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European Cornea and Cell Transplantation Registry

JA2015 - GPSD [705038]

START DATE: 01/05/2016

END DATE: 31/10/2019

DURATION: 36 month(s)

CURRENT STATUS: Finalised

PROGRAMME TITLE: 3rd Health Programme (2014-2020)

PROGRAMME PRIORITY: -

CALL: Call for Proposals for Projects 2015

TOPIC: Common assessment methodology on quality, safety and efficacy of transplantation therapies

EC CONTRIBUTION: 424567 EUR

KEYWORDS: Cell, Cornea, Efficacy, Efficacy, Efficacy, Medical devices, Pharmaceuticals, Quality, Registry, Safety, Safety, Safety

PORTFOLIO: Tobacco

Project abstract

Disease of the cornea (the transparent layer covering the front of the eye) is the second cause of blindness worldwide. The cornea is the most transplanted tissue with over 100,000 corneas transplanted annually. In Europe an estimated 30,000 corneal transplants are performed each year.
Currently there is no harmonisation of information across the European Union on the numbers or origins of the scarce corneas tissue available for transplant, the optimum procedure for transplant and the visual outcome and quality of life of corneal transplant patients.
The ESCRS in 2006 with the support of the Executive Agency for Health and Consumers pioneered an online Quality Registry of the outcomes of cataract and refractive surgeries (EUREQUO). ESCRS continues to support this Registry and has currently a database of over 2,000,000 surgeries.
ESCRS proposes to extend this platform to create a registry of corneal transplantation surgeries in Europe. The European Cornea and Cell Transplantation Network (ECCTR) will link three existing registries and recruit additional centres of excellence and eye banks to contribute data on availability of corneal tissue, methods of transplantation, and visual outcomes of surgery.
The focus of our consortium is on bringing added value and making a positive impact on one of the priority actions set out in the annual Work Programme for 2015; contributing to the fourth overall objective:” To build a common assessment methodology to allow academics, health professionals and authorities to assess and verify safety, quality and efficacy of (new) transplantation therapies and/or other types of clinical applications of human tissues and cells (e.g. assisted reproductive technologies).”
After the completion of this action the ECCTR will have all the data necessary to develop European Guidelines for Corneal Transplant Surgery to better utilise scarce cornea tissue ensure European self-sufficiency and reduce patient waiting lists.

Summary of context, overal objectives,strategic, relevance and contribution of the action

Disease of the cornea (the transparent layer covering the front of the eye) is the second cause of blindness worldwide.
The cornea is the most frequently transplanted intact tissue with over 180,000 transplants performed today. In Europe an estimated 30,000 corneal transplants are performed each year. Currently there is no harmonisation of information across the European Union on the numbers or origins of the scarce corneas tissue available for transplant, the optimum procedure for transplant and the visual outcome and quality of life of corneal transplant patients.
The ESCRS in 2006 with the support of the Executive Agency for Health and Consumers pioneered an online Quality Registry of the outcomes of cataract

and refractive surgeries (EUREQUO). ESCRS continues to support this Registry and has currently a database of over 2,500,000 surgeries.
The European Cornea and Cell Transplantation Network (ECCTR) will link three existing
registries and recruit additional centres of excellence and eye banks to contribute data on availability of corneal tissue, methods of transplantation, and visual outcomes of surgery. The focus of our consortium is on bringing added value and making a positive impact on one of the priority actions set out in the annual Work Programme for 2015; contributing to the fourth overall objective:" To build a common assessment methodology to allow academics, health professionals and authorities to assess and verify safety, quality and efficacy of (new) transplantation therapies and/ or other types of clinical applications of human tissues and cells (e.g. assisted reproductive technologies)."After the completion of this action the ECCTR will have all the data necessary to develop European Guidelines for Corneal and Cell Transplant Surgery to better utilise scarce cornea tissue ensure European self-sufficiency and reduce patient waiting lists.

Methods and means

The core methodology for development of a common European platform, ECCTR will consist of collection, storage and analysis of data and dissemination of analysis across European States.

The methods proposed below are based on successful currently existing methodology of the ESCRS funded European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO). This project initially co-funded by the European Union under the Executive Agency for Health and Consumers and now funded by the ESCRS and sustainably running for more than seven years.

Evaluation of variables for the European platform
The development of the European Cornea & Stem Cell Ophthalmic Transplantation Registry will harmonize existing information systems across Europe and will establish a new European platform. A pool of experts from partner organizations will evaluate existing registers and recommend a model for a European-wide platform with the aim to establish a common assessment methodology, develop benchmarks, promote development of best practice guidelines, and determine need and supply of tissues across Europe. This will be accomplished by the convening of a Steering Committee of experts in the field from the partner organizations who will meet in Month 1-4.

Data collection
Forms for data collection will be developed taking into consideration data already existing in partner registers and selecting indicators for the system. An

Electronic Data Capturing (EDC) platform will be developed.
The system will record data related to both donor and recipient. Data related to donor tissue will be obtained from participating eye banks. Patient related information, including preoperative, preoperative and postoperative data will be collected by participating clinics and universities. Data recorded will include relevant information at the time of surgery, baseline patient information, including preoperative visual status, the indication for transplantation, the primary reason for transplantation (to improve vision or for other reasons), the presence of risk factors likely to influence the graft outcome the supplying eye bank and the donor cornea reference number, and a patient questionnaire. Follow-up data will be provided after two years when it is likely that all sutures have been removed, refractive surgery (where appropriate) performed, and stable refraction achieved. Post-operative complications, visual acuity and astigmatism will be recorded.

Validation of Patient-Reported Outcome Measures (PROM's)
Currently, patient-reported outcome measures (PROMs) are less widespread than objective measurements such as visual acuity or refractive error. Implementing PROM's in routine clinical practice has become a priority of clinical investigators as in addition to providing comprehensive evaluation of the safety and efficacy of these treatments it also provides information on patients quality of life before and after surgery. For this reason PROM's for corneal transplantation will be developed and validated as a novel tool to be included in the database. PROM's developed by ESCRS for assessing quality of life after cataract and refractive surgery are currently being tested in six European languages. Building on this experience and lessons learned PROM's will be developed for corneal transplant surgery. Patients will be given access to online questionnaires that they complete in the doctor's office before surgery and online after completed surgery.

Validity of Data
Data entry will be regulated by the coding guidelines, which require that data is collected on all consecutive cases during the agreed time period, not just selected cases. An electronic reminder system will be set up to reduce the number of cases lost to follow-up. The forms will be filled in by selecting from a menu of categories or numeric values; there will be no option to enter free text or numbers. An audit committee will periodically validate data captured.

Data output

Work performed during the reportingperiod

- The first four months of the project the Steering Committee focused on the development of a common assessment methodology for corneal transplantations.
- Each partner provided the coding guidelines and parameters of the Registry

existing in Sweden, Netherlands and England.
- Prof Mats Lundstrom initiated a master document that indicated the necessary information needed about donor cornea, the recipient, the surgery and follow up data.
- The mapping of the three existing EU registries by assessing the existing parameters contained in each European Registries concerning patients, donor, transplant, surgery and eye details have been assessed and discussed in details by the ECCTR Steering Committee
- The ECCTR Steering Committee members through e-mails and meetings decided the process of establishing a model for the EU web-based registry that will allow to establish a common assessment methodology, develop benchmarks, promote development of best practice guidelines, and determine need and supply of tissues across Europe.
- The ECCTR workflow starts with:
- Patient – I.1 Identify Patient I.2 Review/enter Patient details
- Donor – II.1 Identify Donor II.2 Review/enter Donor details
- Tissue .– III.1 Identify Tissue III.2 Review/enter Tissue details
- Surgery – IV Surgery details
- Eye details – V Eye details
- Follow up details – Collect follow up details
- Graft failure details – Collect graft failure data
- The Pilot Database Guidelines (M4) has been developed and contains details concerning the software functionality, follow up and patient reported outcomes.
- The graft failure and immune reactions core pilot data set has been included in the software parameters.
- The prototype databased was ready to be tested by month 12 and the EU web-based registry is linked to the ECCTR web-site.
- The partner FBOV/EEBA has been recruited clinics willing to participate and collect surgeries in the system across Europe
- The system is live and clinics are ready to start to collect surgeries in the system.
- ECCTR has been liaising with the EU funded projects EuroGTPII and VISTART. The SEC and donor parameters have been included in ECCTR following the request of VISTART and EU.

The main output achieved so far and their potential impact and use by target group (including benefits)

The main objective during this time frame of the project focused on the development, test and roll out of the EU-web based registry across Europe.

The main outputs up-to date are as follow:

1)All ECCTR Partners have agreed on the definitions of the EU web-based registry concerning dataset and functionality in order to build a common assessment methodology for assessing and verify the safety, quality and efficacy of corneal transplantation.
2)The IT provider developed the software for the EU web-based registry under the specifications provided by the ECCTR Steering Committee.
3)The system has been tested few times by all partners and few clinic's before being rolled out.
4)EEBA recruited 21 clinics across Europe that wished to record their surgeries in the system
5)ECCTR has been promoted during the international medical congresses of the ESCRS, EuCornea and EEBA.

The main target groups informed about ECCTR during the first 18 months of implementation of the project are ophthalmic corneal surgeons.

Once the collection of surgeries will start, the project will have a positive impact and add value in the exchange of information in cornea transplantation across specialists and academics across Europe.

The ECCTR partners have been attending and gave presentations and updates the about the ECCTR project milestones the audience at the Competent Authorities meeting organised by the EU.

The project leaders of ECCTR, GTPII and VISTART exchanged information about the objectives and milestones of the projects and possible synergies amongst work packages. Furthermore it was agreed to develop a joint newsletter that has been sent to all NCAs and stakeholders informing about the development and milestones of these projects funded by the EU.

Achieved outcomes compared to the expected outcomes

Overall the activities of the project are proceeding according to the workplan established, as the Eu web-based registry has been developed, tested and clinics have been recruited for the start of collecting transplantations in the system.

Dissemination and evaluation activitiescarried out so far and their major results

During this first year of activities, ECCTR has been involved in a major marketing campaign to encourage surgeons to enrol in the project and to explain the benefits of monitoring and comparing results confidentially with colleagues.

The pre-registration process for surgeons interested in participating in ECCTR has already started. There are two ways of registering, one is the on line form by filling the expression of interest at the ECCTR web-site or paper forms are available at congresses with ECCTR participation.
Podium presentations of ECCTR have been organised at the ESCRS, EuCornea and EEBA congresses

1) 7th EuCornea Congress. 9-10 September in Bella Center, Copenhagen, Denmark. Launch of ECCTR during the Opening Ceremony
2) XXXIV Congress of the ESCRS. 10-14 September Copenhagen, Denmark. Launch of ECCTR during the Opening Ceremony Annual
3) XXIX Annual EEBA Meeting in Prague 2017
G. Jones - European Quality Register for Corneal Grafting
4) 8th EuCornea Congress Friday 6-7 October 2017, Lisbon
M. Dickman - European registry for quality improvement in corneal transplantation surgery
5) XXXV Congress of the ESCRS 7-11 October 2017, Lisbon
M. Dickman - European registry for quality improvement in corneal transplantation surgery
6) XXXV Congress of the ESCRS 7-11 October 2017, Lisbon
M. Lundstrom, M. Dickman Instructional Course: Using the European Cornea and Cell Transplant Registry (ECCTR) for clinical improvement

The ECCTR web-site has been developed and contains information related to the project including objectives, activities and timeframe, participating partners. The web-site is updated on a regular basis as the main source of information is the web-site.

Partners will be keeping promoting the project and disseminate results during international medical congresses. The final report guidelines will be disseminated to a wider audience through the organisation of the final conference

Work package

Work Package 1: Coordination of the project

Start month: 1
End month: 36
Work Package Leader: ESCRS

Description of work
ESCRS will be responsible for coordinating and managing the technical and financial aspects and the day-to-day running of the project.
The Lead of this WP will oversee:
o the financial administration and the reporting to the European Commission;
o ensure adequate synchronization of the work packages and associated methodologies, and smooth communication among work packages;
o Communicate project findings to relevant stakeholders, policy makers and the European Commission.

This work package is divided in five tasks:

Task 1.1. Project Start-up
- The Leader of this WP will organise the kick off meeting in Luxemboug. The coordinator and all partners will call for participation the representatives of CHAFEA/SANTE.
- The Agenda of the kick-off meeting will be agreed between the partners and with CHAFEA/SANTE. During the meeting the partners will discuss and commit to the project overview: project objectives, work packages, activities, reporting and financial aspects.

Task 1.2. Legal and administrative management
- The Coordinator will prepare a Consortium Agreement that will govern the consortium activities and resolution of conflicts between partners
- The Coordinator will facilitate the setting up of the ECCTR Steering Committee formed by one or two members of ESCRS, EuCornea, EEBA, and National Quality Registries member and Prof. Mats Lundstrom.
- The Coordinator will keep-up-to date the CHAFEA and the Consortium and deal with all other legal issues during the project.
- The Coordinator will be responsible for adequate document management during and after the project, also covering the official reporting to the Commission, including periodic Reporting, submission of the deliverables and all issues that need to be communicated or discussed with the Commission
- The Coordinator will be responsible for the management of the sub-contracting costs
- The coordinator will be responsible for the procurement procedures and management of sub-contracting costs

Task 1.3 Financial management

The project's financial management will be the responsibility of ESCRS. As such, it is not only responsible for generating accurate financial interim reports regarding the project's resources and expenditures, it also monitors whether funds are used for their intended purposes, in an efficient and cost-effective way.
For financial monitoring we will make use of tools and instruments used for the execution of other projects. Our computerized accounting system will be used for recording, processing and reporting on the project's transactions, and regular budget reports and interim internal financial reports will be used for project budget monitoring.
The Financial Director of ESCRS will be responsible for the financial control and reporting for the project. All expenditure will follow the reimbursement policies of each associated partner and funds will be released on the presentation of suitable receipts for vouched expenses.
Disbursements will be tracked on SAGE online accounting system. Annual audits will be executed in accordance with EU requirements.

Task 1.4 Coordination of Steering Committee
- The project coordinator will oversee the process of the Steering Committee, will organise Steering Committee meetings, disseminate regularly updates about project milestones and activities
- The coordinator will organise follow-ups and report on progress through conference call, e-mails and reports.
- Prof Mats Lundstrom and Dr Mor Dickman will oversee and guide the IT provider for the development of the ECCTR and ensuring the quality of the clinical part of the system.
- Members of the Committee will be responsible for checking and validating the medical part of the ECCTR in relation to: datasets and development of outcome reports from the registry.

Task 1.5 Project management, follow-up, assessment and adjustments
The project progress will be measured against the Gantt Chart, deliverables, milestones and

Work Package 2: Dissemination of the project results

Start month: 3
End month: 36
Work Package Leader: EuCornea

ESCRS, EuCornea and EEBA sit at the hub of an authoritative dissemination network and offer a unique forum for discussion and learning which ensures that international expertise is shared by ophthalmologists all over Europe. This is accomplished by organising annual international conferences, developing educations programmes and tools for ophthalmologists, maintaining Society news and educational websites, publishing ophthalmic news magazines and peer reviewed scientific journals.
All partners are involved and will be committed to:
- Promote the philosophy of quality Registries and the Europe-wide network and

importance of the registry aiming to report a unique overview of information, concerning Corneal Transplantation across Europe
- Disseminate the project activities at International level

This work package is divided in six tasks as follow:
Task 2.1 Design promotional materials for the project
- Development of project brand: logo, ppt template, design templates
- Design and Development of project brochure
- Development and design of ECCTR website
All printed materials and communications will acknowledge the European Union visibility and funding. The logos of the European Commission and CHAFEA Agency will be in all publications.
Task 2.2 ECCTR Launch amongst ophthalmologists in Europe
- The Annual Congresses are the most prominent and central activity of the Societies and attracts annually over 8,000 ophthalmic surgeons.
- It is intended to launch the ECCTR project at the XXXIV Congress of the ESCRS and EuCornea, 10-14 September 2016. Bella Center, Copenhagen, Denmark.
- The aim of the launch is to create awareness of the project and invite a large number of stakeholders that could contribute to make the programme successful during its implementation at European and international level.
- The ESCRS President will present the ECCTR project during the ESCRS Opening Ceremony; visibility of EU funds for this project will be highlighted.

Task 2.3 Dissemination Plan
- Agreement on dissemination plan, including a stakeholders analysis, the different tools and channels (see also listed under tasks 2.1, 2.2, 2.3, 2.5, WP5 communication plan and respective deliverables), anticipated project results and indicators. The plan will clearly state how the target groups can be reached. The dissemination plan will be approved by the Steering Committee and shared between all project partners. The approved dissemination plan will be shared with the EC.

Task 2.4 Promotion of the ECCTR project during medical congresses
All Partners will cooperate in organising and including podium presentations during the sessions of the scientific programmes of the ESCRS, EEBA and EuCornea Congresses. The visibility of EU co-financing in accordance with the EU guidelines will be ensured.

The promotion at the following congresses will offer a unique forum to the ECCTR project for discussion, exchange of best practices and visibility of the findings shared by ophthalmologists all over Europe at the following congresses:
- XXXIV Congress of the ESCRS and EuCornea,
10-14 September 2016. Bella Center, Copenhagen, Denmark
- XXXV Congress of the ESCRS, Lisbon, 7-11 October 2017.
FIL – International Fair of Lisbon, Lisbon, Portugal
- XXXVI Congress of the ESCR and EUCornea,
22-26 September 2018. Reed Messe, Vienna, Austria
- EEBA Annual meeting for 2017 and 2018
- Annual National Registry Meetings

Task 2.5 Organisation of instructional course for doctors during the medical Congresses
It is planned to organise a ECCTR instructional course at the medical congresses of the ESCRS and EUCornea in Lisbon and Vienna where doctors and nurses could participate and learn about the use of the ECCTR system.
The course will be prepared by Prof. Mats Lundstrom and Dr Mor Dickman.
The course content will address: ECCTR purpose, background and design, presentation of the ECCTR system, tools for clinical improvement, output from the ECCTR system for ben

Work Package 3: Monitoring and Evaluation

Start month: 1
End month: 36
Work Package Leader: ESCRS

A plan will be put in place to establish the guidelines for evaluation in order to verify that the project is being implemented as planned.

Monitoring the project activities and results and measuring how these contribute to achieving the specific objectives will be a continuous effort throughout the project. Project staff will prepare and collect all documents and information that is relevant in the process of monitoring the project process, such as reports, minutes of the meeting, periodically exchange of information thought e-mails and teleconferences. In order to verify if and to what extend the results of the activities contribute to achieving the specific objectives, the key indicators listed under each of the specific objectives must be closely monitored and evaluated. During the inception phase the project management team will prepare an evaluation plan with key evaluation questions related to a) the establishment of the EU web-based registry b) impact of the EU registry with regard to scares donor tissue to the benefits of patients and society c) how the EU registry allows health professionals and local authorities to asses and verify the safety quality and efficacy of transplantations, the key questions will take in considerations the process indicator related to each objective and workpackages.
- A clear role and task division will be agreed upon and the most appropriate project partner will be made responsible. At the first Steering Committee meeting the evaluation plan will be shared amongst all partners. The plan will also form an annex to the consortium agreement. Before each Steering Committee meeting, and at least every quarter, the responsible partner reports on progress and results per envisaged activity, and the targets related to the process and output indicators to check if the envisaged results are on track.
It is the responsibility of ESCRS to overall monitor progress on activities, and how these contribute to achieving the specific objectives. In the final year of the project emphasis will be put on monitoring progress on the outcome/impact indicators to ensure that the targets are being met and the impact on the target groups is according to the agreed plan.
The Steering Committee meets every twice a year to monitor progress and to take

action and decide on measures if required. All project activities, and how these contribute to achieving the specific objectives and overall goal of the project, will be extensively evaluated and the results achieved, the lessons learnt and best practices will be transferred to the academics, health professionals and authorities. Results on project achievements will be shared among stakeholders across Europe.

Work Package 4: Development of the software for the EU web-based registry

Start month: 1
End month: 36
Work Package Leader: ESCRS

ESCRS with Associated Partners will meet and agree the final dataset and reporting function for the IT infrastructure of the registry.
ESCRS and ECCTR Steering Committee will lead the discussion with the IT provider for the development of the software in order to accomplish the technical roll out of the system across Europe.
The following tasks will be carried out during this work package:
Task 4.1 Review and Evaluation of data set for the system
Prof Mats Lundstrom will lead the discussion with the Steering Committee for the finalisation of the database guidelines for the system. For this purpose, the Partners will need to agree on:
- Review and evaluate the clinical data set for the system
- The description of parameters and dataset for the system
- Parameters for the Patient Report Outcomes
- The reporting outcomes of the registry.

Once all Partners have agreed, Prof Mats Lundstrom will prepare the Coding guidelines document for the system. The document will contain data set dictionary, value sets data management and coding guidelines for the purpose of building the EU registry.

Task 4.2 Developing of the system
The It provider will develop the system under the Database guidelines received by Prof. Mats Lundstrom. The It provider will be in charge of:
- Design and the develop the entire database
- Development of the Patient Outcome Questionnaire
- Development of user guide and paper forms

Task 4.3 Testing of the system
The testing phase is very important before rolling out the system, the following tasks will be carried out:
- The It provider and a selected group of people will be involved in the testing phase of the system
- The system should be tested on the response time of different areas such as: different types of input devices and Network, (i.e. Laptop, Personal Computer, iPad,

and other Tabs)
- Test on different Operating systems and networks, loading volume and security
- Each module will be checked separately and make sure that everything will reflect the desire output

Task 4.4 Development of interfaces with Existing Registries across Europe
Prof Mats Lundstrom and Dr Mor Dickman will take care of the finalisation of the interfaces documentation and make sure that the ECCTR will includes all parameters in connection with the implementation of tasks of WP5.

- They will carry out the quality control of clinical compatibility amongst the existing European Registries and the ECCTR database
- Evaluation and validation of the systems
- The IT provider will develop the user interface document
- The IT provider and the staff of the European registries will cooperate for interfacing the systems and guarantee the direct transfer of surgeries to the ECCTR.

Task 4.5 The system goes live
- ESCRS and all partners will promote the roll-out of the ECCTR database and inform all members of participating Society (ESCRS, EEBA, EuCornea) in relation to the availability of the system.

Task 5.5 Finalisation of EU web-based registry
The Clinical director and Steering Committee members will make sure that all inputs and exchange of knowledge discussed during all meetings outlined in the Progress Reports concerning corneal graft failure and adverse (immune) reactions agreed during the implementation of WP5 will be included in the ECCTR.

Work Package 5: Active clinical cooperation and networking with VISICORT

Start month: 1
End month: 36
Work Package Leader: MU

Dr Mor Dickman will be responsible for the development of a communication plan between the different stakeholders of ECCTR and the researchers involved in the actual EU-funded projects.

This work package it is fundamental to guarantee the synchronisation, exchange of knowledge and good practice about new clinical findings related to failure of corneal transplants and adverse (immune) reactions.
Prof. Jesper Hjortdal, as one of the members of the Steering Committee of ECCTR, also, actively involved in FP7□HEALTH□2013 VISICORT will guarantee the efficiency of the exchange of scientific findings to be considered for:

- Establishment and validations of parameters to be included in the system related to failure of corneal transplants and adverse (immune) reactions.
- During the final phase of the project, data collected from the system will be analysed by the Steering Committee with a view to beginning dissemination of information and initiation of recommendations for clinical variables related to quality, efficacy and safety of corneal transplantations.

Prof Rudy Nuijts and Dr Mor Dickman will be responsible for finalising the decision about data sets and value sets to be included in the EU wide Platform and co-operate on the exchange of information with Prof. Jesper Hjortdal.

Dr Mor Dickman will keep active communication with Prof. Lundstrom and Steering Committee for including any updates on new findings and make sure that any new parameters will be included in the system and guarantee the correlation within WP4, WP5 and WP6.
The clinical findings will be included in the deliverable : Final report Guidelines reccomandations

Moreover, Prof. Nuijts, Prof. Hjortdal and Dr Dickman will be responsible for the development of a recommendations report on quality, efficacy and safety of corneal transplantations to be disseminated by the end of the project.

This work package will also guarantee the exchange of information with European joint action VISTART (Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation).

The progress report and recommendations reports deliverables of this WP will take into account: corneal graft failure, adverse (immune) events following corneal transplantation, risk factors and treatment(s) used against rejection.

Work Package 6: Data collection, recruitment of clinics across Europe

Start month: 12
End month: 36
Work Package Leader: FBOV

ESCRS and FBVO/EEBA will be working together for the recruitment of the clinics and eye banks across Europe.
All associated partners; the existing European Registries will participate in the collection of data
The following tasks will be carried out during this work package:
Task 6.1 Recruitment of clinics
- EEBA receives data from 84 eye banks members coming from 24 European countries.
- EEBA and ESCRS will work together for recruiting the major number of clinics and

Eye Banks willing to participate in the collection of data for the ECCTR project

Task 6.2 Training of personnel involved in the data collections
- The IT provider will prepare an online demo on the use of the ECCTR and will be available for all personnel involved in the project.

Task 6.3 Development of |Interfaces within the 3 existing EU Registries
- The already existing Registries will share information related to: data sets and coding lines of the system
- Prof. Mats Lundstrom and Dr Dickman will map and evaluate the data available of the 3 systems
- Prof. Mats Lundstrom and Dr Dickman will develop the Clinical compatibility for each Registry and circulate the document amongst the members of the Executive Committee
- The Executive Committee will agree on the compulsory dataset of the Registry and agreed on the choice of eventually transferring historical data to the Registry.
- The IT provider will develop the web service based interfaces
- The European Registry will have interfaces to the existing Registries and ensure direct transfer of data
- Prof Mats Lundstrom and Dr Dickman will ensure that all information will be included in ECCTR and guarantee the relationship of the tasks implemented during WP4 and WP5

Task 6.4 Start of data collection for clinics and universities
- The ECCTR project team will monitor the progress of collection of data in the system (direct transfer and manual input)
- The project staff will be available by phone or e-mail for any information and support needed to guarantee a successful roll out of the system.

Work Package 7: Evaluation of data collected and development of an evidence based European protocol

Start month: 24
End month: 36
Work Package Leader: NTS

The Steering Committee will meet regularly and discuss on the progress for the development of the registry, validation process and review of the data collected.

Validation process: The database software should have built-in validation functions that include possible limits for all values. The system should also have cross-analysis functions that sort out impossible combinations of data. All dates will also have a validation function so preoperative dates must precede surgery dates and surgery dates must precede follow up dates.
On a regular basis data from each source database should be validated towards the European database. This means regular checks about number of reported cases,

type of surgeries, donor corneas and follow up visits. The aim is also to check that detailed data for a case in source databases corresponds to data in the European database. This validation process will not take place on a regular basis but on single occasions when need is indicated by the analysed data
The Steering Committee will meet regularly and discuss on the progress and review of the data collected.

The Steering Committee will analyse and make recommendations for the following:
-Analyse corneal transplant outcomes: Graft survival, Visual acuity, Endothelial cell density, Refractive astigmatism, Topographic astigmatism
- Analyse corneal transplant safety: Donor tissue loss, Primary graft failure, Graft rejection, Secondary glaucoma, Infection of the graft, Recurrence of original disease, Cataract
-Analyse the number and type of corneal transplantations performed in each country and measure where the grafts are coming from (national eye bank, EU eye bank, third country eye bank)
-Evaluate 2 years outcomes stratified by reason for grafting:
1) improve vision 2) relieve pain 3) Preserve eye

Prof Mats Lundstrom and Dr Mor Dickman will support the Leader of this WP, as well as all members of the Steering Committee will participate on analysing the data collected in the Registry.

The data analysed in the Registry will concern: content Donor and recipient demographics, Donor preservation and processing, annual number of corneal transplantations per transplantation technique and country, indications for corneal transplantation per transplantation technique and country, Core outcomes and safety data per transplantation technique and country)

Prof Mats Lundstrom and Dr Mor Dickman and all members of the Steering Committee will support the Leader of this WP for the development of the guidelines recommendations.

The final report guidelines will include data on: preoperative and intraoperative data, preoperative Examination (Visual Acuity, Refraction), ocular comorbidity, difficult surgery, type of anesthesia, surgical complications, Follow –up data: visual outcomes, refractive outcomes, post-operative complications.

The Final Report Guidelines recommendations will be directed to ophthalmologists and European organisations involved in corneal transplantations and competent local Authorities.

The Coordinator will call for participation and support of CHAFEA for the dissemination and visibility of the Final Report Guidelines at EU level and targeting relevant stakeholders.

COORDINATOR, LEADER CONTACT AND PARTNERS

COORDINATOR

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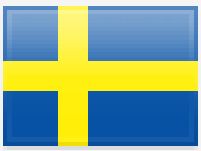

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OUTPUTS

MD 4 - Layman version of the final report

EuCornea
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 07/01/2020
Layman version of the final report for stakeholders

MD 2 - Final report

ESCRS
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 23/01/2020
Final report on project activities and results

Finalisation of EU web-based registry

ESCRS
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 29/11/2019
Online Registry: online forms available: donor data form, recipients data form , pre-operative data form, surgery form, follow-up form.

Primary report based on Registry data

NTS
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 29/11/2019
Preliminary clinical finding report based on the analysis of the data included in ECCTR

Final report Guidelines reccomandations

NTS
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 29/11/2019
Evidence based report based on the final clinical analysis of the data of the ECCTR

Progress report on new clinical findings

MU
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 29/11/2019
Report: describing any new relevant information outlined during the implementation of this WP

Recommendations report

MU
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 29/11/2019
Report summarising the conclusions of the studies across Europe concerning graft failure and adverse (immune) reactions.

Final Core dataset for graft failure and adverse (immune) reactions

MU
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 29/11/2019
This document will include the final data sets dictionary, value sets data management for graft failure and adverse (immune) reactions

Evaluation Report

ESCRS
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 21/12/2018
The report will analyse if the project has been implemented according to the plan

Database guidelines

ESCRS
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 25/10/2018
This document will include the final data sets dictionary, value sets data management, outcomes report for ECCTR

Online demo
FBOV
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 25/10/2018
Online training for the system.

MD1 - Interim Report
ESCRS
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 28/02/2018
Preparation of Interim report on project activities and results.

Prototype database ready to be test
ESCRS
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 08/12/2017
IT platform and database ready for being tested

MD 3 - Leaflet
EuCornea
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 20/11/2017
This leaflet contains project information

Pilot Database Guidelines
ESCRS
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 06/04/2017
This document will contain the pilot data sets dictionary and value sets data management for transplantation techniques to be included in the system

Graft failure and adverse (immune) reactions core pilot data set
MU
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 06/04/2017

List of pilot data set dictionary to be included in prototype system

MD 5 - Website

EuCornea
European Cornea and Cell Transplantation Registry (ECCTR)
Published on: 06/02/2017
General website on the project