European Reference Network
for rare or low prevalence complex diseases

Network Paediatric Cancer (ERN PaedCan)

Evaluation and Quality Assurance Plan (E&QP)

Final Submission
06.2023

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1 Introduction

This Evaluation and Quality Assurance Plan (E&QP) outlines the evaluation (EV), quality control (QC), quality assurance (QA) and continuous process improvement for the project to provide a foundation on which the project milestones will be built to meet the expectations and needs of the project. The E&QP presents the various roles and responsibilities of the team in managing the project's quality processes and ensuring they are implemented, evaluated, and followed. In addition, the E&QP lists the quality planning tools and evaluation techniques to be used on the project and the process for ensuring the project adheres to the required standards and controls, issue tracking, risk management, reporting and amendment control procedures. The E&QP refers to the contractual project documentations which outlines all rights and duties, commitments and agreed work plan to which all partners are legally bound. The E&QP mentions and provides guidance for all documents, deliverables, milestones and other work products that support the ERN PaedCan´s implementation methodology.

1.1 Overview

Below, the ERN PaedCan Organisational Structure and the Management of the network are outlined and all relevant stakeholders and their role described. Description of roles is relevant for all network members and ensures a successful project implementation. Section, 2.3 and 2.4 outlines tasks and responsibilities of the bodies and the different management types of the network. In Chapter 3, Quality objectives important for implementation and evaluation are stated. In the second half of the document project dissemination, organisations of meetings and communication tools and strategies within the network are illustrated. Finally, the projects´ contractual rules and financial aspects are outlined and the reporting methods described.

1.2 Purpose & Scope

The major purpose of the E&QP is to provide a broad overall framework and guideline for implementing quality management and to ensure the quality of the proposed activities and reach and evaluate the desired impact of the European Reference Network for Paediatric Cancer (ERN PaedCan). The audience of this plan is the ERN PaedCan General Assembly including all ERN PaedCan members and the respective steering structures (Figure 3).

The structure and approach to ensure a successful implementation of ERN PaedCan implies:

1.2.1 Quality Assurance Cycle in ERN PaedCan

The quality assurance and evaluation in the ERN PaedCan as outlined below is based on the four pillars: planning, implementation, evaluation and review. All of the four pillars are embedded in the overall structure.

Planning: Annex I of the Specific Grant Agreement provides a detailed work plan and management structure to be followed. Any necessary changes of this plan will require a sequence of procedures already anticipated. In the planning phase, specific, measurable, achievable, realistic and time bound deliverables and objectives were stated and the human resources necessary for delivering the objectives outlined.

Implementation: Establish procedures to ensure that appropriate methodologies, standards, procedures, and guidelines are implemented. The ERN PaedCan members must be made aware of their importance and trained in their use.

Evaluation: Ensure that quality is measured, monitored and defects identified, along with performing appropriate corrective actions. To implement this procedure, a series of Quality Control Indicators and mechanisms for the evaluation of achievements will be described further in this document (for details see Section "Quality Indicators").

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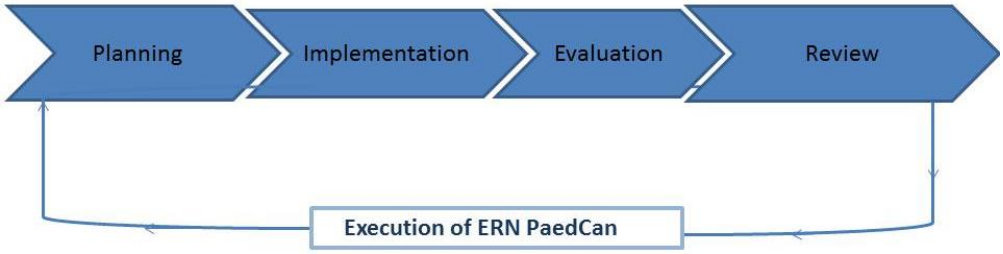
Review: Procedures will be developed and outlined below that assure the feedback is implemented appropriately and procedures for change achieved. Ultimately, the E&QP will ensure that identified faults are rectified, and that the chance of recurrence is minimized.

Figure 1: Quality Assurance Cycle



1.2.2 Quality Indicators

Quality indicators are fundamental quantifiable outputs that allow the assessment of the project performance. After each reporting period, self-evaluation will be carried out to acquire the current project output and increase if necessary quality and outputs.

Quality indicators to address the performance of the project per activity type are:

- Percentage of Milestones achieved per reporting period
- Percentage of Deliverables achieved per reporting period
- Average delay of Milestones per reporting period
- Average delay of Deliverables per reporting period per work
- Number of European Standard Clinical Practice documents developes
- Numbers of successful internal meetings per reporting period
- Number of European and International meetings delivered per reporting period
- Number of dissemination and communication activities
- Number of dissemination documents and material
- Monitor website (web analytics indicators, search engine optimization, etc., monitoring internal and external use with geographical breakdown …)

The following self-evaluation process will be followed:

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Figure 2: Self-evaluation process based on Quality Indicators in ERN PaedCan

1.2.3 References

For drafting this plan, the following documents were taken into account:

- ERN PaedCan Work Plan (Annex 1 of the Grant Agreement)
- ERN PaedCan Deliverables and Milestones
- EU Quality assurance in vocational and educational training retrieved at: http://www.eqavet.eu/qa/gns/home.aspx

2 Management

2.1 Organisational Structure

The objective of this management structure is to show an effective and transparent body for any action undertaken within the project's lifetime on behalf of a/o with the consortium. The structure will allow taking rapid and efficient decisions as needed to avoid a blocking situation. Information to the wider community about project execution, planned actions and enhancement will be transmitted to respective stakeholders.

The chosen structure will:

- Ensure that strategic decisions can be made and are aligned with the SIOPE Oversight Committee
- Allow a close collaboration on different levels and the integration of external collaborations via the Project Management Team
- Ensure the successful alignment with the Quality Assurance Cycle as described above.

All bodies included in the organisational structure are described in greater detail below.

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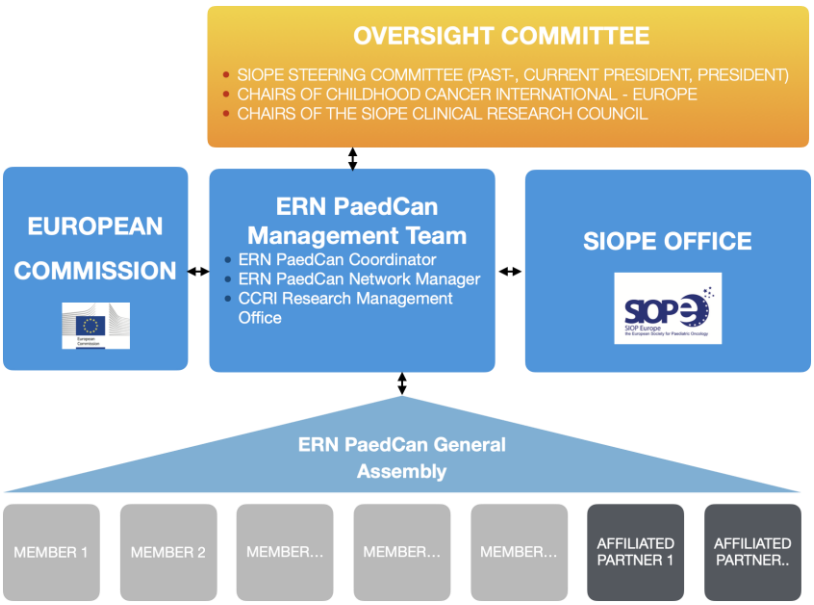
Figure 3: **Organisational structure of ERN PaedCan**



SIOPE= the European Society for Paediatric Oncology, SIOPE CRC = Clinical Research Council, SIOPE SC = SIOPE Steering Committee, CCI-E= Childhood Cancer International – Europe

2.2 Respective Roles

2.2.1 ERN PaedCan Coordinator

The ERN PaedCan Coordinator, Prof. Ruth Ladenstein, represents the legal entity Children´s Cancer Research Institute (CCRI) and is acting as the intermediary between the ERN PaedCan members, DG Santé and the Health and Digital Executive Agency (HaDEA) from the European Commission (EC).

The ERN PaedCan Coordinator will assure together with the Network Manager (NM) the responsibility of the technical, financial and administrative management of the project on a day-to-day basis, according to the contractual guidelines. In accordance with the HaDEA contract, CCRI will administer the Community contribution as allocated to contractors and for specific activities.

Roles:

- Management of administrative, contractual and financial aspects
- Organisation of inter-and intra-consortium communication and animation
- Organisation of reporting
- Management of dissemination and exploitation
- Resolving conflicts on technical, financial and strategic issues
- Chairing the General Assembly
- Monitoring compliance by the Parties with their obligations
- Keeping the address list of Members and other contact persons updated and available
- Providing, upon request, the Parties with official copies or originals of documents which are in the sole possession of the NMT when such copies or originals are necessary for the Parties to present claims
- To be advised by the SIOPE Oversight Committee
- Working closely with the SIOPE Office on specified special tasks
- Interacting with the EC and the ERN coordinators on a regular basis (WebEx conferences or face-to-face meetings, etc.)

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2.2.2 Network Manager and Research Management Office oft he CCRI

The Network Manager (NM) will be working closely with the ERN PaedCan community as required taking on the responsibility for the financial and administrative management on a day-to-day basis.

Roles:

- Creating the Quality Assurance Plan and Methodology together with the Project Coordinator in close collaboration with the SIOPE Oversight Committee to support the internal management requirements and expedited reporting and the follow-up on the project indicators (Gantt chart, manpower matrix, milestones list).
- Survey objectives implementation and completion of the project within the approved budget
- Management of the delivery and the follow-up of administrative and financial documents and monitoring cost performance to detect deviations from the plan
- Supporting the reporting through common templates adapted to the ERN PaedCan and send it to the sub-contractors for official reporting
- Notifying due dates and send out deadline reminders, assisting sub-contractors and partners to respect deadlines
- Support meeting organisation and notify the ERN PaedCan members of due dates
- Supporting the ERN PaedCan coordinator in interacting with the EC (DG Santé and HaDEA) and other ERN Coordinators and carry out all tasks as necessary

The NM will be supported by a very experienced in-house Research Support Office (RSO) in:

- Grant & Financial Management
- Administrative and Implementation Management

2.2.3 The European Society for Paediatric Oncology

The European Society for Paediatric Oncology (SIOP Europe or SIOPE) is the only pan-European organisation representing all professionals working in the field of childhood cancers. SIOPE connects healthcare providers across Europe and ensures to reduce the burden of cancer for all children and adolescence in Europe.

SIOPE currently has 2500 members from 35 countries in the European region; and is led by an elected president and Executive Board whose terms of office are described in the Society's Satutes.

2.2.3.1 SIOPE Presidency:

The current president is Prof Carmelo Rizzari (Professor of Paediatrics and Head of the Paediatric Haematology-Oncology Unit at the Department of Pediatrics of the University of Milano-Bicocca, MBBM Foundation, ASST Monza, Italy.) The President Elect is Prof Uta Dirksen from the University Hospital of Essen (Westdeutsches Tumorzentrum Essen (WTZ), Universitätsklinikum Essen)

Former presidents:

- Prof. Pamela Kearns (United Kingdom) from 2019 to 2021
- Prof. Martin Schrappe (Germany) from 2016 to 2018
- Prof. Gilles Vassal (France) from 2013 to 2015
- Prof. Ruth Ladenstein (Austria) from 2010 to 2012
- Prof. Kathy Pritchard Jones (United Kingdom) from 2008 to 2009
- Prof. Andrea Biondi (Italy) from 2006 to 2007

The current president, the president-elect and the last former president form the *SIOPE Steering Committee (SC).*

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Roles in ERN PaedCan: included in the SIOPE SC are members of the SIOPE Oversight Committee providing strategic advice and guidance to enable the NMT to achieve the stated objectives of the ERN PaedCAN.

2.2.3.2 SIOPE Office

The SIOPE office is headed by the Chief Executive Officer (CEO) and supports the SIOPE Board and the SIOPE General Assembly. The SIOPE office has extensive experience in facilitating collaboration among European professionals in the field of paediatric oncology, empowers SIOPE board members and facilitates relationships with key stakeholders and policy makers. The SIOPE office has a vast experience in dissemination & communication and has supported policy actions on behalf of the paediatric oncology community.

The SIOPE office is already strongly interlinked with all ERN PaedCan partners by its generic mission and hence has a crucial role by working closely with the NMT on special tasks as shown in the ERN PaedCan organizational structure. Skills in communication and delivery of dissemination tasks as well as event management for ERNPaedCan are based on an extensive underlying experience within high quality EU projects (ENCCA, ExPO-r-Net, JARC etc.). The SIOPE office is the central point supporting and delivering quality assurance measures for ERN PaedCan based on its ability to interact seamlessly with all ERN PaedCan stakeholders. The SIOPE Office will evaluate the quality of the network once a year in accordance with the Quality Assurance Cycle (described above).

2.2.3.3 SIOPE Board

The SIOPE Board provides strategic advice for the paediatric oncology community in Europe under the direction of the respective presidents and provides expert input on scientific policy and management issues. The chairs of SIOPE – CRC are an integral part of the SIOPE Board. Hence, SIOPE Board's may provide first-hand scientific and management advice to the ERN PaedCan NMT.

2.2.3.4 SIOPE Clinical Research Council for paediatric and adolescent oncology (SIOPE-CRC)

Having been initiated within the ENCCA project in 2011, the SIOPE- CRC represents today the paediatric oncology clinical research community across Europe and brings together existing paediatric oncology clinical trial groups and national Paediatric Haemato-Oncology societies. The SIOPE- CRC has a formal structure and CRC members are representatives of either European Clinical Trial Groups (ECTGs) or National Societies of Paediatric Oncology (NaPHOS). There is one chair representing the respective category (ECTGs and NaPHOS). The SIOPE-CRC is an executive decision-making body and expresses the unified voice of the paediatric oncology community. Chairs of the CRC are included in the Oversight Committee of the ERN PaedCan who also provide the Quality Assurance metrics. Individual council members will be invited to contribute to ERN PaedCan activities at a given time.
The SIOPE-CRC seeks the integration of the pre-existing major tumour and leukaemia therapeutic networks running clinical trials and consists of all their respective chairs or their nominated representative. The SIOPE-CRC was established to facilitate good research practice exchange among international co-operative groups. This Council integrates and represents local expertise and infrastructures, and needs and legal authority issues for clinical and translational research. Cross healthcare issues will be addressed by i) integration of pre-existing major European Paediatric Oncology tumour and leukaemia therapeutic networks running clinical trials by calling for the respective chairs or their nominated representative, ii) integration of knowledge across different cancer entities for higher translation of basic and preclinical research to clinical application, iii) inclusion of clinical trial centres for specific entities as pre-existing hubs for future tumour boards, iv)

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invitation of the chairs of the European national paediatric oncology societies (NaPHOS) to better integrate and represent local expertise and infrastructures, needs and legal authority issues for clinical and translational research and cross border health care issues at the national level.

Composition:

- Chairs of all European tumour and leukaemia trial networks
- Chairs of all European national paediatric oncology societies (NaPHOS)

Roles in ERN Paed Can: The Chairs of the CRC are part of the SIOPE Oversight Committee to ensure the involvement of the network in all paediatric oncology activities across Europe and to avoid duplication of efforts at the European level.

2.2.4 CCI Europe

CCI-Europe is the European branch of Childhood Cancer International (CCI); previously called the International Confederation of Childhood Cancer Parent Organizations (ICCCPO) presenting a global network of childhood cancer parents and survivors support groups. The CCI Europe Regional Committee (formerly PPAC - Parents and Patients Advocacy Committee) was created in 2012.

CCI Europe works closely with the medical and psychosocial professionals, researchers & scientists, civil society, private organizations and industry, aiming to help children and adolescents with cancer to be cured, with no – or as few as possible – long-term health problems / late effects.

CCI Europe is part of the Oversight Committee to represent the views of parents and survivors. As stakeholder community they will be involved in the evaluation of the network at regular intervals to ensure transparency. They will contribute to the dissemination actions and policy actions; support the implementation of standard of care and the visibility of respective care pathways ad well as guidelines in close collaboration with SIOPE. Besides information for parents and childhood cancer survivors will be improved in cooperation with CCI-E, including information on clinical trials and clinical research.

CCI Europe's integration process into PaedCan was ensured already from the beginning of the network. The structure is outlined in the image below and ensures interaction between the ERN PaedCan coordinator and the national contact points of patients' and parents' groups in Europe to support the special challenges arising from CBHC situations. A national contact point must not necessarily be a national umbrella organization but should be in regular contact and collaborate closely with other (regional) organizations in the respective country. One main aim of CCI Europe is to keep the community up to date on ERN PaedCan developments and achievements and to ensure spreading of this knowledge within their respective stakeholder community. CCI-Europe will provide its advocacy activities also to the ERN PaedCan and will try to represent the patients' and parents' voice as effectively as possible. CCI Europe will be a contact point for affected children and their families and will incessantly work on being as supportive as possible.

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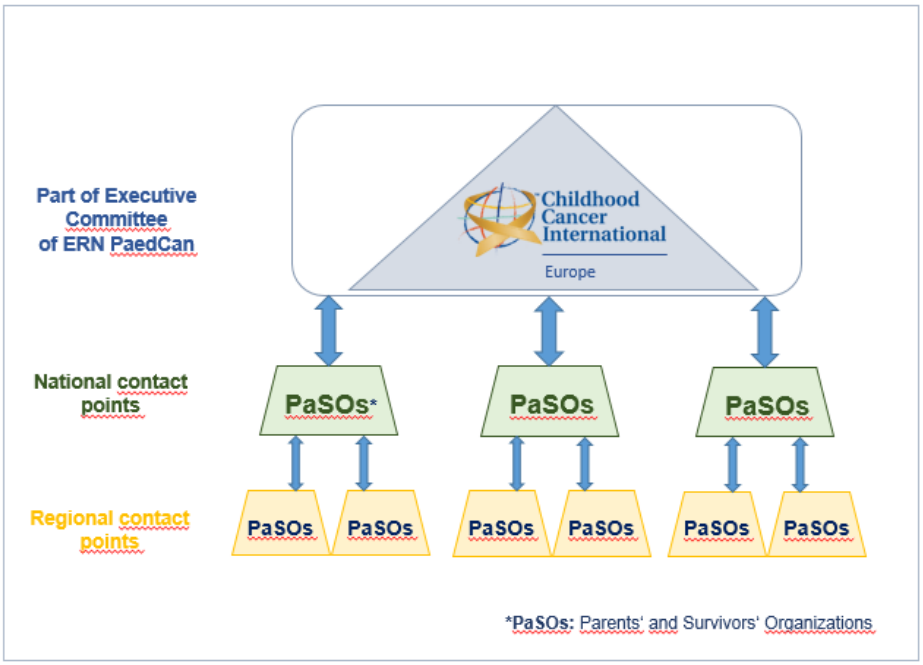
Figure 4: CCI Europe integrated in the ERN PaedCan



CCI Europe is also included in the European Patient Advocacy Group (ePAG) for the ERN PaedCan. ePAGs were created by EURORDIS to bring together elected patient representatives and affiliated organisations to ensure that the patient voice is heard within each ERN. The following CCI-Europe members (CCI Europe Regional Committee) are the ePAG representatives for ERN PaedCan:

- **Anita Kienesberger**, Chair of CCI Europe Committee
- **Luisa Basset**, Vice-Chair of CCI Europe Committee

2.2.5 ERN PaedCan Evaluation

The internal evaluation of the network will be carried out through the SIOPE office having the necessary experience and tools in place. The SIOPE Office together with the ERN PaedCan Management Team aims to conduct regular surveys to ensure that the quality criteria of the network are met. This evaluation process is crucial to ensure quality of the project activities and stakeholder satisfaction. Regular feedback loops are paramount to undertake timely corrective measures if needed. The Oversight Committee will advise on and support corrective measures eventually. The review cycle is outlined in Figure 1.

2.2.6 ERN PaedCan members

Currently, 92 full and affiliated members across 27 EU countries and in Norway are included in the ERN PaedCan. Members are Healthcare Providers (HCP) that were designated as centres of expertise by their national authorities, went through a thorough assessment by the EC and the Individual Assessment Body (IAB) and finally were approved by the Board of Member States (BoMS). In the future, additional members might join the network for which the same or a similar procedure will apply. The ERN PaedCan Members constitute the General Assembly.

2.2.7 European Commission

The European Commission plays a vital part in the ERN PaedCan. The ERN PaedCan Coordinator is in continuous interaction with the European Commission aiming to implement important policies as

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appropriate for ERN PaedCan. Reports will be handed over (through the online system) to HaDEA after each reporting period.
The EC also provides external evaluation (AMEQUIS) of the ERN PaedCan network every five years. Results of the evaluation will be discussed in the Oversight Committee (OC) and activities changed as considered appropriate.

2.3 Tasks and Responsibilities of bodies

2.3.1 General Assembly (GA)

The General Assembly (GA) of ERN-PAEDCAN is chaired by the ERN Coordinator, Prof Dr Ruth Ladenstein, and it is composed of the ERN PaedCan members. The General Assembly therefore consists of representatives from all ERN PaedCan members.

Roles: Whereas the NMT and the Oversight Committee are responsible for the strategic management and quality assurance the main role of the ERN PaedCan members is the support to implement the CBHC strategy as outlined in the continuously growing paediatric oncology cross-border healthcare roadmap. Virtual tumour board structures play a central role and need the implementation activities of ERNPaedCan members to support Cross Border Healthcare (CBHC) situations on the level of advice but also by accepting potential referrals.

Chair: Professor Ruth Ladenstein

Representatives: Representatives of all the ERN PaedCan members.

Decisions: In matters relevant within and for the SIOPE community, ERN PaedCan will seek agreement within the General Assembly and eventually propose voting on topics considered relevant for the whole PO community. Every single vote from each associated partner will be taken under consideration in the decision-making process and a simple majority is needed. The General Assembly has the right of a veto and to propose alternative solutions.

In the case of a split vote situation, the PMT will carry the deciding vote.

Meetings: The General Assembly meetings are held at least once a year.

2.3.2 Oversight Committee (OC)

The Oversight Committee (OC) is composed of the SIOPE SC, Chairs of CCI-E and Chairs of SIOPE CRC and provides independent oversight of the activities of ERN PaedCan network and ensures that actions are aligned with SIOPE's strategic plan. The OC helps decision-making within ERN PaedCan as relevant and needed.
The Oversight Committee supports the strategic management and the implementation of the ERN PaedCan's objectives i.e. steering the adoption of agreed best practice guidelines or defining training and dissemination programmes. The OC also oversees the Quality Assurance Cycle and ensures that evaluation of the network activities´ implementation. The OC will receive (oral or written) reports on the activities of the NMT and its progress towards achieving the objectives and milestones of the ERN PaedCan. Critical questions should be submitted in writing in a timely fashion to the NMT and, when appropriate, such questions or proposals will be circulated prior to the GA meetings in order to allow coordination of the proposals to be voted on.

Associated Centres (ACs) to the network as defined above by default will have no voting rights, unless they become full ERN members. The same holds true for sites identified as affiliated HCP to a full ERN

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PaedCan HoC. The same method occurs with the Local PaSOs organisations, to which no voting rights will be given.

Roles: The Oversight Committee and the ERN PaedCan Coordinator share the responsibility to discuss and prepare high-level strategic decisions aligned with the project objectives and the SIOPE strategic plan. They are also responsible for adopting activities accordingly depending on the outcomes of the review process.

The Oversight, Quality Assurance and Evaluation metrics will be provided by the Oversight Committee. The Oversight Committee will also take advice from the Ethics Advisory Committee, once this is formed.

Chair: President of SIOPE.

Decisions: The Oversight Committee and the ERN PaedCan Coordinator seek agreement in high-level strategic suggestions and decisions aligned with the project objectives and the SIOPE Strategic Plan to present for the European Commission on ERN related issues. The ERN PaedCan Coordinator will make the Committee aware of technical aspects, financial issues, work schedules, current and future partnerships, desired dissemination activities, high impact meetings and potential exploitation.

Meetings: The Oversight Committee will meet face-to-face or in teleconference at least twice a year. Extraordinary meetings could be called for, should the need arise.

2.3.3 The Network Management Team (NMT)

The Network Management Team (NMT) consists of the ERN Coordinator, Network manager (NM), The Research Management Office (RMO) of the CCRI including also SIOPE Office with its special task activities for ERN PaedCan.

Meetings: The NMT will meet face–to-face or in teleconference at least on a quarterly basis. Extraordinary meetings could be called for, should the need arise.

Role: the NMT is responsible for the management and implementation of activities decided by the OC in accordance within the projects scope and financial guidelines. .

2.4 Type of Management Activity

2.4.1 Strategic Management

Strategic Management is the management of the ERN PaedCan resources to achieve the objectives and goals as set in Annex 1 of the Grant Agreement. The strategic management involves the quality assurance cycle as outlined in figure 1. Best Strategic Management in ERN PaedCan is reached when threats can be foreseen and reacted on as soon as possible.

Only if the operative management works well, can the strategic management goals be achieved. The Oversight Committee with the ERN PaedCan Coordinator and the NMT are in charge of the strategic management.

The Strategic Management will be driven by the ERN PaedCan Coordinator aligned with the Oversight Committee and includes close interaction and advisory support or guidance by the European Commission.

2.4.2 Operational Management

Operational Management concerns the everyday management of the network and represents the ground level of the network management with the overall aim to manage processes as effectively as possible in the network. Successful operative management will be measured in delivering high quality

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outputs (deliverables, milestones, reports, documents, etc.) It is up to the Network Management Team (NMT) (described above) to ensure highly effective operational management.

Roles: The NMT will survey the networks´ progress and resources status and be responsible for dissemination, standardization as well as exploitation in accordance with the propositions of the corresponding committees.

Decisions: Will take day-to-day decisions regarding the operative management tasks on the project with enrolment of advisory functions only when strategic management tasks need to be solved and ensure an efficient day-to-day management of the project.

2.4.3 Conflict Resolution & Decision making mechanism

The objective is to implement a management structure which will give the possibility to take rapid and efficient decisions whenever necessary and allow each individual organization to be simultaneously represented, in order to anticipate and avoid the occurrence of disagreements/conflicts.

All the participants are used to collaborating with international groups to reach common ambitious scientific objectives; nonetheless, it cannot be excluded that a conflict could occur during the life of the project. To resolve any conflicts that may arise, the following steps are proposed:

- Mediation via the ERN PaedCan Network Coordinator representing the CCRI, with help of the NMT as needed within 1 month of being officially informed of the issue by letter
- Consultation with the European Health and Digital Executive Agency (HaDEA)
- Vote by the Oversight Committee (if an extraordinary session is needed, at the expense of the parties).

If no other solution is foreseen, exclusion of the party (-ies) may take place.

3 Quality and Evaluation Objectives

3.1 Definition of Scope of the work in Work Packages

The CCRI, together with the sub-contractors, are responsible for the leadership of work packages defined in the Grant Agreement, Annex 1 and approved by the EC.

Roles: The CCRI and all sub-contractors are committed to:

- Monitor the progress of the scheduled work within the Work Package (WP) in terms of technical achievement, planned deliverables and expenses in order to ensure the accomplishment of the technical objectives of the WP.
- Assess the quality of the outputs of their WP deliverables and milestones.
- Initiate and participate actively in the technical meetings necessary for the work progress, and to provide minutes of relevant meetings.
- Refer to the NMT for support in case of a major issue that affects the completion of the work foreseen.

Meetings: The sub-contractors will keep in close contact with the CCRI. CCRI will organise meetings or phone conferences at least every 3 months to follow the work in progress, in order to anticipate and resolve any issue that may arise.

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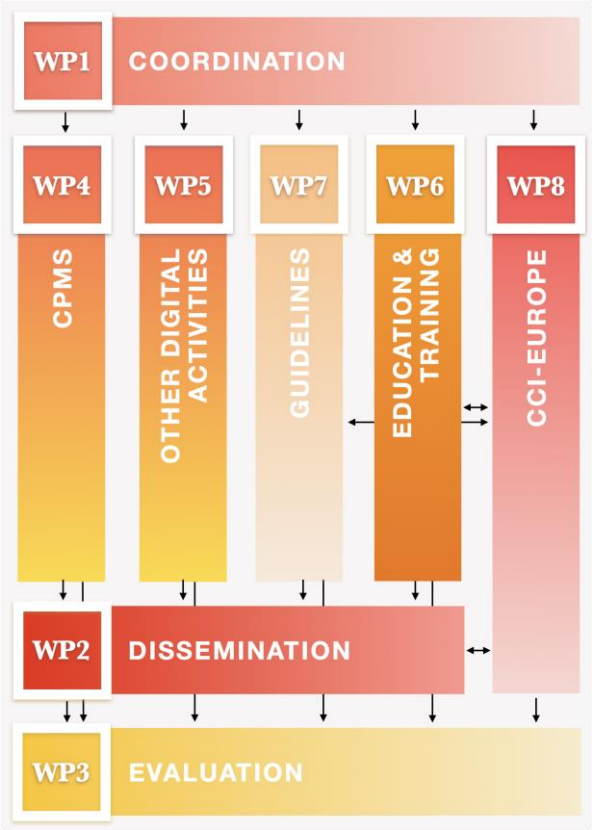
Table 1: Overview table of the ERN PaedCan work packages:



3.2 Management of Deliverables

According to the HaDEA definition, a deliverable represents a verifiable output of the project. Each work package will produce one or more deliverables during its lifetime. Deliverables are often written reports but can also take another form, for example the completion of a prototype.

All Deliverables are contractual and therefore CCRI is obliged to report on their status. In case a deliverable is seriously delayed or cannot be fulfilled, HaDEA must be informed (through the online exchange service) and Amendments to the project submitted.

The deliverables specifically under Management activities of ERN PaedCan are:

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Table 2: Management deliverables

Deliverable No	D n	Deliverable Name	WP	Lead Beneficiary	Due Date (M)	Description	Due Date (Actual date)
D1.1	1	ERN Development strategy	1	CCRI	12	Document summarising the ERN Development Strategy (in English language); published on the ERN PaedCan website.	28.02.2023
D2.1	2	Dissemination Plan	2	CCRI	2	A report in English language summarising the actions planned and tools used for disseminating the activities of the network and the knowledge generated.	30.04.2022
D2.2	3	Dissemination Report	2	CCRI	18	A report in English language summarising the dissemination activities.	31.08.2023
D3.1	4	Evaluation Plan	3	CCRI	6	A report in English language summarising the actions planned and tools used for evaluating the results of the activities of the network, and network itself.	31.08.2022
D3.2	5	Evaluation Report	3	CCRI	18	A report in English language summarising the evaluation activities.	31.08.2023
D4.1	6	Report on the CPMS pilot project	4	CCRI	18	Report in English language on the implementation of the CPMS pilot project.	31.08.2023
D5.1	7	Report on the Digital Tools of ERN PaedCan-Y6-7	5	CCRI	18	Reportin in English language for the European Commission and for the stakeholders of the paediatric cancer community	31.08.2023
D6.1	8	Webinar series successfully launched	6	CCRI	18	Report in English language submitted to the European Commission summarising the successful webinars organised by the network	31.08.2023
D6.2	9	Twinning and exchange programmes completed	6	CCRI	18	Report in English language submitted to the European Commission summarising the successful twinning and exchange programmes organised by the network	31.08.2023
D7.1	10	Standards of Childhood Cancer Care Guideline	7	CCRI	18	Report to the European Commission in English language on the successful publication of the guideline.	31.08.2023
D7.2	11	ESCP guidelines	7	CCRI	18	Report to the European Commission in English language on the successful completion of the ESCP project.	31.08.2023
D8.1	12	Complete List of CCI-E National Contact Points	8	CCRI	18	Report for the community on the ERN PaedCan and SIOPE webistes	31.08.2023

Additional management activities (not mentioned as specific deliverables)

1	Interim and Final Financial and Technical reports
2	Call for Proposals on ERN 2023-2027 funding opening March-April 2023

The remaining deliverables of the ERN PaedCan are implemented in the Work Packages (as indicated in the strategic management section). For a detailed overview of Objectives, Deliverables and Milestones, including their respective due dates and responsible partners, please refer to Annex I of the Grant Agreement.

As a monitoring procedure, sub-contractors responsible for each Deliverable will be alerted by email reminders one month in advance before the deadline by the NMT.

In order to ensure the quality of deliverables, a task progress updating system will be implemented. This type of update will be further explained in detail in section *Reporting*. Basically, every 6 months the coordinator will request from every task performer a brief report/feedback on the status of each task and therefore identify possible delays or obstacles to the normal progress of those tasks. This process will enable to quickly solve problems to ensure that dependent tasks are not seriously delayed nor impacted in any way.

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3.3 Evaluation of the Progress Towards the Specific Objectives

ERN PaedCan's Specific Objectives

For bridging grant's period of the project implementation, activities and indicators used for assessing them were adapted based on the experiences made, and needs explored during the implementation during the first five years.

As described in detail under 1.1 of the Application, comparative population-based cancer registry research has provided robust evidence for significant inequalities in survival from childhood cancer across Europe: the difference may be as much as 30%, with worse outcomes in Eastern Europe. The survival gap may be even greater for the majority of European children whose outcomes are not covered by cancer registries.

Activities initiated in the first five years of ERN-PAEDCAN will be further fostered, further developed and implemented. All activities aim at facilitation of successful cross-border healthcare activities to improve health care scenarios for patients, parents, and survivors´ across Europe and to close the survival gap. In the current work plan we **will focus on the following:**

- **Specific Objective 1: Coordination:** Quality assured coordination, management and operational activities of ERN PaedCan to meet the challenges of managing a network of almost 100 HCPs, and to coordinate the implementation of a complex work plan
- **Specific Objective 2: Dissemination:** Dissemination of the ERN-PAEDCAN function and its activities – inside and outside the paediatric cancer and ERN community, to have a broadened impact of the network resulting in a direct positive relationship to delivering cross-border best care to paediatric patients.
- **Specific Objective 3: Evaluation:** Quality Assurance and Evaluation of the action's implementation, according to the Quality Assurance Plan (QAP) and evaluated by the Evaluation Plan to ensure that the project's implementation takes place in a quality controlled way, its deliverables and results are evaluated, and the necessary conclusions are drawn upon the evaluation for the sake of the successful continuation of the network's future development.
- **Specific Objective 4: CPMS**: Integration of the European Clinical Trial Group Coordinating Centres, located within ERN PaedCan – embracing their advisory capacities and guiding them towards the use of CPMS as a communication platform.
- **Specific Objective 5**: **Other Digital Activities**: Sustainability, further development and enhancement of the registries and other digital tools (such as the Survivorship Passport) created and launched for the rare disease community of paediatric cancers
- **Specific Objective 6: Education and Training**: e-Training and increased capacity building activities – in closed collaboration with SIOPE and CCI-E – to improve the quality and reach of the e-training opportunities towards the widening countries and all stakeholders of the community. This strategy will contribute to cross-border best care to rare childhood cancer populations.
- **Specific Objective 7: Guidelines**: Continue the guideline development and best practice sharing, ensure that they are available to all stakeholders of the community, resulting in an improved treatment outcome for very rare childhood cancers in Europe and especially in the widening countries

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- **Specific Objective 8: Integration of Patient Representatives (CCI-E)**: Ensure that the patient representatives are integrated into the network, that their feedback is taken into account for the network's development and all paediatric and adolescent cancer patients in Europe have access to ERN PaedCan structures and to multidisciplinary virtual tumour board advice

For each objective we have developed the process-, output- and outcome indicators, with respective targets, where (when applicable) the previous performance of the network was used as a baseline,

Specific Objective 1	**Coordination: Quality assured coordination, management and operational activities of ERN PaedCan**
Process Indicator(s)	**Target**
• Organise 2 GA meetings, including all relevant stakeholders. This task will be carried out by the ERN PaedCan Management Team 's team in Month 8 (virtual meeting) and month 15 (physical meeting) • Organise regular working meetings. • Participate in stakeholder meetings and meetings with other ERNs, meetings of adult cancer groups and parents´/patients´ survivor organisations. • Organise regular TCs with ERN members and ESCP developers. Frequency of the TCs is subject to the demand. These activities will be organised by the ERN PaedCan Coordinator & NM. • ERN Development Strategy Delivered	-Successful GA meetings will be held with the network's partners and ERN PaedCan successfully represented at relevant meetings. -Meeting documents (agenda, presentations) on meetings organised by ERN PaedCan, presentations, dissemination material provided at stakeholder meetings. -Development Strategy developed and delivered in close collaboration with SIOPE
Output Indicator(s)	**Target**
• Quality of the meeting documents (agenda, presentations) and outcome of the meetings is assessed through feedback from the participants. • Quantity of dissemination material provided to others at stakeholder meetings.	-Meeting participants are presented with the and presentations related to the meetings. -Dissemination material and actions are acknowledged by 75% of the meeting participants.
Outcome Indicator(s)	**Target**
• All stakeholders are reached and informed on the activities of ERN PaedCan. • Improved rate of consensus to establish e.g. new European Standard Clinical Practice guidelines and other best practice guidelines. • Impact indicators are expected to be measured through questionnaires and surveys	-Duplication of efforts is avoided. -Meeting participants will make use the newly acquired information. -Higher awareness of ERN PaedCan. -All ERN PaedCan members are aware of the European Standard Clinical Practice guidelines developed and with the

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	support of the National Haemato-Oncologic Societies, their implementation is ensured.

Specific Objective 2	**Dissemination: Continue dissemination of the ERN PaedCan function and its activities. By ensuring dissemination of ERN PaedCan activities inside and outside the paediatric cancer and ERN community, the impact of the network will be broadened which has a direct positive relationship to delivering cross-border best care to paediatric patients.**
Process Indicator(s)	**Target**
• Continue to update and manage the ERN PaedCan website and intranet. • Develop a new Dissemination Plan of activities for the bridging grant and outline the plans beyond the 18 months' period • Create and update dissemination material (e.g. brochures, banners, etc.) and promote ERN PaedCan in external meetings. • Place a special focus on the dissemination of the ESCP documents	-Dissemination Plan developed with a special focus on the ESCP
Output Indicator(s)	**Target**
• Quality and quantity of i) website, ii) intranet, iii) dissemination materials, and iv) meetings attended. • ESCPs launched before and during the 18 months' duration and promoted in widening countries	-High satisfaction of dissemination material among the Paediatric Oncology Community (survey). -Awareness raised in Widening Countries
Outcome Indicator(s)	**Target**
• Broader outreach and awareness of the ERN PaedCan and its European Standard Clinical Practice Project throughout Europe.	-Increased information and consequent impact of ERN PaedCan for patients seeking cross-border healthcare. -Standards of Care transparent all across Europe – especially in the widening countries

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Specific Objective 3	**Evaluation: Quality Assurance and Evaluation of the action's implementation. The ERN PaedCan work plan will be implemented according to the Quality Assurance Plan (QAP) and evaluated by the Evaluation Plan. Outlines the quality control, quality assurance and evaluation methods and presents the various roles and responsibilities of the team in managing the project´s quality processes and ensuring they are implemented, followed and evaluated.**
Process Indicator(s)	**Target**
• Monitor the implementation of ERN-PAEDCAN activities, particularly for ensuring high impact and quality of the achievements. • Evaluation Reports to assess the overall quality of the project's implementation.	-QAP updated -Evaluation Plan delivered -Evaluation Report delivered
Output Indicator(s)	**Target**
• Monitoring reports prepared and submitted • Evaluation Report delivered.	- 2 monitoring reports submitted (for the year 2022 and for 2023) -Evaluation Report approved by the Oversight Committee
Outcome Indicator(s)	**Target**
• Implementation of the network's activities is met with high quality standards, assessed based on the QAP and evaluated by the EP.	-Optimal implementation of the network's activities with high impact and quality of the achievements.

Specific Objective 4	**CPMS: Integration of the European Clinical Trial Group Coordinating Centres, located within ERN PaedCan (embracing their advisory capacities and guiding them towards the use of CPMS as a communication platform**
Process Indicator(s)	**Target**
• Identify European Clinical Trial Group Coordinating Centres wishing to implement a VTB based on the CPMS. • Spread the use of CPMS to at least four new ECTG CCs • Report on progress of implementation and user friendliness of the CPMS • Collect feedback for the development of the new CPMS and revert them to the EC	-Representable number of ECTG CCs engaging with the CPMS system.
Output Indicator(s)	**Target**
• Questionnaires assessing the user friendliness of the CPMS will be set up and (in alignment with the EC) distributed to the involved partners.	-Accurately assess the number of ECTG CCs satisfied in the pilot phase launched by the present call for proposals
Outcome Indicator(s)	**Target**
• Change or impact on original treatment plans of patients presented in the CPMS panels	-Number of successful virtual consultations significantly increased

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	(more than 50% increase compared with the panels managed during the first five years' period (pro rata).

Specific Objective 5	**Other Digital Activities: Ensuring the sustainability, further development and enhancement of the registries and other digital tools (such as the Survivorship Passport) created and launched for the rare disease community of paediatric cancers**
Process Indicator(s)	**Target**
• Ensure the PARTNER Registry's sustainability • Launch the ESCP Registry • Initiate the Bioregistry App's development and deliver it within this period of ERN PaedCan	-PARTNER registry is running, its sustainability is ensured within the grant -The ESCP registry is up and running, and further entities are added (developed within Objective 7) -The Bioregistry App is initiated – serving the needs of the paediatric cancer survivors' community
Output Indicator(s)	**Target**
• The number of registered cases in the PARTNER registry in increased • ESCP registry opens and the ECTGs identified within Objective 4 started support cases from widening countries, and the patients concerned are registered • Bioregistry App launched	-Significant increase in the number of registered cases (between 30-50% increase pro rata) -Necessary training (coordinated within Objective 4 and 6) for the CPMS and the ESCP registry make the registration of patients from widening countries registered in the ESCP registry -Bioregistry App has all the desired functions needed by the community
Outcome Indicator(s)	**Target**
• Clinicians in widening countries have up-to-date information about the digital tools developed and launched, and these tools help them for the benefit of their paediatric cancer patients • Surveys collect feedback concerning the satisfaction of the stakeholders	-The paediatric oncologists in widening countries have access to the tools -Widening countries' CCI-E National Contact Points are provided with materials developed in Objective 2 promoting

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	these tools to raise awareness among patients and parents

Specific Objective 6	**Education and Training: e-Training and increased capacity building activities. In closed collaboration with SIOPE and CCI-E, following the first five years' programmes we will continue to improve the quality and reach of the e-training opportunities towards the widening countries and all stakeholders of the community. This strategy will contribute to cross-border best care to rare childhood cancer populations.**
Process Indicator(s)	**Target**
• Webinar series "Most Challenging Cases in Paediatric Oncology) – in close collaboration with Young SIOPE, and with the direct involvement with CCI-Europe continued, CME accreditation arranged for the webinars • ESCP registry specific trainings organised	-The webinars are scheduled, and recordings are available online for later access -ESCP registry trainings organised for the widening countries; material available online
Output Indicator(s)	**Target**
• Number of webinars delivered • Number of attendees joining the webinars	-At least 5 webinars on the topic of Most Challenging Cases delivered with at least 30 attendees -At least 2 ESCP registry trainings scheduled
Outcome Indicator(s)	**Target**
• Attendees of webinars and trainings have benefited from the newly acquired skills. Confirmed by satisfaction rating captured after respective webinars • Widening country experts use the ESCPs, the digital tools, and patients benefit from this (even if this benefit can only be measured on a long run (10 years)) – questionnaires will capture the user's satisfaction grade	-Increase of knowledge achieved – Kirkpatrick eval. Methodology or other suitable methodology used for the evaluation showing success of the programmes launched

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Specific Objective 7	**Guidelines: Continue the guideline development and best practice sharing, ensure that they are available to all stakeholders of the community, resulting in an improved treatment outcome for very rare childhood cancers in Europe and especially in the widening countries**
Process Indicator(s)	**Target**
• New ESCP entities identified, and their development is initiated • Open access journals for ESCP publications identified • Authors of the ESCP publications identified	-New ESCPs are approved by the SIOPE Board and launched -ESCP publications' development plan is set up
Output Indicator(s)	**Target**
• Number of new ESCPs launched • Number of open-access ESCP publications	-3 new ESCP documents available -At least 2 publications scheduled for delivery or delivered
Outcome Indicator(s)	**Target**
• Standard of Care is defined for the entities covered within the ESCP project	-All National Paediatric Cancer Societies in widening countries are aware of the ESPC and are promoting them

Specific Objective 8	**Integration of Patient Representatives (CCI-E): Ensure that the patient representatives are integrated into the network and paediatric and adolescent cancer patients in Europe have access to ERN PaedCan structures and to multidisciplinary virtual tumour board advice**
Process Indicator(s)	**Target**
• Identification of CCI-E National Contact Points • Identification of respective NAPHOS leadership in widening countries • Contributing to Objective 2, 6 and 7	-National Contact Points identified in all CCI-E member countries -CCI-E NCPs connected to the NAPHOS -CCI-E is directly involved in the webinar series' development, in the webinars as panellists -CCI-E with the help of the National Contact Points promotes the ESCPs
Output Indicator(s)	**Target**
• Number of CCI-E NCPs identified	-Contact points identified in all CCI-E member countries -Number of CCI-E National Contact Points promoting the ESCPs
Outcome Indicator(s)	**Target**

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• Childhood Cancer International – European Branch – Parents' and patients' association fully integrated into ERN PaedCan	-Integration completed

Table 3: ERN PaedCan's Specific Objectives and Indicators measing progress towards them

3.4 Evaluation of the Network

- **What is evaluated?**
  - In-depth survey for ERN members on
    - their satisfaction,
    - their training needs
    - they financial needs for Cross-border healthcare
    - the extent of integration into the national healthcare
  - The ERN PaedCan organised training courses
    - satisfaction,
    - knowledge gained,
    - skills extended,
    - general results)
  - Conferences / online working meetings organised,
    - cost-effectiveness
    - participation
  - ERN PaedCan website
    - Number of visitors
- **How is the evaluation planned?**
  - **Surveying ERN members**: with the help of EUSurvey – data analysis and statistics generated with MS Excel.
  - **Training courses**: with the help of EUSurvey – data analysis and statistics generated with MS Excel based on the most relevant methodology (e.g. Kirkpatrick Model)

The Kirkpatrick Model
Level 1: Reaction
The **degree to which participants find the training favourable, engaging, and relevant** to their jobs
Level 2: Learning
The **degree to which participants acquire the intended knowledge**, skills, attitude, confidence, and commitment based on their participation in the training
Level 3: Behaviour
The **degree to which participants apply what they learned during training** when they are back on the job
Level 4: Results
The **degree to which targeted outcomes occur as a result of the training** and the support and accountability package

  - **Conferences**: comparing price offers received, costs vs. previous years - data analysis and statistics generated with MS Excel
  - **ERN PaedCan website**: tools offered by the website's provider – metrics compared to previous years' metrics - data analysis and statistics generated with MS Excel

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- **When** is the evaluation scheduled?
    - **Surveying ERN members:** after the time consuming 5-year ERN Evaluation – between M12-M18 of the bridging grant
    - **Training courses**: upon the completion of the webinar series launched within the bridging grant – after M18, during the final report preparation.
    - **Conferences**: upon the end of the bridging grant – after M18, during the final report preparation.
    - **ERN PaedCan Website**: upon the end of the bridging grant – after M18, during the final report preparation.
- **Why is the evaluation carried out?**
  To evaluation the effectiveness of the activities, their efficiency and to learn more about the feasibility of activities planned in the upcoming periods of ERN PaedCan.

4 Communication and Meetings

An efficient communication across the project will ensure that all the participants are fully informed of the project status, the planning and all other issues, therefore the synergy of the co-operation between them will increase.

4.1 Clinical Patient Management System

What is it?

- **A system to enable clinicians to exchange information to diagnose and treat patients.**
- Sharing of clinical data, including medical imagery
- **Needs regular input for use** – which is ensured by the participation in respective working groups of the ERNs (the Network Coordinator and the CPMS Manager are participating).

Communication support:

- Proof system and make it suitable for the ERN PaedCan´s and each hospital needs
- Current communication with the EC on the System itself
- Help all users to access the platform and familiarize themselves with the platform
- Creating expert panels
- Support the panel lead and overlook the processes

4.2 ERN Collaborative Platform

What is it?

- It is a restricted online space to share, organise, communicate; Members can publish, discuss, schedule, vote
- Secure Access and user authentication (EU Login)
- User support is provided – Demos and training manual online
- All ERN PaedCan members shall request access to the Platform

ERN PaedCan Internal communication support

- Must accept/reject the persons applying for the platform
- Create new panels for discussion and upload necessary project related information
- Liaise with European Commission on a regular basis

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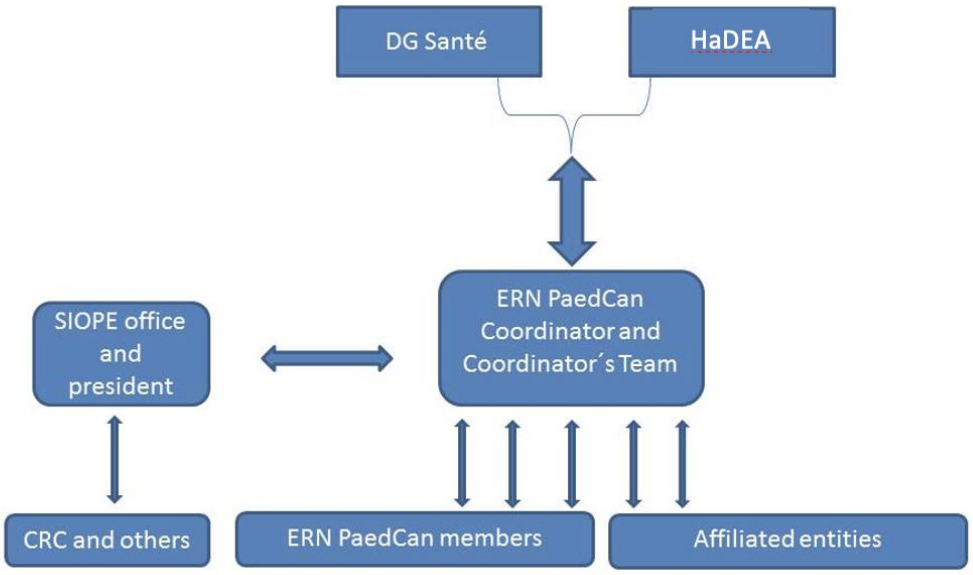
4.3 ERN Online Meetings

Permanent communication will be maintained according to the specific needs of the ERN members through emails, teleconferences, online meetings, and the ERN PaedCan website. The Executive Committee (NMT+OC) will additionally meet face-to-face or virtually at least twice a year. The NMT will also have regular communication, at least once every month, to assess current needs of the network members, implement the annual work plan objectives and discuss dissemination activities.

4.4 Communication with HaDEA

It is the general obligation of the ERN PaedCan coordinator to be the intermediary for all communications between the beneficiaries and the European Commission. The communication between the ERN PaedCan members and the Network Management Team are outlined in Figure 5 below.



CRC= Clinical Research Council

Figure 5: Communication details of ERN PaedCan

4.5 Convening meetings

The Coordinator´s team will organise at least one GA meeting (virtual of f2f) per year, including all relevant stakeholders. The best practice meeting will be organised by the member that takes the lead of the meeting and will be supported by the Coordinator´s team.

For the GA meeting: All participants who are entitled to receive a reimbursement for their participation, need to ensure they submit transport invoices, and boarding passes, tickets, proofs of payment and other supporting documents to the ERN PaedCan Coordinator's Team after the meetings.

Table 4: Overview of ERN PaedCan management body meeting schedules and convoking procedures

Meeting	Description and Frequency	Participants

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GA	General Assembly (GA) meeting will take place at least once a year	All ERN PaedCan Members, NMT & representation from the Oversight Committee
Best Practice Meeting	One best practice meeting will be held every year (ideally organised together with the GA meeting)	Specialists for the discussed tumour entity / ECTG
NMT meeting	NMT will meet once every month	NMT
Working meetings	Will be organised by the responsible ESCP developer in liaison with the NM	Coordinator´s Team and ESCP developer

NMT = Project Management Team, GA =General Assembly, HoC= Hubs of Coordination, ESCP = European Standard Clinical Practice

The NM/ERN PaedCan Coordinator shall give notice in writing of a meeting to all ERN PaedCan Member as soon as possible and no later than the minimum number of days preceding the meeting as indicated below.

Table 5: Overview of timelines of notices preceding meetings:

Meetings/Conferences	Project Body	Timelines of notices
Major Meetings	General Assembly	60 calendar days
Medium meetings	Executive Committee	45 calendar days
Working Meetings	Network Management Team integrating Advisory Board members, Work Package leaders and/or others	28 calendar days
Small Meetings	Network Management Team	14 calendar days

The NM shall prepare and send the agenda to each ERN PaedCan member and all parties involved no later than the minimum number of days preceding the meeting as indicated below.

Table 6: Overview on timelines of agenda distribution preceding meetings

Meetings/Conferences	Project Body	Timelines of agenda
Major Meetings	General Assembly	30 calendar days
Medium meetings	Oversight Committee	20 calendar days
Working Meetings	Network Management Team integrating Advisory Board members, Work Package leaders and/or others	14 calendar days
Small Meetings (WebEx)	Network Management Team	7 calendar days

Any ERN PaedCan Member (or others included in the GA) may add an item to the original agenda by written notification to the Coordinator's Team up to the minimum number of days preceding the meeting as indicated below to be added as Any Other Business (A.O.B.).

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Table 7: Overview of timelines to add new items to meeting agendas

Meetings/Conferences	Project Body	Timelines of agenda
Major Meetings	General Assembly	7 calendar days
Medium meetings	Oversight Committee	At any time
Working Meetings	Network Management Team integrating Advisory Board members, Work Package leaders and/or others	At any time
Small Meetings	Network Management Team	At any time

4.6 Meeting Minutes

The NM shall produce written minutes of each meeting and of decisions made without a meeting, which shall be the formal record of all decisions taken. The NM shall send the draft minutes to all Members within 3 months after the meeting or of the decision without a meeting.

The minutes shall be considered as accepted if, within 7 calendar days from sending, no Member has objected in writing to the NM with respect to the accuracy of the draft of the minutes and no Party has issued a veto of any decision contained within such minutes.

5 Dissemination procedures

In order to ensure a highly efficient dissemination of scientific information at the European level, the SIOPE has identified communication and dissemination actions in order to examine and implement the best way to promote the project's results. To raise scientific and public awareness on ERN PaedCan's progress on building a roadmap to approved expert referral sites and tumour advisory boards for healthcare providers, systematic public information will be disseminated through internal and external dissemination routes as detailed in key sections below. (For more details see the Dissemination Plan.)

5.1 Key actions:

SIOPE shall be supervising the dissemination activities and will have the following tasks:

Development of a strategy for internal and external dissemination

- Publicize the project to all relevant network stakeholders
- Identify the most appropriate results to be announced to relevant target audiences by means of publications and information outlets/tools
- Proactively identify and maintain a database of the most efficient opportunities to reach these target audiences
- More detailed tasks are described in the respective WP-Description in the Grant Agreement

5.2 Target groups:

SIOPE created a Dissemination Plan in order to organise actions to increase the visibility of ERNPaedCan for respective project partners & other communities. The target groups are identified as follows:

- ERN PaedCan members and partners
- ExPO-r-NeT partners

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- SIOPE, SIOP International, ENCCA, CRC, PanCare, Eurordis, Rare Cancers Europe, ECPC, CCI Europe
- Healthcare and research professionals
- Patients, families and advisory groups (including teenagers and young adults)
- Policy makers: EU institutions and (sub)national authorities
- Industry: pharmaceutical and medical device organisations
- Regulatory agencies
- General public
- Outreach to interest groups such as partners in the Joint Action on Rare Cancers and other relevant European Projects
- Outreach to new Member States and European countries outside the EU. Translations will be encouraged.

5.3 Internal dissemination

The ERN PaedCan infrastructure aims to guarantee that all partners are informed about the progress and activity outcomes, network-planning and all other issues which ensure well-informed and well-briefed partners. This ensures the maximum efficiency of resources, consistency of results, and increases the synergy and integration of the partners. All management meetings and technical coordination meetings will play an important role in this task. All information generated within the project will be communicated to the NMT who will be in charge of channelling this information to the other contractors, where appropriate.

5.4 External dissemination

ERN PaedCan aims at communicating effectively with parties outside the consortium, in particular other healthcare providers (members and non-members), as well as with other European consortia, policy makers, and more generally with the scientific community and its citizens at large. We will pro-actively reach out to the communities that we anticipate will be most interested in and benefit from the outputs of ERN PaedCan, through participation in key meetings and organizing dissemination events with relevant groups (e.g. parents and survivor associations).

Since the EC is also providing communication material generally about the ERN, the ERN PaedCan Dissemination Partner (SIOPE) will liaise with the European Commission with regards to additional material.

In line with the obligations regarding dissemination of results and achievements, the NM and the SIOPE office will assure continuous, complete and highly visible PR activities to the various target audiences identified. This includes the provision of all public documents (including, but not restricted) to the following material:

- Use of online tools provided by the EC and already existing platforms (SIOPE):
    - Project website (including detailed statistics)
        - An interactive ERN-PAEDCAN website linked with the ExPO-r-Net website and hosted by the European Commission will be established. SIOPE is responsible for administering the website and will serve as the main contact point for external users, will include general information and updates on the

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progress, and will have direct access to the intranet section. The ERN-PAEDCAN intranet, included in the ERN Collaborative platform, will be accessible by partners to gather and share documents and to communicate online on special topics.

  - Project intranet
  - Project electronic newsletter/bulletin
  - Social media (including hashtag and detailed statistics)

- Promotional Materials:
  - Dissemination package including logo, PowerPoint presentation, including acknowledgement to the EU
  - Information brochure
  - Flyers, bookmark, roll-up banner and any other relevant promotional material

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- Media and Scientific Publications:
    - Press releases
    - Articles
    - Abstracts
    - Scientific Articles/Papers
    - Advertisements
    - Interviews
    - Encouraging other types of coverage (e.g., TV or radio)

5.5 Data Gathering, Sharing and Monitoring

The collaboration of the SIOPE office team with the NMT, gives a strong added value to ERN PaedCan. Since SIOPE interacts closely with the National Paediatric Haematology Oncology Societies (NaPHOS) and the European Clinical Trial Groups, which are all represented in the SIOPE Clinical Research Council (SIOPE CRC), it will enable enhanced communication, coordination and dissemination of information to the whole paediatric oncology community in a very effective manner. SIOPE is an established voice of the paediatric oncology community and drives respective ´oncopolicy´ actions. The Board of SIOPE is composed of key players in the paediatric oncology field and hence is ideal to provide advice to the ERN-PaedCan strategic agenda.

Progress of developments related to ERNs will be monitored and mapped, i.e. the EC-action plan of the cross-border healthcare directive implementation will be monitored and any news communicated to the consortium.

Coverage as part of SIOPE's broader communications will include:

- Use of the SIOPE database, which enables the targeting various interest groups
- SIOPE website
- SIOPE newsletter
- SIOPE social media
- SIOPE events and projects

5.6 Attendance at Events

Some of the most effective possibilities for disseminating knowledge are based on the participants' own initiatives, for example, in the course of attending meetings, self-organized conferences, workshops, training sessions, seminars and self-published websites, publications, press releases, multimedia tools, TV etc.

The benefits of disseminating knowledge on the consortium's own initiatives are evident: The participants are free to decide on the framework, matters and ways of presenting the knowledge, and can, additionally, systematically advertise within the target group, always within the rules established by the Grant Agreement.
Dissemination will also take place within third party activities, e.g. in speeches, presentations and information booths within conferences, exhibitions, training sessions organised by third parties (conferences organised by IRCs or by national or regional governments etc.).

ERN PaedCan project material will be distributed and the project will be presented at events such as:

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- The annual International Childhood Cancer Day (ICC, 15 February) and annual Childhood Cancer Awareness Month (September)
- SIOPE Clinical Research Council (CRC) meetings
- Scientific Congresses (e.g., SIOPE Annual Meeting, ESMO Congress, ASCO, AACR, EORTC Survivors Summit, ECCO Summit, SIOP International Congress, ESTRO Congress, TYA Internal Congress, ACCELERATE Congress, CCI Europe Annual Conference)
    - Expert speaking contributions from project stakeholders
    - Scientific abstracts and posters generated by the network
- Policy events (ICC event at the Parliament, MEPs Against Cancer (MAC) events, and others)
- European Commission events
- SIOPE and other member-led events (annual national meetings)

5.7 The EU Emblem (ERN Paedcan Logo) and Acknowledgement of EU Funding

Unless HaDEA requests otherwise, any dissemination activity related to the specific actions (including at conferences, seminars, in information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via social media, etc.) and any infrastructure, equipment or major result funded by the specific grants must display the EU Emblem and include following text and acknowledgement:

This ERN PaedCan project has received funding from the European Union's EU4Health Programme under the grant agreement number 101085543.

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The EU Emblem must have prominence when displaying with another logo and can be used by the partner without first obtaining permission from the Agency. However, solely for the purpose above.

In addition, any communication activity with respect to the specific action, in whatever form and or by whatever medium, must specify that it reflects only the author's views and that HaDEA/European Commission is not liable for any use that may be made of the information contained therein.

5.8 Publications

Since ERN PaedCan is funded via a mono-beneficiary grant, provisions of the E&QP are not obligatory. Dissemination activities including but not restricted to publications and presentations are recommended to be governed to the following provisions.

Prior notice of any planned publication/dissemination activity, with a copy of it, shall be made 30 days before the publication/dissemination activity to the NMT. Any objection to the planned publication shall be made in accordance with the NMT in writing to the NMT and to any Party concerned within 10 days after receipt of the notice. If not resolved through discussion with the NMT, the Executive

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Committee will ultimately be involved in the decision making process. If no objection is made within the time limit stated above, the publication is permitted.

If foreground Information / Intellectual Property or Background Information / Intellectual Property of another Party is needed for publication of a student degree thesis, approval for use shall be obtained from the appropriate Party owing such rights or affected by the use. The approval of the relevant parties shall be sought at least 30 days before the latest date of which the contents of the planned publication can be altered. For the avoidance of doubt, no such publication will be made without such approval of a party who would be adversely affected by that publication. Approval shall not be unreasonably delayed or withheld.

Depending on the type and level of involvement, please use one these options for the acknowledgement of the Network

1. **"The (two or more of the/several) author(s) of this publication is/are (a) member(s) of the European Reference Network on Paediatric Cancer (ERN PaedCan)."**

*This is a general option that members can use **regardless of there being two or more HCPs involved.** This gives attention to the existence of ERN PaedCan without it acknowledging any direct input from it.*

2. "**This work is generated within the European Reference Network on Paediatric Cancer (ERN PaedCan)."**

*Please use this option if the work was carried out **by at least two or more ERN members**.*

3. **"This study/project/publication/guideline/survey has been supported by European Reference Network on Paediatric Cancer (ERN PaedCan), which is funded by the European Union within the EU4Health Programme 2021-2027"**

Use this reference if funding is allocated to a publication/project/etc.

6 Contractual Issues

6.1 Grant Agreement (GA)

The Grant Agreement (SGA) is an agreement between HaDEA and the Children´s Cancer Research Institute (CCRI). The duration of the bridging grant's action will be 18 months as of 1 March 2022. The ERN coordinator has the possibility to re-apply for additional funding of the network for the period of 2023-2027.

6.2 Amendments

The GA may be amended.

If an amendment is requested it needs to be submitted through the electronic exchange system and signed electronically. The request amendment must include the reason why and the appropriate supporting documents. Upon request of the Agency the Coordinator must supply them with additional documents. The amendment enters into force on the day of the signature of the receiving party.

The duration of the agreement cannot be amended.

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6.3 Sub-Contracting

The call for tender / collection of offers and price quotes will ensure that the best possible choice was made (best value for money), unless there is a justification available, why only one certain provider is considered as suitable for a certain task and appointment. Contracts will be set up with all sub-contractors. The sub-contractors will invoice their costs to the ERN PaedCan coordinator. The sub-contractor has to prove that the sub-contracting is supported by accounting documents in accordance with national accounting law. The tasks and the costs for the sub-contracting action will be in line with Annex 1 of the GA.

7 Financial Aspects

The financial provision in ERN PaedCan will follow strictly the General Conditions agreed in the Grant Agreement (following Chapter 3 / Article 6 of the GA).
Cost eligibility: to be eligible, costs and contributions must meet the eligibility conditions set out in Article 6 of the GA.

A selection of provisions are listed below, for the rest, the project managers consult the GA which is binding, and of course supersedes this deliverable.

§6.1 of the GA on general eligibility for actual costs: they must be incurred by the beneficiary, within the period set out in article 4 (with the exception of costs relating to the submission of the final periodic report, which may be incurred afterwards; see Article 21 of the GA).

§6.2 of the GA on specific eligibility conditions: direct costs are: personnel costs, subcontracting costs, purchase costs (within this category travel and subsistence costs, equipment costs, other goods, works and services and other costs. Indirect costs will be reimbursed at the flat-rate of 7% of the eligible direct costs (categories A-D, except volunteers costs and exempted specific cost categories, if any).

8 Reporting to HaDEA

The ERN PaedCan Network Coordinator has the contractual obligation to prepare the interim and final reports in line with the GA. This report includes the request(s) for payment and must be drawn up using the forms and templates provided in the electronic exchange system. The ERN PaedCan Coordinator will store information on the electronic exchange system and let the Agency know as soon as possible if an event is likely to affect the implementation of the actions as outlined in the agreement.

8.1 Reporting Periods:

Interim report: M1-M9
Final report: M1-M18

8.2 Final Report to be submitted to HaDEA:

Final reports must include a final **technical report and a final financial** report and must be submitted latest within 60 days following the end of the reporting period. Through the final report a request for payment of the balance must be submitted as well.

8.2.1 The final technical report must include:

An explanation of the work carried out, an overview of the implementation of the specific action, including milestones and deliverables (as in Annex 1 described). The final report must also explain the differences between the work expected and the actual work carried out in that year. Furthermore, a

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summary for publication for the Agency shall be written and the questionnaire on action implementation and its impact must be filled in.

8.2.2 Final Financial Report:

The final financial report must contain an **individual financial statement** for the reporting period. The financial statement must describe in detail the eligible costs that occurred. All eligible costs must be declared, even if for actual costs and flat-rate costs they exceed the amounts indicated in the estimated budget.

A **certificate on the financial statements** might be needed if a request for EU contribution for about EUR 325 000 or more as reimbursement of actual costs is made and the maximum EU contribution indicated in the estimated budget is EUR 750 000 or more. All financial statements must be drafted in euro or converted in its accounts into euro at the average of the daily exchange rates of the European Union.

The NM will be supporting the sub-contractors with the reporting through templates, notifying due dates and send out deadline reminders, assisting partners to respect indications and guidelines assigned by HaDEA and will be collecting the WP leaders contributions to prepare the consolidated annual (including the final) project progress reports in collaboration with the NMT.

8.2.3 Recall of ERN PaedCan fundamentals

- 92 ERN Members from 28 countries (27 EU countries + Norway)
- 8 WPs, 12 Deliverables and 8 Milestones planned for the bridging grant's period
- 1 final technical and financial reports, 1 internal report

Periodic reports must be prepared and submitted within 60 days of the end of each reporting period. All templates necessary to deliver reporting material will be available on the EC Portal. Apart from content on scientific development, sub-contractors will have to provide a detailed reports together with respective invoices.

After the pre-financing payment

- Final payment (Balance) at the end of the project after approval of the final report.

After reception of reports HaDEA may:

- Approve and perform payments
- Suspend the time-limit requesting revision/completion
- Reject them giving justification, possible termination
- Reject certain costs that are ineligible
- Reduce the grant
- Suspend the payment

After receipt of all documents, HaDEA has 60 days to evaluate and execute the corresponding payment.

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8.3 Continuous reporting (during and after the project)

8.3.1 Internal reporting

Internal reporting is crucial to assure constant and efficient monitoring of the project development. This type of reporting implies mostly communication on the status of tasks, milestones and deliverables from the sub-contractors and partners involved in the specific activities to the NM.

The project progress will be shared, presented, reviewed and analysed regularly and it is structured in the following frame:

- Monthly basis: Internal milestone progress updates and ExeCom meetings, The NMT is expected to attend (online meetings);
- Every four months: Internal update on Progress of certain Deliverables; the NMT with the responsible WP Leader or sub-contractor (online meetings); and
- General Assembly meetings: All WP key contributors and ERN members are expected to attend.

The objective will be to assess the project progress on the basis of deliverables produced.

In order to facilitate the bureaucratic burdens and other reporting activities accumulated by every participant, the NMT team will provide templates for the Report consisting of key fields to fill-in by each partner concerned (involved in the activities as outlined in Annex 1 of the GA) and sub-contractors. This approach will facilitate enormously the internal reporting.

Partners involved in WP will need to hand in their deliverables at least one month prior to its respective deadline to the ERN PaedCan Coordinator´s Team. The Coordinator´s Team needs to upload the deliverables in the Exchange platform of the EC.

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8.3.2 Summary of Rights & Duties during reporting activities

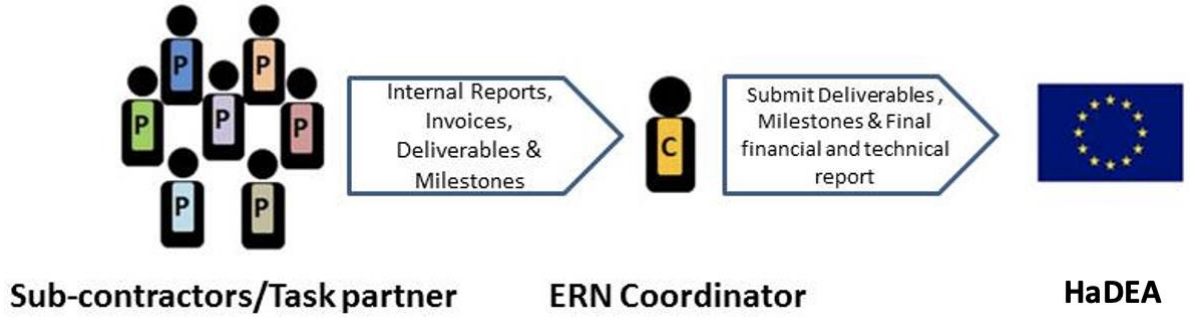

Figure 6: Summary of Rights & Duties during reporting activities

8.3.3 NMT is required to:

- Collect the financial statements (invoices, etc.)
- Write deliverables together with the partners involved in the WP (Reports etc.) and submit them through the online exchange system.
- Write the final financial and technical report on the basis of the work performed Submit the Final financial and technical report to HaDEA
- Provide clarifications, or any required additional information to the Project Officer (PO)
- Serve as an intermediary between the PO and all subcontractors

8.3.4 All sub-contractors are required to:

- Invoice their services
- Prepare an overview of activities and fill in and sign the internal reporting template
- Send Deliverables to the ERN Coordinator and Network Manager 1 month in advance of the submission deadline

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