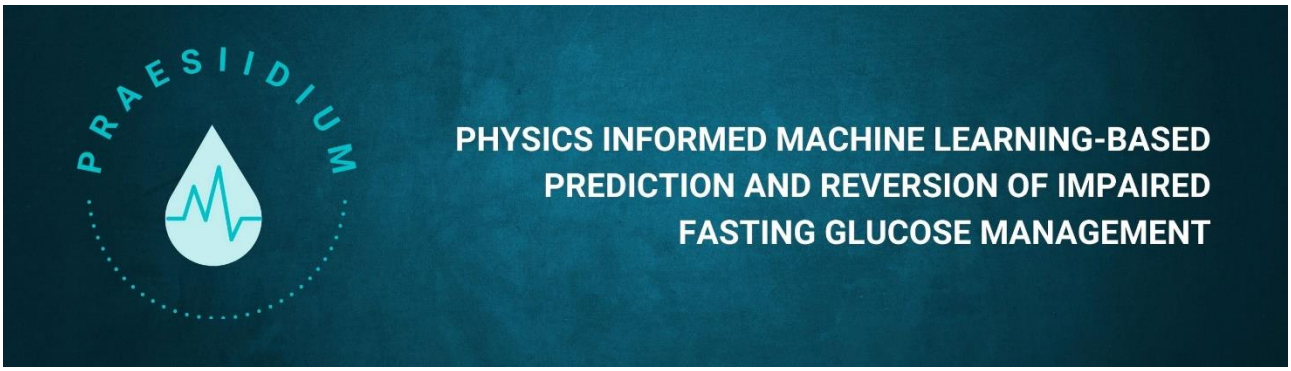

D1.3 - Project Management Plan Report v1

Due date of deliverable: 31/01/2024

Responsible partner: SPXL

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DOCUMENT DETAILS

Title	**Project management plan report (v1)**
Deliverable No.	1.3
Work Package	WP1 – Project management & coordination
Task	T1.2
Deliverable Type	R – document, report
Lead Partner	SPXL
Contributing Partner(s)	N/A
Due date of deliverable	31/01/2024
Actual submission date	31/01/2024
Abstract	This deliverable summarises the Project Management Plan (v1) of the PRAESIIDIUM project, with reporting activities and progresses until M13, with specific focus on structure after amendment.
Keywords	Project Management, Amendment, Project Governance Structure, Project Management documents, Project Meetings
Dissemination level:	
PU Public	x

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CHANGE HISTORY

Version	Date	Changed by	Changes made
V1.1	11/12/2023	Giulia Masetti (SPXL)	ToC definition
V1.2	15/01/2023	Leonardo Napoletani Giulia Masetti (SPXL)	Complete First Draft
V1.3	30/01/2023	Leonardo Napoletani Giulia Masetti (SPXL)	Internal Review + final version

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EXPLANATION OF ACRONYMS AND ABBREVIATIONS

Acronym	Full name
CA	Consortium agreement
DM	Dissemination manager
DMP	Data Management Plan
DoA	Description of Actions
EDB	Ethics & Data Protection Board
EAB	External Advisory Board
EC	European Commission
EM	Exploitation manager
EU	European Union
GA	Grant Agreement
MoM	Minutes of Meeting
PC	Project Coordinator
PM	Project Manager
PI-ML	Physics-Informed Machine Learning
RCP	Risk Control Plan
RP	Reporting Periods
SC	Steering Committee
STM	Scientific and Technical manager
ToC	Table of Contents
TL	Task leader
WBS	Work Breakdown Structure
WP	Work Package
WPL	Work Package leader

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TABLE OF CONTENTS

Document Details 1
Change history 2
Explanation of acronyms and abbreviations 3
Table of Contents 4
List of Figures 5
List of Tables 5
1. Overview of the deliverable 6
1.1. Scope 6
1.2. Audience 6
1.3. Structure 6
2. Project Structure after Amendment 7
2.1. Consortium composition 7
2.2. Work Breakdown Structure (WBS) 7
3. Project Management Structure 9
3.1. Steering Committee (SC) 9
3.1.1. Project Coordinator (PC) 10
3.1.2. Scientific and Technical Manager (STM) 10
3.1.3. Dissemination & Communication Manager (DECM) 10
3.1.4. Exploitation Manager (EM) 11
3.2. Ethics & Data Protection Board (EDP) 11
3.2.1. Ethics Board 11
3.2.2. Data Manager 11
3.2.3. Relationship with clinical ethical committee 11
3.3. General Assembly (GA) 12
3.4. Work Package Management Structure 12
3.4.1. Work packages Leaders (WPL) 12
3.4.2. Task Leader (TL) 12
3.4.3. Collaborators 12
3.5. External Advisory Board (EAB) 14
4. Project Management tools 14
4.1. PRAESIIDIUM SharePoint 14
4.2. Workplan and resources 16
4.3. Deliverable & Milestones 16
4.4. Reporting Periods 18
4.5. Project Meetings 18

This project has received funding from the European Union's Horizon Europe research and innovation program under grant agreement **No 101095672**

5. Conclusions 19

LIST OF FIGURES

Figure 1- PRAESIIDIUM's GANTT after Amendment 8
Figure 2- PRAESIIDIUM's Management Structure 9
Figure 3- PRAESIIDIUM's SharePoint 15

LIST OF TABLES

Table 1 – Consortium members 7
Table 2 - Work Package Management Structure 13
Table 3 – Workplan and resources 16
Table 4 – Deliverables & Milestones submitted until M13 17
Table 5 – Technical and financial details to be documented during Interim Reports 18

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1. OVERVIEW OF THE DELIVERABLE

1.1. Scope

This deliverable shows the Project Management Plan (v1) of the PRAESIIDIUM project, with reporting activities and progresses until M13.

The document includes processes and structures adopted for an effective project management, for Project Manager (project coordinator) but to be intended for all partners involved in the project. Within project management structure, the responsible person/body that will ensure the management is being appointed.

For which concerns PRAESIIDIUM's workplan, we will comment activities and actions after the Amendment of DoA (starting from October 2023). In describing Project Management Processes, we will also refer to related deliverables and documents already submitted as per DoA.

1.2. Audience

This document is public. To maximise the impact of the project, we have pre-identified some targeted audience groups:

- **Technology providers** such as researchers in academia, SMEs or other institutions working on artificial intelligence (AI)-based algorithms for preventative and personalised medicine.
- **Clinicians and healthcare professionals** e.g., in the fields of endocrinology, hepatology, metabolism, etc.
- **Patients, caregivers, and healthy people** will be the end-users of the solution.
- **Industry** including (but not limited to) pharma companies, wearable devices manufacturers, patients remote control manufacturers, etc.

1.3. Structure

The deliverable D1.3 is divided into the following sections:

1. **Section 1**– *Overview of the deliverable*, which contains the general highlights and the structure of the deliverable,
2. **Section 2** –*Project Structure after Amendment*, which provides an overview of the key changes in workplan and consortium composition after the amendment (October 2023).
3. **Section 3** –*Project Management Structure*, which provides an overview of the consortium composition, appointed representatives and responsibility, as described in DoA,
4. **Section 4** –*Project Management tools*, which provides an overview of the tools being employed to facilitate project management amongst partners.

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2. PROJECT STRUCTURE AFTER AMENDMENT

2.1. Consortium composition

The PRAESIIDIUM project underwent an amendment of the workplan in October 2023. As with the Amendment and differently from what has been stated in ***Deliverable 1.2 (Project Quality Plan)***, the composition of the consortium has been updated with the entrance of ALPHA Consult (IT) as an affiliated entity to EURONET:

Table 1 – Consortium members

Number	Organisation Legal name	Short name	Role	Country
1	SPINDOX LABS SRL	SPXL	Coordinator	IT
2	CONSIGLIO NAZIONALE DELLE RICERCHE	CNR	Beneficiary	IT
3	ELEKTRONIKAS UN DATORZINATNU INSTITUTS	EDI	Beneficiary	LV
4	EURONET CONSULTING	EURO	Beneficiary	BE
4.1	***ALPHA CONSULT***	***ALPHA***	***Affiliated***	***IT***
5	SCUOLA DI ROBOTICA	SdR	Beneficiary	IT
6	CHECKHEALTH SWEDEN AB	CHK	Beneficiary	SE
7	FONDAZIONE ITALIANA FEGATO ONLUS	FIF	Beneficiary	IT
8	MEDIZINISCHE UNIVERSITAT GRAZ	MUG	Beneficiary	AT
9	HK3 LAB SRL	HKL	Beneficiary	IT
10	LATVIJAS UNIVERSITATE	UNIL	Beneficiary	LV
11	SCUOLA UNIVERSITARIA PROFESSIONALE DELLA SVIZZERA ITALIANA	SUPSI	Associated Partner	CH

2.2. Work Breakdown Structure (WBS)

Differently from what has been included in ***Deliverable 1.2 (Project Quality Plan)*** and in the original DoA, the following key changes in workplan have been requested and obtained through the amendment:

- Two deliverables cancelled due to redundancy with other deliverables (D2.5 and D2.6),
- Some Deliverables deadlines postponed (e.g., D3.2, D4.4, D7.3, D7.5)
- New deliverables being created (D3.4 at M12 – D5.4 at M12 – D5.5 at M36),
- New Milestone being created (M11 at month 24),
- WP3 was restructured into 5 tasks from the 7 initially proposed,
- Some tasks duration was extended/anticipated (e.g., T2.3, T4.2, T4.4, T6.1, T6.2, T6.3, T6.4, T7.3).

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The following GANTT shows the changes of the WBS and deliverables/milestones deadlines:

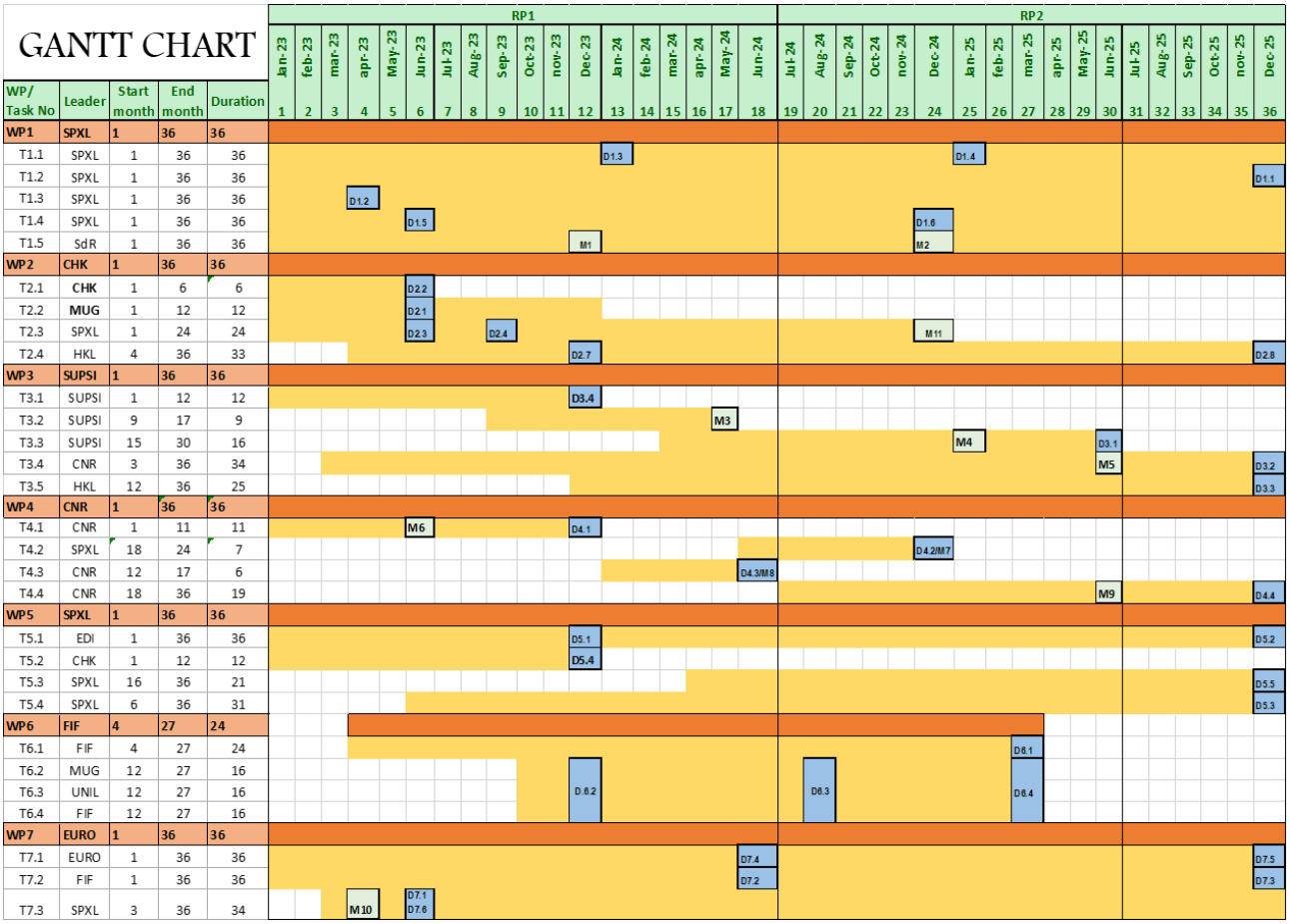

Figure 1- PRAESIIDIUM's GANTT after Amendment

The rest of the present deliverable will comment and consider the new WBS after amendment.

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3. PROJECT MANAGEMENT STRUCTURE

The project consists of the following organizational hierarchy of responsible bodies as described in the ***Grant Agreement after amendment*** (GA) and in the ***Consortium Agreement*** (CA) and reported below.

At management level, the Steering Committee (SC) is the central decision-making body, composed by the Project Coordinator, the Scientific and Technical manager, Ethics & Data Protection Board, and the Dissemination and the Exploitation Managers. The General Assembly, as later described, supports, and checks the SC activities. At operational level, the project is divided into work-packages, under the lead of Work Package Leaders, Task Leaders, and Collaborators. Each of the governing body is hereinafter described (**Figure 1**).

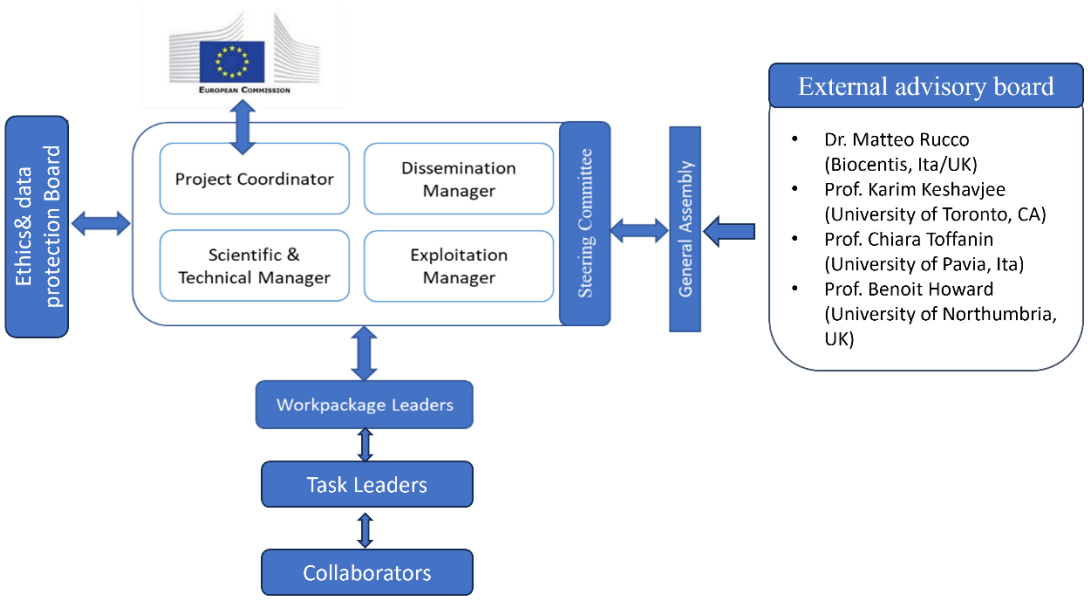

Figure 2- PRAESIIDIUM's Management Structure

3.1. Steering Committee (SC)

The Steering Committee includes the above-mentioned bodies: Project Coordinator, the Scientific and Technical Manager, the Dissemination Manager, the External Advisory Board, and the Exploitation Manager. It is responsible for the global steering, monitoring and management, and the execution of its decisions. The proposals made by the Steering Committee have to be validated and approved by the General Assembly, as later described. Decisions are taken by simple majority, where in case of even votes, the coordinator vote decides. The responsibilities of the Steering Committee include:

- Making proposals upon the allocation of the Project's budget in accordance with the EU contract; Making proposals in relation with possible defaulting partners;
- Making proposals upon the entering into the consortium of new partners;
- Making proposals upon reviewing or amending the work-plan, the costs and time schedules;
- Deciding about the project strategies within the framework of the contract, including exploitation;

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- Resolution of conflicts between project partners which cannot be solved at a lower level;
- Monitoring and assessment of the progress of the project.

The steering committee is held at least quarterly starting from the kick-off meeting or upon request by any of the partners. The meeting can be a physical one or through videoconference. The scheduling of the physical meetings is arranged to coincide, if appropriate, with project milestones and meetings, so that technical reviews are to be included in the agenda. In case of technical discussions, specific partners can be invited to attend.

3.1.1. Project Coordinator (PC)

The project is **coordinated by Spindox Labs** (SPXL, Italy), which acts as project coordinator (PC, Cristiano Carlevaro) and project manager (PM, Leonardo Napoletani), and therefore is the intermediary between the consortium members and the Granting Authority (Euorpean Commission, EC). The PC is the head of the Steering Committee, and he is responsible for:

- The correct execution of the whole research program;
- The communication among the partners and between the consortium and the EC;
- The global project management (planning implementation and control of all project activities);
- The coordination of the overall project administrative and financial aspects;
- The report of project financial and budgetary status to the Steering Committee;
- The preparation of the project progress reports (M6 and M12 so far).

3.1.2. Scientific and Technical Manager (STM)

Prof. Claudio Tiribelli (FIF, Italy) has been appointed project's **Scientific coordinator**. The **Technical Manager** is instead upon SPXL's responsibility (Roberto Larcher, SPXL, Italy). The STM must control and monitor the work done in the different WPs supporting the Project Coordinator in assuring that efforts are verifiable with results and the results themselves are coherent with the objective proposed (deliverables and milestones). Their responsibilities include also:

- Reporting to the SC on WPs overall status;
- Presenting the WP reports;
- allocates the responsibilities to the supervision of all ethics-related and gender-related aspects to the Ethics & Data Protection Board.

3.1.3. Dissemination & Communication Manager (DECM)

Fondazione Italiana Fegato Onlus (FIF) has been appointed PRAESIIDIUM's **Scientific Dissemination manager**, while SPXL is the **Communication manager**. Both will:

- take care that the dissemination activities are executed according to what defined in the '***Communication plan for Dissemination and Exploitation***' (see ***D7.1***);
- regularly monitor relevant international publications in Open Access and Peer-reviewed journals and those events where PRAESIIDIUM objectives and results should be presented and appropriately disseminated,
- propose a communication plan to other partners for regular updates and posts on project' social media accounts (website and LinkedIn).

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For an efficient communication flow between DECM and partners, a list of "**D&C representative**" per partner has been prepared. The nomination of such representative would also create connections with already existing communication and marketing teams within each consortium institution.

3.1.4. Exploitation Manager (EM)

EURONET (along with its affiliated entity ALPHA Consult) has been appointed PRAESIIDIUM's **Exploitation Manager**, whose role is:

- to investigate potential business and identify all exploitation opportunities for project results and solutions,
- studying the best way to transform project results in business opportunities.

The related activities will be detailed and reported in two-steps with ***Deliverable 7.4 (M18)*** and ***Deliverable 7.5*** including the definition of the final Exploitation Plan due at M36.

3.2. Ethics & Data Protection Board (EDP)

3.2.1. Ethics Board

The **Ethics & Data Protection board** is chaired by Scuola di Robotica (SdR) with Fiorella Operto and Gianmarco Veruggio held responsible for project's overall ethical concerns and for delivering the Ethics Assessment. At least one representative per partner is part of the EDP (which coincides with the General Assembly, as below), given the fact that project deals with clinical data derived from both retrospective and prospective clinical studies. The EDP will oversee and regularly assess all activities carried out within PRAESIIDIUM to ensure that they follow ethical standards and principles. The EDP will contribute to the design of each study and its informed consent to be delivered to participants in research activities and oversee the ethics-by-design nature of the physics-informed machine-learning (PI-ML) model and mobile app development. Participants of the EDB will perform an ***Ethics Self-Assessment*** twice during the project duration (***Milestones at M12 and M24***), which will evaluated by SdR and presented at General Assembly meeting and submitted to EC in form of deliverables.

3.2.2. Data Manager

For **Data Management Plan (DMP),** Giulia Masetti (SPXL) is the representative of the coordinator and responsible for the (see ***Deliverable 1.5*** for first version of DMP), supported by SPXL Data Protection Officer and SdR.

Along with the EDP, we appointed a "**data management representative**" within each partner institution and we defined the responsibilities within each partner in terms of data provider/owner, data manager and data recipients/controller (see ***Data Management Plan v1 – Deliverable 1.5*** and ***Deliverable 1.6-ANNEX 2*** in preparation for M24).

3.2.3. Relationship with clinical ethical committee

As the project involves clinical studies, three clinical partners (FIF, MUG and UNIL) liaised and obtained the clearance from their respective regional **clinical ethical committee** before commencing the patients' enrolment (see ***Deliverable 6.1***). The EDP and clinicians' internal legal advisors are also working toward the preparation of "*Material Transfer Agreements*" subscribed

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within members of the consortium, to ensure the GDPR and Informed Consent-compliant transfer of human material (e.g., blood, serum, faeces) for research purposes only.

3.3. General Assembly (GA)

The **General Assembly** is composed of one authorized representative of each of consortium partners. Decisions are taken by simple majority (except the cases detailed in the Consortium Agreement). Responsibilities of the General Assembly include:

- Approving upon the allocation of the Project budget in accordance with the EU contract;
- Approving or making proposals in relation with possible defaulting partners;
- Approving upon the entering into the consortium of new partners;
- Approving upon reviewing or amending the workplan, the costs and time schedules;
- Approving upon press releases and joint publications regarding the Project,
- Providing the ethics self-assessment twice per project duration (M12 and M24).

3.4. Work Package Management Structure

3.4.1. Work packages Leaders (WPL)

For each single work package, a **Work Package Leader** has been designated (see **Table 2** below) and appointed in DoA. The Work-Package Leader reports to the STM about the work done. The Work-Package Leader is responsible for:

- Coordination of the work in the work packages;
- The technical progress of the activities in his/her WP;
- Participation in the detailed planning, monitoring, and reporting of each task in his/her WP;
- Ensure the involved partners commit the required resources to carry out the tasks in the WP;
- The technical co-ordination and preparation of their deliverables and technical reports for periodic reporting (both ***interim and periodic M18-M36***, see below).

Each WP leader will call a meeting on a monthly base for checking the status of the project and identify as soon as possible risks and deviation from the plan (until now presented in the M6 and M12 Technical Reports). In Case of deviation or problem, the Scientific and Technical Manager has to be alerted and the steering committee convened.

3.4.2. Task Leader (TL)

Work packages are divided into tasks, according to DoA (**Table 2**). For each task, a **Task Leader** has been appointed, whose responsibility is to coordinate its work and the work of collaborators (participants) according to DoA. The TL reports and presents progresses of its task when required and requested by the Work Package Leader.

3.4.3. Collaborators

More than one consortium partner collaborates in a specific task. Therefore, **collaborators** of each tasks perform their work according to the DoA and reports results when required by Task Leader.

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Table 2 - Work Package Management Structure
(In orange: work package leader followed by task leader)

WP/ Task No	Leader	Collaborators	Start month	End month	Duration
WP1	**SPXL**		**1**	**36**	**36**
T1.1	SPXL	all	1	36	36
T1.2	SPXL	(none)	1	36	36
T1.3	SPXL	all	1	36	36
T1.4	SPXL	all	1	36	36
T1.5	SdR	all	1	36	36
WP2	**CHK**		**1**	**36**	**36**
T2.1	CHK	SPXL, EDI, HKL	1	6	6
T2.2	MUG	FIF, UNIL, SDR, SUPSI	1	12	12
T2.3	SPXL	EDI, CHK, SUPSI, CNR, SDR	1	24	24
T2.4	HKL	CNR, CHK	4	36	33
WP3	**SUPSI**		**1**	**36**	**36**
T3.1	SUPSI	CNR, SPXL	1	12	12
T3.2	SUPSI	CNR	9	17	9
T3.3	SUPSI	(none)	15	30	16
T3.4	CNR	HKL	3	36	34
T3.5	HKL	(none)	12	36	25
WP4	**CNR**		**1**	**36**	**36**
T4.1	CNR	SUPSI	1	11	11
T4.2	SPXL	CNR	18	24	7
T4.3	CNR	CHK	12	18	6
T4.4	CNR	SUPSI, HKL	18	36	19
WP5	**SPXL**		**1**	**36**	**36**
T5.1	EDI	(none)	1	36	36
T5.2	CHK	(none)	1	12	12
T5.3	SPXL	EDI, CHK	16	36	21
T5.4	SPXL	CHK	6	36	31
WP6	**FIF**		**4**	**27**	**24**
T6.1	FIF	(none)	4	27	24
T6.2	MUG	(none)	12	27	18
T6.3	UNIL	(none)	12	27	18
T6.4	FIF	(none)	12	27	18
WP7	**EURO**		**1**	**36**	**36**
T7.1	EURO	all	1	36	36
T7.2	FIF	all	1	36	36
T7.3	SPXL	all	3	36	34

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3.5. External Advisory Board (EAB)

PRAESIIDIUM consortium will benefit of an external panel of experts, or the **External Advisory Board members** (EAB), which is composed by expert professionals involved in several of the project's research topics. The advisory board involves:

- Dr. Matteo Rucco (Biocentis, Ita/UK)
- Prof Karim Keshavjee (University of Toronto, Canada)
- Prof. Chiara Toffanin (University of Pavia, Ita)
- Prof. Benoit Howard (University of Northumbria, UK)

As described in the Consortium Agreement, they will be not involved in research activities development but will be part of intermediate technical review meetings and of the general assembly. The EAB members will strength the collaboration with other initiatives (e.g., research grants, working group, etc.), and they will guide the consortium to identify alternative research solutions.

4. PROJECT MANAGEMENT TOOLS

Within PRAESIIDIUM, the following tools and documents are available to each partner and admin to help with management procedures and to monitor every project's progress efficiently and compliantly, both on technical and financial aspects (as requested by EC).

4.1. PRAESIIDIUM SharePoint

According to DoA, SPXL created and provided access each project partner to an internal, secured, and protected repository (PRAESIIDIUM SharePoint), which constitutes the official platform for document sharing/storage amongst partners, see ***Milestone 10*** prepared at M4. A set of mailing lists has been implemented for a general project-wide address and for each project WP and constitute the official communication channel between coordinator and partners.

The **PRAESIIDIUM SharePoint** is organised in main folders and sub-folders systems, as in Figure 3:

- "***Documents***" contains a folder per WP (from WP1 to WP7), each of them internally organised in sub-folders for shared documents, collaborative deliverables (all versions saved), milestones, meeting minutes, other communications. WP Leaders, Task Leaders, and collaborators are responsible for the maintenance and updating of their relative folders/documents. Naming convention and types of documents/templates to be used have been defined in ***Deliverable 1.2 – Project Quality Plan***.
- "***Main project documents***" collects important project documents to be shared and made easily available amongst partners, usually uploaded by Project Coordinator: Grant Agreement (plus amendment), Consortium Agreement, Periodic Reports (technical and financial) and projects official templates.
- "***Project Meetings***" (as commented below) contains the documents (agenda, recording, minutes, presentations, etc.) of the official project meetings stated in the DoA.
- "***Contact List***", as stated before, this is the official project contact list which is used to generate and update the official general/WP mailing lists.

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- "***Deliverable List***" serves as a tracking system of the projects' forthcoming deliverables or those already being submitted. The table shows all the deliverables of the project along with their deadline, related WP, dissemination level, deliverable leader, assigned reviewers and final submitted file (when already submitted). The list is easily accessible with searching filters (e.g., according to due date, WP, etc.).
- "***Risk register***" is represented as an interactive table, with each pre-identified risk being assessed according to "***Risk contingency plan***" (***deliverable D1.2***). following the will be commented below (see Figure 3 below). Each risk has been pre-identified in DoA or during continuous monitoring by project partners (usually WP leaders).

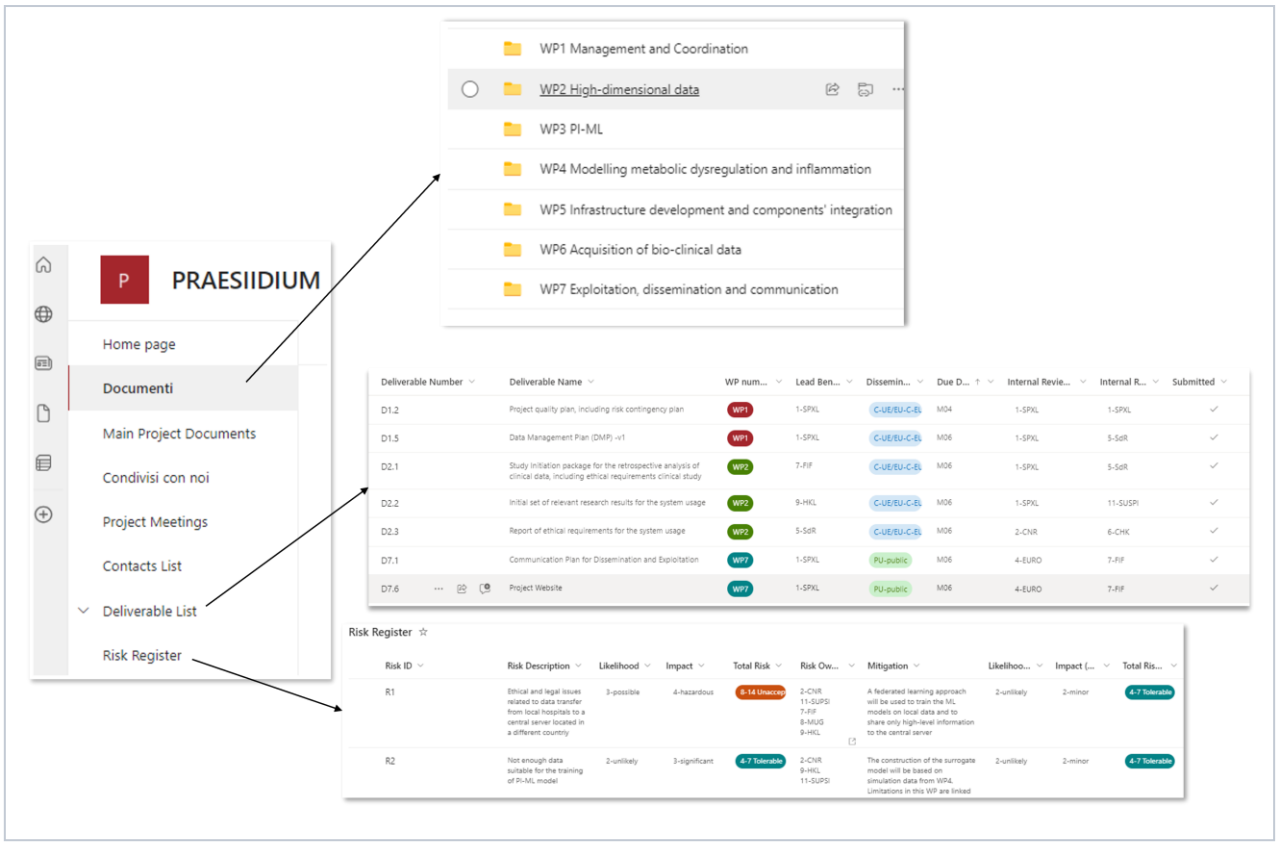

Figure 3- PRAESIIDIUM's SharePoint

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4.2. Workplan and resources

PRAESIIDIUM workplan follows the contractual ***Grant Agreement – Annex 1 DoA after Amendment***. We obtained an amendment of the workplan in October 2023. Financial monitoring started with the break-down of resources from WP to each task, using the template example in Table 3. The breakdown structure follows the workplan post-amendment:

Table 3 – Workplan and resources

WP/ Task No	Name	Lead	Start	End	Duration	SPXL	CNR	EDI	EURO	ALPHA	SdR	CHK	FIF	MUG	HKL	UNIL	SUPSI	TOT
WP1	**Project management & coordination**	**SPXL**	**1**	**36**	**36**	**20**	**3**	**3**	**2**	**1**	**12**	**3**	**3**	**3**	**3**	**3**	**3**	**59**
T1.1	Overall administrative, contractual and financial management	SPXL	1	36	36													0
T1.2	Coordination, monitoring and communication flows management	SPXL	1	36	36													0
T1.3	Risk contingency plan	SPXL	1	36	36													0
T1.4	Data Management	SPXL	1	36	36													0
T1.5	Ethics assessment and requirements	SdR	1	36	36													0
WP2	**High-dimensional data: acquisition, stratification and drift analytics**	**CHK**	**1**	**36**	**36**	**6**	**16**	**12**	**0**	**0**	**4**	**24**	**12**	**12**	**24**	**18**	**4**	**132**
T2.1	Review and acquisition of enabling technologies	CHK	1	6	6													0
T2.2	Clinical case studies definition and retrospective data ingestion	MUG	1	12	12													0
T2.3	Requirements elicitation and consolidation	SPXL	1	24	24													0
T2.4	Data acquisition, drift analytics and endo-phenotypes stratification	HKL	4	36	33													0
WP3	**Multi-scale physics-informed ML for T2D modelling**	**SUPSI**	**1**	**36**	**36**	**6**	**40**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**24**	**0**	**48**	**118**
T3.1	Literature review	SUPSI	1	12	12													0
T3.2	ML-based risk prediction	SUPSI	9	17	9													0
T3.3	PI-ML model development	SUPSI	15	30	16													0
T3.4	EXplainable ML (X-ML) model development	CNR	3	36	34													0
T3.5	Impact of Data Drift	HKL	12	36	25													0
WP4	**Modelling metabolic dysregulation and inflammation**	**CNR**	**1**	**36**	**36**	**10**	**45**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**9**	**0**	**2**	**66**
T4.1	First data set generation	CNR	1	11	11													0
T4.2	Integration of the microbiota model	SPXL	18	24	7													0
T4.3	Integration with sensor data	CNR	12	17	6													0
T4.4	Model calibration, validation and generation of the second data set	CNR	18	36	19													0
WP5	**Development and demonstration to multiple stakeholders of interpretable physics-informed ML-solutions**	**SPXL**	**1**	**36**	**36**	**60**	**0**	**58**	**0**	**0**	**0**	**24**	**0**	**0**	**0**	**0**	**0**	**142**
T5.1	Development of a prototype of a wrist-worn wearable device with bioimpedance sensing and signalling processing capabilities	EDI	1	36	36													0
T5.2	Development of a LinkWatch plaftorm for remote monitoring and self-managements of patients during clinical trials	CHK	1	12	12													0
T5.3	Technologies integration for the final App	SPXL	16	36	21													0
T5.4	Infrastructure development	SPXL	6	36	31													0
WP6	**Acquisition of bio-clinical data from clinical study**	**FIF**	**4**	**27**	**24**	**0**	**0**	**6**	**5**	**3**	**0**	**0**	**52**	**30**	**0**	**43**	**0**	**139**
T6.1	Individuation of blood-based inflammatory biomarkers in metabolic risk cohorts	FIF	4	27	24													0
T6.2	Clinical study 1: Patients with low risk of prediabetes	MUG	10	27	18													-
T6.3	Clinical study 2: Patients with metabolic risk factors	UNIL	10	27	18													-
T6.4	Clinical study 3: Plasma bio-banking and clinical data collection	FIF	12	27	16													-
WP7	**Exploitation, dissemination, and communication: paving the way for PRAESIIDIUM's acceptance**	**EURO**	**1**	**36**	**36**	**17**	**2**	**2**	**19**	**18**	**2**	**2**	**13**	**2**	**2**	**2**	**2**	**83**
T7.1	Business Plan and Exploitation strategy	EURO	1	36	36													0
T7.2	Scientific dissemination	FIF	1	36	36												1	1
T7.3	Communication and dissemination	SPXL	3	36	34												1	1
						119	106	81	26	22	18	53	80	47	62	66	59	739

4.3. Deliverable & Milestones

As we approached M13 of the project, the following deliverables and milestones have been submitted to the EC. As per amendment, the Dissemination Levels of each deliverable (after October 2023) changed from C-UE/EU-C-EU Classified into Sensitive (SEN – i.e., *limited under the conditions of the Grant Agreement*). No changes done for deliverables considered public (PU).

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To ensure that all the Deliverables/Milestones meet the required standards, an internal review process is required, with two partners appointed by the SC and approved by the WP leader. Timeline for deliverable preparation is included in ***Deliverable 1.2 – Project Quality Plan***.

The following table summarises Deliverables and Milestones submitted until M13 represented as *Deliverable ID, Title, Dissemination Level* and *Submission Due Date* according to relative WP.

Table 4 – Deliverables & Milestones submitted until M13

Deliverable/ Milestone ID	Title	Dissemination level	Due date
WP1 – Project Coordination & Management			
D1.2	Project quality plan, including risk contingency plan	EU-Classified	M4
D1.5	Data Management Plan (DMP), v1	EU-Classified	M6
M1	Ethics Self-Assessment report (v1) - Report and annual meeting	Sensitive (SEN)	M12
WP2 – High dimensional data: acquisition, stratification and drift analytics			
D2.1	Study Initiation package for the retrospective analysis of clinical data, including ethical requirements clinical study	EU-Classified	M6
D2.2	MUG Initial set of relevant research results for the system usage	EU-Classified	M6
D2.3	Report of ethical requirement for the system usage	EU-Classified	M6
D2.4	PRAESIIDIUM framework requirements, KPIs and success criteria	Sensitive (SEN)	M9
D2.7	Definition of rules and algorithms for endophenotypes stratification and tracking drift along time and domains V1	Sensitive (SEN)	M12
WP3 - Multi-scale physics-informed ML for T2D modelling			
D3.4	Literature review and selected mathematical models	Sensitive (SEN)	M12
WP4 - Modelling metabolic dysregulation and inflammation			
D4.1	Report on first data set generation	Sensitive (SEN)	M12
M6	First dataset generated for surrogate model (File in a dedicated private repository)	Sensitive (SEN)	M11
WP5 - Development and demonstration to multiple stakeholders of interpretable physics-informed ML-solutions			
WP6 - Acquisition of bio-clinical data from clinical study			
D6.1	Study Initiation Package	Sensitive (SEN)	M12
WP7- Exploitation, dissemination and communication: paving the way for PRAESIIDIUM's acceptance			
D7.1	Communication Plan for Dissemination and Exploitation	Public	M6
D7.6	Project Website	Public	M6
M10	Communication Kit PRAESIIDIUM and website (brochure and website)	Sensitive (SEN)	M4

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4.4. Reporting Periods

As stated in the GA, two official Reporting Periods (RP) are planned to be conducted with the EC:

1. RP n°1: M1-M18 (01 January 2023 – 30 June 2024)
2. RP n°2: M19-M36 (01 July 2024 – 31 December 2025)

As we approached M13, the consortium worked on two Interim Reports (every 6 months: M6 and M12) whose templates follows the same as the official reporting periods.

Table 5 – Technical and financial details to be documented during Interim Reports

Technical Report	- Overall progress toward Project Objectives - Work carried out by the beneficiaries in each WP - Impact assessment - Exploitation and dissemination plan updates - Data Management Plan (DMP) updates - RCP updates - Significative deviation from plans with respect to the DoA
Financial Report	- Gap analysis between planned and actual resources spent during the period - Any changes reported by the beneficiaries (and approved) in relation to their items of expenditure with reference to Budget for the action detailed in Annex 2 of the GA

4.5. Project Meetings

During the project, all the partners are encouraged to regularly meet on a frequent basis to ensure that the activities to be carried out within their scope and responsibilities achieve the desired outcomes. Foreseen project meetings are detailed and described in ***Deliverable 1.2 – Project Quality Plan***. As of M13, PRAESIIDIUM's partners already met three times and, whose documents are available in the project SharePoint. We are now planning for the first General Assembly.

- **Virtual Kick-off Meeting** (Teams) on 12th January 2023: virtual kick-off with presentation of partners institution and capabilities, presentation of DoA and general project management aspects (consortium agreement, pre-financing, etc.);
- **In-presence Kick-off Meeting** (at SPXL office in Trento, Italy) on 30th and 31st January 2023: presentation of specific project management activities, discussion on pre-financing, presentation of each WP and specific discussion in working groups (technical and clinical);
- **1st Plenary Meeting** (virtual on Teams) on 27th July 2023: presentation of progresses in terms of project management (definition of documents for amendments) and each WP
- **1st General Assembly** (at SPXL office in Trento, Italy) on 20th and 21st February 2024: TBC, Agenda has been finalised.

Minutes of each project meeting are being collected and revised and are supposed to be submitted to EC in ***Deliverable 1.1 – Minutes of General Assembly*** due at M36.

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5. CONCLUSIONS

The present document displays the overall strategy and structure adopted by the PRAESIIDIUM project manager and consortium to efficiently manage the project, so far presented until M13. Changes after obtaining the amendment are presented. Also, a list of appointed person/body is shown with their relative responsibilities. A second (updated) version of the project management plan will be delivered at a more matured stages of the project (M24).

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