WP 4 'LIVING DONOR REGISTRIES'

Deliverable 6:

REPORT ON PILOT STUDY

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SUMMARY

The final recommendations from the ACCORD Work Package (WP) 4 project will be 'piloted' recommendations. ACCORD WP4 milestones have already resulted in a data set and data dictionary as well as a document in which the technical, organizational and governance requirements for a European Living Donor Registry are described. A pilot is performed to test the recommendations of these two milestones and to see whether they lead to a comprehensive registry of living donors. Important is that the pilot results in valuable data and that the registry is a feasible tool to implement in different European Union (EU) Member States (MS). This document describes the results of this pilot.

The ACCORD WP4 pilot registry is built on the platform that resulted from the previous EU co-funded project EULID. Hospital Clinic in Barcelona facilitated the technology and technical support. The Dutch Transplant Foundation performed the project leadership of WP4 and performed the data analysis as well as the technical and practical evaluation of the pilot. This report is of course a result of close co-operation between all participating partners in WP4.

The pilot registry is a web-based application with the possibility to enter living donor follow-up data by direct key entry as well as by file upload from an existing registry. Nine countries actively participated in the pilot by entering follow-up data of donors that donated a kidney in 2010 and 2011. Their donor demographic information as well as one-year follow-up data was collected. Five countries without a national living donor registry tested the direct data entry. These countries contributed with a total number of 90 donors. Four countries that participated in the pilot had already a national living donor registry and extracted the follow-up data from the existing registry to upload it into the ACCORD WP4 pilot registry. They contributed with 2,819 living donor follow-up data, resulting in a total number of 2,909 living donors that were included.

An online questionnaire was used to collect information on the experience using the database. Several questions lead to an insight in the use of the database and the positive and negative experiences. Eighteen professionals from 9 countries were invited to take part in completing the questionnaire. In total, 9 questionnaires were completed. In summary, the overall experience using the registry is positive.

The summary of the data analysis is that both the key entry and the upload of existing donor data are feasible. Some countries had an incomplete registration of their donors, due to missing values in the original database, but also due to problems with the upload settings. The translation of items in already existing databases into ACCORD definitions was very time consuming, although it was possible to accomplish. The outcome of the analysis showed that all data fell in expected ranges. Only a few complications immediately after donation were found, and at one year after donation very few health issues were encountered. Two deaths were reported at 1 year of follow-up, but these were not related to the donation procedure. No deaths occurred in the weeks after donation. No donors needed renal replacement therapy in the first year

after donation. Almost all donors returned to their previous activity level within three months after donation.

1. INTRODUCTION

1.1 GENERAL INTRODUCTION

The objective of ACCORD WP 4 is to present a set of recommendations for the development of a European Living Donor Registry and to present recommendations for Member States (MS) without a Living Donor Registry (LDR) to create such a database.

Part of the ACCORD project is to test the recommendations that have been described in the project's milestones by performing a pilot phase. The two previous milestones that were tested in the pilot were the dataset and data dictionary (Annex I) as well as the technical specifications. The pilot can be seen as a proof of concept. A thorough evaluation of the pilot have led to the final recommendations of the project that are described in this Report on the pilot study (Deliverable 6).

1.2 PILOT APPROACH

1.2.1 Preparations for starting the pilot phase

The pilot phase is an essential part of the project. The feasibility of the recommendations will be concluded from this pilot. In month 16 and 17 of the project, the first preparations for performing a pilot were started. There were some ambiguities about the way the pilot should be performed and to what extent this pilot should be performed. After these were discussed the scope and expected end point of the pilot were clear. A set of 'general' pilot specifications was described. These specifications were:

- Complete ACCORD data set and data definitions – **KIDNEY** only
- Relational database
- Web-based application
- Approachable by common Internet surfing programs
- Official language: English
- Direct data entry possibility
- File upload possibility (from national databases)
- Data download possibility

Two collaborating partners with prior experience in setting up a(n international) registry were asked to write their proposals about performing a pilot. Eurotransplant's experience derived from the EU funded project EFRETOS. Hospital Clinic of Barcelona has experience with setting up a registry as a result of the EU funded project EULID. During the interim meeting in Madrid from 16-17 October 2013, both Eurotransplant as well as Hospital Clinic of Barcelona presented their plans and the possibilities for performing the pilot within the given budget. Time and money were limiting factors in setting up the pilot registry. Hospital Clinic of Barcelona had already a registry structure in place that would fit for the ACCORD pilot as well, within the given budget.
As a result of the possibilities presented, it was decided to perform the pilot in close cooperation with the Hospital Clinic of Barcelona.

1.2.2 Subcontract Hospital Clinic of Barcelona

The conditions and agreements between the Dutch Transplant Foundation and the Hospital Clinic of Barcelona for performing the ACCORD WP4 pilot were confirmed in a subcontract, signed by parties on 30 April 2014. The responsibilities, obligations and reimbursements were described in this subcontract. Hospital Clinic of Barcelona would facilitate the ACCORD data collection based on the specifications that were established by the working group. Data protection, but also technical support were supplied by Hospital Clinic of Barcelona. The ACCORD consortium, more specifically, the countries that participated in the pilot, are the owner of the data. The Dutch Transplant Foundation was responsible for performing the analysis. No results of the analysis may be published without the ACCORD WP4 working group's prior consent.

1.2.3 Pilot cohort and countries included

During a WP4 meeting in Amsterdam on 14 January 2014 it was decided to include the one-year follow up data of all living kidney donors that donated a kidney in 2010 and 2011. The enthusiasm to actively participate in the pilot resulted in interest shown by ten partners. Active participation involved the collection of follow-up data in the ACCORD WP4 pilot registry. One partner eventually withdrew its first interest because of capacity problems, not due to lack of interest.

Eventually five countries entered their living donor's follow up data in the ACCORD WP4 pilot registry using the direct data entry possibility. Four other countries tested the data entry of larger number of records from their existing living donor follow-up registry into the ACCORD WP4 pilot registry, using the file upload possibility. The countries that were involved in the pilot are listed in chapter 3.

1.2.4 Pilot performance

The ACCORD WP4 Pilot Registry started the data collection by facilitating the direct data entry possibility in the last week of April 2014. All the participating countries had received their login details to enter the secured website to approach the registry. The second phase of the data collection involved the file upload possibility. The file upload module became available in the first week of July 2014. All partners finished their data inclusion in the second week of October 2014.

2. EVALUATION

2.1 SCOPE OF THE EVALUATION

As mentioned before, the pilot cohort included all donors that donated a kidney in 2010 or 2011. Their baseline characteristics, peri-operative data and one-year follow-up data were collected. The main goal of the pilot is to test whether the recommendations of milestone 2 and 3 can be applied to a RoR. A second goal of the pilot is to evaluate the follow-up data of the donors included. Many different aspects were tested and from the evaluation of these tests, adaptations can be made and recommendations are based on piloted experience. The focus of the evaluation was on three main elements:

1. Practical evaluation
2. Technical evaluation
3. Data evaluation

The parameters that were used to perform the evaluation are listed in Annex II. This document describes the outcome of the analysis and presents the piloted recommendations per element.

2.2 PROJECT EVALUATION

2.2.1 Cooperation with Hospital Clinic of Barcelona

Cooperation with Hospital Clinic of Barcelona went very smooth. Especially in the phase of establishing the ACCORD WP4 pilot registry, frequent contact between the project leader and Hospital Clinic of Barcelona was necessary. After the pilot phase had started, Hospital Clinic of Barcelona was available for answering questions from the project leader as well as from participating countries. Weekly reports were sent to the project leaders to give updates on the number of login moments per country and the number of donors that were included in the registry. These reports were used to monitor the progress of the data collection and to see if any adaptations in the project planning should be anticipated. Before starting the data analysis, the downloaded data had to be checked for any extraordinary values or possibly incorrect records. During this phase, which was performed in October 2014, Hospital Clinic of Barcelona was available for support and made modifications in the database (business rules) if necessary. Their response has always been very prompt and accurate. The contract between the WP4 leader and Hospital Clinic of Barcelona terminated on 31 December 2014. All users that were involved in ACCORD WP4 were deactivated on this date. The collected data will be destroyed after the project is finished unless specific permission is given to maintain the database by the ACCORD WP4 partners that actively participated in the pilot.

2.2.2 Cooperation with participating partners

Eighteen professionals, representing 9 countries were involved in the data collection. Communication as well as collaboration between the partners, Hospital Clinic of

Barcelona and WP4 leader went well. Some countries were enthusiastic with their participation and shared their progress in the data collection. Other countries needed an extra reminder, but everyone has responded to requests eventually. Frequent reminders and friendly recalls were sent if deadlines were close to expiring or even far behind schedule. The project process went according to expectations, keeping in mind the calculated delays and uncalculated struggles that regularly appear in a project with a size like this.

2.3 PILOT EVALUATION

To achieve a genuine insight in the practical experience of the people that used the ACCORD WP4 pilot registry, an online questionnaire was sent to all actively involved participants. These 18 professionals received an e-mail with the link to the tool. The questionnaire could be completed at once, or could be interrupted and restarted at another moment, saving the results that were completed in an earlier stage. The questionnaire included questions about different practical aspects of the registry. The questions and results will be evaluated in the paragraphs following.

Data collection by completing the questionnaire was available during a period of two and a half weeks (12 effective working days). Two reminders were sent during these two and a half weeks to stimulate the participants to complete the questionnaire. In practice the questionnaire remained 'open' until November 20th.

A total number of 9 respondents completed the questionnaire. Since it is an anonymous questionnaire, it is not possible to check whether these respondents represent all participating countries, but an analysis of the answers leads to the assumption that (almost) every country has completed the questionnaire. Four respondents answered that they used the direct data entry possibility and four respondents answered that they used the file upload module. One respondent did not make a choice between these two possibilities of data entering.

Thirty-two questions were formulated to collect information about using the registry, about the look and feel and about the practicalities using the registry (Annex III).

2.3.1 Experiences using the registry: Results of the questionnaire

2.3.1.1 Logging on to the registry and using the instructions

No respondents experienced any problems logging in to the pilot registry. Two instruction files were available; one for the direct data entry possibility (Annex IV) and one for the file upload module (Annex V). Answers to the questionnaire show that 3 out of 9 respondents experienced difficulties using the ACCORD WP4. All three respondents gave a specification of this answer. They specified the difficulty as follows:

- Difficulty understanding the instructions
- Difficulty finding an answer to a question
- Other, specify:

- There were some mistakes in the instruction file
- At the first moment can't save the number of data with 'O', like blood type. But at the end everything goes fine.

2.3.1.2 Look and feel of the registry

Once logged in to the pilot registry application, the user can register a new donor, download data or import data (depending on the user's authorization). The respondents all agreed on the fact that the registry felt intuitive. It was easy to find the way around the application. Eight respondents (88.9%) said 'Yes' to the question 'Did you recognize the application as the ACCORD WP4 pilot registry?'. One respondent specified the answer 'No' by giving a suggestion to improve the look and feel of the application by adding headings to the applications that it is the ACCORD database.

2.3.1.3. Permission to use donor's follow-up data

Two of the respondents said that their national legislation prescribes to ask permission to all living donors whose (anonymized) follow-up data is included in the ACCORD WP4 pilot registry. This means that by far the most respondents live in a country where (anonymized) data can be collected in a(n international) (pilot) registry without the condition to ask specific permission to the donor. Even the countries that needed consent from the living donors to use their data in the ACCORD WP4 pilot registry experienced no problems to obtain this permission. This is an interesting outcome, keeping in mind one of the main goals of a(n international) registry to collect large amounts of anonymized data for research purposes.

2.3.1.4 Direct data entry

Four respondents (44.4%) entered data by direct key entry. Due to the almost equal distribution of respondents who used the possibility of direct key entry and the possibility of file upload, a good insight in the experiences using both functionalities was given.

Of the four respondents that used the direct key entry possibility, one experienced difficulties in completing the donor demographic information. Three respondents experienced difficulties in completing the follow-up data. Specification of this outcome gave insight in these difficulties:

- Difficulty to obtain items with a different unit (1 respondent)
- Difficulty to obtain the specified items from the donor's file (3 respondents)

Main problem that both users faced was the fact that the data that was asked, was not collected in the patient files in the transplant centers. For example the donor's weight was collected as baseline information, but is only collected in the follow-up *"if something goes wrong with the patient"*, replied this respondent.

2.3.1.5 File upload

The file upload module was used by four respondents (44.4%). No respondents using the file upload module had problems extracting the data from their existing (national) registry. They did however have to convert items from their existing registry to make it

compatible with the ACCORD definitions and values. Three of the respondents that used the file upload module had problems with the conversion of the data from their existing registry. A specification of these difficulties was given:

- Different definitions are used (25%)
- Different values are used with difficulties to calculate into other values (8.3%)
- A large number of missing values in existing registry (25%)
- Difficulty to merge the downloaded data from the existing registry into the ACCORD upload file format (16.6%)
- Very time consuming (25%)

One respondent motivated: *"Very time consuming because definitions were sometimes completely different and therefore complicated translations had to be carried out".*

The experience in working with the upload file and module was motivated in a free-text box in the online questionnaire. Respondents had to adjust the extracted data from the existing registries to fit the ACCORD WP4 pilot template. When a file was uploaded and it contained invalid values or other errors as defined in the pilot registry, a notification popped-up. This notification specified "*what was wrong in the upload file and changes could be made easily before uploading again"*, concluded one respondent. One country has recorded the syntax for recoding the variables, to anticipate on a future situation in which the system might be implemented. Another country has harmonized the ACCORD WP4 data set with the data set of the existing national registry. This was done by creating a new data set for the national registry according to the ACCORD data set (for the future) and to merge the national data into the ACCORD WP4 pilot items (for the pilot). An important outcome of the pilot was that the module could not process a large number (>350) of donor follow-up data at once. This meant that the pilot participant had to split the data into multiple spreadsheets to upload it. This was a drawback since the data upload, as a result of this, took more time than expected. This respondent suggested increasing the size of the upload. One respondent suggested making the headings in the upload template clearer, since the headings were not always easy to interpret with the given number (for example P32) instead of the name of the item (date of donation).

2.3.1.6 Data download

Six users (66.7%) did not make an extraction of their 'own' data. Therefore, the conclusion concerning the data download possibility can only be drawn from three respondents. Two out of the three respondents that made an extraction of their data, and checked whether the downloaded data were identical to the data they entered / uploaded. One respondent found no discrepancies in the data. One respondent found a difference in gender. This mistake appeared in the download file and was easy to correct (with support from the Hospital Clinic of Barcelona).

2.3.1.7 General opinion and suggestions for improvement

It is concluded that the ACCORD WP4 pilot registry is a good tool for countries without a (digital) follow-up registry. One respondent answered that the country has legal acts for living donation and follow-up after kidney donation, but transplant centers still could not ensure all the data to the pilot database. One respondent emphasized the difficulty to complete the item 'proteinuria' in the pre-donation as well as the post-donation situation. *"PCR (Protein Creatinine Ratio) values (in mg/mmol creat) of the respondent's patients were all far out of the ACCORD reference values (0-0.08 mg/mmol creat). The range of our values was 3.6-19.0; in accordance with international values for PCR"*.

Conclusion:

- The ACCORD WP4 pilot registry is a suitable way to collect living donor follow-up information.
- Direct data entry and file upload are both good possibilities to enter data into the registry.
- The data download functionality worked well and is a good possibility for countries to extract their own data.
- The size of the upload file (number of records to be uploaded in one shift) was limited due to a technical setting in the application. This can easily be adapted.
- The headings in the upload template are not easily identifiable as numbers are used as a reference instead of the column title.
- Users responded that they were faced with a lot of missing values in the patient's medical files.

2.4 TECHNICAL EVALUATION

In the contract between the Dutch Transplant Foundation and the Hospital Clinic of Barcelona the data, practical and technical evaluation were enlisted. Since Hospital Clinic of Barcelona performed the technical support and facilitated the ACCORD WP4 pilot registry, they were asked for their experiences and feedback on positive results and difficulties they faced in the technical support and database facilitation. Of course, the feedback of the nine countries that were involved in the direct data entry and file upload, is also processed in the following chapter.

2.4.1 Adjustments in existing EULID application

The EULID application is a tool that has been working properly for over 7 years already. The technicians involved in the ACCORD WP4 pilot are very experienced in working with the EULID registry. Some adaptations had to be made in the registry however, to make it fit the ACCORD specifications, data set and data definitions. Beside this, the upload module was no part of the EULID registry and one of the most important prerequisites for the ACCORD WP4 pilot registry. This module had to be developed for the ACCORD WP4 pilot registry.

As mentioned, the ACCORD data set and dictionary differs from the data set that was already processed in the running application. Therefore, adaptations had to be made. Hospital Clinic of Barcelona has had no problems processing these adaptations. Many correspondence and deliberation took place between the WP4 leader and Hospital Clinic of Barcelona. For example, Hospital Clinic of Barcelona suggested to collect only the date of birth, as age can then be calculated, as well as collecting the date of discharge, as this can be used for calculating for example ‘length of hospital stay’. Since the WP4 project group agreed upon the items in the data set, the abovementioned suggestions were denied. Not every country collects for example the date of birth, which would make it difficult to collect this item for the pilot. Another suggestion was to set unknown values as code ‘Null’. If the option unknown would be referred to as a certain value, this will lead to miscalculations in the analysis. This suggestion was accepted. Some other items led to questions to Hospital Clinic of Barcelona, but solutions were always easily found and applied without any problems.

Hospital Clinic of Barcelona had implemented a codification system to trace and place items in the corresponding places in the database. Even though this codification was different from the codes that were given in the ACCORD WP4 data set, it was agreed upon to use the codification for the pilot that had already been established.

Some conversion–tools were integrated in the ACCORD WP4 pilot registry. These were for example:

- Weight: kg ↔ pounds (lb)
- Height: cm ↔ inches
- Creatinine: (umol/L ↔ mg/dl)

All adaptations were done within very acceptable time periods. When adaptations were ready to be tested, Hospital Clinic of Barcelona informed the Dutch Transplant Foundations and acceptance tests were performed to check the result of the modification and the impact of the changes on the system.

2.4.2 Authorizations and standards

One of the prerequisites of a living donor follow-up registry, defined by the WP4 project group was that the registry needed to be an online application, approachable by all common browsers. The Dutch Transplant Foundation has reported several problems logging in to the registry, using Internet Explorer. The Barcelona database specialist could not reproduce the problems, but it was suggested to use another browser. Google Chrome caused no problems. According to Hospital Clinic Barcelona the registry has been tested in several browsers (Internet Explorer, Chrome, Firefox, Safari, etc.) and platforms (Windows, Android, and Apple iOS), and this all worked well. It is recommended to use the latest versions of browsers. Chrome and Firefox are able to update themselves, but this process needs to be done manually for Internet Explorer. This could be an acceptable explanation.

As described in Milestone 3: technical, organizational and governance requirements, different levels of authorization were identified. Depending on the level of authorization, a user could see local, national or global information. Besides this subdivision, the users were also given different authorization to use the registry. The countries that were to use the direct data entry possibility had no button to use the file upload possibility.

Once donors were entered into the database, it was possible to make adjustments in the donor's data, regardless of the way that was used to enter the donor's information into the registry. The registry keeps track of changes that are made and links these changes to the username that performed the actions. In Milestone 3 the possibility of changing the language to the native language of the user, driven by the browser's configuration was mentioned. This aspect was not a part of the ACCORD WP4 pilot, but could still be recommended for a future registry (of registries).

2.4.3 Technical evaluation of direct data entry

The direct data entry function was already a part of the EULID registry and only needed minor adjustments. Donor demographic information needed to be completed first. The registry automatically generated a unique identification code to the donor. After the donor was entered in the registry, the peri- and postoperative data could be completed as well as the follow-up data. Users reported only one difficulty using the direct data entry possibility. It turned out that it was impossible to choose blood type '0' (numeric). Solution to this problem was to choose 'O' (symbol) instead. Besides this, no problems were reported.

2.4.4 Technical evaluation of file upload module

Data had to be uploaded from an existing registry. The items from the existing registries had to fit the values that were defined by the WP project group. Besides

possible adaptations in the values, the data needed to fit the template file that was developed by Hospital Clinic of Barcelona. The template file assures that all the items that are uploaded correspond with the correct cell in the database. Some respondents that completed the questionnaire reported that once they had converted the data from the existing registry, it was another challenge to create the template file. Other countries experienced no difficulty matching the predefined format in the template file. In contrary to the direct data entry, it is not necessary to upload the donor demographic information apart from the follow-up data. All data can be uploaded in the single template file. The data that are uploaded via the module are easily identified by a batch-number that is given to the uploaded file.

A remark that was made concerning the template was that the headers contained 'codes or numbers' as a title. This made it difficult to understand what data was collected in a certain column. It was advised to add header titles that can easily be interpreted.

From the questionnaire we learned that it was not possible to upload large amount of data at once. Apparently no warning was given at the time of the upload, but when the user looked at the data, it only showed around 300 donors. To enter the rest of the donors, the data was split in several groups with smaller amounts and each file was imported separately. This user experienced that the application imported varied amounts each time. Sometimes it would allow over 300 and other times slightly less. This situation was not reported to the Dutch Transplant Foundation nor to the Hospital Clinic of Barcelona during the pilot itself, so no support was given at the time of occurrence. It turned out that, in order to protect the system, the registry has limited the size of the file to upload, but this limit can be modified if required. If the situation had been reported during the pilot, Hospital Clinic of Barcelona would have increased the maximum amount of data to upload at once.

2.4.5 Technical evaluation of data download

Three authorization levels were identified for the data download possibility. These are:

- Local: the user can only extract the data from the own center from the database
- National: the user can download all the data from their own country.
- Global: the user can extract all the data that was entered or uploaded by all countries.

For the pilot registry, the users from eight countries were given national authorization to download all the data for their own country. The Dutch Transplant Foundation, as project leader, was given authorization to download all the data that was entered, enabling data analysis.

It turned out that only three users used the data download possibility. There were two different sets of data to download:

- Donor data: this includes the donor demographic information

- Survey data: this includes the pre-, peri- and post-operative data set that is defined by the ACCORD WP4 project group.

Data downloaded is presented in an Excel file. During the data evaluation and analysis, it was found that there was a problem with the conversion of data, using dots (.) and commas (,). The download of the data produced a sort of excel file. This file led to false results. Feedback from the Hospital Clinic of Barcelona learned that this problem was a result of the interpretation that Excel gave to the data extracted from the registry. The decimal point used in the registry for numeric values is '.' but Excel is interpreting this in several European countries as the thousands separator. Different countries, but also different computers use different notations, which are hard to change in the correct format. During the pilot it was not possible to make proper changes to the system to avoid these inconveniences. Another problem with the download file is that all fields are set to 'general' instead of the proper types like 'numeric' or 'date'. This makes the processing of the download file for statistical purposes very laborious.

Conclusion:

- The follow-up registry (of registries) as an online application functioned well.
- The pilot can be approached by all common browsers, preferably using the latest version. Internet Explorer is less convenient to use, because updates are not installed automatically and could therefore cause difficulties when running the registry.
- The installation of a support team that responded to any technical difficulties within a short period of time was very valuable.
- The file upload file for uploading data from an existing registry had a predefined template, which was easy to use. Conversion had to take place of data from existing registries into the ACCORD pilot registry.
- Countries were able to download their 'own' data in an Excel file, as this was part of their user profile's authorization. The issue of the 'decimal separator' was not solved during the pilot.

3. DATA EVALUATION AND STATISTICAL ANALYSIS

To present the results of the data evaluation in a synoptic way, the next chapter will focus solely on the data analysis and the consequences for the health of living kidney donors, one year after donation, in 9 participating countries. The analyses that have been performed were agreed upon by all WP4 partners in the Pilot Evaluation Plan (ref: NTS\21367-1_kol).

3.1 PILOT SPECIFICATIONS

According to the pre-set outlines of the pilot, information on donors who donated in 2010 and 2011 a kidney was collected. Of these donors, the pre-donation data, the peri-donation data, and the one-year follow-up information is included, according to the predefined ACCORD pilot data set and data dictionary (Annex I). Data could be included in the pilot database in two different ways:

1. Key entry of data
   The participants of this part of the pilot are shown in Table 1. The expected number of donors by key entry based on the Newsletter Transplant 2011 and 2012 was 163 donors.

Table 1. Participants of the pilot with key entry and number of living kidney donors as recorded in the Newsletter Transplant 2011 and 2012.

Direct data entry			
Country	Number of living kidney donors in 2010 Newsletter Transplant 2011	Number of living kidney donors in 2011 Newsletter Transplant 2012	Number of living kidney donors in 2010 and 2011 Newsletter Transplant 2011+2012
Croatia	20	9	29
Latvia	2	3	5
Lithuania	8	3	11
Portugal	51	47	98
Slovakia	7	13	20
Sub Total	88	75	163

2. File upload
   The participants of this part of the pilot are shown in Table 2. The expected number of donors by file upload, based on the Newsletter Transplant 2011 and 2012 was 3,607 donors. The countries that participated in the file upload part of the pilot already have a national or local follow-up database in place.

Table 2. Participants of the pilot with file upload and number of living kidney donors as recorded in the Newsletter Transplant 2011 and 2012.

File upload			
Country	Number of living kidney donors in 2010 Newsletter Transplant 2011	Number of living kidney donors in 2011 Newsletter Transplant 2012	Number of living kidney donors in 2010 and 2011 Newsletter Transplant 2011+2012
The Netherlands	473	440	913
Poland	50	40	90
Spain	240	312	552
United Kingdom	1026	1026	2,052
Sub Total	1789	1818	3,607

3.2 GENERAL OUTCOME

The total number of donors included in the pilot was 2,921 donors. Two donors were excluded because only a donation number was given, while all other data was missing. Ten were excluded because of problems with the donation date (should be between 1-1-2010 and 1-1-2012): in 6 cases no donation date was entered and in 4 cases the donation date was outside the predefined borders. Finally the analysis was done with the remaining 2,909 donors, which corresponds with 77% of the total number of living donors in 2010 and 2011 in the participating countries.

In table 3 the data are shown of the participating countries. The United Kingdom had by far the largest number of living kidney donors (70.4% of all included donors). In the last column of table 3 the percentage is shown of the number of included donors in relation to the expected number of donors. The expected number of donors was based on the total number of living donors as provided in the Newsletter Transplant 2011 and 2012. Three countries, participating in the key entry pilot included 100% of the expected number of donors. Portugal and Croatia included 39.8% and 51.7% of the expected number respectively.

Two countries, which entered data by file upload, had 100% and nearly 100% of the expected number of donors. The other two countries (The Netherlands and Spain) with upload entry had a percentage of inclusion of expected donors that ranged from 36.9% to 62.1%. Particularly The Netherlands had a very low percentage (36.9%). Interesting additional information is whether this low percentage is the result of problems using the upload module or that the donors were not included in the national database. Further analysis proved that for The Netherlands both possibilities were true. In the Dutch database 663 donors had sufficient follow-up, but due to a limitation error in the upload module the number of donors that could be uploaded in one shift was restricted and only 337 were included in the ACCORD database. This remark was also mentioned in

the questionnaire by the UK who had noticed it during the process of file upload. On the other hand in the Dutch national database 250 donors had insufficient follow-up data, and could not be uploaded at all. In Spain all available donors with sufficient follow-up data were included in the ACCORD database. It should be emphasized that in both countries basic data are available for 100% of the donors. However, both countries only uploaded donors when both baseline and follow-up data were available.

Table 3. Number of donors included in the ACCORD pilot registry according to country

Country	Number of donors	Percentage of the total included donors	% of expected*
Spain	343	11.8	62.1
United Kingdom	2049	70.4	99.8
Croatia	15	0.5	51.7
Lithuania	11	0.4	100
Latvia	5	0.2	100
The Netherlands	337	11.6	36.9
Poland	90	3.1	100
Portugal	39	1.3	39.8
Slovak Republic	20	0.7	100
Total	**2909**	**100**	

**Based on the total number of living donors as reported in the Newsletter Transplant 2011 and 2012*

Conclusion: The entry of donors, either by key entry or by file upload did technically not give many problems. The upload module had a limitation for the number of donors that could be included in one time, which resulted in a loss of donors from the Netherlands. The incompleteness of the national or local databases was another important reason for the reported low number of included donors.

3.3 CHARACTERISTICS OF THE PRE-DONATION DATA

The donor characteristics before donation are shown in Table 4. The age of the donor at the moment of donation ranged from 18 (minimal allowed age for donation) to 82 years, with a mean age of 47 years. More women than men donated a kidney, which was also the outcome in each individual country. The mean Body Mass Index (BMI) was slightly above 25 kg/m^2. In case the length was below 120 cm the value was set to 'unknown'. In case the weight was below 40 kg or above 140 kg the value was also set to 'unknown'. The most frequent blood group was O as can be expected in a living donation situation (universal donor). The most common ethnicity was white (86.3%). The ethnicity was the item in the pre-donation evaluation with the most missing values

(26.9%). Several countries did not collect this item, which is also not mandatory in the ACCORD database.

Table 4. Characteristics of the donor (missing values excluded from analysis)

Variable name		Lowest value	Highest value	Percentage missing values
Age (yr); mean ± sd*	47.4 ± 12.0	18	82	0.1
Gender (male);%	43.4	-	-	0
Weight (kg); mean ± sd	75.4 ± 14.0	39.5	140	7.7
Height (cm); mean ± sd	168 ± 9.9	122	198	10.3
Blood group; %				1.5
- A	34.3	-	-	
- AB	0.7	-	-	
- B	9.2	-	-	
- O	55.8	-	-	
Ethnicity; %				26.9
- Asian	7.5	-	-	
- Black	4.4	-	-	
- Mixed	0.3	-	-	
- Oriental	0.5	-	-	
- White	86.3	-	-	
- Other	0.9	-	-	

*sd=standard deviation

Additional pre-donation data are shown in Table 5. The relation between donor and recipient was almost always available and in the majority of cases genetically related (>60%). The pre-donation antihypertensive treatment counted many missing values (77.1%), because this item was not present in many countries. From Table 5 it is clear that if this item was completed, less than 10% of the donors used antihypertensive medication before donation. The mean serum creatinine value before donation was 74 µmol/L with a low standard deviation as can be expected in this population. The highest value was 158 µmol/L. In some cases the value of the serum creatinine had to be divided with 10,000 because some countries experienced problems with the conversion of units. In one case the serum creatinine at the start of the donation procedure was 541 µmol/L, while this was 64 µmol/L after the donation. We changed this serum creatinine to 54.1 µmol/L. Nearly no country had the item proteinuria before donation in its database, so this item is almost always missing. Further analysis revealed that several countries used other units for proteinuria, which could not easily be translated into predefined ACCORD units. The item proteinuria is however available in almost all cases. The comorbidity in the pre-donation phase was also rather low, as can be expected in this group of 'patients'. In the predefined dataset we anticipated on a set of comorbidities that could be filled in with Yes or No. We can conclude that most comorbidities were referred to as 'other'. Further analysis of the item 'other' revealed that some countries had filled out all comorbidity in the item 'other', and did not

correspond the actual comorbidity to the right ACCORD item. Additional analyses revealed that most items could be categorized into predefined ACCORD items. Table 6 shows the distribution of the items 'other' into the predefined ACCORD items. Pre-donation cardiovascular problems were the most frequent mentioned item of the predefined ACCORD items, followed by respiratory problems.

Table 5. Data before donation (missing values excluded from the analysis)

		Lowest value	Highest value	% missing values
Relation type (%)				1.3
Related genetically (%)	61.4	-	-	
Related non-genetically (%)	26.9	-	-	
Unrelated (%)	11.7	-	-	
Antihypertensive treatment (%)				77.1
- Nothing (%)	91.6			
- Diet only (%)	0			
- Medication (%)	8.4			
- Other treatment (%)	0			
Antihypertensive treatment (%)				
- Diuretic (%)	13.6			
- Beta blocker (%)	38.1			
- ACE inhibitor (%)	12.9			
- A2 antagonist (%)	24.6			
- Vasodilator (%)	13.3			
- Other medication (%)	0			
- Two or more treatments (%)	19.6			
Creatinine (µmol/L); mean ± sd*	74 ± 14	37	158	7.2
Proteinuria (mg/mmol creat); mean ± sd	1.5 ± 3.9	0	19.0	98.5
Comorbidity (Y) %	8.6			15.6
- Abdominal surgery (%)	0.2			
- Malignancy (%)	0			
- Hematology (%)	0			
- Neurology (%)	0			
- Cardiovascular (%)	0.2			
- Respiratory (%)	0.1			
- Gastroenterology (%)	0.1			
- Psychology (%)	0.1			
- Renal (%)	0			
- Other (%)	8.0			

*sd=standard deviation

Table 6. The item 'other' in comorbidity. Breakdown in predefined ACCORD items**

ACCORD item	Frequency
Other	77
Cardiovascular	69*
Respiratory	39
Psychology	17
Unreadable	8
Hematology	6
Renal	6
Abdominal surgery	3
Neurology	3
Malignancy	0
Gastroenterology	0

**including hypertension*
*** donor can have more than one comorbidity*

Conclusion:

- Except for the pre-donation antihypertensive treatment and the pre-donation proteinuria, most predefined ACCORD items were available in the pilot registry.
- The reported values are for most items within the expected range.
- The predefined comorbidity items were not specified to the ACCORD subdivision, and mostly 'Other' is chosen. Particularly the countries, which entered data by file upload, had problems to include their comorbidity in the predefined ACCORD items. Further analysis revealed that, although laborious, their data could be transferred to the right ACCORD items.
- Some conversion problems with the creatinine value were encountered.

3.4 DATA DURING THE DONATION PROCEDURE *(from donation until discharge)*

The data of the donation procedure are shown in Table 7. The mean length of stay in the hospital was 4.2 days, which is rather short, particularly because open procedures were also included in this average number. In three cases the length of stay was more than one year. In these cases the value was set to 'unknown'. The item about admission to the ICU was almost never available in the participating countries. The majority of donated kidneys were left kidneys, as can be expected because of the longer veins. In the investigation period (2010 and 2011) most donation procedures were laparoscopic and in only 10% of the cases an open procedure was performed. The item 'complications during the donation procedure' was not completed in more than 35% of the cases. This is remarkable, because one would expect that this is one of the key items for a living donor registry. When the item was filled out, it was clear that the percentage of complications during operation is very low, and the items that were mentioned were mostly a switch from laparoscopic to open procedure and blood loss. These can be considered as not very complicated side effects of the operation procedure.

Table 7. Data during the donation procedure (missing values excluded from the analysis)

		Lowest value	Highest value	% missing values
Length of hospital stay (days); mean ± sd*	4.2 ± 2.5	1	36	20.2
Number of days in ICU; mean ± sd*	0.09 ± 0.3	0	1	99.0
Left kidney donated; %	84	-	-	12.0
Operation technique; %		-	-	8.3
- Open (costal resection) %	0.4	-	-	
- Open (no costal resection) %	8.5	-	-	
- Open (mini incision) %	3.2	-	-	
- Laparoscopic (standard) %	45.8	-	-	
- Laparoscopic (hand assisted) %	42.0	-	-	
- Other %	0	-	-	
Complications during operation (Y); %	3.0	-	-	35.9
- Blood loss %	1.3	-	-	
- Kidney damaged %	0	-	-	
- Other organ damaged %	0	-	-	
- Switch of laparoscopic procedure %	1.6	-	-	
- Cardiac arrest %	0	-	-	
- Other severe complications %	1.3			

*sd=standard deviation

Some additional data about complications during the first admission until discharge are shown in the Table 8. This item was completed in more than 90% of the cases. Also in this data the percentage of complications during admission is about 10%. Remarkable in this case as well, was that most of the time the item 'other' was chosen and not one

of the predefined ACCORD items. We also combined the complications during donation and until discharge, which resulted in a complication percentage of 15.9%.

Table 8. Early complications after donation (before discharge; missing values excluded from the analysis)

		Lowest value	Highest value	% missing values
Complications (Y) %	10.1	-	-	9.7
- Blood loss %	0.2	-	-	
- Re-operation %	0.8	-	-	
- Infection %	1.9	-	-	
- Thrombo/embolic %	0	-	-	
- Dialysis %	0	-	-	
- Cardiac arrest %	0	-	-	
- Other %	9.0	-	-	
Combined complications (Y) % (operation until discharge)*	15.9			34.7

**If either complication during operation or early complication after donation is YES then the combined item is YES. If no complication was recorded neither in complication during operation or early complication after donation then the combined item is NO. If in the complication during operation or early complication after donation one item is missing and the other value is NO then the combined value is set to missing.*

Analyzing the complications led to the conclusion that some countries have registered the complications not according to the ACCORD items, but registered all items under the item 'other'. Table 9 shows an overview of the distribution of the item 'other'.

Table 9. Early complications after donation (before discharge). Breakdown in predefined ACCORD items.

ACCORD item	Frequency
Infection	66*
Other	40
Blood loss	4
Thrombo/embolic	2
Dialysis	0
Cardiac arrest	0
Re-operation	0
Unreadable	49
Wound problems	18
Pain	14
Readmission	10
Fever	8
Ileus	6
Urinary retention	6
Splenectomy	6
Bowel injury	4
Fatigue	4
Nerve injury	4

**mainly respiratory infections*

Several complications were not written in English, and are depicted here as 'unreadable'. Some complications in Table 9 are not very severe and it is questionable whether these complications should be included at all. Examples of this are fatigue, urinary retention, fever, pain. The complication 'readmission' is also questionable because the follow-up is until the first discharge. Other complications are severe, like splenectomy, bowel injury, and ileus. Two important conclusions can be drawn from Table 9. In the first place that the complications that were filled out as 'other' could be easily classified in the predefined ACCORD items. Adding, deleting or replacing predefined ACCORD items is therefore not necessary. Secondly, to avoid discussions about which complications are severe enough to be listed in the RoR, only SAE (serious adverse events) should be included according to international definitions. Several guidelines are suitable for this purpose and during the implementation of the RoR a selection should be made. The definitions of complications should therefore be adapted.

Conclusion:

- Most data are completed except for the number of admission days on the ICU.
- Data are in line with expectations for the items 'side of the kidney', and 'complications during donation procedure till discharge'.
- Many complications were rated as 'other' and not sub-categorized according to the proper 'ACCORD standard'.
- No extra classifications within the complications categories are necessary, because with some effort all complications could be classified in predefined ACCORD items.
- The definition of complications should be adapted to international standards to avoid the registration of minor problems.
- The length of hospital stay was rather short with an average stay of 4 days.

3.5 THE FOLLOW-UP FROM DISCHARGE UNTIL 1 YEAR AFTER DONATION

The follow-up was set at one year. That means that morbidity or mortality after one year is not included in this analysis. The data about follow-up are depicted in Table 10 Two patients died in the predefined follow-up period 2.4 and 3.0 months after donation. One patient died suddenly as a result of a circulatory problem, the other died in a car accident.

The antihypertensive treatment was reported in much more cases than in the pre-donation phase, but is not available in several countries. Only 2% of the donors used antihypertensive drugs after donation and nearly no one used more than one drug. The mean creatinine value was 105 µmol/L and this is of course higher than the pre-donation values for creatinine. Remarkably enough, the item proteinuria is still not filled in very frequently. Additional search for the reasons why this important item is missing revealed that proteinuria was available in all databases, but not in the units that were defined by the ACCORD group. Sometimes it is available as no and not as a number, sometimes it is only available as gram per day or gram per liter. These units could not be easily translated to the ACCORD units. During the one-year follow-up we also counted the health issues of the donors and surprisingly this item was often missing. For the donors where this item was filled in it became clear that the incidence of health issues is very low. No donors needed dialysis in the year after donation. The item ‘did the donor return to his or her previous activities’ was answered with Yes in the great majority of the cases. The mean value for the return to previous activities was 2.5 months.

Table 10. Follow-up from discharge to 1 year after donation (missing values excluded from the analysis)

		Lowest value	Highest value	% missing values
Donor lost to follow-up %	24.0	-	-	6.1
Death within 1 year (Y) N	2	-	-	
Mean death interval after donation (months)	2.7	2.4	3.0	
Weight of the donor (kg); mean ± sd*	75.9 ± 14.0	39.5	140.0	18
Antihypertensive treatment		-	-	29.3
- Nothing %	92.9	-	-	
- Diet only %	0	-	-	
- Medication %	3	-	-	
- Other medication %	4.1	-	-	
Antihypertensive treatment				
- Diuretic %	34.0	-	-	-
- Beta blocker %	56.0	-	-	-
- ACE inhibitor %	28.8	-	-	-
- A2 antagonist %	36.2	-	-	-
- Vasodilator %	27.7	-	-	-
- Other %	NA	-	-	-
- Two or more treatments (%)	9.5			
Creatinine (µmol/L); mean ± sd	104 ± 21.4	46	189	29.8
Proteinuria (mg/mmol creat); mean ± sd	4.1 ± 11.1	0	80	93.4
Health issues (Y) %**	20.2			91.8
- Abdominal surgery %	0	-	-	
- Malignancy %	0.4	-	-	
- Hematology %	0	-	-	
- Neurology %	0.4	-	-	
- Cardiovascular %	0.4	-	-	
- Respiratory %	0	-	-	
- Gastro intestinal %	0	-	-	
- Psychiatry %	0.4	-	-	
- Psychology %	0	-	-	
- Renal %	1.2	-	-	
- Renal replacement therapy %	0	-	-	
- Pregnancy %	0	-	-	
- Diabetes mellitus %	0	-	-	
- Other %	2.9	-	-	
Did the donor return to previous activity level (Y); %	98.2	-	-	42.0
Return to previous activity (months); mean ± sd	2.5 ± 1.7	1	12	53.5

*sd=standard deviation

**for several donors no specification of the health issue was filled out.

Conclusion:

- 2 deaths were encountered in the first year after donation, which makes the death rate within one year 0.07%. The deaths were not related to the donation procedure. No deaths were reported in the immediate postoperative phase.
- No donors needed renal replacement therapy during follow-up.
- In the one-year follow-up period few donors used antihypertensive drugs and few donors were reported with health issues.
- The great majority of the donors returned to pre-donation activities within 3 months after donation.
- Proteinuria was registered in the RoR during follow-up very infrequently, because of different units in different countries. Because this item is important for the follow-up of the donor, the units for the ACCORD items should therefore be reconsidered.

4. GENERAL CONCLUSIONS

To give a short overview of the conclusions that are drawn in the previous chapters, all conclusions are listed below. A summary of the conclusion is given in the second paragraph.

4.1 OVERVIEW OF CONCLUSIONS

4.1.1 Pilot evaluation

- The ACCORD WP4 pilot registry is a suitable way to collect living donor follow-up information.
- Direct data entry and file upload are both good possibilities to enter data into the registry.
- The data download functionality worked well and is a good possibility for countries to extract their own data.
- The size of the upload file (number of records to be uploaded in one shift) was limited due to a technical setting in the application. This can easily be adapted.
- The headings in the upload template are not easily identifiable as numbers are used as a reference instead of the column title.
- Users responded that they were faced with a lot of missing values in the patient's medical files.

4.1.2 Technical evaluation

- The follow-up registry (of registries) as an online application functioned well.
- The concept of a web-based application proved to be very useful, and can be recommended.
- The pilot can be approached by all common browsers, preferably using the latest version. Internet Explorer is less convenient to use, because updates are not installed automatically and could therefore cause difficulties when running the registry using Internet Explorer.
- The installation of a support team that responded to any technical difficulties within a short period of time was very valuable.
- The file for uploading data from an existing registry had a predefined template which was easy to use. Conversion had to take place of data from existing registries into the ACCORD pilot registry.
- Countries were able to download their 'own' data in an Excel file as this was part of their user profile's authorization. However, special caution should be paid to the 'decimal separator'.

4.1.3 General outcome

The entry of donors, either by key entry or by file upload did technically not give many problems. The upload module had a limitation for the number of donors that could be included in one time, which resulted in a loss of donors from the Netherlands. The incompleteness of the national or local databases was another important reason for the reported low number of included donors.

4.1.4 Characteristics of the pre-donation data

- Except for data of the pre-donation antihypertensive treatment and the pre-donation proteinuria, most data for predefined ACCORD items were available in the pilot registry.
- The reported values are for most items within the expected range.
- The predefined comorbidity items were not specified to the ACCORD subdivision, and mostly 'Other' was chosen. Particularly the countries that entered data by file upload had problems to include their comorbidity in the predefined ACCORD items. Further analysis revealed that, although laborious, their data could be transferred to the right ACCORD items.
- Some conversion problems with the creatinine value were encountered.

4.1.5 Data during the donation procedure

- Most data are completed except for the number of admission days on the ICU.
- Data are in line with expectations for the items 'side of the kidney', and 'complications during donation procedure till discharge'.
- Many complications were rated as 'other' and not sub-categorized according to the proper 'ACCORD standard'.
- No extra classifications within the complications categories are necessary, because with some effort all complications could be classified in predefined ACCORD items.
- The definition of complications should be adapted to international standards to avoid the registration of minor problems.
- The length of hospital stay was rather short with an average stay of 4 days.

4.1.6 Follow-up from discharge until one year after donation

- Two deaths were encountered in the first year after donation, which makes the death rate within one year 0.07%. The deaths were not related to the donation procedure. No deaths were reported in the immediate postoperative phase.
- No donors needed renal replacement therapy during follow-up.
- In the one-year follow-up period few donors used antihypertensive drugs and few donors were reported with health issues.
- The great majority of the donors returned to pre-donation activities within 3 months after donation.
- Proteinuria was registered in the RoR during follow-up very infrequently, because of different units in different countries. Because this item is important for the follow-up of the donor, the units for the ACCORD items should therefore be reconsidered.

4.2 SUMMARY OF CONCLUSIONS

This evaluation provides very valuable information. It can be concluded that a pilot version of a registry of registries can be established by the facilitation of an online application. Any modifications in the online application can be easily made, enabling all countries to have the latest (and best functioning) version at their dispose. The direct key entry possibility as well as the file upload possibility were very suitable ways for countries to enter their living donor's follow-up information. However, the conversion of data from an existing database into the ACCORD format was very time-consuming. The consequence of this was that not all items were filled out in the proper predefined ACCORD items. The pilot shows that a central registration is absolutely necessary. An alternative would be to send national data to a central European database periodically (for instance once in the three years), where analysis can be done. The pilot shows that with the current national databases that is impossible. This would only be an option if all countries use exactly the same items and the same definitions.

The number of records to be uploaded at once using the upload file was limited due to a technical setting in the application. This became clear during the evaluation so it was not adapted during the pilot, but this setting can easily be changed. The expected number of living donor follow-up records was higher than the actual number of 2909 donors. The incompleteness of the data in the patient's charts as well as in the existing national databases was the mean reason for the discrepancy in the expected and the actual number of living donor follow-up data. Another reason for the discrepancy is the upload problem.

With this pilot it is impossible to conclude about the long-term consequences of living donation, since only one year follow-up data is included. It is still difficult to draw absolute conclusions about the consequences of living donation for a living donor within the European Union after one year, from the data that is collected in the ACCORD WP4 pilot registry. From the data that were collected in the ACCORD pilot registry, we can learn that few severe early complications were reported (splenectomy, bowel injury). Two deaths were reported, but these were not related to the kidney donation procedure. No donors needed renal replacement therapy after donation. It seems as if the donors returned to their previous activity level within 3 months and without facing large problems after donating one of their kidneys.

5. RECOMMENDATIONS

The experiences using the ACCORD WP4 pilot registry and the analysis of the data result in the conclusions as presented in the previous chapter. The following recommendations result from these conclusions:

- ✓ A common data set and data definitions are essential for an international registry, enabling (international) data analysis (Chapter 15);
- ✓ Appropriate governance arrangements should be in place (as detailed in Chapter 8);
- ✓ The new database for the collection of follow-up data of living donors should be a web-based application;
- ✓ The web-based application should have the possibility of direct data entry;
- ✓ Countries with a small number of living donors could use the registry of registries as their national follow-up registry, using the direct key entry possibility. It should be taken into account that the data set for a national registry is different from the data set for an international registry, so the country should have the possibility to collect the data that is set to be necessary on a national level;
- ✓ The web-based application should have an upload facility. The size of the upload file (number of records to be uploaded at once) should not be limited;
- ✓ Standardized conversion rates from one value (from an existing registry) to the future registry value should be available;
- ✓ The web-based application should have a download facility, where data can be extracted easily by participating countries;
- ✓ Special attention will be needed for the internet browser program of the user, to assure all web browsers working correctly with the web-based application.
- ✓ A support team should be available and respond within short period to support in case of any questions and/or problems;
- ✓ The official language of the web-based application should be English, and also commentary fields should be in English;
- ✓ When in the future ACCORD database historical items of national database have to be included, some mandatory items should be made optional to ensure sufficient upload possibilities. Preferably this change from mandatory to optional is temporarily;
- ✓ Several standard reports should be available;
- ✓ It is suggested to add an explanation about the background, goal and responsible institution or consortium in the home-page of the online application;
- ✓ The registry as well as the upload template and the reports that can be extracted from the registry should contain clear headings and logos and should be recognizable as being a product of the future follow-up application;
- ✓ Donor centres should be obliged to collect living donor follow-up data in order to ensure sufficient follow-up;
- ✓ A follow-up registry, based on the ACCORD recommendations, must be implemented.

ANNEX I

DATASET REGISTRY OF REGISTRIES: KIDNEY

2.1 DONOR DEMOGRAPHIC INFORMATION

Nr.	Item	Definition	Units	M/O[1]
1	Identification (ID number, initials)	The unique identification code that is given by the national authorities to each person, or a possibility to collect initials.		M
2	Date of birth		DD/MM/YYYY	O
3	Age	Actual age at the time of donation	years, no decimals	M
4	Gender		Male/Female	M
5	Weight		kg, no decimals	M
6	Height		cm, no decimals	M
7	Blood group	Menu: - A - B - 0 - AB	Choosing one from this menu	M
8	Country of residence		ISO code 3166	M
9	Nationality		ISO code 3166	M
10	Ethnicity	Menu: - White - Asian - Black - Oriental - Mixed, please specify - Other, please specify	Choosing one or multiple from this menu and free text field for 'specify:…..	O

2.2 PRE-DONATION DATA

Nr.	Item	Definition	Units	M/O[2]
1	Relation type	Menu: - Related a. Genetically b. Non-genetically - Unrelated	Choosing one from this menu	M
2	Antihypertensive treatment	Menu: - Nothing - Diet only - Medication: - Diuretics - Beta blockers	Choosing one from this menu	M

[1] M = Mandatory, O= Optional
[2] M = Mandatory, O= Optional

		- ACE blockers - A2 antagonists - Vasodilators/Calcium channel blockers - Other		
3	Creatinine		Umol/L or mg/dl	M
4	Proteinuria	PCR (protein creatinine ratio)	mg/mmol creat	M
5	Any significant co-morbidity	Menu: - No - Yes, specify: - Abdominal surgery, specify… - Malignancies, specify... - Hematological disease, specify… - Neurological disease, specify… - Cardiovascular disease, specify… - Respiratory disease, specify… - Gastrointestinal disease, specify… - Psychiatric disease, specify… - Psychological disorder, specify… - Renal / urinary tract disease, specify… - Other, specify… - Unknown	Choosing one or multiple from this menu and free text field for 'specify:…..	M

2.3 PERI- AND POST-OPERATIVE DATA (until discharge)

Nr.	Item	Definition	Units	M/O[3]
1	Country of donor hospital	The country in which the donation takes place	ISO code 3166	M
2	Date of donation		DD/MM/YYYY	M
3	Left or right kidney		Left / Right	M
4	Operation technique	Menu: - Open technique a. Classic technique - Costal resection - No costal resection b. Mini-incision - Laparoscopic a. Standard b. Hand assisted laparoscopic - Other, specify…	Choosing one from this menu	M
5	Complications during operation	Menu: - No complications - Blood loss: need for transfusion - Kidney damaged during retrieval a. Kidney can be used for transplantation b. Kidney is discarded for transplantation	Choosing one or multiple from this menu and free text field for 'specify...'	M

[3] M = Mandatory, O= Optional

		- Other organ damaged during surgery - Switch from laparoscopic procedure to open technique - Cardiac arrest - Other severe complications (i.e. pneumothorax, anaphylactic reaction) (specify…)		
6	Complications after operation – until first discharge	Menu: - No complications - Blood loss: need for transfusion - Need for re-operation - Infection (urinary, wound, other) - Thrombo/embolic complications (DVT, pulmonary embolism) - Renal Replacement Therapy, specify… - Cardiac arrest - Other severe complications (specify…)	Choosing one or multiple from this menu and free text field for 'specify…'	M
7	Length of hospital stay (LOS)	The number of days in hospital during the first admission (from day of surgery until discharge)	Number of days	O
8	Number of days in ICU	The number of days in Intensive Care Unit during the first admission (until discharge)	Number of days	O

2.4 FOLLOW-UP DATA

Nr.	Item	Definition	Units	M/O[4]
1	Date of follow-up		DD/MM/YYYY	M
2	Donor lost to follow-up		Yes / No	M
3	Death		Yes / No	M
4	Cause of death	All coding systems are allowed		M
5	Date of death		DD/MM/YYYY	M
6	Weight		kg, no decimals	M

7	Antihypertensive treatment	Menu:
		- Nothing
		- Diet only
		- Medication:
		  - Diuretics
		  - Beta blockers
		  - ACE blockers
		  - A2 antagonists
		  - Vasodilators/Calcium channel blockers
		  - Other
			Choosing one from this menu	M

8	Creatinine		Umol/L or mg/dl	M
9	Proteinuria	PCR (protein creatinine ratio)	mg/mmol creat	M

[4] M = Mandatory, O = Optional

10	Health issues	Menu:
		- No
		- Yes, specify:
		  - Abdominal surgery, specify…
		  - Malignancies, specify...
		  - Hematological disease, specify…
		  - Neurological disease, specify…
		  - Cardiovascular disease, specify…
		  - Respiratory disease, specify…
		  - Gastrointestinal disease, specify…
		  - Psychiatric disease, specify…
		  - Psychological disorder, specify…
		  - Renal / urinary tract disease, specify…
		  - Renal Replacement Therapy, specify…
		  - Pregnancy, specify (when)….
		  - Diabetes mellitus, specify…
		  - Other, specify…
		- Unknown
			Choosing one or multiple from this menu and free text field for 'specify:…..	M

11	Did the donor return to previous activity level? (This item should only be collected during the 12 month follow-up visit.)	Menu: - Yes, within …. months - No - Unknown	Choosing one from this menu and free text field for ' … months'	O

GLOSSARY OF TERMS

Not every item needs specification in this Glossary of terms. Some items however need an extra explanation about the way the item should be measured or collected. Another important issue is the way the registration in a national database will be translated into the supranational Registry of registries.

Item	Definition

Antihypertensive treatment	- Nothing: this means a donor does not use any diet and/or drugs
	- Diet only: diet is not specified. Anything a person calls a diet and is appropriate to control the person's blood pressure is considered a diet.
	Medication:
	The following classes of antihypertensive drugs can be identified:
	  - Diuretics
	  - Beta blockers
	  - ACE blockers
	  - A2 antagonists
	  - Vasodilators/Calcium channel blockers
	  - Other
	
	It is assumed that every patient with a class of antihypertensive drugs has had diet advice before the treatment with medication started.

Any significant co-morbidity (KIDNEY)	Menu: - No - Yes, specify: - Abdominal surgery, specify…

	- Malignancies, specify... - Hematological disease, specify… - Neurological disease, specify… - Cardiovascular disease, specify… - Respiratory disease, specify… - Gastrointestinal disease, specify… - Psychiatric disease, specify… - Psychological disorder, specify… - Renal / urinary tract disease, specify… - Other, specify… - Unknown
Blood pressure	Actual blood pressure (independent of the method of measurement): the method to collect the actual blood pressure is not defined.
Cause of death	All coding systems are allowed
Complications during operation (KIDNEY)	Complications during operation means from the start of the surgery until arrival at the recovery room. Menu: - No complications - Blood loss: need for transfusion - Kidney damaged during retrieval: this means that the kidney that is procured from the donor (graft) is damaged a. Kidney can be used for transplantation b. Kidney is discarded for transplantation - Other organ damaged during surgery: this means another organ (not the procured organ) is (physically) damaged during the operation. - Switch from laparoscopic procedure to open technique - Cardiac arrest - Other severe complications (i.e. pneumothorax, anaphylactic reaction), specify...: this will be a free text field.
Complications after operation – until first discharge (KIDNEY)	Complications after operation means from the departure from the recovery room until discharge from the hospital. Menu: - No complications - Blood loss: need for transfusion - Need for re-operation, specify… - Infection (urinary, wound, other): therapeutic use of antibiotics - Thrombo/embolic complications (DVT, pulmonary embolism) - Renal Replacement Therapy, specify… - Cardiac arrest - Other severe complications (specify…): this will be a free text field.
Complications (within the first 12 months)	Menu: - Nothing - Thrombo/embolic complications (DVT, pulmonary embolism, arterial thrombosis, portal thrombosis, lung embolism) - Infection (wound, surgical side infection, infected collection, other) - Non-infected collection - Biliary stricture - Biliary fistula - Liver insufficiency - Hemorrhage - Pleural effusion - Other complications, specify
Country of residence	This is the country where the person lives during 7 months of a year.
Did the donor return to previous activity level?	This item should only be collected during the 12 month follow-up visit. This should be based on the person's answer and should not be an objective measurement.

	Menu: - Yes, within …. months - No - Unknown
Donor lost to follow-up	A donor is lost to follow-up if he/she has regularly been invited to follow-up appointments, but did not show up during 10 years. Because the mandatory follow-up frequency is at discharge, 1 year after donation and then every 5 years, this means the donor did not show up during at least three visits.
Ethnicity	Menu: - White - Asian - Black - Oriental - Mixed, please specify - Other, please specify

Health issues
 	
(KIDNEY)
	Menu:
	- No
	- Yes, specify
	  - Abdominal surgery, specify…
	  - Malignancies, specify...
	  - Hematological disease, specify…
	  - Neurological disease, specify…
	  - Cardiovascular disease, specify…
	  - Respiratory disease, specify…
	  - Gastrointestinal disease, specify…
	  - Psychiatric disease, specify…
	  - Psychological disorder, specify
	  - Renal / urinary tract disease, specify
	  - Renal Replacement Therapy
	  - Pregnancy, specify (when)….
	  - Diabetes mellitus, specify…
	  - Other, specify…

Hypertension	Hypertension: Yes / No Hypertension should be considered 'yes' when a person uses a diet or medication to treat the hypertension. If a person does not use a diet or medication, but has a blood pressure >140/90 mmHg, the person is also considered hypertensive.
Identification	The national authorities in (almost) every MS give a unique identification code to each individual. This code could be used to identify a person without collecting their name. If a country decides not to use the unique identification code, another method should be used to prevent collecting data about the same person twice. For example a combination of initials and date of birth.
Length of hospital stay (LOS)	The number of days in hospital during the first admission from day 0 to the day of discharge, with day 0 being the day of surgery.
Nationality	In case of a double nationality, register both.
Number of days in ICU	The number of days in Intensive Care Unit during the first admission (until discharge)
Readmission (within the first 12 months)	Menu: - Yes, length of hospital stay (in days) - No - Unknown
Relation type	The definition that is applicable for the national kidney database differs from the definition of the Registry of registries. To be able to collect the information, the national and supranational registries should be able to communicate with each other. The possibilities from the national database should correspond with the simplified definition:

	National: - A/ Related - A1/ Genetically related: a. 1st degree genetic relative: parent, sibling, offspring b. 2nd degree genetic relative: e.g. grandparent, grandchild, aunt, uncle, niece, nephew, c. Other than 1st or 2nd degree genetically related, for example cousin - A2/ Emotionally related: Spouse (if not genetically related); in-laws; adopted, friend - B/ Unrelated: non-related = not genetically or emotionally related.	Supranational ➔ Related ➔ Genetically related ➔ Genetically related ➔ Genetically related ➔ Genetically related ➔ Non-genetically related ➔ Non-related: this means donor and recipient do not know each other

ANNEX II

Evaluated parameters

PRACTICAL EVALUATION

- Evaluation of the user-friendliness (direct data entry and file upload)
    - Logging into the application
    - Manuals and instructions
    - Look and feel of the registry
    - Using the application
- Finding and extracting the necessary data from patient's files (% completeness of data)
- Obtaining permission to use the patient's collected (anonymized) follow-up information for (international) data sharing in a registry of registries;
- Obtaining permission to use the patient's collected (anonymized) follow-up information for (international) research / analysis;
- Extracting data from existing registries;
- Experiences with data conversion from existing registries into ACCORD pilot registry (time, technique, number of missing values);
- Keeping the ACCORD WP4 pilot registry in mind: evaluation of the described governing, operational and technical rules for living donor registries;
- Evaluation of the co-operation / interaction between project leader, participating project partners (in the pilot), and collaborating partner (Hospital Clinic of Barcelona);
- Suggestions from participating partners for a future sustainable registry.

TECHNICAL EVALUATION

- Evaluation of the choice to build a web-based platform;
- Evaluation of the direct data entry possibility;
- Evaluation of the technical challenge in data conversion (programmed possibilities versus manual conversion);
- Evaluation of the file-upload module;
- Evaluation of the extraction module (export data);
- Evaluation of the difference in using the registry as a national registry or a supranational registry of registries;
- Evaluation of data security.

DATA EVALUATION

For the evaluation of the pilot the following items and statistical analyses are included:

- The number of donors included in the pilot in total and divided by country;
- The number of donors included in the pilot by file upload and per direct entry;

The following data is evaluated on a global level, not on a national level:

- Before donation (mean, mediate and modus):
    - age
    - weight
    - length
    - BMI
    - creatinine
    - proteinuria
- Distribution of gender, blood group, ethnicity, relation between donor and recipient, left/right kidney donated;
- The presence of antihypertensive medication (also type and total count), co-morbidity;
- During and after operation:
    - Distribution of operation technique;
    - Occurrence of complications during operation and in the first weeks after donation;
    - Any health issues in the first year after donation;
    - Death;
    - The use of antihypertensive drugs;
    - The average creatinine and proteinuria at 1 year, length of stay in the hospital and in the ICU, return to previous activity.
- Number of missing items;
- Statistical analysis
    - Descriptive analysis of the abovementioned items;
    - Changes in creatinine, proteinuria, use of antihypertensive drugs before donation and at 1 year after donation;
    - Health issues during the first year after donation in relation to age, gender, BMI, left/right kidney;
    - Length of stay in the hospital and ICU in relation to age, gender, BMI, left/right kidney;
    - Change in creatinine, proteinuria, and the use of antihypertensive drugs (before donation and at 1 year after donation) in relation to age, gender, BMI, left/right kidney;
    - Occurrence of death in relation to age, gender, BMI, left/right kidney;
    - Operational technique in relation to complications, health issues during the first year and length of hospital stay.
    - Complications during operation and in the first weeks after donation in relation to age, gender, BMI, left/right kidney;
    - Length of time to return to previous activity in relation to age, gender, BMI, left/right kidney.

ANNEX III

Questionnaire on the experiences using the ACCORD WP4 pilot registry

1. Did you experience any difficulties logging on to the pilot registry (via https://www.eulivingdonor.eu/donors/ACCORD.2013.12/)?
   - No
   - Yes

2. If you've answered question 1 with 'Yes', please specify:

3. Did you experience any difficulties using the ACCORD WP4 Registry instructions?
   - No
   - Yes

4. If you've answered question 3 with 'Yes', please specify:
   - Difficulty understanding the instructions
   - Difficulty finding an answer to a question
   - Other, please specify in text box

5. How did you experience the 'look and feel' of the application?

a). Did it feel 'intuitive'? Was it easy to find your way around the application?
   - No
   - Yes

b). Did you recognize the application as the ACCORD WP4 pilot registry?
   - No
   - Yes

c). Do you have any suggestions for improving the 'look and feel' of the application?

6. Did your national legislation prescribe you to ask permission to all of the living donors who's (anonymized) follow-up data you included in the ACCORD WP4 Pilot Registry?
   - No
   - Yes

7. Did you experience any difficulties obtaining permission for using the living donor's (anonymized) follow-up information in the ACCORD WP4 Pilot Registry?
   - No
   - Yes

8. If you've answered question 7 with 'Yes', please specify the difficulties.

9. Did your country enter data by direct key entry?
   - No
   - Yes

10. Did you experience any difficulties completing the DONOR DEMOGRAPHIC INFORMATION?
   - No
   - Yes

11. Did you experience any difficulties completing the follow-up data?
   - No
   - Yes

12. If you've answered question 10 and / or 11 with 'Yes', please specify the difficulties:
   - Difficulty to complete items with a different unit
   - Difficulty to obtain the specified items from the donor's file
   - Other, please specify

13. Did your country enter data, using the file upload module?
   - No
   - Yes

14. Did you experience any difficulties extracting the data from your existing registry?
   - No
   - Yes

15. Was it necessary to convert items from your existing registry into the ACCORD definitions and values?
   - No
   - Yes

16. If you've answered question 15 with 'Yes', did you experience any difficulties converting data from existing registries?
   - No
   - Yes

17. If you've answered question 16 with 'Yes', can you please specify the difficulties (multiple answers are possible):
   - Different definitions are used
   - Different values are used with difficulties to calculate into other values
   - A large number of missing values in existing registry
   - Difficulty to merge the downloaded data from the existing registry into the ACCORD upload file format.
   - Very time consuming, please specify:

18. How did you experience working with the upload file?

19. Do you have suggestions to improve the upload module?

20. Were you able to download the data from your own country from the ACCORD WP4 registry?
    - No
    - Yes
    - Don't know

21. Did you make an extraction of your 'own' data?
    - No
    - Yes

22. Did you check whether the downloaded data were identical to the data you entered / uploaded?
    - No
    - Yes

23. If you found any discrepancies between the data you downloaded from the ACCORD pilot registry and the data you uploaded from your existing registry, please specify the discrepancies.

24. Is there anything else you would like to share with us concerning the ACCORD WP4 pilot? Do you have any suggestions for improvement?

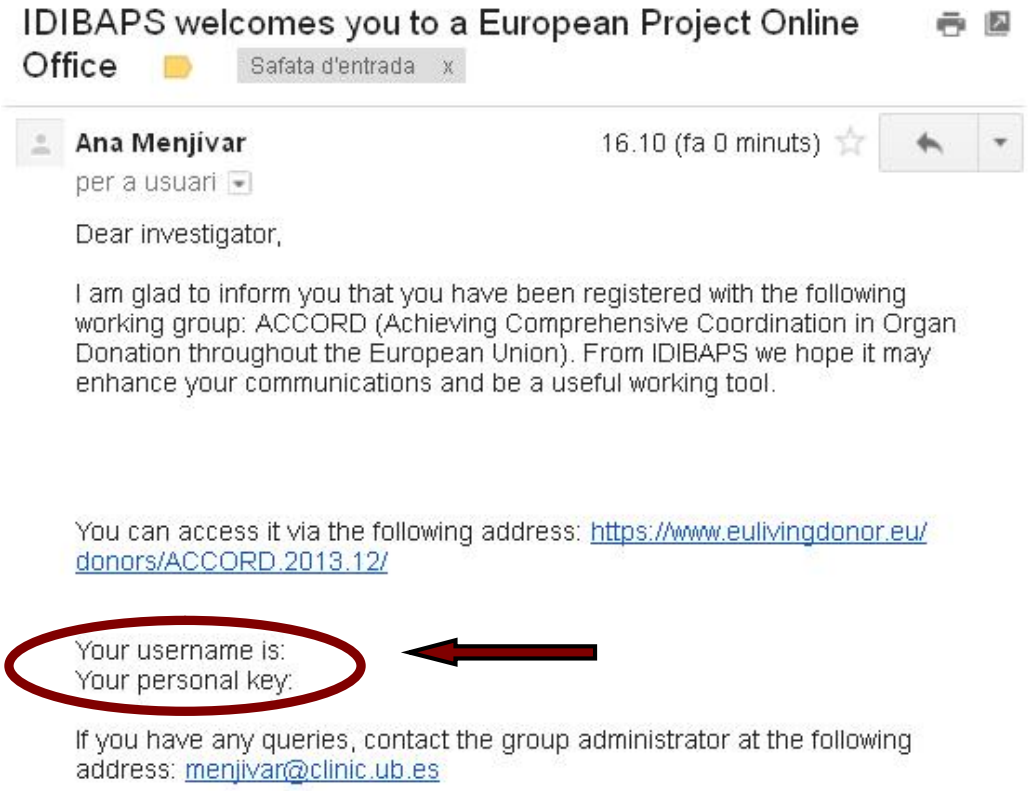
ANNEX IV

GUIDELINE

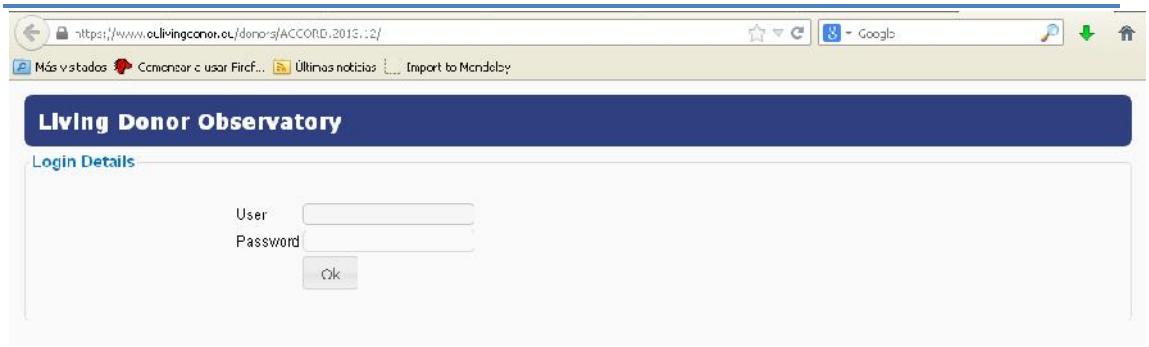
HOW TO USE "DIRECT DATA ENTRY" MODEL FOR ACCORD PILOT REGISTRY

1- All the participants of Each member State will receive an email with the following subject: "**IDIBAPS welcomes you to a European Project Online Office**" containing access data: username and password.

NOTE: For the security of the ACCORD pilot registry **t**he username and password are personal and no transferable.



2- Click the following link: https://www.eulivingdonor.eu/donors/ACCORD.2013.12/ and introduce your personal accessing data.



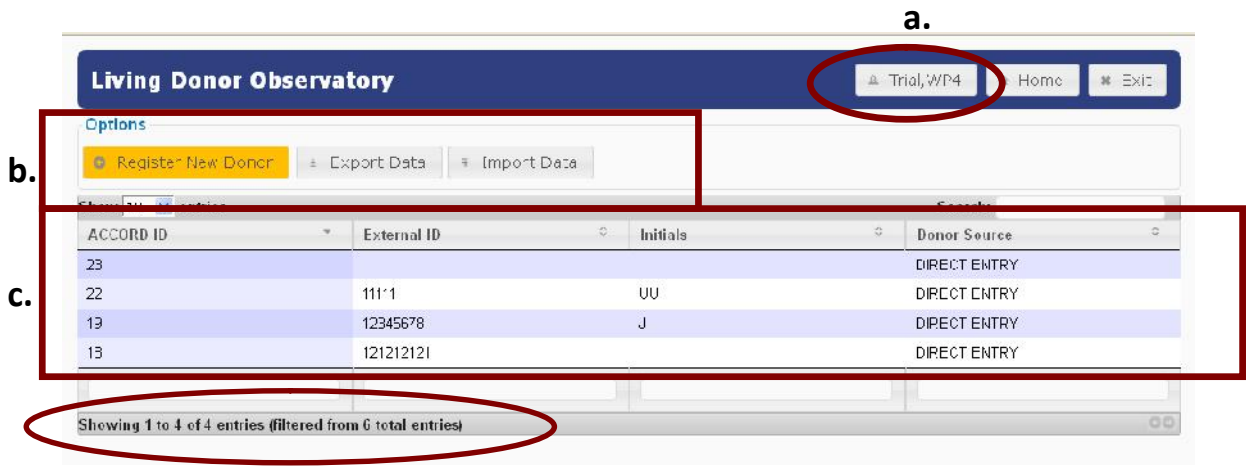
3- The main page will be opened.

There you will find:

a. Personal information

b. Different actions available in the registry – using the **national visibility profile**.

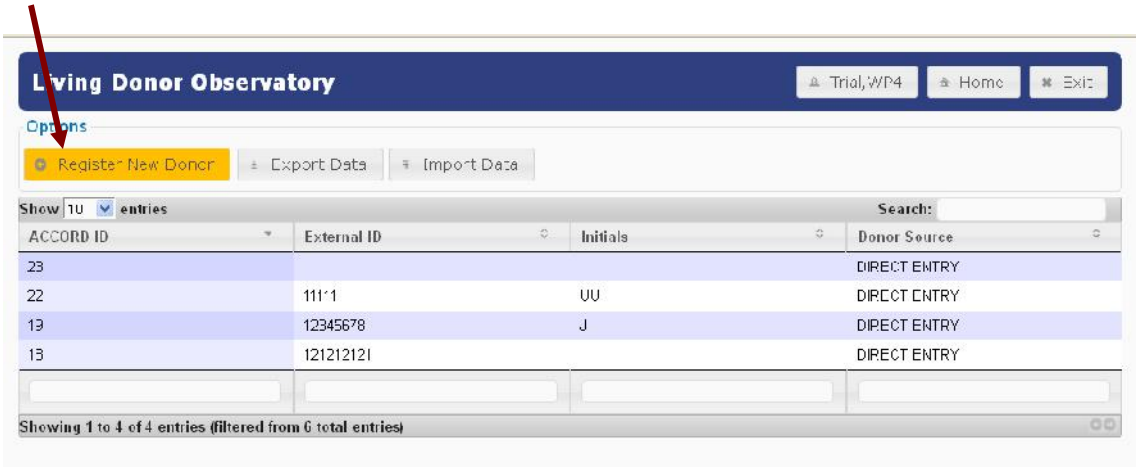
c. Summary of your current registered donors – due to the **national visibility** you can see only the registered donors of your country regardless of the person who introduced the donor.



Note: The total number of entries includes all the donors registered in the pilot registry and the system automatically filters the donor of your country.

1- How to register a new donor?

In the main page click the bottom **"Register a new donor"** (yellow color)



Subsequently a new window contains the Donor Demographic Information will be opened. After you will complete the required, please click **"Save"** and the system automatically will save these data and you will be redirected in the main page.

The ACCORD ID is correlative and given automatically by the system when a new donor is registered.

After the data are saved, the ID of the new donor will appear in the main page. Please click in the number ID and a new menu with different actions for this donor will be displayed.

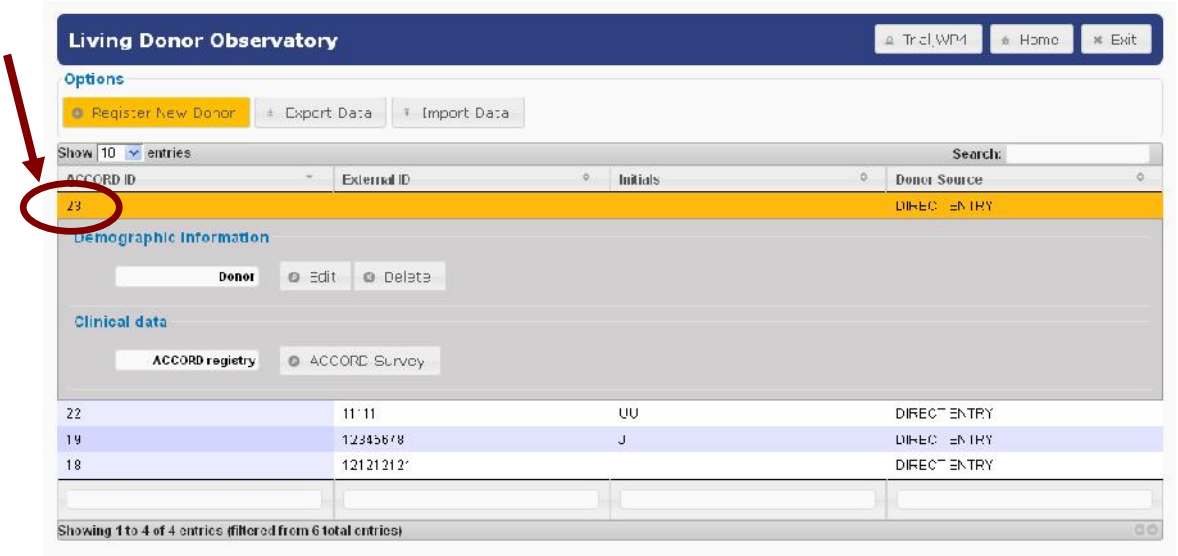
- **Demographic information:**
  Edit: To modify the demographic information previously introduced.

  Delete: To delete this ID and the specific information previously introduced.

  In order you will need to delete the data the system will require you to confirm the action and afterwards to write down the reason of the action.

  This information will go directly to the administrator.

- **Clinical data:** There is only the option to introduce the data collected for ACCORD survey.

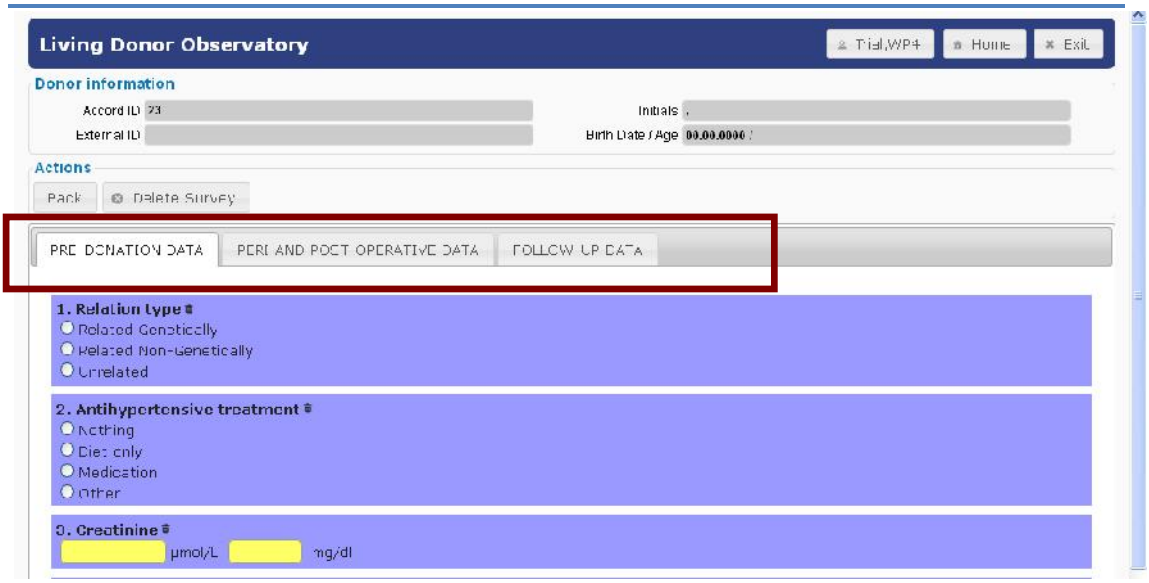


Afterwards you could introduce the clinical data, separated in three different labels:

- Predonation data

- Peri and Postoperative data

- Follow-up data



The information you will be introducing is automatically saved, when you change the label. After finishing with the data entry, please click BACK and the information is already stored into the registry and you could start the process for a new donor.

Additional information:

We include in the pilot registry a specific function for automatic conversion of units and warnings messages for extremes values.

Please keep in mind that while the page is inactive for more than 15 minutes the system for safety reason logs out from the session. You will need to sign in again.

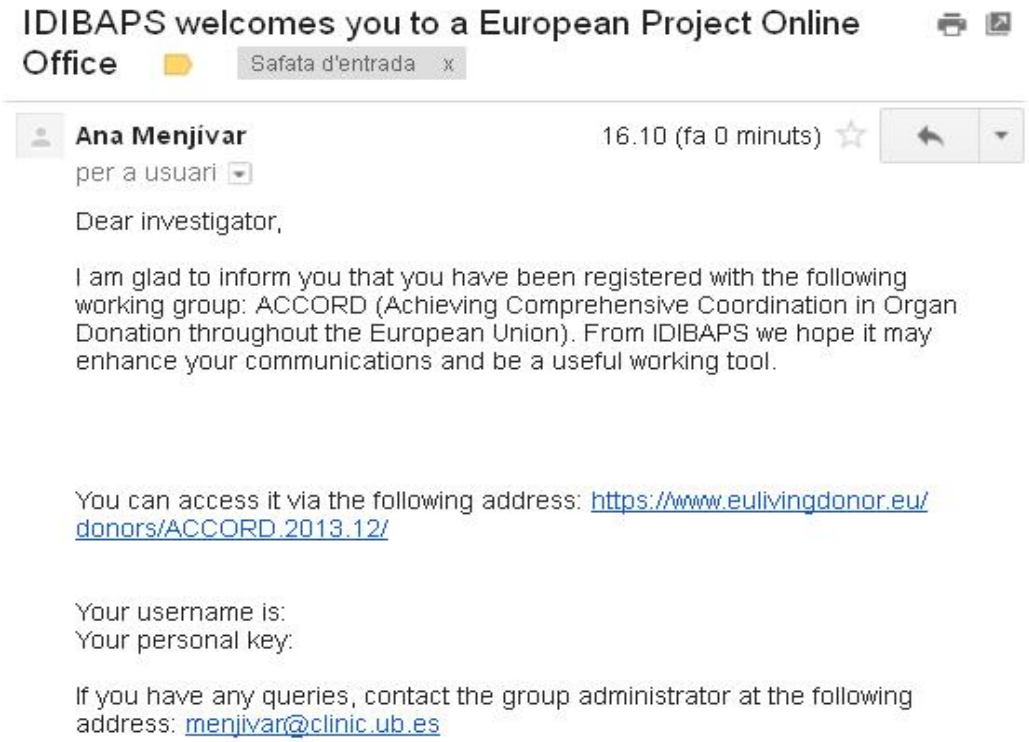
ANNEX V

GUIDELINE

HOW TO USE "FILE UPLOADING" MODEL FOR ACCORD PILOT REGISTRY

1- All ACCORD WP4 participants of each member State will receive an email with the following subject: "**IDIBAPS welcomes you to a European Project Online Office**" containing access data: username and password.

NOTE: For the security of the ACCORD pilot registry **t**he username and password are personal and not transferable.



IDIBAPS welcomes you to a European Project Online Office

Safata d'entrada x

Ana Menjivar 16.10 (fa 0 minuts)

per a usuari

Dear investigator,

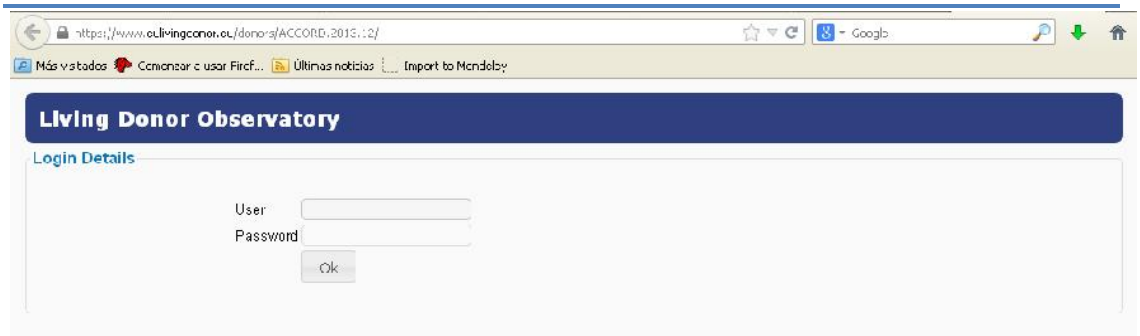
I am glad to inform you that you have been registered with the following working group: ACCORD (Achieving Comprehensive Coordination in Organ Donation throughout the European Union). From IDIBAPS we hope it may enhance your communications and be a useful working tool.

You can access it via the following address: https://www.eulivingdonor.eu/donors/ACCORD.2013.12/

Your username is:
Your personal key:

If you have any queries, contact the group administrator at the following address: menjivar@clinic.ub.es

2- Click the following link: https://www.eulivingdonor.eu/donors/ACCORD.2013.12/ and introduce your personal accessing data.



3- The main page will be opened.

There you will find:

a. Personal information

b. Different actions available in the registry – using the **national visibility profile**.

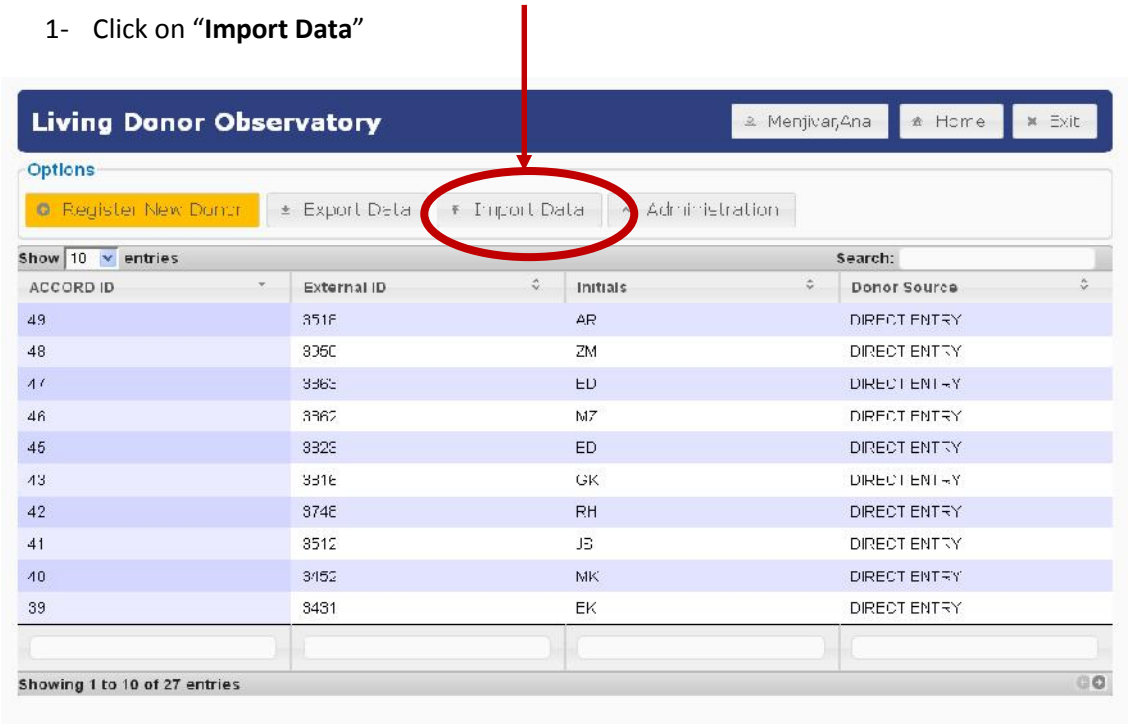
c. Summary of your current registered donors – due to the **national visibility** you can see only the registered donors of your country regardless of the person who introduced the donor.

Note: The total number of entries includes all the donors registered in the pilot registry and the system automatically filters the donors of your country.

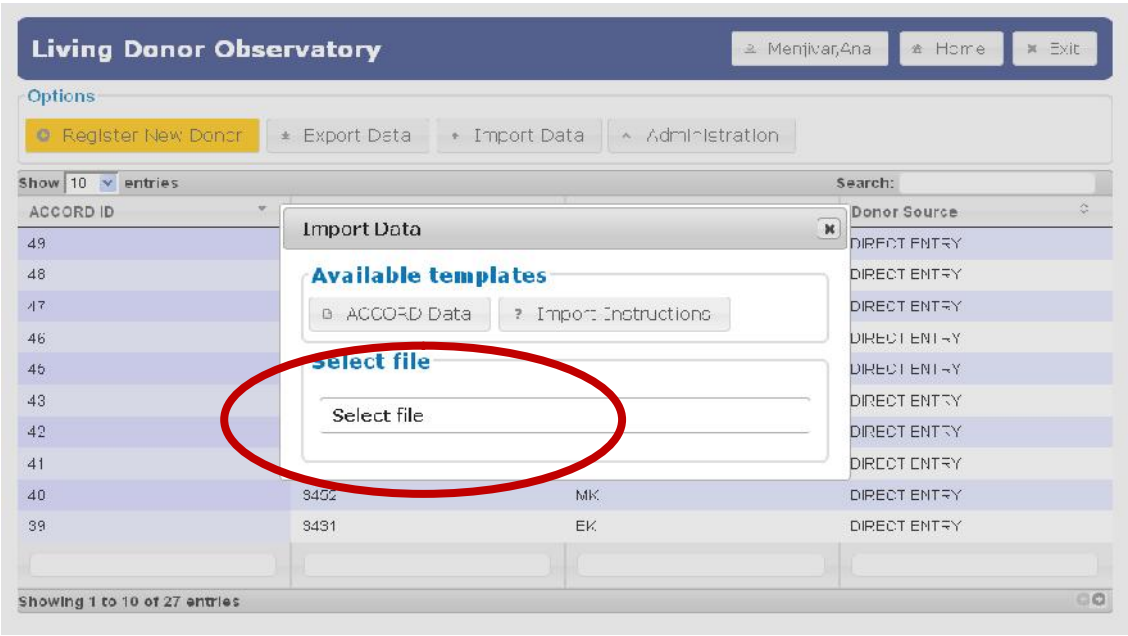
Guide for the import data module

Main page:

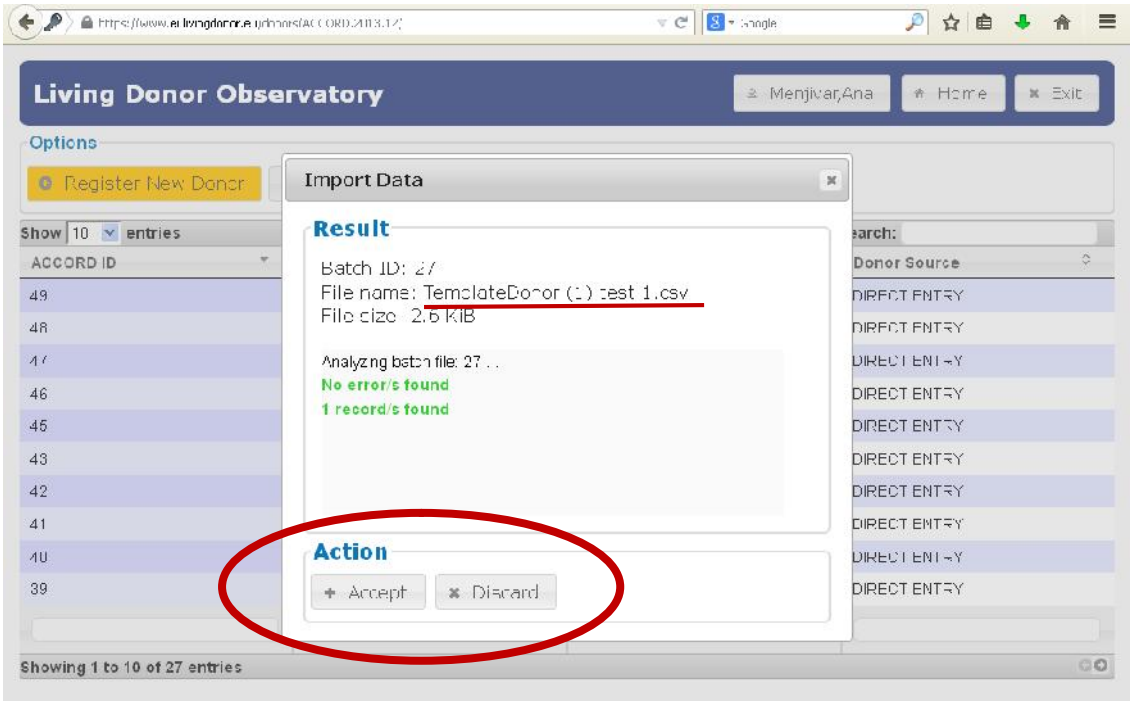
1- Click on "**Import Data**"



2- Select the file to be imported.



3- When the file is opened the system automatically analyzes the information in order to check any incongruence.
As you could see during this demonstration the system informs: “No error/s found” and offers two different actions: “Accept” or “Discard”

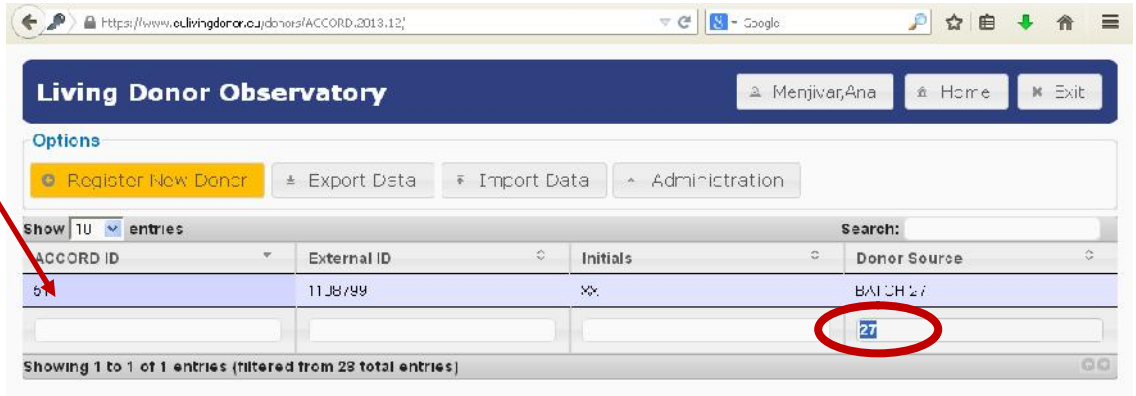


4- When you click :

a- **“Accept”** - the information is correctly saved and the system returns to the main page and the new donor just registered appears in the list.

b- **“Discard”**- the file will be completely discarded and no data will be loaded into the system.

5- After the data are saved, the IDs of the new/s donor/s will appear in the main page.



Note: After importing a file, to help identifying the imported data, the main screen filters the information by the batch ID (as shown above). To show all the donors again, please remove the batch ID from the search box.

More clarifications:

- In case a modification of the uploaded data is needed it should be done only manually and only going through each donor that needs modification (the respective ID of the donor in the registry). There is no possibility to delete or edit a full batch. Each modification should be done donor by donor.
- The system shows an alert in those cases when the External ID exists already. However, this is just an alert and the user may continue the process (accepting or discarding) the file.
  If you are uploading a file in where an ID is repeated the system does not give any alert. All the responsibility of the data is up to the person who is registering. The data must be checked before being uploaded.

NOTE: Please remember to download and read the instructions that are in the website before uploading any file. In the instruction you may find all the specific information for each variable.