



D14.1

Project Management Handbook

NATIONAL TECHNICAL UNIVERSITY OF ATHENS (NTUA)

30/11/2024

Project Information

ACRONYM	SENSOPAD
TITLE	SENSING ENDOMETRIOSIS ON PORTABLE AUXILIARY DEVICES
GRANT AGREEMENT No	101130516
START DATE OF THE PROJECT	01/09/2024
DURATION OF THE PROJECT	48 months (2024-2028)
TYPE OF ACTION	Research and Innovation Action (RIA)
TOPIC	HORIZON-CL4-2023-RESILIENCE-01-33 - Smart sensors for the Electronic Appliances market (RIA)
WEBSITE	TBA
COORDINATOR	National Technical University of Athens (NTUA)
PROJECT OVERVIEW	To significantly reduce the diagnosis time of endometriosis (ED) through innovative, non-invasive detection technologies, thereby empowering women with early, accurate, and accessible diagnostics that improve health outcomes and reduce healthcare costs.

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RE	Restricted to a group specified by the consortium (including the EC Services)	
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Abbreviations

CA	Consortium Agreement
CMT	Coordination and Management Team
CO	Coordinator
DoA	Description of Action
EIEA	External Independent Ethics Advisor
GA	Grant Agreement or General Assembly
STC	Scientific and Technological Committee
WP	Work Package
WPLG	Work Package Leaders Group
EC	European Commission
QA	Quality Assurance

Table 1: Abbreviations

Executive Summary

This document outlines the internal management and governance structure and the project procedures and details the proposed risk management activities. It complements the information in the project's Grant Agreement (GA) and Consortium Agreement (CA). The document has two main objectives:

- i) to clearly define the bodies established within the project, their roles, internal functions, and procedures, ensuring high-quality standards through a detailed account of their responsibilities; and
- ii) to provide comprehensive descriptions of the contingency actions to be implemented, if necessary, leveraging the collaborative efforts of the partners and employing effective and reliable management tools and methods

1. Introduction

The Deliverable 14.1 “Project Management Handbook” delineates the foundational management structure guiding the project's operations. As a multidisciplinary initiative, SENSOPAD project brings partners with diverse expertise across various scientific domains. Its nodes and activities are thoughtfully designed to foster the implementation of efficient procedures and proactive strategies, ensuring the seamless functioning of its governance bodies and overall activities.

2. Project Governance Structure

The organizational structure of the project consists of the following Governance Bodies: i) the General Assembly (GA), as the primary governance body; and ii) the Scientific and Technological Committee (STC) and the Work Package Leaders Group (WPLG) as the preparatory group bodies responsible for overseeing the smooth conduct of project activities.

2.1 Coordination and Management Team (CMT)

From the beginning of the project, a Coordination and Management Team (CMT) will serve as the main body responsible for ensuring the efficient and timely conduct of all SENSOPAD activities and achieving timely and maximum cohesion between administrative and scientific tasks. The CMT will be accountable for undertaking:

- i) the daily management of the project and the implementation of all relevant, daily administrative tasks;
- ii) the overall monitoring of the project's progress and obligation compliance among partners;
- iii) the creation, collection, and review, as well as the timely and appropriate submission of all deliverables in cooperation with Work Package (WP) leaders and the Project Coordinator (CO);
- iv) the creation, collection, and review of financial statements, certifications, and other specific requested documents to the Funding Authority, as well as the timely distribution of the budget deriving from the Granting Authority to the project beneficiaries;
- v) the storage of all data, results, and findings retrieved from all WPs,
- vi) leading and monitoring the scientific and technical activities concerning the implementation of the project;
- vii) the communications between consortium partners and between consortium partners and the general public or other scientific entities or stakeholders;
- viii) the organization and preparation of the project's governance bodies' meetings;
- ix) communication and reporting to the Granting Authority and European Commission, essentially as the link between them and the consortium. The composition of the CMT is described in Table 1.

The integration of additional representatives of consortium partners can be continuous throughout the project.

Table 2: Members and roles of the SENSOPAD Coordination and Management Team

Role	Person Responsible	Organization	Contact details
Project Coordinator	Constantinos Charitidis	NTUA	charitidis@chemeng.ntua.gr Tel: +30 210 7724046 9 Heroon Polytechniou St., Zographos, 15773, Athens, Greece
Coordination and Management Team Member	Georgios Lolas	NTUA	georgioslolas@gmail.com Tel: +30 210 7723323 9 Heroon Polytechniou St., Zographos, 15773, Athens, Greece
Coordination and Management Team Member	Stylios Makrogkikas	NTUA	smakro@chemeng.ntua.gr Tel: +30 210 7723323 9 Heroon Polytechniou St., Zographos, 15773, Athens, Greece
Coordination and Management Team Member	Konstantinos Zafeiris	NTUA	kzafeiris@chemeng.ntua.gr Tel: +30 210 7723131 9 Heroon Polytechniou St., Zographos, 15773, Athens, Greece
Administrative & Financial Support Staff	Vasilis Markakis	NTUA	vmarkakis@chemeng.ntua.gr Tel: +30 210 7723323 9 Heroon Polytechniou St., Zographos, 15773, Athens, Greece

2.2 General Assembly (GA)

From the onset until the conclusion of the SENSOPAD activities, the GA will serve as the main regulatory body, chaired by the CO and consisting of one representative for each consortium partner authorized to deliberate, negotiate, and make decisions in all matters presented in the GA. Ordinary GA meetings will be held at least every 6 months throughout the project, with the coordinator notifying the members at least 28 calendar days prior and sending the agenda at least 14 days before the scheduled meeting and 7 before extraordinary situations. Regular GA meetings will refer to operational management issues unless stated otherwise in the meeting agenda. The GA can decide on all matters surrounding content, finances, and intellectual property rights (i.e. proposals for amendments to the GA for submission to the Granting Authority or modifications to the consortium plan or structure). All decision-making and intra-team reporting (i.e. on activities, deliverables, and internal reports) can and will be presented to the GA. All partners are invited to attend those meetings.

All decisions requiring voting will be sought to be achieved through consensus, but if this is not feasible, a quorum of 2/3 of members will be needed for a valid decision. Each GA member shall have one vote. GA members have the right to exercise a veto in case any legitimate interests of theirs would be severely affected by a specific decision of a Consortium Body. GA voting members are listed below in Table 2. In

case of unforeseen absence in a GA meeting, a partner can inform the CO beforehand about their decision if they cannot attend.

No	Organization	Short Name	Member
1	ETHNICON METSOVION POLYTECHNION	NTUA	Constantinos Charitidis
2	COPENHAGEN BUSINESS SCHOOL	CBS	Angelos Stamos
3	UNIVERSIDADE DA CORUNA	UDC	Alejandro Criado Fernández
4	WHITE RESEARCH SRL	WR	Pol Camps
5	BIOG3D MONOPROSOPI IKE	BIOG3D	Anna Karatza
6	SIGNALGENERIX LIMITED	SG	Marios Milis
7	ALMA MATER STUDIORUM – UNIVERSITA DI BOLOGNA	UNIBO	Giovanni Valenti
8	GRAPHENEA SEMICONDUCTOR SL	GSEMI	Amaia Rebollo
9	UNIVERSIDADE DE COIMBRA	UC	Goreti Sales
10	INNOVATION IN RESEARCH AND ENGINEERING SOLUTIONS	IRES	Elias P. Koumoulos
11	LABORATORIO IBERICO INTERNATIONAL DE NANOTECHNOLOGIA LIN	INL	Lorena Diéguez
12	GALS BIO LTD	GALS BIO	Hilla Saviv
13	FREDA HEALTH PRODUCTS LTD	FREDA	Afsaneh Pavrizi-Wayne
14	THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD	UOXF	Lysimachi Demetriou

2.3 Scientific and Technological Committee (STC)

The Scientific and Technological Committee (STC) is an assessment group of the Consortium, without formal decision-making power. Its compilation is based on the state-of-the-art nature of the SENSOPAD FEMTECH research and will be composed of three Consortium members, namely, NTUA (Constantinos Charitidis), INL (Lorena Diéguez), and UC (Goreti Sales). The STC plays a preparatory role by consolidating preliminary findings and aligning them with the strategic goals of the Work Package Leaders Group (see below). This ensures that discussions within the group are focused and productive.

STC will prepare recommendations on risk mitigation and technical adjustments related to both SENSOPAD biosensors, enabling Work Package leaders to make informed decisions. Ordinary STC meetings will be held every 3 months throughout the project, with the coordinator notifying the members at least 2 weeks prior and sending the agenda at least 1 week before the scheduled meeting. STC meetings will be held prior the Work Package Leaders Group (WPLG) meetings (see below).

2.4 Work Package Leaders Group (WPLG)

Supporting the work of the GA and the STC, the Work Package Leaders Group (WPLG) will serve as an assessment group of the Consortium without formal decision-making power. It shall assess the individual and overall implementation of the Project. Ordinary WPLG meetings will be held every 3 months throughout the project, with the coordinator notifying the members at least 2 weeks prior and sending the agenda at least 1 week before the scheduled meeting. Regarding decision-making processes, the WPLG shall seek a consensus among its members.

Regular WPLG meetings will refer to execution and implementation matters unless stated otherwise in the meeting agenda. The WPLG can and will support the CO in the following ways:

- i) monitoring project progress by providing guidance and ensuring the timely preparation and submission of project deliverables, data, and any material related to meeting with the Granting Authority,
- ii) agreeing on specific actions to ensure successful implementation and cohesion among the project's inter- and intra-WP activities;
- iii) monitoring the quality of work produced within the nodes of the different WP;
- iv) discussing and advising the CO on legal matters and;
- v) preparing the content and timing of press releases and joint publications in the attention of the GA. WPLG members are listed below in Table 3.

If a partner cannot attend a WPLG meeting due to unforeseen circumstances, they may notify the CO in advance regarding their decision.

Table 3: Voting members of the SENSOPAD Work Package Leaders Group (WPLG).

WP	Organization	Short Name	Member
1	ETHNICON METSOVION POLYTECHNION	NTUA	Constantinos Charitidis
2	ETHNICON METSOVION POLYTECHNION	NTUA	Constantinos Charitidis
3	UNIVERSIDADE DE COIMBRA	UC	Goreti Sales
4	UNIVERSIDADE DA CORUNA	UDC	Alejandro Criado Fernández
5	LABORATORIO IBERICO INTERNATIONAL DE NANOTECHNOLOGIA LIN	INL	Lorena Diéguez

6	SIGNALGENERIX LIMITED	SG	Marios Milis
7	SIGNALGENERIX LIMITED	SG	Marios Milis
8	LABORATORIO IBERICO INTERNATIONAL DE NANOTECHNOLOGIA LIN	INL	Lorena Diéguez
9	INNOVATION IN RESEARCH AND ENGINEERING SOLUTIONS	IRES	Elias Koumoulos
10	THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD	UOXF	Lysimachi Demetriou
11	WHITE RESEARCH SRL	WR	Michail Ntovas
12	WHITE RESEARCH SRL	WR	Michail Ntovas
13	WHITE RESEARCH SRL	WR	Pol Camps
14	ETHNICON METSOVION POLYTECHNION	NTUA	Constantinos Charitidis
15	ETHNICON METSOVION POLYTECHNION	NTUA	Constantinos Charitidis
16	ETHNICON METSOVION POLYTECHNION	NTUA	Constantinos Charitidis

2.5 External Independent Ethics Advisors (EIEA)

To maximize the efficiency of all project proceedings, an External Independent Ethics Advisor (EIEA) has been appointed to advise on matters surrounding the project, for example, potential ethics and technical risk identification and management. The EIEA is an external ethics advisor to the SENSOPAD project, providing the consortium with an independent evaluation of the project work plan and valuable guidance and recommendations on ethical/legal matters and procedures. The EIEA will sign a Non-Disclosure Agreement (NDA) with all the consortium partners (the NDAs are currently pending/ongoing).

The CMT after carefully examining all available options for the role of the EIEA, has concluded that Georgia Livieri, holds the necessary experience and expertise to uptake this role. Mrs. Livieri was unanimously accepted by the SENSOPAD Consortium, since no conflicts of interest were raised.

Georgia Livieri is a distinguished professional specializing in ethics compliance, particularly in digital health and public health policy. Her research contributes to the field as an Ethics Manager and Consultant for various EU-funded projects (e.g., LUMINOUS, augMENTOR, Twin4Twin). Her leadership roles include Chair of the External Ethics Advisory Board at University College Dublin and membership on the Board of Directors of the Hellenic Society of Pharmaceutical Medicine. Mrs. Livieri's comprehensive training spans multiple specifications in areas such as Research Ethics, Bioethics, Human Rights, and AI Ethics from globally respected institutions such as Johns Hopkins University and ETH Zurich.

3. Quality Assurance and Risk Management

The Project Quality Assurance Plan summarizes the internal procedures for ensuring the quality of the project outcomes, ensuring smooth operation in the consortium and the quality of the developed work throughout the SENSOPAD project.

3.1 Documentation and Deliverables

3.1.1 Document management and record keeping

The SENSOPAD Consortium uses the Microsoft 365 SharePoint online platform for document management, record keeping, and file storage. Only members of the Consortium have access to the project's shared platform, and access rights are granted upon request by the Coordination team. Using this shared repository system brings considerable efficiency to the project, enabling different functionalities that facilitate the smooth workflow. Among its various possibilities, it allows the Consortium to provide a common access point to all the project documentation and decrease the exchange of uncontrolled and untracked email attachments by keeping the newest version of all documents.

3.1.1.1 Basic Microsoft SharePoint functions:

Microsoft 365 SharePoint platform offers the following basic functionalities:

- Upload or create files and folders
- Share and organize files and folders
- Use SharePoint files offline

The SENSOPAD Microsoft 365 SharePoint platform has been created by the coordinator and will provide access to all consortium members, enabling file sharing and exchange, raw and secondary data storage and sharing, as well as communication materials derived from consortium meetings, workshops, and events. All SENSOPAD Consortium members are invited to join and utilize the platform and may refer to the CMT for any assistance needed to access the shared space.

3.1.1.2 How to access the SENSOPAD file storage

The access to the SENSOPAD Microsoft 365 SharePoint platform, has been shared by the CMT team to all Consortium members. The CMT team has granted access to all Consortium members involved in the SENSOPAD project in any way and work within the project. In case a member of the Consortium cannot access the SENSOPAD Microsoft 365 SharePoint using their institutional e-mail account, they should inform the CMT team via e-mail to be granted access using a different personal e-mail account. To ensure the proper functioning of the project, the members who leave the project must inform the CMT team that they will no longer work in the project and delete them from all communications from the moment they leave and onwards.

3.2 Deliverables and Templates

The main output to be produced during the project implementation will be the SENSOPAD project deliverables. In SENSOPAD, three types of deliverables are planned:

Report: All document deliverables shall be based on the provided template.

Demonstrator, pilot, prototype: a piece of code, which will be accompanied by a short technical report explaining the main functionalities, technical design, downloading information, installation manual, and licensing schema. The technical report will also have to follow the provided template for deliverables.

Other: This type corresponds to all outputs that are neither documents nor software. The Data Management Plan (DMP), website, and other dissemination material (e.g., posters, flyers, etc.), as well as Ethics requirements deliverables, fall under this category.

Ethics: This type corresponds to the deliverables that will be prepared by the project's external Ethics Advisor. These deliverables will encompass independent reports from the Ethics Advisor, compiled at two different stages of the project implementation (month 18 and month 48).

The deliverables must be prepared and submitted according to the specifications and timeline outlined in the Description of Action (DoA). The lead partner oversees this process and coordinates closely with the corresponding Work Package (WP) leader. All deliverables are subject to review and approval by the Consortium, the General Assembly, and, ultimately, the European Commission (EC).

3.2.1 Quality Assurance

Quality assurance (QA) of deliverables in SENSOPAD is based, firstly, on the project deliverable template that is provided with a predefined set of formatting and structure rules and secondly, on internal peer review performed by the Consortium members as an approval prerequisite for the release of each deliverable. The CO will ensure that these two aspects of QA take effect, including a final review of deliverables before the submission to the EC.

The main objectives of the QA procedures are to:

- Produce high-quality and fit-for-purpose deliverables on time
- Identify potential risks or deviations at an early stage
- Realize any necessary corrective actions as soon as possible.

The deliverables' quality can be measured in the following ways:

- Readability:
 - Abbreviations and acronyms are appropriately explained in a separate list
 - Spelling and language checked
 - Layout/template checked
 - Length checked
 - References included where appropriate
- Completeness:
 - Is it addressing the original project objectives and meets the success indicator?
 - Does it contain all the required chapters?

- Does the summary give a short, non-confidential description of the deliverable? Is it self-contained?
- Consistency
 - Are the chapters consistent with each other?
 - Is it consistent with other deliverables?
 - Is it consistent/connected with the requirements other WPs?

The template for the report deliverables is provided in the project repository.

The following general considerations must be followed for producing any kind of project deliverable:

- Deliverables should be kept short and focused on the goals. The maximum recommended length is 50 pages. Additional information shall be placed on Appendixes.
- The deliverables measure progress against the objectives; therefore, all deliverables need to include statements regarding their purpose and their contribution to the overall SENSOPAD objectives.
- In compliance with quality assurance methods, goals and requirements should be SMART, which means:
 - Specific
 - Measurable
 - Appropriate
 - Realistic
 - Timely
- Two types of incidents may happen in the production and delivery process:
 - The author anticipates a delay in the delivery and must report it to the WP leader, or Project Coordinator. Prompt notification will enable the swift implementation of the contingency plan.
 - Following an internal review, the Coordinating Team, or WP leader, may reject the final delivery if it does not meet the required quality standards.

In both situations, some contingency actions must be defined to reduce the impact and minimize the delay caused.

- The Project Coordinator or the CMT must inform the Project Advisor about significant delays.
- The CMT is responsible for ensuring the quality of other types of project deliverables and outcomes, such as the project website. To do so, he can ask relevant experts or partners for help.

4. Communication

4.1 Consortium Contact List

All people involved in SENSOPAD and their contact details are listed in an Excel file available in SENSOPAD Microsoft 365 SharePoint . This includes an overview of the WPs each person is involved in and who should be contacted in case of administrative issues, dissemination/communication activities,

etc. This ensures smooth communication between all Consortium partners by providing them with the latest member additions and enabling communication with new people as soon as they enter the project. This list is updated every time a new subscription /de-subscription occurs.

4.2 E-mails and mailing lists

E-mails will be the foremost means of communication in the SENSOPAD project, considering the geographical distribution of all Consortium partners. The CMT team and the consortium members will provide all relevant project-related information using this communication channel and upload all necessary documents of interest to SENSOPAD and SENSOPAD Microsoft 365 SharePoint. File attachments should be avoided, when possible, especially when these are over a few kilobytes and require inputs and versions from different partners. To share these documents, they should be uploaded to SENSOPAD Microsoft 365 SharePoint, and a link to the repository where the file is stored should be provided in the body of the email.

To facilitate effective communication between all the members of the Consortium, the Coordination team has created a series of Working Groups divided by WP and topic. All project partners should include at least one of the members of their entity who are relevant to the Working Group. To request inclusion in a Working Group, the people interested must send an e-mail to the management team stating their name, the e-mail address they want to include, and the Working Groups they wish to be included in. Only the management team can edit the Working Groups and the Partner and Contact list.

4.3 Planning and Reporting

The purpose of planning and reporting tasks is to allow the regular tracking of project progress and to ensure that possible problems are recognized early so there is time to take corrective actions. The project's overall planning is the responsibility of the project Work Package Leaders Group (WPLG), which is led by the Coordinator and assisted by the Coordination and Management team. The WP leaders are responsible for resource planning at the WP level to realize the project's overall plan. The task leaders assist them when necessary. The WP Leaders, according to the current version of the DoA, are:

Table 4: Work Package Leaders list

Work Package	Lead Organization	Work Package Leader
1	NTUA	Constantinos Charitidis
2	NTUA	Constantinos Charitidis
3	UoC	Goreti Sales
4	UDC	Alejandro Criado Fernández
5	INL	Lorena Diéguez
6	SG	Marios Milis

7	SG	Marios Milis
8	INL	Lorena Diéguez
9	IRES	Elias Koumoulos
10	UoO	Lysia Demetriou
11	WR	Michalis Ntovas
12	WR	Michalis Ntovas
13	WR	Pol Camps
14	NTUA	Constantinos Charitidis
15	NTUA	Constantinos Charitidis
16	NTUA	Constantinos Charitidis

4.3.1 Periodic Report

The project coordinator is required to submit the periodic report within 60 days after the conclusion of each reporting period. This report includes both technical and financial sections and must address any deviations (in budget or content) from the Description of Action (DoA).

The “Periodic Technical Report” is divided into two parts: Part A and Part B, as outlined below:

Part A: Part A is generated by the IT system using data provided by participants through the periodic and continuous reporting modules in the electronic exchange system of the Participant Portal. Participants can update this information at any time during the project’s duration. Part A includes:

- The cover page,
- A summary intended for publication by the European Commission (EC), and
- Responses to a questionnaire addressing project implementation and its economic and social impact.

The Project Coordinator is responsible for managing Part A.

Part B: Part B is the narrative section that details the beneficiaries’ activities during the reporting period. It must be uploaded as a PDF document, adhering to the template for the Part B Periodic Technical Report.

Work Package (WP) leaders, in collaboration with their task leaders, compile reports on their respective WPs (Part B) and submit them to the Project Coordinator at least one month before the upload deadline. The Project Coordinator consolidates all the information and forwards the complete Periodic Technical Report to the WPLG for review. Once approved, the Project Coordinator uploads the final version to the Participant Portal.

The 'Periodic Financial Report' consists of:

1. Individual financial statement for each partner for the reporting period concerned. This financial statement must detail the eligible costs for each budget category. Each partner and linked third parties must declare all eligible costs, even if costs exceed the amounts indicated in the estimated budget.
2. An explanation of the use of resources and information on subcontracting and in-kind contributions provided by third parties from each partner for the reporting period concerned.
3. The electronic exchange system will automatically create a 'periodic summary financial statement,' consolidating the individual financial statements of the partners, including the request for an interim payment. Each partner's Financial Signatory (FSIGN) will be able to complete their own Financial Statement online, including explanations on the use of resources (also for their third parties). The project coordinator will have a final check on the statements and submit them electronically to the EC.

4.3.2 Final Report

The coordinator is required to submit the final report within 60 calendar days after the conclusion of the last reporting period, alongside the periodic report for that period.

Similarly to the periodic report, the final report will include the following:

1. A 'final technical report' with a summary for publication containing:
 - an overview of the results and their exploitation and dissemination
 - the conclusions on the action and
 - the socio-economic impact of the action.

The project coordinator compiles this final technical report in consultation with the partners.

2. A 'final financial report' containing:
 - a 'final summary financial statement' will be created automatically by the electronic exchange system, consolidating the individual financial statements of the partners for all reporting periods
 - a 'certificate on the financial statements' for each partner (and for each linked third party) if it requests a total contribution of EUR 325 000 (or more) reimbursement of actual direct costs and unit costs.

5. Risk Management

Due to the multidisciplinary nature of the SENSOPAD Project and the need for the efficient and simultaneous completion of multiple tasks, a strict risk management plan has been set out to carry out continuous evaluation, minimize potential risk consequences, and increase the availability and urgency of effective mitigation measures. The CO will provide a centralized risk management strategy and constantly communicate with all WP leaders and consortium partners to ensure the quality of the work produced within the project nodes.

Given the multidisciplinary nature of the SENSOPAD Project and the need to efficiently manage and complete multiple tasks simultaneously, a robust risk management plan has been established. This plan ensures continuous assessment, mitigates potential risks effectively, and enhances the readiness and implementation of prompt mitigation strategies. The Coordinator will oversee a centralized risk management framework, maintaining constant communication with both the STC and WP leaders as

well as the Consortium partners to uphold the quality of outputs across all project nodes. To achieve this, the CO will:

- a. define and promote the use of templates for documentation, presentations, and communication policies,
- b. install or ensure the existence of the necessary mechanisms for the identification, communication, and mitigation of potential;
- c. monitor the achievements produced according to the proposed Key Performance Indicators (as outlined in the Description of Action-DoA), and;
- d. promote cost-effective mitigation measures to minimize the spending of resources towards mitigation actions. This collaborative effort will allow for anticipating potential risks and proactively completing mitigation measures before their potential appearance.

In this context, the following STEPwise approach will be adopted according to the stages outlined below:

i. Risk Analysis and Evaluation Process

This initial step focuses on risk planning from the outset of the project, emphasizing the prediction and identification of risk management procedures and responsibilities. The foundation of this process is built upon the risks already identified in the project's Description of Action (DoA), as detailed in Table 4. In addition to these predefined risks, a continuous process of risk identification will be maintained throughout the project, aimed at detecting new risks associated with emerging or ongoing activities. Should a novel risk be identified, the Coordinator (CO) and the STC and the Work Package Leaders Group will be promptly informed. Risk analysis will then evaluate the likelihood and severity of the risk, estimating its potential impact on specific project tasks or the overall project. Efforts will focus on minimizing these impacts to ensure project stability and progress.

ii. Development of mitigation measures

Each newly identified risk will be classified as urgent, upcoming, or realized. The CO and the relevant task leader will promptly develop mitigation strategies for each risk, outlining them in a detailed mitigation proposal. In collaboration with the CO, a designated individual from the appropriate partner organization will be assigned to carry out the risk mitigation process. Mitigation measures for risks already identified in the Description of Action (DoA) are presented in Table 4.

iii. Review schedule, process, and responsible parties

A schedule for regular reviews will be established during the implementation of each mitigation measure, allowing the CO and the relevant Task Leader to assess its effectiveness and ensure maximum impact. All responsible parties are encouraged to present proposals and implemented measures to the STC and the Work Package Leaders Group for evaluation. The STC and Work Package Leaders Group, in turn, will monitor the process and escalate any critical issues to the General Assembly (GA) as needed.

Description of risk <i>Likelihood (Low, Medium, High) / Severity (Low, Medium, High)</i>	WP	Mitigation Measures
Consortium Management Risks		

Partner not performing well or leaving the project (L/M)	All	Assessing task reassignment ensuring consistent competencies, technical and exploitation capabilities as per EC/Agency guidelines
Delaying executing WPs (L/M)	All	WP Leaders/Coordinators will analyze delays in planned activities by proposing a new plan (EC/Agency).
International travel restrictions (L/M)	All	Online meetings, online tools to be used
Financial resource issues (L/H)	14-16	WPs leaders will re-distribute resources accordingly, monitoring potential deviations and risks during T14.2/15.2/16.2
Unpredicted risk during the project(L/M)	14-16	Risk assessment (T14.5/15.5/16.5) will re-assess risks, update the current table, and aim to prevent potential problems.

Scientific and Technological Risks

Raw materials cost and availability (L/L)	1	Implementation of alternative raw materials
Low outputs for synthetic/modification procedures (L/L)	2	Utilize SAPS from alternative synthetic/modification procedures
Unpredicted problems of the production process (L/M)	2	Dedicated efforts will be strengthened by allocating resources.
Additives fail to provide the required properties (L/M)	2	Alternative materials will be investigated and incorporated into the SENSOPAD project
Loss of the recognition ability of the antibody in the ink (M/M)	3	Producing graphene-based electroactive ink, then immobilizing antibodies after printing on the electrode.
Unwanted adsorption of blood sample components into the sensing unit of the autonomous device (H/M)	3	Remove the plastic antibody from the anode, assemble it separately, and interface it in the electrical circuit like the ECH. Employ origami approaches to protect the sensing unit from severe interfering components, using an appropriate membrane/paper.

Failure in FET device performance (L/M)	3	Other transduction techniques, such as electrochemiluminescence, will be used for the PoC device. Expertise in this biosensing approach is already present in the consortium (UNIBO)
Poor detection performance of the wearable sensor (L/M)	3	Colour sensor will be used for the wearable sensor
Low limit of detection of target analytes through gFETs M/M	1, 4	Two different strategies will be considered to overcome this limitation: i) chemical modification of gFETs with a charged RNA reporter without bioconjugation of CRISPR protein, and ii) The use of deformed graphene channel in gFETs to overcome charge screening limitations. If necessary, the combination of both can be tackled.
Suboptimal design of sgRNA (L/L)	4	Design of additional sgRNAs for the same SNPs
Unstable conjugation of graphene with the biomolecules (L/M)	4	Using the EC process, a single electron transfer reaction with aryldiazonium salts will create anchor points on graphene for precise covalent grafting.
Cell isolation system has low-efficiency M/M	5	Increase the volume of the input sample. Perform cell isolation with alternative benchtop protocols.
DNA extraction and capture modules have low efficiency (L/M)	5	Use commercial kits
Inaccurate results obtained from sensor electronics (M/M)	6,7,8	Validate offline algorithms using PC data and specific metrics refined based on Mobile App/MF device results.
Failure in the integration of various MF modules and gFET biosensor (H/L)	8	Individual modules are connected externally, each running sequentially and independently, as needed.
PCBs design/manufacturing errors. (M/M)	6,7,8	Developing initial breadboard prototypes to validate PCB design. Adequate timescale for design and manufacturing iterations
Patient recruitment	10	Additional patients will be recruited.

Out-of-the-radar/ emerging competition could hinder innovation and threaten commercialization. (H/M)

11, 12, 13

Continuous market analysis and monitoring, with detailed reports overseen by WR. Updates to the exploitation plan and assessment of new avenues for risk reduction and expansion

6. Conclusions

The proposed governance structure and risk management strategies are designed to ensure the successful implementation of all SENSOPAD activities. All governance bodies, the project coordinator, and partners will work closely and collaboratively to guarantee the high quality and timely completion of the project's planned outcomes.

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Partners		Short Name
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 COPENHAGEN BUSINESS SCHOOL	COPENHAGEN BUSINESS SCHOOL	CBS
 UNIVERSIDADE DA CORUNA	UNIVERSIDADE DA CORUNA	UDC
 WHITE	WHITE RESEARCH	WR
 BIOG3D	BIOG3D MONOPROSOPI IKE	BIOG3D
 Signal Generix Ltd Advanced Signal Solutions	SIGNALGENERIX LIMITED	SG
 ALMA MATER STUDIORUM UNIVERSITA DI BOLOGNA	ALMA MATER STUDIORUM - UNIVERSITA DI BOLOGNA	UNIBO
 Graphenea	GRAPHENEA SEMICONDUCTOR SL	GSEMI
 UNIVERSIDADE DE COIMBRA	UNIVERSIDADE DE COIMBRA	UC
 IRES Innovation in Research & Engineering Solutions	INNOVATION IN RESEARCH AND ENGINEERING SOLUTIONS	IRES
 INTERNATIONAL IBERIAN NANOTECHNOLOGY LABORATORY	INTERNATIONAL IBERIAN NANOTECHNOLOGY LABORATORY	INL
 GALS BIO LTD	GALS BIO LTD	GALS BIO
 freda	FREDA HEALTH PRODUCTS LTD	FREDA
 UNIVERSITY OF OXFORD	THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD	UOXF