ERN-PAEDCAN Partner - Paediatric Rare Tumours Network - European Registry

(N°777336)

Quality Assurance Plan

D3.1 Quality Assurance Plan (QUAP) is completed

(Version 27.04.2018)

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1 Introduction

The Quality Assurance Plan (QAP) corresponds to the first deliverable of **Work package 3 - Evaluation of the project** (WP3), ***D3.1 Quality Assurance Plan (QUAP) is completed***, and to milestones ***MS5 Quality Assurance Plan (QUAP)*** and ***MS6 Evaluation Plan template is ready***, of project PARTNER. This QAP will outline the quality control (QC) and quality assurance (QA) of the project's work plan and the continuous process for improvement of the implementation of the project. The QAP will also outline the various activities, deliverables, milestones, roles and responsibilities of the project parties involved, to ensure the quality of the project's implementation processes and follow-up.

The QAP will refer to the contractual project documentation which outlines all rights and duties, commitments and agreed work plan to which all partners are legally bound. The QAP will mention and provide guidance for all documents and templates that support the implementation methodology of PARTNER.

The QAP will list the quality planning tools and metrics to be used on the project and the process for ensuring it adheres to the required standards and controls, risk management, reporting and amendment procedures. The tables indicated in the following sections will basically consist of the ***Evaluation Plan template*** to conduct the Evaluation Reports proposed under **Work package 3 - Evaluation of the project**.

2 Purpose

The QAP is inspired in the Grant Agreement and Consortium Agreement of project PARTNER but it is not a repetition of these documents. The major purpose of the QAP is to provide a broad overall framework and guidelines for implementing quality management on the project to ensure a successful execution of PARTNER. The audience of this plan is all PARTNER participants and the respective team members. This plan covers the period of time for the complete life cycle of PARTNER.

A realistic structure and approach to ensure a successful implementation of PARTNER implies:

Planning for Quality: Basic up-front planning process for ensuring that the achievement of quality objectives is met. The Annex 1 to the Grant Agreement N.777336 provides a detailed work plan and management structure to be followed. Changes of this plan will require an assessment of the activities' impact and, possibly, amendments.

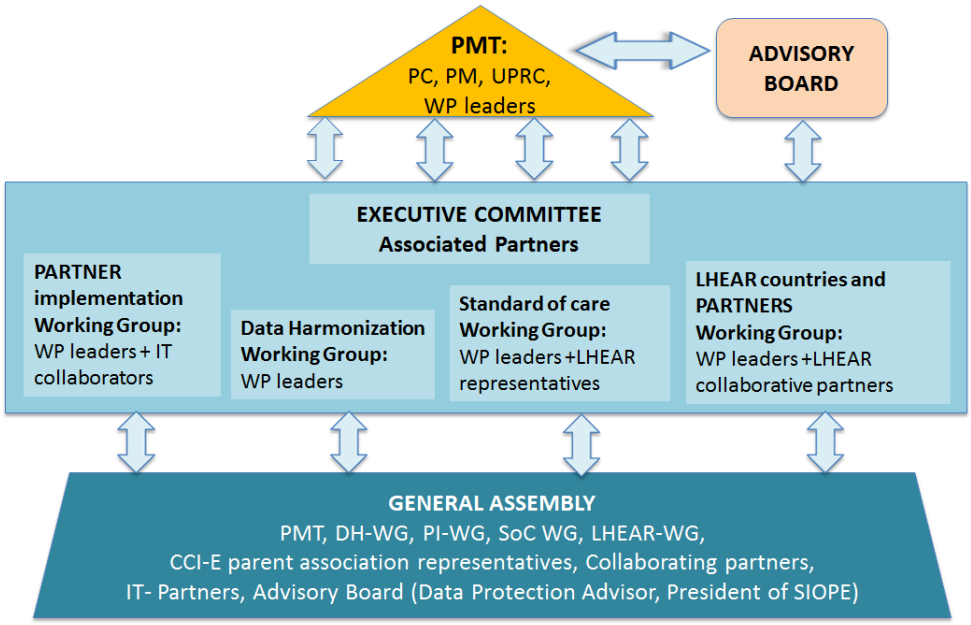
Establishing the Quality Assurance Framework*:* Ensure that appropriate methodologies, standards, procedures, and guidelines are implemented, with full management support.

***Perform Quality Control Activities**:* Ensure that quality is measured, monitored and deviations identified, along with performing appropriate corrective actions. To implement this procedure, a series of Output Indicators and respective targets will be described further in this document (for details see Section "*Performance Indicators and Targets*").

***Implementing corrective actions & Process Improvement**:* Ultimately the QAP will ensure that identified deviations are rectified, and that the chance of recurrence is minimized. Good quality standards in any project are achieved when all deliverables are produced:

- According to specifications and standards
- Free of defects or unintended consequences, or at least minimized
- That meet users' needs and expectations
- On time
- Within budget

3 Management structure and Roles



PMT = Project Management Team, PC = Project Coordinator, PM = Project manager Manager, CCI-E Childhood Cancer International - Europe

Figure 1. Management structure of project PARTNER

The coordinating Institution (AOPD) has a proven track record of administrative and financial management of large national and international projects; AOPD has participated to more than 40 International Projects, with 10 of them ongoing (project Coordinator in 2). The Unit "Progetti e Ricerca Clinica" (UPRC) is an AOPD structure dedicated to support research projects.

Project coordinator: Prof. Gianni Bisogno, may count on UPRC for the routinely monitoring of the projects' operative and financial implementation. Together they will manage all the coordinating activities including scientific and financial reporting, amendments, relation with partners, meetings organization. They will also assist the financial department in the budget management and distribution.

A ***Project Management Team*** including the project coordinator, UPRC representative, project manager and WP leaders will directly monitor all aspects of project implementation and the status of deliverables and milestones, as illustrated below in ***Figure 1*** – *Management structure of project PARTNER.*

During project implementation every important issue involving decision-making will consider the single vote of each associated partner.

AOPD will work in close collaboration with the ERN PaedCan Coordinator (CCRI) that has a successful experience in EU projects managements dedicated to paediatric oncology (ENCCA, ExPO-r-Net). CCRI will be fundamental to connect this project with ERN activities. Additionally, Associated partners are well-established organizations with experience in multinational projects.

3.1 List of Beneficiaries and Contacts

N°	Name	Short name	Country	Project entry month	Project exit month
1	**Azienda Ospedaliera Di Padova** Gianni Bisogno (Coordinator) gianni.bisogno@unipd.it Serena Mancini (Project Manager) serena.mancini@aopd.veneto.it	AOPD	Italy	1	36
2	**St. Anna Kinderkrebsforschung** Ruth Ladenstein (ERN-PAEDCAN coordinator) ruth.ladenstein@ccri.at Karoline Noworyta (ERN-PAEDCAN manager) karoline.noworyta@ccri.at Nuno Andrade nuno.andrade@ccri.at	CCRI	Austria	1	36
3	**Klinikum Dortmund Ggmbh** Dominik Schneider (Person-in-charge) Dominik.Schneider@klinikumdo.de Esther Münstermann Esther.Muenstermann@klinikumdo.de Nadine Tietsch Nadine.Tietsch@klinikumdo.de	KlinikumDo	Germany	1	36
4	**Eberhard Karls Universitaet Tuebingen** Ines Brecht Ines.Brecht@med.uni-tuebingen.de Susanne Stoppel susanne.stoppel@med.uni-tuebingen.de Clemens Lässing clemens.laessing@med.uni-tuebigen.de	EKUT	Germany	1	18
5	**Institut Curie** Daniel Orbach daniel.orbach@curie.fr Emily Juillot emily.julliot@curie.fr	CURIE	France	1	36
6	**Gdanski Uniwersytet Medyczny** Ewa Bien ebien@gumed.edu.pl Teresa Stachowicz-Stencel tsten@gumed.edu.pl	GUMed	Poland	1	36

3.1 List of Collaborating stakeholders

The table below lists the **collaborating stakeholders** that will provide strategic support in the achievement of the objectives proposed by project PARTNER. These collaborators have supported their commitment to the project by signing Letters of Commitment.

Institution	Contact person (First name and last name)	City & Country
1. Istituto Nazionale per la Cura dei Tumori	Andrea Ferrari	Milano, Italia
2. Royal Manchester Children's Hospital	Bernadette Brennan	Manchester, United Kingdom
3. Hospital Universitario Cruces	Ricardo Lopez	Baracaldo (Vizcaya), Spain
4. University Medical Centre	Maja Cesen	Ljubljana, Slovenia
5. Clinical Hospital Centre	Jelena Roganovic	Rijeka, Croatia
6. University Children Hospital	Alexandra Kolenova	Bratislava, Slovakia
7. University Hospital Santariskiu Klinikos	Jelena Rascon	Vilnius, Lithuania
8. University Children's Hospital	Kata Martinova	Skopje, FYR Macedonia
9. Hospital Luis Calvo Mackenna	Milena Villarroel	Santiago, Chile
10. Sahlgrenska University Hospital	Gustaf Osterlundh	Goteborg, Sweden
11. Hellenic Society Pediatric Haematology Oncology	Apostolos Pourtsidis	Athens, Greece
12. Childhood Cancer International Europe (CCI)	Anita Kienesberger	Wien, Austria
13. CHU de Saint Denis	Yves Reguerre	Saint Denis, La Réunion, France
14. Hadassah University Hospital	Tal Ben Ami	Jerusalem, Israel
15. Marciniak Hospital	Jan Godzinski	Wroclaw, Poland
16. Institute of Oncology	Monica Désirée Dragomir	Bucharest, Rumania
17. Institutul Oncologic "Ion Chiricuta"	Rodica Cosnarovic	Cluj-Napoca, Rumania
18. University Children Hospital	Dragana Janic	Belgrade, Serbia

4 Consortium Meetings

A **kick-off meeting** will be organized in month 1; participants will receive an informative package including a project overview, schedules, reporting and financial guidelines and templates. Thereafter, Consortium Meetings will be organized every **6 months** to support an effective project implementation.

Any Party which is a member of a PARTNER Consortium Body should be present or represented at any meeting; may appoint a substitute or a proxy to attend and vote at any meeting; and shall participate in a cooperative manner in the meetings.

Convening meetings

The chairperson of a Consortium Body shall convene meetings of that Consortium Body.

Meeting type	Ordinary meeting	Extraordinary meeting
General Assembly	At least once a year	At any time upon written request of the Executive Committee or 1/3 of the Members of the General Assembly
Executive Committee	At least twice a year	At any time upon written request of any Member of the Executive Board

Notice of a meeting and sending the agenda

The chairperson of a Consortium Body shall **give notice** in writing of a meeting to each Member of that Consortium Body as soon as possible and no later than the minimum number of days preceding the meeting as indicated below.

The chairperson of a Consortium Body shall prepare and send each Member of that Consortium Body a written **agenda** no later than the minimum number of days preceding the meeting as indicated below.

Meeting type	Ordinary meeting	Extraordinary meeting	Sending the agenda
General Assembly	45 calendar days	15 calendar days	21 calendar days, 10 calendar days for an extraordinary meeting
Executive Committee	14 calendar days	7 calendar days	7 calendar days

Table 1. Table template of PARTNER consortium meetings.

Reporting Period covered: *dd/mm/yyyy* to *dd/mm/yyyy*

Meeting title	Date	N° of participants	Type of audience	Status[1]
Kick-off meeting				
2nd Consortium meeting				
3rd Consortium meeting				
4th Consortium meeting				
5th Consortium meeting				
6th Consortium meeting				
Final Consortium meeting				
			Assessment date	

[1] Accomplished, not accomplished, partially accomplished.

5 Financial management

The individual budgets within the consortium have been negotiated in detail and reflect the needs and charge of responsibilities from each partner. Individual budgets were defined according to cost categories that each participant has to finance in order to accomplish their proposed tasks within specific work packages.

The unit “Progetti e Ricerca Clinica” (UPRC) in coordination with the Financial Department of the coordinator, which utilises certified financial tools, will perform the budget monitoring and distribution. Direct individual communication with a project partner is established whenever necessary. All administrative and financial activities are recorded and stored as defined by law.

Additionally, the Project Management Team will constantly monitor the budget status and an overview will always be presented twice a year in the consortium meetings. This will offer participants and advisors the opportunity to analyse the financial status of the project and, if necessary, make decisions for adjustments.

In addition to the consortium meetings, general communication about scientific and financial aspects between the Project Management Team and any participant with an issue to be addressed will be kept through teleconferences, emails and specific meetings on demand.

5.1 Payments

As defined in the Consortium Agreement, **payments to Parties are the exclusive tasks of the Coordinator.** In particular, the Coordinator shall:

- Notify the Party concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references;
- Perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts;
- Undertake to keep the Funding Authority’s financial contribution to the Action separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.
- With reference to Articles 15 and 16 of the Grant Agreement, no Party shall before the end of the Action receive more than its allocated share of the maximum grant amount from which the amounts retained by the Funding Authority for the Guarantee Fund and for the final payment have been deducted.

The payment schedule, which contains the transfer of pre-financing and interim payments to Parties, will be handled according to the following:

- Funding of costs included in the Consortium Plan will be paid to Parties after receipt from the Funding Authority without undue delay and in conformity with the provisions of the Grant Agreement. Costs accepted by the Funding Authority will be paid to the Party concerned.

- The Coordinator is entitled to withhold any payments due to a Party identified by a responsible Consortium Body to be in breach of its obligations under this Consortium Agreement or the Grant Agreement or to a Beneficiary which has not yet signed this Consortium Agreement.
- The Coordinator is entitled to recover any payments already paid to a Defaulting Party. The Coordinator is equally entitled to withhold payments to a Party when this is suggested by or agreed with the Funding Authority.

Table 2 below will support the internal evaluation reports in the monitoring of the project budget consumption.

Table 2. Consumption of the PARTNER budget.

Reporting Period covered: *dd/mm/yyyy* to *dd/mm/yyyy*

Participant	Total costs	EC co-fund rate (%)	EC Budget	Budget consumed 1RP[2]	Budget consumed 3RP[2]	Budget consumed 3RP[2]
1 AOPD	279.320,29	60%	167.592,00			
2 CCRI	79.211,03	60%	47.526,00			
3 KlinikumDo	34.818,87	60%	20.891,00			
4 EKUT	107.893,45	60%	64.736,00			
5 CURIE	81.855,00	60%	49.113,00			
6 GUMed	83.545,60	60%	50.127,00			
Totals	666.644,24	60%	399985,00			
					Assessment date	

[2] Indicate accumulated consuption of the budget as a percentage of the total budget.

6 Quality Assurance of Work packages, Deliverables, and Milestones

The tables below indicate the Work packages, Deliverables, and Milestones of PARTNER, and will also serve as templates to **monitor the performance** of the project and to deliver the Evaluation Reports of the project.

6.1 Work packages

Reporting Period covered: *dd/mm/yyyy* to *dd/mm/yyyy*

WP Number	WP Title	Lead beneficiary	Start month	End month	Status[3]
WP1	Coordination of the project	1 - AOPD	1	36	
WP2	Dissemination of the project	2 - CCRI	1	36	
WP3	Evaluation of the project	2 - CCRI	1	36	
WP4	Analysis and harmonization of data acquisition of the existing national VRT registries	4 - EKUT	1	18	
WP5	Creation of a European registry for paediatric patients with very rare tumours	1 - AOPD	1	36	
WP6	Standard of care recommendations for children with VRT	5 - CURIE	1	36	
WP7	Integration of LHEAR countries in a EU platform dedicated to VRT in paediatric age	6 - GUMed	1	36	
				Assessment date	

[3] Status can be indicated as: ***on time***, ***delayed***, ***achieved, or partly achieved***.

6.2 Deliverables

Reporting Period covered: *dd/mm/yyyy* to *dd/mm/yyyy*

Deliv. N°	Deliverable Title	WP N°	Lead beneficiary	Type	Due date	Status[4]	Justification of delay(s) and Corrective measure(s) *(if applicable)*
D2.1	Dissemination & Communication plan established.	WP2	2 - CCRI	Report	3		
D2.2	Leaflet.	WP2	2 – CCRI	Other	3		
D2.3	Project website launched.	WP2	2 – CCRI	Websites, patents filling, etc.	3		
D2.4	Layman version of the final report.	WP2	2 - CCRI	Report	36		
D3.1	Quality Assurance Plan (QUAP) is completed.	WP3	2 - CCRI	Report	3		
D3.2	Preparation of the Interim Report.	WP3	2 - CCRI	Report	18		
D3.3	Preparation of the final Evaluation Report.	WP3	2 - CCRI	Report	36		
D4.1	Gathering of VRT entities and variables of national registries and preparation of consensus core data sheet for with entities and variables for European data base.	WP4	4 - EKUT	Other	12		
D4.2	Report and recommendations on harmonized procedures of primary source data verification, registration and documentation.	WP4	4 - EKUT	Report	18		
D4.3	List of variables that will be selected to link the	WP4	4 - EKUT	Other	18		

[4] Status can be indicated as: ***on time***, ***delayed***, ***achieved, or partly achieved***.

	PARTNER to the virtual consultation system.						
D5.1	Report on the operative status of the registry structure.	WP5	1 - AOPD	Other	34		
D6.1	List of VRT that need standard of care elaboration.	WP6	5 - CURIE	Other	6		
D6.2	Development of standard of care recommendations for paediatric very rare tumours.	WP6	5 - CURIE	Other	36		
D7.1	Report describing the results of the EU survey.	WP7	6 - GUMed	Report	16		
D7.2	Creation of a manual (in English and local language) to access the virtual consultation system and the PARTNER VRT platform.	WP7	6 - GUMed	Other	34		
						Assessment date	

6.3 Milestones

Reporting Period covered: *dd/mm/yyyy* to *dd/mm/yyyy*

Mile. N°	Milestone Title	WP N°	Lead beneficiary	Due date	Means of verification	Status[5]	Justification of delay(s) and Corrective measure(s) *(if applicable)*
MS1	Kick-off meeting will be organized.	WP1	1 - AOPD	1	Organisation of kick-off meeting with all stakeholders.		
MS2	Consortium meetings.	WP1	1 - AOPD	36	Every 6 months Consortium meetings are organised to address the progress of the project.		
MS3	PARTNER logo available.	WP2	2 - CCRI	3	PARTNER logo available.		
MS4	PARTNER communication tools available.	WP2	2 - CCRI	6	PARTNER communication tools available.		
MS5	Quality Assurance Plan (QUAP).	WP3	2 – CCRI	3	Quality Assurance Plan (QUAP).		
MS6	Evaluation Plan template is ready.	WP3	2 - CCRI	6	Evaluation Plan template is ready.		
MS7	Consensus meeting on entities and variables to be collected within PARTNER.	WP4	4 - EKUT	12	Consensus meeting on entities and variables to be collected within PARTNER.		
MS8	List of duties for IT partners.	WP4	4 - EKUT	18	List of duties for IT partners.		
MS9	Development of the International Registry structure	WP5	1 - AOPD	12	Development of the International Registry structure.		
MS10	Development of the EUPID application and integration in the national registry.	WP5	1 - AOPD	18	Development of the EUPID application and integration in the national registry.		

[5] Status can be indicated as: ***on time***, ***delayed***, ***achieved, or partly achieved***.

MS11	User manual is defined.	WP5	1 - AOPD	24	User manual is defined.		
MS12	Established VRT standard of care working group.	WP6	5 - CURIE	3	Established VRT standard of care working group.		
MS13	European consensus meeting for VRT standard of care.	WP6	5 - CURIE	36	European consensus meeting for VRT standard of care.		
MS14	Creation of a VRT Working Group for LHEAR countries.	WP7	6 - GUMed	3	Creation of a VRT Working Group for LHEAR countries.		
MS15	Elaboration and circulation of a VRT questionnaire for LHEAR countries.	WP7	6 - GUMed	10	Elaboration and circulation of a VRT questionnaire for LHEAR countries.		
MS16	Full Integration of PARTNER in the SIOPE communication plan and tools.	WP2	2 - CCRI	6	In order to achieve maximum reach, full integration of PARTNER in the SIOPE communication plan and tools is expected.		
MS17	Linkage of the EU VRT to the virtual consultation system.	WP5	1 - AOPD	30	Linkage of the EU VRT to the virtual consultation system.		
MS18	Registry structure fully operative.	WP5	1 - AOPD	34	Registry structure fully operative.		
MS19	Dedicated access to the PARTNER for selected LHEAR countries.	WP7	6 - GUMed	34	Dedicated access to the PARTNER for selected LHEAR countries.		
						Assessment date	

6.4 Critical Implementation risks and mitigation actions

Reporting Period covered: *dd/mm/yyyy* to *dd/mm/yyyy*

Risk N°	Description of risk	WP N°	Proposed risk-mitigation measures	Did risk materialized?	Mitigation measures applied?
1	Management risk.	WP1	PMT will prepare a risk analysis and agree on contingency plan at the beginning of the project.		
2	Different opinion between national groups.	WP4, WP5, WP7	National groups will agree a decision making process at the beginning of the project.		
3	Presence of nonhomogeneous data in the national registries.	WP4	Data will homogenised at a national level before they will be transferred to PARTNER.		
4	Impossibility to reach consensus on standard of treatment for certain VRTs.	WP6	A process to reach consensus will be defined. If consensus would be impossible this will be clearly reported in the final documents.		
5	Differences in the regulation of registries and data transferring in the different countries.	WP5, WP7	Data pseudonymization will allow overcoming these problems.		
6	Lack of effective IT system interoperability.	WP5, WP7	IT partners should demonstrate the effective interoperability of the systems before starting their work.		
7	Lack of resources for LHEAR to participate to PARTNER.	WP7	No or very low costs will be asked to LHEAR countries to access VRT platform and PARTNER LHEAR countries. In addition involvement of LHEAR countries will be progressive according to their resources.		
				Assessment date	

6.5 Gantt Chart

	Year 1												Year 2												Year 3													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
WP1	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36	M37	M38
Task 1.1																																						
Task 1.2																																						
Task 1.3	K						BA						BA						BA						BA						BA					FA		
Task 1.4																																						
WP2	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36	M37	M38
Task 2.1						M																																
Task 2.2			M																																		
Task 2.3																																						
Task 2.4																																						
Task 2.5																																						
WP3	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36	M37	M38
Task 3.1			M																																		
Task 3.2						M																																
Task 3.3																																						
Task 3.4																																						
WP4	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36	M37	M38
Task 4.1																																						
Task 4.2												M																										
Task 4.3																		M																				
Task 4.4																																						
WP5	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36	M37	M38
Task 5.1												M												M														
Task 5.2																		M																				
WP6	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36	M37	M38
Task 6.1			M																																		
Task 6.2																																						
Task 6.3																																				M		
WP7	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36	M37	M38
Task 7.1			M																																		
Task 7.2										M																												
Task 7.3																																						
Task 7.4																																						

Legend: K = Kick-off meeting; BA = Biannual meeting; FA = Final meeting; M = Milestone

7 Specific objectives of the project and Performance metrics

The tables below indicate all the seven specific objectives of PARTNER, and will also serve as templates to monitor the performance of the project and to deliver the Evaluation Reports of the project.

The **achievement status** should be **described as *ongoing, achieved, or partly achieved.***

Reporting Period covered: *dd/mm/yyyy* to *dd/mm/yyyy*

Specific Objective 1 Effective project coordination and management in order to timely achieve the project objectives		
Process Indicator(s)	**Target**	**Achievement status**
• Regular teleconferences with the project management team (PMT) including the project coordinator, UPRC representative, project manager and WP leaders every other month or at least quarterly starting Month 1 • Creation of a meeting calendar by Months 2 • Organisation of regular working meetings • Organisation of biannual meetings including all relevant share and stakeholders • Preparation of Interim and Final reports for Months 12, 24, 36	- TCs of PMT scheduled	
	- Project meeting agenda agreed	
	- Meetings of network's partners - arranged and achievements documented (agenda, minutes, presentations).	
	- Respective reports available as scheduled	
Output Indicator(s)	**Target**	**Achievement status**
• Scheduled meetings • Preparation of Interim and Final reports	- >90% achieved according to proposed schedules	
	- Successful report deliveries on target	
Outcome/Impact Indicator(s)	**Target**	**Achievement status**
• Consortium meetings	- 2 per year	
	Assessment date	

Specific Objective 2 Dissemination of the project		
Process Indicator(s)	**Target**	**Achievement status**
• Definition of a dissemination and communication plan to promote PARTNER and facilitate communication towards all target groups in collaboration with National Paediatric Haematology – Oncology Societies (NAPHOs) during months 1 to 3	- Dissemination &communication plan established by Month 3	
Output Indicator(s)	**Target**	**Achievement status**
• Creation of the project kit including logo, dedicated brochure, templates, 1-page factsheet and presentation for project partners during Months 1 to 6 . • Integration of PARTNER in the EXPeRT public website & SIOPE Intranet	- Complete project kit available by Month 6	
	- Project website integration by Month 8	
Outcome/Impact Indicator(s)	**Target**	**Achievement status**
• PARTNER newsletter disseminated via emails and integrated in the SIOPE newsletter	- 2 newsletters per year	
	Assessment date	

Specific Objective 3 Evaluation of the project		
Process Indicator(s)	**Target**	**Achievement status**
• Creation of the Quality Assurance Plan outlining the activities and the organisational and management structure of PARTNER guiding the successful implementation of the project (Months 1-3)	- QAP developed and implemented	
Output Indicator(s)	**Target**	**Achievement status**
• Surveillance of project management and internal processes – on target evaluation of Deliverables and Milestones. • Solution-based monitoring and evaluation processes via written feedback to project partners for corrective action, (monitor-review-remedy model). Indicators will include frequency of deadlines being met to deliver reports; participation in meetings and telephone conferences; and internal audit of project targets and resolution of problems. • Questionnaires to allow systematic appraisal of the quality of the project assessing the utility of project outcomes to meet user needs. (Questionnaires to healthcare professionals, patients and families, policy makers will be approached with questionnaires, to evaluate the utility and progress of the project outcomes • Systematic appraisal of the effects of the project. Here Measures will include assessment of public dissemination (on-line review of e-media), impact on public policy documents.	- >80% of Deliverables and MS on target	
	- >80% of actions on target	
	- >80% of questionnaires send returned within 3 months	
	- At least 2x year documented dissemination activity	
Outcome/Impact Indicator(s)	**Target**	**Achievement status**
• Quality Assurance Plan (QUAP) (preparation phase M1-3) • Interim Evaluation Report (preparation phase M12-17, delivered in M18) • Final evaluation report (preparation phase M30-35, delivered in M36)	- QAP and evaluation reports available at target times showing successful project implementation	
	Assessment date	

Specific Objective 4 Analysis and harmonization of data acquisition of the existing national VRT registries		
Process Indicator(s)	**Target**	**Achievement status**
• Identification and agreements within project participants of VRT entities and variables to be included in PARTNER. • Harmonization of data definition and quality among the different national registries. • Definition of list of variables that will be selected for transfer from the Virtual Consultation system into the PARTNER database.	- 100% agreement within the partners by M12	
Output Indicator(s)	**Target**	**Achievement status**
• Preparation of a document containing the VRT candidates and variable included in the national registries during M2 to 6.	- List of VRT and variables documented by national registries by M6	
• Preparation of core data sheet for with variables and entities to be transferred and prospectively registered by the PARTNER (preparation during M6 to12)	- Agreed core data-sheet for PARTNER by M12	
Outcome/Impact Indicator(s)	**Target**	**Achievement status**
• Preparation of a report and recommendations for harmonization of data verification, registration and documentation during M12- 18	- Report on harmonization procedures between data registries by M18.	
	Assessment date	

Specific Objective 5 Creation of a European registry for paediatric patients with very rare tumours		
Process Indicator(s)	**Target**	**Achievement status**
• Create the registry infrastructure based on the core data set identified in WP4 (M12 to 18) with EUPID as an integral part • Integrate EUPID to respective national registries of France, Germany, Italy and Poland (M12-18) • Connect the virtual consultation system (VCS) to PARTNER using the EUPID system (M18- 24) • Define access modality to PARTNER for countries without national registries during above cited developments and time periods	- PARTNER infrastructure established	
	- EUPID applied retropsectivly and for prospective use in respective registries	
	- VCS and PARTNER connected by Month 24	
	- LHEAR access modality to PARTNER defined	
Output Indicator(s)	**Target**	**Achievement status**
• Development of the EUPID application to provide interoperability between national registries and PARTNER for data transfer and regular future updates (M18- 24) followed by the implementation test phase (data transfers M24 – 30) and corrective measures M30 to 34)	- Integration of all national registries achieved by M32 and PARTNER fully operable and live by M36	
Outcome/Impact Indicator(s)	**Target**	**Achievement status**
• Final report by M36 describing the scope of PARTN- ER and data included in the newly established EU VRT – (PARTNER) registry with full interoperability and the potential to be linked with the EU proposed IT platform for ERNS as needed.	- Final Report ready on the successful PARTNER development	
	Assessment date	

Specific Objective 6 Elaboration of Standard of care recommendations for children with VRT		
Process Indicator(s)	**Target**	**Achievement status**
• Identification of VRT entities without standardized recommendations and evaluation of available evidence for harmonization of recommendations by M6	- VRT entities identified qualifying for standardized recommendations	
Output Indicator(s)	**Target**	**Achievement status**
• Preparation of harmonized recommendations and discussion with international external partners (e.g. ERN EUROCAN in Europe and Children's Oncology Group in USA) during M12 to 24.	- Consensus meeting on harmonized recommendations for selected VRT	
Outcome/Impact Indicator(s)	**Target**	**Achievement status**
• Preparation of publication of consensus recommendations on 2 entities in peer reviewed journals and distribution through the project website (M25 to 35).	- Successful publication or at least acceptance of 2 new VRT consensus recommendations by M36	
	Assessment date	

Specific Objective 7 Integration of LHEAR countries in a EU platform dedicated to VRT in paediatric age		
Process Indicator(s)	**Target**	**Achievement status**
• Development and circulation of a dedicated questionnaire to identify LHEAR countries with and without pre-existing national institutional VRT data collection or registries to understand their special needs for support given their less favourable economic situation during M2 to 10.	- 80% of LHEAR questionnaires received back by Month 10	
Output Indicator(s)	**Target**	**Achievement status**
• Letters of commitment of LHEAR countries with and without pre-existing structures to feed or use the PARTNER received by M12	- 80% of LHEAR countries committed by M12	
Outcome/Impact Indicator(s)	**Target**	**Achievement status**
• Preparation of report describing the results of the LHEAR countries' questionnaires during M10 to 14. • Creation of a manual in different languages explaining how to use the virtual consultation system and how to access and use the new VRT PARTNER platform starting M12 for VCS and for registry in M30. • Translations in LHEAR language of standard of care recommendations for VRT during M30 - 36 to inform also the wider non- expert audience (patients and families) • Creation and implementation of a dedicated access to the newly established PARTNER VRT registry for selected LHEAR countries by M28- 32	- LHEAR questionnaire report completed by M16	
	- Manual translated in at least 3 different languages by M34	
	- At least 2 standard of care recommendations translated in at least 3 languages by M36	
	- At least 2 LHEAR countries operative and successfully accessing the PARTNER platform by M34	
	Assessment date	

8 Dissemination

PARTNER has its own **Dissemination and Communication Strategy Plan**, which has been delivered with the expertise of the subcontractor the European Society for Paediatric Oncology (SIOPE). SIOPE is a natural collaborator regarding dissemination to maximise the project visibility. Indeed, SIOPE is the sole pan-European network of paediatric oncology professionals active at EU level, with over 1,600 members in some 35 countries and established relations with actors representing all project target groups including policy makers and parents, patients and survivors.

This QAP will not repeat the content of the Dissemination and Communication Strategy Plan, but it will support the monitoring of its implementation by collecting performance metrics indicated in the table in the following page.

Table 3. Dissemination performance by project reporting period.

Reporting Period covered: *dd/mm/yyyy* to *dd/mm/yyyy*

Dissemination categories	List all relevant events and/or items and respective involved project partners	Status[6]
Websites, newsletters, and social-media	-	
External workshops and conferences	-	
Internal consortium meetings	-	
PARTNER publications (scientific, clinical, lay public, etc.)	-	
		Assessment date

[6] Status can be indicated as: ***dissemination according to plan, dissemination below expectations, dissemination above expectaion***.