coordinated by ONT, Spain

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Why "achieving comprehensive coordination in organ donation"?

Organ transplantation benefits more than 30,000 patients in the European Union (EU) every year, but the **availability of organs does not properly satisfy the transplantation needs of the European population**. These transplantation needs are also unequally met by Member States (MS), notably due to variability in living and deceased donation activities. This heterogeneous scenario, along with the necessity of establishing **a common framework** for quality and safety of human organs intended for transplantation led to the development of two EU initiatives: *Directive 2010/53/EU* (hereinafter, the Directive) and the *European Commission's Action Plan on Organ Donation and Transplantation (2009–2015): Strengthened Cooperation between Member States,* with ten identified priority actions. Under the Second Public Health Program, the European Commission has co-funded a specific Joint Action, named '**A**chieving **C**omprehensive **C**oordination in **OR**gan **D**onation throughout the European Union' (**ACCORD**), an Action that **comprehensively** supports targeted initiatives that will contribute to effectively implement the Directive and the Action Plan. **ACCORD** has been developed by a consortium composed by 23 Associated partners and 10 Collaborating partners (Figures 1 and 2). The project has been led by the Spanish National Transplant Organization (ONT).

Three issues on the floor

Living donation is a necessary adjuvant to meet the transplantation needs of patients. The donation of organs (mainly kidneys) from living organ donors is progressively increasingly across the EU. Yet a person who donates an organ during his life time faces medical and psychosocial risks, which makes it mandatory for EU Countries to adopt an appropriate framework for the protection of the living donor. This framework should be in compliance with a core of basic international principles and guidelines based on common good practices. An essential element in ensuring the protection of the living donor, is to build knowledge on the consequences of donating an organ during life time. **How should we develop a living donor follow-up registry? How could we share as much information as possible on the living donor follow-up across countries?**

One of the main reasons justifying differences in **deceased donation** rates across countries is failure to identify and refer potential organ donors. If all patients who die in conditions consistent with organ donation are to be

offered the chance of becoming organ donors if so they wish, the treating physician should necessarily consider the option of organ donation at the end-of-life care pathway. This requires a close cooperation between critical care professionals, dealing with end-of-life care, and donor transplant coordinators, dealing directly with organ donation. **What would be key recommendations for EU Countries to build integration between these two professional groups?**

International cooperation between different EU Countries is considered to be an effective tool to improve performance, but models for planning and implementing **twinning activities** should be developed to ensure the proper transfer of tools, expertise and knowledge from one country to another.

The Consortium

Bulgaria: BEAT
Croatia: MOH
Cyprus: Ministry of Health
Czech Republic: KST
Estonia: TUH
France: ABM
Germany: DSO
Greece: HTO
Hungary: HNBTS
Ireland: HSE
Italy: ISS-CNT
Latvia: PSCUH
Lithuania: NTB
Malta: MHEC
Norway: HDIR
Poland: Poltransplant
Portugal: IPST
Romania: ANT
Slovenia: Slovenija Transplant
Slovak Republic: NTO
Spain: ONT
The Netherlands: DTF
United Kingdom: NHSBT

Organ Exchange Organizations

Eurotransplant
Scandiatransplant

Professional societies

European Hospital and Healthcare Federation (HOPE)
European Society of Intensive Care Medicine (ESICM)
European Donation and Transplant Coordination Organisation (EDTCO)

Others

Organisation des Établissments de Soins (Belgium)
Hospital Clínic Barcelona (Spain)
Ghent University Hospital (Belgium)

COLLABORATING PARTNERS (10)

ACCORD Joint Action:
Looking for solutions

wp 4

How to develop living donor follow-up registries?

WP leader: Dutch Transplant Foundation, The Netherlands

A group of **fifteen** European MS collaborated to this activity. After performing an **overview of existing national and international living donor registries**, including information on the collected variables and on the governing, operational and technical rules applied a **minimum and an expanded data set of variables** to be collected in the registry was defined for kidney and liver living donors, together with an accurate data dictionary.

Eventually **a model for sharing data internationally on the outcome of living organ donors was developed**. The model is built on the concept of a European registry of living donor registries (RoR); this means the merging of data from existing national registries. An analysis was performed on the legal constraints and the governing, operational and technical requirements of such a RoR were defined. Some of these requirements are detailed in *Table 1.*

This model was **piloted** during the project lifetime by 9 participating countries. Five countries without an existing (national) living donor follow-up registry participated by directly entering their living donors follow-up data (direct key entry). Four countries with an existing national living donor registry tested the file upload module by extracting the follow-up data from their registries and uploading them –using a predefined template– into the ACCORD registry. These countries supplied data on living kidney donors from the years 2010 and 2011. Information was compiled on a total of 2,909 living kidney donors across Europe. Baseline characteristics, peri-operative data and one year follow-up data were collected.

Table 1: Some of the ACCORD Requirements for a European Registry of Living Donor Registries.

Requirements for Registry of Registries:
• ACCORD items and ACCORD definitions
• Relational database
• Web based application
• Approachable by common internet surfing programs
• Official language: English
• Direct data entry possibility
• File upload possibility (from national databases)

The pilot confirmed the viability of drafted recommendations and the feasibility of the proposed model.

The pilot was not designed to draw conclusions about the long-term consequences of living donation, since only one year follow-up data was included. But from the data that was collected in the ACCORD pilot registry, it could be learned that severe early complications were exceptional. Two deaths were reported, but these were not related to the kidney donation procedure. No donors needed renal replacement therapy after donation.
Donors returned to their previous activity level within 3 months and without facing large problems after donating one of their kidneys.
Most importantly, the basis had been established for successful international data sharing on the outcome of living organ donors. Lessons learned from the pilot allowed the consortium to improve a model that will be especially **helpful for countries that do not have any register in place yet!**

wp 5

Promoting the cooperation between Intensive Care professionals and Donor Transplant Coordinators

WP leader: National Health Service Blood and Transplant, United Kingdom

Which are the pathways of care applied to patients who die as a result of a devastating brain injury in Europe? Do they differ? To which extent do these pathways impact on organ donation? ACCORD has worked to answer these questions.

As a first action point, each country nominated a senior, respected ICU clinician to provide advise on implementation of the project, encourage and support participation of the initiative in hospitals and donation teams in their respective countries, thus forming the **Clinical Reference Group**.

Next, an in-site review of **variations in end-of-life care pathways** for patients dying as a result of a devastating brain injury was performed at a sample of hospitals from participating MS. The 67 participating hospitals from 15 MS (Croatia, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Portugal, Slovenia and Spain and UK) were required to identify and collect data on a maximum of 50 consecutive patients who had died of pathologies known to be common causes of brain death. They supplied data for a total of 1,670 patients, by replying to specifically-developed questionnaires. The analysis of the data identified a clear picture of differences in end-of-life care across countries and, very importantly, to identify barriers to donation in the European setting. *Figures 3 and 4* graphically represent the pathway of donation after brain death (DBD) and that of donation after circulatory death (DCD) in Europe, with evident opportunities for improvement.

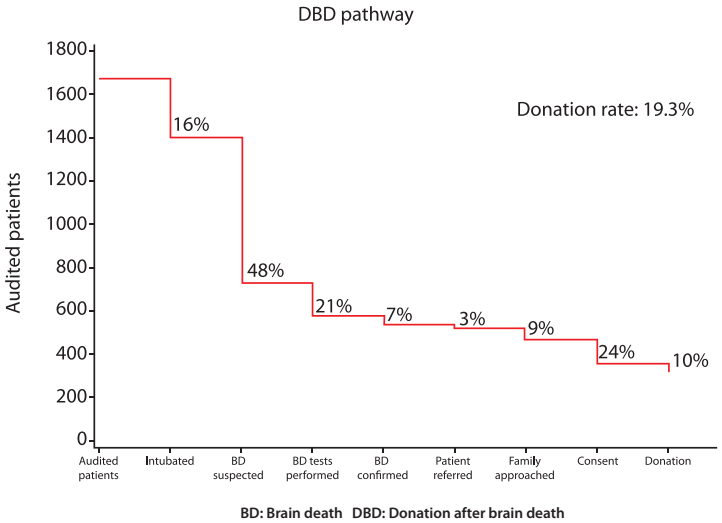

Figure 3: The pathway of donation after brain death in Europe.

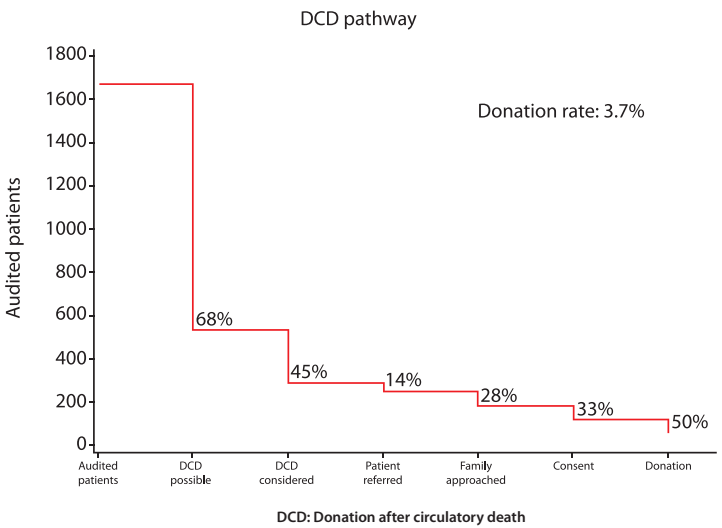

Figure 4: The pathway of donation after circulatory death in Europe.

A tested methodology (Plan, Do, Study, Act) for prompting needed changes in participating hospitals was presented and taught at dedicated training sessions. This included training experts that could support clinicians to identify achievable interventions and use the methodology to change practise.

This part of the ACCORD JA developed **excellent networking opportunities** between critical care and organ donation teams, in particular through the Clinical Reference Group, training days, and feed-back meetings. Additionally a methodology for further implementation in each European Union country was developed. Starting from the analysis of **his/her own hospital local data**, each expert developed an improvement plan in order to intervene effectively and remove barriers to organ donation. Improvement plans were implemented from September 2013 to July 2014 **in 56 participating hospitals**. The effectiveness of the changes was monitored and evaluated. A variety of approaches were identified and implemented such as the use of protocols and guidelines, the education and training of professionals, the appointment of additional staff, or different dissemination strategies, to name a few.

As an example, the approach at San Camillo Hospital (Rome–Italy) is summarized in this brochure. The hospital made a thorough assessment of why potential organ donors were not being identified in the Emergency Department and therefore not referred to the donor coordination team. The hospital was able to identify a number of obstacles to organ donation following an analysis using a fishbone diagram depicted in *figure 5*.

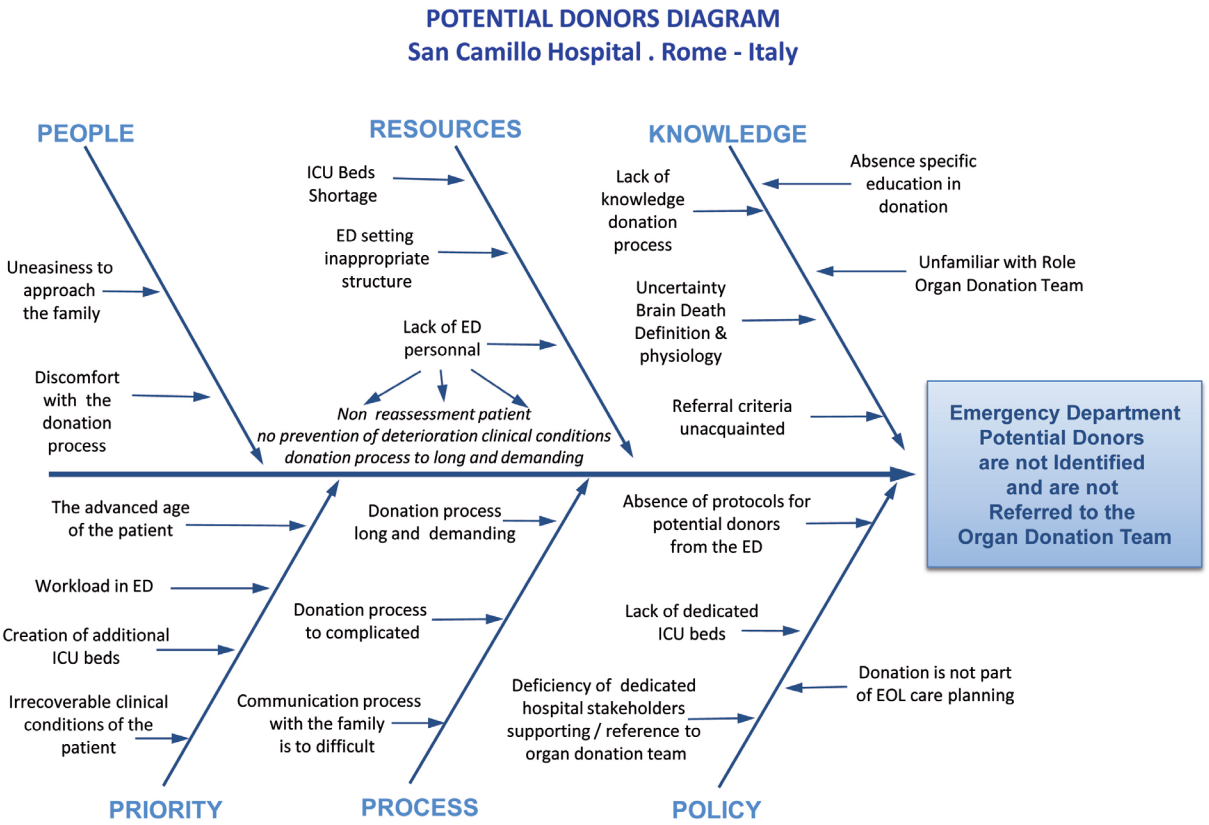

Figure 5: Fishbone diagram prepared by San Camillo Hospital (Acronyms: ED Emergency Department, EOL end of life, ICU Intensive Care Unit).

On the results of such analysis, the hospital reference person developed a plan to improve the daily practice of communication and donor referral between the Emergency Department and the Coordinating Office, summarized in *Figure 6*.

Despite the short timescale and small number of patients studied, 9 of the plans developed in ACCORD reported an increase in organ donation, and 8 further plans reported an increase in their targeted stage of the process.

The tested service improvement model is expected to have a large impact in daily practice, since it is easily transferrable to other European hospitals as a method to increase the number of organ donors.

Figure 6: Poster drawn by San Camillo hospital ICU in order to raise awareness about organ donation.

wp 6

The pathways of Twinnings

WP leader: Agence de la biomédecine, France

ACCORD twinnings were meant on one side to implement practical collaborations for the transfer of knowledge, expertise or tools in specific areas between involved countries and on the other to draw lessons from such experiences and therefore providing recommendations for future similar initiatives. At the end of an internal selection procedure, ACCORD supported the implementation of three twinning actions, namely:

1. The development of a **national training program for abdominal multiorgan** retrieval targeting junior surgeons in Hungary (supported by The Netherlands).
2. The structuring of the **organ procurement system at regional and national level and improving the monitoring and evaluation system of organ donation and of transplantation activities** in Bulgaria (supported by France).
3. The development of a national **Authorisation and Audit system for transplantation centres** in Czech Republic, Cyprus, Lithuania and Malta (supported by Italy).

1. ***The national training programme for abdominal multiorgan retrieval twinning*** was implemented by the Dutch Transplant Foundation (DTF) as the main partner (in collaboration with the Universities Medical Centre of Leiden and of Groningen, and ESOT) and by the Hungarian National Blood Transfusion Service– Organ Coordination Office (OCO) (in collaboration with the surgeons from Semmelweis University). In The Netherlands, a national complete trajectory from the **training of surgeons in abdominal organ procurement surgery** to the quality assessment of the procured abdominal organs was developed and implemented in 2010. It comprises training and certification modules: E–learning, training–on–the–job and a practical session. As a first step, under the ACCORD twinning, this model was adapted to suit the Hungarian needs, the E–learning platform was modified and made available in English language, and subsequently tested by 52 surgeons. Next, 3 Senior and 3 junior Hungarian surgeons were selected to complete the E–learning phase, assisted to the first practical hands–on session organised in The Netherlands and

kept on with the registration of the training–on–the job to be reported to the Hungarian OCO (in terms of organ retrieval procedures performed within the hospital) *(Table 2)*.

Then, the OCO supervised the setting of the first national practical (hands–on) session organised in Hungary at the OCO Headquarters *(Figure 7)* and at Semmelweis University in Budapest, in collaboration with the Department of Human Morphology and Developmental Biology (mastering body preparation). The Hungarian surgeons were assessed according to a standardized technical skills evaluation form.

Table 2: Training–on–the–job on–going procedures of the Hungarian trainees and reported by OCO.

Surgeons	Kidney retrieval		Liver retrieval		Pancreas retrieval	
	Assistant	Main surgeon	Assistant	Main surgeon	Assistant	Main surgeon
Junior trainee 1	16	21	14	19	1	1
Junior trainee 2	5	25	3	33	1	7
Junior trainee 3	10	17	7	30	2	0

Figure 7: The first National Practical (hands–on) session in Budapest.

2. The twinning for supporting organ procurement system and improving the monitoring and evaluation systems of organ donation and transplantation in Bulgaria was dealt by the Agency of biomédecine (ABM and the transplant team of Robert Debré Hospital in Paris), who supported the Bulgarian Executive Agency for Transplantation (BEAT and the transplant team of Pirogov Hospital in Sofia).

Figure 8: French and Bulgarian Coordinators teams.

First of all the two national agencies collaborated strictly for the **development and organisation of the organ procurement system at national and regional levels**. French experts organized on-site visits in Bulgaria, during which a thorough analysis of Bulgarian existing system was performed. Bulgarian experts had also the opportunity to study the national and regional French organization and therefore drafted a plan for intervention. A set of Standard Operating Procedures (SOPs) addressed to professionals was laid down. The SOPs are to be gathered in a Donation and Transplantation Manual to be printed in Bulgarian and to be distributed to targeted units of all sites and to be available for the hospital personnel.

Concerning **paediatric kidney transplantation**, previous experiences of training of the Bulgarian transplant team had been led from 2006 to 2010, resulting in six transplants performed. Two children were evaluated for transplantation during the twinning. Unfortunately, due to organizational issues, it was impossible to perform the transplants in Bulgaria, but the children have been subsequently referred to French hospitals and further actions for re-launching the paediatric kidney transplant in Bulgaria were strongly suggested.

Finally, the twinning pursued the improvement of the Bulgarian **donation and transplant information and informatics system for traceability** and for increased transparency, with the concrete objective of producing and disseminating an annual activity report. A long exchange visit was performed, in order to allow for expertise transfer. Bulgaria then appointed an IT expert, who was fully involved in the development process. Data from donor hospitals were collected through a devoted questionnaire, filled in by 7 hospitals in Sofia and 9 more from throughout the country. Data collection was subsequently improved through a qualitative analysis, traceability and data security issues were analysed and a series of solutions were proposed, in order to overcome them, information system and database were strongly improved. Thanks to a very good collaboration between the French and Bulgarian teams, a first report of donation and transplantation activities in Bulgaria was prepared, but the know-how and guidance for the preparation of future activity re-

ports were fully transferred. Some of those data and analysis are going to be uploaded on the BEAT website for information to the professionals and to the public at large, thus greatly contributing to the process of transparency in organ transplantation.

Figure 9: Auditors face-to-face training.

3. ***Twinning for developing an Authorization and Audit System for transplant centres*** was indeed a multilateral experience.

Supported by the Italian National Transplant Centre, the national donation and transplant authorities of Czech Republic, Cyprus, Lithuania and Malta worked together in order to develop an **Authorization and Audit System for transplant centres**.

As first step, a **Guide on Essentials for Authorizing and Auditing transplant centres** was drafted by the Italian partner, followed by a series of **onsite visits** in each country by a team made up of national Italian experts. During the visits, the feasibility of the proposed process was verified and a proposal for setting up quality assurance systems was put forward. The guide included chapters on aspects to be audited, including the organization and administration of the transplant center; quality of the structure; management of the waiting lists; transplant activity; quality of transplant outcomes – results, to name a few.

Some months later, the Italian authority organized a **training course** addressed to potential auditors, including a three weeks E-Learning phase and three days of face-to-face sessions. Having trained and certified 9 experts from the participating countries (Czech Republic, Lithuania and Malta) it was decided to finalize the supporting activity with a second visit by an Italian team in the form of a joined audit together with the newly certified local experts.
At the same time, each supported partner **developed its own national system** on the basis of the information/recommendations provided by CNT and also taking into account the newly acquired knowledge from the seminars.

The major results were implemented in Czech Republic, where by the end of the Action an audit of all its transplant centers has already performed, as well as in Lithuania, where an ad-hoc regulation was officially adopted and is being implemented. For small size countries like Malta and Cyprus, devoted proposals for the improvement of the local situation and for achieving the objective of international comparison of transplant activity were however constructively put forward.

Coordinator

Spain: Organización Nacional de Trasplantes (ONT)

Partners

Bulgaria: Bulgarian Executive Agency for Transplantation (BEAT)
Croatia: Ministry of Health Republic of Croatia (MOH)
Cyprus: Ministry of Health
Czech Republic: Czech Transplantation Coordination Centre (KST)
Estonia: Permanent Representation of Estonia to the EU / Tartu University Hospital (TUH)
France: Agence de la biomédecine (ABM)
Germany: Deutsche Stiftung Organtransplantation (DSO)
Greece: Hellenic Transplant Organisation (HTO)
Hungary: Hungarian National Blood Transfusion Service (HNBTS)
Ireland: Health Service Executive (HSE)
Italy: Centro Nazionali Trapianti (ISS–CNT)
Latvia: Pauls Stradins Clinical University Hospital (PSCUH)
Lithuania: National Transplant Bureau (NTB)
Malta: DG Health Care Services within the Ministry for Health, the Elderly and Community Care (MHEC)
Norway: The Norwegian Directorate of Health (HDIR)
Poland: Poltransplant
Portugal: Blood and Transplantation Portuguese Institute (IPST)
Romania: National Transplant Agency (ANT)
Slovenia: Slovenija Transplant
Slovak Republic: National Transplant Organisation (NTO)
Spain: Organización Nacional de Trasplantes (ONT)
The Netherlands: Dutch Transplantation Foundation (Nederlandse Transplantatie Stichting) (DTF)
United Kingdom: NHS Blood and Transplant (NHSBT)

Project duration

36 months.

Cost and EU Contibution

Total: € 2,431,576
EC contribution: € 1,439, 988

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Accord
Achieving Comprehensive
Coordination in Organ Donation

ASSOCIATED PARTNERS

Organización Nacional de Trasplantes – ONT (Spain, coordinator and WP3 leader); Italian National Transplant Centre, Italian National Institute of Health – CNT-ISS (Italy, WP2 leader); Dutch Transplant Foundation – DTF (Netherlands, WP4 leader); National Health Service Blood and Transplant – NHSBT (UK, WP5 leader); Agence de la biomédecine – ABM (France, WP6 leader); Executive Agency for Transplantation – BEAT (Bulgaria); Ministry of Health Republic of Croatia – MOH (Croatia); Ministry of Health of the Republic of Cyprus – MoH CY (Cyprus); Czech Transplantation Coordinating Center – KST (Czech Republic); Tartu University Hospital – TUH (Estonia); German Organ Transplantation Foundation – DSO (Germany); Hellenic Transplant Organization – HTO (Greece); Hungarian National Transfusion Service – HNBTS (Hungary); Health Service Executive – HSE (Ireland); Pauls Stradins Clinical University Hospital – PSCUH (Latvia); Lithuanian National Transplantation Bureau – NTB (Lithuania); Ministry for Social Policy, Health, the Elderly and Community Care – MHEC (Malta); The Norwegian Directoreate of Health – HDIR (Norway); Polish Transplant Coordinating Centre, Poltransplant (Poland); Instituto Português do Sangue e da Transplantação – IPST (Portugal); National Transplant Agency – ANT (Romania); National Transplant Organization – NTO (Slovak Republic); Institute for Transplantation of Organs and Tissues of the Republic of Slovenia – Slovenija Transplant (Slovenia).

COLLABORATING PARTNERS

European Directorate for the Quality of Medicines and Healthcare – EDQM; World Health Organization – WHO; European Hospital and Healthcare Federation – HOPE; European Society of Intensive Care Medicine – ESICM; European Transplant Coordinators Organizations–European Donation Committee (ETCO–EDC) a section of ESOT; Eurotransplant; Scandiatransplant; Organisation des Établissments de Soins (Belgium); Hospital Clínic de Barcelona (Spain); University Clinc of Gent (Belgium).

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