them (15MS out of 22)
- $\geq 50\%$  EU 22 carries out 3), 4) and 5) under specific conditions

Furthermore, the common form had to comply with the Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation, and more precisely to organ and donor characterization.

Taking all the above-mentioned points into account, the newly designed common form (below) was provided (in English). This form can also be translated by each partner in its own languages and kept internally, to avoid mistakes filling in at national levels (or in organ acceptance at local level).

So as to make the best of this common form, the Agency of Biomedicine FOEDUS team also performed a retrospective study on the French donor registry to assess most common cause of death for organ donors and also selected most relevant key words to characterise medical imaging based on national experts working groups on X-ray/ CT Scan and on Echography/UL-trasounds. It is easier to simply tick on a key word than having to look for the proper English word. Not only language problems were taken into account, but since at least 90% of the dedicated coordinators at allocation platform level are not medical doctors, filling in the form has to be straightforward. Once agreed, the common form was customised to each organization with logo and contact details. Each form can be enclosed to the organ offer send thought the IT portal.



The security level of the system was verified.

Although the donor form is sent via email through the portal (attachment appears on the original message), it is impossible to open the form enclosed without being connected to the IT portal with personal login and password.

Interestingly, although not planned at first, the Agency of Biomedicine also proposed a common “Fast Track form”, to be sent back by the country having accepted an organ to be transplanted to their national recipient. Likewise for the organ offer form, the same methodology was applied since countries also already had existing national ones. A common English form was generated and customised to each country with logo and contact details (see below).

This “Fast Track form” is to be sent back immediately if the organ was not transplanted (or not and if not why), and is only to be sent back after 10 days if the organ was transplanted (to give brief feedback on transplant outcomes).

This form is very valuable for traceability and for the vigilance system. It allows rapid actions should a problem arise.

This form complies with the Commission implementing Directive 2012/25/UE laying down information procedures for the exchange, between Member States, of human organs intended for transplantation.

Uses of those two forms through the IT portal will be monitored by WP5 leader.

Secondly, although set as an optional task of WP5, a guideline for organ donor maintenance shall be drafted. Participants to the working group were invited to send an English version of their guidelines should they have some. A transversal analysis of the different guidelines and common practices shall be drafted and used as a basis for discussions. This guideline shall include a list of common agreed definitions and justification for the selected items that were adopted for donor evaluation - if necessary - and more importantly recommendations on donor maintenance shall include DOs and DON'Ts, and dedicated sections for the different organs as well as a clear distinction between recommendations for adults and for paediatrics organ donors. This

guide shall as well include annexes to be used as practical tools. Annexes shall indeed be adaptable to national needs and could generate Standard Operational Procedures or operational sheets.



(Photos of French facilities, ©Benoit Rajau for the Agency of Biomedicine)

*Such medical recommendations, based on good on site practices and long term experience, shall be a valuable support for countries where specific transplant programmes are not yet in place by facilitating both the implementation of quality and safety standards and the evaluation of potential donors for organs that are not usually retrieved.*

*Sharing knowledge and experience of transplant practices EU wide shall directly impact organ exchanges and shall support Member States seeking to develop their activities. Above all, guidance and recommendations to be generated shall not only facilitate cross-border organ exchanges but also speed-up exchanges by avoiding the loss of time consequent to the request of complementary test(s) and language misunderstandings and so decrease ischemia time, which on the top of recommendations on donor maintenance and good evaluation practices shall directly impact on the quality and safety of organs exchanged.*

## UPGRADING IT PLATFORM FOR INTERNATIONAL EXCHANGE OF ORGANS FOR TRANSPLANTATION

*WP leader: Koordinační Středisko Transplantací*

Koordinační Středisko Transplantací (KST), Czech Republic, is in charge of one of the core work packages. Building on the results of COORENOR project, KST is responsible for further development of the IT platform aimed at international exchange of organs for transplantation.

At the beginning of WP6 activities KST added new partners and users to the portal and in addition to this the result of the survey conducted by WP4 will answer to most of COORENOR unsolved questions.

The testing phase of the IT portal has shown two substantial steps to be taken and in particular: the need to attach documents relating to organ donor or urgent patient (Donor Form, WP5) and guarantee the safety of the information shared through the portal, whereas the second request was to enable the users to create any groups of recipients of request/offer messages so that bi-lateral and multi-lateral agreements on offer of organs for transplantation can be guaranteed. Both these requests have been solved and the IT platform now enables the users to attach any documents as well as to select addressees of their communication through the portal. Finally all the partners agreed on the responsibility of each user of the portal to use, share and update information without prejudice to the safety bearing in mind that personal data cannot be misused nor revealed to any third party.

The terms of use of the portal were to be published in month 14. The deliverable has been discussed with the coordinator and had some delay due to the importance of having it accepted by all the associated partner. KST is now gathering information regarding user's experience with from the partners and will include all the relevant information in the final deliverable of WP6 – Results of pilot testing.

At present KST opened a tender for a supplier of further improvements of the portal. It will include information part where all useful details regarding national legislations and specifics could be found. Another improvement will include mobile application so that information can be also shared through

smartphones in order to speed up organ exchange and make it more flexible. We also plan to implement tools for assisting the users in transport and logistic and financial issues relating to concrete cases of organ exchange between countries. We expect strong support and feedback from all partners so that the final result meet their expectations and needs.

## COMMUNICATION AND PUBLIC AWARENESS

*WP leaders: Slovenija Transplant and Deutsche Stiftung Organtransplantation*

FOEDUS WP7 on communication and public awareness led by Slovenija Transplant and Deutsche Stiftung Organtransplantation aims to professionalize communication with media in order to raise public awareness. In order to achieve this objective, a structured approach in communication will be developed as well as a methodology for evaluating the effects of communication measures.

The project will be carried out on the basis of a twofold focus: the communication with media on one hand, and general strategies to increase public awareness. Both subject areas are closely linked as they mutually influence each other. Figure 1 shows the focus and objective of WP 7.

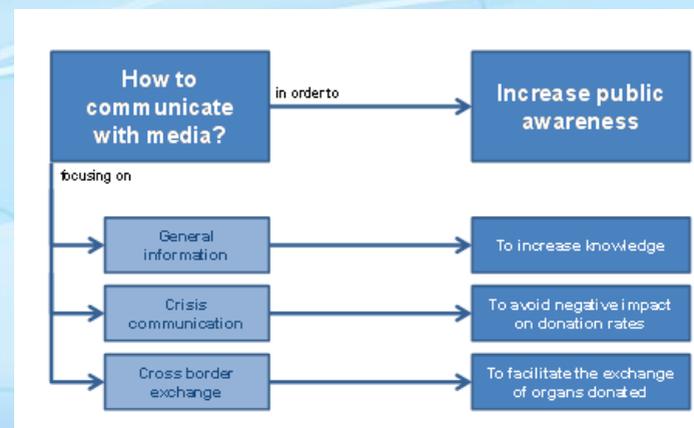


Figure 1: Project alignment WP 7

Final outcome of WP7 will be a manual on 'How to communicate with media on the field of organ donation and transplantation at national and international level?' with a special emphasis on cross-border exchange. Though general public is considered as final target group (as stated in Joint Action 2012 – Application Form – p.5), the manual aims at the Competent Authorities in charge of organ donation & transplantation in EU Member States as well as transnational organisations, as stated in Directive 2010/53/EU. Based on their expertise and knowledge Competent Authorities are considered as the most important multipliers.

In order to achieve the objective five milestones have to be fulfilled:

1. survey within the consortium on good/bad experience of communication and analysis
2. analysis of studies with positive/negative experiences in communication
3. workshops with experts
4. elaboration of messages for traditional/print media and new media/internet for national and international journalists
5. test on the effectiveness of messages in 5 countries

So far, WP 7 consortium completed first two milestones (1, 2), milestone 3 and 4 are partially fulfilled. Three technical meetings have been held.

Milestone 1 has been carried out at the beginning of the project in order to analyze the partners' experiences and needs when communication with media. A questionnaire was distributed via e-mail to the FOEDUS consortium in order to obtain relevant data. The questionnaire consisted of three parts: media experience, media influence, and expectations for WP7. 18 out of 25 partners responded. Results and analysis were presented at 1st technical meeting of WP7 in Ljubljana on July 4th 2013. Findings confirmed that the majority of partners communicate with media "frequently" or "very frequently", whereby only 2/3 of all respondents receive professional PR help. Almost every respondent assumed that certain events and publications do affect donation rates, whilst the extent of the impact was only measured for negative events and publications.

Milestone 2, analysis on studies, had a dual purpose. It aimed at giving an overview of the current state in evaluating campaigns. Also, it sought to provide some practical advice on how to communicate effectively about organ

donation. Findings of the second milestone were presented at 2nd technical meeting of WP7 in Paris on January 16th 2014.

An initial review showed that the already small number of publications differs significantly in terms of design and objectives. While some publications focus directly on organ donation and organ donation willingness, others only try to explain certain effects by using the example of organ donation. Therefore, a classification regarding the papers' objective was made. The classification categories set were "theory-based publications", "practice-oriented publications", and "publications with limited relevance". The literature search yielded 34 publications, from which ten publications were assigned to the category "theory-based publications" and nine to "practice-oriented publications". 15 publications were excluded from further analysis as they were considered to be of limited relevance. Recommendations derived aim, among other things, to increase public knowledge with a special focus on health professionals.

Milestone 3 covers the organization of two expert workshops, one of which already been held in Ljubljana on 2-3 July 2014.

The 1st expert workshop started with four key lectures on different aspects of communication. A theoretical introduction to social marketing was followed by a best practice presentation from the related field of bone marrow transplantation. Next presentations were on crisis communication in health care settings and an overview on frequently used communications strategies in organ donation. After the introductory session, participants were assigned to four groups according to different subject areas. Purpose of the group work session was to discuss and narrow corresponding subject areas, to focus and define all relevant issues, and to develop messages (as requested in milestone 4).

Developed messages are going to be analysed by experts in a second workshop, which will take place in Munich on 25.-26. November 2014. Additional to the analysis, another priority of the 2nd workshop will be the preparation of an empirical study to test the effectiveness of developed messages in five countries (Milestone 5). The participants invited will be delegates of the five countries as well as several specialists, including marketing experts, market researchers, statisticians, and experienced practitioners. The participating specialists will furthermore be asked to provide their appraisal regarding the structure and contents of the manual in order to obtain a maximum benefit in terms of quality and applicability.

## **ASSOCIATED PARTNERS**

Centro Nazionale Trapianti – Istituto Superiore di Sanità - CNT-ISS (Italy, Project Co-ordinator)

Országos Vérellátó Szolgálat – OVSz (Hungary, Dissemination leader)

Hellenic Transplant Organization – EOM (Greece, Evaluation leader)

Eurotransplant International Foundation – ETI (Netherlands, WP4 leader)

Agence de la biomédecine – ABM (France, WP5 leader)

Koordináční Středisko Transplantací – KST (Czech Republic, WP6 leader)

Institute for Transplantation of Organs and Tissues of the Republic of Slovenia – Slovenija Transplant (Slovenia, WP7 co-leader)

Deutsche Stiftung Organtransplantation – DSO (Germany, WP7 co-leader)

Federal Public Service, Public Health – FPS PH (Belgium)

Ministry of Health of the Republic of Croatia – MoHRC (Croatia)

Bulgarian Executive Agency for Transplant – BEAT (Bulgaria)

National Transplant Bureau – NTB (Lithuania)

Mater Dei Hospital – MDH (Malta)

Instituto Portugues do Sangue e da Transplantacao – IPST (Portugal)

Národná transplantáčná organizácia – NTO (Slovakia)

NHS Blood and Transplant Department of Health– NHSBT (UK)

Polish Transplant Coordinating Centre “Poltransplant” (Poland)

Fundeni Clinical Institute – FCI (Romania)

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Organisation Nacional de Transplantes, Spain

Renal Foundation, Moldova

Sotsiaalministeerium, Estonia

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Swisstransplant, Switzerland

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