Meeting:	Kick off Meeting
Place:	European Commission, Rue Froissart 101, Brussels
Participants:	Lisa Bradbury (NHSBT), Peter Branger (ET), Mirela Bušić (MoHCR), Dave Collett (NHSBT), Cecile Couchoud Heyer (ABM), Rianne de Jong (AMC on behalf of ERA-EDTA), Paola di Ciaccio (ISS-CNT), Fritz Diekmann (IDIBAPS), Daniela Bulach (DSO), Benedicte Faure (EKHA)- only second day, Francis L. Delmonico (EAB), Marja Guijt (ET), Aline Hemke (NTS), Andries Hoitsma (NTS), Franz Immer (EAB) – only first day, Kitty Jager (AMC on behalf of ERA-EDTA), Marti Manyalich (IDIBAPS), Sándor Mihály (OVSZ), Sergio Monteagudo (IDIBAPS), Ziad Massy (Current Chairman of ERA-EDTA Registry), Alessandro Nanni Costa (ISS-CNT), Orsolya Deme (OVSZ), Axel Rahmel (DSO), Undine Samuel (ET), Vianda Stel (AMC on behalf of ERA-EDTA), Mark Murphy (European Kidney Patients Federation), Sara Martin (EKHA)- only first day, Mireia Collado (IDIBAPS)
Agenda / Presentations	Agenda and presentations of the meeting are part of the minutes. All presentations will be made available on the website, when finally established (during the course of March).
First day February 16th 2017	
WP 1 **Coordination**	After the welcome by Axel Rahmel (DSO) and a short introduction of all participants of the meeting Axel Rahmel informed about the organisational framework of the Pilot project and announced that by today's meeting the Consortium Agreement was signed by all consortium members. Next the Steering Committee of the project was officially established consisting of the following members: Axel Rahmel, Sándor Mihály, Mirela Bušić , Kitty Jager, Alessandro Nanni Costa, Bernadette Haase, Marti Manyalich, Peter Branger and Dave Collett. For further details please refer to the Presentation of WP 1.
	Please note for future presentations not to include pictures in your slides where you don't have the property rights.
WP 5 LDR	Aline Hemke (NTS) gave a presentation outlining the needs and benefits of a living donor registry (responsibility towards living donor/special attention to ECD/legal requirements). She reported on the outcome and findings of ACCORD. EDITH will go beyond ACCORD, the objectives being: - Support MS with the establishment of national systems to follow-up living kidney donors by providing advice and offering a tool for data collection - Development and implementation of a common, supranational tool to share living kidney donor follow-up data that is sustainable (European Living Donor Registry ELDR) Francis Delmonico (EAB) raised the question of what is the leverage for Countries to participate in the Pilot Project and to provide data – if at all possible. Axel Rahmel (DSO) pointed out that the ELDR will on the one hand give a better insight into the long-term safety of living donors and the respective influencing factors thereby being of interest both for treating physicians and potential living donors. On the other hand this WP will support MS in fulfilling

	their legal obligation to establish a living donor registry. A discussion followed on what follow up data of the living donor have to be collected and how to obtain it. There was consensus that a mandatory data set has to be defined quickly based on the experience gained during the ACCORD project. A modular approach is favoured by the consortium, focussing on a limited but realistic data set right now with the option to collect more data in the future, in order to be able to give an evidence based answer on whether living donation is safe or not. The aim of the registry is to enable a lifelong sustainable follow up on a modular basis that has to be attractive enough for MS to use it. Fritz Diekmann (IDIBAPS) in his presentation reported about the pilot registry developed within ACCORD consisting of direct data entry module and a file uploading module. He proposed to use the KISS principle (keep it simple stupid), as a guideline for the consortium when setting up the practical tools that are to be developed in the course of the project.
Objectives and next steps	Obviously a close cooperation of the WP leaders IDIBAPS and NTS is required. An important first step is the definition of the data set to be collected. To this end it has to be identified what is feasible and essential. The dataset will be sent to the Steering Committee for comments. Based on the so defined core elements of the LDR a) A questionnaire has to be developed that shall be send to all EU Member States to evaluate the willingness and ability to participate in the ELDR. This questionnaire will lay the grounds for the report on outcomes about the willingness to participate among EU-Member States that is **due in September 2017.** Prior to sending out the questionnaire it will be made available to the Steering Committee for comments. b) IDIBAPS can work on further refining the technical tool to collect the agreed upon data The focus of this WP lies on EU-Member States only. Other than in WP 4 non-EU countries like Switzerland, Norway and Turkey need not to be included.
WP 6 Transplant Recipient Registry	Dave Collet (NHSBT) gave a presentation outlining the broad aims of the WP that are namely the establishment of a European Kidney follow up registry and to convey a study of Quality of Life in transplant recipients. For further details see the presentation attached. Peter Branger and Undine Samuel (ET) in their presentation gave an overview on the results of EFRETOS Project regarding the framework for establishing a European Registry and reported on their experience what data collection would be feasible. For further details see the presentations available soon via website. In the discussion Frank Delmonico reminded the consortium of the three main possible goals of a European transplant registry: - Improve patient care - Improve center performance - Develop policy that enhances the capacity to achieve improved patient care and center performance. Depending on the focus of a registry the data set might vary to some degree. There was general agreement that it is not up to the consortium to decide upon the focus of the individual national registries. In the first step the focus

	of the international data collection will be to allow a basic description and comparison of the different national experiences with regard to transplantation and the safety of the patients, comparison of individual centers is not part of the objective or the international transplant registry – this falls under the responsibility of national authorities. Nevertheless the collected data could of course influence national and international policy making in this field. This brought up the discussion whether it would be feasible to link dialysis register data to the transplant registry data (Mark Murphy, European Kidney Patients Federation) with the goal to follow a patient already from the beginning of renal replacement therapy (RRT). This would for example allow to monitor treatment modalities and to identify differences in the access to transplantation. Undine Samuel (ET) pointed out that it would be interesting to follow the patient even after a return to dialysis in case of graft failure. Alessandro Nanni Costa (CNT) suggested to start data collection for the transplant follow-up registry when a patient enters the waiting list. Axel Rahmel made clear that the different treatment modalities for patients with the need for RRT are the focus of WP4. Including all patients with the need for RRT in the transplant recipient follow-up registry in WP6 is currently way beyond the scope of the pilot project but should be kept in mind as a future goal for a comprehensive data collection in this field. There was consensus that important waiting list data, like start of RRT and treatment modalities used should be included in the transplant follow-up registry. According to the call and Grant Agreement it is mandatory to include all patients that received a kidney transplant in the follow-up registry. Whether to include patients already at the time of waitlisting was not finally decided during the discussion, this issue will be addressed by the WP leaders in the course of the project taking into account availability of the data and goals of the pilot project. As mentioned above, it might be a long term political goal to broaden the scope of the registry for example by including patients either at the initiation of RRT or registration on the waiting list or by extending the data to be collected. At this moment, it is considered important to achieve that systematic transplant related data collection takes place in all Member States at all. In order to reach this goal it will be important to identify the needs of the Member State with regard to installing a national registry and forwarding data to an European registry. Peter Branger stressed the substantial overlap between WP5 and WP6 concerning structural elements of an international registry like: • Governance • Legal and ethical requirements • Quality assurance • Authorization and Security • Person ID methodology (Donor and recipient) • (Pseudo) anonymisation strategy • Build on Open Source philosophy (TBD) All consortium members agreed on this point and in the discussion it became

	clear that ERA-EDTA hosting an international registry already since many years, might be of help with these structural questions. Therefore it was agreed that exchange of ideas between WP 4 and WP5+6 also in this area could be of importance for the smoothness and success of the project and should be addressed quickly.
Objectives and next steps	Setting up a meeting of WP5 and WP6 in particular on the following issues • Governance • Legal and ethical requirements • Quality assurance • Authorization and Security • Person ID methodology (Donor and recipient) • (Pseudo) anonymisation strategy • Build on Open Source philosophy (TBD) During this meeting questions to be addressed to WP4 could be collected and forwarded to ERA-EDTA. Identify which member states have a transplant follow up registry and their need for financial and other support through EDITH on one hand and identification of MS who need support in the establishment of their national registry. The Consortium agreed that this should be carried out in one questionnaire that should be designed and distributed asap in order to facilitate the Report on status of existing national kidney follow up registries, their content and requirements for future development **due in September 2017.** Parallel to this the work package leaders have to define a final data set based on the finding of EFRETOS project (Tier 1 and Tier 2) in order to lay the grounds for the Report on variables that need to feature in a national transplant registry that is **due in September 2017.**
2nd Day February, 17th 2017	
EU role and expectations	(Slight change of the agenda, this talk was given after the presentation of Vianda Stel but has been inserted in the minutes). Andrzej Rys (European Commission DG SANCO) Welcomed the participants and stressed the great political interest of the European Parliament in this topic and then elaborated on the main reasons for this project from the Commissions point of view. 1) Insight in economic aspects Stakeholders need to have a basis for their decision of spending money for patient treatment. Ideally the project provides evidence to the debate. 2) Availability of up-to-date data In recent years it has become more and more important to have the most recent data available in political discussions but also in the interaction with the media or the general public. Three or four year old data are in this context often considered as “out-dated” 3) Broad representation of EU Member States including also smaller EU member countries.

	EU-commission is very interested in the current situation within the Micro States 4) Big Data Standardization of data collection and its analysis in the increasing digitalisation allowing to identify trends and new developments that stay undetected looking only at limited national data. In this context linking of data on broader scale in the future might be of special interest. Later during the meeting Stefaan van der Spiegel added information mainly for WP5 and WP6, stressing that all WP's are of equal importance for the EU. Because the feasibility of a multinational living donor registry has already been shown and tools for collecting data have been built and used during the ACCORD project the EU expects that in **WP5** of EDITH the national and multinational tools can be further refined to achieve a sustainable ELDR with data from if possible all EU countries – well knowing that data delivery to such a multinational registry is voluntary making complete data collection challenging. **WP6** focussing on recipient follow-up can build on formal recommendations of the EFRETOS project. Prototypes of tools for collecting national and combining supranational data do not exist here. Therefore it will be of importance to set-up a registry involving as many EU countries as possible to derive lessons from this effort that will lay the basis for further improvements of such a registry that would then involve more organs and hopefully also more/all EU-countries. Similar to the KISS-principle discussed on day 1 he pointed out that it is not important to build "the most luxurious car but one that brings us as far as possible!"
WP 4 Treatment modalities	Vianda Stel (AMC on behalf of ERA-EDTA) gave a presentation in which she first introduced the work of ERA-EDTA Registry relevant for the EDITH Project, namely the data collection via national and regional renal registries. Then she guided the participants through the objectives of WP4 (please refer to the presentations available soon via website). On slide 21 she pointed out that ERA-EDTA Registry currently is confronted with the difficulty to find contact persons for the so called "Micro States". Fritz Diekmann (IDIBAPS) offered to provide for a contact to Andorra. Mirela Bušić (MoHRC) for Kosovo, Franz Immer (EAB) shall be approached for a contact to Liechtenstein, Cecile Couchoud Heyer (ABM) might be able to provide contact to Monaco, Alessandro Nanni Costa (CNT) will take care of the contact to San Marino. Alessandro Nanni Costa (CNT) gave a presentation focussing on the tasks of the Co-Leader CNT namely starting with their planned approach for the analysis of the financial implications of RRT: In addition to an analysis regarding the *reimbursement* of hospitals and other facilities offering the different relevant treatments in the different countries a study on the *real costs* of these treatment options is planned. This part of the analysis shall be done with a limited number of centers and in collaboration with an experienced external partner. Please refer to presentation for further details. Frank Delmonico (EAB) and Kitty Jager (AMC on behalf of ERA-EDTA) pointed

	out that dialysis is a profit business, in many countries dialysis companies have a monopoly position so the data collection on real costs could become quite a challenge. Stefaan van der Spiegel agreed that difficulties might result from particular interests of dialysis companies and physicians working in this area. Mark Murphy (European Kidney Patients Federation) pointed out that it will be interesting to find out whether in some countries dialysis is less cost intensive than transplantation e.g. due to availability of nurses. Cecile Couchoud Heyer raised the question if a further differentiation between the cost of treatment (RRT) and the total cost per patient including e.g. comorbidities, possible side-effects of immunosuppression (tumor disease etc.) should be included in the analysis and offered her support in involving data from ABM in the cost analysis part. It was decided to keep the analysis rather simple and focus on the cost of dialysis vs. transplantation and follow up on a yearly basis. Regarding the practical approach to the cost analysis Sándor Mihály (OVSZ) reminded the group that such an analysis was performed in WP 5 of the DOPKI project and the techniques used and results achieved could be taken into consideration for this WP of EDITH. Stefaan van der Spiegel (EU Commission) offered to establish contact to a team in charge of health technology assessment that is also part of the directorate of Andrzej Rys. Finally the possible impact of the new General Data Protection Regulation of the European Parliament and of the Council on the project, especially the data collection part was shortly discussed. Stefaan van der Spiegel informed the consortium that a legal expert in this field will join the group at the EU and offered that he could help with possible questions coming up. This proposal and offer was welcomed by the consortium members.
Objectives and next Steps	Close cooperation of WP Leaders and establishing a link to WP Leaders of WP 5 and 6. Preparation of a table for the collection of aggregated data with increased granularity for completion by renal registries and a table for the collection of aggregated data for completion by other sources as basis for the design of the study for cost analysis that is **due April 2017** Survey report on registry‘s completeness of registered deceased and living donor transplants and their follow-up: **due June 2017**
WP 2 Dissemination	Sándor Mihály (OVSZ) presented the logo designed for EDITH and pointed out the dissemination rules laid down under point 9 in the Consortium Agreement. He informed that a project website with a private and a public area will be available within a month and asked all consortium members to establish a link on their institutional website to this website. The domain will be www.edith-project.eu. An important next step will be the development of a leaflet introducing the project and the partners. This leaflet will be made available as .pdf and in addition a limited number of paper prints that can be used for meetings etc.

	OVSZ will provide a draft and will distribute it to Consortium Partners for revision. Ziad Massy proposed to distribute this leaflet to Presidents of National Societies of Nephrology during the next ERA EDTA meeting with them in Madrid to increase their awareness and collaboration. Stefaan van der Spiegel (EU-Commission) asked for information on relevant publication prior to their publication so that the Commission is informed in advance and is able to react in case they confronted with questions based on those publications. The different target groups of the project were discussed and Kitty Jager offered to write an article for "Nephrology, Dialysis and Transplantation" because she has already been approached by the editor. It was suggested to try to place a similar article in "Transplant International" to raise the awareness for EDITH in the transplant community. Stefaan van der Spiegel (EU-Commission) furthermore pointed out that the political level should be included in the target group and he strongly recommended giving the EU-Parliament an update on the ongoing project once in a while. Everyone agreed to this proposal and welcomed his offer to support the consortium in doing so. Mark Murphy wishes to support the dissemination process by informing patient associations. It was suggested to establish a list of external experts and contact persons in the different EU countries for this project and to make them available on the internal part of the project website. On the one hand the idea was considered very helpful on the other hand there were major concerns that such an approach could lead to the situation that these contact persons could then be overwhelmed by requests from the different WPs resulting in an overall low response rate to the questionnaires that will be an essential part of the start-up phase of the several WPs. It was therefore agreed to collect that names and contact details as suggested on the internal part of the website but to aim at extremely close cooperation between the work packages so that it can be agreed among each other when and to whom to send the different questionnaires! Simply using the contact list for sending out questionnaires is not considered acceptable.
Objectives and next steps	Instalment of Project website and production of a first leaflet introducing the project and the partners for which OVSZ will provide a draft and will distribute it to Consortium Partner for revision. The leaflet will be available as download pdf and 500 printed copies.
WP 3 Evaluation	Mirela Bušić (MoHCR) presented her proposal for an external advisory board (EAB) consisting of Francis Delmonico (New England Organ Bank Professor of Surgery, Harvard Medical School Massachusetts General Hospital Boston, MA, USA), Franz Immer (Medical Director of swisstransplant) and Roman Danielewicz (Polish Transplant Society). Andries Hoitsma, and Ziad Massy suggested to include a nephrologist in the EAB. Mirela Bušić and Axel Rahmel will discuss the possibility of enlarging the EAB preferably by a nephrologist from Scandinavia taking the budgetary limitations into account. Consortium members agreed that it would be great to have someone from Scandinavia in the EAB, because the corresponding countries are currently not represented in the EDITH project. The EAB member could next to his key task as evaluator

	also support the project by advocating participation in the project questionnaires and registries. Ziad Massy was asked to come up with a name of a Scandinavian nephrologist, and he proposed Bengt Lindholm. Furthermore Mirela Bušić (MoHCR) elaborated on the formative (implementation, progress) and summative (outcome) evaluation. It is evident that a close cooperation of WP 1, WP 3 and the EAB is required in order to fulfil the tasks of this WP.
Objectives and next steps	Final assignment of all EAB members, development of a draft evaluation plan.
WP 1 Coordination **Next Steps**	During the kick-off meeting it became evident that close collaboration between the partners in each WP but also between the different WPs is of crucial importance for the success of the project. As a first step detailed arrangements for the next practical steps will be made between the co-leaders of each WP preferentially via telephone conferences. In addition WP5 and 6 will coordinate their activities using the close contacts of the two respective co-leaders located in Leiden. In addition it was considered helpful and important to plan a meeting of the WPs on practical details to be arranged in the Netherlands (Leiden/Amsterdam/Schiphol) in order to ensure that consistent methodologies throughout the project are applied, double work is avoided and synergies are utilized. If possible the legal expert on the General Data Protection Regulation should already join this meeting; availability still has to be determined. In order to make this joint meeting most effective it was suggested to already exchange the topics and questions that should be addressed during the combined meeting in advance. The coordinator will organize a first technical meeting for WP 4, 5, 6 in the first half of the year.