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PaEdiatric Transplantation European Registry

JA2015 - GPSD [705038]

START DATE: 01/07/2020

END DATE: 30/06/2023

DURATION: 36 month(s)

CURRENT STATUS: Ongoing

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

PROGRAMME PRIORITY: -

CALL: Call for Proposals for Projects 2019

TOPIC: Rare disease registries for the European Reference Networks (Heading 2.1 of the AWP 2019)

EC CONTRIBUTION: 399962.84 EUR

KEYWORDS: European Registry Platform, Haematopoietic Stem Cell Transplantation, Interoperability, Paediatric Transplantation, Patient'S Reported Experiences, Patient'S Reported Outcomes, Registries, Solid Organ

Project abstract

Paediatric transplantation has dramatically changed the life expectancy of many children by providing treatment for organ failure who would otherwise have not survived. European Reference Networks (ERN) for rare diseases should serve as research and knowledge centres, updating and contributing to the latest scientific findings, treating patients from Member States and ensuring the availability of subsequent treatment facilities where necessary. ERN TransplantChild is focussed on both paediatric Solid Organ Transplantation (SOT) and Hematopoietic Stem Cell Transplantation (HSCT). Both SOT and HSCT are low-prevalence and complex conditions that require highly specialised expertise and resources. Current approaches are insufficient to fully address long-term graft and patient survival while providing the best possible QoL. The overall objective of the project is to create PETER, a new rational, efficient, interoperable, open, accessible paediatric transplant registry for all type of paediatric transplantation that allows generating real-world evidence monitoring by the identification of common outcomes for all types of transplant, and which can be used as a model to support care and research for the benefit of patients, improvement of the transplanted patient healthcare, their life expectancy and long-term quality of life of children and their families. Peter will lean on an interoperable technology platform with a module of business intelligence that will allow it to be a predictive registry directly impacting on the (a) process of patient care, improving the process of personalised clinical decision-making in the healthcare systems. PETER shall be built with the support and according to the standards set up by the European Platform on Rare Diseases Registration (EU RD Platform).

Work package

Work Package 1: Management of the project and coordination activities

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

T1.1 Administration and management of the Consortium (SERMAS- HULP, M1-M36)
T1.2 Technical Coordination (SERMAS- HULP, M2-M36)
T1.3 Risk Management (SERMAS- HULP, M1-M36)
T1.4 Quality Assurance (IPCZD-CMHI, M2-M36)
T1.5 Ethical standards / Informed Consent / Data Protection (IPCZD-CMHI, M2-M36)
T1.6 Sustainability and financing plan (SERMAS- HULP, M1-M36)
T1.7 Development and implementation Plan (SERMAS- HULP, M1-M36)

Work Package 2: Dissemination and communication activities

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

T2.1 Planning outreach and dissemination activities (AOP, M1)
T2.2 Design a portal-web project (AOP, M3)
T2.3 Training activities (AOP, M2-M23)
T2.4 Monitoring of the Communication Plan (AOP, M2-M36)

Work Package 3: Evaluation of the project's output and impact

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

T3.1 Definition of the validation and evaluation plan (SLL-KI, M0-M12)
T3.2Implementation risk, quality and follow up' monitoring (SLL-KI, M12-M36)

Work Package 4: Methodological and analytical clinical

outcomes for registry development

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

Requirements Analysis (M0-M6)
T4.1 1Existing registries review and the state of the art including Interoperability requirements (SERMAS-HULP, M3-M6)
T4.2 Stakeholder analysis, elicit expert opinion & create advisory board (SERMAS-HULP, M3-M6)
T4.3 Map of Functional Requirements and Technical Design (SERMAS-HULP, M3-M6)
Technical Design (M6-M12)
T4.4 Review Current state of the art & Interoperability requirements (SERMAS-HULP, M6-M12)
T4.5 External and internal sources of information (SERMAS-HULP, M6-M12)
Prototype Testing and Validation (M12-M23)
T4.6 Test and validation plan (SERMAS-HULP, M12-M18)
Development (M12-M23)
T4.7 Registry Development and release (SERMAS-HULP, M12-M23)
T4.8 Business Intelligence component (SERMAS-HULP, M12-M23)

Work Package 5: Patients/Families outcomes. Legal and ethical issues.

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

T5.1 Legal & Confidentiality Aspects on PROMs and PREMs (IPCZD-CMHI, M2-M8)
T5.2 Definition of patient's reported outcomes (PROMs) and patient's reported experiences measures (PREMs). (SERMAS-HULP, M1-M6)
T5.3 Pilot PROMs and PREMs: specific sites and populations. (SLL-KI, M12-M24)
T5.4 Validation of PROMs and PREMs in the paediatric transplanted patient. (SERMAS-HULP, M24-M36)
T5.5 Definition of education and training plan. (SERMAS-HULP, M12-M23)
T5.6 Health Outcomes Analysis (SERMAS-HULP, M24-M36)

Work Package 6: Registry Quality Assurance and monitoring

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

T6.1 Data Considerations: Quality, Information types, and Dimensions. (IPCZD-

CMHI, M2-M12)
T6.2 Audit & Quality Assurance plan. (IPCZD-CMHI, M2-M12)
T6.3 Evaluation and Improvement of Registry Service. (IPCZD-CMHI, M12-M23)
T6.4 Analysis of the overall results. (IPCZD-CMHI, M23-M36)

COORDINATOR, LEADER CONTACT AND PARTNERS

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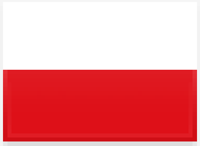

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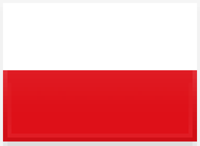

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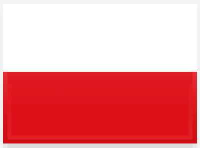

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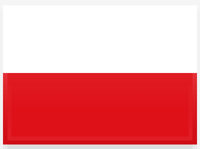

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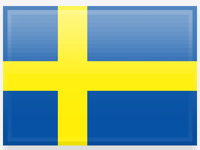

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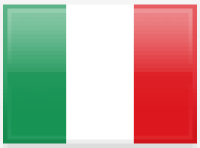

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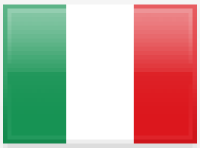

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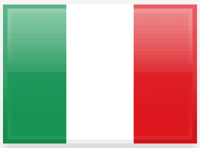

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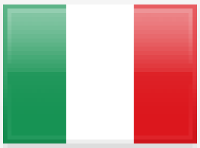

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OUTPUTS

Layman version of the final report

SERMAS
PaEdiatric Transplantation European Registry (PETER)
Expected on: 30/06/2023
This is a short (e.g. 10 pages) version of the final report, written for the interested public as target group.

Monitoring and evaluation plan

SLL
PaEdiatric Transplantation European Registry (PETER)
Expected on: 30/06/2021
This document describes the methodology for the evaluation of the project

Specifications and Validation Plan

SERMAS
PaEdiatric Transplantation European Registry (PETER)
Expected on: 30/06/2022
Document which contains the prioritisedprioritized objectives and requirements of the registry and validation and evaluation plan

PROMs and PREMs Implementation and evaluation plan

SERMAS
PaEdiatric Transplantation European Registry (PETER)
Expected on: 31/07/2021
Document containing how an organisation should be prepared, structural characteristics and type of service. Preparing the staff through training programmes. (Confidential document: subject to publication

Education and training plan

SERMAS
PaEdiatric Transplantation European Registry (PETER)
Expected on: 31/05/2022
Document containing training programmes for healthcare staff to familiarise

with PROMs and PREMs and how to use the data in their clinical practice (Confidentia document: subject to publication)

Leaflet of action

AOUP
PaEdiatric Transplantation European Registry (PETER)
Expected on: 31/08/2020
A leaflet to promote the project will be produced at the beginning, after kick off meeting.

Business and operational Plan

SERMAS
PaEdiatric Transplantation European Registry (PETER)
Expected on: 30/06/2023
Business model and operational plan document

Quality Data assurance Plan

IPCZD
PaEdiatric Transplantation European Registry (PETER)
Published on: 25/04/2022
In accordance with Project Management Guidelines, Quality Plan includes all aspect to assure quality of the registry and the processes and procedures related to it. Some relevant aspects are quality of data, ethical standards, Informed Consent and data protection issues.

Website of the action

AOUP
PaEdiatric Transplantation European Registry (PETER)
Published on: 25/04/2022
PETER project webpage which will be posted from ERN TransplantChild website (https://www.transplantchild.eu/en/

Report on the state-of-the-art, existing registries and requirements analysis

SERMAS
PaEdiatric Transplantation European Registry (PETER)
Published on: 11/04/2022

Document which includes the information collected information during the analysis of situation. It includes information about the problem domain and the current system, review of existing registries and the state of the art, stakeholder analysis, expert opinions, and functional, information and technical ological requirements.