European Reference Network

for rare or low prevalence complex diseases

Network
Paediatric Cancer
(ERN PaedCan)

Coordinator
St. Anna Kinderspital &
St. Anna Kinder-
krebsforschung — Austria

Quality Assurance Plan

(QAP)

Final submission

12.2017

INDEX

1 Introduction

The Quality Assurance Plan (QAP) corresponds to the deliverable 1.1 outlined in Annex I (Part A) of the Specific Grant Agreement and Annex I of the Framework Partnership agreement. The overall Quality Planning for ERN PaedCan will be based on the defined internal management rules, methodologies and work plan specified in the Grant Agreement.

This QAP outlines the 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 QAP presents the various roles and responsibilities of the team in managing the project's quality processes and ensuring they are implemented and followed. In addition, the QAP lists the quality planning tools and 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 QAP 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 QAP 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 latter 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 QAP is to provide a broad overall framework and guideline for implementing quality management and to ensure the quality of the proposed activities and reach 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). This plan covers the period of time for the complete life cycle of the ERN PaedCan (start 03/2017, duration 60 months).

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 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.

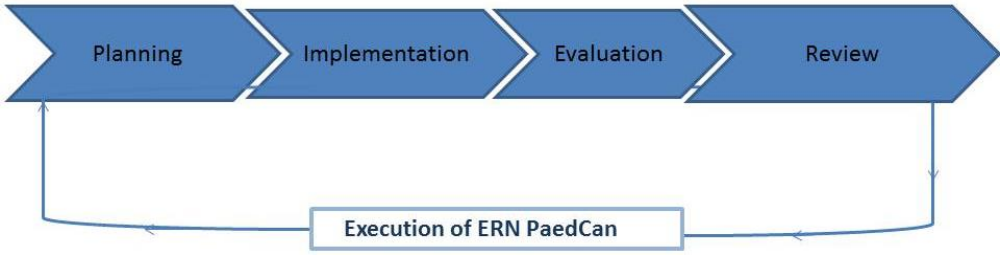
Planning: Annex I of the Specific Grant Agreement provides a detailed work plan and management structure to be followed. Any necessary changes of this plan will require a sequence of procedures already anticipated. In the planning phase, specific, measurable, achievable, realistic and time bound deliverables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

Review: Procedures will be developed and outlined below that assure the feedback is implemented appropriately and procedures for change achieved. Ultimately, the QAP 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 publications
- Average provision of publications and achievements
- Numbers of successful WP partners planned meetings per reporting period
- Number of European and International meetings delivered per reporting period
- Number of published abstracts, specialized or lay press articles
- Number of dissemination documents
- Number of released animations and/or videos
- 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:

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 Specific Grant Agreement)
- ERN PaedCan Deliverables and Milestones
- *Patients and Parents within the ERN PaedCan. CCI Europe, 2017*
- EU Quality assurance in vocational and educational training retrieved at: http://www.eqavet.eu/qa/gns/home.aspx

2 Management

2.1 Organisational Structure

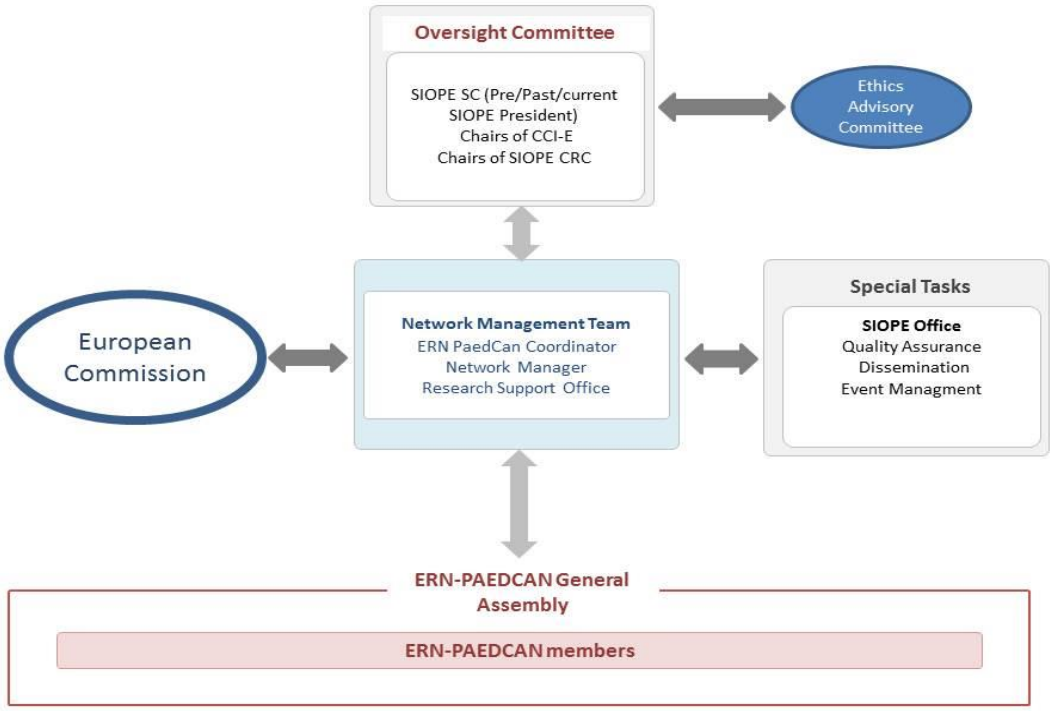
The objective of this management structure is to show an effective and transparent body for any action undertaken within the project's lifetime on behalf of a/o with the consortium. The structure will allow taking rapid and efficient decisions as needed to avoid a blocking situation. Information to the 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.

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 Consumers, Health and Food Executive Agency (CHAFEA) 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 CHAFEA 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.)

2.2.2 Network Manager and Research Support Office

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 CHAFEA) 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 1,500 members; 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 Martin Schrappe from University Hospital Kiel, Germany. Prof Martin Schrappe was involved in several European projects and his institution is also an approved ERN PaedCan member. The President Elect is Prof Pamela Kearns from the University of Birmingham, Cancer Research UK, Clinical Trial Unit (also an ERN PaedCan member health care provider).

Former presidents:

- Prof Gilles Vassal (2012-2015)
- Prof Ruth Ladenstein (2010-2012)
- Prof Kathy Pritchard Jones (2008-2010)
- Prof Andrea Biondi (2007-2008)

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

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 will be 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) 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.

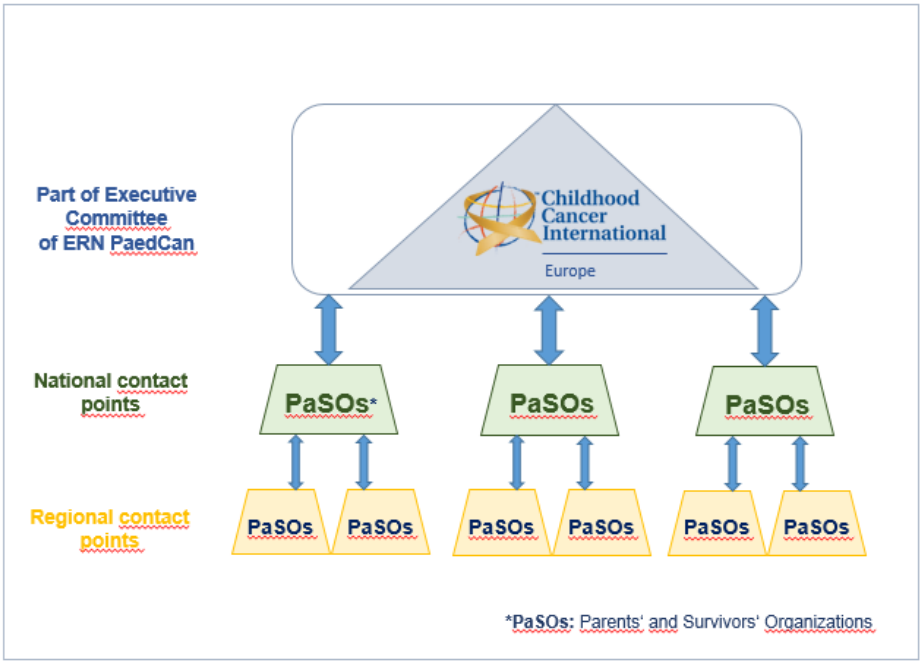
CCI Europe works closely with the medical and psychosocial professionals, researchers & scientists, civil society, private organizations and industry, aiming to help children and adolescents with cancer to be cured, with no – or as few as possible – long-term health problems / late effects.

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 has recently built a sub-network dealing with special tasks within the ERN PaedCan related to CBHC and advisory tumour boards. . 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.

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 CCIEurope members (CCI Europe Regional Committee) are the ePAG representatives for ERN PaedCan:

- **Anita Kienesberger**

Austrian Childhood Cancer Organization

- **Stephanie Schremmer**

Austrian Childhood Cancer Organization

- **Luisa Basset**

Federación Española de Padres de NIÑOS CON CÁNCER

- **Lejla Kamerić**

Heart for kids with cancer – Bosnia and Herzegovina

CCI Europe Regional Committee

2.2.5 Ethical Advisory Committee

The EAC is a non-executive body addressing ethical issues raised by the Oversight Committee (OC). It will be composed of external experts (approx. 3-4 EAC members) who will provide advice to the Oversight Committee and will be established in the first year of the project.

The EAC will ensure that the project adheres to ethical standards and will help to identify ethical issues related to ERN PaedCan activities. The EAC is expected to act proactively by identifying relevant issues. The EAC may deal with a broad range of ethical matters connected with specific societal ethical issues and activities related to, but

not limited to, cross-border healthcare and inequalities. The EAC may also study broader ethical and social issues, such as the protection of humans in research and the appropriate uses of biomedical technologies. The EAC will be invited to the biannual GA meetings.

2.2.6 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 will 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.

2.2.7 ERN PaedCan members

Currently, 57 members across 18 EU countries 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.

2.2.8 ERN PaedCan Affiliated Centres (AFCEs)

The European Commission is currently re-evaluating the terminology of affiliated centres and associated Healthcare Providers (HCPs).

So far affiliated centres were defined as healthcare providers that are connected with ERN PaedCan members (HCP) fulfilling certain requirements (i.e. they offer special services that are unavailable at the ERN Paedcan member site; this i.e. applies for proton therapy centres). Affiliated Centres have to obtain the national designation to be formally included in the network. Therefore, Affiliated Centres have to go through a certain process to be able to be accepted in the network.

2.2.9 2.2.8 ERN PaedCan Associated Centres (ASCEs)

Associated Centers (ASCEs) to the ERN PaedCan network were defined within ERN PaedCan as centers located most likely in widening (LHEAR) countries but having to yet reach the top level of expertise as compared HCP identified and approved in well-resourced member states. These sites are prone for twinning activities to elevate local standard in health care and research. They are likely to act as relay contact points for the respective countries to connect with ERN PaedCan qualified HOCS identified for their high-level of expertise to allow bringing advice and teaching capacities into LHEAR countries.

2.2.10 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 appropriate for ERN PaedCan. Reports will be handed over (through the online system) to CHEAFEA after each reporting period.
The EC also provides external evaluation of the ERN PaedCan network. 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 twice 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 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 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 and Quality Assurance 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 Support Office (RSO) including also SIOPE Office with its special task activities for ERN PaedCan.

Meetings: The NMT will meet face–to-face or in teleconference monthly. 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 Work Plan (in the SGA). 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 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. *It will s*ecure respect of Intellectual Property Rights (IPR) when needed and needs to report to the Oversight Committee and involve the OC at the strategic management level and resolve conflict on technical, financial and strategic issues**.**

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 of the Consumer´s Health and Food Executive Agency (CHAFEA)
- 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 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, which were defined in the Framework Partnership Agreement 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.

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

WP	Description
1	Roadmap – ERNPaedCan Roadmap (including 2 new sub-networks each year)
2	Patients and Survivors Organisation (PaSO) Integration - PaSO contact points identified in year 1 with further integration of national local PaSOs throughout the project

3	Virtual Tumour Board – Identify centers willing to integrate VTBs and monitor existing VTBs
4	Twinning Programme - Twinning Network Programmes established (at least 1 per year)- Final report on success of twinning programmes
5	Establishment of Survivorship Passport (SurPass) as a standard of care in Europe – SurPass integration in at least 1 MS
6	Knowledge sharing and dissemination - Dissemination and communication plan established in M6; dissemination continued throughout the project
7	Very Rare Cancers Integration in VTB
8	Best practice - Building capacity and knowledge in the VRT settings and aim to publish best practice guidance (at least 1 topic/year)
9	Training and capacity building – Movies, Webinars etc. and fellowship training

3.2 Management of Deliverables

According to the CHAFEA 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, CHAFEA must be informed (through the online exchange service) and Amendments to the project submitted.

The deliverables specifically under Management activities of ERN PaedCan are:

Table 2: Management deliverables

N°	Deliverable Title	D N°	WP leader	Delivery date
1	Quality Assurance Plan (QAP)	D1	CCRI	M6
2	Dissemination and Communication Strategy Plan	D2	CCRI partner SIOPE	M6
5	Internal evaluation report of project	D11	CCRI partner	M12
6	2 General Assembly meetings each year	D8	CCRI	M5, M11
7	Meeting Minutes and Presentation	D4	CCRI	M12
Additional management activities (not mentioned as specific deliverables)				
2	Annual Financial and Technical report	-	CCRI	M12
3	Financial Report & Questionnaire on impact	-	CCRI	M12
4	Grant Agreement Application opening Sept 2017 – Feb 2018	-	CCRI	M12

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 NM.

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 4 months the coordinator will request from every task performer a brief description 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.

3.3 The Ethics Advisory Committee (EAC)

It is planned to address previous members of the ENCCA Advisory Committee within the first project year to explore if they are willing to pursue this function for ERN PaedCan. Alternatively we will launch a call in our community to identify persons entitled to fulfil this role.

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.**
- OpenApp is developing the system and delivered a system for all 24 ERNs in July 2017 (System still needs to be adapted to the ERN specific needs)
- Sharing of clinical data, including medical imagery
- **Needs regular input for use** in the test phase in July

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
- Support the panel lead and overlook the processes
- Set up tumour board in the St. Anna hospital through the system (liaises with responsible personnel in the hospital; ensure upload of pictures, etc.)

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 must request access to the Platform

ERNPaedCan Internal communication support

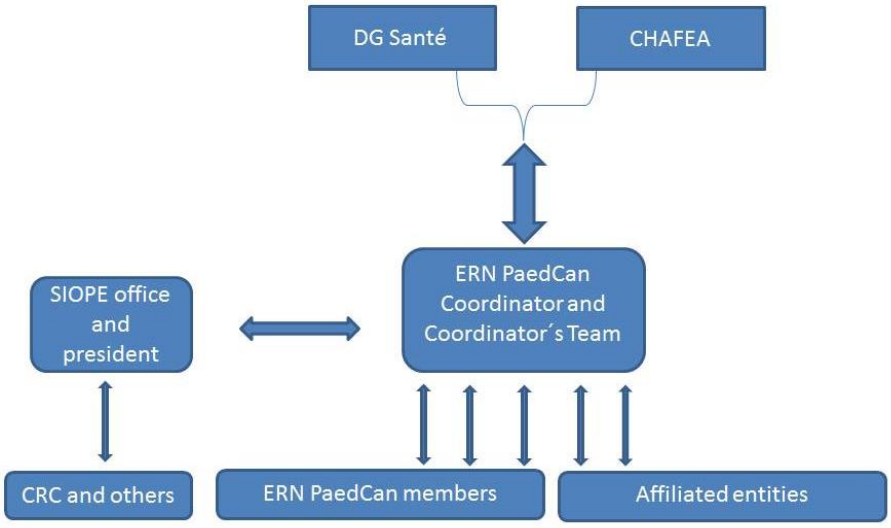
- Must accept/reject the persons applying for the platform
- Create new panels for discussion and upload necessary project related information
- Liaise with European Commission on a regular basis

4.3 ERN Teleconferences

Internally, information will be disseminated to project partners through meeting minutes and through regular TCs with relevant partners. Permanent communication will be maintained according to the specific needs of the ERN members through emails, teleconferences, and the ERN PaedCan website. The Executive Committee (including the NMT, AB and QAP) will additionally meet face-to-face or via teleconferences 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. The WebEx tool, which is provided by the European Commission free of charge, will be used as a main feature of communication in addition to the informal teleconferences.

4.4 Communication with Consumer´s Health and Food Executive Agency (CHAFEA)

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 two GA meetings 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 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 3: Overview of ERN PaedCan management body meeting schedules and convoking procedures

Meeting	Description and Frequency	Participants
GA	General Assembly (GA) meeting will take place 2 times a year	All ERN PaedCan Members, NMT & representation from the Oversight Committee
Best Practice Meeting	One best practice meeting will be held every year	Specialists for the discussed tumour entity (sub-network)
NMT meeting	NMT will meet once every month	NMT
Working meetings (WebEx)	Will be organised by the responsible roadmap developer in liaison with the NM	Coordinator´s Team and roadmap developer

NMT = Project Management Team, GA =General Assembly, HoC= Hubs of Coordination

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 4: 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 (WebEx)	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 5: 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.).

Table 6: 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 (WebEx)	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. Meeting minutes are ERN PaedCan deliverables.
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 ERN PaedCan consortium will create and carry out key communication actions addressed in WP6 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.

5.1 Key actions:

SIOPE will 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, together with the Network Manager will create 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
- 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 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 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
- 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 CD-ROMs, 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:

- 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., 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)

According to Article 27. 1.2 Information on EU funding – Information and right to use the EU Emblem unless CHAFEA 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:
"This [insert appropriate description, e.g. report, publication, conference, infrastructure equipment, insert type of result, etc.] was funded by the European Union's Health Programme (2014-2020)."

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 CHAFEA/European Commission is not liable for any use that may be made of the information contained therein.

5.8 Publications

Dissemination activities including but not restricted to publications and presentations shall 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 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.

6 Contractual Issues

6.1 Framework Partnership Agreement (FPA)

The Framework Partnership Agreement (FPA) is an agreement between the Consumer´s Health and Food Executive Agency (CHAFEA) acting under the powers delegated by the European Commission and the Children´s Cancer Research Institute (CCRI), which is the Coordinating institute of the ERN PaedCan. Through the FPA the long term cooperation (framework partnership) is guaranteed and terms and conditions as well as rights and obligations are also applicable to the specific grants that may be awarded for the specific actions under the framework partnership. Hence, two different agreements exist. Firstly the FPA, outlining the network and implementation of the action for the project duration of 60 months (cannot be extended) and a Specific Grant Agreement (SGA), which guarantees funding of the network for one year and needs to be applied for each year. The partner must respect objectives of the framework partnership and implement it as described in Annex 1 of the FPA. The SGA and the FPA contain important contractual information which will be outlined below.

The FPA is composed of:

Terms and Conditions
Annex 1 – Implementation Strategy
Annex 2 – Model Specific Agreement
- Annex 1 Description of the specific action
- Annex 2 Estimated budget for the specific action
- Annex 3 Model for the financial statements
- Annex 4 Model for the certificate on the financial statements (CFS)

The FPA enters into force after signature by the legal representative of the coordinating institution and CHAFEA (day of last signature).

6.2 Specific Grant Agreement (SGA)

The Specific Grant Agreement (SGA) is an agreement between the Consumer´s Health and Food Executive Agency (CHAFEA) and the Children´s Cancer Research Institute (CCRI). The duration of the specific action will be 12

months as of 1 March 2017. The ERN coordinator has the possibility to re-apply each year for additional funding of the network.

6.3 Acknowledgement of EU funding

It is specified in the grant agreement that any communication activity related to the specific actions (including at conferences, seminars, in information materials etc.) and any other infrastructure, equipment or major result funded by the specific grants must display the EU emblem and include the following text: *"This (insert description e.g. report, publication, conference, Infrastructure, equipment, insert type of result, etc.) was funded by the European Union´s Health Programme (2014-2020)."*

Any communication actively related to the specific action must indicate the following disclaimer:

"The content of this [insert appropriate description, e.g. report, publication, conference, infrastructure equipment, insert type of result, etc.] represents the views of the author only and it is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains."

6.4 Amendments

The FPA and the SGA may be amended, unless the amendment entails changes to the agreements which would lead to a question to the decision of awarding the special grants or framework partnership.

Amendments exclude the duration of the FPA or SGA.

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 agreements cannot be amended.

6.5 Sub-Contracting

The call for tender will ensure that the best possible choice was made (best value for money). 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 SGA. Additional sub-contractions might be added only if they are justified in the technical report and do not change the Specific Agreement.

The NMT will send the SGA and FPA to the sub-contractors to ensure that they comply with the Conflict of interest (Article 25), Confidentiality (Article 26) and roles and responsibilities towards the agency (Article 30).

7 Financial Aspects

The financial provision in ERN PaedCan will follow strictly the General Conditions agreed in the Grant Agreement. Costs are eligible within the duration of the action and 60 days after the end of the action if they are directly linked to the completion of the final report (i.e. staff costs, editing, printing the report etc.).

7.1 Pre-financing and payment of the balance

This project is a co-funding instrument with the reimbursement of 80% (EUR 200,000.00) of the eligible costs of the action, which are estimated at EUR 250,000.00). A pre-financing payment of 140,000.00 will be made either within 30 days after entry into force of the Specific Agreement or from 10 days before the starting date of the specific action, whichever is the latest.

The payment of the balance reimburses the remaining part of the eligible costs incurred by the partner for the implementation of the specific action. Payment is subject to approval of the final report and the amount is calculated by the Agency by deducting the total amount of pre-financing and already made from the final grant amount determined in accordance with Article 10 of the FPA.

The table below illustrates a general example of the payment fractions being applied by CHAFEA.

Table 7: Illustration of the payment procedures by CHAFEA

Co-funding by CHAFEA (80%)	**€ 200,000.00**
Total Budget	€ 250,000.00
Pre-financing payment (upon entry into force of the GA)	€ 140,000.00
Balance (after final report)	€ 60.000,00

Eligible costs must be declared under form of costs or cost forms for direct personnel costs, direct costs of sub-contracting and other direct costs. All these are stated as actual costs and have to meet the following criteria:

- Must be incurred by the CCRI (or sub-contracting partner);
- Must be incurred in the 12 months as outlined in the SGA (except costs related to submission of the final report);
- Must be indicated in the budget set out in Annex 1 of the SGA;
- Must be incurred in connection with the specific action and for its implementation;
- Must be identifiable and verifiable (through account records);
- Comply with the applicable national law on taxes, layout and social security,
- And they must be reasonable, justified and in line with a sound financial management (i.e. economy and efficiency)

These conditions must apply to direct personnel costs, direct costs of sub-contracting, other direct costs and indirect costs. (Indirect costs are costs not directly linked to the implementation and therefore cannot be attributed directly).

The table below highlights the eligible costs in the different budget categories.

Table 8: Outline of eligible costs per budget category

Category	**Eligible if…**
Direct Personnel costs	- **Related to the personnel working for the partner under an employment contract and assigned to the action** (costs for employees or equivalent). Costs must be limited to salaries, social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract.

	The partner may include additional remuneration for persons assigned to the specific action if it is part of the partner´s usual practice and paid In a consistent manner (regardless of the funding source) - Costs for **natural persons working under a direct contract with the partner other than an employment contract** or seconded by a third party against payment are eligible if the person worked under the partner´s instructions and the result of the work belongs to the partner and the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the partner
Direct costs of sub-contracting	- Including related duties, taxes and charges such as non-deductive value added tax (VAT) paid by the partner, if it is not a public body acting as public authority; - The partner is in line with the rules for sub-contracting (outlined in Article 8.1 SGA)
Other direct costs	- Travel costs and related subsistence allowances (related duties, taxes and charges such as non-deductive value added tax (VAT) paid by the partner, if it is not a public body acting as public authority) are eligible if they are in line with the usual partners practices of travel - Depreciation costs for equipment, infrastructure, or other assets are eligible if they were purchased in accordance with Article 7.1.1 of the SGA and written off in accordance with international and the partner's usual accounting practices. The costs of renting or leasing equipment, infrastructure etc. is also eligible if they do not exceed the depreciation costs of similar equipment and do not include any financial fees. (Proportion of costs taken into account is only the one related to the duration of the action and rate of actual use for the purpose of the action). - Costs of other goods and services paid by the partner if they are purchased specifically for the specific action and in accordance with Article 7.1.1 of the SGA (goods and services include for instance: consumables and supplies, dissemination, protection of results, certificates on the financial statements, translations, publications etc.
Indirect costs	- If declared on the basis of the flat-rate of 7% of the eligible direct costs

8 Reporting to CHAFEA

The ERN PaedCan Network Coordinator has the contractual obligation to prepare the periodic and final reports requested in Article 11 of the SGA. 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:

The specific action under the SGA has one reporting period from month 1 to month 12. For the whole project this would sum up to 5 reports.

8.2 Final Report to be submitted to CHAFEA:

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 to be submitted to CHAFEA 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 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 to be submitted to CHAFEA:

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. The individual financial statements must also detail all receipts of the specific action. Under FPA Article 10.3.3 all specific action´s total receipt are the consolidated total receipts generated during the duration. Receipts are income generated by the specific action and financial contributions given by third parties to the partner specifically to be used for costs that are eligible under the specific action.

Furthermore, the final financial report must state **an explanation of the use of resources and the information on subcontracting for the reporting period**. Furthermore a **final summary financial statement** will be created automatically through the electronic exchange system include the request for payment of the balance. 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 CHAFEA 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 at project start

- 57 ERN Members from 18 EU countries
- WP distributed, 12 Deliverables and 10 Milestones planned for a period of 5 years
- 5 final technical and financial reports, 5 internal reports (progress report from WP leaders and sub-contractors)

8.2.4 Timeline to submit reports and requests for a payment of balance to CHAFEA

In the below table the whole ERN PaedCan Reporting and is outlined (including financial cycle).

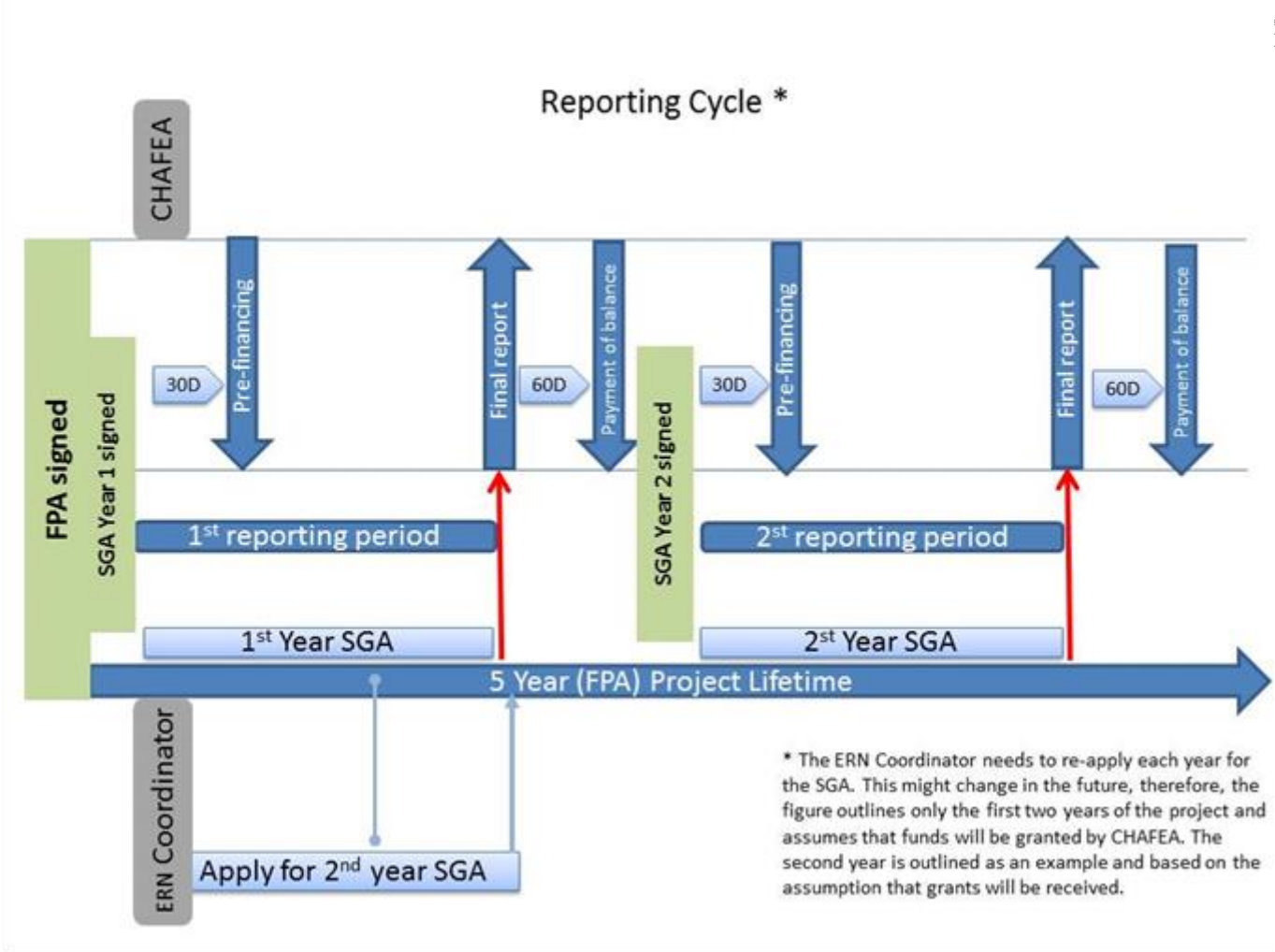


Figure 6: ERN PaedCan reporting cycle

As outlined in figure 6, periodic reports must be prepared and submitted within 60 days of the end of each reporting period. Since the SGA needs to be re-applied for each year and funding is subject of approval of the grant, the figure below outlines only the first two years as an example for the years to follow. The SGA procedure might be changed in the years to follow.
All templates necessary to deliver reporting material will be available on the website of CHAFEA. Apart from content on scientific development, sub-contractors will have to provide a detailed breakdown of costs incurred during the respective reporting periods 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 CHAFEA 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, CHAFEA has 60 days to evaluate and execute the corresponding payment.

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 (WebEx meetings);
- Every four months: Internal update on Progress of certain Deliverables; the NMT with the responsible WP Leader or sub-contractor (e-mail or WebEx); and
- General Assembly meetings: All WP leaders 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 (involved in the activities as outlined in Annex 1 of the SGA) and sub-contractor. This approach will facilitate enormously the internal reporting.

Partners involved in WP are will need to hand in their deliverables min. one month in advance to the ERN PaedCan Coordinator´s Team. The Coordinator´s Team needs to upload the deliverables in the Exchange platform of the EC.

8.3.2 Summary of Rights & Duties during reporting activities

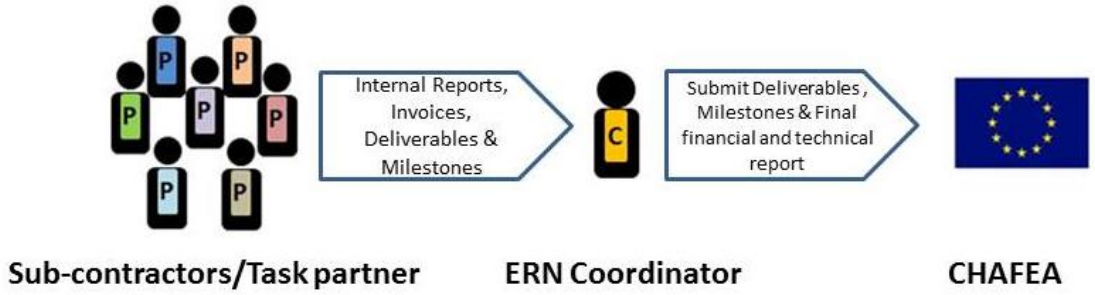


Figure 7: Summary of Rights & Duties during reporting activities

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 CHAFEA
- Provide clarifications, or any required additional information to the Project Officer (PO)
- Serve as an intermediary between the PO and all sub-contractors

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

8.4 Workflow for reporting in ERN PaedCan

Figure 8: Illustration of the reporting steps within ERN PaedCan