European Commission
Innovation and Networks Executive Agency (INEA)

Connecting Europe Facility

Final report

1. INFORMATION ON THE ACTION

Grant Agreement Nº	INEA/CEF/ICT/A2018/1816948
Action Title (Art. 1 of G.A.)	Integration systems for specific dataset, e-learning and support of ERN Core Services in the ERN TransplantChild
Action number (Art. 1 of the G.A.)	2018-ES-IA-0176

Author of the report

Name	Paloma Jara Vega
Position	Coordinator ERN TransplantChild
Coordinator's Legal Name	SERVICIO MADRILEÑO DE SALUD – HOSPITAL UNIVERSITARIO LA PAZ (SERMAS-HULP)
Telephone Nº	+34 91 727 75 76
E-mail	coordination@transplantchild.eu

2. IMPLEMENTATION OF THE ACTION

2.1. Overall completion of the Action

Planned Start/End date[1]		Actual Start/End date		Completion[2]
01.09.2019	28.02.2021	01.09.2019	30.04.2021	100%

2.2. Completion per activity/work package

Activity 1	Title[3]	Planned Start/End date[3]		Actual Start/End date		Completion
	Adaptation of a specific dataset on paediatric transplanted patients´s clinical data	01.09.2019	31.01.2021	01.09.2019	31.01.2021	100%
Milestone no	**Title[3]**	**Planned date[3]**		**Actual date**		**Reached (Y/N)**
2	Establishment of new datasets or interoperability improvement of existing ones demonstrated	31.01.2021		31.01.2021		Y

Activity 2	Title[3]	Planned Start/End date[3]		Actual Start/End date		Completion
	Implementation of an e-learning system	01.09.2019	28.02.2021	01.09.2019	30.04.2021	100%
Milestone no	**Title[3]**	**Planned date[3]**		**Actual date**		**Reached (Y/N)**
1	Active use by the CPMS and ECP demonstrated	31.01.2021		30.04.2021		Y

Activity n 3	Title[3]	Planned Start/End date[3]		Actual Start/End date		Completion
	Maintenance of ERN TransplantChild online supporting tools	01.09.2019	28.02.2021	01.09.2019	30.04.2021	100%
Milestone no	**Title[3]**	**Planned date[3]**		**Actual date**		**Reached (Y/N)**

[1] As specified in Art. 2.2 of the Grant Agreement.
[2] The completion of the Action and of each activity/work package should be indicated as a percentage.
[3] As specified in the Grant Agreement.

3	Actual use of the e-learning /e-training tools demonstrated	30.12.2020	30.04.2021	Y

Activity n 4	**Title[3]**	**Planned Start/End date[3]**		**Actual Start/End date**		**Completion**
	Dissemination activities	01.09.2019	28.02.2021	01.09.2019	30.04.2021	100%
Milestone no	**Title[3]**	**Planned date[3]**		**Actual date**		**Reached (Y/N)**
4	Dissemination of e-learning course among the ERN members and stakeholders	30.12.2020		30.04.2021		Y

Activity n 5	**Title[3]**	**Planned Start/End date[3]**		**Actual Start/End date**		**Completion**
	Coordination, Management and Evaluation of the Action	01.09.2019	28.02.2021	01.09.2019	30.04.2021	100%
Milestone no	**Title[3]**	**Planned date[3]**		**Actual date**		**Reached (Y/N)**
5	Publication of Final Operational Report	28/02/2021		30.04.2021		Y

2.3. Description of the implementation of the Action, including the actual status at the end of the Action and possible deviations from the planned activities, and, if applicable, compliance with any relevant specific provisions as indicated in the Annex I of the GA

Activity 1: Adaptation of a specific dataset on paediatric transplanted patients´s clinical data

Activity 2: Implementation of an e-learning system

Activity 3: Maintenance of ERN TransplantChild online supporting tools

Activity 4: Dissemination activities

Activity 5: Coordination, Management and Evaluation of the Action

European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialised treatment and a concentration of knowledge and resources. TransplantChild is a European Reference Network for Paediatric Transplantation, is focused on both Solid Organ Transplantation (SOT) and Hematopoietic Stem Cell Transplantation (HSCT) with a cross-cutting approach to support common areas as immunosuppression, rejection, tolerance, infections and psychological wellbeing.

Our main goal is to have a significant impact on the quality of life of children and their families in the long term. To achieve it, the methods implemented are giving the patients network access to diagnostic advice and joining with members of the network and stakeholders to increase the information, innovate and expertise in the transplant procedures.

Abreviations

BoN - Board of the Network

CMS - Content Management System

CPMS - Clinical Patients Management System

ECP - ERN Collaborative Platform

ERN – European Reference Network

HSCT - Haematopoietic Stem Cell Transplantation

ICT - Information and communication technology

IT - Information technology

LMS -Learning Management System

LCMS - Learning and Content Management System

SOT - Solid Organ Transplantation

WG - Working Group

The main objective of this Action was to improve the use of European Reference Network on Transplantation in Children (ERN-TransplantChild) existing dataset(s) quality and data validation of the Clinical Patient Management System (CPMS) to increase the knowledge generation supported by e-learning training activities within the medical community and

stakeholders, and ensure adequate and efficient use of the ERN core service platform (European Collaborative Platform and Clinical Patient Management System).

For doing so, The activities included: 1) Specific dataset collection, adaptation and real-time analysis of paediatric transplanted patients clinical data related with healthcare quality of healthcare providers, 2) Implementation of a e-learning systems aligned with the training needs into the ERN TransplantChild to allow a work environment to ERN stakeholders across the knowledge generated by the network, and 3) Maintenance ERN Transplant online supporting tools to ensure the connection of Healthcare Providers to the ERN Core Services.

ERN core service platforms Information technology (IT) and e-Health tools play a valuable role in facilitating collaboration. Interoperable and semantically compatible information and communication technology (ICT) systems facilitate the exchange of health data and patients information, and the establishment and maintenance of shared databases and registries. The Commission delegated decision of 10 March 2014 setting out criteria and conditions that European Reference Networks (ERNs) and healthcare providers wishing to join a European Reference Network must fulfil (2014/286/EU) clarifies that further horizontal and structural criteria and conditions related to the exchange of expertise, information systems and eHealth tools should help developing, sharing and spreading information and knowledge and fostering improvements in the diagnosis and treatment of diseases within and outside the Networks and to collaborate closely with other centres of expertise and networks at national and international level. To enable and facilitate this cooperation, the European Commission together with the ERNs set up the e-Health Digital Service Infrastructure for the European Reference Networks (ERNs).

Implementation of e-learning training along with the creation of a dataset helps to improve the QoL of transplanted children. With this solution in place the ERN objectives are easily achieved. The Action provides a quantifiable scenario of population that may benefit from the provision of the ERN services. ERNs will boost research and contribute to the development of new treatments, and will lead to economies of scale and ensure a more efficient use of costly resources, which will have a positive impact on the sustainability of national healthcare systems, and for tens of thousands of patients in the EU suffering from rare and/or complex diseases and conditions.

Activity 1: Adaptation of a specific dataset on paediatric transplanted patients´s clinical data

The objective of this activity is to create a data model adapted to paediatric transplantation. Since the implementation of the digital systems, the different ERN's have been offered the possibility of customizing the data collection model to perform virtual consultations in the CPMS. This customized data model allows different networks to include fields to collect the variables corresponding to their group of rare diseases. The ERN TransplantChild has been one of the first to add its own fields in the CPMS and start organizing the panel information more specifically for transplantation in children.

With the new call for registries open for ERNs, it is of great importance to work on the creation of this data set that allows interoperability and integration of different sources, concentrating knowledge and promoting research.

For this, the hospital's clinicians, together with the personnel dedicated to the action, work together to analyse the data set fields that can best collect the variables of a transplant process. This work must be a combination of both clinicians and technicians so that a correct way of collecting the specific fields of the disease is agreed upon, as well as taking the necessary measures so that these fields allow subsequent semantic and technical interoperability. To achieve this objective, different activities have been carried out within the project:

i. Stakeholder analysis

In the first place, an analysis of the interested parties was executed, for them the action support team together with the hospital staff carried out an extensive review of the bibliography as well as the existing tools for data collection in the transplant field. This was the starting point for the development and implementation of this data set in the information platforms of the ERN. The revision of the paediatric transplant data framework allowed us to draw a series of conclusions which helped to accomplish a more specific analysis of stakeholder needs in relation to the creation and implementation of the transplantation dataset.

We always work with the idea of including all types of transplantation to follow the cross cutting approach of the mission of the network. So the aim is to define the data set that could cover the needs of the professionals of all the types of paediatric transplantation (solid organ transplantation and haematopoietic stem cell transplantation).

After this review, the main gaps and weaknesses of the data collection systems in child transplantation were identified. The development of the data set should be largely focused on meeting these needs to ensure a more efficient and complete data collection in both virtual consultation and registries.

- Partners proposal development

  A proposal was developed within the action plan to receive feedback from the comments of the partners and the possible suggestions and contributions that European network experts have. We received a response from the members of the network with their vision of the proposal made from the action and possible suggestions on the data set and fields.

- Feedback from the meetings with the partners

  After sharing the data set we received the feedback from some of the partners which included more details in some specific areas. We had to take a decision on the data set keeping in mind the cross cutting approach of the network and that the data set should keep as general as possible in order to make it useful for all the transplant programs included in the network.

- Action plan for dataset development and revision

  In this analysis, the different European initiatives in the area of data collection were contemplated, ensuring maximum synchronization between projects in order to facilitate and ensure interoperability between systems.

  This task is of particular importance since the creation of a specific data set for the TransplantChild disease group allows the standardized and structured data collection of clinical patient information.

ii. Implementation of standardized interoperability models

To implement interoperability models between the CPMS system and the PETER Registration System, the possibilities of exchanging personal data between both platforms must first be assessed. To this end, the new data protection regulation of the European Union has been reviewed and the conditions for collecting and managing personal data of patients been taken into account following the UE Regulation 2016/679 on protection of personal data. (https://ec.europa.eu/info/law/law-topic/data-protection/data-protection-eu_en)

To comply with legality and legitimacy, we consulted to *Hospital Universitario La Paz* ethical committee to assess the existing CPMS informed consent model and make the necessary modifications to allow two-way data exchange between the systems. In addition, this consent should be approved again by the ethics committee of each hospital in order to be used.

While designing the PETER Registration System some key future-proof aspects are defined regarding the latter connection that will exist between some of the different platforms used. Creating the platform from scratch posted a perfect opportunity to implement these requirements in the foundations, making them a key definition of the technical base. This futureproofing regarded all four of the FAIR principles: findability, accessibility, interoperability, and reusability; seeking an easier integration with future tools, algorithms and workflows by providing a machine-readable data and describing metadata. The first step on (re)using data is to be able to access it; with suitable metadata this can be easily obtained and would provide automatic discovery of services and datasets. However even if this data is easily findable, without proper indication on how to access it would make any sense, hence the second FAIR principle. Often, data is not only accessed and used, it is usually combined with additional datasets for a particular application, making necessary for it to be interoperable. The particular characteristic of data as a resource is that it can be continuously used and it never depletes, making it able to use it and reuse it several times; following the last principle, optimizing the reuse of data is the ultimate goal of the FAIRification process. All these principles were taken into account in the technological structure of the technological support applications of ERN TransplantChild.

iii. Specific dataset tools

To promote the exchange of data between the CPMS and the PETER registry, a specific database tool has been created that collects the data from the PETER registry. A service provider has been hired that meets the network's requirements for data collection needs. The contracted company has provided an open and intuitive data collection system that allows storing and handling the required data of the child transplant process.

The ERN TransplantChild has developed a data dictionary with the fields and encodings defined to collect the most significant data from the transplant process. For this, the network has made an analysis of which are the most relevant indicators of the transplant process, thus creating a proposal for a data dictionary where the structured information of the patients will be collected and stored.

This tool will have a data collection notebook with the fields and encodings provided by the ERN TransplantChild.

During the process we have also worked in the definition of a data set of information about the Patient Reported Outcomes and Patient Reported Experience (PROs and PREs). The objective of including patient outcomes into the clinical data collection tool is to have available also this information in order to improve the care of the patient. As shown by several research studies, PRO and PRE data are highly useful as they reflect the underlying health status better than clinical reports; significantly predict outcomes, including survival; increase patient satisfaction; are valued by clinicians; facilitate patient-clinician communication, and improve symptom management as well as the patient's overall quality of life, among others. We have conducted a systematic review to identify the standardised instruments that systematically document patient's perception of their symptoms that are best suited to our transplant patient population. Thus, we selected PedsQL Infants, Core, Transplant, and Stem Cell Transplant Modules.

We plan to collect the PROs from the patient and their parents (or only from the parents depending on the age of the patient) at the same periodicity and just before the follow up visits. The inclusion of this measures will allow the HCP work on making improvements in the process of transplantation, not only considering objective clinical outcomes but also subjective evaluation of disease outcomes and treatment from a patient’s perspective.

We also plan to develop and launch a mobile/tablet application to facilitate the collection of this information from patients.

iv. Design of integrative model of analysis and exchange of data

Once the data collection dataset has been defined, a data exchange model was designed in collaboration with the technical staff to allow the technical and semantic interoperability of the CPMS and PETER systems. The data collection tool is prepared to communicate and share the information to and from the CPMS system. That has been designed in order to ease the uploading of data to the patient related tools used within the network.

The development and implementation of a specific dataset with advance IT tools for the integration and analysis of paediatric transplantation data as a whole, is the best way of pooling data that would serve as a recruitment tool for the launch of studies focusing on disease etiology, pathogenesis, diagnosis or therapy increasing the QoL of these children. The dataset has been designed secured and anonymisation of personal data are carried out. Through the database we have defined needs for efficient health information exchange on different levels (patients, healthcare providers, researchers, payers, decision makers, etc.) and ways to address those. It also promotes collaboration, reduces redundancies, and improves transparency.

v. Requirements for implementation of ERN TransplantChild Clinical Data adaptation

The information collected has been transferred to the European Commission for his consideration and approval. This information must follow the basic aspects requested. At the moment, we are waiting the confirmation of the changes implemented at the Clinical Data.

All the multidisciplinary team at *Hospital Universitario La Paz* took part in the definition of the data set, revision of the existing tools and bibliography and added their knowledge and experience using other data set collecting tools.

Activity 2: Implementation of an e-learning system

Education & Training and, more specifically, e-learning, has always been one of the main priorities and activities in TransplantChild. In fact, the Education & Training WG has been working during these years on the development of educational webinars and courses both for patients and health professionals.

i) E-learning training needs

TransplantChild e-learning materials were always uploaded to the TransplantChild Youtube Channel and to the TransplantChild website. Because of this, one of the main motivations to implement a specific e-learning platform was to collect all the e-learning material that has been created during these years and have it all together organized in different courses that can be addressed to specific populations.

Moreover, owning an e-learning platform would facilitate the monitoring of the e-learning materials and provide important data that could help take decisions for future content development and course design.

As part of the Coordinators Knowledge Generation Working Group, the first step consisted of a search of the e-learning perspectives:

- LMS in which there is interactivity between learners and teachers.
- CMS, act as a documentation repository
- LCMS, hybrid system

We though that the best option would be a LMS, where participants could communicate, collaborate, access activities and resources and coordinators could assess and report via web.
Among the LMS, there are two types of online e-learning systems:

- Synchronous: participants connected at the same time. The main advantage is that there is an immediate feedback and interaction.
- Asynchronous: the participant uses the most convenient time and place.

To combine synchronous and asynchronous systems seems to be best option.

Within the working group, a comparison of two e-learning management systems were performed with this results:

End user license agreement	General Public License
Expensive	Freely available (with only some functionities)
US-centric	International community
Rigid design	Flexible and customisable
Blackboard	Moodle
.com	.org

For further comparison, these are some data about different tools available:

	LMS oriented	CMS oriented	Strengths / Issues
Cisco Webex Training	LMS	not	++ Virtual classrooms
Google Hangouts	LMS	not	-- Data Protection concerns (Cloud-based, not hosted in Eu)
BlackBoard Collaborate	LMS	not	-- Data Protection concerns (Cloud-based, not hosted in Eu) ++scheduler --Java plugin security concern. To check the new pure HTML5 version --detail the licensing cost --operational continuity to be checked
Appear. IN	LMS	not	-- Data Protection concerns (Cloud-based, not hosted in Eu)
Moodle	not	CMS	++ opensource ++very versatile, extensible features (PHP) ++ scalable (>1000.000 users in >30 countries EC DEVCO Academy)

We found that due to the flexibility Moodle would be the best option for us. Afterwards, the DG SANTE reached a similar opinion, and decided to offer Moodle service to all ERNs (beginning 2022) for featuring the training content.

ii) Technical requirements

A market analysis was performed to identify the technical characteristics offered by different companies regarding e-learning and hosting of the platform. Several hosting services and different types of e-learning platforms were explored. With this analysis, many different platform and server characteristics were identified as requirements for the e-learning system:

- Hosting of a Moodle platform for 1 year
- 500 GB of storing

- Monthly transfer of 6TB
- 1.eu domain
- 50 simultaneous users
- 80 monthly active users
- 1 Gb/s bandwidth
- SSL certificates included
- Custom Moodle initial setup
- Weekly server backups
- Custom platform design
- Training to manage and use the platform
- Moodle installation
- 2 GB RAM
- Unlimited registered users
- Unlimited courses
- Firewall, Antivirus and Antimalware
- Servers located in the European Union
- 24/7 support both by mail and phone
- Uptime of at least 98%
- Unlimited databases
- Minor Moodle updates included
- Design and creation of videos and other types of training materials like infographics, dynamical presentations, etc to establish two different Moodle courses:
  - i) One course for health professionals with 20 modules of 20 minutes each, with evaluations
  - ii) One course for patients with 3 modules of 5 minutes each, with evaluations
  - iii) If possible, create interactive contents for the courses
- Certificate ISO 27001.

These requirements were presented to the three companies which are official Moodle partners in Spain: 3&Punt Solucions Informàtiques SL, Insynergy Consulting España SA and Inserver. Teleconferences were held with these three companies, in order to better explain them the desired characteristics for the platform and the project. Then, they presented their proposals and budget for this project, according to the platform necessities stated in the characteristics document and during the teleconferences.

After studying the different options to build the TransplantChild Moodle platform, it was decided to go with ISYC (Insynergy Consulting), that presented a proposal with the following details:

- Hosting in cloud servers
- Implementation of a subdomain in the TransplantChild website
- 30 GB of storing
- Up to 1,000 active users per year
- Up to 200 concurrent users
- Complete server administration: updates, security, monitoring and optimization
- Daily back-ups with immediate data recovery if necessary
- Minor Moodle updates included, with their respective security patches
- Database software updates to guarantee compatibility
- Corrective maintenance

- UNE-ISO/IEC 27001:2014 certificate
- ISO 22301 certificate
- Multi-language content
- Custom login screen
- Custom header and logo
- Custom colours
- Custom fonts for text and titles
- Development of two courses:
  - 20 modules course for medical professionals.
  - 15 mins pills course for patients.
- 4h Moodle training for platform management.

iii) Content & platform development

While the new platform was being developed, a temporary MoodleCloud portal was created to be used as a repository for the TransplantChild e-learning webinars, to be later moved to the final Moodle platform. A test user account was provided to all the members for them to log in the platform and check these lessons.

The platform was designed by the ISYC team, using the TransplantChild website as a reference, for the colours and fonts. They were provided the official ERN logos to be included in the platform. The whole design process was supervised by the TransplantChild Technical Secretariat via email: the developers informed TransplantChild of the state of the platform at every point, and the latest changes and additions.

When the platform was ready, two training sessions were organized by the ISYC team, to give the TransplantChild Technical Secretariat the necessary training to be able to manage the platform, create the different courses, register users, upload content and activities, monitor the use of the platform, etc.

For the courses design, several teleconferences were held with the responsible of the ISYC content department, to explain the objectives of each one of the different courses. With that, they received a specific vision of the TransplantChild ideas to develop these courses. Then, the content templates, preliminary media and texts were sent to ISYC to start the development. From ISYC, they created a short demo (1 min video) to show their animations and character design, to make sure that it fit the necessities of the patients.

A first version of the pills for patients was reviewed by the TransplantChild Coordinating Team, so that the content team at ISYC could get some feedback on the videos and change them accordingly to meet all the requirements.

Again the team at *Hospital Universitario La Paz* worked in the design and definition of the material, content and thematic areas for the development. The coordinator of the Education and Training working group at ERN TransplantChild and the coordinator of the nurse's team took part in the activity.

iv) Content & software implementation

Once the platform was ready, it was migrated to a subdomain depending on the TransplantChild Website (education.transplantchild.eu), so that all the ERN resources are integrated. Then, the two previously mentioned courses were uploaded. The third course, consisting of a collection of the TransplantChild e-learning webinars, was also moved to this platform.

Up to date, the Moodle tool of TransplantChild includes the following material:

- PETER: PaEdiatric Transplantation European Registry

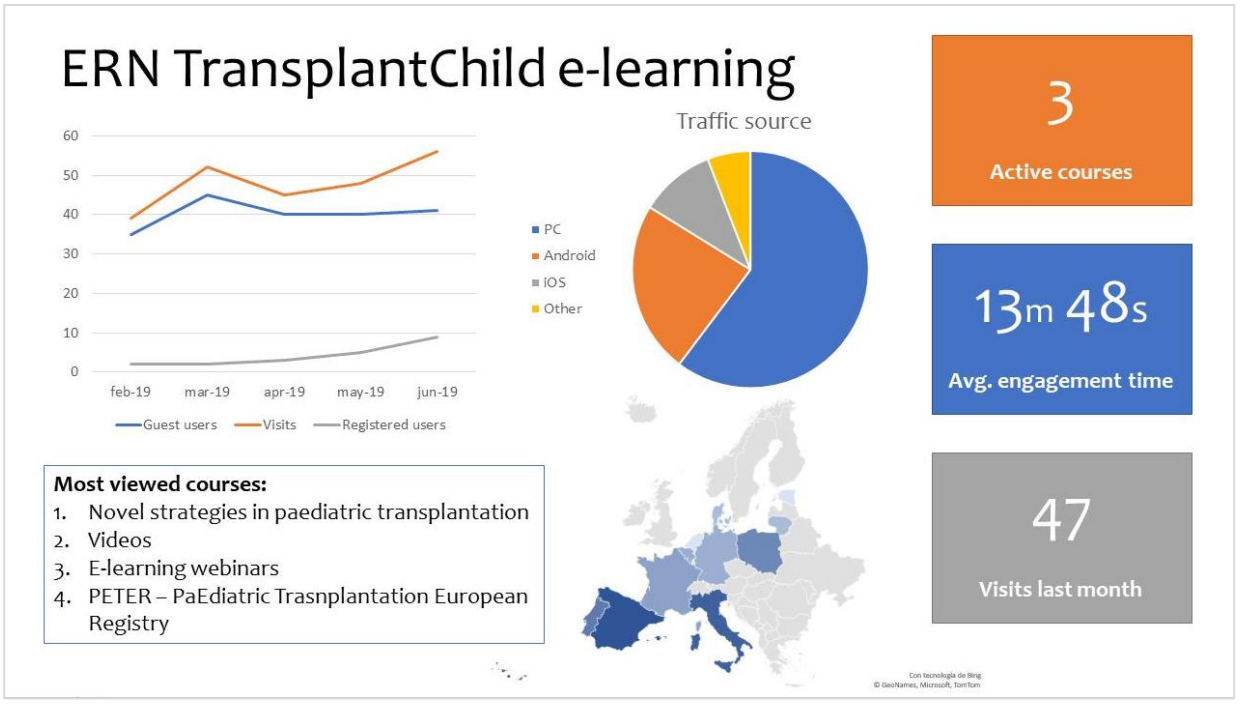
- PETER Quick start
- PETER handbook

- Workshop: Novel strategies in paediatric transplantation
- Pills for patients
  - School
  - Active Life
  - Friends & social life
  - Holidays & sunny days
  - Pets
  - Alcohol, tobacco & drugs
  - Sexual relations
  - Piercing & tattoos
- E-learning sessions
  - Anesthetic Management of Organ Donors
  - Surgery practical aspects in Solid Organ Transplantation
  - Recommendations for immunization of solid organ transplant (SOT) and Hematopoietic Stem Cell (HSCT) candidates and recipients
  - Post-Transplant Lymphoproliferative Disease
  - Immunosuppression treatment
  - Graft Engineering and Organ Split
  - Rejection
  - Non pharmacological strategies to induce tolerance
  - Liver transplantation

v) Content monitoring

Once the platform was ready, there has been a monitoring activity plan which consist on a biannual report which includes different metrics such as:

- Number of active courses
- Number of visits to the domain
- Main source of traffic
- Referral sites of traffic origin
- Number of registered users
- Number of different users visiting
- Average engagement time
- Country of visit origin
- Technological platform used to access



vi) Adaptation of the material created for the training and support of the platforms.

i. Integration with the e-learning system within one of the training plans.

ii. Support of the two platforms through online training improving existing content.

1- Analysis of needs, content, problem and risk in the implementation of e-learning tools	The objective of this phase is to gain a complete understanding of the goals and constraints of ERN TransplantChild. The analysis phase will provide the information to properly define the scope of the training activities and will be the primary input into the design phase.
2- Environment Design of a e-learning system	The design phase takes into consideration all that has been learned in the analysis phase and creates a total solution that meets the training requirements. The design process will address all of the instructional needs as well as the infrastructure and technical requirements.
3- Training Content Development	This phase includes graphic, video, audio and multimedia production. The production team will use the storyboards to create all of the content that makes up the instruction. This is a very labor-intensive and expensive part of the job which is why it is so very critical that the storyboards be carefully reviewed.
4- E-learning Software Development	Using the software functional specification document and the prototype, the programmers will create the training software application.
5- E-learning Implementation	After the production is complete and the training system is finished, the implementation phase addresses the details with final delivery, installation and the final testing/acceptance by the stakeholders.
6- Evaluation	This evaluation that can determine if the objectives of the training have been met. Evaluation can drive the continuous improvement of the training for better and better results.

iii. In order to analyse the Gap analysis for patients, physicians, nurses and researchers, surveys were launched focused on the different stakeholders. Once analyses the surveys, the needs were identified.

iv. Based on the needs found and identified, different training actions have been carried out, including webinars, courses, workshops, webinars, e-learning, courses, etc.
v. Once identified the more suitable platform for the developed of the training actions, this is implemented.
vi. Development of material in the selected platform E-learning through a development plan.

Activity 3: Maintenance of ERN TransplantChild online supporting tools

During the development of the activity, there have been several changes affecting the CPMS platform. These changes comply from graphical and conceptual modifications to changes in the procedure of panel staging and patient data introduction. These minor changes have been cumulative and delivered in stages, which created the necessity to adapt different documents continuously.

The following areas of the training section (that includes videos and written guides) that were affected by the update are:

- EU Login:
  - Creating an account.
  - Requesting access to the platform.
- CPMS:
  - Overview guide
  - Enrolling a patient in the platform.
  - Creating a panel: basal information.
  - Creating a panel: specific information blocks.
  - Creating a panel: uploading medical documents.
  - Creating a panel: inviting fellow experts.

We have been continuous with the support to the members of the network in the uploading of clinical cases in the CPMS when needed.

Activity 4: Dissemination activities

The dissemination activities are intended to engage and bring results to as many relevant stakeholders as possible including clinical healthcare staff, researchers, transplanted children, patient associations and the general public. Promoting the different actions and its results is one of the main goals of the action.

The following actions have been carried out during the period according to the target public in order to benefit them. To reach a large number of stakeholders and to share the results with them we have been using the social media tools:

i. TransplantChild Website. https://www.transplantchild.eu/en/
ii. Twitter account: https://twitter.com/TransplantChild
iii. Webinars: e-learning sessions
iv. Newsletters: All subscribers are informed about the activities developed by the Network, their progress and conclusions. This information is available on https://www.transplantchild.eu/newsletter/
v. Special communications announcing the workshop, the webinars and the launch of the tool
vi. Via email and face-to-face meetings - BoN and workshops
vii. Share documents through IT Tools such as ECP and CPMS

We have worked also in the dissemination and promotion of the CPMS as a specific tool developed by the European Commission for sharing knowledge and ask for the opinion of other professionals in this difficult cases. We have included dedicated sessions on the meetings for the discussion and promotion of the use of CPMS and monitoring its use among the members and affiliated partners.

The dissemination activities started early enough, in order to get feedback from the target groups, thus allowed us to anticipate to any unexpected problem.

Activity 5: Coordination, Management and Evaluation of the Action

From the start of the action different type of activities have been carried out for the successful development of the action, however due to the global pandemic situation caused by COVID-19 some of them were affected. We have tried to adapt to the situation making use of the tools available but not always we were able to adapt to this global challenge unexpected.

For example, we had to rearrange the 2nd TransplantChild Workshop on translational research which was planned for the 14th May 2020 in Warsaw. Finally, it took it online the 30th November. The content and material of this workshop was to be added to the e-learning platform which documents are available in the Moodle.

The pandemic caused the delay in development of the activities and its monitoring, this was the main reason why we asked to the Commission European for an extension of the execution period for two months (new end date: 30th April 2021).

Collaboration between SERMAS and FIBHULP is carried out through a prior general collaboration agreement, by means of which the latter handles the financial and administrative aspects of the hospital services involved in research and innovation projects, including all issues relating to the employment and payment of additional personnel etc. The FIBHULP manages the projects using a special tool for the management of projects, keeping separate accountability by project. Also the institution comply with the Spanish Public Procurement Law for contracting services and for subcontractors.

<u>Management</u>

The general rules regarding governance of the ERNs were defined in the Commission implementing decision 2014/286/EU setting out criteria for establishing and evaluating ERNs and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks. ERN TransplantChild obeys the principles laid down in the said decision, as further detailed below.

According to decision 2014/286/EU, ERNs are allowed to have different organisation models, but it is required that they all choose one of their Members as the coordinating Member. The coordinating Member shall appoint one person acting as the coordinator of the Network ('Coordinator'). ERN TransplantChild has a clear governance and coordination structure. Hospital Universitatio La Paz is the coordinator centre of ERN TransplantChild and Dr. Paloma Jara Vega was chosen from among the health professionals to represent the ERN. Dr. Jara will support and facilitate the internal coordination within the Network and with other healthcare providers.

ERN TransplantChild is governed by a Board of the Network composed of representatives from each Member in the Network. The Board is in charge of producing and adopting the rules of procedure, work plans and progress reports and any other documents related to the activities of the Network. Dr. Jara will ensure the dissemination of adopted rules and documents within the Network.

Dr. Jara participates in the ERN Coordinators Group (ERN-CG). The ERN-CG brings together the Coordinators of the ERNs approved by the ERN Board of Member States. The ERN-CG focuses its activities on strategic issues relevant to the ERNs implementation, functioning and governance and shall ensure the consistency and efficiency of the ERNs' actions, in particular with regard to those issues which are common to all ERNs. When needed, it may also provide advice to the European Commission and the Member States in matters related to the ERNs.

ERN TransplantChild consists of 18 members and 9 affiliated Partners. The hospitals which are part of the network come from 20 countries.

Below you can find the table presenting each member:

Country	**City**	**Name of Healthcare Provider**	**Representative**	**Specific Role in ERN**
Spain	Madrid	La Paz University Hospital	Dr .Paloma Jara	Coordinator (IT coordinator role)
France	Paris	Necker Hospital- Enfants malades	Pr. Christophe Chardot	Member
France	Paris	Bicêtre Hospital- Paris	Dr. Sophie Branchereau	Member
Germany	Hannover	Hannover Medical School	Dr. Ulrich Baumann	Member
Italy	Palermo	ISMETT, University of Pittsburgh Medical Center Italy	Dr. Marco Sciveres	Member
Italy	Bergamo	Ospedale Papa Giovanni XXIII	Dr. Lorenzo D´Antiga	Member
Italy	Rome	Ospedale Pediátrico Bambino Gesù	Dr. Manila Candusso	Member
Lithuania	Vilnius	Vilnius University Hospital Santariskiu Klinikos	Dr. Virgilius Tarutis	Member
Netherlands	Utrecht	Wilhelmina Children´s Hospital (part of UMC Utrecht)	Dr. Caroline Lindemans	Member
Poland	Varsow	Children´s Memorial Health Varsovia	Dr. Pior Kalicinski	Member
Portugal	Porto	Centro Hospitalar do Porto	Dr. Conceicao Mota	Member
Portugal	Lisbon	Hospital Santa Maria. Centro Hospital Lisboa Norte	Dr. Rosario Stone	Member
Sweden	Malmö	Children's Hospital, Skåne University Hospital	Dr. Jacek Toporski	Member
Sweden	Stockholm	Karolinska University Hospital	Dr. Lars Wennberg	Member
United Kingdom	London	King´s college KCH Trust	Dr. Emer Fitzpatrick	Member
Italy	Padova	Azienda Ospedaliera di Padova	Dr. Giorgio Perilongo	Member
Belgium	Brussels	Cliniques universitaires St Luc (BruxellesUniversité catholique de Louvain	Dr. Catherine de Magnée	Member
Denmark	Odense	Odense University Hospital	Martin Tepel	Affiliated Partner
Malta	Msida	Mater Dei Hospital	James Clark	Affiliated Partner
Estonia	Tartu	Tartu University Hospital	Inga Vainumäe	Affiliated Partner

Hungary	Budapest	Semmelweis University, Institute of Genomic Medicine & RD	Judit Molnár Mária	Affiliated Partner
Croatia	Zagreb	University Hospital Centre Zagreb	Daniel Dilber	Affiliated Partner
Denmark	Copenhagen	Rigshospitalet	Finn Gustafsson	Affiliated Partner
Luxembourg	Luxembourg	Centre Hospitalier du Luxembour	Martina Gdergen	Affiliated Partner
Latvia	Riga	Children´s Clinical University Hospital	Ivars Vegeris	Affiliated Partner
Austria	Vienna	Medical University of Vienna	Edith Nachbour	Affiliated Partner

The organisational structure and decision making mechanisms of ERN TransplantChild will fulfill the specific objectives:

- To improve patient healthcare. Ensuring equity, transparency and coordination at local, regional and European level in order to allow the patient and family access to the best and continuous care throughout the network by using mechanisms of coordination and communication. Through e-learning material and implementation of specific dataset for paediatric transplanted patients

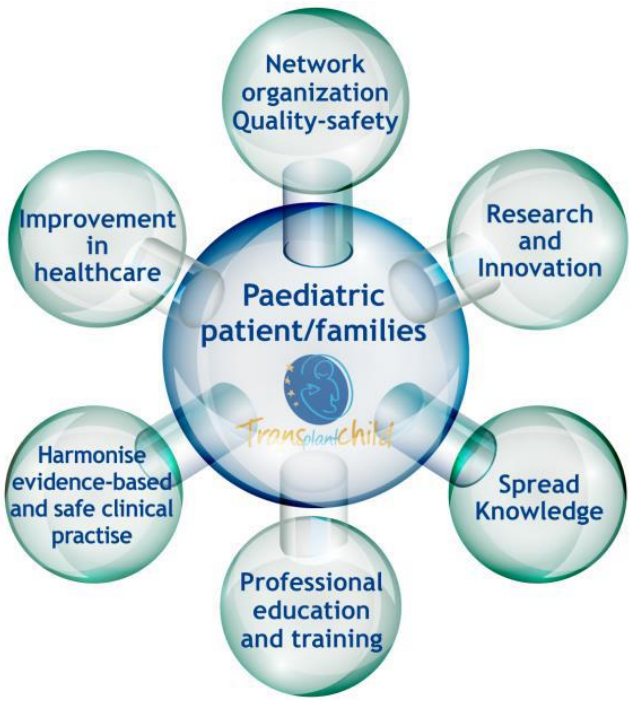
- To harmonise clinical best practices. Discussing new evidence-based treatments, therapies, and healthcare technologies and standardising the different alternatives, therapeutic options and best practices for the whole transplant process (prevention, diagnostic and surgical techniques as well as treatments).

- To harmonise research and innovation. Identifying, aligning and prioritising 13 research area gaps focused on facilitating continuous improvement transplanted patient care and health outcomes. Research will be improve through exploitation of data sets.

- Spread knowledge. Exchanging and disseminating knowledge and best practices within and outside the network and closely collaborating with other Centres and Networks at both national and international level. E-learning material will spread knowledge to different stakeholders. It will be flexible and update.

- Education and training. Identifying and fulfilling educational, training, and professional development gaps in PT, promoting the use of standardised continuous education training programmes and tools for providing education and training to healthcare and non-healthcare professionals involved in transplantation at different healthcare levels. This is the main aim of e-learning material that will be developed in this Action.

- Network organisation, quality and safety. Facilitating the development of effective organisational structures and defining the mechanisms needed for planning-monitoring and reviewing their strategic approach and operating rules in order to achieve the established objectives.



Strategic areas in ERN TransplantCHild

A systematic for Strategic areas deployment are included in the organisational structure of ERN TransplantChild. This systematic is aimed at defining the required concrete and concise activities, obtaining reliable information about their progress and facilitating their monitoring and control by the Board of the Network (BoN).

Activities and action in this proposal has been follow the **organisational structure of ERN TransplantChild**:

Board of the Network (BoN)

The Board of the ERN TransplantChild keeps the overall responsibility for the Network governance and decision-making. It is chaired by the coordinator of the Network selected by the coordinating centre. The BoN is composed by the coordinator of the Network appointed in the coordinating member (chairperson), one representative of each of the members of ERN TransplantChild, one representative of patients' organisations, one representative of each Committee that integrates the Network structure: (EOC, Healthcare Committee and the Ethics and Transparency Committee), one representative of Affiliated and Collaborative centres, one representative of the Network stakeholders (except industry).

Coordinator of the Network

The Coordinator of the Network has been appointed by its coordinating Member, La Paz University Hospital. He is the chair of the BoN and is in charge of: supporting and facilitating the coordination within all the members of the Network and with other Healthcare providers; Representing the Network at the EC and whenever required; Promoting and facilitating the expansion of the Network when necessary; Presenting the strategic approach of the Network and the related Multiannual Work Plan and Annual Work Plan to the BoN; presenting the Action Plans set up by every WG to the BoN and their status; Amending the Board Terms when required; Updating the BoN with information about the status and results of the Network.

Healthcare representatives

Each Healthcare provider member of the ERN TransplantChild has appointed a Healthcare representative who shall attend BoN meetings. Healthcare representatives should have a wide experience in the area of expertise of the Network, and they have the capacity to decide and act in the name of the Healthcare provider they represent.

Representative of patients' organisations

The representative of patients' organisations act as a full member of the BoN in order to: report information and relevant results from the Patients Subcommittee; Provide the point of view and information of patients and their families; Provide advice on planning, assessment and evaluation of the ERN; Identify and recommend expert centres and other healthcare professionals that should join the ERN, either as a full member or an affiliated partner; Establish relations with relevant disease-specific patient organisations when necessary.

Executive Operating Committee

The EOC is composed by a multidisciplinary team from the Coordinating member with wide experience in SOT & HSCT. The EOC supports the Coordinator and the Board of the ERN TransplantChild in the achievement of the Network objectives by promoting the development of a consistent and cross-cutting management approach of PT.

Healthcare Committee

The Healthcare Committee is composed by a multidisciplinary team of members from the Network HCPs. Members of the Healthcare Committee are allocated by the BoN taking into consideration their experience, expertise and knowledge on the specific topics to be addressed. The Healthcare Committee is the contact point of the Network for any patient through their Healthcare professional at national, regional or local level.

The Healthcare Committee coordinates three Advisory Groups: Pre-Transplant, Transplant and Post- Transplant. These Advisory Groups provide highly specialised support and advice at national, regional and local level for the development of accurate and specific comprehensive care plans for the patients and their families. The Advisory Groups are also composed by a multidisciplinary multidisciplinary team of members allocated by the BoN bearing in mind their related experience, expertise and knowledge.

Ethics and Transparency Committee

The Ethics and Transparency Committee is composed by a multidisciplinary team from the Network HCPs., one patient's representative and one stakeholder´s representative (not industry). Members of the Ethics and Transparency Committee are allocated by the BoN taking into consideration their experience, expertise and knowledge on the topics to be addressed.

Patients Subcommittee

The Patients Subcommittee is composed by a selection of representatives from different patient's organisations. It is coordinated by one member of the EOC in order to ensure consistency in the development of the Network. All patients´organisations are invited to participate and become members of the Patients Subcommittee.

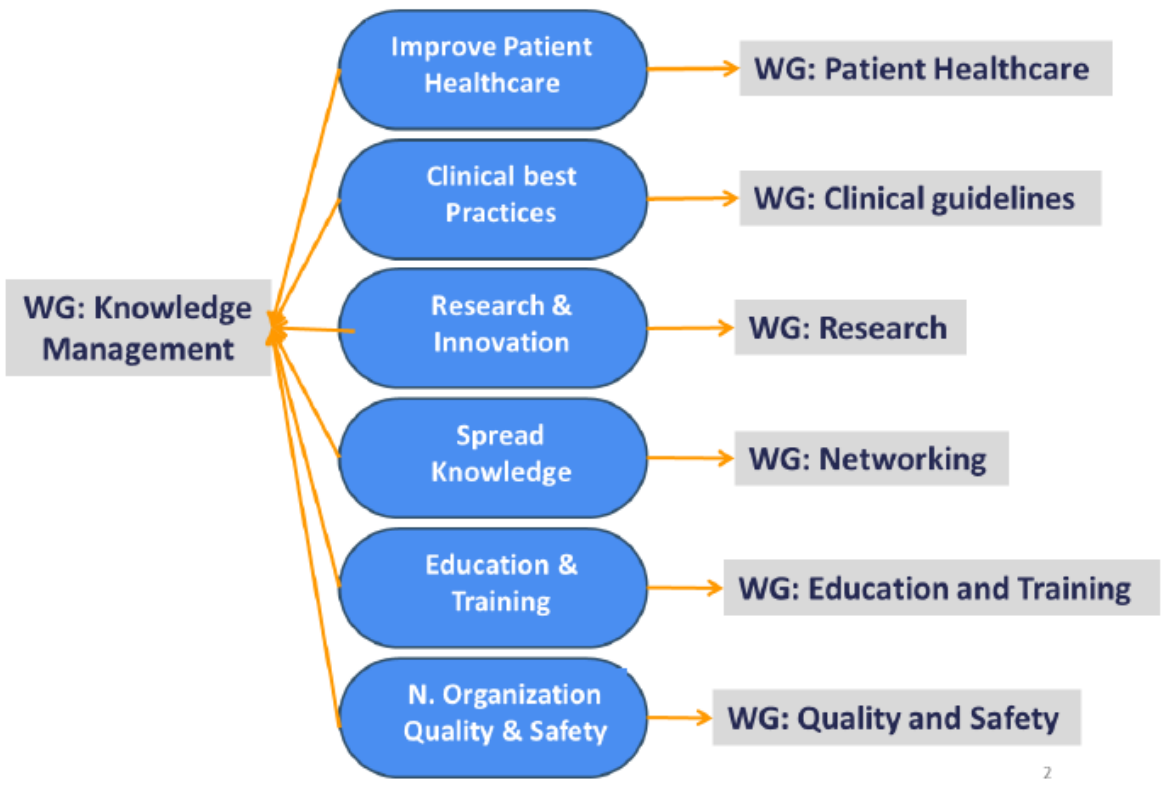
Affiliated/Collaborative Partners Subcommittee

The Affiliated/Collaborative Partners Subcommittee is led and chaired by one member of the EOC and it is composed by one representative of each Affiliated/Collaborative Partner. Affiliated/Collaborative Partners representatives have both the capacity to decide and act in the name of the Centre they represent and have a wide experience in the area of expertise of the Network.

Working Groups

WGs are led by a Technical Director allocated by the BoN taking into consideration their experience, knowledge and expertise on the related topic. WG are also coordinated by one member of the EOC in order to ensure consistency in the development of the Network. WG are members of the HCPs, Committees and Subcommittees of the Network,

patient´s representatives and stakeholder´s representatives allocated by the BoN depending on the topic to be addressed. the working groups are constituted according to the objectives of the network as indicated below:



2.4. Conclusions on results of the Action, including the impact of the possible deviation on 1) the objectives of the action, 2) the completion of the planned activities and 3) the cost-breakdown

The action has produced diverse results from which a series of conclusions can be drawn. Since the beginning of the action, different objectives focused on the main three goals of this Action.

The first objective of the Action was to work on the establishment of a sound dataset of clinical data taking into account the experience learnt during the previous years with the CPMS and the importance of having the definitions of this data set to make compatible with the collection system develop in the future, baseline for future research activities and quality of patient improvement plans. This objective was covered during the foreseen timeline with no deviations except for the delay of the DG SANTE in the modification of the specific datasets in the CPMS, which depend an external company and the provisions for a change in the provider in a near future. Nevertheless, we have made all the definitions and activities with the compliance of FAIRification criteria in order to make it interoperable with CPMS and eventual registries of other ERNs.

The second main objective was the set up and creation of an education and training took that allowed us to include all the material we had created in previous years and the new material produced during the Action targeting both professionals (medical doctors and nurses) and patients and their family. In May 2020 ERN TransplantChild was going to hold the 2nd Workshop on Paediatric Transplantation in Warsaw, where most of the content for professionals were going to be produced. Unfortunately, due to the Covid-19 outbreak, the workshop was postponed until November 2020 in an on-line edition. This situation caused the delay in the production of the educational material. Even on the 28th of February we had most of the content ready and uploaded in the Moodle tool, we did not had data for monitoring the

access to the course. Thanks to the extension of the Action we have been able to have some more data about the use of the tool and courses. We have carried on with the production of webinars during the last months and made available through the Moodle tool.

The third objective was to keep on giving support to the members and affiliated partners on the IT core system and update any material. We have been carrying this out during the Action.

The dissemination of the content of the Moodle platform is something in which we have been working since the beginning of the Action. We shared the different webinars and the launch of the Moodle platform using dedicated communications and newsletters.

Finally, as a transversal activity we have been monitoring the development of the Action' activities. As said before we count on a dedicated tool for produce accountability by project.

Final conclusions

In conclusion, the implementation of the action has been generally successful since the objectives have been achieved within the extension timeline. It is considered that the knowledge of a complete data set applicable to the collection tool and the inclusion of the patient reported outcomes within the data to better provide care to patients has been a great achievement. On the other hand, the selection of the training tool has been a success too, but also the production of extra material.

Budget completion

These are the main concepts for the Action:

1. Personnel
    - New staff has been dedicated to the different activities within the Action:
        - Belén López Álvarez
        - Gonzalo Sofío Toro
        - Laura Pruneda González
        - Marisa Tejedor
    - Professionals of the hospital has been dedicated to the activities.
        - Dr Esteban Frauca: Medical doctor specialist in paediatric hepathology; member of the Executive Operating Committee at ERN TransplantChild and Coordinator of the Healthcare Working Group.
            - Activity 1: directions for developing the work on this activity. Analyse the existing data sets for different paediatric transplant registries (dedicated to only one program) and selection of the key one as common to all types of transplants.
            - Activity 2: contributed to the production of training material and thematic areas.
        - Dr Francisco Hernández: Head of surgical paediatric transplantation section; member of the Executive Operating Committee at ERN TransplantChild and Coordinator of the Education and Training Working Group.
            - Activity 1: participation as surgeon in the definition and agreement of the most suitable data set of all professionals.
            - Activity 2: definition, together with the coordinator of the Research and Innovation WG, of the contents and plan for training and education. Analysis of the results obtained from the survey to identify the gaps.

- Dr. José Jonay Ojeda: Medical doctor specialist in preventive medicine and head of the Quality Department; member of the Executive Operating Committee at ERN TransplantChild and Coordinator of the Quality and Safety Working Group.
    - Activity 1: contribution to the definition of the dataset and added value of the inputs about confidentiality agreements, Ethics Committee approval and other aspects to take into account regarding the security and quality of the data.
    - Activity 2: contribution to the evaluation plan for training activities
- Mr Mª Jesús Pascau: head of Nurses specialist in paediatric transplantation; member of the Executive Operating Committee at ERN TransplantChild and Coordinator of the Nurses Team.
    - Activity 2: participation on the definition and agreement on the topics of the workshop. And also the development and monitoring of the training content for patients.
- Dr Esther Ramos: paediatric gastroenterologist
    - Activity 1: collaboration in the definition of the data set from the gastroenterologist point of view.
- Dr Gema: paediatric hepatologist
    - Activity 1: collaboration in the definition of the data set from the hepatologist point of view.

2. Subcontracting: design and development of training material for Moodle tool
3. Other goods and services:
    - Webserver acquisition, installation, hosting, and maintenance
    - Modular Manager system software license
    - Multimedia recording tools for e-learning material production
    - Translations, local adaptations and dissemination activities
    - Travels of personnel to training activity about the implementation of FAIRification criteria. Travel expenses of speakers authors of the training material to Warsaw (the cost of most flights was returned for cancellation)

3. VISIBILITY OF UNION FUNDING

What measures have been taken to publicize the Action, including EU funding (GA II.7.1)?

As in the rest of the network activities, the dissemination and dissemination of the results is an important part, in the same way importance has been given to publicizing this action being one of the key and fundamental activities of the network, recognizing also the source of EU funding. For this purpose, different dissemination tools have been used such as the web page, the ECP collaborative tool, social networks, etc.

During the development of the activity, different documents and materials have been generated, in all of them the official logo of the ERN and the logo of the co-financing agency CEF appear. This is intended to reflect the organization and the source of funding who have developed the document. Especially on those focused on the dissemination of the objectives of the action to healthcare professionals and patients and families like the informative brochures and the promotional videos. Moreover, all the activity carried out through the CEF call has been published on the ERN TransplantChild website so that users and members of the network were aware of the source of funding for the different activities of the network.

In order to publicize the different activities of the action, there is a monthly Newsletter in which, the helpdesk activities were described together with other network activities and news. The newsletter has a global reach, in it the members of the network, families and patients, members of other networks and other professionals interested in the work of the ERNs are subscribed. Especially those activities with the greatest impact such as training visits to centres and CPMS workshops have been published.

Social networks have also been used to promote the action and the funding source, in particular Twitter is a tool widely used by medical professionals in which news or work opinions are transmitted. TransplantChild has been using this social network incrementally to make different communications and to show the activity of the network. The action and the different activities carried out in it have also been disseminated through this medium, especially the local training visits in the member hospitals, the CPMS workshops and some of the results obtained throughout the period.

A special space has also been dedicated to the activities carried out by the action in all the member meetings, promoting the awareness of the EU funding in this action

4. OTHER SOURCES OF EUROPEAN UNION FUNDS

If applicable, provide information about other sources of EU funds (CEF, ERDF, Cohesion Fund, H2020, TEN, EEPR, EIPA, etc.) used for the action (including previous or subsequent phases not covered by the Grant Agreement).
N/ A

5. COMPLIANCE WITH EU LEGISLATION

Where relevant, provide information on the compliance with EU legislation regarding other matters (notably public procurement, competition, regulatory matters, etc…).

The action has fully comply with the EU policies such as The General Data Protection Regulation (EU) 2016/679 on the protection of personal data (GDPR), which has modernised and overhauled the legal framework for privacy and the protection of personal data across the EU. The action has been committed to protect patient privacy by ensuring the rights of the data subject and complying with the principles of the regulation.

First, it was ensured that platform users were aware of the responsibility and restrictions with the use of personal data. User accounts for EU tools were created through the EU Login in which some conditions of use must be accepted. Especially, for the CPMS platform where personal and sensitive data is managed, it has been necessary to implement special measures to ensure compliance with the policies of the EU and each country member of the ERN TransplantChild.

An informed consent approval process has been initiated in each of the centres, the Standardized Consent Forms must be reviewed by ethical and legal professionals of each hospital to ensure that they comply with local requirements before participating in the collection of data. For this purpose, different documents generated by European working group of ERNs have been disseminated as Good-practices of the informed consent, compliance with interoperability requirements Data hosting and multi-level role-based Access.

Access to CPMS has an extra security method for greater information protection and to avoid possible gaps. This consists of a second verification method using the user's mobile phone so that to access the system it was necessary to have the mobile phone previously registered to the account other than the usual username and password. Additionally, when patients are enrolled in the CPMS system, the treating doctor must accept their responsibilities regarding the protection of patient data. Also, when uploading any type of medical documents in a consultation panel the expert should confirm that no personal data is visible in the documents. In this way, the protection of the patient's personal data is guaranteed at all times, protecting their rights.

The PETER Registration System access is secured via user identification with an expiring password and with certain obligatory characteristics such as the use of capital letters, numbers and special symbols. Moreover the user creation process is not available to the public and it must be mediated through the Technical Secretariat of ERN TransplantChild. Each user is given a role which limits the access to certain write/read rights to the platform.

Similarly to the PETER registry, the e-learning platform has private courses to which user identification with password is needed and those which are intentionally available are accessible directly. Nonetheless all the tracking information for both identified and guest users and failed attempts to login are stored in a log. Also the registering process of users is made through the Technical Secretariat. Currently pre-made Moodle user roles are being used in junction with custom defined user roles that limit the available tools present in the platform for the different type of user that make use of the platform.

Moreover, the work activities underlying in this action have fulfilled obligations and obeyed the rules set up by:

- Directive 2011/24/EU on the application of patients' rights in cross-border healthcare
- Commission implementing decision of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

- Commission delegated decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (2014/286/EU)
- National plan and strategies to support rare disease patients (adopted by MS as recommended in 2009 by European Council of Health Ministers)

6. COMPLIANCE WITH CORE PLATFORM AND POLICY OBJECTIVES

Information on the compliance with the core service, including conformity with relevant technical specifications and alignment with the policy objectives of the Digital Service Infrastructure (as specified in the relevant CEF Telecom Work Programme).

The Commission delegated decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (2014/286/EU) clarifies that further horizontal and structural criteria and conditions related to the exchange of expertise, information systems and eHealth tools should help developing, sharing and spreading information and knowledge and fostering improvements in the diagnosis and treatment of diseases within and outside the Networks and to collaborate closely with other centres of expertise and networks at national and international level. Interoperable and semantically compatible information and communication technology (ICT) systems would facilitate the exchange of health data and patients' information, and the establishment and maintenance of shared databases and registries.

To enable and facilitate this cooperation European Commission together with European Reference Networks set up the eHealth Digital Service Infrastructure for European Reference Networks. With support of funds from Connecting Europe Facility Work Programme 2015, DG SANTE developed two IT systems necessary for ERN proper cooperation. Those systems are the: ERN Collaborative Platform and Clinical Patient Management System. At this stage of development of the ERN we have included more platform to reach the objectives of sharing knowledge for improving the quality of life of patients. We have defined the data set and the tool for collecting this data in an interoperable way with the CPMS.

ERN TransplantChild has complied with the Integration systems for specific dataset, e-learning and support of ERN Core Services in the ERN TransplantChild in which the action has focused on achieving the objectives defined in the Digital Service Infrastructure. The activities developed aim at promote and facilitate the data set elements and in the other hand provide a friendly tool for e-Leaning targeting professionals but also patients and their families.

The action has been focused on ensuring the adequate definition of data set and collecting tool, especially favouring the application of the requirements for interoperability and FAIRification. Secondly, we have focused on the selection of the most suitable tool for hosting the e-learning material and developing useful content for professionals (medical doctors and nurses) but also for the patients and their families.

ANNEX: Financial statement