BABYLUX

Programme	CIP – Competitiveness for innovation
Type of Action	Pilot B
Project Title	An optical neuro-monitor of cerebral oxygen metabolism and blood flow for neonatology
Acronym	BabyLux
Project n.	620996

D1.1 PROJECT MANAGEMENT PLAN

Work Package	WP1
Lead Partner	FPM
Contributing Partner(s)	ALL
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1 Executive summary

This deliverable provide an overview of the BabyLux project and illustrates how it is coordinated: it describes the governance, the organizational structure and the collaboration processes and tools, adopted in order to fully support the project activities and to ensure the achievements of the BabyLux objectives.
The Project Management Plan includes the main targets to be achieved within the first year as well as an estimation of the effort necessary per workpackage and partners in the same period.
Moreover, it presents the strategies to monitor and control the progress and quality of the on-going project activities. It provides guidelines and principles that ensure a high quality delivery of the BabyLux project throughout its lifetime.
Finally, it contains a section devoted to risk management, which introduces the procedures and the tools adopted for this activity and a detailed list of the risks currently identified and assessed, together with the related remedial action.
This document reflects the current organization, strategy and plans defined by the BabyLux Consortium; further development and update will be incorporated in the next Project Management reports.

2 Introduction

The present document intends to make explicit and further develop and detail the project management organization as it appears in the Description of Work (DoW). It deals with all practical aspects of the management of the project.
The document will be updated yearly and in general according to the needs during the lifetime of the BabyLux project.

3 Project Overview and Workflow

3.1 Project overview

The BabyLux project aims to provide a precise, accurate and robust integrated system to continuously monitoring cerebral oxygen metabolism and blood flow in critically ill newborn babies. Over the last two decades, the percentage of preterm births in the Western hemisphere rose by 20%. During early stages of brain development, injury from lack of blood flow and oxygen delivery may induce cognitive and physical handicaps. In fact, preterm births now account for a significant portion of children with cerebral palsy and cognitive, visual, and hearing impairments. A non-invasive, continuous, cot-side monitor of cerebral oxygen metabolism and blood flow is an unfilled niche in clinical care. The project takes up complete R&D works and extends already tested prototypes to the level of demonstrator, bridging the gap between research products and commercialization. The system uses photonic technologies (diffuse correlation spectroscopy, DCS, and time resolved near-infrared spectroscopy, TRS) to non-invasively and safely measure cerebral oxygen metabolism and blood flow. This innovative combination provides the state-of-the-art in accuracy and robustness in TRS, and introduces, for the first time, DCS in a combined instrument. The instrument will first undergo a demonstration phase in laboratory settings and later an operational phase in real-life settings, conducted in parallel in two public hospitals of two different countries. The advantages of the proposed system will be evaluated by professional end-users during validation tests carried out in conditions fitting in the clinical workflow, protocols and procedures. Dissemination and exploitation activities will promote accelerated acceptance and wider deployment of the proposed biophotonic solution. The BabyLux consortium gathers service content providers (physicists and engineers for biophotonic applications), professional end-users (neonatologists), and SMEs (photonic components producer, medical device manufacturer).

The list of the entities composing the consortium are reported in Table 1 Beneficiaries.

	Part. Organisation Name	Part. short name	Part. acronym	Country
1	POLITECNICO DI MILANO	POLIMI	PoliMi	Italy
2	FONDAZIONE POLITECNICO DI MILANO	FPM	FPM	Italy
3	FUNDACIO INSTITUT DE CIENCIES FOTONIQUES	ICFO	ICFO	Spain
4	FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V	Fraunhofer	IPT	Germany
5	HEMOPHOTONICS SL	HEMOPHOTONICS	HP	Spain
6	PicoQuant GmbH	PQ	PQ	Germany
7	COMPETITIVE NETWORK S.L.	Loop Business Innova	Loop	Spain
8	REGION HOVEDSTADEN	REGIONH	RH-Neo	Denmark
9	FONDAZIONE IRCCS CA' GRANDA - OSPEDALE MAGGIORE POLICLINICO	FONDAZIONE IRCCS CA'	IRCCS Ca' Granda	Italy

Table 1 Beneficiaries

3.2 Project structure

The project is composed by seven blocks of activities, namely workpackages:

WP 1 Project management
WP 2 Service integration
WP 3 Service demonstration in laboratory settings
WP 4 Service localisation
WP 5 Service demonstration in real-life settings
WP 6 Dissemination
WP 7 Exploitation and standardisation

The Figure 1 - Project structure illustrates the main dependencies among the workpackages, providing an overview of the flow of activities.

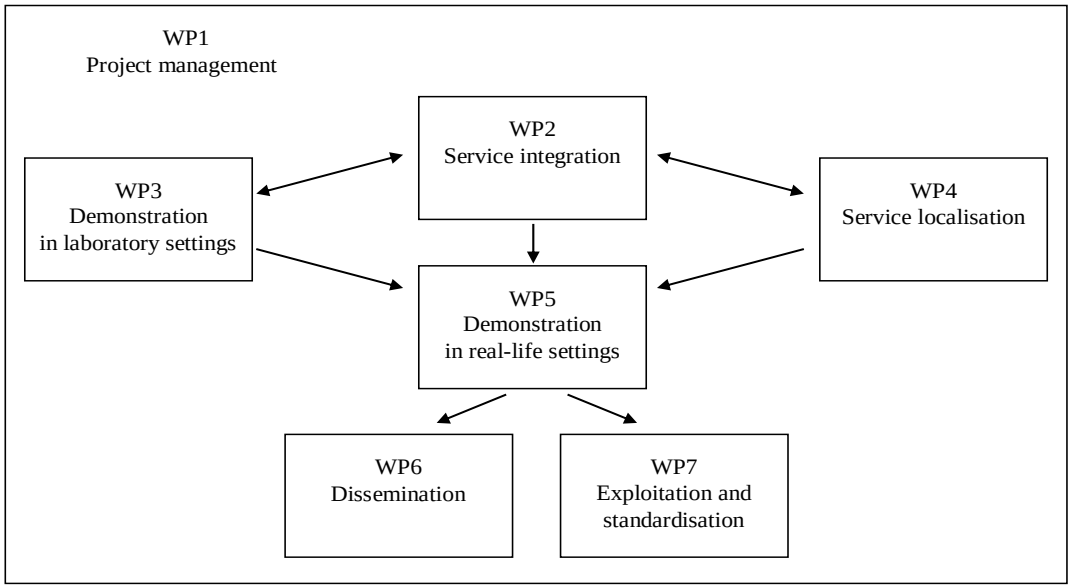

Figure 1 - Project structure

Each workpackage is composed of individual tasks, which originate tangible results named deliverables.
The project has started on the 1st January 2014 and will last for three years, until 31st December 2016.
The activity plan, specified at the level of the individual tasks is reported in Figure 2 - Project Gantt Chart, in which the deliverables and more detailed dependencies are represented.

The activity plan has been designed to go through 5 milestones, each closing a phase of the project.

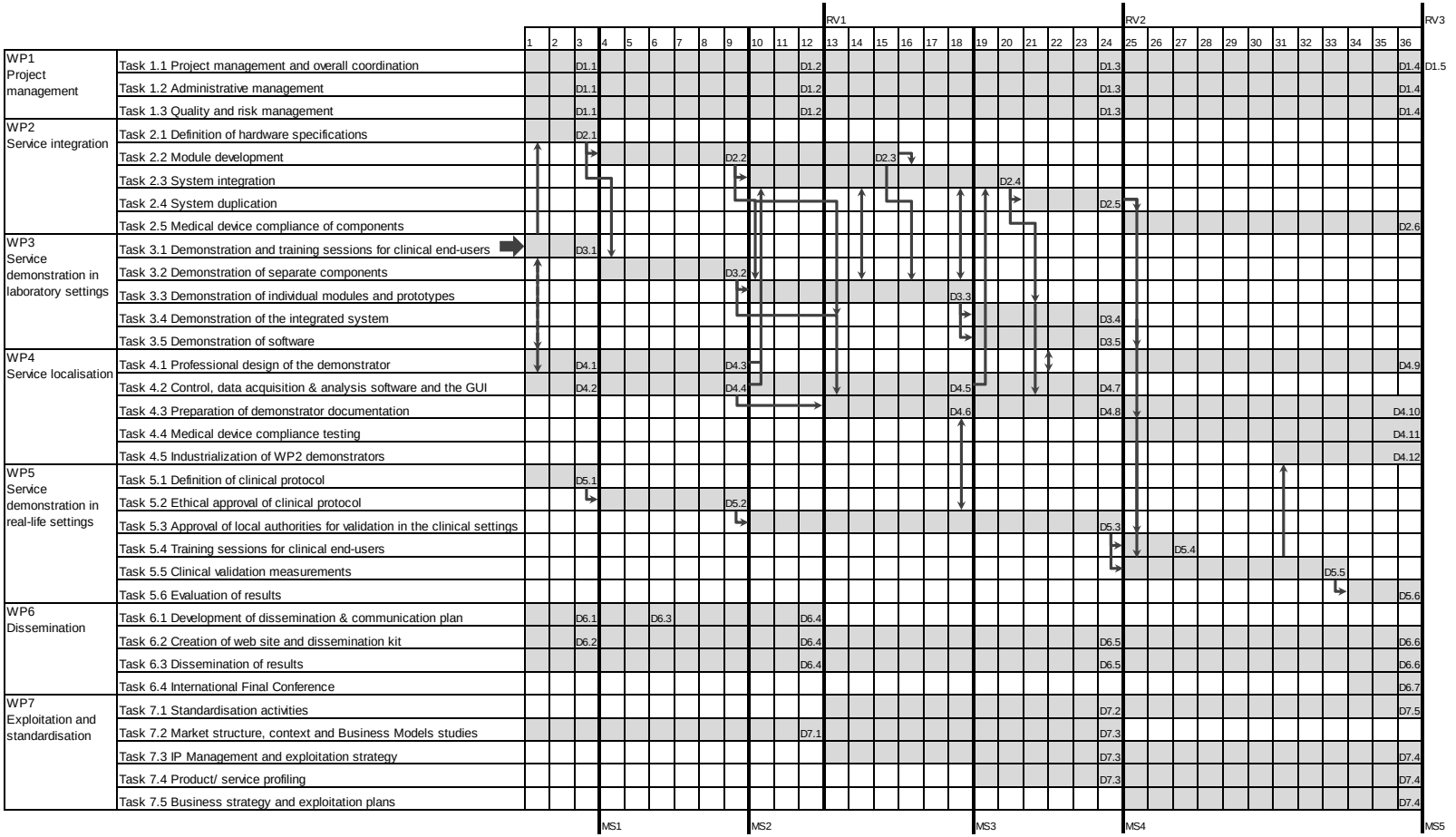

Figure 2 - Project Gantt Chart

4 Project Governance and Organization

4.1 Project Management Structure

This section describes the internal project management structure and techniques to be used within the BabyLux project. It details the description currently included in the DoW annexed to the contract and in the Consortium Agreement (CA).

At the centre of the management structure and process is the **Project Coordinator**, who is the single point of contact to the EU and will respond towards the EU and any external body for all the decisions made within the project at all levels.

Decisions will be made collectively and delegated to the governing bodies defined within the project as further detailed in this section.

The consortium bodies of the BabyLux management structure are:

- the **Consortium General assembly** (CGA);
- the **Advisory Board** (AB);
- The **Project Board** (PB).

An overview of the BabyLux management structure is provided in Figure 3.

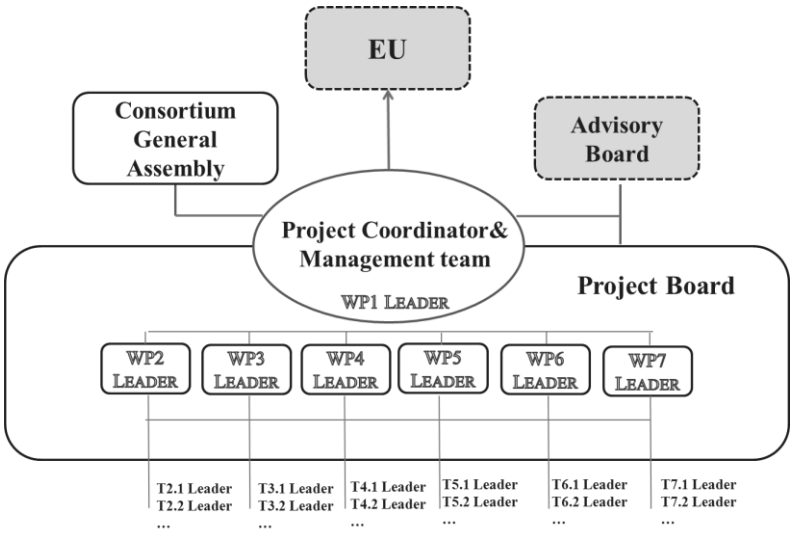

Figure 3 BabyLux Management Structure

The **Consortium General Assembly** (CGA), consisting of one representative for each partner, acts as the main governing body of the project, with final authority on all the budgetary and contractual decisions.
The **Advisory Board** (AB), composed of representatives of BabyLux ecosystem, including public authorities, standardization bodies and other stake-holders, provides independent feedback for the major project strategic decisions and results.
The **Project Coordinator** (PC) chairs the Project Board, and will be directly responsible for

the execution and the technical coordination of the entire project and is the reference person versus the European Commission. The PC will be assisted by the **Management team**, including the Administrative Manager (AM) and the **Intellectual Property Manager** (IPM).
The **Project Board** (PB), composed by the PC and all of the WP Leaders, will be the main executive body of the project, in charge of operational management and with direct responsibility for most operational decisions.
WP Leaders (WPL) will be responsible of coordinating the execution of the activities pertaining to the Tasks into which their WPs are subdivided, whereas individual **Task Leaders** (TL) will be in charge of managing the day-by-day activities associated with the execution of their Tasks.
Key roles and responsibilities and relevant operational and decisional procedures are further detailed in the following paragraphs and, wherever appropriate, will be explicitly included in the Consortium Agreement.

4.2 Detailed management structure

The actual management structure with the responsible person for each role is summarized in Table 2.

Body	Role Name	Responsible Person	Organization
Consortium General Assembly	CGA Member	Antonio Pifferi	PoliMi
	CGA Member	Michele Morganti	FPM
	CGA Member	Turgut Durduran	ICFO
	CGA Member	Niels Koenig	IPT
	CGA Member	Udo Weigel	HP
	CGA Member	Rainer Erdmann	PQ
	CGA Member	Ignacio Rocchetti	Loop
	CGA Member	Gorm Greisen	RH-Neo
	CGA Member	Monica Fumagalli	IRCCS Ca' Granda
Project Board	Project Coordinator and WP1 Leader	Alessandro Torricelli	PoliMi
	Administrative Manager	Paola Fantini	FPM
	Intellectual Property Manager	Sergi Ferrando	ICFO
	WP2 Leader	Udo Weigel	HP
	WP3 Leader	Davide Contini	PoliMi
	WP4 Leader	Turgut Durduran	ICFO
	WP5 Leader	Gorm Greisen	RH-Neo
	WP6 Leader	Monica Lancini	FPM
	WP7 Leader	Matteo Bogana	FPM

Table 2 BabyLux Key-Roles

4.2.1 Consortium General Assembly

The CGA is the BabyLux body responsible for the overall direction of the project and will consist of one representative from each project partner.
The CGA will have final decisional authority in the Project and, generally on the basis of specific proposals forwarded by the PB.
The relevant minutes will be distributed to all partners before the following ordinary meeting or within a maximum of 20 calendar days after the meeting. The preferred tools for

distributing minutes, agendas and all other documents will be e-mail and project repository (BabyLux Folder, Private Area of the project web-site).
All CGA decisions will conform to the rules detailed in the CA.

The following table summarises the key elements characterising the CGA:

Activities	• Approval and revision of the budget, and distribution of funds among the partners. • Revisions of the work-plan implying changes in matters subject to contractual obligations. • Handling of defaulting partners and changes in the consortium partnership. • Organizational changes affecting key positions. • Overall legal, contractual, ethical and financial management of the consortium. • Appointment, if deemed necessary, of advisors. • Comply with all decision of the EU, in so far as compliance with such decisions does not conflict with the statement of work annexed to the Grant Agreement.
Composition	• **Chairman**: PoliMi CGA Representative; **Members**: All partners of the project will have one representative in the CGA and will have one vote.
Organisation	• **Meetings**: yearly on the occasion of the scheduled BabyLux plenary meetings, or upon written request of the PC, or of 2 of the Project Partners. Any decision requiring a vote at a CGA meeting must be identified as such on the pre-meeting agenda, unless there is unanimous agreement to vote on a decision at that meeting and all partners are present or represented; • The CGA will deliberate or take decision **only if 2/3 of its members are present or represented**. Decisions shall be taken by a **simple majority of the votes** of the CGA members present or represented. The detailed operating procedures of the CGA are part of the Consortium Agreement.

Table 3 CGA Key elements

4.2.2 Advisory Board

The Advisory Board (AB) offers to the project:

- feedback on the way the project is proceeding;
- suggestions on how to improve both project results and their impact on the industrial community;
- whenever possible, advices on possible exploitation and dissemination activities and possibilities to linking the consortium to other international initiatives.

To achieve these goals, the AB will attend annual meetings (virtually or physically) in which the project partners will present the main results achieved in the period and the plan for the next phases of the project. The AB members will provide feedback verbally or in writing, if this is suitable for them. Members of the consortium will take care of taking notes during the meeting and will send the minutes to the AB for comments, additions and approval.

Upon request of the AB, the Project Coordinator will provide papers and deliverables that can be useful to support the assessment by the AB.
AB meetings will be tentatively held in the second half of each project year so that the results produced in the first part of the year can be presented and can still be evolved before the delivery to the Project Officer, based on the AB feedback.
AB members offer their services on a voluntary basis and will be refunded for their travel expenses.
The confirmed AB members are:

- Prof. **Sergio Cerutti**, Fellow of IEEE, EAMBES and AIMBE, Chairman of SC62D – Electromedical Equipment of CEI (Comitato Elettrotecnico Italiano).
- Dr. **Juan Sahuquillo**, Vall D'Hebron University Hospital, Institut Catala De La Salut (Barcelona), MD, PhD: Chairman of the Department of Neurosurgery, member of the Executive Committee of the European Brain Injury Consortium (EBIC), member of the Steering Committee of the Brain IT network, and a regular collaborator with the Cochrane Collaboration, McMaster Online Rating of Evidence (MORE), and Faculty of 1000 (f1000.com).
- Prof. **Axel Franz**, MD- Head Study Design / GCP / Regulatory Affairs at the Center for Paediatric Clinical Studies and Department of Neonatology University Children's Hospital University of Tuebingen Germany

Prof. Axel Franz is an external independent Ethics Advisor, in charge of overseeing the ethical concerns involved in this research. The Ethics Advisor has been indicated at the beginning of the project (month 1). A report by the Ethics Advisor will be submitted to the European Commission with the Periodic Reports.
Should AB Members resign their position or be unable to continue serving as AB Members, the Consortium General Assembly (CGA) will appoint alternative AB member. Each CGA member can suggest candidates for AB with CV.
All relations between the BabyLux consortium and the AB members have been defined and formalized in the "Terms of Reference for External Advisory Board in the BabyLux project" (ToR AB BabyLux), that will be signed by the Project Coordinator (on behalf of the consortium) and by the AB Members before Month 6. The ToR AB BabyLux reports the content of this section and defines the rules for non-disclosure of information.

4.2.3 Project Coordinator

In the BabyLux Organizational Structure, in addition to maintaining the relations between the CGA and the PB, the PC will have overall Project coordination responsibility and will act as the main contact point between the Project and the EU.
In particular, as chair of the PB he will have to:

- Ensure that all CGA decisions and directions are properly implemented.
- Ensure that all WPs are progressing and delivering in accordance with the work-plan objectives and schedule.
- Provide appropriate periodic reporting (including contractual and administrative ones) to the CGA, and the EU.
- Immediately inform the CGA of any important issue or critical problem encountered and propose the necessary actions.

The designated BabyLux PC is Prof. Alessandro Torricelli from partner 1 PoliMi. He will be assisted by the *Administrative Manager*, Paola Fantini (partner 2 FPM) who will take care of the administrative and contractual issues, and by the *Intellectual Property Manager*, Sergi Ferrando (partner 3 ICFO).

4.2.4 Project Board

The PB, that will be chaired by the PC and will comprise all of the WP Leaders, is the body that, within the BabyLux organization, will be in charge of the operational management and the technical coordination of the Project.
PB meeting minutes will be distributed to all PB and CGA members before the following ordinary meeting or within a maximum of 20 calendar days after the meeting.
The preferred tools for distributing minutes, agendas and all other documents will be the e-mail and project repository (Private Area of the project web-site).
All PB decisions will conform to the rules detailed in the Consortium Agreement.

Activities	• Coordinating all technical activities and decisions, within and across WPs. • Detecting potential problems, significant deviations from the work-plan and all other important issues that need to be brought to the attention of the CGA. • Identifying, proposing and implementing the necessary corrective actions. • Ensuring that all relevant IP and knowledge issues are appropriately addressed and managed throughout the Project. • Ensuring that Quality Assurance and Risk Management procedures and standards are duly applied • Establishing and developing relationships with other external stakeholders and scientific communities that will be required to complement the consortium own competences.
Composition	• **Chairman**: Project Coordinator (PC); **Members**: PC, all the WP Leaders. Each member has one vote.
Organisation	• **Meetings**: continuous communication. PB will convene at least **monthly** or upon written request of the the Project Coordinator, or of at least 2 of the other WP Leaders. All meetings will be preferably held by phone conference or other appropriate electronic means. Moreover, physical meetings can be held on the occasion of the scheduled BabyLux plenary meetings (every six months); • The PB will deliberate or take decision **only if 2/3 of its members are present or represented** Decisions shall be taken by a **simple majority of the votes** of the PB members present or represented. The detailed operating procedures of the PB are part of the Consortium Agreement.

Table 4 PB Key elements

4.2.5 WP Leaders

Besides sitting in the PB to ensure overall Project execution and coordination, each WPL will be specifically responsible of:

- Coordinating the execution of the tasks into which his WP is subdivided and ensuring that all relevant CGA and PB decisions are properly communicated and implemented.

- Controlling that work progress is on schedule and in line with both the WP specific and the overall Project objectives, especially with respect to milestones and deliverables.
- Providing the required WP reporting for the PB and the CGA.
- Ensuring that all relevant Quality Assurance procedures and standards are duly applied
- Identifying, and possibly anticipating, risks that could jeopardize the achievement of the WP goals, continuously updating the risk register and activating the necessary corrective actions.
- Arbitrating, if necessary, any conflicts that could arise among the Task Leaders.
- Immediately escalating to the PB level all problems that could not be solved at the WP level and/or that could potentially affect other WPs and the whole Project.

Indicatively, it is expected that each WPL will have direct weekly interaction with their respective TLs and that they will organize formal meetings with all of them at least monthly.

4.2.6 Task Leaders

TLs will be responsible for the day-by-day execution of their assigned task, including in particular the timely release and quality of deliverables, and for coordinating and integrating the individual contributions of the participating partners. They will also be responsible of immediately notifying to their respective WPL any significant deviation from schedule and any problem arising in the execution of their tasks that could impact other parts of the Project or that would require attention, and possibly a decision, at a higher level.
The TLs will be identified at the start of the project.

4.3 Key procedures and decision making processes

As a general rule, all decisions will be taken by consensus at the same level at which the need arises. In case no consensus is reached, a decision by vote will be taken if applicable voting rules exist at that level and for that decision. Otherwise, the decision will be escalated to the next level together with a summary of relative positions and voting results. Ultimate decision level will be the CGA.

4.4 Release of Deliverables and Reports

Deliverables of the project will be produced by the Project Coordinator, WP leaders, Task leaders, and other partners according to the responsibilities assigned in the description of work. Deliverables will either be paper documents or prototypes. Prototypes will always be accompanied by a document that contains the information needed to use the prototype. Prototypes will be either made available in form of executable software or in form of devices and services operated by some of the project partners. The public deliverables will be available through the project web-site (Public Area). The confidential deliverables will be available for the project partners and for the EU only in the Private Area of the project web-site (Box Folder). Furthermore, relevant disclosable contents from confidential deliverables will be extracted and published on the web site to foster dissemination of project activities. The periodic reports (D1.2, D1.3, D1.4) and the Final Report (D1.5) will be under the responsibility of the PC.
Each deliverable/report will mention the name(s) of its author(s) as well as a confirmation that any work or result described therein is either genuinely a result of this project or that any other source is properly referenced

5 Planning Year 1

Year 1, corresponding to January to December 2014, is characterized by the two milestones illustrated in the table below.

Milestone number	Milestone name	WP number	Lead beneficiary number	Delivery date from Annex I [60]	Comments
MS1	Problem definition and project setup	WP1, WP2, WP4, WP5, WP6	1	3	A means of verification is the availability of proper specifications (D2.1, D4.1, D4.2, and D5.1) and the setting up of project procedures and tools (D1.1, D6.1, and D6.2).
MS2	Basic elements for the demonstration of the BabyLux solution	WP2, WP3, WP5	1	9	A means of verification is the demonstration in lab settings of the components (D3.2), the availability of modules (D2.2), and the approval of clinical protocols by ethical committees (D5.2).

Table 5 Milestones Year 1

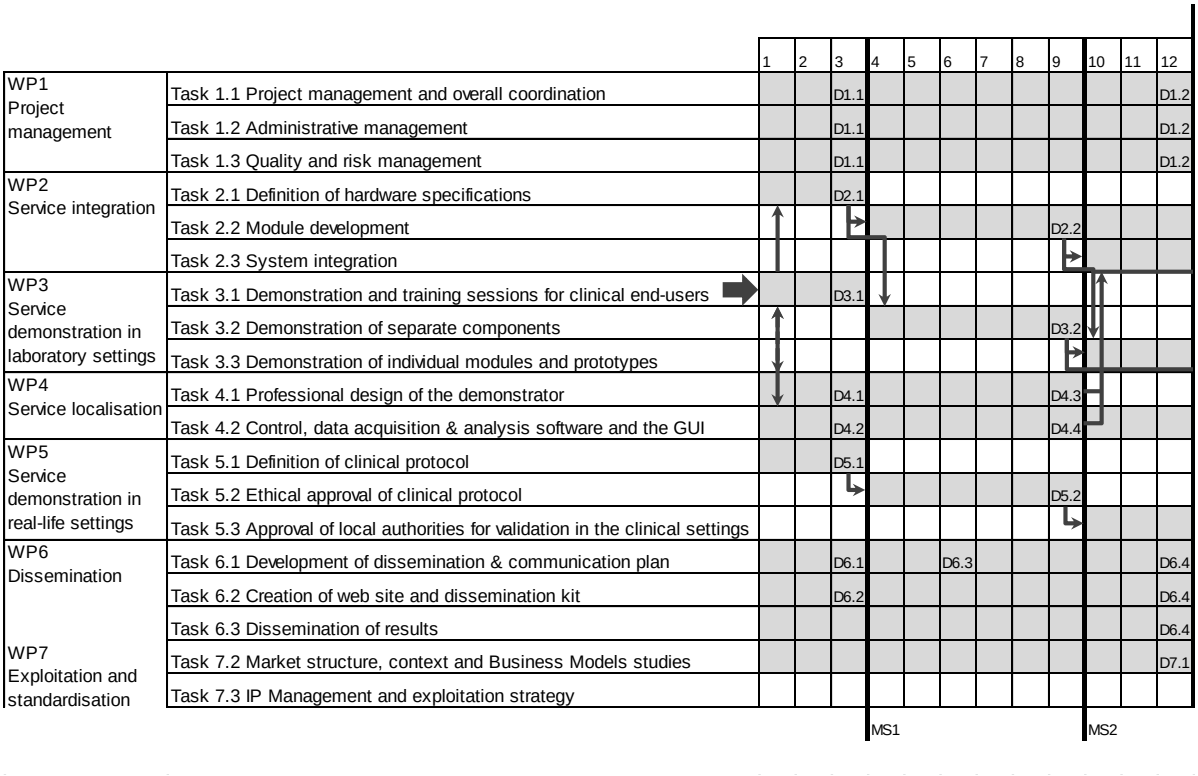

Figure 4 Plan Year 1

In order to carry out the activities defined for year 1, partners have allocated staff and planned the effort to be spent for each workpackage, as reported in Table 6 Planned effort Year 1 (Person Months).

Person months in Year 1									
Part. N.	**Participant**	**WP1**	**WP2**	**WP3**	**WP4**	**WP5**	**WP6**	**WP7**	**TOT**
1	PoliMi	6,50	12,00	9,60	1,80	3,30	3,40	1,80	**38,40**
2	FPM	3,40	0,00	0,00	0,00	0,00	6,60	6,50	**16,50**
3	ICFO	0,80	18,00	8,40	15,30	4,40	4,50	4,80	**56,20**
4	IPT	0,80	10,00	1,80	0,00	0,00	2,20	0,00	**14,80**
5	HP	0,50	10,00	1,40	6,00	0,50	0,50	2,30	**21,20**
6	PQ	0,80	3,00	2,80	0,70	0,00	0,50	0,20	**8,00**
7	Loop	0,80	4,30	3,60	1,20	0,00	1,00	0,60	**11,50**
8	RH-NEO	0,80	0,50	0,70	0,70	2,00	1,00	0,10	**5,80**
9	IRCCs Ca' Granda	0,80	0,50	0,70	0,70	2,00	2,20	0,20	**7,10**
	TOT	**15,20**	**58,30**	**29,00**	**26,40**	**12,20**	**21,90**	**16,50**	***179,50***

Table 6 Planned effort Year 1 (Person Months)

6 Information management and knowledge sharing

6.1 Communication Strategy

Information will flow within the project both vertically and horizontally. The vertical flow of information will be adopted mainly for the administrative issues (e.g. financial progress reports, consolidated reports, meeting minutes and cost claims/advance payments), whereas technical work packages will adopt a less formal, horizontal flow, where opinions are exchanged among peers, ideas are discussed either face to face or in meetings, conference calls, and the like.

6.2 Project meetings

In Year 1 BabyLux plenary meetings – scheduled on M1, M5, M10, – are foreseen. The project kick-off, held in January, has marked the effective launch of the project. The other project meetings are timed according to technical issues to be addressed. According to the principles of economy, efficiency and effectiveness, CGA and PB meetings will be held on the same date and place. In addition, Skype meetings and Conference Calls will be organized in order to continuously share information and take decisions related to the project activities.

Meeting	Date	Venue	Purpose /outcomes	Participating Partners
Kick Off Meeting	21-22/01/14	Milano	Plenary Meeting (technical and management issues)	ALL
February Conf. Call	24/02/2014	Telco	Planning and coordination of work and actions. Follow up actions.	ALL
March Conf. Call	18/03/2014	Telco	Planning and coordination of work and actions. Follow up action	ALL (IPT missing)

Table 7 Meetings and Conference Calls already performed

Meeting	Date	Venue	Purpose /outcomes	Participating Partners
April Conf. Call	15/04/14	Telco	Planning and coordination of work and actions. Follow up actions.	ALL (expected)
May Conf. Call	13/05/2014	Telco	Planning and coordination of work and actions. Follow up actions.	ALL (expected)
2nd Plenary Meeting	26-27/05/14	Berlin	Plenary Meeting (technical and management issues)	ALL (expected)
3rd Plenary Meeting	16-17/10/14	Barcelona	Plenary Meeting (technical and management issues)	ALL (expected)

Table 8 Foreseen Meetings and Conferences Calls

The Project Coordinator shall give each of the Parties at least 30 calendar days' notice in writing of such meetings or 15 calendar days' notice in case of an emergency situation, sending a draft agenda by e-mail.

The Project Coordinator shall draft the minutes of each meeting to formalize in writing all decisions taken and shall dispatch them to all the Partners before the following ordinary meeting or within a maximum of 20 calendar days after the meeting by e-mail and project repository (Private Area of the project web-site). All the minutes shall be considered as accepted by the Parties if, within 15 calendar days from the receipt thereof, no Party objected in writing to the Project Coordinator.

6.3 Collaboration tool, website, etc.

6.3.1 BabyLux Box Folder

For its internal communication the Consortium uses tools for communication and document repositories: BabyLux Box Folder.

The core of the information exchange is the 2014 BabyLux area on the Box platform, made available by FPM. Box - www.box.com - is a simple, scalable and affordable solution to manage documents, media and content online.

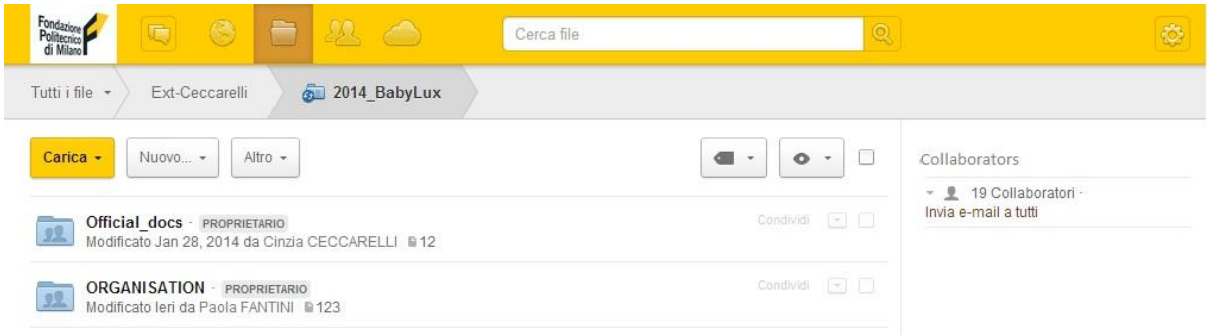

Figure 5 BabyLux Folder

The system is accessible from the BabyLux partner organisations through the provision of username / passwords for the individual users. From M6, it will be also accessible through the private area of the BabyLux web site.
The platform allow teams to share information providing collaboration facilities, making it easy for the users to share and/or work together on meetings agendas, minutes, deliverables, track file versions , post comments and discussions, assign and manage tasks, get a detailed, real-time view of everything going on with the content. Moreover, it's possible to combine Box's content management and administrative capabilities with Google Docs' real time collaboration tools.

The project calendar with the dates of the upcoming conference calls, meetings and events

is available on the platform.

A contact list with the names and references of all the participants to the BabyLux project is also available on the platform.

6.3.2 Project web site

For external communication towards interested communities and general public the Consortium reference point is the project web site.
The BabyLux website offers information about the project and its partners and presents the results of the project itself.
The website will be used for public dissemination and will inform about previous and forthcoming events and activities of the project as well as other relevant news on project topics.
Specifically, the project website will contain all of the released publishable summaries, presentations and any other dissemination material (in a non-modifiable format), the list of the events (meetings, workshops,…).
The project website is accessible. The URL of the website is http://www.babylux-project.eu/.
The website has been online since 24 March 2014, its home page is shown.

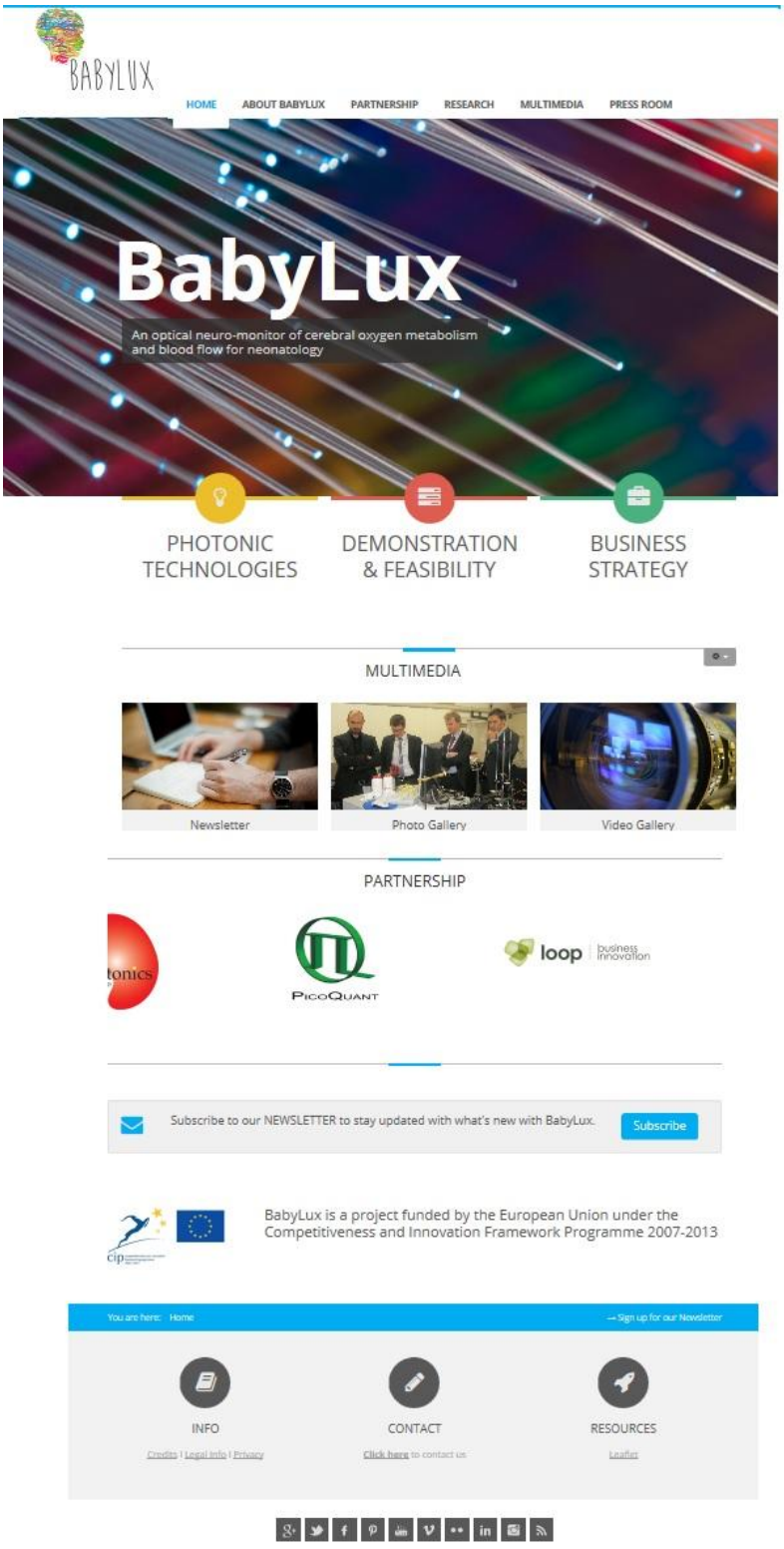

Figure 6 Website Homepage screenshot

The project website support bidirectional communications with the visitors, who may post

their comments or inquiries through the page illustrated in Figure 7.

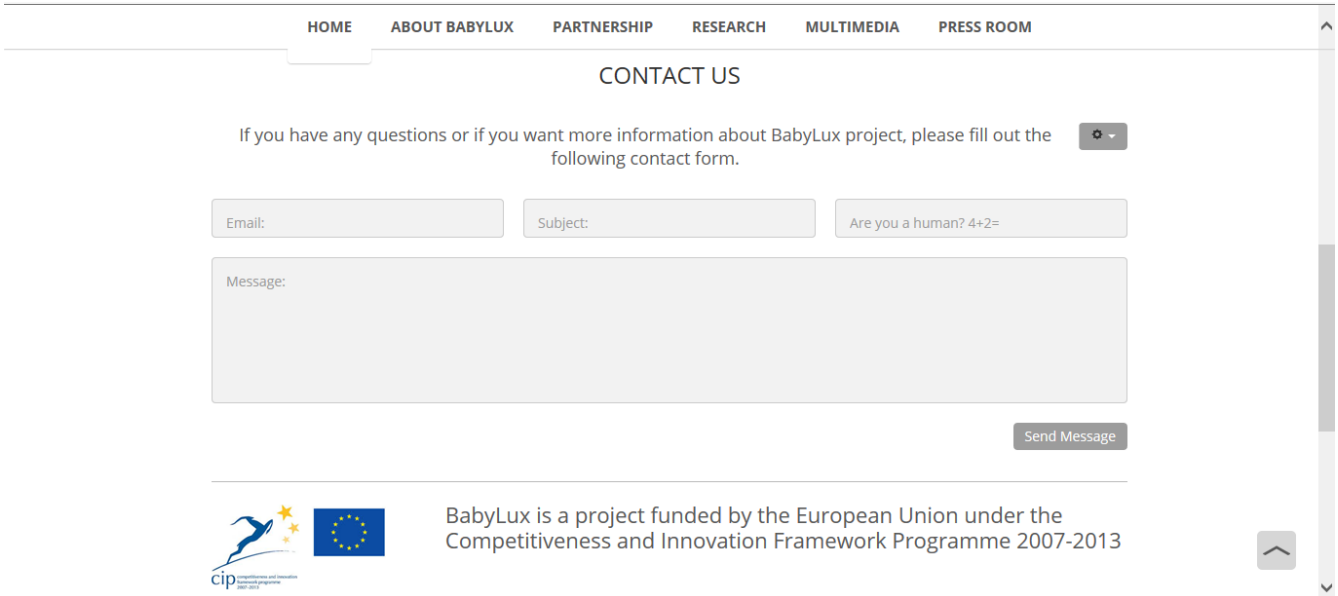

Figure 7 "Contact Us" form

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7 Project monitoring and reporting

7.1 Project monitoring

The BabyLux Consortium has set a calendar of monthly conference calls as a coordination mechanism among workpackages, to keep the project in track and to early detect possible stumbling stones or deviations, to make decisions and to define action assignments to address issues and to prepare future decisions.

Furthermore, BabyLux Consortium has set a framework of indicators that allow monitoring the progress of the project against the plan, from a multidimensional perspective

Table 9 specify all the measurements that the project manager has to implement in order to monitor the progress and achievements of the projects during its first year of development.

Indicator No.	**Relating to which project objective / expected result?**	**Indicator**	**Method of measurement**	**Expected Progress**
				Year 1
I1.1	O1	Internal meetings	N° of internal meeting with all the project partners, Minutes	3
	excellent project management			
I1.2	O1	Internal procedures	N° delivery/update of internal procedures	1
	excellent project management			
I1.3	O1	Conference calls	N° of conference calls	12
	excellent project management			
I1.4	O1	Progress Reports	N° of report presented and accepted by the EC	1
	excellent project management			
I1.5	O1	Time-scheduled respected	N° of deliverables of good quality submitted on time and accepted by EC	All the deliverables in Y1
	excellent project management			
I1.6	O1	Level of risk found and corrective actions implemented with good results	Risk register updated twice a year	2
	excellent project management			

I1.7	O1 excellent project management	Costs monitoring	Declared costs in line with the expected budget	% deviation actual vs. plan <=10%
I1.8	O1 excellent project management	Funds transfer	N° of days cumulated delay for funding distribution	0
I2.1	O2 Integrated system development	Technical specifications	N° of technical specifications	1
I2.2	O2 Integrated system development	Demonstrators	N° demonstrators made available	0
I2.3	O2 Integrated system development	TRL	Technology readiness level of proposed solution	5
I2.4	O2 Integrated system development	Medical device compliance	N° innovative components with compliance	0
I3.1	O3 Lab demonstration	Performance protocols	N° defined/adapted protocols	1
I3.2	O3 Lab demonstration	Demonstrations	N° of laboratory demonstrations	6
I4.1	O4 Localisation	Technical specifications	N° of technical specifications	2
I4.2	O4 Localisation	Documentation	N° of documentation releases	0
I4.3	O4 Localisation	Medical device compliance	N° innovative systems with compliance	0
I5.1	O5 Demonstration in the clinics	Training sessions	N° training sessions delivered	2
I5.2	O5 Demonstration in the clinics	Trained users	N° final users trained on the usage of the demonstrator	0
I5.3	O5 Demonstration in the clinics	Users involved	N° final users involved in the demonstration	0

I5.4	O5 Demonstration in the clinics	Patients involved	N° patients involved in each target test	0
I5.6	O5 Demonstration in the clinics	Device comparison	N° comparison with traditional devices	0
I5.7	O5 Demonstration in the clinics	Clinical protocols	N° clinical protocols defined	1
I5.8	O5 Demonstration in the clinics	Ethical approval	N° approval by ethical committee	2
I5.9	O5 Demonstration in the clinics	Authorisations	N° approval by local authorities	0
I6.1	O6 Results dissemination	Web site	N° of visitors, n° of registered users, n° of documents' download	250
I6.2	O6 Results dissemination	Press releases	N° of press releases published	2
I6.3	O6 Results dissemination	Newsletter	N° of newsletters released	3
I6.4	O6 Results dissemination	Articles	N° of published articles	2
I6.5	O6 Results dissemination	Interviews	N° of interviews on media	1
I6.6	O6 Results dissemination	Participation at local and international conferences, workshops, events, exhibitions, forums	N° of conferences, workshops, events, exhibitions, forums attended	6
I6.7	O6 Results dissemination	Relevant stakeholders	N° of relevant stakeholders contacted	50

I6.8	O6 Results dissemination	Relevant stakeholders	N° of relevant stakeholders involved	5
I6.9	O6 Results dissemination	Final conference	N° of participants	0
I6.10	O6 Results dissemination	Dissemination to Networks and on-going project	N° of network and on-going projects	4
I7.1	O7 Results exploitation	Contacts with standardisations bodies	N° of communication activities with the standardisation bodies	1
I7.2	O7 Results exploitation	BabyLux patents	N° of patents obtained	0
I7.3	O7 Results exploitation	Potential customers	N° of potential customers met	2
I7.4	O7 Results exploitation	Standards	N° standards analysed	0
I7.5	O7 Results exploitation	Standards	N° standards with which the demonstrators is compliant	0
I7.6	O7 Results exploitation	Standards	N° specifications candidate for standardisation	0

Table 9 Performance indicators Year 1

7.2 Project reporting

The following reports are foreseen to be provided:

- Internal Management Report (IMR, to be issued every six months);
- Project Periodic Report (to be issued yearly to the EC).

Partners will provide their report every six months to the Coordinator based on a word based template provided by the Coordinator. The partner reports will be consolidated and used for the preparation of the Project Periodic Report.

The structure of the IMR will be based on the forms and template provided by the EC and available on the BabyLux Folder.

The main components concern:
- Self declaration
- Publishable summary
  Project objectives and achievements during the period (detailed per WP);
- Publications and participation to meetings and other events;
- Usage of resources
  Cost claims (only for periodic report)

Periodic Progress Report must contain data updated at the closure of the previous 6 or 12 months and are to be released within 60 days from the end of each period.

8 Quality Management

8.1 Templates

All documents will be produced using the appropriate Word & PowerPoint templates agreed for the purpose.
Deliverables will be released in pdf format and will be compiled using MS Word. Independently from the used formatting tool, all deliverables will have a uniform cover composed of three pages (the first page containing deliverable title, editor, authors, reviewers, as well as information concerning the type and status of deliverable; the second page featuring the executive summary; the third page the table of contents), will use uniform fonts and styles for headings (see the following sections for details).

8.2 Document Naming and Versioning

Files containing official BabyLux documents should follow the naming convention defined below.
BabyLux_DocType&Number_Version
Where
<DocType&Number> can take the following values: D (deliverable), MIN (meeting minutes), PRES (presentation), IMR (Internal Management Report), OTH (other). Moreover, the identifier will be added:

- For D, the number of the deliverable;
- For MIN, PRES, IMR or OTH, the WP and the date of the meeting/presentation/internal management report/other (ddmmyyyy).

8.3 Typing

The project adopted language is British English. Spelling and punctuation will have to follow the convention of British English. For ALL punctuation characters, the general rule is therefore: no space before, one space behind. This includes the following: ?; !:
For « – », put one space before and one space behind the hyphen.
For the titles, the practice is to start the nouns with a capital letter.

8.4 Formatting

No direct formatting except for bold, italics, underlined. Always apply the style sheet in the template.

8.5 Document and Text Arrangement

8.5.1 Documents

The template foresees for the deliverables

- An executive summary

Executive Summary: in one page max. It should give to the reader a view of the content, i.e. the objectives of the document, some hints on the reasoning and indicate the key conclusions.

8.5.2 Text

The text should be written, arranged and formatted to be easily read and understood.
Chapter/section numbering should be automatic. A maximum of three levels of paragraph numbering is advised.

The text should be short and pertinent, that means concrete. No statements like: the project should… Say: the project will… Avoid conceptual text.
Avoid sentences like: « we shall… » Instead say: « the project will… » or "the consortium will…"

Important points in a paragraph should be highlighted (using bold, italics or underlined) so as to allow quick identification of the key message by the reader (only a few words in a paragraph should be highlighted. If most of the text is in bold, there is no highlighted message anymore!!).

Very specialized technical terms should be defined at the first occurrence through, for instance, a note at bottom of the page. If long technical developments or demonstrations are necessary, they should be put in annex with a short summary of the conclusions which the text uses for its message.

When a figure/table to support the text is used:

- Figures/tables must be automatically numbered.
- Each figure/tables MUST HAVE A TITLE.

In case of long tables encompassing more than one page it is possible to derogate from this rule, provided that these are self-explanatory.

8.5.3 Meeting Minutes and Action Points Numbering

Meeting minutes shall sum-up, for each discussion, the main arguments and the conclusion(s) reached. For each decision, a short summary of the arguments/assumptions having led to that decision shall be recorded (this in order to be able later – when for example the context has changed – to reconstitute the rationale of a decision).

For each Action Point (AP) in the minutes, the corresponding should be specified, the persons or partners responsible for it and the deadline for completion.

All APs shall be grouped in a specific section at the end of the minutes. Subsequent discussions/decisions shall be recorded under the heading of each AP. Any completed AP is reported as closed in the published minutes and will disappear from subsequent minutes.

Preparation of minutes is the responsibility of the WP leader. Minutes of CGA and PB are

the responsibility of the Project Coordinator.

8.6 Deliverable Review and Approval

All deliverables have to be submitted to a formal review following the process described hereafter and showed by Figure 8.
The identified Responsible Person should provide a **final** draft of the deliverable for review 15 calendar days **prior** to the deadline. The PB have the responsibility to check all aspects and provide a quality check prior to release within 7 calendar days. Comments should be provided to the Responsible Person. The PB will assess the review. In the case of major comments the deliverable will be sent back to the Responsible Person for discussion and fixing as appropriate; a new release should be provided within 5 calendar days and then the deliverable will then go through iteration for review and approval. For minor comments that do not required additional experts' discussion, the Project Coordinator will proceed with the editing. The PB will be responsible for the final approval prior to release. Approved deliverables will be double checked by the Project Coordinator who will then submit them to the EU.

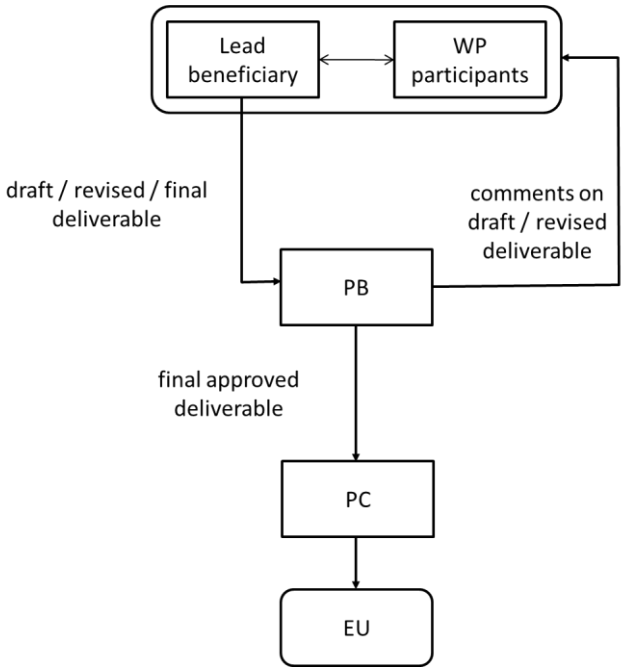

Figure 8 Deliverable Management Process

9 Risk Management

Risk Management Procedures

Each WPL will be responsible of continuously identify and monitor internal and external risks for the project and inform the AM to update the register. Furthermore, each risk has to be qualified in terms of probability and impact, and associated to appropriate mitigation and control actions by the WPL with the collaboration of the AM. Each WPL is then responsible for the implementations of the control and mitigation actions. In case of risks that concern more WPs, the involved WPLs will agree on the assessment and in the definition and assignment for controls and mitigation actions. Every six month the AM will submit the risk register to the PB to be revised and approved.

Table 10 Risk register

Description of possible risk	**Impact**	**Probability of occurrence**	**Remedial Actions**
Task 2.1 Definition of hardware specifications Failure to provide a definition of hardware specification	low	low	The definition of hardware specifications is intended to tailor the proposed solution to the needs of the clinical end-user and to take advantage of the latest innovations in materials and devices that the partners in the BabyLux consortium have obtained before the start of the BabyLux project. In case of occurrence of this risk, the definition of specifications will be based on the characteristics of the existing TRS and DCS prototypes. This remedial action has a low impact since the existing prototypes have been already successfully tested in clinical environment on adults and neonates.
Task 2.2 Module development Failure to develop the TRS and / or the DCS modules	low	low	Partners 1 PoliMi, 3 ICFO and 6 PQ have a long expertise in the development and validation of state-of-the-art TRS and DCS modules and prototypes. In case of occurrence of this risk, the TRS and DCS modules that have been already implemented in the existing prototypes will be used. This remedial action has a low impact since the existing modules have been thoroughly tested in laboratory and clinical demonstrations.

Task 2.2 Module development Failure to develop the optic fibre probe	medium	low	Partner 4 IPT has a long expertise in the field of design, simulation, fabrication and assembly of fibre optic sensors and probes. In case of occurrence of this risk, the existing probes for TRS and DCS will be used. This remedial action has a medium impact since it requires more space on the head of the neonates to place the two separate probes.
Task 2.3 System integration Failure to integrate the TRS and DCS modules	medium	low	Different levels of integration of the two technologies are envisaged at the beginning of the project: low (TRS and DCS use separates detectors and electronics, while share the casing and the software); medium (sharing of electronics, casing and software); high (sharing of detectors, electronics, casing and software). The decision on which solution to implement will be taken in Task 2.1 Definition of specifications so as to take advantage of the latest innovations developed before the starting of the BabyLux project. Whichever the type of integration, the BabyLux partners 1 PoliMi, 3 ICFO, 4 IPT, 5 HP, 6 PQ and 7 Loop, thanks to their long expertise in prototype development and components integration, ensure commitment to its realisation. In case of occurrence of this risk, separate products will be realised by improving the existing TRS and DCS prototypes. This remedial action has a medium impact on the clinical demonstration since it will require driving two separate demonstrators simultaneously on the very same neonate.
Task 2.4 System duplication	medium	low	After successful realisation of previous tasks, duplication is straightforward. The risk can originate by delay in the delivery of required components either by partners within the BabyLux consortium (e.g. partners 4 IPT for fibre probes, or 6 PQ for optoelectronic devices) or by external providers. In case of occurrence of this risk we will run the clinical demonstration with the unique developed demonstrator.

Failure to duplicate the system			This remedial action has a medium impact on the clinical demonstration since it prevents parallel demonstrations in Milan and Copenhagen, but forces serial demonstrations (e.g. 3 months in Copenhagen and 3 months in Milan).
Task 3.1 Demonstration and training sessions for clinical end-users Failure to organise training sessions for clinical end-user	low	low	Partners 1 PoliMi, 3 ICFO and 5 HP have developed existing prototype and products that can be profitably used to demonstrate the basic principles behind the technology and to train the clinical end-users. In case of occurrence of this risk demonstration and training will be later performed with the innovative system. This remedial action has a low impact on project's activities since partners 8 RH-Neo and 9 IRCCS Ca' Granda are able to drive the definition of specifications of the innovative system on the basis of their previous experience in the use of NIRS devices.
Task 3.2 *Demonstration of separate components* Task 3.3 *Demonstration of individual modules and prototypes* Task 3.4 *Demonstration of integrated system* Failure to develop calibration kits and phantoms	low	low	Partners 1 PoliMi has already developed phantoms and calibration kit for TRS systems, while innovative phantoms (e.g. with movable perturbation) are planned to better test the components, the module and the systems. In case of occurrence of this risk, the consortium will utilize world-wide contacts and collaborators and embark on a short collaboration to develop the calibration kits. This remedial action has a medium impact since can cause a minor delay (e.g. 2 months) in the project timing.
Task 5.1 *Definition of clinical protocol*	low	low	Clinical partners 8 RH-Neo and 9 IRCCS Ca' Granda have a long expertise in the use of NIRS instrumentation on preterm neonates.

Failure to define clinical protocol for demonstration of the proposed solution			In case of occurrence of this risk the BabyLux consortium will adopt protocols for the use of NIRS instrumentation defined by in past or on-going validation studies (e.g. in the SafeBoosC project). The remedial action has low impact since these protocols have been already successfully tested in clinical settings.
Task 5.2 *Ethical approval of clinical protocol* Task 5.3 *Approval of local authorities for validation in the clinical settings* Failure to obtain ethical approvals and / or Approval of local authorities	high	low	Clinical partners 8 RH-Neo and 9 IRCCS Ca' Granda have a long expertise in the preparation of documentation for ethical approval of clinical protocols, while partners 1 PoliMi and 3 ICFO have similar expertise for obtaining the authorisation for clinical tests with innovative prototypes or medical devices. In case of occurrence of this risk in one country, the remedial action will be to perform demonstration in a single country, possibly involving a second hospital. In case of occurrence of this risk in both countries, we will have a go/no-go decision (MS2). The project may be halted or the effort would be shifted to further demonstration in the laboratory settings.
Task 5.4 *Training sessions for clinical end-users*	medium	low	Clinical partners 8 RH-Neo and 9 IRCCS Ca' Granda have a long expertise in the use of NIRS instrumentation on preterm neonates. The integrated system proposed by the BabyLux consortium aims at fitting as much as possible in the clinical routine and procedures, therefore its use would not differ too much from a classical NIRS device.

Failure to organise training sessions for clinical end-user			In case of occurrence of this risk the clinicians will rely on their expertise on the use of noninvasive monitoring devices. The remedial action has medium impact since the proper functioning of every medical device requires a specific training and outcomes could be influenced by incorrect use.
Task 5.5 *Clinical validation measurements* Failure to obtain the target number of measured patients	medium	low	Clinical partners 8 RH-Neo and 9 IRCCS Ca' Granda on average assist 1000 and 600 newborns per year admitted to neonatal intensive care units. In case of occurrence of this risk, evaluation of the proposed solution will be based on a limited number of patients. The remedial action has medium impact. Although the BabyLux project does not aim at providing statistical significance of results on large population of patients, it is a fact that every preterm neonate yields a peculiar case story. Therefore demonstrating the system on a small but significant number of individual cases would be more effective.
Task 6.1 *Design of a detailed dissemination plan* Failure to define a proper dissemination plan	high	low	Partner 2 FPM has a long expertise in managing dissemination activities in national and international events. In case of occurrence of this risk, every partner will operate following the normal channels at their institutions. The remedial action has high impact on project activities since sub-optimal dissemination could imply a reduced exploitation phase.

Task 7.1 *Standardisation activities* Failure to define a standard for the proposed solution	low	high	There is no agreement at the international level on standardisation of brain monitors (e.g. tissue oximeter) based on NIRS. An IEC/ISO initiative has recently started triggered by the Japanese companies (e.g. Hamamatsu, Shimadzu, Hitachi). Several external factors may influence the definition of the standard for characterisation of this type of products. Although partner 1 PoliMi is directly involved as national expert in this procedure, there is a high probability that a protocol for standardisation is not defined in due time during the lifetime of the BabyLux project. In case of occurrence of this risk we will use the protocols defined in previous European project (e.g. Medphot, nEUROPt). The remedial action has a low impact on the project activities since these protocols have been already tested in multi-centric trials.

10 Conclusions

The present document summarizes the organization structure, the procedures, the decision making processes and all the mechanisms and plans settled by the BabyLux Consortium in order to effectively and efficiently carry out the project, ensuring appropriate quality of results and management of risks.
The coordination and management activity will use this document as a reference point and, whenever during the project development, needs for modifying the described organization mechanisms and tools will emerge, the Consortium will elaborate appropriate measures and will update the project management plans in the next deliverables D1.2 First periodic report, D1.3. Second periodic report, D1.4 Third periodic report and in D1.5 Final report.