SUSTAINABILITY AND IMPLEMENTATION PLAN OF THE JOINT ACTION

ACHIEVING COMPREHENSIVE COORDINATION ON ORGAN DONATION THROUGHOUT THE EU

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Poland: Poltransplant
Portugal: Blood and Transplantation Portuguese Institute (IPST)
Romania: National Transplant Agency (ANT)
Slovenia: Slovenija Transplant
Slovak Republic: National Transplant Organisation (NTO)
Spain: Organización Nacional de Trasplantes (ONT)
The Netherlands: Dutch Transplantation Foundation (Nederlandse Transplantatie Stichting) (DTF)
United Kingdom: NHS Blood and Transplant (NHSBT)

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1. INTRODUCTION

Organ transplantation benefits more than 30,000 patients in the European Union (EU) every year, but the availability of organs does not satisfy the needs, unequally met by MS (MS), notably due to variability in living and deceased donation rates. This heterogeneous scenario and the need to establish a common framework for quality and safety of human organs intended for transplantation, has led to two EU initiatives in the field: *Directive 2010/53/EU* (hereinafter, the Directive) and the *Action Plan on Organ Donation and Transplantation (2009-2015):Strengthened Cooperation between Member States*, with ten identified priority actions.

Living donation activity is increasing in the EU to better meet the transplantation needs of patients. But the living organ donor faces medical and psychosocial risks which makes mandatory to adopt an appropriate framework of donor protection in compliance with a core of most common good practices. These include the development of a living donor follow-up registry, as set down in the *Directive*, essential to donor safety and to build evidence on the consequences of donating an organ during lifetime, but not yet available in many MS.

One of the main reasons justifying differences in deceased donation rates across countries is failure to identify and refer potential organ donors. A close cooperation between critical care professionals dealing with end-of-life care, and donor transplant coordinators is fundamental to possible donors becoming actual donors. Providing recommendations on how to build this integration, based on a benchmarking approach, has proven effective in different countries.

International cooperation is considered an effective tool per se to improve performance, since Twinning activities facilitate the transfer of tools, expertise and knowledge in one Member State to others having requested such transference.

In this framework, the Joint Action (JA) ACCORD has addressed these challenges by working in 3 specific areas:

1. **The development of living donor follow-up registries.**

2. **The cooperation between critical care professionals and donor transplant coordinators.**

3. **Twinning activities in the field of organ donation and transplantation.**

Even if there are differences in the local situation of donation and transplantation among MS, issues addressed are similar: shortage of organs and the need to ensure the highest possible quality and safety of organs transplanted taking into account transparency and security. A continuous comparison of different realities sharing similar goals can only foster a virtuous circle allowing benchmarking actions and more homogeneity among EU countries. ACCORD facilitates the comparison of different realities that will lead to the identification and application of good practices in the field of organ donation and transplantation. The comparison with the best and most positive realities in different areas will foster several key aspects in the end: a) an increase in the number of organs available for transplantation, either through a better identification and referral of possible donors by critical care professionals, or through more organs properly recovered and available for clinical uses with; b) an improvement in quality and safety of living and deceased donation procedures.

- Specifically, there are many aspects of sustainability of the project that can be considered an added value: First, the obligation for MS to implement the *Directive makes* this JA certainly a useful tool and an incentive for MS that have not yet fully adopted the requirements laid down by the *Directive*. From the point of view of the resources spent, JAs allow to optimize the resources available, for example for the training. Similar realities have similar training needs, and countries that are "strong" on a particular aspect can provide their expertise taking into account the training needs of the participants. People trained become themselves a "vehicle" of training, becoming trainers in their own country. They are the most suitable vehicle of knowledge because on one hand they are familiar with the local situation with its positive and negative aspects and on the other, after being properly trained, they learn what the best practices are and how to put them into practice.

- Another result that fosters long-run sustainability is networking, to let all the professionals working in the field of transplantation feel as part of a community and that they can support each other.

2. OVERVIEW OF THE SUSTAINABILITY PLANNING PROCESS

One of the main factors that is widely known to enhance long-term sustainability is having a written sustainability plan. This serves for many purposes: it helps to build agreement about the contents of the plan, it can be used to communicate the critical success factors for sustainability to other people (consortium members, stakeholders, funders, policy-makers), and it provides a management tool to turn plans into action.

The process to follow in this plan includes the following steps that need to be specified for each priority domain:

1. **Getting organized.** A group that engages in sustainability planning process should be identified.

2. **Set sustainability vision and results.** What is intended to sustain and to achieve should be defined, along with the expected results and duration.

3. **Assessment of the current situation.** It is important to acknowledge and build upon past work, as well as to utilize strengths that are already in place. It is therefore useful to assess where the single activities and core work packages (WPs) stand with respect to the key elements of sustainability and to take an inventory of the past work and other assets related to sustainability. A self-assessment is therefore needed.

4. **Plan for community support.** Two critical elements of sustainability are a broad based community support and stakeholders support. Target audiences, key messages and communication strategies for this purpose need to be identified.

5. **Assessment of internal systems.** Having a strong internal system and the ability to adapt to changing conditions are pivotal elements of success for sustainability. Most organizations and bodies in our JA consortium are indeed long-standing and fully committed, thus ensuring long-term responsibility, but a related issue is how to build and sustain strong strategic partnerships so that a solid collaboration is maintained to continue driving the initiative over time.

6. **Create a strategic financial plan.** Finances can be addressed at this point since the results of the preceding steps allow having a clear picture of the resources that are needed to ensure sustainability and why those resources are needed.

7. **Develop an implementation plan.** By definition, a sustainability plan is a long-range blueprint with strategies that may take several years to fully implement. The final step is to make it “actionable” by creating a detailed

one-year implementation plan that shows specifically who will do what, by when, during the following twelve months, in order to make progress toward the goals and strategies of the long-term sustainability plan.

3. IDENTIFIED KEY ELEMENTS FOR SUSTAINABILITY AND IMPLEMENTATION

The main key elements that have been taken into account approaching the issue of sustainability in each priority domain identified in the ACCORD JA are specified below.

Political Support

Political support or at least the full support of responsible stakeholders to be identified in the different priority domains may be pivotal in the sustainability of some actions. Commitment here is already partially ensured by the common legal framework and by the EU Commission Action Plan, as well as by the interest shown at various levels by relevant Competent Authorities regarding the identified priority domains. Yet continuity of support may be necessary to ensure sustainability and progress in single fields, e.g. for some specific actions involving professionals at political level may be a prerequisite.

Funding Stability

Funding can be a direct result of political support. It is important that there is continuity in both the political and funding support in order to guarantee funding stability. In any case there must be a control, a feed-back between the funding and the effectiveness of actions, in other words, there must be a synergy between the various stakeholders, those who fund (political level) and those who co-ordinate (Competent Authority of transplantation) in order to plan, fund and carry out actions foreseen.

Leadership

Identification of a leading authority or group is necessary in each priority domain in single countries for the specific activity, in order to fix clearly responsibility in a planning process of future steps. Identified leaders should have the real capability and power to implement planned action incumbent on them.

Partnerships

Partnership both at national and international level is another key element of sustainability. If necessary, partnership should be officially established through ad hoc agreements signed bilaterally or multilaterally. This could be especially needed in particular priority domains, such as the one involving twinning activities.

Organizational Capacity	The organizational aspects are really important in our field and more than ever in the particular priority domains that were identified under the ACCORD JA. Each involved body should carefully evaluate the organizational effort needed in each domain in order to sustain planned activities in time. This key element also involves an assessment of needed staff resources and it is strictly linked to funding stability.
Communication	Effective communication activities are also part of a long-standing strategic planning for sustainable actions. Both internal and external communication may be needed for ensuring the involvement and continued support of all partners in a specific domain (e.g. professionals working at different levels). A careful thought should therefore be given to communication issues during the strategic planning phase.
Strategic Planning	The whole sustainability process should be the object of strategic planning and periodic progress evaluation. Whenever major deviations from planned actions are identified, remedial actions should be soon strategically planned in order to keep sustainability on track.

4. ACTION PLANS FOR PRIORITY DOMAINS

4.1. PRIORITY DOMAIN #1: REGISTRIES OF LIVING ORGAN DONORS FOLLOW-UP

The aim of this activity is the improvement of MS data collection and information systems on living organ donation through the provision of recommendations for the design and management of structured living donor registries and through setting down a model for supranational data sharing.

The activities were divided in 3 stages:

- **Stage 1**: Description of existing national and international living donor registries, including information on the collected variables and on the governing, operational and technical rules applied.
- **Stage 2**: Development of recommendations for developing a national living donor registry, defining a minimum and an expanded data set of variables, elaborating a data dictionary for variables in the minimum data set and specifying governing, operational, and technical rules.
- **Stage 3**: Design of a model for international data sharing through setting the basis for a European registry of living donor registries (RoR), this including an analysis of the legal constraints and requirements, the development of a protocol, data modelling as well as governing, operational and technical requirements. This model is now being piloted with 9 participating countries.

The main goal of this WP was first of all to have a clearer picture of the different situation of donor registries already in place in participating countries (variables taken into account and how they are managed), in order to allow a comparison among them and possibly carry out some benchmarking actions.

This was meant to serve as an input especially for those countries that do not have registries in place yet, since the set of recommendations derived could be of great help in starting a registry de novo whereas countries where a registry is already running could benefit from knowing how this is dealt with in other countries. Furthermore, this WP would allow harmonizing registries and practices in place and set down a model for sharing data internationally among the existing registries in place.

Dutch Transplantation Foundation – DTF (The Netherlands)

A. Rationale

The Dutch Transplant Foundation (DTF) already facilitates data collection, using a specific living donor follow-up module of the Dutch Organ Transplantation Application (NOTR). The NOTR is developed, hosted, maintained and managed by the DTF. The Dutch transplant centres are the owner of the data. They complete the living donor's follow-up data periodically. The data from the NOTR are frequently used for (statistical) analysis as well as (scientific) publications.

The living donor follow-up data that are currently collected in the NOTR are not equal to the ACCORD data set. It is the intention to implement the ACCORD data set and data dictionary as this will also be recommended in the *Draft Resolution CM/Res (20xx) of the Committee of Ministers to MS on Establishing harmonizing national living donor registries with a view to facilitating international data sharing*.

Participation in a future international follow-up RoR depends on the way the future registry will be built, hosted, organized, managed, financed, etc. Of course, recommendations on a future sustainable Registry of Registries will be done in the final report of WP4.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Analysis of the implications and consequences for the Dutch transplant centres and the NOTR of implementing the ACCORD data.	DTF	Mid 2015
Depending on this analysis, an implementation plan can be written. If it turns out that implementing the ACCORD WP4 data set and data dictionary is not a suitable or even an undesirable solution, it could be decided that no implementation will take place at all.	DTF	Depending on the implications and consequences
Actual implementation depends on the above mentioned steps.		TBD

C. Resources

- Final data set and data dictionary as described in the final piloted ACCORD WP4 recommendations.

- Consent from the Dutch Kidney and Liver Advisory Committees on adjustments in the data set and data dictionary. These Advisory Committees consist of representatives of the Dutch transplant programs.
- Human resources to describe the implications and to write an implementation plan.
- Human resources (IT, project management) to implement the ACCORD WP4 data set and data dictionary.

D. Potential Challenges and Obstacles

- Lack of consent from the Dutch Kidney and Liver Advisory Committees on adjustments in the data set and data dictionary. Without their consent and their efforts to collect the donor's follow-up information or not according to the standardized data set and data dictionary, the ACCORD data set will not be adopted and no (international) data sharing can take place.
- Lack of Human Resources to perform the necessary actions.

Contingency plan

- Early communication about the actions that are currently being performed within WP4 and the possible advantages of implementing the ACCORD data set and data dictionary, enabling international data sharing.
- Early awareness of the time and resources that are necessary to perform the actions. This will help to anticipate and manage the available human resources.

Agence de la biomédecine – ABM (France)

ABM experts dedicated to the WP4 contributed to discussions during meeting, decision making, provided guidance and recommendations for the WP4, and gave feedback to all drafted documents that were sent. At the beginning, it was planned to only deal with kidney but since discussions were most advanced, ABM agreed for the data set and data dictionary for liver to be assessed as well and actively contributed to it.

Regarding next steps and sustainability, ABM has actually already everything in place, the only item ABM does not have is the one concerning donor Ethnicity and in accordance to French uses, it shall not be implemented.

Ministry of Health and Social Welfare of the Republic of Croatia – MOHSW (Croatia)

A. Rationale

A Croatian living donor registry is essential for monitoring short- and long-term effects of organ donation on donor health. Croatia will build national transplant registry, part of which will be a living donor registry.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
In order to establish a national living donor registry, Croatia has started the process of upgrading the existing deceased donor registry to include also living donor data. This registry will become part of the National Transplant Network database. Datasets will be based on ACCORD WP4 recommendations. The National Transplant Network database already contains medical data from deceased donors and will also serve as a platform for building-up a comprehensive Croatian Transplant Registry.	The Ministry of Health is providing coordination and the funding for this project and will manage the Registry.	The Croatian Transplant Registry should be ready by June 2015.

C. Resources

Funds needed to carry out the action steps described above are secured in the budget of the Ministry of Health.

D. Potential Challenges and Obstacles

Croatia has to build a national living donor registry. Since the deceased donor registry is already present, it should not be difficult to upgrade it to include living donor data. The main challenge will be to integrate (to build an interface) it with the information systems of donor hospitals, in order to avoid as much as possible manual data entry.

Contingency plan

A series of workshops with possible providers of IT solutions and all relevant stakeholders has already begun to find the solutions for registry build-up, and its integration with hospitals IT systems.

Ministry of Health - MOH (Cyprus)

A. Rationale

Despite the fact that Cyprus had not directly taken part in this WP, Cyprus has already developed a registry for the annual systematic collection of clinically relevant data from living organ donors and their outcomes. Data from the single Transplant Centre in the Country are reported to the Cyprus Transplant Council (the authority with regulatory and licensing powers). The creation of such a registry has been enshrined in the Law since 2012 for the benefit of gaining the trust of the public in living donation and the protection of the living donor in general.

The National Living Donor Dataset of variables collected in Cyprus has already adopted the draft dataset formulated for the purposes of the ACCORD project in order to maintain the potential for facilitating future international data sharing in this context.

B. Action Steps for Implementation

As Cyprus has a single Transplant Centre and a single regulatory body, it would be simple and fast to coordinate the adoption of an International Dataset of *variables to be kept based on the initiatives of the ACCORD project.*

Action Steps ***(How will you get to where you want to be?)***	***Responsibility*** ***(Who will make it happen?)***	***Timeframe*** ***(When will it happen?)***
Wait for a final agreement on the ACCORD dataset of variables	ACCORD	TBD
Adopt the Dataset of variables	Cyprus Transplant Council	TBD
Submit the new Dataset to Nicosia General Hospital for adoption	Nicosia General Hospital (The Transplant Centre)	TBD

C. Resources

There is no need for allocating further resources as Cyprus has already set up the framework for this and adoption of any changes in the dataset can be instituted within a month of an International Agreement.

D. Potential Challenges and Obstacles

Not expected

Deutsche Stiftung Organtransplantation – DSO (Germany)

A. Rationale

There is a call for a national transplant registry in Germany in order to improve quality and patient safety. The DSO also recommends the establishment of such a registry. The plan is to establish a system that pools different data sets, many of which are already collected by different organizations involved in organ donation and transplantation. Moreover, the registry should not only be focused on deceased donation, but also include living organ donor follow-up. The establishment of such a registry will not only improve the quality and safety of care of the transplant recipients and the living donors, it will also be a key element of ongoing efforts to improve all aspects of the organ donation and transplantation process at a national level. It is expected that the transplant registry will strengthen public trust into the transplant system.

The call for a national transplant registry has been included as priority action in the government's coalition agreement of 2013.

The results of the ACCORD project can be used for the promotion of a national transplant registry in Germany.

The major goals of introducing a national transplant registry are:

- Improving overall quality and patient safety.
- Pooling of data which are already collected.
- Establishing trust by improved transparency.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Actual implementation of the registry	German Ministry of Health, supported by different organizations, including DSO	n/a
Support of a rapid implementation	DSO	ongoing

C. Resources

Information needed: Expected outcomes, state of the art in other countries (best practices), and knowledge about (inter-)national legal requirements.

D. Potential Challenges and Obstacles

The decision on a national registry has to be taken by several parties.

Health Service Executive – HSE (Ireland)

A. Rationale

Ireland is in the process of creating a national registry of living organ donors follow – up. The criteria to comply with the international registry and compatibility are being assessed.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Review current system for dialysis to extend to living donor follow- up.	Living Donor Program, Ireland	TBD
Attend LIDOBS conference to learn more about international registry	ODTI, Living Donor Program, Ireland	November 2014

C. Resources

The living donor registry costs are funded by the Living Donor Program.

D. Potential Challenges and Obstacles

- Motivating the living donors to return for their assessment as requested.
- Tracking the living donors that have moved.

Centro Nazionale Trapianti – CNT-ISS (Italy)

A. Rationale

CNT intends to build an Italian registry of organ living donors using the data set developed by the European ACCORD working group. The main objective is to build a retrospective and prospective database with information on all living organ donors in Italy over the past 10 years and to assess the impact of donation on their health condition.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Setting up of the software for data collection	IT System of CNT	Mid 2015
Collection of data from living donors, from 2004 onwards	Medical Area of CNT and transplant centres	1 year
Publication first report of collected data		6 months
Annual publication of the report	Medical Area of CNT	1 year

C. Resources

- List of transplants carried out from living donors in Italy since 2004.
- Cost for the software and for the data collection (foreseen about 50,000 €).
- Collaboration of the IT System of CNT and of all the Italian transplant centres is pivotal.

D. Potential Challenges and Obstacles

- Lack of complete data on the follow-up of the donors could be an obstacle also in the records of the transplant centres collaborating to the project.
- It is a complex and costly work and there might be difficulties in getting the collaboration and compliance of the transplant centers.

Contingency plan

- Involve the transplant centres in the development phase of the project.
- CNT will balance providing support with the data entry.

Paul Stradins Clinical University Hospital – PSUCH (Latvia)

Rationale

Latvia´s aim for this activity during the ACCORD project has been focusing on recommendations for developing a living donor registry. The standpoint is that an international registry would be very useful for the region, the Baltic States. However, no activities have been planned since there is no financial support in the nearest future.
However we have started collaboration with Estonian partners to establish partnership “Joint Data Base of Lung recipients and donors”.

Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Partnership at international level: Planning to collaboration with Estonia partners to establish partnership and develop joint data base of Lung recipients and donors.	Latvian Transplant Centre, Ministry of Health	Starting in 2015
Communication: both internal and external, strategic planning and periodic evaluation.	Latvian Transplant Centre, involving stakeholders (Ministry of Health)	Regularly

Resources

- Final data set and data dictionary as described in the final piloted ACCORD WP4 recommendations.
- Human resources to describe the implications and to organize workshops to write an implementation plan.
- Human resources (IT, project management) to implement the plans regarding data bases.
- Funds to implement idea about registry.

Potential Challenges and Obstacles

Establish clear procedures, to attract funds, to persuade and involve stakeholders.

Contingency plan

A series of workshops, face-to –face communication.

National Transplant Bureau – NTB (Lithuania)

A. Rationale

NTB take part in the activities of the Registry, providing data on living donors remotely

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Participation in the international RoR, once logins are provided (Lithuania has participated in the pilot).	NTB; Specialists of the Transplant Coordination Division	Under the terms set

C. Resources

D. Potential Challenges and Obstacles

Establish clear procedures for cooperation with transplant centres, so all necessary data are prepared on time.

Contingency plan

Contacting with the responsible people by phone.

Ministry for Health, the Elderly and Community Care – MHEC (Malta)

A. Rationale

- Upon input of ACCORD Project, living donor register was set up.
- Follow-up of donors was standardized and such data will also be useful for regular auditing and during accreditation visits.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Medical record form for donor follow-up needs to be endorsed by nephrologists.	Transplant coordinator	End October 2014
SOP for follow-up procedure to be prepared and endorsed by Medical Director.	Lead Nephrologist	15 December 2014
Implementation of SOP.	Nephrologists and Transplant coordinator	January 2015
Audit of follow-up activity.	Transplant coordinator	June 2015
Based on Audit to fine tune SOP and implement improvements as necessary.	Nephrologists and Transplant coordinator	September 2015

SOP: Standard Operating Procedures

C. Resources

Resources non needed.

D. Potential Challenges and Obstacles

Running late due to recent appointment of Medical Director.

The Norwegian Directorate of Health – HDIR (Norway)

A. Rationale

Norway aims at improving the already existing living donor registry in the country and that of Scandiatransplant, while taking care that a possible European RoR does not create difficulties for the functioning and national control of the existing registry and for the collaboration within Scandiatransplant.

B. Action Steps for Implementation

In each step of the process, close contact with the transplant centre in Norway, Scandiatranplant and the National Society of Nephrology is required.

Making the RoR a practical tool for an overview of the living donation activity in Europe and especially for the long-term follow-up of donors.

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
For the function of local and national living donor registries the most important is to have clear regulations of the responsibility and a close follow-up of how well the registry is functioning. Without well functioning local/national registries, a RoR will not be possible.	National Health Authorities in collaboration with the transplant centres	

C. Resources

The creation of well-functioning local/national registries takes great resources at a local and national level. The resources for the functioning of a RoR must be evaluated after the pilot study.

D. Potential Challenges and Obstacles

The main challenge is to create motivation, logistics and continuing surveillance of the input of data into the local/national registry, especially of long-term follow-up.

Poltranslant (Poland)

A. Rationale

To complete Polish living donor registry.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
To adjust the data set primarily collected in the Polish living donor registry to the ACCORD specifications.	Poltransplant	End of 2014
To complete the data for early and long-term monitoring of donors already registered (from 2007).	Poltransplant and living donor centers	End of 2016
To complete the data collection for all recorded data (years 1967-2006) living donations – about 500 cases.	Poltransplant and living donor centers	End of 2017

C. Resources

- **Resources:** A web-net specialist funded through the National Program for Development of Transplantation Medicine will be hired. To involve transplant coordinators from living donor centers.
- **Information:** Donor case histories from years 1967-2014.
- **Costs:** Not calculated yet.

D. Potential Challenges and Obstacles

To involve people with no extra payment.

Contingency plan

- Funds from grants.
- Free of charge work of students and nurses or doctors who are going to do their msc or phd diplomas.

Instituto Português do Sangue e da Transplantação, IP (Portugal)

A. Rationale

Living donation registries in Portugal are set as hospital registries, at a transplant center level; data is reported to IPST and uploaded in the Portuguese Transplantation Society database.

The National Registry for Transplantation is a nationwide project and a legal obligation since the EU directive transposition; this registry is in development since 2014 and, in what living donation is concerned, is being planned according to previous European projects, such EULID and EULOD, and future recommendations from ACCORD, regarding the registry of registries, as well as the LIDOBS recommendations.

B. .Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
SOPs	IPST,IP	2015
Institutional development of nationwide registry	IPST,IP	2015
Testing	IPST,IP	Midterm 2015
dissemination	IPST, Ministry of Health	End term 2015
Interchange of data(international)	IPST,IP	2016

C. Resources

- LIDOBS recommendations for compatible databases.
- Cost supported by Ministry of Health budget.
- Definition of an international glossary supporting SOPs.
- Involve transplant centers in living donation registryPotential Challenges and Obstacles.

D. Potential Challenges and Obstacles

Transferring local database to a national registry.
Health professionals' adherence to a new registry.
Achieve high rates of data completeness.
Being this the first national registry to be implemented, we expect that it will need a full year for training and users' adaptation, as well as some development that may be needed according to the users' needs.

Contingency plan

To involve health professionals in early testing phases supporting the decisions for future development.

Considering that the National Transplant Registry is a legal obligation, the financial support due to each transplant center for each transplant performed, will be suspended in case of noncompliance with the registry and SOPs defined for this regard.

National Transplant Agency – ANT (Romania)

A. Rationale

In Romania every transplant center has its own data base with patients on waiting lists and/or transplanted and also with information from living and deceased donors. The country counts on a National Transplant Registry for patients on the waiting lists, but does not have a registry for donors. Work has already started to introduce this donor registry in accordance with ACCORD WP4 work and EULID project.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
A registry for donors will be structured using the work performed in ACCORD WP4	National Transplant Agency will structure the Registry and the Ministry of Health will provide by secondary legislation	2014 - 2016

C. Resources

- The ACCORD WP4 final structure will be needed in order to use the same structure; in this way it will be easier to upload data from the Romanian Registry to the European RoR.
- Probably financing for software and for the payment of the personnel will be required.
- Once the national registry is established, help will be needed to start uploading data from the Romanian Registry into the European RoR.

D. Potential Challenges and Obstacles

Lack of financing and subsequent lack of personnel.

Contingency plan

Proper financing by the Ministry of Health through the National Transplant Program will be tried to be obtained.

National Transplant Organisation – NTO (Slovakia)

A. Rationale

The living organ donors registry is established at the Transplant Information System Slovakia (TISS), but the reporting of follow-up is at a low level at the present time. Efforts are planned to get as much of the requested information from the hospitals which take medical care of the living donors. To participate in the international RoR with data imported from the national registry, the national form will need to be changed.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Improvement of reporting follow-up data from hospitals.	NTO in cooperation with hospitals	Till mid 2015 and afterwards
Changes of the Transplant Information System Slovakia forms to correspond with international registry.	NTO	June 2015

C. Resources

- Information is required on the final structure of data in the international RoR after the project is finished.
- The costs for TISS changes will be covered by the National Transplant Organization budget, which depends on the Ministry of Health.
- Close cooperation with the hospitals is needed.

D. Potential Challenges and Obstacles

Reporting the data is the major problem. In the last year, the collection of follow-up data of transplanted patients has improved but there are limited resources in hospitals and there is a need to find a way for financing people who provide the data. The living donor report faces the same problem but the living transplantation activity is lower than that from deceased donors.

The changes in data structure of complex information system is always connected with the some problems: costs, validation of the changes and the necessity of training the users of a new layout on the web.

Contingency plan

To improve the budget for NTO from the Ministry of Health to upgrade the central information system (TISS).

To improve the communication with the hospitals, looking for resources for the people who are providing the data and for their training.

Organización Nacional de Trasplantes - ONT (Spain)

A. Rationale

Spain has already developed a national registry for the systematic collection of data related to the baseline characteristics of living organ donors and their outcomes in the short, mid and long-term. Data are regularly reported by centres to the national registry, hosted and managed by ONT, which degree of completeness is improving each year. The results provided by this registry are expected to extend living donation activity and to improve the knowledge of health-care professionals and of the population about the specificities and benefits of living donation.

Relevant to the work performed in ACCORD, it is intended the alignment of the data set and related dictionary in the Spanish registry with that agreed upon during the JA. This will also facilitate future international data sharing in the field.

Should the International RoR be established following the JA lifetime, Spain intends to participate in the said international registry.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Review of national data set and dictionary and comparison with those of ACCORD (after the pilot has finalized).	ONT	Q2-2015
Identification of required changes for alignment	ONT	Q3-2015
Presentation of required changes to the transplant centres for discussion and approval.	ONT	Q4-2015
Implementation of the required changes.	ONT	Q1-2016
Participation in the RoR (conditional to its establishment).	ONT	TBD

RoR: Registry of Registries; TBD: To be defined

C. Resources

- The first requirement to initiate the previously described action steps is the finalization of the pilot of a RoR in ACCORD. While before embarking in the said pilot there has been an agreement on a data set and dictionary for national living donor registries and for a RoR, there is a need to assess the results of the pilot, since they may derive in a modification of the initially agreed upon data set and dictionary.
- Costs and human resources needed for the action steps are foreseen in ONT´s budget and structure, as well as those related to the Spanish participation in international registries should the RoR be established.

D. Potential Challenges and Obstacles

- Main possible obstacle is reluctance of the transplant centres to adapt the data set and dictionary.
- In the event the International RoR is established, technical, organizational and governance aspects will require to be defined more precisely (expected by the end of the project).

Contingency plan

- ONT to present the results of the pilot to the transplant network to make evident possible benefits derived from international data sharing.
- ONT to present the final data set and dictionary to the transplant network as the result of an international panel of experts in the field.
- ACCORD consortium to develop further efforts in clarifying aspects of the RoR before the project ends.

Department of Health, Organ and Tissue Transplantation – NHSBT (United Kingdom)

A. Rationale

The UK Living Donor Register is well established and is part of the UK Transplant Registry database. It is acknowledged that further development is appropriate, and when such developments are made they will, as far as is possible, align with the data set and data definitions from the JA. However it is not possible to set a timescale for this as there are a number of competing IT software and hardware developments within NHSBT.

As and when the UK Registry is revised the UK would intend to submit as much data as possible to the RoR subject to acceptable governance arrangements and any other IT constraints.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Revise the data sets and definitions within the UK Living Donor Registry.	NHSBT	tbc

C. Resources

- Internal IT resources will be required, but the timescale is uncertain.
- Information required: results from WP4.
- Costs: none – utilise existing meetings.
- Resources/ assistance: it would be helpful if the data could be provided as a Power Point presentation, to support dissemination and ensure correct messaging.

D. Potential Challenges and Obstacles

As above.

Finding space on agendas/ programs may be challenging.

Contingency plan

It is unlikely that the UK would continue to submit data collected in the current format to the RoR. Continued participation is therefore dependent on revision of the UK Registry.

Put in early requests for an agenda item; early and continued engagement with relevant stakeholders.

4.2. PRIORITY DOMAIN #2: IMPROVEMENT OF END-OF-LIFE CARE PATHWAYS

The aim of this WP was to describe the usual pathways applied to patients with a devastating brain injury and to explore their impact on the potential of donation and on the realization of the deceased donation process across participating countries. Specific activities also aimed at developing and providing an effective rapid improvement toolkit that would be applicable in supporting modifications in end-of-life management.

As first action point, each country was asked to appoint a senior, respected ICU clinician to advise on implementing the JA, encourage and support implementation of the JA in hospitals and work with donation teams. Such appointed clinicians were established as Clinical Reference Group, supporting the design and implementation of these priority domain activities.

The activities have been developed as follows:

- **Stage 1:** In-site review of variations in end-of-life care pathways for patients presenting with a devastating brain injury at a sample of hospitals from participating MS.

- **Stage 2:** The impact of such differences in end-of-life care on the potential for donation after brain death and after circulatory death, and on the realization of the deceased donation process was explored and barriers to donation were identified.

- **Stage 3:** Proven change management tools were introduced to enable modifications that would promote donation within existing pathways at participating countries. This included training an expert for each associated partner, supporting clinicians to identify achievable interventions and use the methodology to change, supporting participating countries to implement change in 56 selected hospitals, monitoring and evaluating effectiveness of changes, agreeing modifications to changes in care practice to be extended and writing up a methodology for further implementation in each European Union country.

This WP has provided a focus and impetus to bring together the donation and critical care communities, to share their experiences and make changes to practice to ensure that the option for organ donation is preserved. More specifically the work developed led to:

- 66 critical care clinicians and Donor Transplant Coordinators attending training sessions on the service improvement methodology.

- Networking opportunities between critical care and donation teams, in particular through the Clinical Reference Group, training days and feed-back meetings.

- Critical care clinicians and Donor Transplant Coordinators in 56 hospitals across the EU submitting and implementing improvement plans to address barriers to organ donation within their institutions.

The first and most immediate result of this WP is that each participating country had to evaluate its own local situation with respect to the connection between the ICU and the donation.

The second result was that each country had the opportunity to know and to compare other realities of the partner countries, and use the experiences of other countries such as best practices, adapting them to their own national situation.

The developed service improvement model and this priority domain in general is the one where we expect to have easier sustainability plans in other European hospitals as a means for increasing the number of organ donors and to have a responsible senior clinician could serve as an input to be more in control of the national situation and to foster collaboration.

Department of Health, Organ and Tissue Transplantation – NHSBT (United Kingdom)

A. Rationale

It is intended that the improvement model and the PDSA methodology is used as an additional framework alongside other tools available as a method to implement change in hospitals who have not participated in the ACCORD JA.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Dissemination of Final Report and Toolkit to all SNOD teams and CLODs	ACCORD Business Lead	January 2015
ACCORD documents, reports and toolkit on the NHSBT ODT clinical website	ACCORD Business Lead	April 2015
Attend Regional Manager, Team Manager, Regional Collaborative and Critical Care Network meetings to discuss and feedback joint action results and to encourage use of the improvement model	ACCORD Business Lead	April 2015
Improvement Model training is part of SNOD training	ACCORD Business Lead ODT Education Team	April 2015
Sessions at the NHSBT Congress	Congress organisation committee	March 2015
Report for NHSBT Organ Donation Senior Management Team	ACCORD Project Manager	November 2014
Include information about ACCORD in the NHSBT Associate Medical Director Bulletin	ACCORD Project Manager	April 2015
Submit abstracts to the British Transplant Society Congress	ACCORD Working Group	March 2015
Send Final Report and Toolkit to UK Professional Societies (Intensive Care Society, Society of Emergency Care Medicine)	ACCORD Business Lead	January 2015

SNOD is Specialist Nurse Organ Donation, CLOD is Clinical Lead Organ Donation and ODT is Organ Donation and Transplantation which is part of NHSBT

C. Resources

- **Information required:** UK is working to develop a toolkit, which will support the roll-out of learning from WP5. This includes a toolkit, templates and slides that can be shared with and used by others with no involvement in ACCORD and no prior knowledge of service improvement methodology.

- **Costs/ resources:** The resources outlined above will support implementation in the UK and elsewhere. Existing resources and funding to support on-going implementation beyond the ACCORD timescales will also be used, through providing training sessions etc. for the relevant stakeholders.

- **Assistance required:** Ideally an Improvement Service Manager would be needed, if funding is available to ensure the Improvement Model becomes embedded practice in the UK.

D. Potential Challenges and Obstacles

Improvement Model is not valued and is not implemented by clinical teams.

Contingency plan

Use SNODs and CLODs already trained in the Improvement Model as advocates and Champions for the PDSA methodology.

Ministry of Health and Social Welfare of Republic of Croatia – MOHSW (Croatia)

A. Rationale

Split:

The University Hospital Split has 1,800 active beds on two locations and 10 ICU's. Beds are inadequate in location where are departments of neurology, pneumology, neurosurgery, abdominal surgery, trauma surgery and thoracic surgery. Limitations of available beds in ICU have caused resistance to the intervention that was tried to be implemented among intensivists.

The average of death due to brain stroke in the Neurology Department is of 20 patients *per* month. It is impossible to transfer all these patients to the ICU. At this moment, guidelines are available with inclusion/exclusion criteria for identifying only those patients with a high likelihood of becoming donors and they are transferred to the ICU. Potential donors do not equal successful organ transplantation and it is impossible to predict how many of the missed potential donors would have ended up brain dead. The major goal is continuing with the development of a Stroke Unit until it reaches the level of Potential Donor Care that is present in the ICU. Another goal is to include EEG and Evoked Potentials as ancillary tests besides transcranial doppler and cerebral panangiography. Ancillary tests are obligatory in Croatia due to the whole brain death concept.

CHC Zagreb

Main goals are: motivating ICU staff for early detection and referral of a patient with a devastating brain injury, better communication with ICU staff, education and raising awareness of organ donation among hospital staff and implementation of Standard Operating Procedures for the timely referral and optimal management of neurocritical patients.

B. Action Steps for Implementation

Split

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Stroke Unit Development	Ministry of Health Hospital's principal Department of Neurology	3-4 years
Guidelines: - Admission to CCU - Ancillary tests	DTC	done
Panel of experts, DTC (review potential case)		1-2 months
EEG and EP (ancillary tests	Department of Neurology	1-2 months

CHC Zagreb

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Education of staff		
Employment of new staff	Hospital	unknown
Responsibility measures for doctors on duty who do not contact a hospital coordinator		1 month
Extra bed in ICU for potential organ donor		

C. Resources

Split

- **Stroke Unit:** lack of respiratory machines, lack of nurse training, lack of neurologists involved in intensive care.
- **Ancillary tests:** lack of portable EEG and Evoked Potential devices.

CHC Zagreb

- More medical staff (doctors and nurses).
- Extra bed in ICU for potential organ donor.

D. Potential Challenges and Obstacles

Split

- Education of nurse staff in Stroke Unit and neurologist is time consuming process and results could be seen after years of implementations. Despite in-hospital guidelines there are problems with "clear call for action" due to personal relationship and lack of awareness for donation after brain death.
- Respiratory machine's supply for Stroke Unit is great financial issue according to economic situation in our country.

CHC Zagreb

- Lack of motivation among the staff.
- Lack of referral of a patient with a brain death to hospital transplant coordinator.
- Lack of staff for additional work when there is a possible organ donor.
- Lack of information about patients at Department that died but did not get to ICU.

Contingency plan

Split: Hospital donor transplant coordinator:

- Development of a local educational strategy.
- Offer formal and informal teaching to staff (stroke unit, CCU).
- Enable discussion regarding planned clinical initiatives.
- Be available via cell phone on a 24-hours basis.
- Be available at all times to provide any advice regarding patient suitability for donation.

CHC Zagreb: Employing new staff in ICU.

Tartu University Hospital – TUH (Estonia)

A. Rationale

Improvement of potential organ donor detection and management in all central and regional hospitals.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Renewal of the legislation for handling cells, tissues and organs.	Ministry of Social Affairs Parliament of Estonia	September 2014 - December 2014
Designation of the national transplant organization for Estonia.	Ministry of Social Affairs	January 2015
Licensing of all central and regional hospitals for the donor organ procurement.	State Agency of Medicines	January 2015 – June 2015
Implementation of the systematic review of deaths in ICUs to assess the identification of potential organ donors.	National Transplant Organization	July 2015 – December 2015

C. Resources

The draft of new law for handling and transplantation of cells, tissues and organs has already developed in close cooperation of medical, bioethical and legal advisers. Now it is necessary to inform the public and achieve a political and financial acceptance. The estimated cost for all planned changes is approximately 800-900 thousands euros *per* year.

D. Potential Challenges and Obstacles

As donation and transplantation are very sensitive topics from the social perspective, a public debate about the need for changes can last a lot longer than expected. It is also difficult to predict, how quickly and how successfully it will be possible to convince policy makers and funders to understand the importance of planned changes.

Contingency plan

A very strong collaboration with medical community, patient societies and decision makers is needed.

Agence de la biomédecine – ABM (France)

Regarding WP5, ABM has participated to WP meetings and to the Clinical Reference Group and involved two hospitals actively coordinating a procurement network of several surrounding hospitals. Approval from a local ethics committee has been obtained. Both procurement teams have been trained by the ABM representative of the Clinical Reference Group so as to be ready for 1st March 2013 to start including patients in the ACCORD WP5 database. Both filled the various initial questionnaires, and contacted the hospitals which have subsequently participated to the study. Both hospitals entered the requested number of donors in the database in the requested period, bringing very valuable data for the study. ABM representative of the Clinical Reference Group followed their work closely during the 6 month inclusion period. The key donation personnel of both hospitals participated to the PDSA training organised in London in October 2013, and are preparing a strategy to implement selected conclusions of the study.

Regarding the PDSA work, the French Cristal Action application software (our PDSA equivalent national tool) is already quite complete. So before starting the ACCORD Joint Action, ABM had already implemented a specific tool that goes further than PDSA work and which is more adapted to our needs and system.

Nevertheless, WP5 was completed a really worthy work and its findings strengthened our views and positions and also highlighted the importance of communication.

Concerning sustainability, ABM started exactly the same process in 2009, with a similar methodology from bottom up at the beginning (from local to national), with a national- wide working group of all key actors:

- Discussion with key donation personnel and from ICU and emergencies Units *etc.*, and notably took care that donor coordinators would not have to fill in this equivalent of your work software and the donor registry as well.
- Software was ready and launched as 1/01/2010
- Likewise ABM started with a few hospitals involved (30 HPs).

ABM also followed the same methodology from bottom to up at the beginning because the reflection started with key operational actors on site, and with volunteer hospitals, but also from one point of view from top to bottom since a national agency also have to communicate on tools to be implemented and to stimulate hospitals participation

Deutsche Stiftung Organtransplantation – DSO (Germany)

A. Rationale

Continued education offered by DSO in order to train medical staff in hospitals. Goal: Improving the identification of donors as well as the family approach. Refining general processes.

B. .Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Direct support available 24 hours a day.	DSO, together with hospitals	ongoing
Training offerings for medical staff (regarding family approach).	DSO, together with hospitals	ongoing
Ongoing analysis of hospitals' needs (regarding support or education).	DSO, together with hospitals	ongoing
Elaboration of a concept for a benchmarking project.	DSO	2014/2015

C. Resources

N/A

D. Potential challenges and obstacles

Minor willingness of hospitals to cooperate due to limited resources, such as finances and personnel and a decrease in trust (medical staff).

Contingency plan

Ongoing communication.

Hellenic Transplant Organisation – HTO (Greece)

A. Rationale

The project gave the opportunity to the participating hospitals to be able to expand their possibilities and to have measurable results of their performance and of the services provided on the organ donation field. The project also gave the opportunity to the hospital personnel to be trained on issues which involve the detection and management of potential organ donors in the framework of "end-life practices" in order to record the reasons why potential organ donors are not detected and the beginning of the donation process is prevented within the hospital.

Through the data collected of the hospital reality and this helpful project, Hellenic Transplant Organization was able to realize the weaknesses of the system providing donors in Greece. HTO's major goal is to adopt any practices/methodologies/policies that will improve the end-of-life care pathways in Greece. Collaboration at all levels is the key to ensure donor detections and increase donation rates.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Supply ICUs with more beds and staff.	HTO / Ministry of Health	unknown
Establishment of donor identification teams into hospitals (please note that there are local donor coordinators in each ICU but still there are not specific identification teams).	HTO/Ministry of Health and Hospitals	unknown
Introduce a communication network among the hospital departments (ICU, neurosurgery, emergency departments, cardiology etc).	the related hospital	May 2014
Dissemination of the project possibilities through all ICUs of the country.	HTO	2014-2016
Creation of written protocols for donor detection and improvement of existed protocols for donor maintenance and support.	HTO in collaboration with ICUs	2014-2016
More training courses for coordinators. and incentives for attending them.	HTO	2014-2016

C. Resources

Greece will use the existing available financial and organizational resources in order to carry out the action steps described above. It would be useful for Greece to participate in European programs like Horizon, which would help countries to implement the needed action steps immediately, efficiently and effectively mainly through their financial assistance.

Finally, any further needed information for the implementation of the steps can be obtained through the ICUs particularly.

D. Potential challenges and obstacles

Through the study of the hospital reality and this helpful project, HTO has detected the weaknesses of the system providing donors in Greece and some of the main points discovered, could be summarized as follows:

- Potential donors can be found in a lot of departments or clinics outside the ICUs.
- Health Professionals are not sufficiently and well trained on the processes concerning the detection and management of an organ donor.
- There are not donor detection teams in Hospitals (not even into the big hospitals of the country).
- There are not written standard operation procedures and as a result health professionals do not manage in the same manner all the incidents.
- Mechanical ventilation of brain dead people continues until the cardiac death occurs and as a result beds in ICUs are occupied without reason. Moreover, organ donors are not utilized because relatives do not understand the meaning of brain death.
- In most cases organ donation takes place thanks to some doctors' awareness or after family pressure and it is not a standard procedure in the ICUs or generally in hospitals. It is a voluntary and not an obligatory task of doctors. Nevertheless, article 32 of law 3418/05 "Code of Medical Ethics" establishes the doctor's obligation to encourage transplantation for therapeutic purposes, providing suitable information to families of possible donors and cooperating with the national authorities of organ donation and transplantation.

The main conclusion is that lack of transplants in Greece is not due to lack of possible donors but mostly due to failure of the system of not turning many possible donors to real organ donors. The key point to successful organ donation is the best and most effective cooperation between the hospital departments and the development of an efficient and effective organizational system among all the stakeholders.

Contingency plan

At the moment, the main problem to adopt developing steps and to avoid or minimize obstacles is mainly related to financial and organizational issues. Collaboration among the medical society, the competent authorities and the decision makers plays also an important role in the identification and solution of many problems.

Hungarian National Blood Transfusion Service – HNBTS (Hungary)

A. Rationale

Implementation of a retrospective brain death audit questionnaire in every Hungarian hospitals where in-house coordinators employed by HNBTS.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Involvement of 10 new hospitals per year into the Hungarian Quality Improvement Program (Finally the program will includes 40 participant hospitals).	HNBTS	2016
First evaluation of the brain death audit questionnaires from participant hospitals.	HNBTS	January 2015

C. Resources

- The Hungarian Quality Improvement Program exists since 2013, the adoption of the ACCORD brain death audit questionnaire did not mean financial burden.
- Currently in 2014: 19 hospitals involved in the program - from these institutes 2 hospitals participated in the activity of WP5.

D. Potential challenges and obstacles

- Financial background is not ensured yet for 40 hospitals.
- Maintaining the continuous motivation of participant in-house coordinators.

Contingency plan

- HNBTS is looking for possible solutions ensuring the financial background of the program.
- Appropriate financing can be the tool of motivation.

Centro Nazionali Trapianti – CNT-ISS (Italy)

A. Rationale

In Italy, organ donation after brain death declaration (DBD) has achieved excellent results that, unfortunately, are still insufficient to meet the increasing transplantation requests. The cornerstone of the donation process is the potential donor identification: a National Registry of Deaths with Acute Cerebral Lesions was implemented in 2006 and proper indicators are used to measure and compare the process efficiency among different regions. Huge differences among Regions in comparison with the National benchmark [150 pmp Acute Cerebral Lesions in Intensive Care Units (ICUs) with 60% brain death declarations] have been detected. Thus a high number of "silent brain deaths" may be suspected, being at the same time the most important critical factor and relevant target of improvement, particularly in regions where the donation rate is low.

A close cooperation between intensivists and coordinators is mandatory. In the ICUs the inadequate awareness of the intensivist role in the donation process is the main barrier, in spite of new reasons of increased interest and direct involvement:

- the new clinical and technical scenarios leading to death in ICU;
- the relevant changes in the epidemiology of acute cerebral lesions, mostly regarding elderly stroke patients;
- the effects of high quality intensive care on organ function and recovery;
- new possible strategies of organ preservation before and after organ retrieval;
- the severe shortage in ICU personnel and resources;
- the end-of-life criteria and policy when futility of treatment becomes evident.

Donation after cardiac death (DCD) occurring after uncontrolled circulatory arrest has been implemented in Italy only by a pilot study, with good results but limited in the number of donors. This tailored experience should be now re-evaluated by a national multidisciplinary committee to overcome the cultural and organizational barriers.

In Italy, age, etiology and timing of death may influence the subjective attitude of declaring brain death (BD) in the absence of clear and homogeneous policies; remarkable regional differences in the probability of BD declaration call for budgeted educational support and improved organization. Thus, critical factors leading to the identification of potential organ donors, i.e. the capacity of declaring BD in all the patients fulfilling BD criteria irrespective of age and etiology, could be captured in the best performing regions and reproduced throughout the country as clear target of the entire hospital, including all the personnel in the critical care area treating acute cerebral injured patients.

Nowadays, the possibility of increasing DBD and shortening the waiting list depends on admission to ICU of patients with acute devastating cerebral lesions and attitude toward BD declaration irrespective of etiology and age. Huge differences in donation rates among regions may derive from unexpected differences in the number of Acute Cerebral Lesions and BD declarations in ICU, reflecting different models and development of acute patient management.

The dissemination of the best affordable model of clinical management, that includes the identification of DBD and DCD potential organ donors in neuro-critical care guidelines and educational programs, will improve both the therapeutic results and the donation potentiality. Thus, organ donation would become an added value of good quality in the critical care of patients with acute cerebral lesions.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Definition of criteria and methodology for controlled DCD in Italy	Scientific societies and CNT	2014-2015
Active uncontrolled DCD programs in selected hospitals: Kidney & liver, lung	CNT & Regions	2014-2016
Pilot controlled DCD programs in selected hospitals		2015-2017
Optimization of the identification of potential DBD & DCD: new models in neurocritical area and ad hoc education	CNT & Regions	2014-2016
Implementation of quality criteria and indicators in DBD & DCD (ODECUS EU Project)	CNT & Regions	2015-2017

DBD: Donation after Brain Death; DCD: Donation after Circulatory Death

C. Resources

- Prospective National monitoring of deaths with acute cerebral lesion inside and outside the ICUs.
- Auditing of dying patients in ICUs and monitoring of end-of-life pathways.
- CNT & Regions support in education and hospital auditing.
- Methodology and experts for systematic auditing.
- Experts for ad hoc courses and dissemination of ACCORD improving (PDSA) methodology.

D. Potential Challenges and Obstacles

Most organ donors die from catastrophic brain injury after BD has been diagnosed in the ICU. Nevertheless, a great number of these patients die following a limitation of ventilatory and circulatory supports. Therefore, of the many patients who die with acute cerebral lesion in the ICU (27,490 in 5 years in Italy), far many more die with cardio-circulatory arrest as opposed to BD (60.1% vs. 39.9%). The implementation of controlled DCD programs in Italy, in spite of age limitation, might therefore generate a great number of potential donors. Hopefully, this should not result in a simultaneous decrease in DBD, as observed in other countries.

DBD and DCD programs must be pursued in a complementary model.

As suggested by the document of the French Society of Anaesthesia and Reanimation (SFAR), taking into account the actual regulations concerning organ procurement in brain-dead patients, we agree that a first useful step could be to restrict this specific way of procurement to severely brain-injured patients, once confirmatory investigations predicting a catastrophic prognosis have been performed. This suggests that the nature of the confirmatory investigation required should be formalized by Italian National Centre for Transplantation (CNT), which should help preserve population trust regarding organ procurement and provide a framework for medical decision.

Contingency plan

At present Italy is far behind other countries with respect to donation after circulatory death. Uncontrolled DCD programs should be encouraged despite the “20 minutes flat electrocardiogram” provided steps are undertaken within regional and national constraints, in selected experienced centers, and possibly within clinical trials. At moment the main obstacle to its implementation seems to be related mainly to organizational and economic aspects.

As far as controlled DCD is concerned, we think that the time has come to promote also in our country a debate among all involved subjects. Starting from the existing documents released by several Scientific Societies about the end-of-life the debate should verify the concrete possibility to share a specific program in this field. The recent experience of the French Society of Anaesthesia and Intensive Care and its Ethic Committee could represent a useful road map to be followed. Their major recommendations were: “firstly, the withdrawal of life support treatments (WLST) decision is independent of the possibility of organ donation; secondly, the strict respect of ‘‘the dead donor and organ transplantation rule’’ and the updated national guidance for the WLST”.

Organ donation after WLST will be authorized only in pilot centres with a locally agreed WLST policy including external second opinion and written transcript of the WLST decision, experienced intensive care staff, a local organ procurement coordination team familiar with DBD and DCD protocols and only in hospitals authorized for organ procurement".

On the other side, - the high grade of expertise of Italian intensive care physicians, combined with the high profile organization of the transplant network; - the protective Italian law with respect to moral issues risen by DCD programs; - the availability of new extracorporeal techniques, all constitute a promising platform for the safe and effective implementation of DCD programs in Italy.

Organ donation should be a declared target of the whole hospital with the entire critical care personnel involved in the identification of the potential donor. The donation and transplantation network can be considered a model for organization, education, safety and quality control. These advanced know-how and methodology can influence the intensive care quality, improving at the same time the appropriateness of critical care patients management and the availability of transplantable organs. These factors may lead to shared educational programs and organizational plans addressed to intensivists, taking into account results of systematic auditing of end-of-life decisions and outcomes in ICUs, Emergency departments, neurosurgical and stroke units.

Pauls Stradins Clinical University Hospital – PSCUH (Latvia)

A. Rationale

During the project, proven change management tools were introduced to enable modifications that helped to increase, promote donation within existing pathways in Latvia.

The Hospital in collaboration with the Latvian Transplant Centre has started to implement an improvement plan to address barriers to organ donation in Latvia.

During this project, actual problems have been discussed and goals in Latvia regarding organ donation have been defined. Information about potential donors have been accessed and a PDSA cycle has been undertaken. The way to improve the situation first requires informing the community and health care professionals about the importance of organ donation. This will be followed by other activities.

In the beginning of the PDSA cycle, it was evident that the tasks to undertake could not be part of a short-term plan. It should be a long term plan including different activities, a plan which Latvia is determined to continue.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	**Responsibility (Who will make it happen?)**	**Timeframe (When will it happen?)**
Joint meeting for intensive care personnel and anaesthetists from all Latvia and transplant-team.	Latvian Transplant Centre	January/February 2015 (every year)
Latvian Transplant Centre account in Social Networks – discussion panels, distribution of information.	Latvian Transplant Centre, PSCUH	Starting from November'2014
The Social campaign: publishing short video and promotion of discussions about donation in social networks. Our aim: to inform public "how to become a donor?"; to promote donation; increasing availability of organs for transplantation; to promote learning process for Latvian inhabitants. Target audience: Latvian inhabitants, possibly Baltic region. Situation in Latvia is very bad regarding availability of organs for transplantation and attitude isn't positive. It will be good and effective way how to promote learning process, to change attitude. At least people will start to think and discuss about the organ donation.	PSCUH	Starting November, December 2014

Planning to Organ Donation Day in Latvia.		Not set
Informative brochures for intensive care personnel (criteria of potential donor, transplantation etc.).	Latvian Transplant Centre	November/December 2014

C. Resources

- The mentioned activities will be implemented by the project ACCORD team and medicine Latvian Transplant Centre' professionals. Mainly financial resources for these activities will be attracted by the Latvian Transplant Centre and Pauls Stradins Clinical University Hospital.
- The short video for social campaign is financed from project ACCORD budget.
- The Government mainly supports only primary activities: operation of Latvian Transplant.

D. Potential challenges and obstacles

Lack of human resources, implementation of planned activities in low-budget conditions.

Impossible to predict the responsiveness of the media during the social campaign and the public attitude.

Contingency plan

Regular project meetings.

National Transplant Bureau – NTB (Lithuania)

A. Rationale

Doctors from Lithuania who have been participating in this working group will give consultations to other doctors from ICU. NTB in collaboration with the Ministry of Health is preparing other documents for the establishment of donation coordinators in hospitals.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
WP5 working group recommendations will be translated into Lithuanian language and when it will be taken to Lithuanian donor hospitals.	Specialist of NTB Translation will be performed by the Translation Bureau	When we will get recommendations from UK; By ACCORD timeframe

C. Resources

D. Potential Challenges and Obstacles

WP5 recommendations will be presented to the Transplant centers and donor hospitals, so human resources for organizing meetings will be needed.

Contingency plan

Doctors from Lithuania who have been participating in this working group will be consulted.

Ministry for Health, the Elderly and Community Care - MHEC (Malta)

A. Rationale

- Increased utilization of marginal deceased donors.
- Developing a non-heart beating donor program in Malta.
- Upon input of ACCORD Project, living donor register was set up.
- Follow-up of donors was standardized and such data will also be useful for regular auditing and during accreditation visits.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Creating a pathway for the utilization of marginal donors (including interacting with experts from other countries where such activity is practiced).	Transplant Nephrologists/Intensivists /Transplant coordinators	January 2015
Making a feasibility study for the introduction of NHBD.	Medical Director	January 2015

C. Resources

Resources non needed.

D. Potential Challenges and Obstacles

- Culture of uncertainty avoidance.
- Fear of failure.
- Closed community might affect patient acceptance of marginal organs.
  Overstretched resources at A&E department (for implementation of NHBD).
  Contingency plan.
- Education campaign with patients on waiting lists that a marginal organ might improve their lifestyle.
- Having a hospital clinical guideline on the use of marginal organs might mitigate fear of clinicians.

Dutch Transplantation Foundation – DTF (The Netherlands)

A. Rationale

The role of end-of-life care decisions in relation to organ donation was monitored by analyzing medical records of patients who died in a hospital with severe brain damage.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Keep on monitoring medical records of patients who were admitted with severe brain damage (DBD) and died in the hospital. Decisions made about end-of-life care and the effect on the possibility of organ donation will be analyzed.	Intensivists in the 4 hospitals that joined ACCORD WP5 and an extra 4 hospitals (within NTS responsibility - not ACCORD).	Q4 2013 Q1, Q2, Q3, Q4 2014 Q1 2015-Q4 2016
Monitoring end of life care decisions in relation to organ donation (DCD donors on ICU).	Intensivist in local hospital in co-operation with 4 other Dutch hospitals.	Q1-Q4 2015

C. Resources

There are no resources, it is just in the interest of the intensivist to learn if some potential organ donors are missed because of decisions made by other physicians.

D. Potential Challenges and Obstacles

- To keep everyone motivated in analyzing patient records.
- There are no resources to help the key doctors (intensivists). It is there one motivation that keeps them going.

Contingency plan

The outcomes of the analysis will help the discussion on end of life care decisions. The Dutch Transplant Foundation will help this discussion from a national level.

Instituto Português do Sangue e da Transplantação, IP (Portugal)

A. Rationale

Donation rates vary across national hospitals depending on end of live care practices. In order to evaluate which aspects or practices are commonly associated to lower donation rates, a national auditing program on the donation process is being implemented; this will allow the identification of which steps of the process are, possibly, in the origin of such results. Furthermore, depending on each hospital results, we will assist them in developing a PDSA cycle to improve end of live care practices concerning organ donation.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Implementation of national auditing program.	Hospital and IPST consortium	2014-2016
Work with hospitals in development of PDSA cycle.	Hospital and IPST consortium	2015-2016

C. Resources

- We will use the quality indicators developed by the ODEQUS Project, associated with the ACCORD WP 5 methodology.
- Cost are supported by IPST (auditing) and Hospital (PDSA cycle) budgets.
- Database analysis and statistical support are needed.

D. Potential Challenges and Obstacles

Challenges: positive impact of this program in organ donation and transplantation in hospitals' performance.

Obstacles: Changing mentalities and behaviour for auditing and performing and testing new procedures.

Contingency plan

Publishing data from other hospitals and its positive impact in donation rates and apply a benchmark program with defined goals and targets.

National Transplant Agency - ANT (Romania)

A. Rationale

Romania did not participate in this WP, nevertheless some activities were carried out.

Romania tries to implement the culture of organ donors in more than 50 ICU departments in the county and emergency hospitals.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
In each of these hospitals we have nominated in house coordinators (TC) and Key Donation Persons (KDP).	National Transplant Agency Ministry of Health	2012 - 2015

C. Resources

- Nomination of in house coordinators and key donation persons together with the head of the ICU department and the management of the hospital.
- Resources needed: 1000 Euros/month/hospital from the National transplant Program.

D. Potential Challenges and Obstacles

National Transplant Agency had to organize training for transplant coordinators and key donation persons and also to identify the persons non appropriate for these jobs and to replace them.

Contingency plan

National Transplant Agency organized sustained campaigns in the county and emergency hospitals in order to explain the importance and the role of the transplant coordinators and the key donation persons and to get support from the management of the hospital and of the medical staff.

National Transplant Agency organized campaigns in order to explain the pathology that can lead to brain death and how must be managed these patients.

SLOVENIJA TRANSPLANT (Slovenia)

A. Rationale

Main focus is on improving the national situation in the deceased donation program, specifically donation after brain death. A main goal e to achieve is to increase the number of deceased organ donors, increase the number of removed organs and improve donor maintenance. In order to achieve this goal, it is believed the need to update the organizational scheme on hospital level and specify roles, tasks and responsibilities of individual participants in the process. Also it is required to improve communication between all partakers on a national level, including relevant associations. It is intended to use the results of the JA ACCORD and comparison to other participating countries as a starting point to achieve these goals.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Preparation of new organizational scheme for all donor hospitals, adapted to specific situation in each hospital.	Slovenija-transplant in co-operation with hospital transplant coordinators and persons in charge of quality and safety on a hospital level	By end of 2016
Implementation of national educational scheme in the field of organ donation.	Slovenija-transplant with responsible experts involved in donor and transplant activities	By end of 2017
Updating national guidelines on donor maintenance.	Slovenija-transplant with experts from related fields of work	By end of 2017
Updating brain death determination protocols.	Slovenija-transplant with experts from related fields of work	By end of 2016

C. Resources

- Human resources: Slovenija-transplant team in cooperation with experts from the related fields and all responsible competent individuals in Slovenia involved in donor program and transplantation activities.
- Technical assistance and resources: provided by Slovenija-transplant, i.e. providing meeting venue, performing organizational tasks, conducting meetings, informing all involved parties, preparing materials, editing,…

- Financial resources: Slovenija-transplant will make a reservation of funds from governmental budget and other sources.

D. Potential challenges and obstacles

Task: Preparation of new organizational scheme for all donor hospitals:

- Lack of experienced personnel.
- Motivation of involved personnel.
- Rationalization of national health system has been announced, which can compromise our plans due to cutbacks in personnel and working hours.

Task: Implementation of national educational scheme in the field of organ donation

- Progress depends on the support of Medical Chamber of Slovenia and Slovene Medical Association - new educational scheme is pending acknowledgement and formalization in the framework of national education system.
- Human resources – difficulties in finding skilled professionals in the field who will be willing to co-operate.

Task: Updating brain death determination protocols

- Difficulties due to different approaches around the world. Current national protocols are well accepted but updating is necessary. We expect different interpretations from experts of various medical specializations.
- Delays due to additional work of the experts needed

Contingency plan

Slovenija-transplant is a national body well experienced in facing challenges and overcoming various obstacles. We continuously look for solutions and alternative plans. Our role is leading the process, supporting and connecting all involved parties. We will take care of motivation and involve more professions and appoint additional experts where necessary. In case of lack finances we will activate our resources and seek for additional sources of funds.

Organización Nacional De Trasplantes – ONT (Spain)

A. Rationale

The methodology applied to evaluate end-of-life practices relevant to organ donation and the PDSA approach in ACCORD has been considered useful by the Spanish donation system. Spain intends to replicate the methodology with a large number of Spanish hospitals (n=70) voluntarily participating in what has been named ACCORD-Spain.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
National protocol approved by the NTC.	ONT + NTC	March 2014
Organization of a National CRG.	ONT	April 2014
Review questionnaires and adapt to the national needs.	ONT + CRG	June 2014
Create a web-based highly secure registry for data collection in Spanish.		August 2014
Prepare project documentation.	ONT	June 2014
Invitation to hospitals (through hospital managers).	ONT+ NTC	August 2014
Approval by local Ethics Committee.	Hospitals	September 2014
First period of data collection.	Hospitals	November 2014-April 2015
Analysis of data.	ONT	April 2015-May 2015
Training in PDSA.	ONT	May 2015-September 2015
Development of PDSA projects.	Hospitals, supported by ONT &CRG	May 2015-October 2015
Second period of data collection.	Hospitals	November 2015-April 2016
Analysis of data.	ONT	April 2016-May 2016
Review of the PDSA plans.	Hospitals, supported by ONT &CRG	June 2016 – July 2016
Final report with recommendations.	ONT + CRG	September 2016

CRG: Clinical Reference Group; NTC: National Transplant Committee

C. Resources

- Understanding the specific information needed to identify areas for improvement in deceased donation is a preliminary step. This has been accomplished through the creation of a Clinical Reference Group composed of three intensive care professionals who actively participated in WP5-ACCORD, on behalf of Spain.
- Costs are required for the web-based platform and the training. These will be covered by ONT national budget (web-based platform) and by ONT ACCORD budget (PDSA training for hospitals). ONT team has assumed the activity as a national project to facilitate further improvements in the process of donation after death.

D. Potential Challenges and Obstacles

- Large number of hospitals participating in ACCORD-Spain (n=70) makes coordination complex.
- Hospitals to engage seriously with data collection, PDSA plans, implementation of cycles and second data collection required for evaluating effectiveness of implemented plans.

Contingency plan

- ONT team composed to address the specific needs of a large scale, long-term duration project.
- ONT compromise to continue supporting and funding the project.
- Continuous contact of ONT with hospitals to maintain engagement and enthusiasm.
- Support by the National Transplant Committee where regional Transplant Offices are represented and will be acting as liaisons with hospitals.

4.3. PRIORITY DOMAIN #3: TWINNING ACTIVITIES

General Domain Rationale

This activity aimed at implementing practical collaborations for the transfer of knowledge, expertise or tools in specific areas related to *Directive 2010/53/EU* and the *Action Plan on organ donation and transplantation*, based on comprehensive and *ad hoc* protocols. This WP is also providing recommendations for future twinning initiatives.

MS (MS) were called for participation and came forward as paired or alone, and then relied on WP leader for matchmaking. A brief overview of twinning sub-program of each candidate was submitted. Sub-programmes were reviewed by WP leader and a selection was carried on by the ACCORD WP leader consortium. Then selected candidates developed and refined their programmes including actions and a budget plan. The Twinning programmes selected were:

- France supporting Bulgaria on structuring the organ procurement system at regional and national level, improving the monitoring and evaluation system on organ donation and transplantation activities and completing the training of the paediatric kidney transplantation team.
- Italy supporting Cyprus, Czech Republic, Lithuania and Malta on setting up a national Authorisation and Audit system for transplantation centres, including a training course for auditors of transplant centres.
- The Netherlands supporting Hungary setting a national training program for abdominal multiorgan retrieval targeting junior surgeons.

Twinning activities were designed on the basis of the needs of the supported country, and sustainability of launched actions had first of all to be evaluated at the level of involved countries, yet sustainability of such experiences could also reside in situations where countries could benefit from already implemented actions that could turn out to be transferrable in their own country due to similar needs. Such assessment is left to the single evaluation of associated partner organisations.

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Agence de la Biomédecine – ABM (France)

As leader of twinning activities, the Agency of Biomedicine is the first to be aware of potential tools developed under twinning activities which could be used by other MS. As a consequence, the Agency of Biomedicine bought some connections (40) for the Abdominal Multiorgan procurement E-learning tool that was translated from the Dutch twinning partner. This E-learning tool has been translated to English and is now available for all MS and running under PC, Mac, tablets and all browsers. This E-learning in abdominal multiorgan retrieval for surgeons already started to be used in France: 6 surgeons were trained in September 2014, and 12 more surgeons will be trained by the end of 2014, Next year (2015) 100 connections will be available for French surgeons.

As a complement, the Agency of Biomedicine is investigating the possibility of developing a complementary specific practical but an advance course for senior surgeons (hands-on session) in collaboration with the Hungarian dedicated collaborator involved in the twinning. Agency of Biomedicine is planning for this course to be set in 2015. To this end, a meeting with the Hungarian collaborators in Budapest was set in October.

CNT (Italy)

A. Rationale

Under this action Italy has been the leader of a multiple twinning, involving bilateral twinnings with Cyprus, Malta, Lithuania and Czech Republic. The aim of the single twinnings was however all the same, that is supporting the four countries in developing a quality assurance system for transplant centres.

This multiple twinning has its roots in the long term exchange of experiences among these Countries that has begun through the ETN (European Transplant Network), an intergovernamental organization created in 2004. ETN has fostered the collaboration among Countries in the transplant field and the participation of many of them in EU funded projects.

For Malta and Cyprus Italy is the nearest country with a well-developed transplant system.

During the action the main goal has been to help the twinning countries to evaluate their transplant network; but in the sustainability phase, the real aim is that Italy is going to collaborate with the twinning countries to support them in their efforts to make progress in specific identified fields that were highlighted during the twinning phase.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Malta, CNT offered support to Maltese Health Ministry and transplant centre in the assessment of possible solution for the lack of a local lab performing HLA study of organ recipients sera.	CNT / MHEC	2015 onwards
Lithuana, Italy is going to ensure full support in the implementing phase of regulations for inspections of Lithuanian transplant centres. In addition, Italy is available to host liver surgeons for devoted training in an Italian hospital.	CNT / NTB	2015 onwards
Cyprus, following interest from Cyprus, Italy is going to insert the evaluation of transplant outcomes from living donor of Cyprus centre in the yearly evaluation done in Italy as soon as risk adjustment is also adopted for such recipients.	CNT / Cyprus Ministry of Health	2016 onwards

Czech Republic is fully implementing the quality system and the solid long standing relationships with this country are also supported by the sound partnership in Foedus Joint Action (http://foedus-ja.eu/).	CNT/KST	To be defined

C. Resources

The above action steps are going to be implemented with the institutional resources allocated to CNT by the Italian Government. Indeed the law 91/99 ascribed to CNT the task of "promoting and coordinating relationships with foreign transplant organizations and competent authorities".

D. Potential Challenges and Obstacles

Potential challenges and obstacles mainly concern possible failure in the commitment to achieve identified objectives in either party of such bilateral activities. This can be due to political changes, changes in priority settings and the lack of a compulsory timetable for achievement does not help in such effort.

Contingency plan

A single plan for future actions and steps should be developed for each bilateral activity between the two parties. Periodic revision of such roadmap should be performed and adjustments to timetable should be done if really needed. As a vantage point, almost all identified bilateral activities fall within one of the fields covered by the EU Action Plan that accompanied the implementation of Directive 2010/53/EU and 2012/25/EU. This approach can be of great help if the need of prioritizing some activities is felt.

Bulgarian Executive Transplant Agency – BEAT (Bulgaria)

A. Rationale

The objective of the twinning between Bulgaria and France is the revision of the organ procurement system at a national and regional level, establishment of Standard Operational Procedures for organ donation and transplantation aligned with European good practices and thus improving the monitoring and evaluation system on organ procurement and transplantation activities in the country. As far as sustainability is concerned BEAT has initiated the following actions:

- The ACCORD project supported BEAT for consolidation of the transplant coordinators network in the country. During the past two years this network expanded considerably which led to increase of the transplantations in number and in cases (from 2 deceased donors in 2012 to 10 deceased donors for 2013 and 12 deceased donors for the first 8 months of 2014).
- The involvement of all transplant coordinators in the ACCORD project work by contributing to the drafting of the 9 SOPs and the discussions on them led to the improvement of the communication between the coordinators and to the increasing of the quality of transplantation in the country.
- Project ACCORD initiated the improvement of the Agency's information system. Due to the ACCORD's review of our system two European projects have been initiated (and now are financed by EC OP "Administrative Capacity") aiming at improvement of all 27 registers that are maintained by the agency and establishment of at least 11 on-line administrative services for the citizens and the business in the country.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Expansion of the transplant coordination network.	BEAT	2015
Training of the new transplant coordinators.	BEAT	2015
Establishment of digital registries and on-line administrative services provided by BEAT to the public.	BEAT	2015
Annual meetings and discussions on problems connected with transplantation with all transplant coordinators.	BEAT	Annually

C. Resources

In order to complete the above actions, BEAT needs all the relevant information about EU best practices in the area. It is intended to participate in all possible EU projects oriented towards practical training of medical staff that is involved in the transplant coordination field in order to improve their professional qualification.

BEAT has the necessary administrative capacity to successfully implement any EU project. As far as now BEAT is involved in the realization of four projects financed by EC Operational Program “Administrative Capacity”, two of them are oriented towards digitalization of BEAT’s information system and the public’s access to it.

A lot of resources are needed in order to organize different actions in the mass media: presentations, discussions, meetings, TV clips etc. for changing the public opinion on the donation and transplantation process and to be able to overcome the high stage of distrust among the population.

Cyprus Ministry of Health (Cyprus)

A. Rationale

The Law concerning Organ Transplants was dated from the mid-80´s and at the end of July 2012 it was replaced by a new law encompassing the provisions of Directive 2010/53/EU. This new law provided for the creation of a new “regulatory and Licensing body”(the Cyprus “Transplant Council”), made up of 10 members representing the Mininstry of Health, patient organizations, the Medical and Legal Professions, the Bioethics Committee and relevant professionals. This body has undertaken the role of overseeing the Field of Organ Transplants, in terms of quality, safety, training and licensing. In view of the small population of Cyprus (last census in 2012 revealed 840,000 of which only around 700,000 were permanent residents of EU citizenship) and the existence of a single transplant centre it was decided that it would be prudent for the purposes of quality assurance to make comparisons with a bigger neighbouring country.

Italy very kindly agreed to twin with Cyprus enabling the exchange of information with regards to the experience gained so far on quality assurance systems for transplant centres. An onsite twinning visit by Italian experts took place in Cyprus in August 2013 when this exchange of ideas and experiences took place. Italy kindly offered electronic internet-based but also on site training in Rome for members of the Cyprus regulatory body (Cyprus Transplant Council) in terms of understanding of the quality indicators and potential ways of auditing outcomes. Furthermore, Italy offered Cyprus to participate in their electronic National Comparative Audit figures as a separate Transplant Unit. As 75% of the kidney transplants in Cyprus are live-donor based and the Italian electronic audit system did not perform risk-adjustment for live donors but only for deceased donor transplants, there was some hesitancy on the part of Cyprus to participate in a joined audit system, just for the 25% of kidney transplants from deceased donors. In view of the fact that Cyprus performs kidney (110 since Feb 2011), pancreatic (only 1 to date) and Blood group Incompatible Kidney Transplants with excellent results to date (median follow-up of 2 years with 1 graft lost to rejection (ABO Incompatible) and 1 patient death (from a myocardial infarct) it was felt that participation in the Italian National Audit system for Cyprus would not bring about any further improvement in terms of quality assurance. Indeed for the deceased donor program there have not been any graft losses or patient deaths since the start of our new Transplant program in Feb 2011. However, the experiences shared by the Italian experts with the Cyprus team were very useful in terms of educating / enlightening members of the Cyprus Transplant Council in mechanisms bigger countries establish for audit purposes.

B. Action Steps for Implementation

Not applicable, for the reasons stated above.

C. Resources

Not applicable, for the reasons stated above.

D. Potential Challenges and Obstacles

The low number of failures (single graft and patient lost to date since the start of the program in Feb 2011) and after 109 kidneys and 1 simultaneous kidney-pancreas transplants, makes it difficult for the generation of any meaningful statistics at present. However, this will of course become necessary as the number of years of follow-up increases. There are no particular challenges expected in the implementation of the good example of the Italian Audit in future here in Cyprus.

Ministry of Health – KST (Czech Republic)

A. Rationale

KST has joined the twinning aimed at accreditation and auditing of transplant centers with much appreciation. As some way of auditing TC´s, though unspecified, is required by the Law, the country was happy to have a possibility to participate in building the system with the contribution of other Project partners and with the experience offered by Italian CNT. The main appointment is derived from *Directive 2010/53/EU on quality and safety standards for human organs intended for transplantation* charging the MS with regular control and auditing of transplant centers. Czech legislation directly stipulates the following:

- The control of health services providers is carried out by the Ministry of Health, however its competencies can be delegated to another body which is, in this case, KST.
- KST has been established by the Ministry to carry our specific tasks in the field of transplantations, such as collaboration with the Ministry in ensuring quality and safety, preparing other operation procedures etc.
- Obligations of a transplant center in the field of quality and safety are derived from the law requiring them to prepare and maintain an internal system of quality and safety in all phases of the transplantation process.

Apart from this, based on the EC Action Plan, the National Action Plan for Transplantations has been adopted by the Czech Government in May 2010, with the commitment to pursue the following activities:

- International certification of transplant coordinators.
- Creation of conditions to ensure quality of health care provided by transplant centers and building up systems of best professional practice in individual centers.

Therefore, regular auditing and accrediting of transplant centers has been implemented into the Czech legislation and adopted by the authorities.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
A survey on existing quality best practices systems and the like in transplant centers.	KST	1st half of 2013
Benchmarking, assessment	KST, MoH	2nd half of 2013
Drafting General Working Procedures for transplant centers.	KST	1st half of 2014
Consultations with MoH.	KST, MoH	1st half of 2014
Issue, publication.	KST	1st half of 2014
Drafting audit checklists.	KST	1st half of 2014
Internal consultations, final version.	KST, (CNT)	1st half of 2014
Consultations in transplant centers.	KST, MoH	1st half of 2014
Training of auditors.	KST, (CNT)	1st half of 2014
First audit.	KST, MoH, (CNT)	June 2014
Evaluation.	KST, MoH	Aug 2014
Presenting the system of transplant centers accreditation and auditing to the professional public.	KST, MoH	Oct 2014
Setting regular accreditation and auditing system.	KST	Oct 2014
Terms and dates for auditing.	MoH	Nov 2014
Regular auditing of all transplant centers on a 3yrs basis.	KST	from Jan 2015 on

C. Resources

No extra resources will be needed. KST has been authorized by the Ministry of Health to carry out some kind of a regular control over the transplant centers regarding quality and safety and, at the same time, has been charged with preparing a system of General Working Procedures for them. The ACCORD Project will enable KST to achieve higher level of accreditation and auditing thanks to methodical leadership and practical experience of the twinning Project leader (CNT). Training course has provided KST with three auditors, with the opportunity to also ask Project colleagues to act as members of a national auditing team. No extra costs are involved, apart from travel and accommodation expenses in case of (possible) participation of foreign auditors.

D. Potential Challenges and Obstacles

The main challenge is to create an atmosphere of willingness of the transplant centers to participate in the system of accreditation and auditing. On the other hand, the existing Law lays down an obligation of transplant centers to create and maintain system of quality and safety management. The only potential obstacle then appears lack of cooperation. This should be avoided by increased collaboration with the transplant centers and the professional Czech Transplant Society in preparing the terms of audits and consulting audits methods and objectives.

National Transplant Bureau – NTB (Lithuania)

A. Rationale

Participating in twining project for auditing gave knowledge and practise and helped to prepare National legislations. There is Confirmed order of individual health care institutions providing human tissue, cell, organ donation and transplantation, scheduled and unscheduled inspections of performance validation rules at this time.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Confirmed order of individual health care institutions providing human tissue, cell, organ donation and transplantation, routine and non-routine inspections of performance validation rules.	NTB; Specialist of Law and Supervisory Division	4 July of 2014
Confirming plan under which in 2015 will be inspecting donor hospitals, transplant centers and tissue banks; This plan will be published on NTB website.	NTB	December of 2014
Confirmed order of individual health care institutions providing human tissue, cell, organ donation and transplantation, routine and non-routine inspections of performance validation rules.	NTB; Specialist of Law and Supervisory Division	4 July of 2014
Confirming plan under which in 2015 will be inspecting donor hospitals, transplant centers and tissue banks; This plan will be published on NTB website.	NTB	December of 2014

C. Resources

The list of experts who can participate in routine and non-routine inspections which will be performed in transplant centres, donor hospitals and tissue banks is needed.

D. Potential Challenges and Obstacles

Inform transplant centers, donor hospitals and tissue banks about inspections on time.

Information must be provided clear.

Contingency plan

Regularly consult with experts from this working group.

Ministry for Health, the Elderly and Community Care – MHEC (Malta)

A. Rationale

Cooperation between critical care professionals and donor transplant coordinators is good. We have arrangements with neighbours Sicily for lung transplantation. Twinning agreement with Italy re support for regulation of transplant centres

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Regulator building capacity in auditing of transplant centres.	SPH	Ongoing
Plan external auditors to review our activity	Regulator (SPH)	Every 2 years
Create a website eHealth website coordinator December 2014.	eHealth website coordinator	December 2014
Regular meetings for the Multidisciplinary.	Medical Director/ his delegate	Every 3 months

C. Resources

D. Potential Challenges and Obstacles

- Limited human resource for implementing the above.
- Training of staff from the Competent Authority.
- Finding time to meet and discuss given the busy time schedules of all involved.
- Problem with small size of transplant activity can lead to very skewed results.
- (especially when comparing to larger countries).
- Increase in administrative work (limited secretarial).

Contingency plan

- Dedicating staff and time to the above.
- Making better use of current resources.
- The Competent Authority is investing in using the persons who have been trained to.
- Audit transplant centres in training other suitably qualified staff to promote capacity.
- Building in the area. SOPs for audit are also being prepared by the Health Care.
- Standards Directorate. The Competent Authority will be utilizing any other future.
- Twinning opportunities/EU funded training to achieve the above.

Dutch Transplant Foundation - DTF (The Netherlands)

A. Rationale

The E-learning module for abdominal procurement surgery which has become internationally available via the ESOT website, will be used as a blueprint for the development of a thoracic e-learning module. The experience from the Twinning between The Netherlands and Hungary has led to another international approach (UK + The Netherlands). It is the intention to also publish the future e-learning module for thoracic procurement surgery via ESOT, fostering international exchange of knowledge and educational programs.

There are no plans or ambitions at this moment to undertake any further actions which derive from other ACCORD WP6 Twinnings.

B. Action Steps for Implementation

Action Steps **(How will you get to where you want to be?)**	**Responsibility** **(Who will make it happen?)**	**Timeframe** **(When will it happen?)**
Developing an e-learning module in close collaboration with thoracic surgeons and IT specialists from The Netherlands and the UK.	DTF and NHSBT	Ready: June 2015

C. Resources

- Money.
  Human resources (project leaders, IT specialists, thoracic surgeons).

D. Potential Challenges and Obstacles

- No(t enough) money.
- No(t enough) human resources.

Contingency plan

The first meeting between The Netherlands and UK already took place. People involved are enthusiastic and money and resources seem to be available. This project looks very promising.

Hungarian National Blood Transfusion Service – HNBTS (Hungary)

A. Rationale

Development of a proposal for establishing a national education program to improve quality and safety of organ procurements in Hungary: establish the Hungarian donor procurement surgery masterclass training program in collaboration with the Semmelweis University and all Hungarian abdominal transplant centres.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
Develop the structure: establish the Scientific Committee of the Hungarian Donor Procurement Surgery Training Program.	HNBTS, OCO; Semmelweis University, Univesity of Debrecen, University of Pécs, University of Szeged	30th June 2015
Finalization and adaptation of the program curriculum and syllabus into the Hungarian local needs.	Scientific cCommittee	31th January 2015

C. Resources

- The Scientific Committee has to assess the potential needs (number of candidates) in the 4 Hungarian medical universities.
- According to the costs of the 1st Hungarian Donor Surgery Masterclass (30-31st January 2014) estimated costs of a course 10.000 € in case of 8 participants.
- Besides the professional activity of the Scientific Committee, HNBTS- OCO as a Competent Authority, provides the administrative background of the training program, it is estimated about 1,000 € per course.

D. Potential challenges and obstacles

- Amendment process of the current legislation about the regional competency and competency for organ retrieval by transplant centres can be time-consuming.
- The financial background is not granted yet.

Contingency plan

- Collation between the Scientific Committee, the leaders of all Hungarian transplant centers, College of Medical Professionals and Competent Authorities: National Institute of Quality and Organizational Development in Healthcare and Medicines, Hungarian National Blood Transfusion Service.
- Commercialization of the course in Middle-Eastern Europe for transplant surgeons could provide the financial background.

National Transplant Agency - ANT (Romania)

A. Rationale

Romania did not participate in this WP, nevertheless some activities were carried out.

Aside of ACCORD twinning activities, Romania started a bilateral twinning program with Moldavian Transplant Agency in order to develop a transplant system in the Republic of Moldova. It is however worthwhile quoting this information reported to ACCORD.

B. Action Steps for Implementation

Action Steps (How will you get to where you want to be?)	Responsibility (Who will make it happen?)	Timeframe (When will it happen?)
We have started the program with bilateral visits in order to teach them how to manage a transplant system.	National Transplant Agency National Committee of Anaesthesiologists Clinical Institute Fundeni	2013 - 2016

C. Resources

Transplant coordinators, anesthesiologists, transplant coordinators, surgeons.
There is no a budget approved. Costs are minimized by voluntary activity of the experts.
In Romania there are many Moldavian physicians (different specialties) who can provide specialized training for the Moldavian colleagues. The particularity of this situation is that the mother language is the same (Romanian) in both countries.

D. Potential Challenges and Obstacles

The Republic of Moldova has a very recent transplant legislation issued in cooperation with National Transplant Agency of Romania.
Moldavia needs resources in order to train and to pay the transplant coordinators and also to get experience in the identification of potential brain dead donors and diagnosis of brain death.

Moldavia tries to develop a national transplant program, but it is not so clear who will be in charge with the financing of this program (government or insurance companies).

Contingency plan

Periodical meetings, professional visits of Romanian experts. During these visits, the Romania experts perform liver and kidney transplant procedures together with the Moldavian colleagues.

When the Moldavian legislation will allow the exchange of organs, most probably these exchanges will be done with Romania

5. CONCLUSIONS

This sustainability plan makes evident the commitment of individual Associated Partners to the whole JA and to further development of the activities carried-out. In analysing the inputs received by different countries, we deem appropriate to provide a general overview of the proposed sustainability plan by core activity and especially on the basis of discussions held during the final ACCORD meeting in Madrid on Jan 14-15, 2015.

Priority domain # 1: Registries of living organ donors follow-up

The two main objectives of this priority domain were: a) to lay down a set of recommendations on how a living donor follow-up registry should be implemented; b) to guide on how to implement a Registry of Registries with a standardized dataset inclusive of actual data provided by the various European organizations involved.

Follow-up of living organ donors is a precise requirement of *Directive 2010/53/E*U, under which each European MS performing such activity is required to establish a registry to record information on the outcome of living organ donors. The first immediate results of this ACCORD activity have therefore been to supply recommendations and prompt tools to implement such a registry to all those countries that have not yet developed one and to provide a common ground for comparison to those countries that already have a running registry. The largest sustainability perspectives are here guaranteed by the set of data agreed for collection on the follow-up of both kidney and liver living donors. Moreover, as conceived, the Registry of Registries (see below) may be considered for use by individual countries as their own national, based on the functions of direct key entry and data download.

On the other hand, from the point of view of sustainability, all countries have reported a growing interest in designing, setting-up and implementing their living donor registry, taking in due account and incorporating the recommendations arising from ACCORD as well as in entering data from their own registries in a supranational Registry of Registries, for the sake of international comparisons. Additionally other countries expressed interest to adapt its registry in accordance with the standards proposed by the project to go beyond the prototype Registry of Registries.

Finally, the required features of the possible supranational Registry of Registries identified in the final outputs, such as the web based access, availability in English, file upload/direct key entry possibility should facilitate its definite implementation.

Priority domain # 2: Improvement if end-of-life care pathways

The aim of priority domain #2 is to support in partner countries the close cooperation between intensive care units and donor transplant coordinators, with a view at increasing the number of potential donors and especially at creating and strengthening a network of professionals and units within the donation system of each country.

During the project a good number of hospitals were engaged at each country, their staff were duly trained in the PDSA methodology and interesting results were obtained in terms of knowledge and action, with some special improvements in the process of deceased donation at some hospitals/countries.

From the point of view of sustainability, this priority domain is the one to offer the best chances of self-propagation. All the countries that participated in the activity have already declared their intention to disseminate the produced tools and guidelines, even translating them, and above all to transfer this experience of quality improvement in their country, increasing the number of involved hospitals, also as a great tool to motivate staff and ensure link between involved units. The countries at the level of the Competent Authority should particularly profit from the final seven recommendations derived from the experience, such as the need to build on what has been done coupling efforts at local, regional and national level; building a long-term quality improving scheme or giving national support to local bodies in order to achieve necessary changes; as well as the recommendation from External Advisory Board to this WP that was to foster the setting up of DCD programs in every country.

Patient data collected for the study into variations into end-of-life care was entered via a secure web based platform. There is the potential that the web based platform could be ‘given’ to countries and translated into their language for local use in the future.

Last but not least, thanks to the awareness gained during the project, several countries have decided to organize programs for the identification of the donor, to increase the awareness of staff in intensive care units and to identify *ad hoc* figures such as donation coordinator and transplantation coordinator. In the long

run the adoption of these measures is going to play an important role in the sustainability of actions in this priority domain.

Priority domain # 3: Twinning activities

Twinning activities were foreseen and meant to promote positive synergies among the various participating countries through the exchange of tools and experiences and the transfer of best practices in-the-field adapted to the different local realities. Twinnings were to be developed from the perspective of continuous improvement that promotes standardization, transparency and quality in this sector, supporting all the participating countries to implement some of the provisions of *Directive 2010/53/EU* within their systems.

It is difficult to tell apart the sustainable features of different twinnings, since the topics varied between the three subsets and sustainability of such twinning actions is much linked to the situations in individual countries, duly reported in the single analyses here above. From a general point of view we can say that all twinnings have fostered virtuous circles in their specific field and have created strong networks between twinned organizations. Such bilateral international relations show their effects in multiple fields, ranging from the consultancy of experts in a particular domain to the request for comparison of some donation or transplant activities. A major role in the sustainability of this transfer of expertise is played by the standardization processes that the *Directive 2010/53/EU* started and that have to be completed yet.

However a clear commitment of each country to perform activities in this specific field is a prerequisite. Twinning agreements are especially useful when new activities have to be launched or a major quality improvement is needed. On the top of bilateral transfers that were the aim of twinning activities, broader twinning outcomes unexpectedly revealed:

a) The e-learning tool for training organ procurement surgeons (focused on the recovery of kidney, liver and pancreas for transplantation) that was adapted for international use during the Dutch-Hungarian twinning. The platform is running on all recent browsers and accessible on the web (100 euros), a fee that could be reduced for a large group of participants from a country. Group enrolments should be discussed bilaterally upon request.

b) The hand-on training session held in Hungary on human bodies for the training of abdominal organ procurement surgeons especially prepared can also be available for future training. Its cost will be related to the number of requesting trainees and tutors, since it is mainly related to the

c) preparation of the bodies and limited to 8 trainees per session.

d) From the experience of the Italy-Cyprus-Czech Republic-Lithuania–Malta multiplet, the manual for the authorisation of liver and kidney transplant centre is available to all MS. Additionally, the course for “Inspectors” or “Auditors” of transplant centres could be available upon request by any Competent Authority, both in terms of the didactic materials (all translated in English), and the E-learning platform for free. Another easily-transferrable feature could be the creation of an international team of auditors of transplant centres, available for “international” audits. Such a system would require volunteer experts and funding for travel expenses. Yet a balance between the benefits from improvements in quality and activities possibly drawn from such experiences and the real cost to be invested seems to be particularly favourable, especially for smaller countries since it would avoid them the setting up of an *ad hoc* quality system that would be poorly cost-effective when compared with the number of required structures.