PROMETEUS
preterm brain-oxygenation and metabolic eu-sensing

D8.8 - RP1 Technical/scientific review meeting documents

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Lead Author:	Sabrina Brigadoi (UNIPD)
Version: F: final; D: draft; RD: revised draft	F
Date:	12/03/2024

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This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101099093

Grant Agreement	101099093
Acronym	Prometeus
Project full title	Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

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Prepared by	Sabrina Brigadoi
Verified by	Marta Pozza

History of Changes

Revision	Date (dd/mm/yyyy)	Author	Changes	Status (Draft/Inreview/ Submitted)
v1	11/03/2024	Sabrina Brigadoi	Prepared deliverable	D

Table of contents

1. Introduction

This report contains the final agenda, the list of attendees and the presentations of the first review meeting of the Prometeus project.

2. Final agenda

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PROMETEUS – Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

1st Review Meeting agenda

Date and time: **13/03/2024, 9.00 am CET**

Meeting location: virtual, via WebEx

Start	End	Event	Speaker
9.00	9.10	**Organizational welcome** by PO and introduction of all attendees	Alina Maria TOMOIAGA, EISMEA PO
9.10	9.30	**Technical overview** of the project ▪ Scientific overview of the project ▪ Objectives and WP organisation ▪ Timeline of the project	Sabrina BRIGADOI, UNIPD
9.30	9.55	**WP 1 - Brain oxygenation and perfusion (neo-opticap)** ▪ Progress made in RP1 ▪ Main results obtained ▪ Deliverables and milestones achieved ▪ Problems occurred and solutions ▪ DEVIATIONS from the DoA ▪ Next steps planned	Davide CONTINI, Polimi
9.55	10.10	Questions and answers	Reviewers, EISMEA and presenters
10.10	10.35	**WP 2 - Continuous Metabolic Monitoring (wearable sensor)** ▪ Progress made in RP1 ▪ Main results obtained ▪ Deliverables and milestones achieved ▪ Problems occurred and solutions ▪ DEVIATIONS from the DoA ▪ Next steps planned	Idan TAMIR, QULAB
10.35	10.50	Questions and answers	Reviewers, EISMEA and presenters
10.50	*11.05*	*Break*	
11.05	11.30	**WP 3 - Metabolic Model and neonatal in silico avatar** ▪ Progress made in RP1 ▪ Main results obtained ▪ Deliverables and milestones achieved ▪ Problems occurred and solutions	Chiara DALLA MAN, UNIPD

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		▪ DEVIATIONS from the DoA Next steps planned	
11.30	11.45	Questions and answers	Reviewers, EISMEA and presenters
11.45	12.10	**WP 5 - Cloud-based platform (digital cloud twin)** ▪ Progress made in RP1 ▪ Main results obtained ▪ Deliverables and milestones achieved ▪ Problems occurred and solutions ▪ DEVIATIONS from the DoA ▪ Next steps planned	Alberto SCARPA, DAVE
12.10	12.25	Questions and answers	Reviewers, EISMEA and presenters
12.25	12.50	**WP 7 - The social culture of preterm birth** ▪ Progress made in RP1 ▪ Main results obtained ▪ Deliverables and milestones achieved ▪ Problems occurred and solutions ▪ DEVIATIONS from the DoA ▪ Next steps planned	Paola RIGO, UNIPD
12.50	13.05	Questions and answers	Reviewers, EISMEA and presenters
13.05	*13.50*	*Lunch Break*	
13.50	14.05	**WP 8 - Dissemination and Communication**	Sabrina BRIGADOI, UNIPD
14.05	14.35	**Innovation potential and Exploitation presentation** ▪ General overview of project potential ▪ Introduction on PEC ▪ Exploitation of subcomponents of the project	Michele LACERENZA, PIONIRS, Prometeus Exploitation Committee member
14.35	14.50	**WP 8 - Data Management Plan**	Sabrina BRIGADOI, UNIPD
14.50	15.05	**WP 8 - Management** ▪ Deviations from Annex 1 and 2 ▪ Use of resources	Sabrina BRIGADOI, UNIPD
15.05	*15.20*	*Break*	
15.20	15.35	**Exploitation Services offered by EIC &EC**	Alina Maria TOMOIAGA, EISMEA PO
15.35	16.15	**Assessment meeting by monitors and PO**	Reviewers, IR Expert and PO
16.15	16.30	**Wrap up by PO**	Alina Maria TOMOIAGA, EISMEA PO

3. List of Attendees

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Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain - Prometeus

Prometeus - GA n° 101099093

1st Review meeting Participants list

Partner	Participant Na	Participant Family r	email	role in the project
DAVE	Alberto	Scarpa	alberto.scarpa@dave.eu	WP5 leader
DAVE	Manuele	Papais	manuele.papais@dave.eu	WP 5 partner
DAVE	Stefano	Dal Poz	stefano.dalpoz@dave.eu	WP 5 Partner PI
ICFO	Turgut	Durduran	turgut.durduran@icfo.eu	WP 1 member, Partner PI
ICFO	Georgina	Tresànchez Lacorte	georgina.tresanchez@icfo.eu	WP1 member, PhD student
ICFO	Mirko	Fornasier	mirko.fornasier@icfo.eu	WP1 member, PhD student
PIONIRS	Michele	Lacerenza	lacerenza@pionirs.com	WP 1 PEC Referee / Partner Representative
Polimi	Alessandro	Torricelli	alessandro.torricelli@polimi.it	WP 1 Partner PI
Polimi	Davide	Contini	davide.contini@polimi.it	WP1 leader
Polimi	Caterina	Amendola	caterina.amendola@polimi.it	WP1 member
Polimi	Fabio	Negretti	fabio.negretti@polimi.it	WP1 member, PhD student
QULAB	Idan	Tamir	idan@qulabmedical.com	WP 2 leader, partner PI
QULAB	Sharon	Lefler	sharon.l@qulabmedical.com	WP 2 member, partner VP R&D
QULAB	Berta	Ben-Shachar	berta@qulabmedical.com	WP 2 member, partner Head, Bioengineering
UCC	Gene	Dempsey	gene.dempsey@gmail.com	WP6 leader and partner PI
UCC	Frederic	Adam	fadam@ucc.ie	WP 6 member
UCC	Lou	Le Gall	llegall@enssat.fr	WP6-7 software developer
UCC	Iyshwarya	Stapleton	istapleton@ucc.ie	WP6-7 research fellow
UCL	Robert	Cooper	robert.cooper@ucl.ac.uk	WP 1 member, Partner PI
UCL	Hubin	Zhao	hubin.zhao@ucl.ac.uk	WP1 member
UdG	Josep	Vehí	josep.vehi@udg.edu	WP 4 leader, partner PI
UdG	Omer	Mujahid	omer.mujahid@udg.edu	WP 4 member, partner technic, Prometeus Exploitation Committee member
UdG	Sara	Casadesús	sara.casadesus@udg.edu	WP 4 member, partner coordinator administrative
UGA	Emmanuel	Barbier	Emmanuel.Barbier@univ-grenoble-alpes.fr	WP 3 member, Partner PI
UGA	Florence	Fauvelle	florence.fauvelle@univ-grenoble-alpes.fr	WP3 member
UGA	Clothilde	Courivaud	clothilde.courivaud@univ-grenoble-alpes.fr	WP3 member, Phd Student
UGA	Romane	Salingue	romane.salingue@univ-grenoble-alpes.fr	WP3 member
UNIPD	Sabrina	Brigadoi	sabrina.brigadoi@unipd.it	Coordinator PI
UNIPD	Chiara	Dalla Man	chiara.dallaman@unipd.it	WP 3 leader
UNIPD	Paola	Rigo	paola.rigo@unipd.it	WP 7 leader
UNIPD	Hadija	Marchiori	hadija.marchiori@studenti.unipd.it	WP3 member, PhD student
UNIPD	Marta	Pozza	marta.pozza@unipd.it	Coordinator administrative staff
UNIPD	Donata	Amato	donatamaria.amato@unipd.it	WP7 member, PhD student

4. Presentations

4.1 Technical Overview of the project

PROMETEUS - Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

Technical Overview of the project

- Scientific overview of the project
- Objective and WP organization
- Timeline of the project

PROMETEUS

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Scientific overview

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Prometeus – Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

↑ Survival rate of preterm babies

↑ Impairment in motor/sensory/cognitive functions

Prematurity associated disability cost for first 2 years of life in Europe

> 50,000 € /year/baby

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Scientific overview

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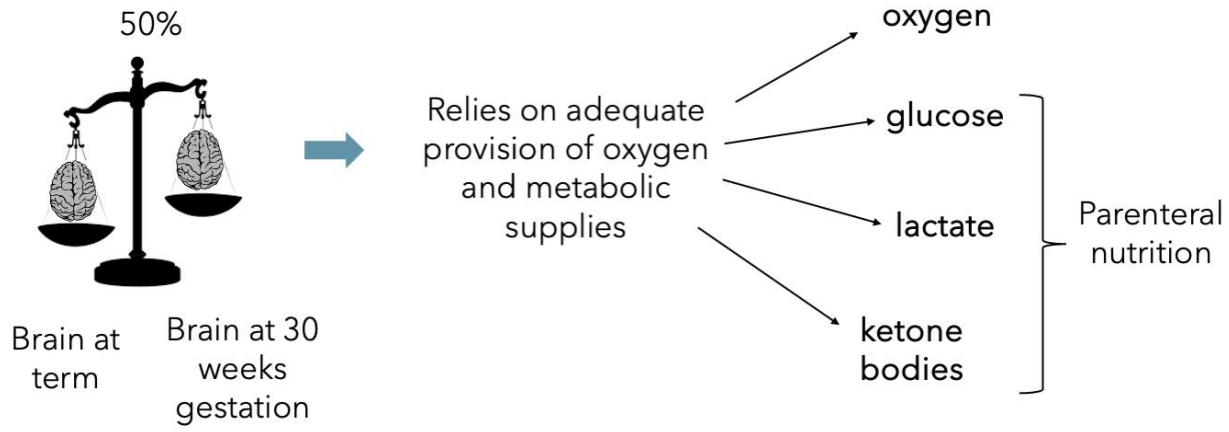

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Scientific overview

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Transient lack of oxygen and key metabolites → Impact brain development and increase risk for disability

There are currently no tools able to continuously monitor in real-time at the cot-side multi-regional brain health and metabolic fuels

Current guidance for neonatal parenteral nutrition is not targeting brain health or considering multi-metabolites

Parents and HCPs feedbacks are not considered in biomedical devices development

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Scientific overview

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Prometeus groundbreaking technology will shift the paradigm of preterm neonatal care and nutrition, through a ***Nutritional Clinical Advisor (NCA)****, that will guide parenteral (intravenous) nutritional intakes of preterm neonates to achieve optimal brain oxygenation*

The development of Prometeus technology will be advised by a feed-forward interaction with families of preterms and HCP to shape the new device aiming at incorporating the needs of the final users. This approach will create a novel paradigm for the industrial development of neonatal devices along with an archive for the future scientists and historians of infancy

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Scientific overview

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To target brain health through parenteral nutrition

State of art

Operational glucose thresholds to adjust nutritional intakes

Prometeus

Real-time advice for glucose, lipid and protein intakes to provide individual brain EU-oxygenation and metabolic fit

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Scientific overview

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Real-time monitoring of CBF, StO_2 and CMRO2 from multiple regions at the cot-side

State of art

Current devices are either not available for cot-side monitoring (e.g., ASL-MRI) or work at the cot-side but are either too bulky, not ideal for neonatal use or not available for multi-site measurements

Prometeus

First multi-channel compact miniaturized cot-side device with preterm-optimized head interface for continuous monitoring of brain hemodynamics

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Scientific overview

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Real-time minimally invasive monitoring of multi-metabolites at cot-side

State of art

Current devices are measuring only glucose and are not adapted for prolonged used in neonates

Prometeus

First multi-metabolites (glucose, lactate, BHB) minimally invasive microprobe-based sensor approach

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Scientific overview

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Model of neonatal plasma-brain metabolic response to guide nutrition

State of art

Lack of models of the effect of glucose and nutrients on preterm brain hemodynamics

Prometeus

Implementation of the first neonatal *in silico* avatar and nutritional clinical advisor (NCA)

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Scientific overview

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The digital twin

State of art

Parental separation, limited access to information and contacts with HCP and on-body devices in NICU can worsen parents' coping with prematurity

Prometeus

Human factor will be considered in Prometeus device development. First European Visual and Oral Archive of prematurity

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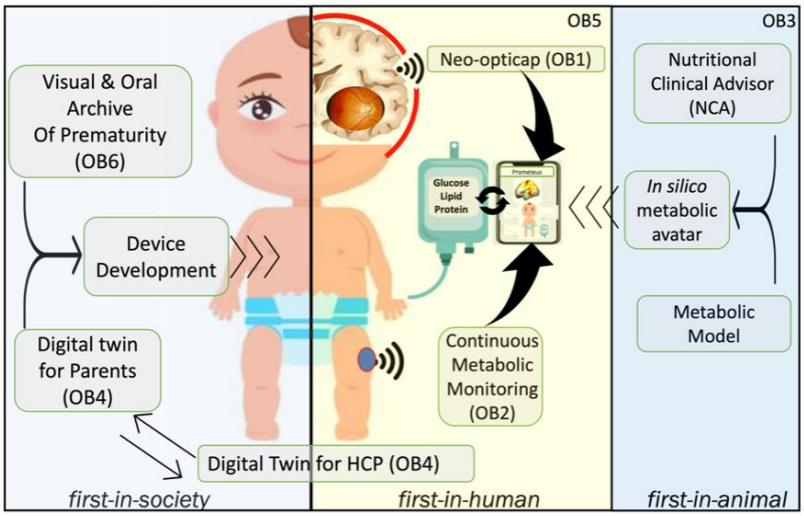
Objectives



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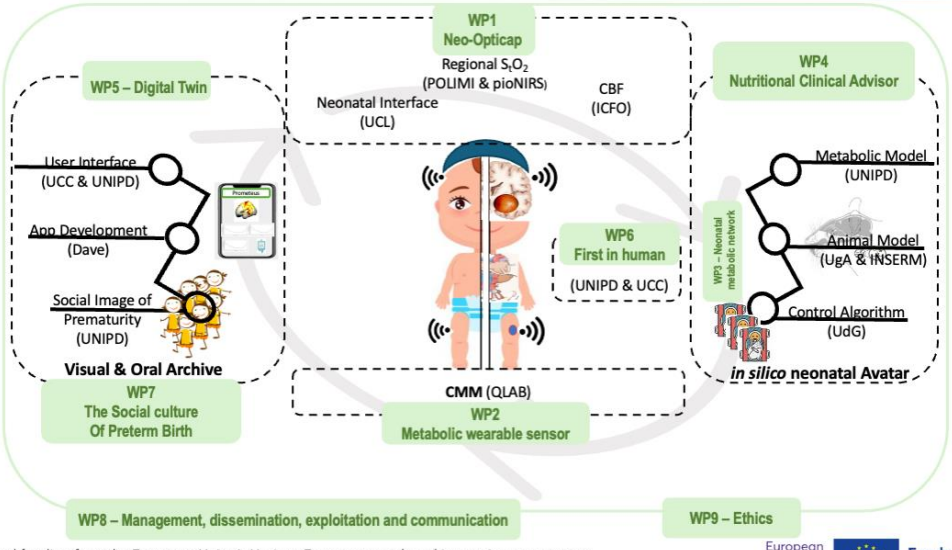
WP organization



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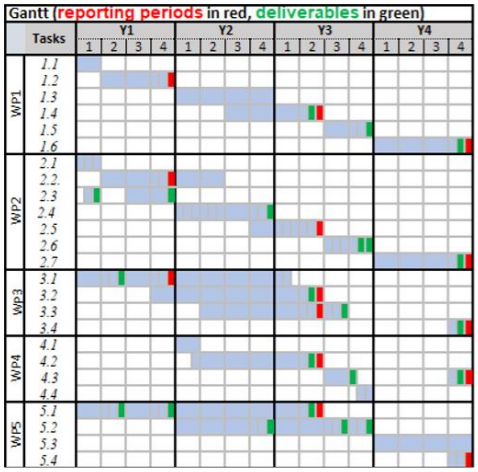
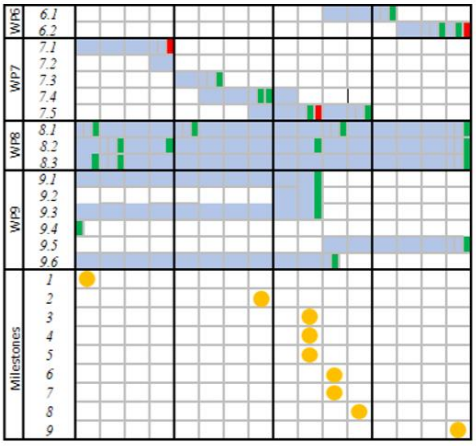
Timeline





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4.2 WP1 - Brain oxygenation and perfusion (neo-opticap)

PROMETEUS - Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

WP1: Brain oxygenation and perfusion (neo-opticap)

Davide Contini
Politecnico di Milano (PoliMi)

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Outline

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- **WP Description**
- **Time-Domain Near InfraRed Spectroscopy (TD-NIRS)**
- **Speckle Contrast Optical Spectroscopy (SCOS)**
- **Neo-Opticap Layout**
- **Optical Probe**
- **TD-NIRS Module**
- **SCOS Module**
- **Conclusions**

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Partners Involvement

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Number	Role	Short name	Legal name	Country
1	COO	UNIPD	UNIVERSITA DEGLI STUDI DI PADOVA	IT
2	BEN	QLAB	QULAB MEDICAL LTD.	IL
3	BEN	UdG	UNIVERSITAT DE GIRONA	ES
4	BEN	POLIMI	POLITECNICO DI MILANO	IT
5	BEN	pioNIRS	PIONIRS SRL	IT
6	BEN	ICFO	FUNDACIO INSTITUT DE CIENCIES FOTONIQUES	ES
7	BEN	DAVE	DAVE SRL	IT
8	BEN	UGA	UNIVERSITE GRENOBLE ALPES	FR
8.1	AE	INSERM	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE	FR
9	BEN	UCC	UNIVERSITY COLLEGE CORK - NATIONAL UNIVERSITY OF IRELAND, CORK	IE
10	AP	UCL	UNIVERSITY COLLEGE LONDON	UK

Neonatology

System integration and WP leading
Module TD NIRS

Module SCOS

Cloud-based platform (digital cloud twin)

Neonatology
Module HEAD CAP

Partner defining needs/constraints from other WPs

Partner designing, building, and testing the neo-opticap

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Tasks and Timing

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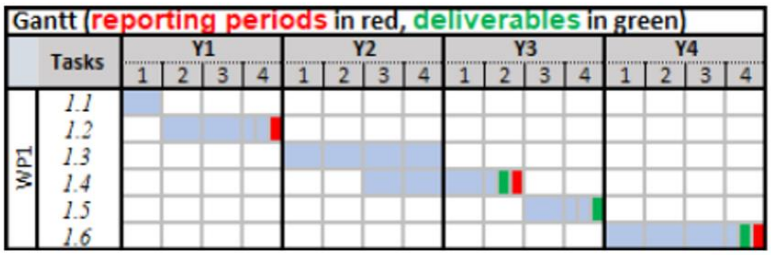
Tasks:

- Task 1.1 (M1-M3) Definition of technical specifications (UNIPD, POLIMI, pioNIRS, UCL, ICFO, Dave, UCC).
- Task 1.2 (M4-M12) Module development (UNIPD, POLIMI, pioNIRS, UCL, ICFO).
- Task 1.3 (M13-M24) System integration (UNIPD, POLIMI, pioNIRS, UCL, ICFO, Dave).
- Task 1.4 (M19-M30) Testing, optimization, and validation (POLIMI, pioNIRS, UCL, ICFO).
- Task 1.5 (M31-M36) Investigational Medical device approval documents (UNIPD, POLIMI, pioNIRS, UCL, ICFO, UCC).
- Task 1.6 (M37-M48) Support to in vivo study and system revision (UNIPD, POLIMI, pioNIRS, UCL, ICFO, UCC).



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Deliverables and Milestones

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Deliverable D1.1 – Neo-opticap evaluation of performance

Deliverable Number	D1.1	**Lead Beneficiary**	4. POLIMI
Deliverable Name	Neo-opticap evaluation of performance		
Type	DEM — Demonstrator, pilot, prototype	**Dissemination Level**	SEN - Sensitive
Due Date (month)	30	**Work Package No**	WP1

Description
Evaluation of performance of the neo-opticap device, report of testing results

Deliverable D1.2 – WP1 Medical Device Approval Documentation

Deliverable Number	D1.2	**Lead Beneficiary**	4. POLIMI
Deliverable Name	WP1 Medical Device Approval Documentation		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	36	**Work Package No**	WP1

Description
Documentation for medical device approval by national authorities

Deliverable D1.3 – WP1 Revision

Deliverable Number	D1.3	**Lead Beneficiary**	4. POLIMI
Deliverable Name	WP1 Revision		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	48	**Work Package No**	WP1

Description
Revision of neo-opticap, based on feedback from first in human (WP6)

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
3	Neo-opticap	WP1	4-POLIMI	Fully operating prototype characterized using standardized protocols based on calibrated phantom Linked tasks: 1.1, 1.2, 1.3, 1.4 Linked deliverables: 1.1	30

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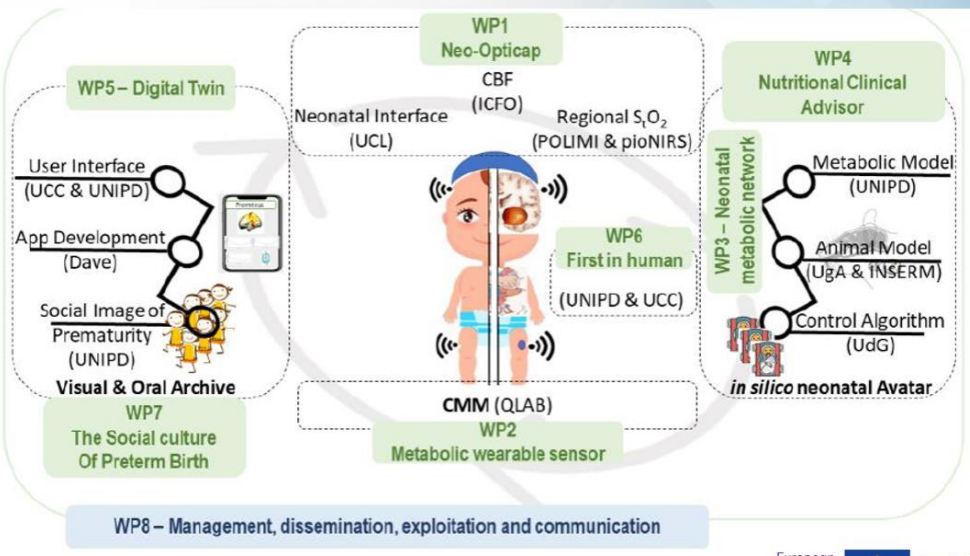
Links with other WPs



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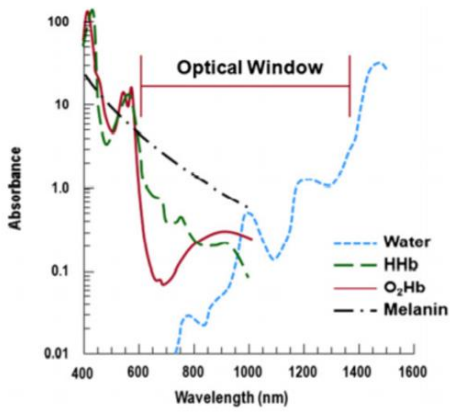
Near-InfraRed Spectroscopy (NIRS)



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TD-NIRS
Time Domain NIRS

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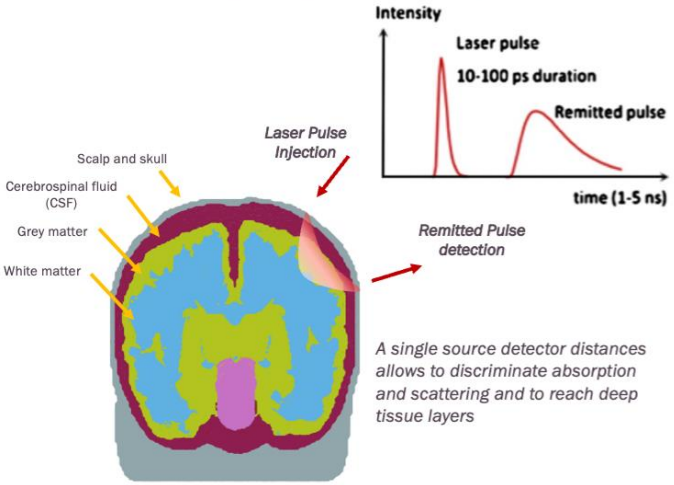

A single source detector distances allows to discriminate absorption and scattering and to reach deep tissue layers

Diffusion approximation of Radiative Transport Equation

$$R(\rho,t) \cong A \cdot t^{-5/2} \left(\mu_s'\right)^{1/2} \exp\left(-\frac{3\mu_s'\rho^2}{4vt}\right) \exp\left(-\mu_a vt\right)$$

$\mu_a(\lambda)$, $\mu_s'(\lambda)$ ➡ pathlength

$$\mu_a(\lambda) = \sum \varepsilon_i(\lambda)\, C_i$$

HHb, O_2Hb

tHb = HHb+O_2Hb

S_tO_2 = O_2Hb/tHb

A. Torricelli et al., "Time domain functional NIRS imaging for human brain mapping," NeuroImage (2014) [doi:10.1016/j.neuroimage.2013.05.106]

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SCOS
Speckle Contrast Optical Spectroscopy

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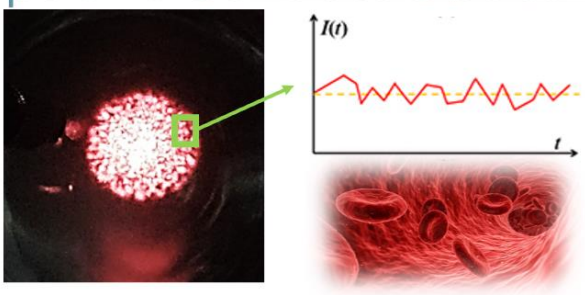
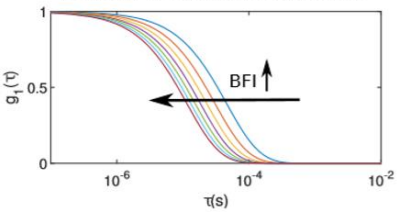
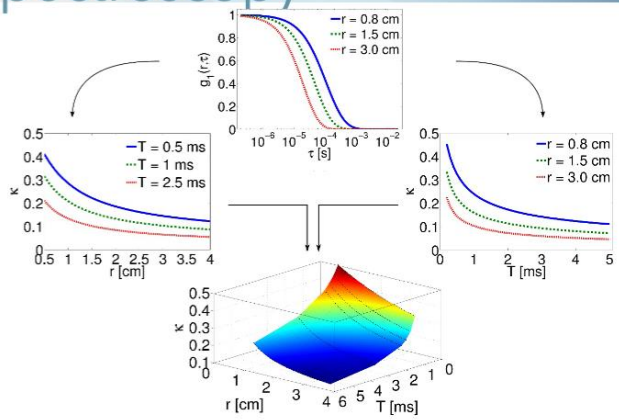


Intensity autocorrelation function





By measuring speckle contrast (k) at different positions or at different measurement time blood flow index can be recovered simplifying the instrumentation and increasing the SNR.

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Probe – General Concept

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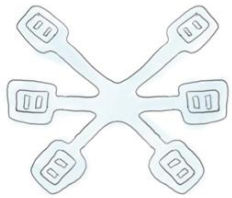

Foam layer stack up construction.
Suitable for mounting probes.
Bottom layer contains a very low tack medical tape which is suitable for placing on infants.

Step One:
Foam structure placed on babies head

Step Two:
Probes placed into foam construction and secured with sticker

Step Three:
Secure the full array in place by stretching over a breathable stretchy gauze

- Patient comfort.
- Smallest footprint allowing the hosting of the 6 optodes.
- Capability to ensure a good optical contact between optodes and patient head.
- Biocompatibility of all materials that contact the patient.
- Possibility to easily sanitize the probe or make parts disposable.
- No interference between the probe and baby's standard care.

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Optode

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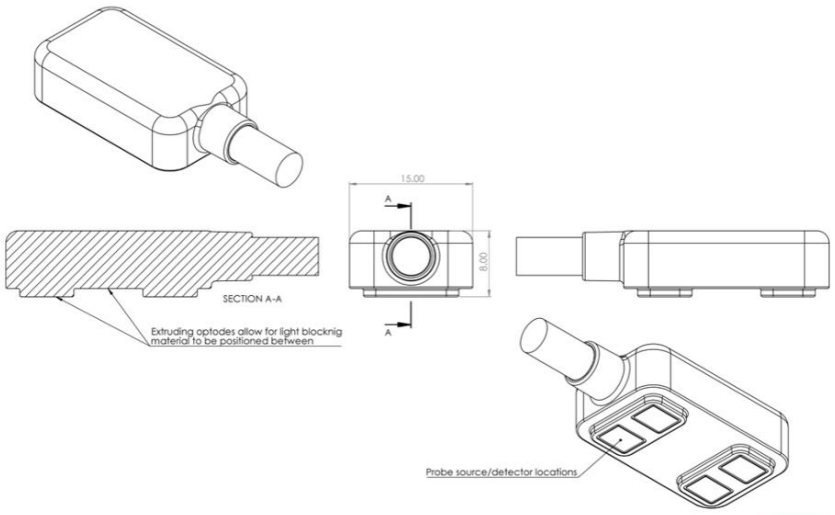

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Optodes – Probe Assembling

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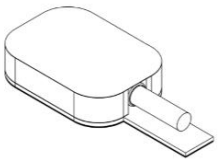

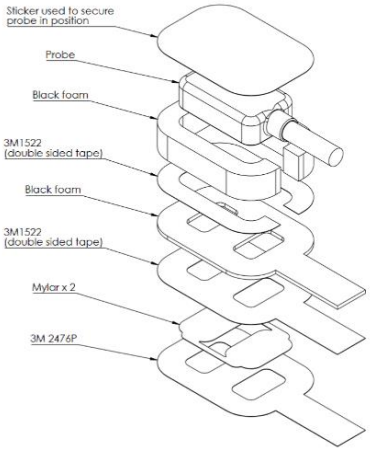

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Measurement Layout

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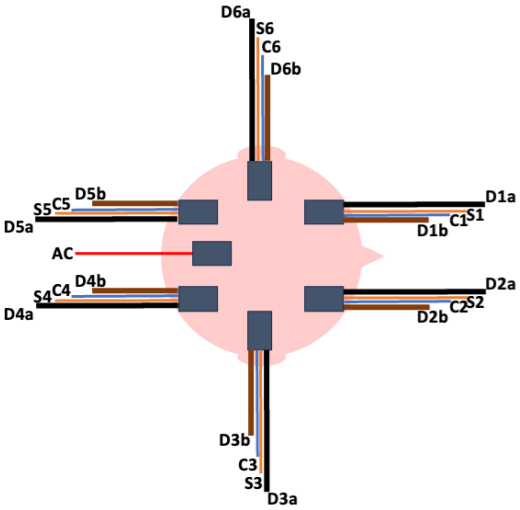

LEGEND

- TD-NIRS DETECTION FIBER (D1a...D6a)
- SOURCE FIBER (S1...S6)
- CONTACT SENSOR ELECTRICAL CONNECTION (C1...C6)
- SCOS DETECTION FIBER (D1b...D6b)
- ACCELEROMETER ELECTRICAL CONNECTION (AC)

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Neo-Opticap Layout

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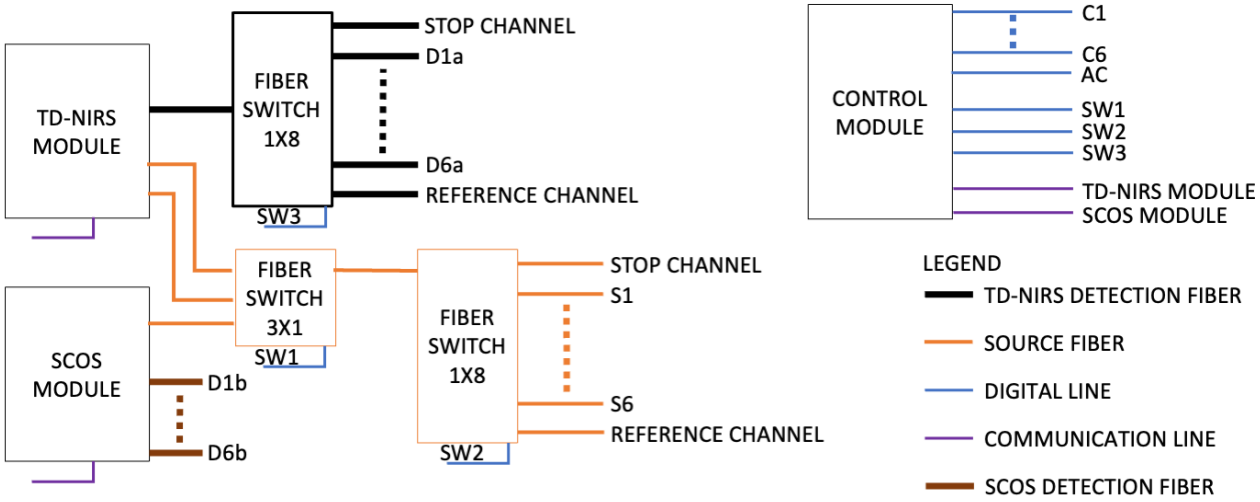

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TD-NIRS Module

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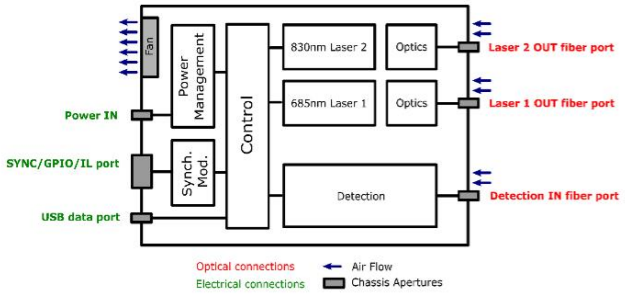

- Two pulsed laser sources at 685 and 830 nm wavelengths (repetition frequency > 50 MHz, average output optical power > 2 mW < 5 mW)
- Automatic equalization of the laser power delivered to the tissue
- A single-photon detection module, based on a solid state photodetector, with a photosensitive area larger than 1.5 mm^2, dark count noise lower than 50.000 counts per second and a temporal resolution better than 150 ps.
- A TCSPC- based (Time-Correlated Single-Photon Counting) timing electronic, able to measure arrival time of each detected photon with 10 ps resolution and conversion rate higher than 2 million events per second.
- Ad-hoc firmware
- A synchronization and GPIO sub-module.

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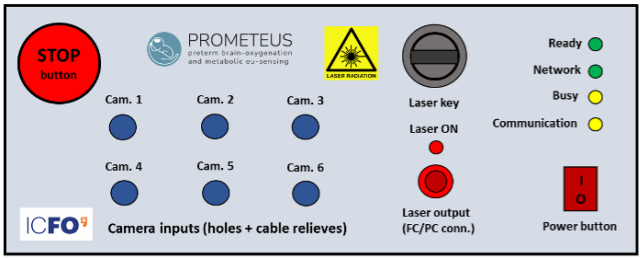
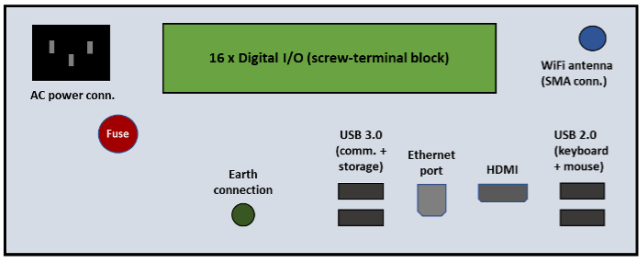
SCOS-Module





- A 785 nm laser with a coherence length >5 m.
- Automatic safety control mechanisms to ensure Laser 1C operation (IEC 60825-1).
- Six ICFO custom SCOS detector modules (~105 independent speckles/detector) and electronics with appropriate optical coupling (~2 pixels/speckle, <0.001 % cross-pixel contamination, ~150 electrons/pixel/frame detection)
- A Dynamic-Linked Library tailored for the control of the module.
- Serial and network interfaces for the real-time transfer of processed data and the periodic transfer of raw data through cloud storage for the latter.
- Digital input/output lines for synchronization with the other modules.

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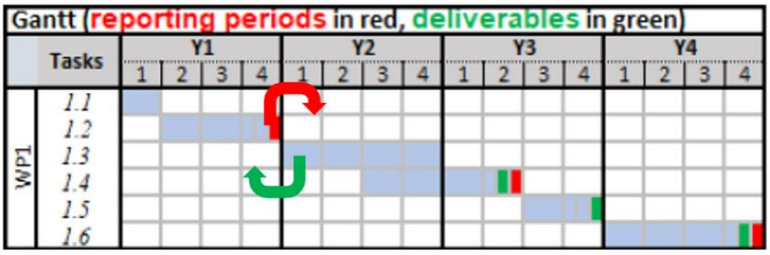
Conclusions

- **Neo-Otpical specs, functionalities and layout defined**
- **TD-NIRS module under deployment to PoliMi labs from PIONIRS**
- **SCOS module under deployment to PoliMi labs from ICFO**
- **First version of the Optical Probe under evaluation by clinical partners**
- **Main ancillary modules for integration under test**



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Future (six-months) Steps

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- **Development of the control Unit**
- **Integrating all the modules together**
- **Writing SW and FW for the synchronization and control of Neo-Opticap**
- **Optode finalization => Probe finalization**

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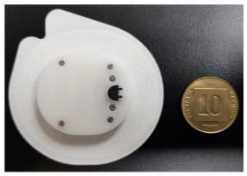
4.3 WP2 - Continuous Metabolic Monitoring (wearable sensor)

PROMETEUS - Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

QULAB.

FirstQ™ - The World's First Minimally-Invasive Patch for Continuous Metabolic Monitoring (CMM)



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WP 2 - Continuous Metabolic Monitoring (wearable sensor)

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1. Progress made in RP1
2. Main results obtained
3. Deliverables and milestones achieved
4. Problems occurred and solutions
5. DEVIATIONS from the DoA
6. Next steps planned

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WP 2 - Continuous Metabolic Monitoring (wearable sensor)

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1. Progress made in RP1

The work carried by QuLab Medical in the first year of the PROMETEUS project was focused on constructing and mechanically testing a novel patch concept for introducing a minimally invasive, microprobe-based sensor array chip into human skin, positioning these sensors at fixed locations within the dermal layer.

QuLab's novel patch concept included two components: 1. A spring-loaded applicator, 2. A skin-attachable patch with a preloaded microprobe sensor array.

The studies performed in the first year of the PROMETEUS project were divided into four parts:

1. *In-vitro* testing of the patch and applicator using artificial skin.
2. Developing and implementing a clean-room assembly protocol for the patch and introducer.
3. Developing and validating a sterilization protocol for the patch and introducer.
4. Testing the safety and efficacy of the patch and introducer in pigs, including a long-term study of patch implantation safety.

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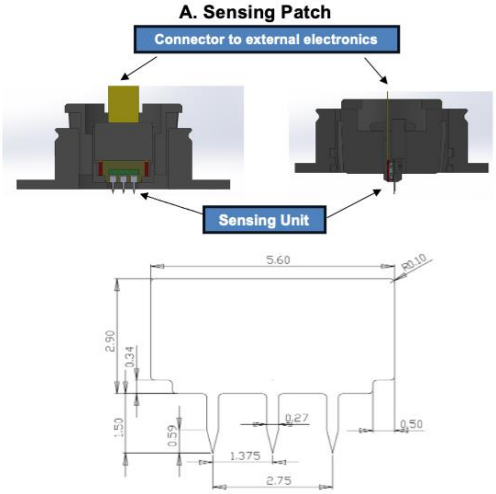
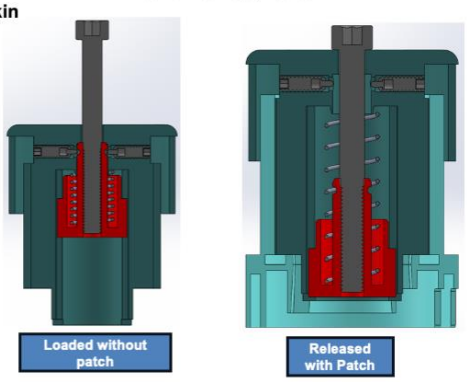
Results: In-vitro testing of the patch and applicator using artificial skin

A. Sensing Patch



B. Mechanical applicator skin



C. Insertion into synthetic

D. Sensing patch with external electronics introduced into human skin.

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WP 2 - Continuous Metabolic Monitoring (wearable sensor)

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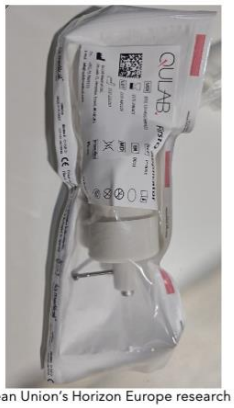
Results: Developing and validating a sterilization protocol for the patch and introducer

ETO-Sterilized Sensing Patch

ETO-Sterilized Mechanical Applicator



- Assembly, sterilization and packing lot release for *in-vivo* validation in pig and FIM studies
- Six-month shelf life was established for this batch to allow for completion of the first in men (FIM) safety study.

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WP 2 - Continuous Metabolic Monitoring (wearable sensor)

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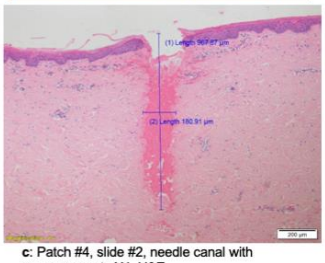
Results: safety and efficacy study of the patch and introducer in pig skin

In-vivo in pig

a: Patches mounted on pig at different body locations

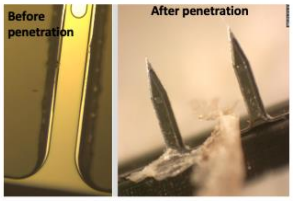
b: Patch #4, microprobes penetration marks on pig skin upon patch removal

Histological analysis of skin biopsy



c: Patch #4, slide #2, needle canal with measurements X4, H&E.

Visual inspection



d: Representative microprobes (x20 magnification) before (a) and after pig skin insertion and removal (b)

Mechanical and safety validation of the FirstQ applicator and patch were established *in-vivo* in a pig model.

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WP 2 - Continuous Metabolic Monitoring (wearable sensor)

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Results: Long-term (14 days) study of safety patch implantation

Day -1

Histological analysis of skin biopsy

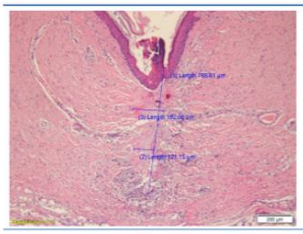

Figure 1: Sample# 1-1, Very clean needle canal with minimal inflammatory reaction. X4, H&E.

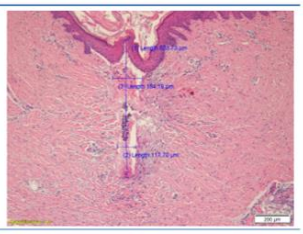

Figure 2: Sample# 1-2, Very clean needle canal with minimal inflammatory reaction. X4, H&E.

Commercial CGM skin biopsy

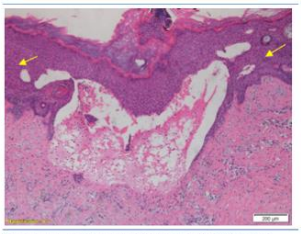

Figure 4: Sample# 4-1, Very strong proliferation of the epidermis (arrow) and only partial canal. X4, H&E.

- Histological analysis of skin biopsies taken after patch removal following 14-days' wear.
- Overall safety of the FirstQ patch sensor has been confirmed, establishing compliance for clinical studies.

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WP 2 - Continuous Metabolic Monitoring (wearable sensor)

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3. Deliverables and Milestones achieved

QuLab Medical (QLAB) leads WP2 of the program. Specific project deliverables for the first year of the PROMETEUS program:

1. Obtaining Ethics Committee approval for conducting patch studies in pigs (D2.1 – M3).
2. Finalizing pig biocompatibility studies (D2.2 – M12).

QLAB has successfully accomplished both deliverables, demonstrating the biocompatibility of its patch and microprobe chip components.

QLAB has demonstrated good patch safety and microprobe skin penetration efficacy in pigs, resulting in no microprobe fracture and excellent skin insertion up to a depth of 1mm in live pig skin.

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WP 2 - Continuous Metabolic Monitoring (wearable sensor)

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4. Problems occurred and solutions – N/A

5. DEVIATIONS from the DoA - N/A

6. Next steps planned:

For the second year of the project, our objectives are reaching POC for simultaneous and parallel glucose and lactate sensing in pigs and then in humans. We will focus on improving the dynamic range of these sensors to optimally respond to the full physiological concentration of both metabolites, by depositing different limiting membranes on top of the hydrogel that immobilizes the metabolite-specific enzyme.

In the first half of the second year of the program, QLAB is planning to complete its First-In-Man study to demonstrate patch safety and MP skin penetration.

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4.4 WP3 - Metabolic Model and neonatal in silico avatar

PROMETEUS - Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

WP3 - Metabolic Model and Neonatal I*n Silico* Avatar

Prof. Chiara Dalla Man
Department of Information Engineering
University of Padova

PROMETEUS

Prometeus Annual Review Meeting, March 13th 2024

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Partners

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- University of Padova (UNIPD)
- University of Grenoble Alpes (UGA)
- University of Girona (UdG)

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Aim

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Development of the mathematical model of glucose, lactate and BHB utilization and production and their effect on CBF, StO2 and CMRO2 (brain hemodynamics).

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Model Development and Use

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- The model will be first developed using the preclinical (animal) data that will be acquired by partner UGA and then revised after our first in human experiment.
- The developed model will be at the basis of the controller developed in WP4 by partner UdG.

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Tasks

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- Task 3.1 *In vivo* animal study (UGA, UNIPD)
- Task 3.2 Tracer and MRI analysis (UGA, UNIPD)
- Task 3.3 neonatal *in silico* avatar (UNIPD, UdG)
- Task 3.4 Metabolic model adaption to human data (UNIPD, UdG)

		Y1				Y2				Y3				Y4			
	TASKS	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
WP 3	3.1																
	3.2																
	3.3																
	3.4																

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Progress made in RP1

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- Recruited human resources.
- Approval of the protocol by the Ethical Committee.
- Optimization of the experimental setting for the *in vivo* animal trial.
- Theoretical analysis of metabolic paths of the tracers.
- Investigating the possibility to incorporate lactate kinetics in an existing metabolic simulator based on in-house data (proof of concept).

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Recruited Human Resources

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@UGA

- 1 PhD student recruited, began 9/2023 for 3 years – Clothilde COURIVAUD
  ➔ Already trained for animal experiment and animal surgery

- 1 biological engineer recruited, began 11/2023 for 2.5 years – Romane SALINGUE.
  ➔ 2 weeks training for animal experiment (11/2023)
  ➔ 1 week training for animal surgery (1/2024)
  These two trainings are mandatory to work in autonomy

@UNIPD

- 1 PhD student recruited, began 10/2023 for 3 years – Hadija MARCHIORI
  ➔ Already trained in basic mathematical modeling

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Protocol Approval

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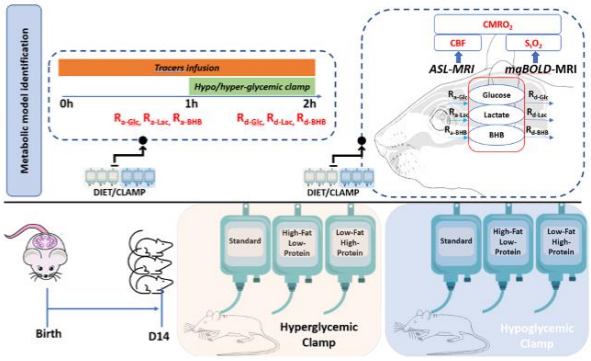
Experimental protocol

- rat pups ~14 days
- 10 animals per group.
- 6 groups for MRI study and 6 groups for blood tracers quantification



Application to the ethical committee: **approved 10/2023 (D3.1, Ethics rats)**

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In vivo Animal Study

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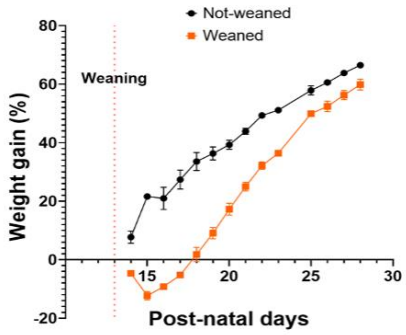
Currently, UGA is optimizing the various bricks of the experimental protocol and is now able to:

- perform early weaning (remove rat pups at 13 days of age from their mother)



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In vivo Animal Study

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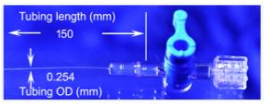
- to place venous catheters (arterial catheters: ongoing)
- to monitor blood glucose over time
- to modify the glycemia using insulin/glucose injection
- to perform cerebral blood flow maps using MRI (adaptation of the cradle, the anesthesia mask).

Femoral artery catheter (left) and venous catheter (right)

Caudal veins catheters



Microcatheter (Doccol's Corporation)

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In vivo Animal Study

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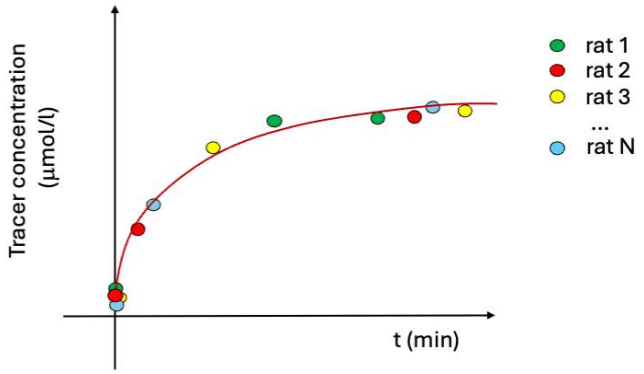
UNIPD and UGA are also optimizing the sampling schedule of the tracers and metabolites to be able to extract from the data as much information as possible

Constant tracer infusion



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In vivo Animal Study

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Next steps

- Tracer injection and detection by NMR and mass spectroscopy.
- Clamp operation to alter glycemia (hypo and hyperglycemia challenges).

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Tracer Analysis

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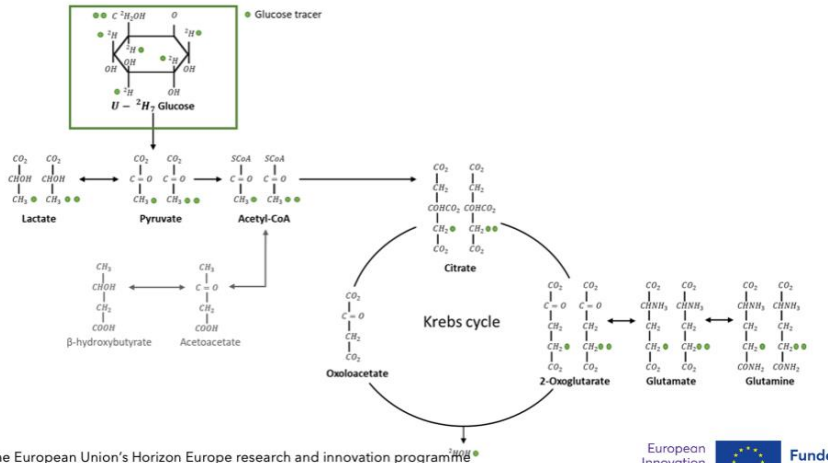
UNIPD analyzed theoretically the metabolic paths followed by the injected isotopic tracers



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Tracer Analysis

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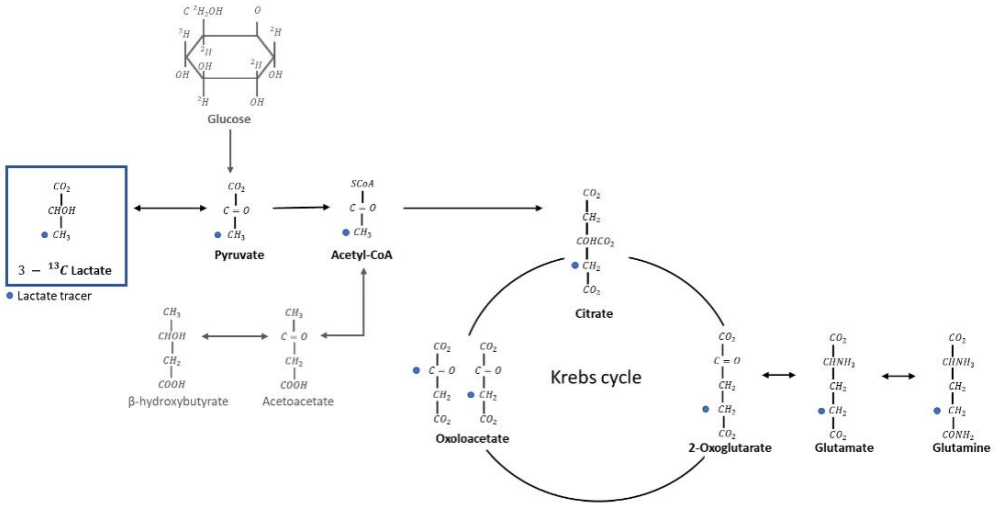

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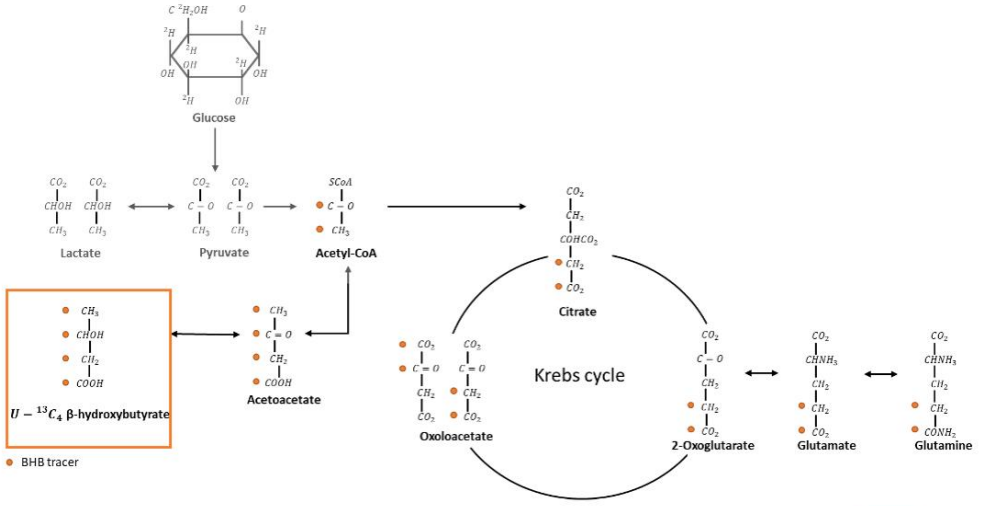
Tracer Analysis



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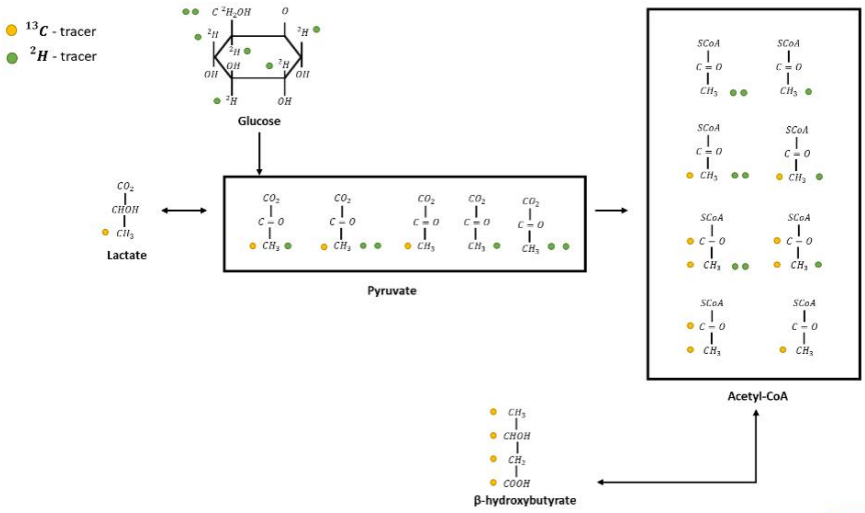
Tracer Analysis



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Mathematical Modeling

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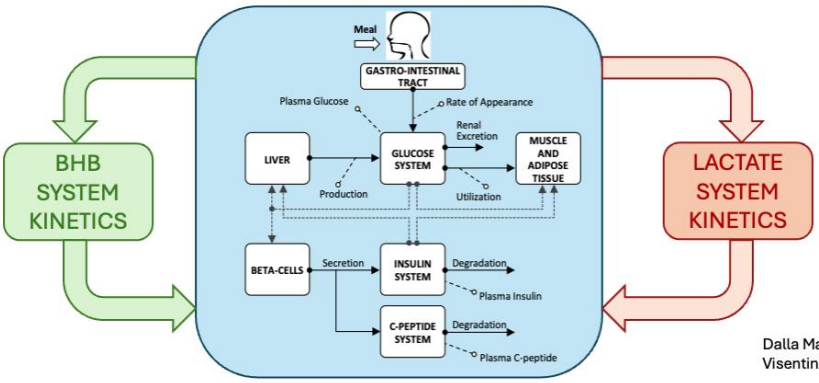
- No data available yet
- Working with The Glucose-Insulin-Cpeptide (Human) Simulator (GIC Simulator) and in-house data in the mean time



Dalla Man et al IEEE Trans. Biomed Eng 2007;
Visentin et al. Diabetes Technol Ther. 2020

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Mathematical Modeling

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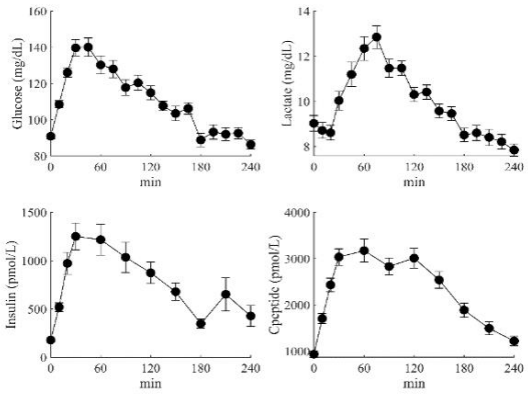
Subjects: 44 obese adolescents (age=16±3, BMI=33±8; M/F=23/21)
Protocol: 75 g OGTT



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Mathematical Modeling

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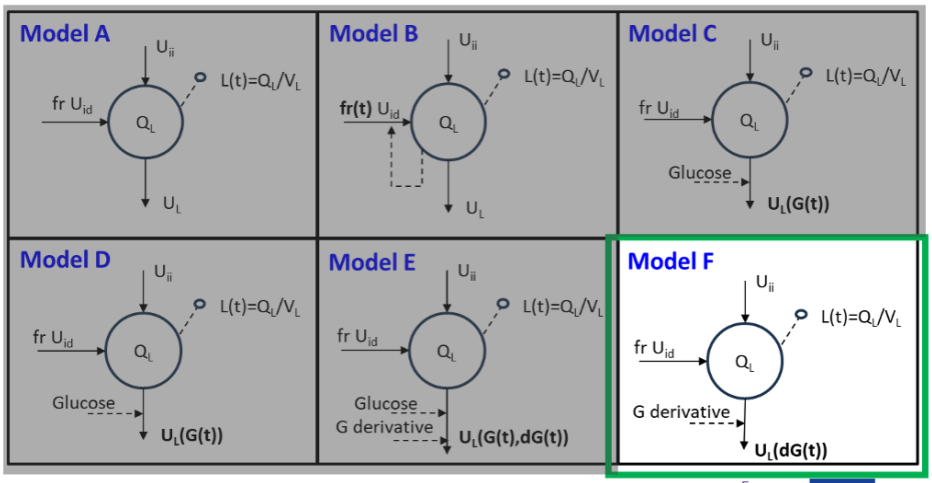
preterm brain-oxygenation
and metabolic eu-sensing

Model Development and Selection



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Mathematical Modeling

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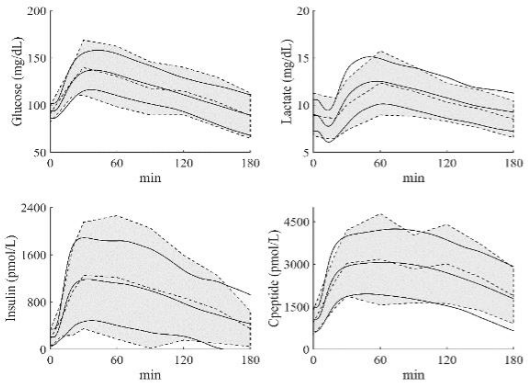
Model Validation



Mean±SD glucose, insulin, C-peptide and lactate *in silico* (continuous line) vs *in vivo* concentrations (dashed lines).

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Main Results

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- Partners have recruited human resources needed for the projects.
- UGA got the approval of the protocol by the Ethical Committee.
- UGA is ready to start the experiments on rat pups.
- UNIPD successfully integrated a model of lactate kinetics in an already available glucose-insulin-Cpeptide simulator using in-house data

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Deliverables

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N	Deliverable name	Short description	WP	Leader	Type	Diss. level	Deliv. date
D3.1	Ethics rats	Ethics approval for animal study	3	UGA	ETHICS	PU	M4
D3.2	Animal	Evaluation of animal study	3	UGA	R	PU	M30
D3.3	Model & Avatar	Evaluation of metabolic model/ avatar	3	UNIPD	R	PU	M32
D3.4	WP3 Revision	Revision of metabolic model	3	UNIPD	R	PU	M48

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Milestones

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Milestone	Milestone name	WP	Due date	Means of verification
3	Metabolic model	WP3	M28	Simulation (*in silico*) study
6	*In silico* neonatal avatar	WP3	M30	Software verified and validated

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Problems Occurred & Solutions

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- No postdoc recruited at UGA, PhD instead
- Delay in ethic authorization
- Tissue fixation equipment delayed

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Deviation from the DoA

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- None

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Next Step

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- Performing the experiments on rat pups
- Analyzing the samples
- Modeling the data
- Developing the neonate simulator based on rat data
- Validating the neonate simulator on human data

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Thank you for your attention

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4.5 WP5 - Cloud-based platform (digital cloud twin)

PROMETEUS - Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

WP5 Cloud-based platform (digital cloud twin)

2023/03/13
Alberto Scarpa - DAVE

PROMETEUS

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WP5 Objectives

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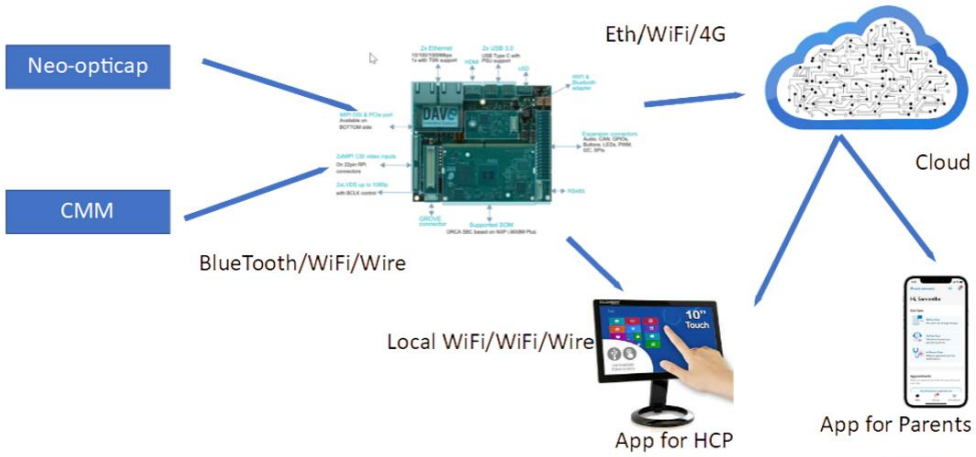
develop the Prometeus Cloud-based environment for NICU on-body monitoring.



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Tasks

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and metabolic eu-sensing

Task 5.1 *Cloud app prototype (UNIPD, Dave, UCC).* HCP's app and parents' app will be integrated into the Prometeus platform through the following components: i) PEU (Prometeus Edge Unit): field device which is in close proximity with the sensing devices and the patients and interoperates with the sensors through their docking stations, manages the Controller execution, interoperates with field equipment and other ICT platforms; ii) PCS (Prometeus Cloud Service): cloud platform.

Task 5.2 *Communication protocol and interoperability (Dave).* Compatibility of the linked devices (connectivity will be set during WP1, WP2) and porting of the control algorithm will be tested: number of connection failures under different environmental scenarios (e.g., distance, on body interference, room temperature); maximum availability, robustness and uptime, especially in the field, which are critical.

Task 5.3 *Support in vivo study (Dave).* Remote support to the in vivo study in WP6 will be provided through remote assistance. 24/7 personnel will be available for troubleshooting for the investigators at the two sites of UNIPD and UCC. Dave will serve as data management site.

Task 5.4 *Prototype revision (UNIPD, Dave, UCC).* To account for feedbacks from NICU personnel with respect to the clinical-user interface of Prometeus in NICU environment.

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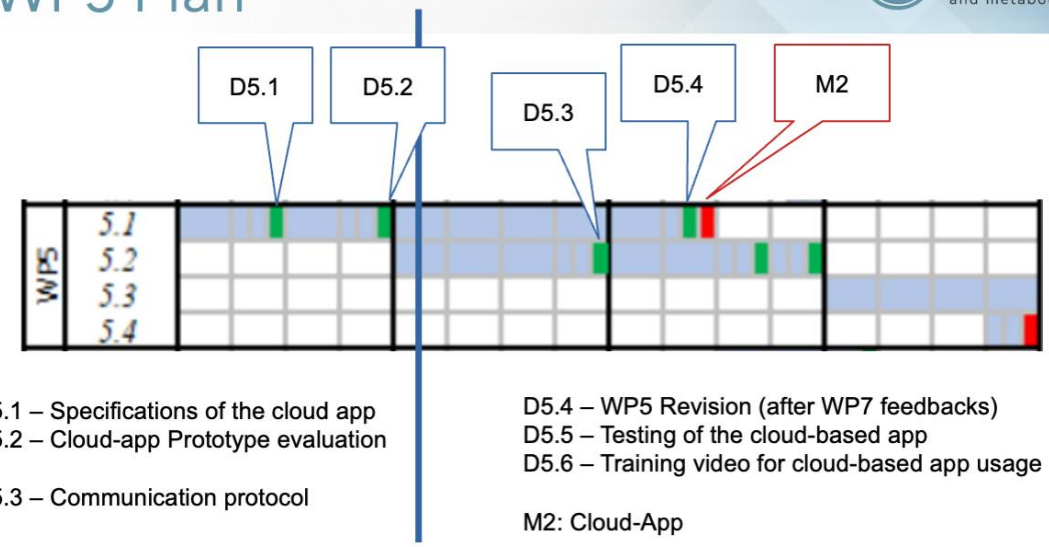
WP5 Plan



D5.1 – Specifications of the cloud app
D5.2 – Cloud-app Prototype evaluation

D5.3 – Communication protocol

D5.4 – WP5 Revision (after WP7 feedbacks)
D5.5 – Testing of the cloud-based app
D5.6 – Training video for cloud-based app usage

M2: Cloud-App

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Deliverables and milestones

Released:

D5.1 Specifications of the cloud app (M 4)
D5.2 Cloud-app Prototype evaluation (M 12)

Work in Progress:

D5.3 Communication protocol (M 22)

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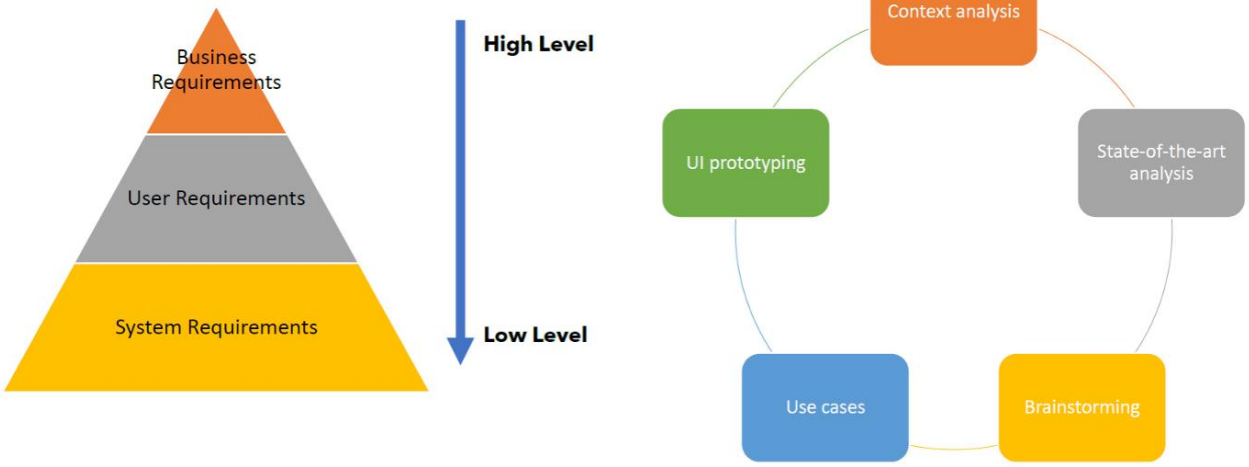
D5.1 Process



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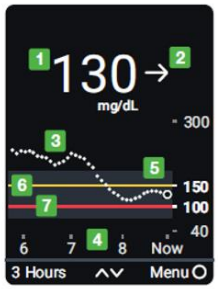
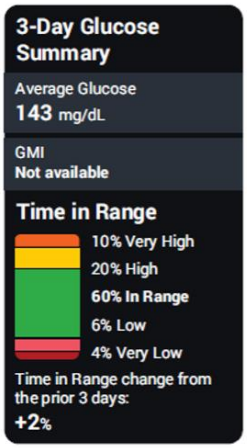
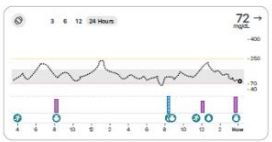
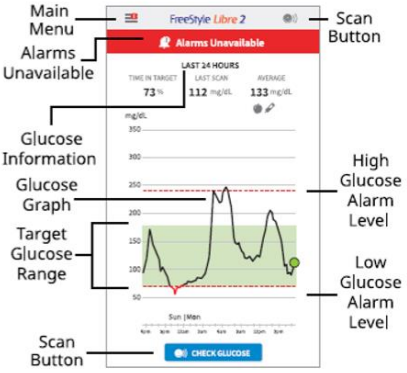
D5.1 Competitors CMM/CGM









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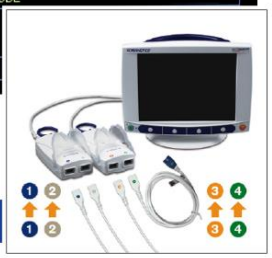
D5.1 Competitors Neopticap



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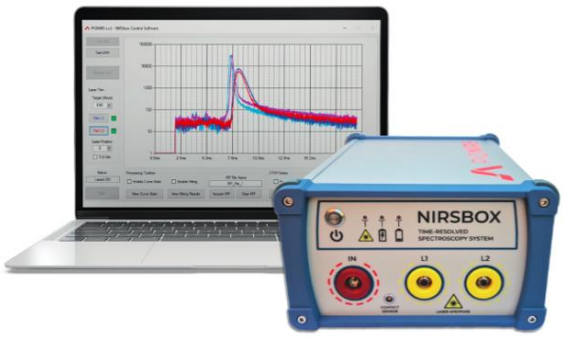
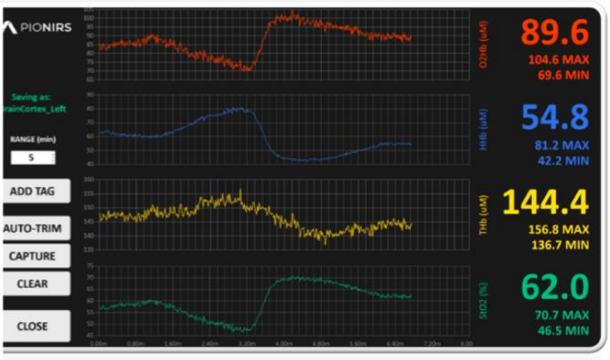
D5.1 Neopticap





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D5.2 Specifications

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	Main topics	Collected specs
Business Requirements	High-level requirements describe the goal and the value of the project/product.	7
User Requirements	User requirements describe what the system should do and how it should work according to the user's point of view. User requirements are designed to satisfy the business requirements.	25
System Requirements	System requirements are the technical requirements needed to satisfy the user requirements.	55

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D5.1 Use cases

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Use case 1
Setup
This use case includes the activities needed to configure the system before starting a monitoring session.

Use case 2
Monitoring
This use case is the core functional usage of the system.

Use case 3
Interaction with parents
This use case describes how the parents at home use the Prometeus system to monitor the health status of their babies while they are hosted at the NICU.

Use case 4
Exam Review
This use case describes the interaction of an HCP with the PCS online to review data from a previous monitoring session.

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Risk Mitigation

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Inter-device Communications Failures (Likelihood M, Severity M)

Communications will be performed in a timed and smooth way, with backup procedures in case of failures (e.g., guaranteeing a critical message which needs to be delivered to the care facility staff in case of a critical condition requiring immediate assistance)

Sesors are directly connected with the PEU.

Alarms generated by the sensors are directly showed to the HCP.
PEU shows alarms/errors both on the HMI with red **pop-ups** and with a **sound alarm**.

PEU monitors the **connection status** with the sensors.
If PEU finds a connection problem an alarm for the HCP is shown on the HMI.

Data sent by the sensors and received by the PEU are stored in **local storage** and **syncronized with the cloud platform (PCS)** for backup.

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D5.2 System Architecture

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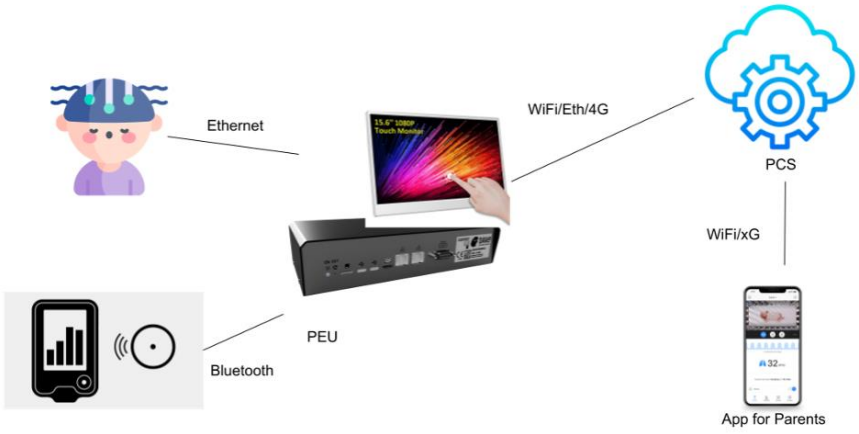

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D5.2 Hardware selection

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Compliance: ISO 60601

- NXP i.MX8M Arm Cortex A53
- Memory: 8 GB LPDDR4
- AI Engine: 2.3 TOPS
- Connectivity: 2 Ethernet, WiFi, Bluetooth
- 15-21” display touch

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D5.2 Software Architecture

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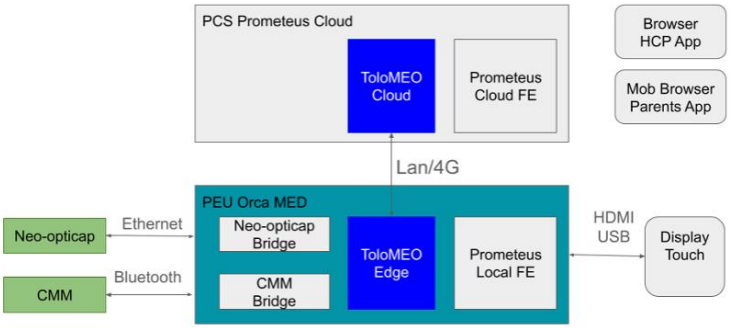

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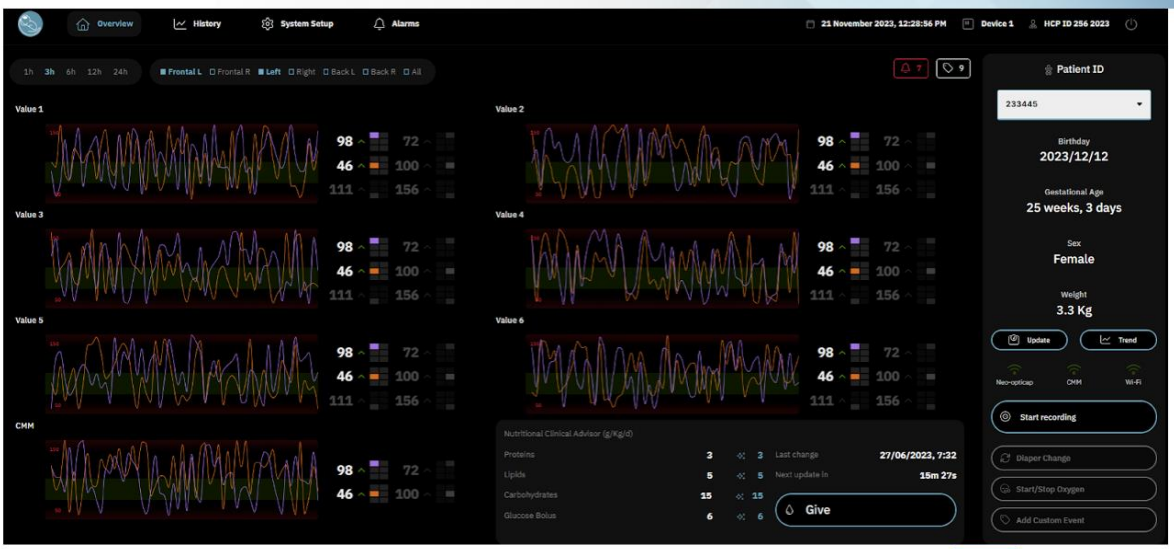
D5.2 Dashboard



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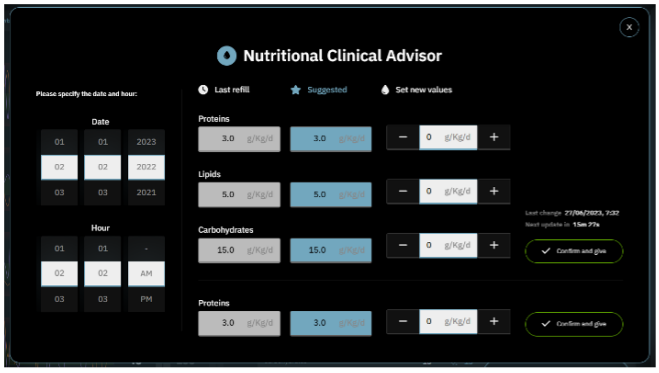
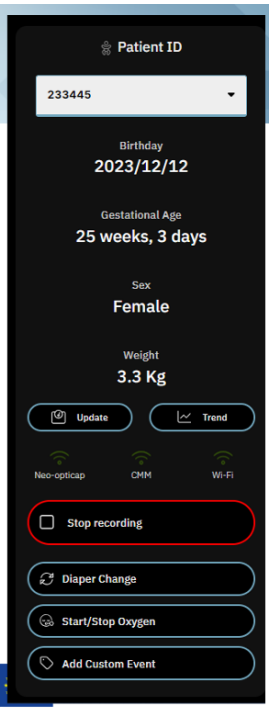
D5.2 Actions and NCA





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D5.2 Events

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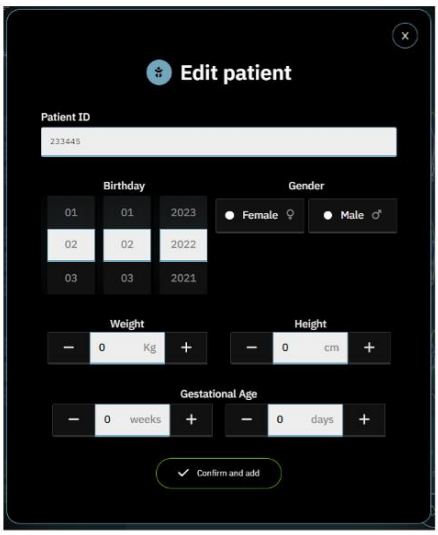

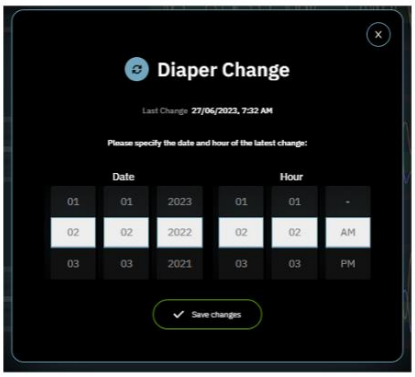

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D5.2 Alarms, Exams, Settings

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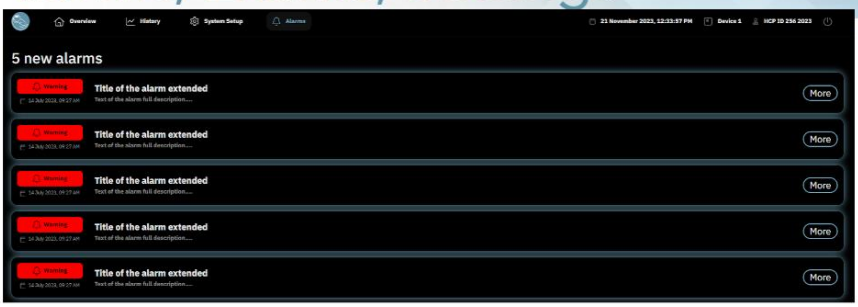

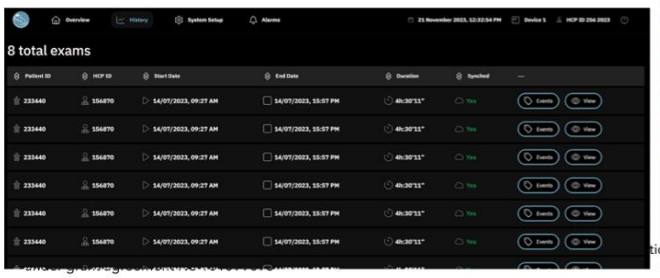

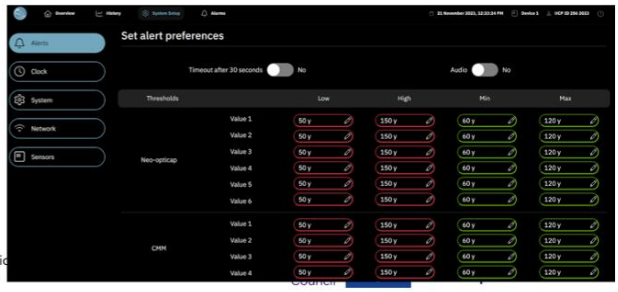

D5.2 Demo

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https://prometeus-01.prometeus.tolomeo.io

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DEVIATIONS from the DoA

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No Deviation

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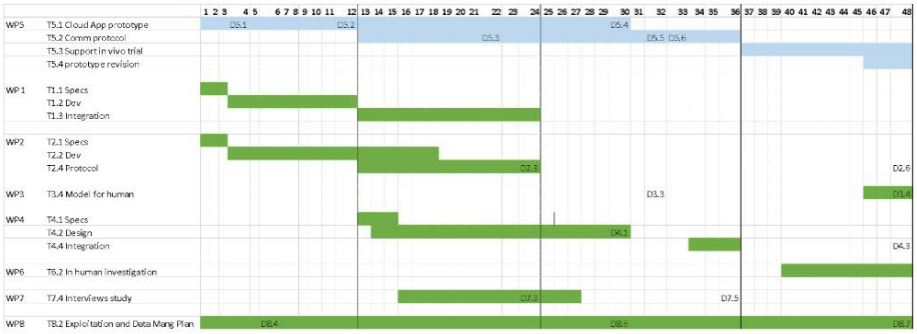
Next steps planned



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4.6 WP7 - The social culture of preterm birth

PROMETEUS - Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

WP7

Partners involved:
UCC, UNIPD

PROMETEUS

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OB6: The social culture of the preterm birth

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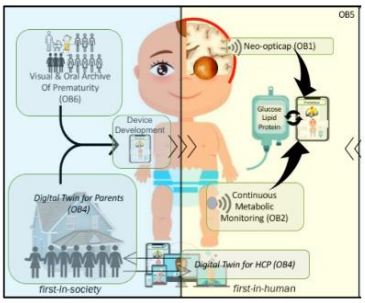
WP7 aims to:

a) evaluate the **potential impact** of on-body monitoring devices on parents and healthcare personnel (HCP) and their personal experience with prematurity

b) create the first **Visual and Oral Archive of prematurity**, containing **longitudinal memories** of the experience related to:

- Prometeus devices development
- premature birth



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Tasks

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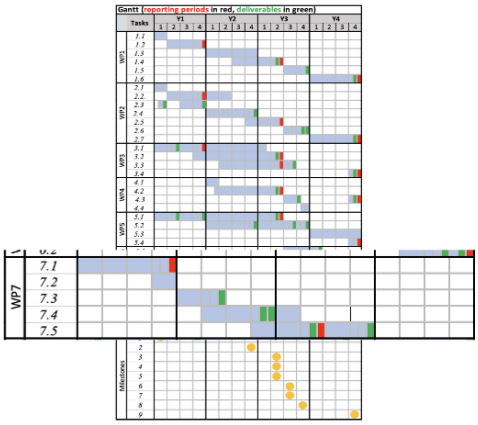
and metabolic eu-sensing

Task	Task Labels (from path-finder project)
7.1	Development of assessment tool (UCC, UNIPD)
7.2	Ethical Committee Approval for the interview collection (UNIPD, UCC)
7.3	Script for video recording (UNIPD, UCC)
7.4	Assessment and interview study for parents and HCP on device development (UNIPD, UCC)
7.5	Visual and oral archive of prematurity (UNIPD)



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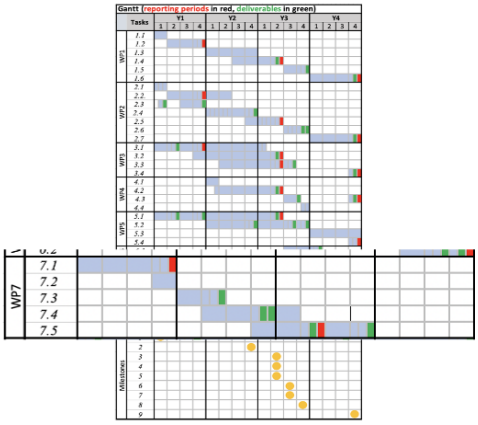
Tasks

PROMETEUS
preterm brain-oxygenation
and metabolic eu-sensing

Task	Task Labels (from path-finder project)
7.1	Development of assessment tool (UCC, UNIPD)
7.2	Ethical Committee Approval for the interview collection (UNIPD, UCC)
7.3	Script for video recording (UNIPD, UCC)
7.4	Assessment and interview study for parents and HCP on device development (UNIPD, UCC)
7.5	Visual and oral archive of prematurity (UNIPD)



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Task 7.1: Development of assessment tool

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Task 7.1 was dedicated to the definition of tools to administer to parents and HCP over a longitudinal period.

Task	Task Labels (from path-finder project)
7.1	Development of assessment tool (UCC, UNIPD)
7.2	Ethical Committee Approval for the interview collection (UNIPD, UCC)
7.3	Script for video recording (UNIPD, UCC)
7.4	Assessment and interview study for parents and HCP on device development (UNIPD, UCC)
7.5	Visual and oral archive of prematurity (UNIPD)

Next step planned: Task 7.4 (Longitudinal data collection)

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Task 7.1: Development of assessment tool

PROMETEUS
preterm brain-oxygenation
and metabolic eu-sensing

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

1 *Integrated Patient Journey Mapping tool*

A medical and emotional assessment of the families through a digital diary developed by UCC that takes into consideration the physical and emotional path of each patient to promote empathy and empowerment.

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Task 7.1: Development of assessment tool

PROMETEUS
preterm brain-oxygenation
and metabolic eu-sensing

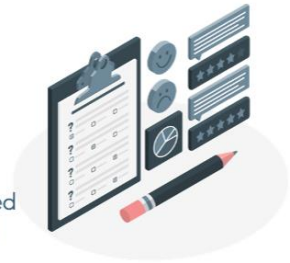
Università degli Studi di Padova

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

A review of the literature was conducted in March 2023 to investigate which tools were mostly administered on parents of preterm infants and HCP working in NICU.

2 *Psychological assessment*

A psychological assessment of both the families and HCP through standardized questionnaires that investigate personal wellbeing and coping strategies.



UCC and UNIPD selected the following test battery:

- **PERMA-Profiler** - wellbeing
- **STAI** - anxiety
- **BDI** - depressive symptoms
- **COPE** - coping strategies
- **PPQ** - PTSD symptoms related to childbirth
- **EPDS** - perinatal/postnatal depression

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Task 7.1: Development of assessment tool

PROMETEUS
preterm brain-oxygenation
and metabolic eu-sensing

Università degli Studi di Padova · UCC University College Cork, Ireland

3 *Impact of on-body monitoring devices*

A psychometric assessment of both the families and HCP through

a) standardized questionnaires
b) a qualitative ad hoc interview

example of questions:

Now some situations that occur in the NICU will be listed. We would like to know how stressful these situations are for you.

1. The smell in the room where preterm newborns are hospitalized
2. To see the newborn inside the incubator

a.

To investigate stressor perception in the NICU and the nurse-parent relationship:

- **PSS-NICU** - stressors perception (parents)
- **PS-ICU** - stressors perception (HCP)
- **NSPT** - perceived support (parents)

b.

To evaluate the impact and perception of Prometeus on-body monitoring devices, **we are developing** the questions of a qualitative ad hoc interview

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Task 7.2: Ethical Committee Approval

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In order to start data collection (Task 7.4), a draft of the entire protocol has to be sent to the Ethical Committee.
The entire protocol (sample and methods) will be the same for UCC and UNIPD.

COMITATO ETICO DELLA RICERCA PSICOLOGICA (AREA 17)
Dipartimenti/Sezione di Psicologia - Università di Padova
Via Venezia 8, 35131, Padova
FAX. +39-0498276600, Email: comitato.etico.area17@unipd.it;
Sito WEB: https://comitati-etici-unipd.scientificnetwork.org/

Univocal code: 111-a
Date of approval: 08/07/23

UCC University College Cork, Ireland

Pending

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Task 7.3: Script for video recording

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Task 7.3 is dedicated to develop the scripts to conduct ***longitudinal narrative sessions***, that are semi-structured interviews repeated over a 4-month period. The scripts consist of a protocol to follow in both sites when data collection starts, which defines the environment, the details and the open-ended questions of the interview.

The interviews aim to bring out **themes** related to parents and HCP experience of prematurity.

Task	Task Labels (from path-finder project)
7.1	Development of assessment tool (UCC, UNIPD)
7.2	Ethical Committee Approval for the interview collection (UNIPD, UCC)
7.3	Script for video recording (UNIPD, UCC)
7.4	Assessment and interview study for parents and HCP on device development (UNIPD, UCC)
7.5	Visual and oral archive of prematurity (UNIPD)

Next step planned: Task 7.5
(Archive Creation)

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Task 7.3: Script for video recording

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Longitudinal narrative sessions aim to bring out **themes** related to parents and HCP experience of prematurity.

The scripts were saved in **two** manuals (one for one for with the following list of contents:

Table of Contents **Page**

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Task 7.3: Script for video recording

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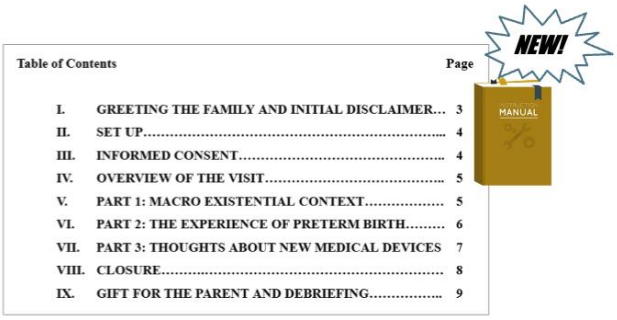
The scripts of the narrative sessions will be adjusted **in the light of the themes emerged** and then used to perform short interviews, that in turn will become part of the Visual and Oral Archive of Prematurity.

IN PROGRESS: **Archive** script and training video implementation (**D7.1, 31/07/2024**).



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Pilot study

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UNIPD conducted a pilot study (may-oct 2023) to test the **feasibility** and **accuracy** of the narrative session script.

Ethical Committee Approval
(specific for pilot study)

Univocal code: 5408
Date of approval: 24/07/2023

Sample: 11 mothers who had a preterm birth. Mother's age: 33-62 (*M*=39,2). Gestational age: 28-36 weeks (*M*=33)
Measure: online semi-structured interviews. Length: 30-55 minutes

Data collection → **speech-to-text conversion** → **Database preparation** → **Script implementation and analysis**

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Pilot study: Analysis

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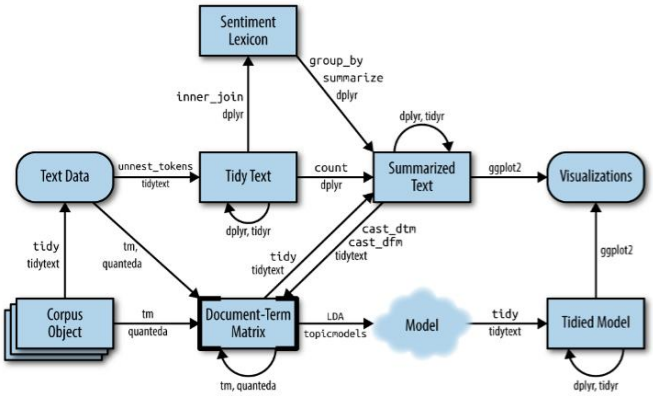

from Silge & Robinson (2017)

- **Text data:** import a CSV with UTF-8 encoding
- **Tidy text:** transform the text in *tokenized* words
- **Preprocessing:** remove *stopwords* (e.g. that, and)
- **Sentiment Lexicon:** classify the sentiment polarity
- **Summarized text:** calculate the frequency for each word
- **Document-Term Matrix:** convert the tidy text in a *document-term matrix*
- **Model:** fit a topic model using LDA
- **Tidied Model:** tidy the model to make handling data easier
- **Visualizations:** visualize the output

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Pilot study: Preliminary results of the sentiment analysis

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Sentiment analysis is used to classify the polarity of a given document (Figure 1), emotion analysis gives scores to different emotions (Figure 2). We performed a sentiment and emotion analysis on our data utilizing the specific function "get_nrc_sentiment" from the syuzhet package (dictionary selected: NRC Word-Emotion Association Lexicon).

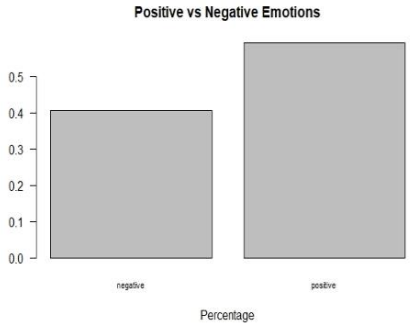

Figure 1: Percentage of Negative and Positive Emotions

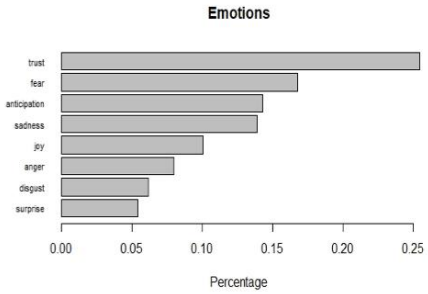

Figure 2: Percentage of emotions: positive (trust, joy, surprise, anticipation) and negative (fear, sadness, anger, disgust).

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Pilot study: Metrics to find k value

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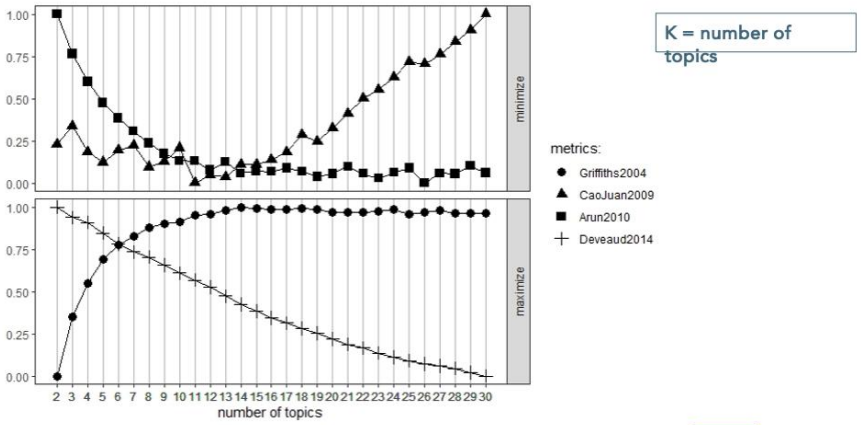
We ran the algorithm by varying k from 3 through 9. We are currently evaluating the optimal k value, using *"FindTopicsNumber"* from the *ldatuning* package, which calculates four different metrics to estimate the most preferable number of topics for a LDA model.



K = number of topics

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Pilot study: Preliminary results of the topic modeling analysis

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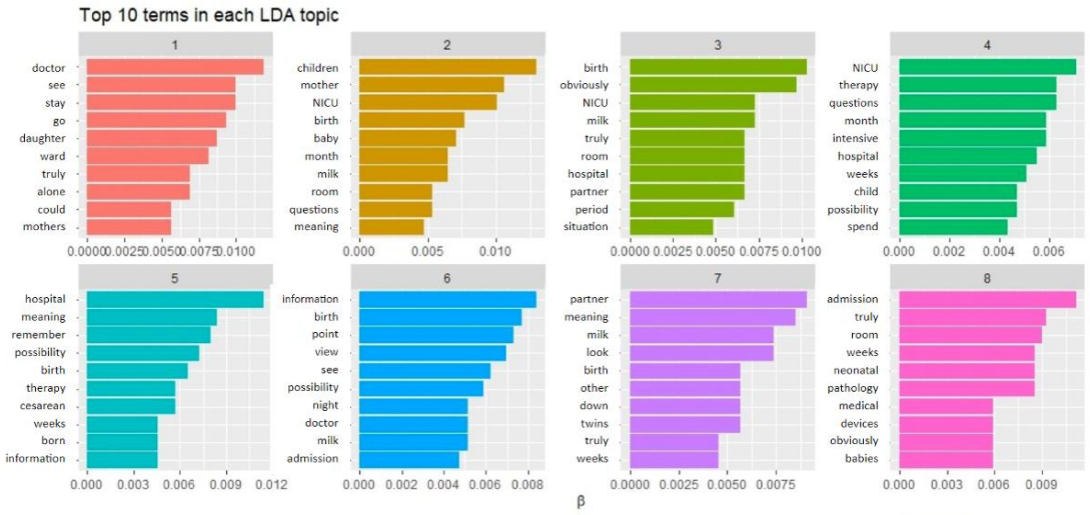

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WP7: Deviations from DoA – Problems and solutions

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- We are still developing the questions of the qualitative ad hoc interview to evaluate the impact and perception of Prometeus on-body monitoring devices (task 7.1)
  - A draft version of the interview has been prepared (revisions are needed)
  - No delays are expected for the next step planned (7.4 – Data collection)

- UCC Ethical Committee Approval (Task 7.2)
  - Still pending
  - No delays are expected for the next step planned (7.4 – Data collection)

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Our team
and its impact on young participants

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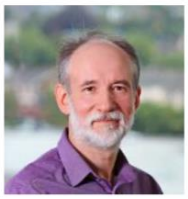
Paola Rigo
Associate Professor
WP7 Leader

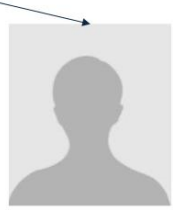
Donata Maria Amato
Research Assistant
Starting period: 01/02/23

Eugene Dempsey
Full Professor



Frederic Adam
Full Professor

Research Assistant
Starting period: 08/02/24



Research Assistant
Starting period: 26/02/24

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UCC University College Cork, Ireland

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4.7 WP8 – Dissemination and Communication

PROMETEUS - Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

WP 8 Dissemination and Communication

PROMETEUS

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WP 8 dissemination

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The PEDR was released on 31st July 2023 as deliverable (D8.3)

Publications (one partner only)

Martelli, F., Pifferi, A., Farina, A., et al. (2024). Statistics of maximum photon penetration depth in a two-layer diffusive medium. Biomedical Optics Express 15(2), 1163-1180

Amendola, C., Maffeis, G., Farina, et al. (2024) Application limits of the scaling relations for Monte Carlo simulations in diffuse optics. Part 1: theory. Optics Express 32(1), 125-150

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WP 8 dissemination

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Dissemination activities:

Name	Type	Target Audience	Description of objectives	Status
Presentations to potential partners and investors	Meetings	Industry, business partners, Investors	Fund raising and strategic alliance	Ongoing
Practical lecture on Diffuse Optics and TD-NIRS. Politecnico di Milano, course in Biophotonics 2023, Physics Engineering.	Education and training events	Research Communities, Other	Practical lesson and hands-on session with TD-NIRS devices, one of the optical technology of Prometeus. Presentation of PIONIRS research activities.	Delivered

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WP 8 dissemination

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CARLA Capsule Milano. Working in photonics in the area around Milan.	Collaboration with EU-funded projects	Research Communities, Citizens, Industry, business partners, specific end user communities, Innovators	Presentation to students about PIONIRS activities and research. Overview on the Prometeus project.	Delivered
Yearly conference of the International Society on Oxygen Transport to Tissue 2023	Conferences	Research Communities, specific end user communities	Presentation of scientific results and preliminary measurements of clinical studies on children, performed with PIONIRS devices, as preliminary steps to Prometeus technology validations.	Delivered

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WP 8 dissemination

Yearly Meeting of the Biomedical Photonics Network 2023	Conferences	Research Communities,citizens, specific end user communities, Innovators, Civil Society	Presentation of scientific results and preliminary measurements of clinical studies on children, performed with PIONIRS devices, as preliminary steps to Prometeus technology validations.	Delivered
OPTICA - From PhD to CEO seminar series, within the Planks 2023 (final of the Physics Olympics).	Clustering Activities	Research Communities, citizens, Industry, business partners	Seminar to students about PIONIRS activities, research projects (comprising Prometeus aim and preliminary results) and personal experiences within the company.	Delivered

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WP 8 dissemination

Invited talk at Innovación para la salud 2023	Conferences	Research Communities, specific end user communities	Presentation of scientific results and preliminary measurements as preliminary steps towards Prometeus technology development. Invited talk Hospital General de México Durduran T. (ICFO)	Delivered

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WP 8 dissemination

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Next planned dissemination activities:

1st workshop at the end of 2024
2nd workshop at the end of 2025
3rd workshop mid 2026
4th workshop at the end of the project (Jan 2027)

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WP 8 communication

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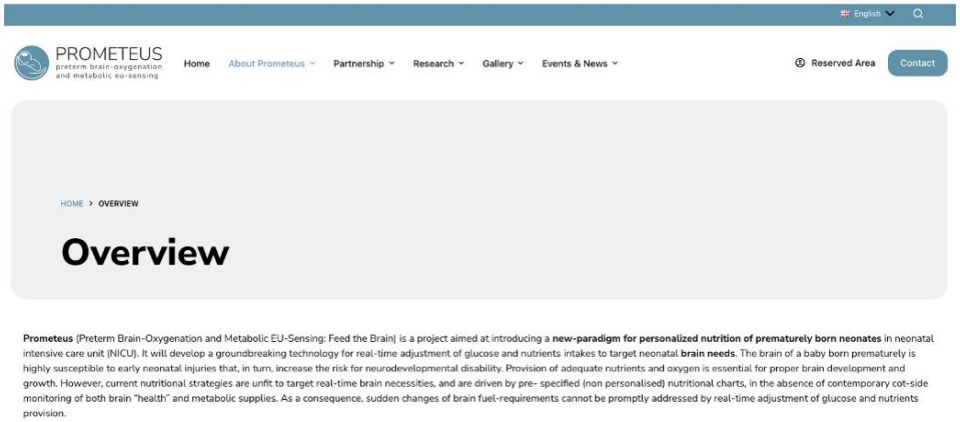
Website and social media (X (former Twitter), Instagram, LinkedIn)



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Communication activities:

Partner Short Name	Communication Activity Name	Description	Target audience	Communication channel	Outcome	Status
UNIPD	Informed family program	Yearly seminaries at the reference country institution targeting families	Specific user communities (if applicable)	Event (conference, meeting, workshop, internet debate, round table, group discussion, etc.)	Online animated cartoon showing in a simple and dedicated language the project's aims and partners involved. In English with subtitles. A few months of delay.	Postponed

Multiple partners

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UNIPD	Visual Identity	Design of the project logo and development of a common visual identity, including a standard format for presentations.	Citizens	Other	General promotional products have been released: project logo, standard template for deliverables,QRcode linked to Prometeus website (created at month 2 and shared with partners)	Delivered
DAVE	Media	Announcement of the Prometeus Project on the DAVE website https://www.dave.eu/it/news-and-media/news/dave-embedded-system-tra-i-partner-di-prometeus	Industry, business partners	Website	received by 3930 visitors read by 12 visitors	Ongoing

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PIONIRS	Social Media	PIONIRS Post presenting project. Linked-in: https://www.linkedin.com/feed/update/urn:li:activity:7061254394394157056 Twitter: https://twitter.com/pionirs_it/status/1655492347390578690	Citizens	Social media	410 views on linkedin 365 views on Twitter	Delivered
PIONIRS	Social Media	PIONIRS Post with a preview of PROMETEUS-related results to be presented at BMPN 2023 event: https://www.linkedin.com/feed/update/urn:li:activity:7143153616911060992	Research communities	Social media	650 views	Delivered

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ICFO	Event	High School British School of Barcelona visit to ICFO	Citizens	Event (conference, meeting, workshop, internet debate, round table, group discussion m, etc.)	25 students & teachers	Delivered
PIONIRS	Media	Dedicated page on PIONIRS website (https://www.pionirs.com/wp/prometeus-project/) describing the aim of the project, its consortium composition, with a link to the official project website.	Citizens	Website	150 unique visitors since page creation (September 2023)	Ongoing

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PIONIRS	Event	PIONIRS booth at ECBO/Laser world of photonics 2023 event (Munich), showcasing its products an activities. Information about PROMETEUS project presented on booth live screen and to audience.	Research communities	Exibition	Event audience: around 1000 persons. Estimated engagement at boot: 5%	Delivered
UDG	Media	UdG Research group website: Post describing the project, partners and objectives of Prometeus. On the official web of the UdG, Post of the press release.	Citizens	Website	57 visits	Ongoing

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PIONIRS	Event	PIONIRS booth at ISOTT 2023 conference (Tokyo), showcasing its products an activities. Information about PROMETEUS project presented on booth live screen and to audience.	Research communities	Exibition	Event audience: around 200 persons. Estimated engagement at booth: 50%	Delivered
PIONIRS	Event	PIONIRS booth at fNIRS Italy 2023 conference (Padova), showcasing its products an activities. Information about PROMETEUS project presented on booth live screen and to audience.	Research communities	Exibition	Event audience: around 100 persons. Estimated engagement at booth: 80%	Delivered

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UNIPD	Website	Creation of a dedicated website translated into the partner languages.	Citizens	Website	The website has been online since early April and fully operational since April 28th 2023. The content has been translated in the partners' languages.	Ongoing
UNIPD	Social Media	Project dedicated pages on Linkedin and Twitter describing the project objectives and aim and informing about its start	Citizens	Social media	Average of 109 views on Linkedin Average 415 views on Twitter	Ongoing

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UDG	Social Media	UdG Post on Linkedin and twitter informing of the start of the project and it's main objectives + Post informing about the in-person plenary meeting that took place in Padova	Citizens	Social media	604 Impressions on LinkedIn - 500 impression on twitter	Delivered
UDG	Media	UdG Press release for the achievement of the project	Citizens	Press release	The article was sent to 167 journalists in Spain and it was shared on different channels. Newspapers: Diari de Girona, El Punt Avui. Online: Europa press, El Gerió, La vanguardia, el Punt avui, Diari de Girona, Gente digital.	Delivered

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UNIPD	Media	UNIPD Press releases announcing the start of the project issued by the University of Padua and local newspapers	Citizens	Press release	364 visits, of which 104 in the first month to news, connection to UNIPD press release, news picked up by local newspapers, permanent place on the website of the department hosting the project	Delivered

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WP 8 Open science

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All publications so far are in Open Access and have been deposited to https://re.public.polimi.it/ (POLIMI is member of EOSC) and are available on the Prometeus website

Future publications will follow the same open science practices, as established in the PEDR. Each partner will deposit their pubs in their institutional or non-commercial repositories

Data recorded so far (WP2 and WP7) are being organized as planned in the Data Management Plan as FAIR (further details in the DMP presentation)

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WP 8 Open science

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To ensure reproducibility of development results of WP2, Qulab Medical has implemented a Quality Management System (QMS) according to ISO 13485:2016 guidelines

The entire patch development process has been documented in Design Inputs and Reviews accordingly

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4.8 Innovation potential and Exploitation presentation

PROMETEUS - Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

EXPLOITATION PLAN (PEC)

PEC: Prometeus Exploitation Commette

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PROMETUS IMPACT

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EARLY BRAIN MONITORING

Neonatal brain hypoxia **80%** incidence in preterm

Reduction of European healthcare prematurity costs (5 y period)

25 M€ -> 5M€

METABOLIC LONGTERM MONITORING

reduce injury due to the **metabolic unbalance** on the growing brain

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2

PROMETUS Market size – HEMO

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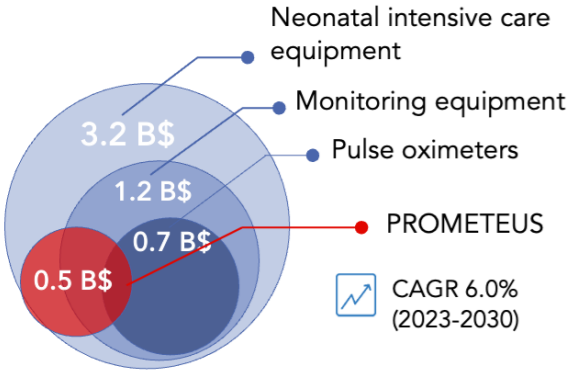


World Health Organization

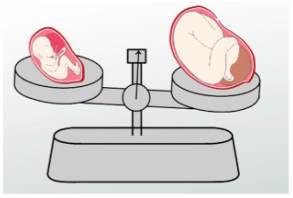
13.4 MLN PRETERM BIRTHS

WHO – 2023 report
ISBN 978-92-4-007389

12%

45.000 $

Hemodynamic Monitoring



88%

4.000 $

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3

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PROMETUS Market size – GLUCOSE

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425 M	33 M	130 M
people WW have diabetes	EU citizens have diabetes	EU citizens have pre-diabetes
► **700M** WW by year 2025[1,2]	That's about 1 out of every 13 people	Around 1 out of 3 adults

€189B is the total annual diabetes cost (direct & indirect) in Europe

- Leading companies in glucose sensors (DexCom, Medtronic, Abbott) have not yet proposed any device for neonatal monitoring due to their prevailing interest in adult/pediatric diabetes market.

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Multilevel exploitation Stages

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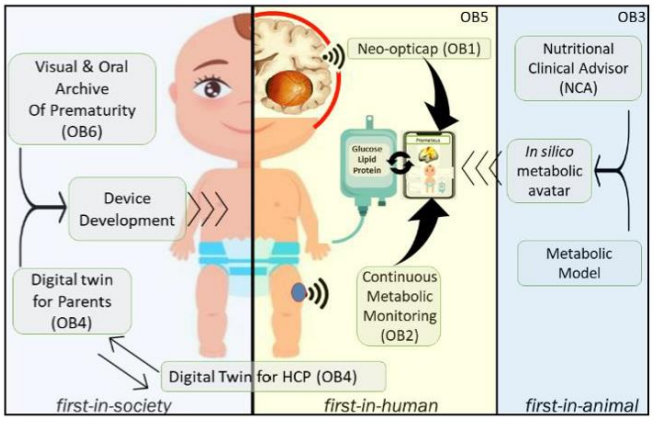
and metabolic eu-sensing

IN-SILICO NEONATAL TWIN

INDIVIDUALIZED NUTRITION STRATEGIES



PROMETEUS FULL PLATFORM EXPLOITATION

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Multilevel exploitation Stages

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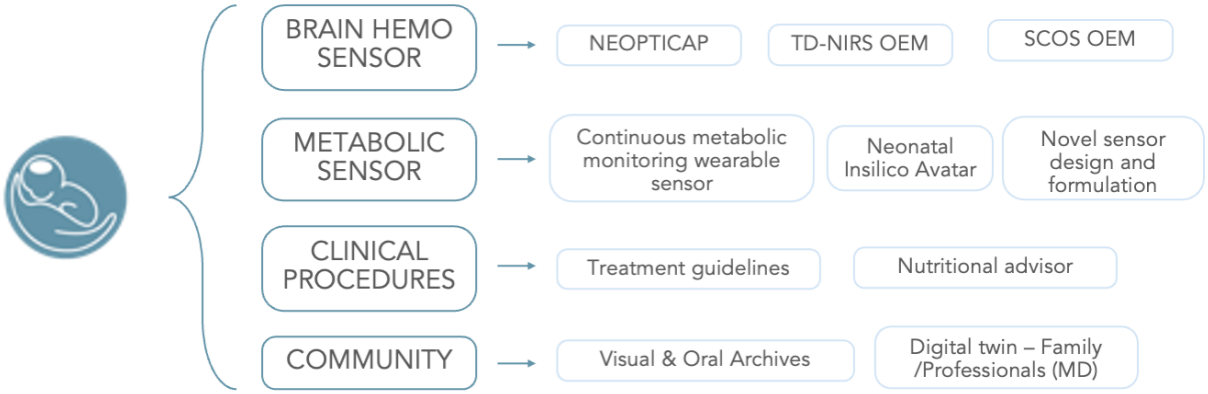

PROMETEUS SUB-COMPONENT EXPLOITATION

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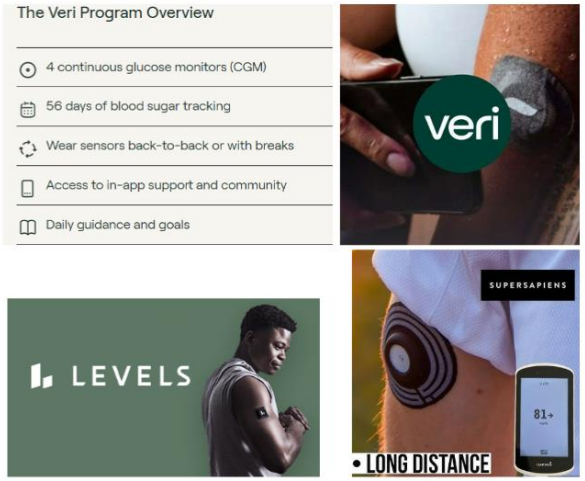
- **PROMETEUS competitors:**
  - Big companies are mainly focussed on ADULTS and Continuous Glucose Monitoring (CGM).
  - Novel Start-ups -> CGM and APP for tracking and guidance no MDR. (LEVELSHEALTH – SUPERSAPIENS – VERI)
  - PROMETEUS:
    Harsh clinical environment - first time integration with CEREBRAL MONITORING
  - CGM (at clinical study level)



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Exploitation admin

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preterm brain-oxygenation
and metabolic eu-sensing

- **IP protection and administration:**

  Within the consortium:

  - Art 8 (CA): Ownership of results: including joint ownership and transfer of results
  - + Art 16 (GA) + annex 5
  - Art 9 (CA): Access Rights: Access right for exploitation and for implementation

- **IP plan:**
  - Continuous monitoring at WP LEVEL each partner
  - Continuous monitoring at GLOBAL level –> Prometeus Exploitation Committee (PEC)

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PEC: Prometeus Exploitation Committee

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- Aim and objectives

PEC should help in preparing the transition towards industrial and commercial usage of the developed products.

Focusses on: intellectual property management to freedom-to-operate and market analyses, coordination of activities related to regulatory documentation, to product and service profiling in liaison with industry, academia, and end-users. [WHAT TO FILE – WHEN TO FILE – HOW TO FILE]

- PEC composition -> PIONIRS | ICFO | UDP | UdG | QULAB | (DAVE)

  6/10 partners are directly represented in the PEC

- Planning

Regularly, each partner will produce a list of the project's outputs that will be submitted to the PEC for evaluating their future exploitation and/or market potential and the adoption of the right protection measures. PEC will benefit from the advice of the The European IP Booster Metagroup to support the "sustainability" of Prometeus over time.

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PEC constitution

PEC First official meeting

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Brain oxygenation and perfusion (neo-opticap)

Continuous Metabolic Monitoring (wearable sensor)

Metabolic Model and neonatal in silico avatar

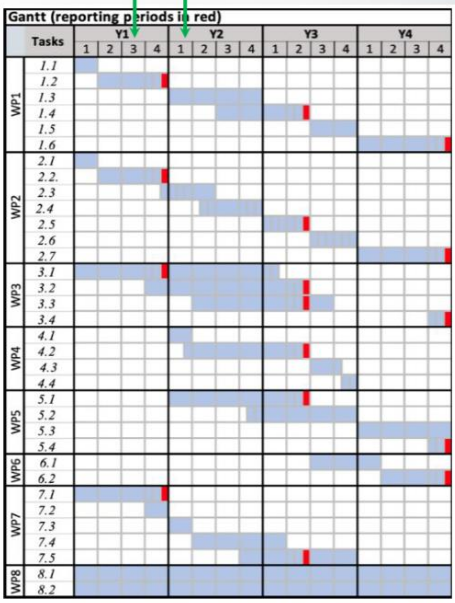
Prometeus Nutritional Clinical Advisor (NCA)

Cloud-based platform (digital cloud twin)

First in human

The social culture of preterm Birth

Management expl / comm



PEC achievements:

- Definition of roles inside the PEC
- First level identification of exploitable outcomes

12 exploitable results

7 products + **5** services

- First level exploitation approach

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Exploitation – Optical Neuromonitoring Platform

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PARTNERS	EXPL. RESULTS	COMPETITORS	END USERS	
PIONIRS POLIMI ICFO UCL	Cerebral TD-NIRS & SCOS monitoring + NEOPTICAP	Research grade: Smal-medium companies [Artinis – NIRx – Gowerlabs – Kernel - Oxiprem]	Research institutions Market size: 100 M€	< 5 years
		Clinical market: big medical company [Medtronics – Edwards – Masimo]	Clinics Market size: 0.5B€	> 5 years

ACTUAL STAGE: prototype multichannel device + sub-components + electronics development / patent

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Exploitation – Glucose monitoring

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PARTNERS	EXPL. RESULTS	COMPETITORS	END USERS	
QLAB	Continuous Multimetabolite Monitoring Patch	Abbott, Dexcom, Medtronic and other smaller-size companies	Diabetic patients: Market size: >€3.0B	< 5 years
			General population (wellness) Market size: >€10.0B	> 5 years

ACTUAL STAGE: Microprobe-based multi-metabolite monitoring patch + Introducer + Electronics development / patent

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Exploitation – Digital Twin - NCA

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PARTNERS	EXPL. RESULTS	COMPETITORS	END USERS	
UdG	Nutritional Clinical Advisor for Personalized Brain Nutrition Recommendation	**Small-medium companies** (Healthy-longer, MindX Sciences, OXYPREM)	Neonatal Intensive Care Unit, Healthcare providers, pump manufacturers **Market size:** Neonatal Intensive Care Market	< 5 years
		Big companies/ Cognitive health market (Novartis, Huma, Johnson&Johnson, Biogen)	Intensive Care Unit, Healthcare providers, pump manufacturers (Medtronic, Lilly, Roche etc.) **Market Size:** Neonatal + adult market	> 5 years

ACTUAL STAGE: NCA controller development

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Identified exploitable results

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Exploitable results	Consortium owner/s	IPR plan/status	Type innovation (e.g. services, new product, new process...)	Next steps	Potential customers /users	Responsible for dissemination
Interoperable App	Dave	industrial design / copyrights	service	SW development	IntensiveCareUnit; Healthcareproviders	Dave
Continuous metabolic monitoring (CMM)	QLAB	industrial design / patent	product/revice		sensor and pump manufacturers (Medtronic, Dexcom, Abbott, Insulet, Lilly, Roche) pharmaceuticals (Lexicon, Sanofi)	QLAB
Novel hydrogel formulations for improved sensor performance	QLAB	industrial design / patent	product	HW development	Sensor and pump manufacturers (Medtronic, Dexcom, Abbott)	QLAB
Electronic circuitry architecture supporting multi-channel electrochemical signal collection and processing	QLAB	industrial design / patent	product/service		sensor manufactures	QLAB
Neo-opticap	UCL,POLIMI,ICFO, PIONIRS	industrial design / patent	product	HW development	Neuroimaging manufacturers (NIRxMedTech, ArtinisMedicalSystem, Gowerlabs)	UCL
Nutritional clinical advisot (NCA) controller	UdG	utility model	product/service		Intensive Care Unit, Healthcare providers, pump manufacturers (Braun, BD Alaris, Medtronic, Lilly, Insulet, Roche)	UdG
Prematurity Visual & Oral Archive	UNIPD	copyright			Preterms' Families and patients, Historians of Science; Psychologists; Exhibitions; Manufacturers / Industries of preterm accessories / medicaldevices	UNIPD
insilico neonatal avatar	UNIPD	copyright			Neonatologists, Biologists, Bioengineers	UNIPD
Nutritionalrecommendations	UNIPD; UdG	freely available / open source			Neonatologists; Neonatal Cochrane; Policymakers	UNIPD
OEM SCOS module	ICFO	patented	new product	Validation and deployment	Research Labs and clinicians	ICFO
Multi-channel FW upgrades	PIONIRS	industrial design / copyrights	new product	Validation and deployment	Research institutions, clinics	PIONIRS
Optical Switch for multi channel TD-NIRS	PIONIRS - POLMI	industrial design / patent	New product	Prototype validation and deployment	optical system manufacturers	PIONIRS/POLIMI

Work in progress...

- Preliminary evaluation

12 exploitable results

7 products + **5** services

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EU innovation network and European Medicine Agency (EMA) Innovation services.

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Strengthening life-sciences innovation across Europe

Tuesday, 21 November 2023

https://www.ema.europa.eu/en/events/strengthening-life-sciences-innovation-across-europe-eu-innovation-network-conference

- European Innovation Network (EU-IN)
- Health Products Regulatory Authority (HPRA)
- European incubators and technology transfer offices (TTOs)

→ power and support the translation of innovative biopharmaceutical and medical technology developments. MDR: regulatory support / contacts and clinical trials

Service name	Date of attendance	Attendees	Recommendations/follow up actions
Strengthening life-sciences innovation across Europe: EU-Innovation Network conference	21/11/2023	- Michele Lacerenza(PIONIRS) - Miguel-Angel Moreno (ICFO) - Omer Mujahid (UdG)	None, but as a comment, we would appreciate more time dedicated to EMA and EU offers rather than presentations of start-ups incubators and TTOs

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PROMETEUS - Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

Thank you!

PEC: Prometeus Exploitation Commette

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4.9 WP8 – Data Management Plan

PROMETEUS - Preterm Brain-Oxygenation and Metabolic EU-Sensing: Feed the Brain

Grant Agreement Number 101099093

WP 8 Data Management Plan

PROMETEUS

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WP 8 DMP

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The DMP was released on 31st July 2023 as deliverable (D8.4)

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WP 8 DMP

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Type of studies

WP1	WP2	WP3	WP4	WP5	WP6	WP7
Phantom and *in-vivo* adult studies to test stability and precision of neo-opticap	*In-vivo* animal studies (pigs) to test CMM sensor biocompatibility and accuracy	In-vivo animal studies (rat litters) to create the metabolic model (tracers, MRI, liquid chromatography-mass spectrometry, histology)	*In-silico* testing of the NCA controller to estimate safety and efficacy	None	In-vivo studies in the preterm population to test the feasibility of using the Prometeus technology	Interviews, standardized questionnaries and narrative sessions for parents and HCPs to evaluate prematurity experience

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WP 8 DMP

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Type of data

WP1	WP2	WP3	WP4	WP5	WP6	WP7
Quantitative	Quantitative & qualitative	Quantitative	Quantitative	None	Quantitative	Quantitative & qualitative
Time-series, optical measurements; Projects and drawings of instrument and modules design	Images	Images; Tissue samples; Blood samples	Generated with simulation		Clinical measurements (time-series, nutritional information, blood samples, blood plasma); Personal data	From interviews and questionnaires; video-audio recordings; personal data
Tb	20-100 Gb	Gb	Gb		Gb	Gb

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WP 8 DMP

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Format and software

WP1	WP2	WP3	WP4	WP5	WP6	WP7
Drawings: Industrial standards and confidential Non-standard software developed by each lab (Matlab, R, Excel, custom-software)	Word, Excel			None	Data from the sensors will be received by the edge application via HTTPS REST or Bluetooth; Stored inside the edge device on a local databased synchronized with cloud	Qualtrics, Zoom, Cloud Speech-to-text (Google)
Binary and text files	.docx, .xlsx, .jpg	. nifti	.csv format			.csv, .xlsx, .mp4, .mp3, .doc

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WP 8 DMP

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FAIR data: Findable

WP1	WP2	WP3	WP4	WP5	WP6	WP7
Non confidential data part of publications: Recognized data sharing repository (e.g., Zenodo)	Dataset identifiable and locatable through DOI	Rules for directory tree in storing preclinical data	Simulated data: stored in Research Data Unipd (a content of OpenAIRE). DOI assigned to each dataset	None	Data store with following metadata (patient ID, health care provider ID, hospital ID, sensor type, start/end date/time)	Anonymized interviews/narrative sessions: Research Data Unipd. Raw data: stored in external encrypted hard-disks Phaidra for the Archive

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WP 8 DMP

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FAIR data: Accessible

WP1	WP2	WP3	WP4	WP5	WP6	WP7
Data confidential will be secured	Data with IP protection will be kept closed	Embargo until first publication		None	PEC will identify proper licences	
	Data deposited using DOI format and accessible through common search tool	Data deposited on zenodo.org with DOI	Simulated data available in Research Data Unipd	None	Data stored for entire project duration up to max 3 years after	Interviews and questionnaire: Research Data Unipd Archive: openly licensed in Phaidra

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WP 8 DMP

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FAIR data: Interoperable

WP1	WP2	WP3	WP4	WP5	WP6	WP7
Forward compatible formats and/or open-source binary formats and/or custom-made binary formats	Interoperable through common SW tools	Interoperable according to standards in each field	.csv file is a standard format that can be easily exported in several software	None	Data will be interoperable according to the standards of each field	Phaidra offers excellent interoperability with other platforms (e.g., Europeana)

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WP 8 DMP

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FAIR data: Reusable

WP1	WP2	WP3	WP4	WP5	WP6	WP7
Data stored in the cloud and on secure hard-drive Best practice defined by IT departments for computer use	All data will be reusable under licence after project finalization	All data reusable according to consortium guidelines	Simulated data stored in repository for project's duration and up to 5 years after	None	Data will be reusable according to consortium guidelines	Data will be reusable according to consortium guidelines

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WP 8 DMP

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Allocation of resources

WP1	WP2	WP3	WP4	WP5	WP6	WP7
No additional resources needed Expertise already present No additional costs since already budgeted	Data stored in the cloud during project duration After project ends, data sent to the coordinator for further storage	Data will be available on zenodo with no cost involved	Research Data Unipd does not require any expense WP3 leader will be responsible for data management	None	Clinical data stored in the cloud. Cost is part of DAVE's budget WP5 leader will be responsible for data management	Research Data Unipd and Phaidra do not require expenses Coordinator will be responsible for data management

All partners will identify a Data Manager who is responsible of data storage and preservation

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WP 8 DMP

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Data security

WP1	WP2	WP3	WP4	WP5	WP6	WP7
Sensible data stored in a secure way Transmission of data using private area of project website or certified platforms	No personal data collected Access to other non-disclosable information through cloud using usernames and passwords	Preclinical data stored in centralized services of UGA (duplicated in different locations, access via login and password)	No problem of security for simulated data	None	Access to the system with login and password Encryption for data from sensors to the cloud Database encrypted and protected by passwords Daily/weekly backup	Only PI and authorized personnel will have access to personal data Encrypted NAS or server with institutional restricted access for data storage Data backup

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WP 8 DMP

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Ethical aspects

Personal data collection compliant with GDPR EU 2016/679

UNIPD and UCC: organizational measure to safeguard privacy of subjects' involved (DPOs appointed -> privacy@unipd.it, gdpr@ucc.ie)

Participants will be allowed to accept/refuse publication of the interview or publish only anonymized scripts

Confidentiality: all subject data will have a unique identification number (no identifiable patient's name when stored)

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WP 8 DMP

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No changes to the DMP have been applied so far

Only WP2 and WP7 have currently collected data

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WP 8 DMP – WP2

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WP2 dataset on pig not yet completed. Once completed -> DOI

So far, data have been saved using record names and version numbering (ISO 13485 QMS guidelines)

Data are stored in a cloud drive

IP-sensitive information protected by restricted access to such data

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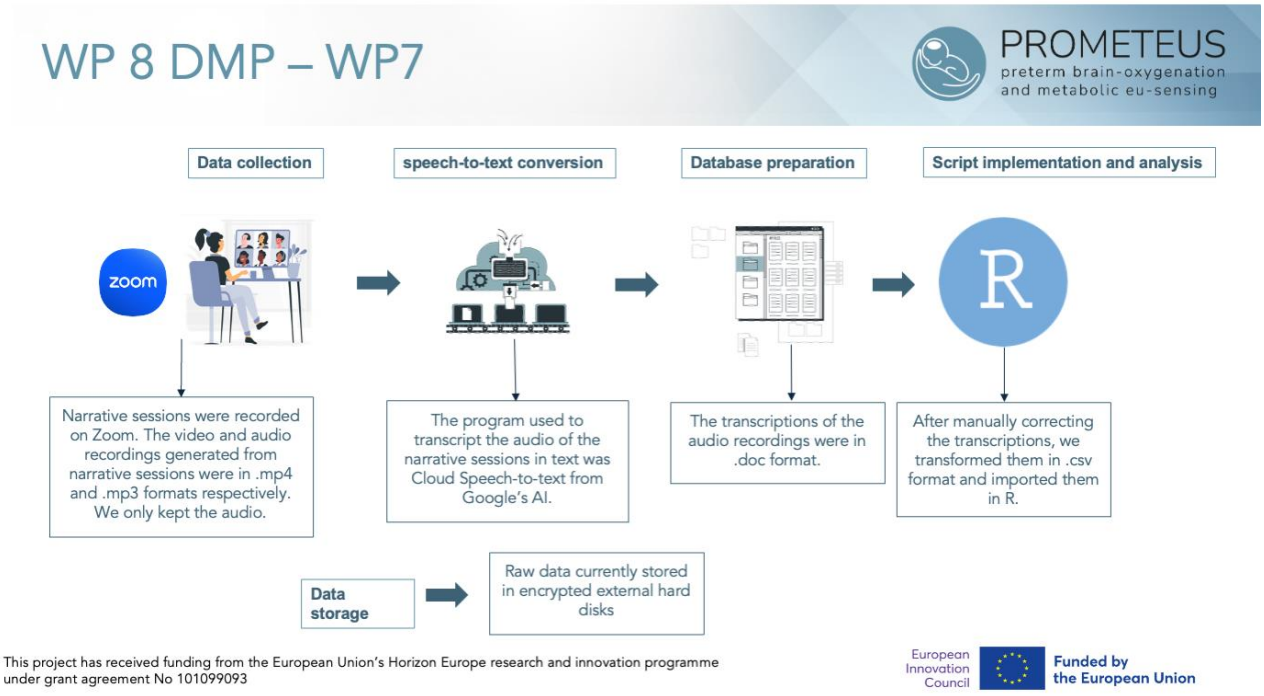
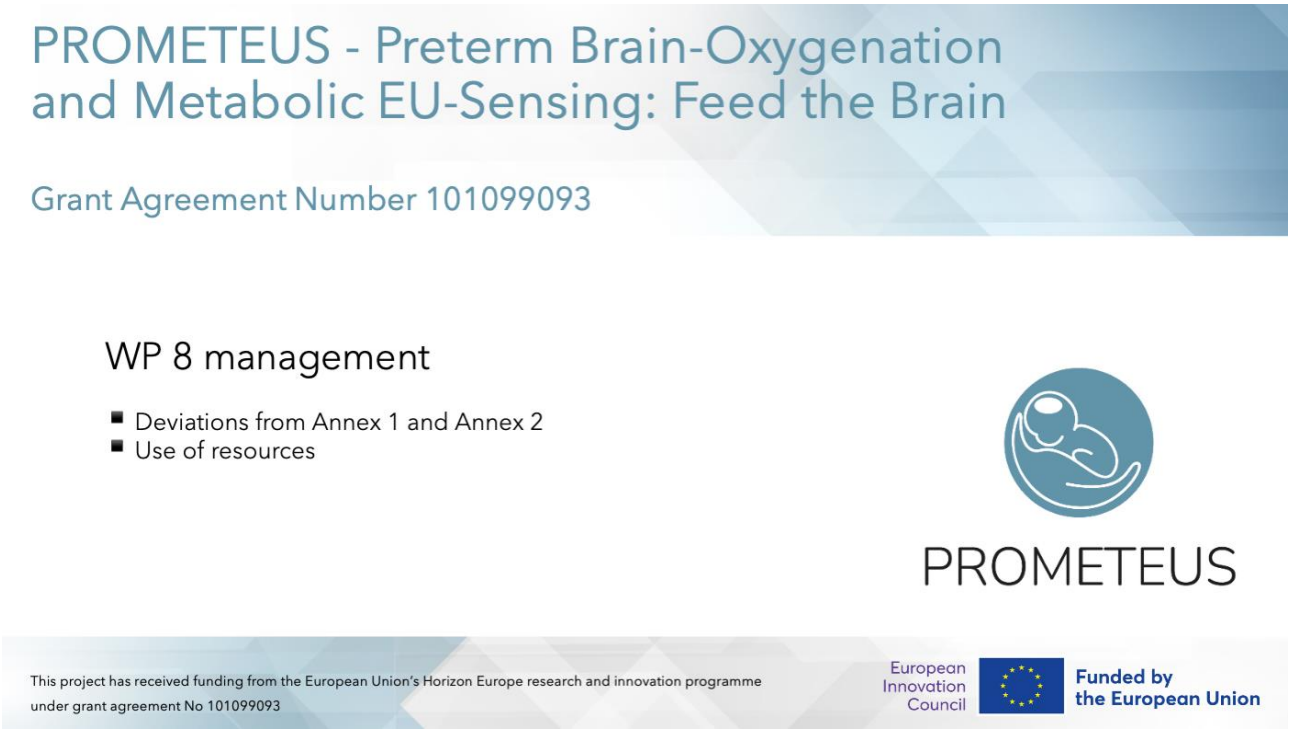


4.10 WP8 – Management



WP 8 management – Deviations from Annex 1

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- Deliverable D9.4 Ethics Advisor
  - Rejection of first appointment proposal
    requested experience in both **neonatal clinical trials** and **ethics aspects**
  - Proposal to appoint **Dr. Westerman-den Boer** endorsed at the **beginning of March 2024**
  - Delay **counterbalanced** by the implementation of clinical trials in year 4
- Deliverable D3.1 - Ethics rats
  - **few months** of **delay** in getting the **ethics approval** for the animal study of WP3
  - start **preliminary development experiments** on mice, using **existing approved protocols**
  - **No** expected **delays** in final results
- Seminar "Informed families" 1st year postponed
  - online **animated cartoon** showing the project's aims and partners
  - few month **delay** for administrative issues

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WP 8 management – Use of resources

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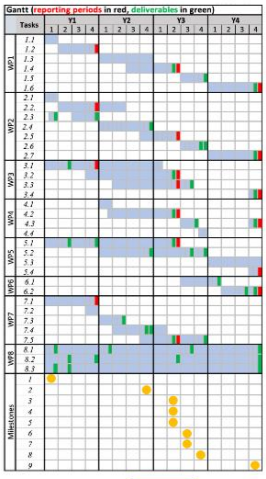
Person-months - distribution on linear basis (Annex 1 GANTT activities)

STAFF EFFORT

Staff effort per participant
Grant Preparation (Work packages - Effort screen) — Enter the info.

Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person-Months
1 - UNIPD	8.00	1.00	24.80	6.60	1.00	13.20	33.50	27.00		115.10
2 - QLAB		82.00						2.00		84.00
3 - UdG			4.00	36.00				2.00		42.00
4 - POLIMI	33.00							3.00		36.00
5 - pioNIRS	18.00							8.00		26.00
6 - ICFO	44.00							2.80		46.80
7 - DAVE	1.00	1.00		7.00	43.00	7.00		5.00		64.00
8 - UGA			67.40							67.40
8.1 - INSERM			10.20					1.00		11.20
9 - UCC	1.00	1.00			10.00	34.00	25.00	2.00		73.00
10 - UCL	14.60							0.60		15.20
Total Person-Months	119.60	85.00	106.40	49.60	54.00	54.20	58.50	53.40	0.00	580.70



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WP 8 management – Use of resources

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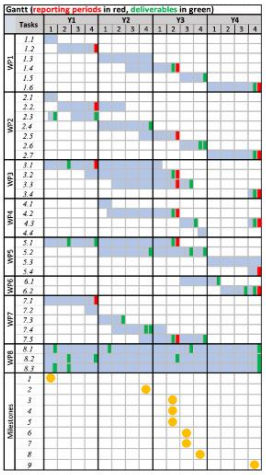
Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person-Months
1 - UNIPD	8.00	1.00	24.80	6.60	1.00	13.20	33.50	27.00		115.10

UNIPD

PM	*WP*	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
1 UNIPD	WP1	6.97%	2.55%	Maternity leave of UNIPD participant involved in WP1	0.64%
	WP2	0.87%	0.34 %	Maternity leave of UNIPD participant involved in WP2	0.08%
	WP3	28.82%	15.52%	**PhD student hired at month 9**	3.87%
	WP4	0%	0%	WP 4 starts at month 13	0%
	WP5	0.87%	0.34%	Maternity leave of UNIPD participant involved in WP5	0.08%
	WP6	0%	0%	WP 6 starts at moth 30	0%
	WP7	38.93%	43.76%	Slightly more resources than expected were used in the first year with respect to a linear distribution.	10.90%
	WP8	23.53%	17.27%	**Dissemination, exploitation and communication will have more relevance in future years. Maternity leave of Coordinator PI**	4.30%
	TOTAL	***100.00%***	***79.78%***		***19.88%***



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WP 8 management – Use of resources PM

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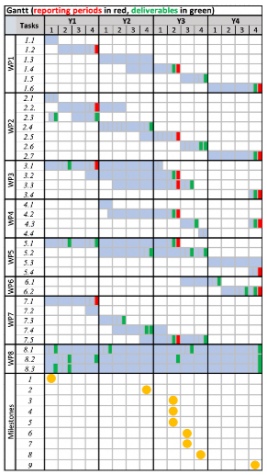
Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person-Months
2 - QLAB		82.00						2.00		84.00
3 - UdG			4.00	36.00				2.00		42.00

QULAB

	WP	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
2. QULAB	WP2	97.62%	94.71%	Slight deviation that **does not result in delays** in the progress of planned activities.	23.68%
	WP8	2.38%	2.38%		0.60%
	TOTAL	***100.00%***	***97.10%***		***24.27%***

UdG

	WP	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
3. UdG	WP3	88.89%	89.11%	A little more time devoted than expected. **No deviation from plan.**	9.55%
	WP4	0%	22%	**Small anticipation of WP4 preliminary activities. No deviation from overall plan.**	2.36%
	WP8	11.11%	3.33%	**Dissemination, exploitation and communication will have more relevance in future years** with respect to a linear distribution in the WP.	0.36%
	TOTAL	***100.00%***	***114.44%***		***12.26%***



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WP 8 management – Use of resources PM

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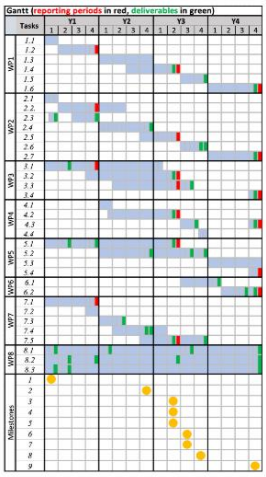
Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person-Months
4 - POLIMI	33.00							3.00		36.00
5 - pioNIRS	18.00							8.00		26.00

Polimi

	WP	% Planned for RP1	% Used for RP1	Deviation from planned to used for given reporting period	% Used of planned for entire period
4 Polimi	WP1	91.67%	63.56%	Despite lower resource utilisation the first year compared with a linear distribution of activities, there **are no deviations from planned.**	15.89%
	WP8	8.33%	9.11%	Though resources used are a bit higher, **no deviation from planned.**	2.28%
	TOTAL	***100.00%***	***72.67%***		***18.17%***

PIONIRS

	WP	% Planned for RP1	% Used for RP1	Deviation from planned to used for given reporting period	% Used of planned for entire period
5 PIONIRS	WP1	69.23%	26.92%	Despite lower resource utilisation the first year compared with a linear distribution of activities, there are no deviations from planned. **Additional time than expected was spent on hiring new dedicated staff.**	6.73%
	WP8	30.77%	11.54%	Though resources used are a bit lower, **no deviation from planned. Dissemination and exploitation activities will be more relevant in future years.**	2.88%
	TOTAL	***100.00%***	***38.46%***		***9.62%***



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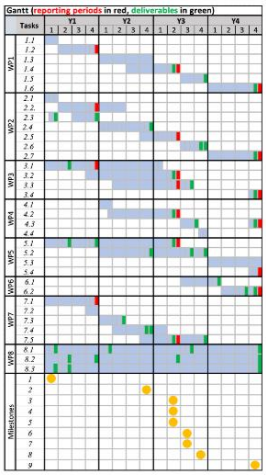
WP 8 management – Use of resources PM

PROMETEUS
preterm brain-oxygenation
and metabolic eu-sensing

Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person-Months
6 - ICFO	44.00							2.80		46.80

ICFO

	WP	% Planned for RP1	% Used for RP1	Deviation from planned to used for given reporting period	% Used of planned for entire period
6 ICFO	WP1	94.02%	66.67%	Despite lower resource utilisation the first year compared with a linear distribution of activities, there are no deviations from planned. **Main issue has been related to the hiring of the personnel. Temporary solution found.**	16.67%
	WP8	5.98%	3.42%	Though resources used are a bit lower, **no deviation from planned.**	0.85%
	TOTAL	***100.00%***	***70.09%***		***17.52%***



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WP 8 management – Use of resources PM

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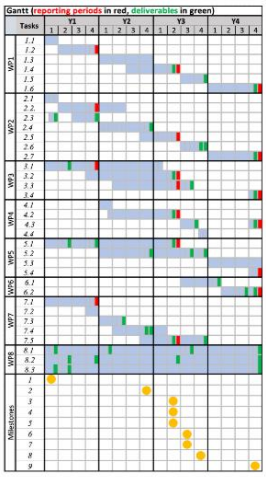
Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person-Months
7 - DAVE	1.00	1.00		7.00	43.00	7.00		5.00		64.00

DAVE

	WP	% Planned for RP1	% Used for RP1	Deviation from planned to used for given reporting period	% Used of planned for entire period
7 DAVE	WP1	2%	1.60%	Despite lower resource utilisation the first year compared with a linear distribution of activities, **no deviations from planned**.	0.31%
	WP2	2%	1.36%	Despite lower resource utilisation the first year compared with a linear distribution of activities, **no deviations from planned.**	0.27%
	WP4	0%	1.36%	**Small anticipation of WP4 preliminary activities**. No deviation from overall plan.	0.27%
	WP5	86%	60.24%	Despite lower resource utilisation the first year compared with a linear distribution of activities, **no deviations from planned**.	11.77%
	WP6	0%	0%		0%
	WP8	10%	10.64%	Though resources used are a bit higher, **no deviation from planned**	2.08%
	TOTAL	***100.00%***	***75.20%***		***14.69%***



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WP 8 management – Use of resources PM

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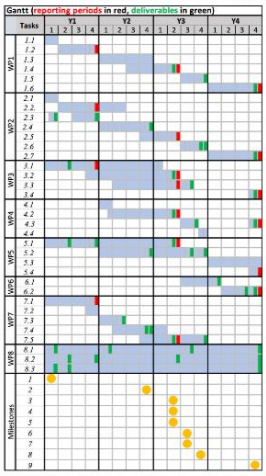
Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person-Months
8 - UGA			67.40							67.40
8.1 - INSERM			10.20					1.00		11.20

UGA

	WP	% Planned for RP1	% Used for RP1	Deviation from planned to used for given reporting period	% Used of planned for entire period
8. UGA	WP3	97.82%	36.27%	More resources are going to be used in the **future years, due to increased activity partner-related** within the WP. **Time lag in recruiting a post-doc candidate (a PhD was hired instead of a post-doc).**	12%
	WP8	2.18%	0%	Though resources used are none, **no deviation from planned. PM have been considered among INSERM (AE) effort.** Dissemination, exploitation and communication will have more relevance in future years.	0%
	TOTAL	***100.00%***	***36.27%***		***12%***

INSERM

	WP	% Planned for RP1	% Used for RP1	Deviation from planned to used for given reporting period	% Used of planned for entire period
8.1 INSERM	WP3	93.15%	136.44%	**Redaction of the application for "authorization of a research project on animals"** required a slight more resources in the first year of activity, **with respect to a linear distribution of effort.**	44.46%
	WP8	6.85%	4.66%	Though resources used are less than expected, **no deviation from planned. Dissemination, exploitation and communication will have more relevance in future years.**	1.52%
	TOTAL	***100.00%***	***141.10%***		***45.98%***



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WP 8 management – Use of resources PM

PROMETEUS
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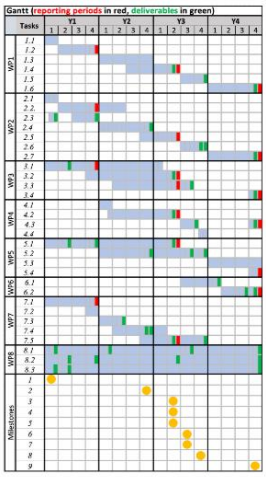
Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person-Months
9 - UCC	1.00	1.00			10.00	34.00	25.00	2.00		73.00

UCC

	WP	% Planned for RP1	% Used for RP1	Deviation from planned to used for given reporting period	% Used of planned for entire period
9 UCC	*WP1*	*0%*	*0%*		*0%*
	WP2	*0%*	*0%*		*0%*
	WP5	*0%*	*0%*		*0%*
	WP6	*0%*	*0%*		*0%*
	WP7	*0%*	*0%*		*0%*
	WP8	*0%*	*0%*		*0%*
	TOTAL	***100.00%***	***0%***	***Though participation in the project is continuous and steady, the partner's activities will be spread mostly over the coming years. No deviations from planned. Problem in recruiting a post-doc candidate (recruited a clincal fellow and RA form month 13).***	***0%***



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WP 8 management – Use of resources PM

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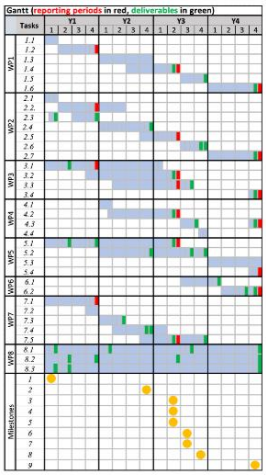
Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total Person-Months
10 - UCL	14.60							0.60		15.20

UCL

	WP	% Planned for RP1	% Used for RP1	Deviation from planned to used for given reporting period	% Used of planned for entire period
9 UCL	*WP1*	*96.05%*	*35.53%*	**Hiring of the PDRA has been delayed**. Due in July, will now likely be May. However, this will not have a negative impact on the project, since UCL's contribution to the project is relatively small and **does not block other work as long as delieverables are met in years 2 and 3.** **Major difference is due also to a linear distribution of effort.**	*8.88%*
	WP8	*3.95%*	*9.74%*	A little more time spent on management activities **for a linear distribution of effort**	*2.43%*
	TOTAL	***100.00%***	***0%***		***11.32%***



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WP 8 management – Use of resources

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ANNEX 2

ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[2] costs (per budget category)										Estimated EU contribution[2]			
	Direct costs								Indirect costs	Total costs	EU contribution to eligible costs			Maximum grant amount[4]
	A. Personnel costs			B. Subcontracting costs	C. Purchase costs			D. Other cost categories	E. Indirect costs[2]		Funding rate %[4]	Maximum EU contribution[3]	Requested EU contribution	
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners and natural person beneficiaries	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services	D.2 Internally invoiced goods and services	E. Indirect costs					
Forms of funding	Actual costs	Unit costs (usual accounting practices)	Unit costs[7]	Actual costs	Actual costs	Actual costs	Actual costs	Unit costs (usual accounting practices)	Flat-rate costs[8]					
	a1	a2	a3	b	c1	c2	c3	d2	e = 0,25 * (a1 + a2 + a3 + c1 + c2 + c3)	f = a + b + c + d + e	U	g = f * U%	h	m
1 - UNIPD	312 500.00	0.00	0.00	0.00	10 000.00	0.00	49 300.00	0.00	92 950.00	464 750.00	100	464 750.00	464 750.00	464 750.00
2 - QLAB	520 000.00	0.00	0.00	0.00	15 000.00	10 000.00	5 000.00	0.00	137 500.00	687 500.00	100	687 500.00	687 500.00	687 500.00
3 - UdG	212 600.00	0.00	0.00	0.00	9 000.00	0.00	2 000.00	0.00	55 900.00	279 500.00	100	279 500.00	279 500.00	279 500.00
4 - POLIMI	161 000.00	0.00	0.00	0.00	10 000.00	20 000.00	25 000.00	0.00	54 000.00	270 000.00	100	270 000.00	270 000.00	270 000.00
5 - pioNIRS	109 160.00	0.00	0.00	0.00	5 000.00	0.00	30 000.00	0.00	36 040.00	180 200.00	100	180 200.00	180 200.00	180 200.00
6 - ICFO	202 000.00	0.00	0.00	0.00	14 000.00	15 200.00	47 000.00	0.00	69 550.00	347 750.00	100	347 750.00	347 750.00	347 750.00
7 - DAVE	281 600.00	0.00	0.00	0.00	7 000.00	0.00	12 000.00	0.00	75 150.00	375 750.00	100	375 750.00	375 750.00	375 750.00
8 - UGA	224 500.00	0.00	0.00	0.00	8 000.00	8 000.00	53 160.00	0.00	73 415.00	367 075.00	100	367 075.00	367 075.00	367 075.00
8.1 - INSERM	101 000.00	0.00	0.00	0.00	5 000.00	0.00	0.00	0.00	26 500.00	132 500.00	100	132 500.00	132 500.00	132 500.00
9 - UCC	315 305.00	0.00	0.00	0.00	6 000.00	2 000.00	36 000.00	0.00	89 826.25	449 131.25	100	449 131.25	449 131.00	449 131.00
10 - UCL														
Σ consortium	2 439 665.00	0.00	0.00	0.00	89 000.00	55 200.00	259 460.00	0.00	710 831.25	3 554 156.25		3 554 156.25	3 554 156.00	3 554 156.00

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WP 8 management – Use of resources ODC

PROMETEUS
preterm brain-oxygenation
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	Direct costs			
	B. Subcontracting costs	C. Purchase costs		
	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services
Forms of funding	Actual costs	Actual costs	Actual costs	Actual costs
	b	c1	c2	c3
1 - UNIPD	0.00	10 000.00	0.00	49 300.00

OTHER DIRECT COSTS	*WP*	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
1. UNIPD	WP6	0%	0%		0%
	WP7	0%	0%		0%
	WP8	100%	68.59%	**Meetings** with participants held **in remote mode** and **the first face-to-face meeting (plenary) held at UNIPD**, Psychology campus spaces made available free of charge. **No significant deviations from plans.**	9.25%
	TOTAL	**100.00%**	**68.59%**		**9.25%**

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	B. Subcontracting costs	C. Purchase costs		
	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services
Forms of funding	Actual costs	Actual costs	Actual costs	Actual costs
	b	c1	c2	c3
2 - QLAB	0.00	15 000.00	10 000.00	5 000.00

	WP	% Planned for RP1	% Used for RP1	Deviation from planned to used for given reporting period	% Used of planned for entire period
2. QULAB	WP2	100%	72%	**Meetings held mostly online** and one plenary meeting attended in Padua. Difference due to a linear distribution of travel costs in budget.	9%
	WP8	0%	0%		0%
	TOTAL	**100.00%**	**72%**		**9%**

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WP 8 management – Use of resources ODC

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	B. Subcontracting costs	C. Purchase costs		
	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services
Forms of funding	Actual costs	Actual costs	Actual costs	Actual costs
	b	c1	c2	c3
3 - UdG	0.00	9 000.00	0.00	2 000.00

	WP	% Planned for RP1	% Used for RP1	Deviation from planned to used for given reporting period	% Used of planned for entire period
3. UdG	WP3	0%	0%		0%
	WP4	0%	0%		0%
	WP8	100%	116.72%	First plenary in person **meeting hosted at UNIPD**. Difference due to linear distribution of travel budgeted costs.	7.96%
	TOTAL	**100.00%**	**116.72%**		**12.26%**

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WP 8 management – Use of resources ODC

PROMETEUS
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	B. Subcontracting costs	C. Purchase costs		
	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services
Forms of funding	Actual costs	Actual costs	Actual costs	Actual costs
	b	c1	c2	c3
4 - POLIMI	0.00	10 000.00	20 000.00	25 000.00

	WP	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
4 Polimi	WP1	66.67%	55.08%	The small difference between budgeted and actual is due to a linear distribution of budgeted costs for equipment and supplies. **No deviations to report.**	5.70%
	WP8	33.33%	19.13%	First plenary **in person meeting hosted at UNIPD. Other meetings held online.**	1.98%
	TOTAL	**100.00%**	**74.22%**		**7.68%**

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	B. Subcontracting costs	C. Purchase costs		
	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services
Forms of funding	Actual costs	Actual costs	Actual costs	Actual costs
	b	c1	c2	c3
5 - pioNIRS	0.00	5 000.00	0.00	30 000.00

	WP	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
5 PIONIRS	WP1	90%	85%	**No deviations from plans.** Costs related to consumables (electronic components, PCBs, optomechanical) for prototyping, assembling and testing of the TD-NIRS module of NeoOpticap.	31.9%
	WP8	10%	8.25%	- **In-person consortium meeting at UNIPD (2 persons), all other meetings held online.** - Travel and lodging for a dissemination event (conference) in Bern, CH (BMPN2023).	2.8%
	TOTAL	**100.00%**	**93.25%**		**34.7%**

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	B. Subcontracting costs	C. Purchase costs		
	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services
Forms of funding	Actual costs	Actual costs	Actual costs	Actual costs
	b	c1	c2	c3
6 - ICFO	0.00	14 000.00	15 200.00	47 000.00

	WP	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
6 ICFO	WP1	71.43%	6.52%	Main **issue** has been related to the **hiring of the personnel** during the first months of the project. This also **meant a lower expenditure of other goods and services**. During the next month's till the end of the project, the expense will be compensated.	0.45%
	WP8	28.57%	0%	No travel costs in the first period. **Most meeting held online**. Difference is due to a linear distribution of travel costs for management purposes.	0%
	TOTAL	**100.00%**	**6.52%**		**0.45%**

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PROMETEUS
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	B. Subcontracting costs	C. Purchase costs		
	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services
Forms of funding	Actual costs	Actual costs	Actual costs	Actual costs
	b	c1	c2	c3
7 - DAVE	0.00	7 000.00	0.00	12 000.00

	WP	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
5. DAVE	WP5	75.00%	58.75%	The small difference can only be attributed to a linear distribution of consumable costs. **No deviations from plans.**	6.18%
	WP8	25%	2.60%	First **plenary in person** meeting hosted at **UNIPD**. Other **meetings held online**.	0.27%
	TOTAL	**100.00%**	**61.35%**		**6.46%**

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	B. Subcontracting costs	C. Purchase costs		
	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services
Forms of funding	Actual costs	Actual costs	Actual costs	Actual costs
	b	c1	c2	c3
8 - UGA	0.00	8 000.00	8 000.00	53 160.00

	WP	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
8. UGA	WP3	70.59%	65.78%	**No equipment was purchased** in the first year as planned. Costs will be included in subsequent RPs.	4.04%
	WP4	0%	0%		0%
	WP8	29.41%	25.69%	**Kick-off meeting and other meetings held online.**	1.58%
	TOTAL	**100.00%**	**91.47%**		**5.62%**

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WP 8 management – Use of resources ODC

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	B. Subcontracting costs	C. Purchase costs		
	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services
Forms of funding	Actual costs	Actual costs	Actual costs	Actual costs
	b	c1	c2	c3
8.1 - INSERM	0.00	5 000.00	0.00	0.00

	WP	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
8.1 INSERM (UGA Affiliated Entity)	WP8	100%	0%	No travel costs in the first period.	0%
	TOTAL	**100.00%**	**0%**		**0%**

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WP 8 management – Use of resources ODC

	B. Subcontracting costs	C. Purchase costs		
	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services
Forms of funding	Actual costs	Actual costs	Actual costs	Actual costs
	b	c1	c2	c3
9 - UCC	0.00	6 000.00	2 000.00	36 000.00

	WP	*% Planned for RP1*	*% Used for RP1*	*Deviation from planned to used for given reporting period*	*% Used of planned for entire period*
9 UCC	WP6	83.33%	83.33%		17.05%
	WP8	16.67%	0%	**Most meetings held online.**	0%
	TOTAL	**100.00%**	**83.33%**		**17.05%**

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WP 8 management – Deviations from Annex 2

- Budget
  - **no** major budget **deviations** to report
- Change of "A. Personnel costs" for PIONIRS and DAVE
  - change **does not result in budget transfers** except within macro-item A1 and A2 **to A4 SME owners**

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WP 8 management – Deviations from Annex 2

PROMETEUS
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PIONIRS	1.Personnel costs			
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		**A.4 SME owners and natural person beneficiaries**	TOT
Forms of funding	Actual costs	Unit costs (usual accounting practices)	Unit costs	
	a1	a2	a3	
GA Annex 2 budget	109 160.00	0.00	0.00	109 160.00
New budget with A.4	39 890.24	0.00	69 269.76	109 160.00

PIONIRS	STAFF EFFORT		
	GA Annex 2 budget	**New budget with A.4**	
	Actual costs	Actual costs	**Unit costs SME owners**
WP 1	20.00	10.00	10.00
WP 8	6.00	2.00	4.00
tot	**26.00**	**12.00**	**14.00**

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WP 8 management – Deviations from Annex 2

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DAVE	1.Personnel costs			
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		**A.4 SME owners and natural person beneficiaries**	TOT
Forms of funding	Actual costs	Unit costs (usual accounting practices)	Unit costs	
	a1	a2	a3	
GA Annex 2 budget	281 600.00	0.00	0.00	281 600.00
New budget with A.4	261 808.64	0.00	19 791.36	281 600.00

DAVE	STAFF EFFORT		
	GA Annex 2 budget	**New budget with A.4**	
	Actual costs	Actual costs	**Unit costs SME owners**
WP 1	1	0	1
WP 2	1	0	1
WP 3	0	0	0
WP 4	7	0	7
WP 5	43	2	41
WP 6	7	1.50	5.50
WP 7	0	0	0
WP 8	5	0.50	4.50
tot	**64**	**4**	**60**

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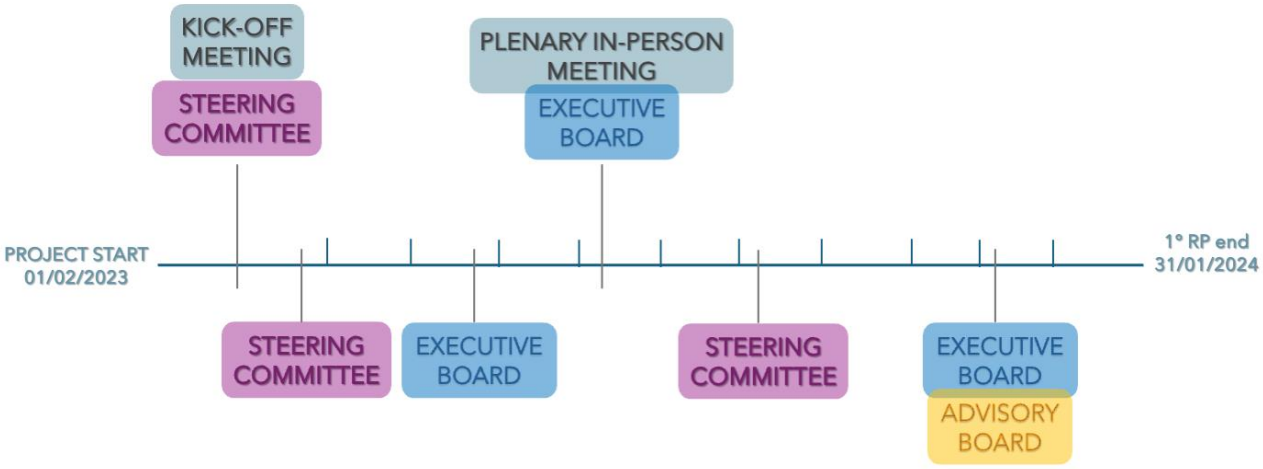
WP 8 management – Meetings



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