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2D BioPAD

Supple Graphene Bio-Platform for point-of-care early detection and monitoring of Alzheimer's Disease

D7.1 Management and Quality Plan

UP-CATRIN

20/12/2023

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Executive Summary

The present document constitutes the Management and Quality Plan (MQP) of the 2D-BioPAD project, funded by the European Union's Horizon Europe Framework Programme for Research and Innovation 2021-2027. 2D-BioPAD aims to introduce a fast and cost-effective, non-invasive, reliable, digitally and graphene-enabled Point-of-Care (PoC) in-vitro diagnostics (IVD) system for supporting the early diagnosis and progression monitoring of Alzheimer's Disease (AD) directly at primary healthcare settings. The 2D-BioPAD system and its impact will be demonstrated in 3 clinical centres in Europe (Finland, Greece, and Germany) under two clinical pilot studies.

In this context, the current Management and Quality Plan defines the overall project management principles and procedures applied to 2D-BioPAD and the quality assurance (QA) provisions for safeguarding high-quality project outcomes. It describes the roles and responsibilities of each project participant, with emphasis on work breakdown and management, progress reporting, financial monitoring, payment processes, risk identification and change management.

QA and risk mitigation measures are put in place for 2D-BioPAD to ensure project outcomes, namely deliverable reports, methodologies, etc., are of high quality and offer value to the project's stakeholders. The underlying management and QA mechanisms, as described in this document, are obligatory for all 2D-BioPAD partners, while they aim at complementing (and not replacing) the provisions of the Grant Agreement and the Consortium Agreement of the project.

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List of Terms and Definitions

Table 1. Terms and definitions

Abbreviation	Definition
AI	Artificial Intelligence
AFM	Administrative and Financial Manager
CA	Consortium Agreement
DM	Dissemination Manager
DoA	Description of the Action
EM	Exploitation Manager
GA	Grant Agreement
IVD	In-Vitro Diagnostic
MQP	Management and Quality Plan
QM	Quality management
PC	Project Coordinator
PMO	Project Management Office
PoC	Point of Care
SC	Steering Committee
SIAB	Scientific and Industrial Advisory Board
TL	Task Leader
WPL	Work Package Leader

1. General Provisions

1.1 Objectives

The current document - entitled Management and Quality Plan (MQP) - has been elaborated within the framework of the 2D-BioPAD project, which is co-funded by the European Union's (EU) Horizon Europe Framework Programme for Research and Innovation 2021-2027 under Grant Agreement No. 101120706.

2D-BioPAD aims to introduce a fast and cost-effective, non-invasive, reliable, digitally and graphene-enabled Point-of-Care (PoC) in-vitro diagnostics (IVD) system for supporting the early diagnosis and progression monitoring of Alzheimer's Disease (AD) directly at primary healthcare settings.

To achieve this, and tackle the scientific challenge, the technological and market gap of PoC IVD for AD, 2D-BioPAD leverages the unique properties of 2D materials, such as graphene and its derivatives. Towards that direction, 2D-BioPAD goes beyond the state-of-the-art of its 2D Materials' pioneer consortium to deliver a graphene-based PoC IVD system that will (i) introduce a versatile surface chemistry that combines nano and DNA technologies towards improved biocompatibility, stability, as well as high sensitivity and specificity for enhanced (bio-)sensing; (ii) be able to reliably identify and quantify in real-time and simultaneously up to 5 AD biomarkers in blood samples effectively supporting healthcare professionals in early diagnosis; (iii) offer an easy to use and understand digital interface with key metrics and insights regarding the measured results; and (iv) employ Artificial Intelligence (AI) to improve the overall system implementation.

The 2D-BioPAD system and its impact will be demonstrated in 3 clinical centres in Europe (Finland, Greece, and Germany) under two clinical pilot studies. In every step, and from the very beginning, 2D-BioPAD will go beyond current norms and involve a wide range of stakeholders, starting from the clinic itself, and led by industrial partners, to identify the essential safety and ethical-by-design principles and guidelines that can accelerate uptake at primary healthcare settings and maximise acceptance and impact to both physical and digital supply chains.

The consortium of 2D-BioPAD consists of 11 partners across 8 different European countries, as presented in the following table.

Table 2. 2D-BioPAD beneficiaries

Partner Role[1]	Partner No	Partner Name	Short Name	Country
CO	1	UNIVERZITA PALACKÉHO V OLOMOUCI - CATRIN	UP-CATRIN	CZECHIA
BE	2	Q-PLAN INTERNATIONAL ADVISORS PC	Q-PLAN	GREECE
BE	3	FUNDÀCIO INSTITUT CATALÀ DE NANOCIÈNCIA I NANOTECNOLOGIA	ICN2	SPAIN
BE	4	GRAPHEAL S.A.S.	GRAPHEAL	FRANCE
BE	5	ARISTOTELIO PANEPISTIMIO THESSALONIKIS	AUTH	GREECE
BE	6	NOVAPTECH S.A.S.	NOVA	FRANCE
BE	7	ITA-SUOMEN YLIOPISTO	UEF	FINLAND
BE	8	ELLINIKI ETAIRIA NOSOY ALZHEIMER KAI SYGGENON DIATARACHON SOMATEIO	GAADRD	GREECE

[1] CO: Coordinator, BE: Beneficiary

Partner Role[1]	Partner No	Partner Name	Short Name	Country
BE	9	EVNIA APS	EVNIA	DENMARK
BE	10	ZENTRALINSTITUT FUER SEELISCHE GESUNDHEIT	ZI	GERMANY
BE	11	UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN	NUID-UCD/CeADAR	IRELAND

In this context, the **main objectives** of the MQP are to:

- Ensure the smooth implementation and on-time completion of the diverse activities foreseen in the framework of the 2D-BioPAD project.
- Safeguard the quality of the project activities and deliverables in line with the contractual obligations of the consortium against the European Commission (Commission).

The MQP provides an overview of the management structure as well as the roles and responsibilities of the partners and defines the procedures for progress monitoring, quality assurance and project management.

Important Remarks

i) Compliance with the MQP is obligatory for all partners of the 2D-BioPAD project.

ii) The MQP complements and does not replace the Grant Agreement (GA) signed with the Commission (including its Annexes) and the Consortium Agreement (CA) of the project.

1.2 Structure

The remaining document consists of **5 sections**:

- **Section 2** presents the project's management structure and describes the partners' roles and responsibilities in this respect.
- **Section 3** analyses the control (quality control, monitoring of changes, management of records/files, etc.) of the project's documents (deliverables reports, etc.).
- **Section 4** addresses project communication issues, both "internal" (between project partners) and "external" (formal communication with the Commission, communication with coordinators/ contractors of other relevant projects or initiatives, etc.).
- **Section 5** outlines the procedures for distributing the payments made by the Commission to the partners.
- **Section 6** describes how the project planning and monitoring are performed (work packages, tasks, checks, etc.).

Finally, the **Annexes** of the MQP include (i) a list of files that are directly related to the MQP (administrative, financial management documents and instructions, templates, etc.); (ii) a Gantt Chart with the work schedule showing the timing of the project's deliverables and milestones; (iii) the Work Breakdown Structure of the project including its Work Packages (WP) and Tasks, list of deliverables, list of milestones, and the interdependencies of the Work Plan components; (iv) a table with the project partners assigned to review the quality of each deliverable foreseen in the context of the 2D-BioPAD project; (v) the Terms of Reference and supporting material for onboarding the Scientific and Industrial Advisory Board members; (vi) the preliminary

constitution of the Scientific and Industrial Advisory Board; and (vii) general project management guidelines, referring to the 2D-BioPAD communication and online repository tools.

1.3 Control

The MQP was produced by the Project Management Office (PMO) and approved by the Project Coordinator (PC). The PC and the PMO are responsible for updating or changing the MQP when necessary. The PC is also responsible for periodically reviewing the MQP and recommending relevant changes. In case of ambiguities or disagreements regarding the content of the MQP, the Steering Committee (SC) of 2D-BioPAD is responsible for making the final decision. Changes may concern any section of the MQP. In any case, changes are marked appropriately (briefly on the cover page of the MQP, new or modified text highlighted accordingly, etc.). After each change, a new version of the MQP will be published and distributed.

Before the new version is put into force, it will be first sent (by the PMO) to the PC and the SC for comments. The PMO will consider the comments of the SC and the PC, finalise the new version of the MQP and distribute it to all partners (in electronic form).

2. Organisational issues

2.1 Management Structure

The **management structure of 2D-BioPAD** is depicted in the following figure.

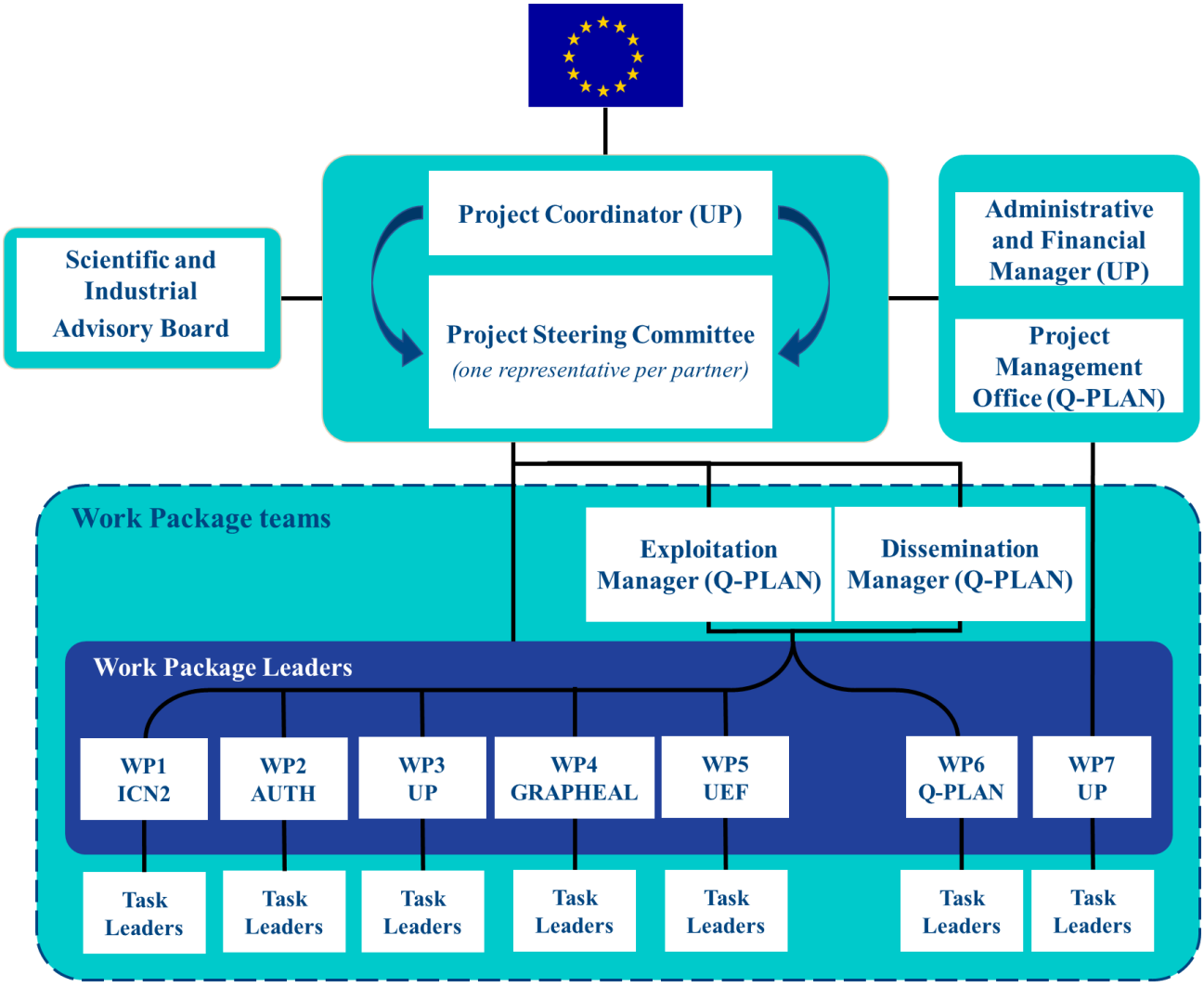


Figure 1. 2D-BioPAD organisational / management structure.

2.1.1 Steering Committee (SC)

The project **Steering Committee (SC)** consists of one representative per partner and is the highest decision-making body of the project, which deals with all key strategic project decisions. Individually, SC members are responsible for the on-time delivery of results on behalf of the partner they represent, assure the quality of the work executed, monitor budgetary and technical results, and gather input for internal and external reporting and documentation. The SC is chaired by the Project Coordinator (PC) and coordinates and manages items affecting the contractual terms with the Commission. The exact authorities, responsibilities and operational procedures of the SC are documented within Annex 1 to the Grant Agreement (GA), namely the Description of the Action (DoA) and, more specifically, within Part A, Section “List of Work packages” (pp. 4) and the provisions of the project’s CA (see Articles 6.2 and 6.3).

2.1.2 Project Coordinator (PC)

The **Project Coordinator (PC)** serves as the chairman of the SC (central decision maker of the project) and is responsible for coordinating project activities. The PC coordinates and manages those items that affect the contractual terms with the Commission and the consortium's technical and scientific activities. The mandate of the PC is described within Part A of the DoA, in the Section "List of Work packages" (pp. 4), complemented by the provisions of Article 6.4 of the project's CA.

2.1.3 Project Management Office (PMO)

The **Project Management Office (PMO)** assists the **Steering Committee (SC)** and the **Project Coordinator (PC)** on project implementation. More specifically, they are responsible to:

- Elaborate and monitor the implementation of the project's MQP;
- Support the evolution of the work plan and provide the PC with advice in terms of monitoring the activities of the project and allocating its resources;
- Provide administrative and organisational support for project meetings (preparation, agenda, minutes, circulation of presentations and minutes, etc.);
- Assist the PC with respect to both internal and external reporting;
- Safeguard the effectiveness of internal communication.

2.1.4 Administrative and Financial Manager (AFM)

The **Administrative and Financial Manager (AFM)** assists the PC in terms of handling the financial aspects of the project (financial monitoring, cost statements, etc.). More specifically, the AFM is responsible to:

- Support PC in financial management
- Ensure that beneficiaries complete their own financial statement on the EU Portal as soon as possible at the end of each reporting period as to allow the PC to submit the consortium Financial and Technical Report within 60 days after the end of each period following the obligations set out in the Grant Agreement (Chapter 3 "GRANT").
- Implement the 2D-BioPAD Consortium Agreement

2.1.5 Scientific and Industrial Advisory Board (SIAB)

The **Scientific and Industrial Advisory Board (SIAB)** is comprised of leading 2D materials, nanotechnology, neuroscience, and ethics stakeholders. The role of the SIAB is to advise the PC and the SC. SIAB members provide their expertise on the needs and problems their stakeholder groups currently face and provide meaningful feedback on our ideas, pilot actions and project outcomes. More importantly, the members of the SIAB facilitate access to important European and international stakeholder communities and drive the widespread acceptance and replication of the 2D-BioPAD results.

The specific Terms of Reference of the SIAB and their composition at the time of submitting this report are presented in Annex VI. Updates on the SIAB and its activities will be included in D6.2 "Dissemination and Communication Plan and Activities, Version 2", due in September 2025 (M24), which will be update in M48 (D6.3 "Dissemination and Communication Plan and Activities, Version 3").

2.1.6 Exploitation Manager (EM)

The **Exploitation Manager (EM)** is responsible for coordinating the 2D-BioPAD innovation activities and for the successful exploitation of the project's results. To this end, the EM defines the project Innovation Management Strategy and prepares the "Exploitation and Sustainability Plan" (D6.4 "Exploitation and Sustainability Plan, Version 1" due in M6/March 2024, D6.5 "Exploitation and Sustainability Plan, Version 2" due in M24/September 2025, and D6.6 "Exploitation and Sustainability Plan, Version 3" due in M48/ September 2027). At the same time, the EM ensures that innovative ideas which arise during 2D-BioPAD are thoroughly examined and assessed for potential exploitation. Finally, the EM is in close communication with the PC and SC to ensure continuous feedback from escalating project activities.

2.1.7 Dissemination Manager (DM)

The **Dissemination Manager (DM)** is responsible for the design and implementation of the "Dissemination and Communication Plan and Activities" (D6.1 "Dissemination and Communication Plan and Activities, Version 3" due in M3/December 2023, D6.2 "Dissemination and Communication Plan and Activities, Version 2" due in M24/September 2025 and D6.3 "Dissemination and Communication Plan and Activities, Version 3" due in M48/September 2027) targeting to create awareness on the scope and activities of the 2D-BioPAD project, coordinates the dissemination and sharing of ideas with external stakeholders, and ensures the widest possible diffusion of 2D-BioPAD's outcomes to its main target groups.

2.1.8 Work Package Leaders (WPL) and Task Leaders (TL)

The **Work Package Leaders (WPL)** are responsible for coordinating the partners collaborating under their respective WPs to ensure the quality of the executed work. The WPL are also responsible for:

(a) resolving day-to-day administrative, technical and resource problems within their WP,
(b) disseminating information relating to all aspects of the work to the other WPL ensuring smooth coordination of WP activities, and
(c) reporting to the upper levels of project management (i.e., the PC and SC).

Finally, **Task Leaders (TL)** are responsible for the on-time elaboration of the deliverables and results of their respective tasks. They work under the direct control of their respective WPL and report directly to them.

2.2 Roles and responsibilities

The roles and responsibilities of the SC and the PC are mentioned in detail in the project CA. **All partners should respect the decisions of the SC.**

Moreover, the roles and responsibilities of each partner are described in detail within Annex 1 to the GA, namely the DoA and, more specifically, within Part A, Section "List of Work packages" (pp. 4) and Part B, Section 3.2 "Consortium as a whole" (pp. 30 - 31).

All partners should take all the necessary **measures** and provide all essential **resources** for the **on-time and smooth elaboration** of their tasks and responsibilities.

The synthesis of the SC and the names of the WPL are available within "**MQP_2D-BioPAD_E01_PartnerData_SC_and_WPL**" (for more information for all MQP files, please see Annex I)**.**

3. Records and quality control of deliverables

3.1 Records

Throughout the project, the PC and all other partners maintain records in electronic and/or paper form. The PC has the responsibility of maintaining the central records of the project. These records include:

- Contractual documents and correspondence with the Commission.
- Correspondence with project partners.
- Deliverables submitted to the Commission.
- The Management and Quality Plan (all versions).
- Meeting minutes and progress reports (internal and external).
- Other important documents.

Important Remarks

i) Each partner should maintain records of all documents that concern them or for which they are responsible.

ii) The PC and all other partners are responsible for storing and maintaining those documents in a way that they are protected against damage, deterioration, or loss.

iii) In particular, concerning electronic records (digital files), all partners should regularly perform back-ups.

The WPLs are responsible for sending the deliverables of the tasks of each WP to the PC. The **PC is the only one responsible for releasing a deliverable** (publicly and/or to the EC). When a deliverable is released, version 1 is assigned to it. The version changes only after important corrections/remarks from the Commission or when a deliverable is updated, according to the work plan described in the DoA annexed to the GA. The **PC is the only one responsible for changing the versions of a deliverable.**

Concerning electronic records (digital files), the following guidelines should be followed in terms of the name of the file:

- File name should preferably not exceed 30 characters. For deliverables, the deliverable number and official name, as stated in the GA, should be part of the file name.
- The author of the file puts the initials of his/her name in the file name. Each file name contains the initials of the name of its last author.
- File name contains the date of the last modification.

The abovementioned rules regarding the naming of electronic files apply to deliverables before the PC releases them. When another version of a deliverable is elaborated, the file name should also contain the last version. **The new version number will be included within the name of the deliverable name only when it is ready for release and only by the PC.**

An **example** demonstrating the rules which apply to the naming of electronic files is provided below:

- **D7.1_Management&QualityPlan_JS_27.11.22.docx** - Deliverable 7.1 (full title: Management and Quality Plan), last author John Smith, date of last modification: 27/11/22, before being released by the PC.
- **D7.1_Management&QualityPlan_v1.docx** - Deliverable 7.1 as it was released by the PC.
- **D7.1_Management&QualityPlan_v1_JD_30.01.23.docx** - Deliverable 7.1, during the elaboration of the second version, last author Jane Doe, date of last modification: 30/01/23, before being released.
- **D7.1_Management&QualityPlan_v2.docx -** The second version of deliverable 7.1 as it was released by the PC.

The latest versions of all deliverables and other documents relevant to the MQP can be found in "**MQP_2D-BioPAD_E08_QMdocuments_and_Deliverable_Q_Reviewers".** The PMO is responsible for updating and versioning internal document forms.

3.2 Quality control of deliverables

All deliverables produced in the context of 2D-BioPAD will undergo a dedicated **quality control process** before their (internal) approval and ultimate release. The (internal) approval of the deliverables will be considered completed only after the successful completion of the respective quality control process.

In this framework, each deliverable will be examined concerning its:

- **Content:** to what extent is the deliverable content relevant and meets its objectives as set out in the DoA; to what degree does it include all the required information.
- **Quality:** whether the quality of the deliverable is acceptable; whether it meets the specifications/ standards that have been set (where relevant).
- **Structure, format and appearance:** where necessary and especially with respect to the deliverable's model template.
- **Data/ Information:** cross-check (where necessary and if applicable) to ensure no contradictions or overlaps between different deliverables exist.
- **Accordance with the timetable:** check the delivery date which has to be in line with the agreed-upon date.
- **Attached documents:** check if all necessary accompanying documents are attached.

With that in mind, the **1st quality check is implemented by the partner responsible for preparing the deliverable**. After its 1st quality check, the deliverable is submitted (keeping the PC in copy) to (i) the WPL of the WP under which the deliverable is being elaborated and (ii) one more partner. Both of them will serve as **quality reviewers** for the respective deliverable. In case the WPL is responsible for the preparation of the deliverable, its quality control shall be performed by two other project partners (see Annex IV for more details on the quality reviewers assigned for each deliverable to be produced in the framework of 2D-BioPAD).

The **quality reviewers are responsible for the 2nd quality check** of the deliverable, which is implemented with the help of a dedicated **quality review form** (see "**MQP_2D-BioPAD_E07_QualityReviewForm"**). The quality reviewers inspect the deliverable, and if there are any remarks/ comments/ deficiencies, it is rejected and returned to the responsible partner for improvement (with the PC in copy). Quality reviewers shall perform the quality check and respond to the partner responsible for preparing the deliverable within **5 working days** by providing the quality review form (QR form) and the commented deliverable. The appropriate adaptations are implemented within **3 working days** by the responsible partner, and the deliverable is sent for another quality check to the quality reviewers. The deliverable is then re-examined to ensure that all comments have been addressed. If necessary, the process is reiterated. When the quality reviewers accept the deliverable, it is submitted for a **final quality check** to the PC (see Figure 2 on the next page of this document).

The PC releases the deliverable to the Commission only after its internal approval. The PC monitors the entire internal preparation and quality control procedure of deliverables. The partners responsible for 2D-BioPAD's deliverables and the quality reviewers assigned to each deliverable are listed in Annex IV.

Important Remarks

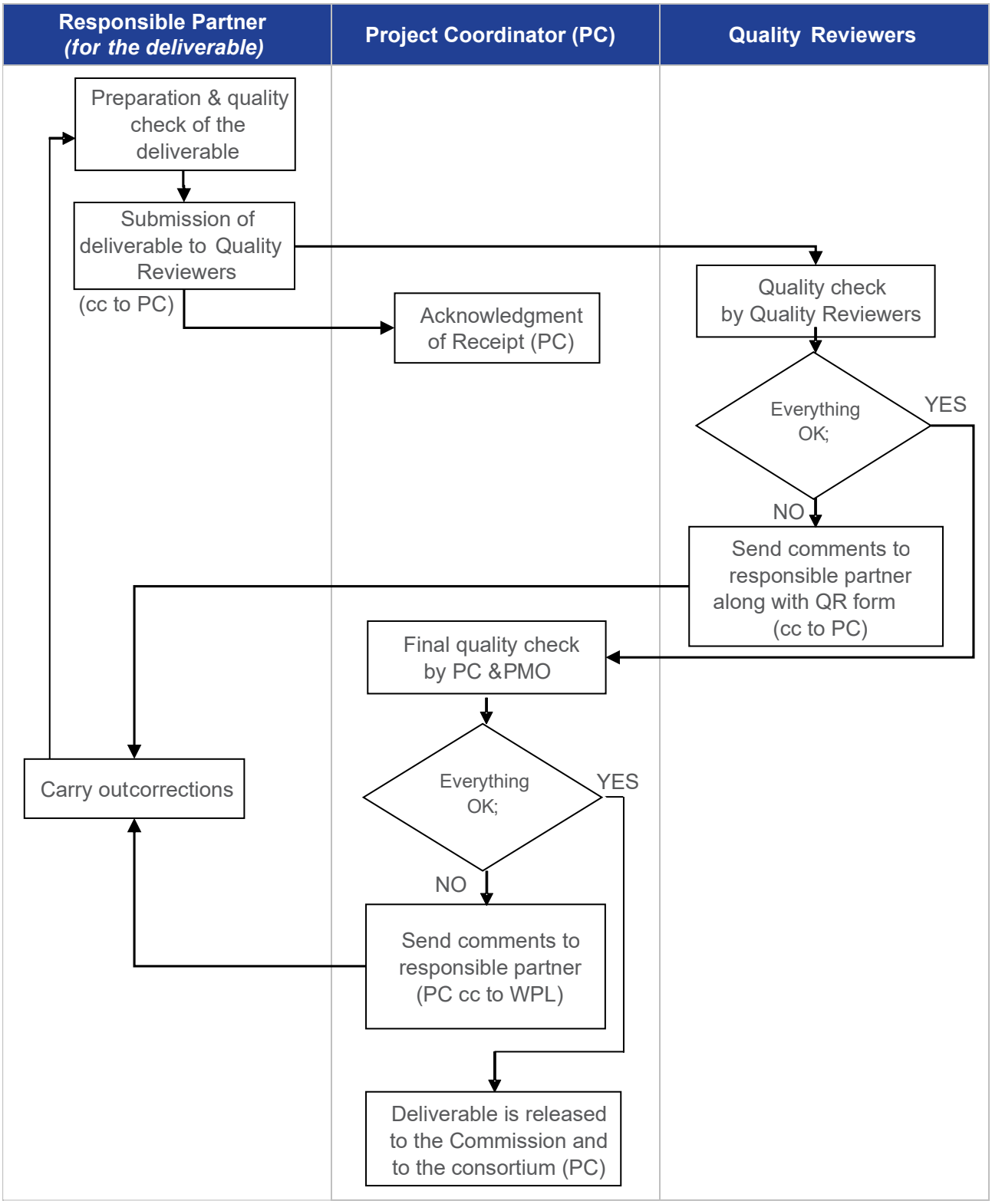
i) Each partner should maintain records of all documents that concern them or for which they are responsible.

ii) Each partner is responsible for the quality of its deliverables. The PC is overall responsible for the quality of the whole project.

iii) Where possible, all deliverables are prepared in a standard format based on the template of the present document.

After the final submission of the deliverable, EVNIA will examine the context of the report (mainly the technical ones) to specify any (additional) regulatory requirements. These will be communicated to the authors, who will have **1 month to elaborate further on these requirements and provide the necessary documentation required**. EVNIA will be responsible for keeping records of these requirements and guiding the implementation and future 2D-BioPAD deliverables.

Figure 2. Internal process for controlling the quality of deliverables until submission to the EC.



4. Project coordination

4.1 Internal communication

Communication between the PC and project partners takes place in any available – convenient way (e.g., email, telephone, teleconferencing, fax, and meetings). Internal communication may be distinguished into formal and informal. The PC has the main responsibility of ensuring smooth and effective internal communication.

The **contact details of 2D-BioPAD partners** are kept in a separate file (see "**MQP_2D-BioPAD_E01_PartnerData_SC_and_WPL**"). If there is any change in the contact details or the project team, partners should notify the PC, who will inform the rest of the partners (and, if necessary, the EC).

Communication for important issues (e.g., sending deliverables and planning meetings), as well as any formal communication (e.g., project meetings), should be documented – written (e.g., by preparing the meeting minutes and maintaining an electronic (e.g., emails) or paper copy record).

Informal communication takes place between the PC, the WPL and the partners (through telephone, informal emails, etc.) and may not be documented. The PC and WPL are expected to communicate regularly with the project partners to follow the project and WPs' progress closely to identify and rectify potential deviations in time.

Close collaboration and communication between project partners are essential, especially in cases where they have to cooperate to perform specific project tasks.

To further facilitate internal communication a set of guidelines has been introduced to the consortium to better describe the project management tools (mailing lists, online repository, collaboration tools, etc.). These guidelines will be updated and communicated to all partners upon any changes or updates.

4.2 External communication

4.2.1 Communication with the Commission

The PC is solely responsible for communicating with the responsible Project Officer (PO) of the Commission with respect to the project. Project partners should not contact the PO. Only in exceptional cases, and if the PO requires so, may a project partner contact the PO directly. In such a case, the PC is kept fully informed (in writing) about the communication content. In particular, in case a project partner wishes to communicate with the PO directly, first the PC should be informed and jointly decide about the next required steps. In case of any critical issues, the project SC will be involved.

The PC is responsible for submitting to the Commission all reports and deliverables of the project. The PC also provides to the Commission any additional information and/ or clarification (that has been requested by the Commission). Finally, the PC keeps all partners informed about any important communication with the Commission.

4.2.2 Communication with third parties

Project partners may and should communicate with third parties (e.g., businesses, public authorities, innovation intermediaries, EEN members, National Contact Points, other EU-funded projects, etc.) within the

context of the project. In all external communications, a reference to the project should be made (e.g., project acronym, EU programme, GA No, etc.).

4.2.3 Complaints – disputes

The members of the SC and the WPL will immediately notify the PC of any events or circumstances that may significantly affect the performance of the work executed in the WP they are leading. Indicative examples include (i) suggestions for considerable improvements and modifications/ changes in the methodology, timetable and task allocation, (ii) potential delays and (iii) disputes between partners.

The PC will be responsible for and try resolving the abovementioned issues by consulting with the QM, the WPL and any partner directly involved in the respective WP. The PC will try to achieve a compromise between the conflicting parties based on consensus, taking into account the conformance to the objectives and work plan of the project.

If the mediation of the PC does not turn out to be successful, then the PC will forward the conflict to the SC for taking the final decision. The SC will try to respond to changes or settle conflicts by achieving consensus among the parties involved. If consensus cannot be achieved and/ or conflicts remain unresolved, the SC will decide on the matter via vote. Further details concerning decision-making, conflict resolution, and the management of internal administrative-financial issues are incorporated in the project's CA. **In any case, the mediation process and the final decision remain to the PC and the SC.** When necessary, the PC informs the Commission requesting feedback.

5. Payments

The Commission provides the EU contribution in 4 payment moments over the project's lifetime:

1. Pre-financing at the beginning of the project (upon signature of the GA): 53.3333% of the total EU contribution (i.e., EUR 3,177,533.07), minus 5% of the maximum grant amount which the Granting Authority keeps for the Mutual Insurance Mechanism (i.e., EUR 297,897.48).
2. Payment after the end of the 1st project period (Interim payment ceiling: 90% of the maximum grant amount).
3. Payment after the end of the 2nd project period (Interim payment ceiling: 90% of the maximum grant amount).
4. Payment after the end of the 3rd project period – end of the project, including the Mutual Insurance Mechanism contribution.

The pre-financing has been distributed to the partners without undue delay. Regarding the 2nd, 3rd and the 4th payment, the steps involved in the payment and distribution process are the following:

1. All scheduled reports and deliverables for the period must have been submitted.
2. The Commission confirms that targets have been achieved through a successful official review meeting.
3. The Granting Authority pays the PC based on the periodic financial reports and other financial provisions.
4. The PC calculates the distribution plan for the entire amount received. All partners are informed accordingly.
5. All partners, through their SC representatives, agree with the distribution plan suggested by the PC and confirm/ update their bank accounts.
6. The PC conducts the payment of the respective amounts.

6. Work-planning, monitoring and control

6.1 Work-planning

The project work-plan is divided into WPs, and each WP is divided into Tasks. The overall work-planning of the project is presented in "**MQP_2D-BioPAD_E02_WorkPlanning"** and includes:

- ✓ the WP and respective tasks.
- ✓ the duration, start and end dates for each task and WP as a whole.
- ✓ the responsible partner and the partners involved; and
- ✓ the respective deliverables, both external (as mentioned in the DoA of the GA with the EC) and internal.

A **Work Breakdown Structure (WBS),** along with a **Gantt chart** and a schedule per task, related deliverables, and dependencies on other tasks, are included in the respective Annexes of this document.

Any modification/ change (which again does not affect the project's overall course) in the work-planning should be approved by the PC. Any significant change should be in line with the contractual obligations and the rules of the Commission.

Important Remark

If the consortium fails to send a deliverable on time to the Commission, the PC should inform the Commission before the deadline, justify the delay and suggest a new deadline. For this reason, **all partners should provide early warnings about delays to the respective WPL and the WPL to the PC** (see also Section 6.5 Risk Management of the current document).

6.2 Project Meetings

A total of **9 project meetings** are anticipated in the framework of the 2D-BioPAD project[2]. For more details, see Part A of the DoA (pp. 17). The PMO is responsible for the initial preparation of minutes for all project meetings, whereas the PC is responsible for the first review and distribution to the consortium. The meeting minutes are sent to all partners for approval by the PC.

6.3 Progress monitoring (internal reports)

Every six months, a short progress report will be prepared by each project partner plus WPL to summarise the work progress (including progress against targets). All the individual semester reports will be integrated and reported in the "**MQP_2D-BioPAD_E04_InternalSemesterReport"** for activity reporting. Based on the individual semester progress reports, the PC, with the support from the PMO, will elaborate the respective "Internal Semester Report" for the whole project. All individual semester progress reports should be sent to the PC no later than 15 days after the end of the respective reporting period. The PC should provide comments within 15 days from the date of submission. If no comment is sent within this period, the submitted report is considered accepted.

[2] Including the kick-off that took place in Thessaloniki on the 10th and 11th of October 2023.

Along with the technical progress reporting, all project partners will be requested to fill in an internal financial report, covering effort and costs incurred in the reporting period (see model templates in "**MQP_2D-BioPAD_E03_FinancialMonitoring"**).

The Internal Semester Report(s) will be incorporated with the major reports to the Commission when the time of their elaboration coincides (in M18, M36 and M48).

6.4 Reports to the Commission (external reports)

The PC is overall responsible for the preparation and on-time submission of the project reports to the Commission. All partners provide the necessary input for the preparation of the reports. In 2D-BioPAD, three such reports are required at the end of the three respective reporting periods (M1 to M18, M19 to M36, and M37-M48). The exact content of the aforementioned reports is specified in the GA (Article 21, pp. 38 - 40).

6.5 Risk Management

Risks that may affect the progress and quality of the project considerably have been identified, and relevant contingency plans have been elaborated. The list of risks will be updated on an ad hoc basis or once every six months.

6.5.1 Main risks and contingency plans

Two types of risks have been identified:

- **Internal** risks. They are linked with the operation of the project team (characterised by a large number of experts, different backgrounds and geographical dispersion), delays, changes in the project team, etc.
- **External** risks. They are induced by the project's targeted stakeholders, though they may still be caused by an inappropriate project approach or inadequate performance.

Risks are assessed separately and reported in the reports to the Commission. Each WPL is responsible for identifying additional risks that may arise during the project's implementation and constantly assessing those identified. Contingency planning may be adapted accordingly.

6.5.2 Risk process and roles

Risks are handled by the SC, PC and WPL. In particular:

- The SC decides which countermeasures should be applied, by whom and when.
- The PC informs the SC about the identified risks, monitors the implementation of the countermeasures, and assesses the results/ outcomes. The PC also supervises the QM concerning risk monitoring and management.
- WPL submit a Risk Report to the PC on the date a new risk is identified or every six months for the already identified risks. Within this report, they provide detailed info about the identified risks, propose countermeasures and report on the implementation of those measures (based on the model template in **"MQP_2D-BioPAD_E06_RiskReport"**). The PC also uses the same document to inform the SC about the identified risk and to communicate the SC decisions per risk back to the responsible WPL.

6.5.3 Risk Assessment

Risk assessment concerns two main factors, namely **Impact** and **Probability** of occurrence.

Table 3. Risk Assessment

Risk assessment factors	Estimation- assessment		
Impact factor	1 - Low	2 – Medium	3 - High
Probability of occurrence	1 - Low (P < 35%)	2 – Medium (35% < P < 70%)	3 – High (P > 70%)

A risk management section is included in the internal semester reports of WPL, referring to the WPs that will be affected by a specific risk. A risk management section will be included in the reports to the Commission, reporting the major risks and the countermeasures taken by the consortium.

6.5.4 Corrective actions - Contingency plans

If a risk is identified and/ or the project's effort does not conform to the project's work-planning and/ or objectives, the PC may apply corrective actions (based on SC decisions). In case of non-conformities, the PC may also activate contingency plans. With that in mind, the table below summarises the main internal and external risks and the respective contingency plans.

Table 4. Risks and mitigation measures

Description of risk (Probability/Impact)	Linked WP	Risk mitigation measures
COVID-19 and participatory activities (High/Med)	ALL	Extensive clinical activities, co-creation and workshops are foreseen in the project. In case we are not able to carry them out physically, a mixed approach (virtual solutions, etc.) will be used.
Delay(s) in the project timetable (Low/Med)	WP7	The SC agrees and applies contingency plans (tailored to the exact circumstances), including: (i) re-allocation of resources, (ii) parallel execution of tasks, (iii) re-scheduling of activities. A contingency plan is activated in case a partner submits his/ her work with an unjustified delay against the internal deadline (internal deadlines are set well before the contractual ones). The partner is contacted to justify the delay, set a new deadline, and is given a warning. If repeated, then the PC will discuss and decide with the SC on appropriate measures.
Poor performance of partners (Low/High)	WP7	As a rule, the distribution of the whole amount of the advance payment to partners will require the on-time submission of 'their deliverables' (as well as their contribution to deliverables following the allocation of work agreed) in proper quality. The procedures for resolving conflicts and controlling changes will be applied, following the articles of the signed (by then) Consortium Agreement.
Poor input to requirements from potential end-users (Low/ High)	WP1	Different groups of potential users will be identified early on, and workshops will be held with each to ensure a wide range of input. Via the training activities, additional input will be collected based on specific Q&A sessions.

Description of risk (Probability/Impact)	Linked WP	Risk mitigation measures
Requirements are hard to reconcile with technical feasibility (Low/High)	WP1	Requirements will be grouped into user stories, and ranked, grouped, and sorted by representatives of the potential user groups, and effort-estimated by the development partners until an achievable "minimum viable product" has been agreed upon.
Poor performance of conjugated MNPs/aptamers/biomarkers (Low/Med)	WP2	Immobilization on MNPs might change the binding capacity and specificity of the aptamers. Intermediate results of WP2 tasks will serve as input for optimization with respect to high sensitivity and specificity before the involvement of graphene. Different types of MNPs with respect to size and magnetic features will be conjugated to selected aptamers at alternative ratios to establish a direct and distinct output signal when attached to specific biomarkers.
Biosensing techniques are not good enough to capture the AD Biomarkers (Med/High)	WP3, WP4	To ensure envisioned results, two core biosensing strategies will be implemented in parallel. This approach will not only allow a better understanding of the technologies at hand but will also provide the necessary benchmarking between the two approaches generating significant knowledge and evidence.
Difficulties in detecting the biomarkers in the sample (blood, serum) due to high salinity or other biomarker interferences (Med/High)	WP2, WP3, WP4	Several biomarkers will be evaluated early in the project to identify the optimal set of five that will be used for the 2D-BioPAD system. On top of that additional mitigation measures will be applied such as reduction of the probe size, optimization of preparation buffer, salinity reduction of the matrix by desalting column, modification of the detection strategy, etc.
Limited subjects for the retrospective and prospective studies (Med/High)	WP5	Identifying good quality and eligible samples for the retrospective study and enrolling subjects with MCI/AD for the prospective study will be challenging. The clinical centres have vast experience in clinical studies and the protocols to ensure the delivery and completion of the 2D-BioPAD pilot studies will be completed as early as possible with the participation of technical experts and our Advisory Board. Potential dropout rates will be considered when enrolling patients, hence ensuring that an adequate number of people will participate until the end.
Non-compliance with national/ organisational regulations for clinical studies approval (Low/High)	WP5	The clinical experts of the consortium as well as the technical partners are well versed in ethical and regulatory restrictions for deploying the two clinical studies foreseen. Approval for the conduct of the studies will be requested as soon as the required documentation has been developed. Both preparation of the documentation and subsequent submission will be monitored and supervised at all times by the delegated partner of the project for regulatory affairs involving actively the experts within the SIAB.

Annexes

Annex I - List of files related to the MQP

Table 5. List of files related to the Management and Quality Plan

Title of document		Remark
Official documents		
2D-BioPAD Grant Agreement		
2D-BioPAD Consortium Agreement		
Internal forms/templates		
Title	**Code**	**Type**
2D-BioPAD partner data	MQP_2D-BioPAD_E01	Spreadsheet
Work-planning	MQP_2D-BioPAD_E02	Spreadsheet
Monitoring expenses file template (per partner)	MQP_2D-BioPAD_E03	Spreadsheet
Internal Semester Report template (per partner)	MQP_2D-BioPAD_E04	Document
Deliverables template	MQP_2D-BioPAD_E05	Document
Risk report	MQP_2D-BioPAD_E06	Document
Quality review form	MQP_2D-BioPAD_E07	Document
List of QM documents and Deliverable Quality Reviewers	MQP_2D-BioPAD_E08	Spreadsheet

Annex II – Gantt Chart

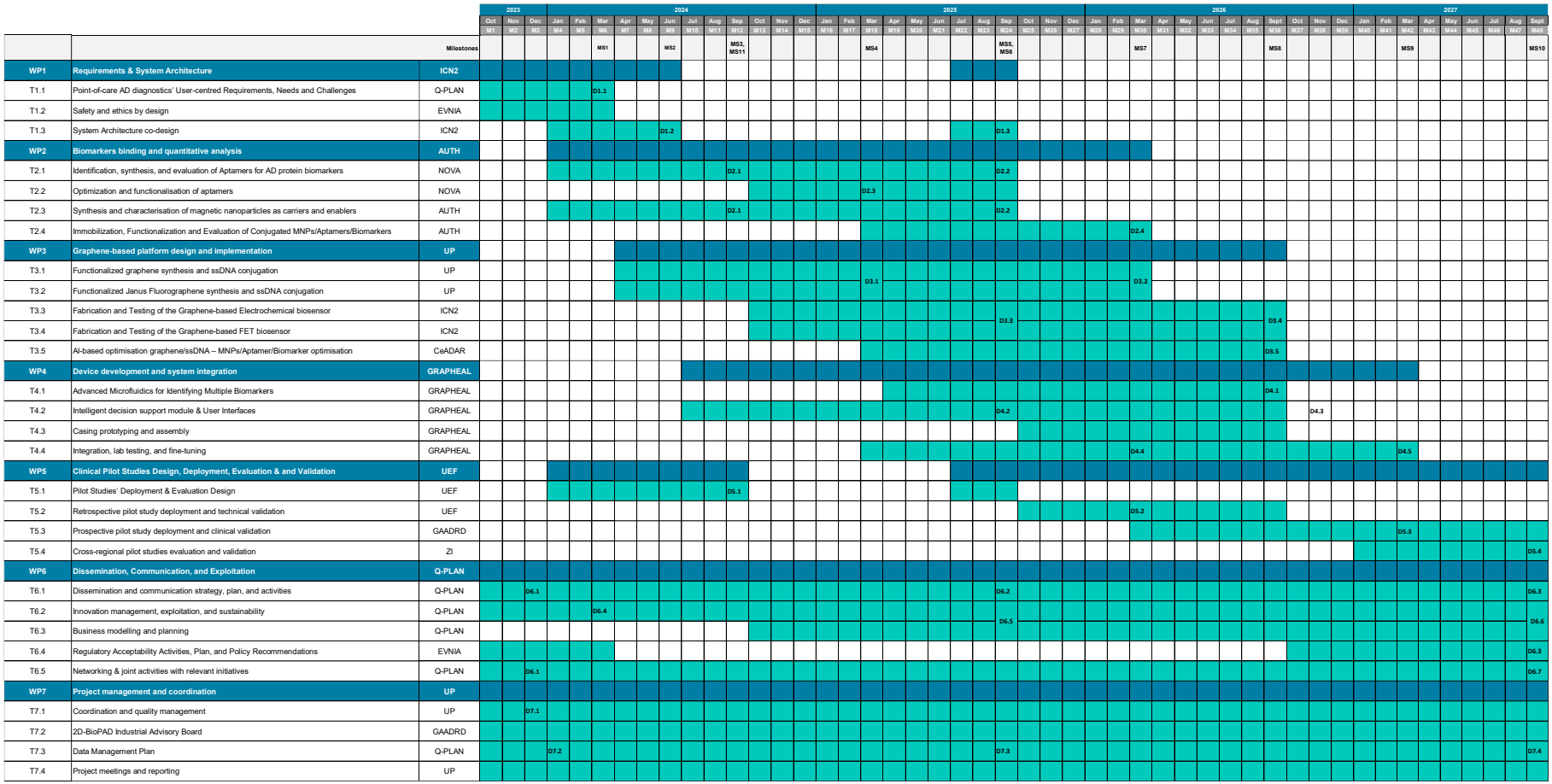


Figure 3. Gantt Chart

Annex III – 2D-BioPAD Work Breakdown by WPs, Tasks, Deliverables and Milestones

Table 6. 2D-BIOPAD Work Breakdown by WPs and Tasks

Activities per Work package		Leader	Start	End
WP1	**Requirements & System Architecture**	**ICN2**	**M1**	**M24**
T1.1	Point-of-care AD diagnostics' User-centred Requirements, Needs and Challenges	Q-PLAN	M1	M6
T1.2	Safety and ethics by design	EVNIA	M1	M6
T1.3	System Architecture co-design	ICN2	M4	M24
WP2	**Biomarkers binding and quantitative analysis**	**AUTH**	**M4**	**M30**
T2.1	Identification, synthesis, and evaluation of Aptamers for AD protein biomarkers	NOVA	M4	M24
T2.2	Optimization and functionalisation of aptamers	NOVA	M13	M24
T2.3	Synthesis and characterisation of magnetic nanoparticles as carriers and enablers	AUTH	M4	M24
T2.4	Immobilization, Functionalization and Evaluation of Conjugated MNPs/Aptamers/Biomarkers	AUTH	M18	M30
WP3	**Graphene-based platform design and implementation**	**UP**	**M7**	**M36**
T3.1	Functionalized graphene synthesis and ssDNA conjugation	UP	M7	M30
T3.2	Functionalized Janus Fluorographene synthesis and ssDNA conjugation	UP	M7	M30
T3.3	Fabrication and Testing of the Graphene-based Electrochemical biosensor	ICN2	M13	M36
T3.4	Fabrication and Testing of the Graphene-based FET biosensor	GRAPHEAL	M13	M36
T3.5	AI-based optimisation graphene/ssDNA – MNPs/Aptamer/Biomarker optimization	CeADAR	M18	M36
WP4	**Device development and system integration**	**GRAPHEAL**	**M10**	**M42**
T4.1	Advanced Microfluidics for Identifying Multiple Biomarkers	GRAPHEAL	M19	M36
T4.2	Intelligent decision support module & User Interfaces	GRAPHEAL	M10	M36
T4.3	Casing prototyping and assembly	GRAPHEAL	M25	M36
T4.4	Integration, lab testing, and fine-tuning	GRAPHEAL	M18	M42
WP5	**Clinical Pilot Studies Design, Deployment, Evaluation & and Validation**	**UEF**	**M4**	**M48**
T5.1	Pilot Studies' Deployment & Evaluation Design	UEF	M4	M24
T5.2	Retrospective pilot study deployment and technical validation	UEF	M25	M36
T5.3	Prospective pilot study deployment and clinical validation	GAADRD	M30	M48
T5.4	Cross-regional pilot studies evaluation and validation	ZI	M40	M48
WP6	**Dissemination, Communication & Exploitation**	**Q-PLAN**	**M1**	**M48**
T6.1	Dissemination and communication strategy, plan, and activities	Q-PLAN	M1	M48
T6.2	Innovation management, exploitation, and sustainability	Q-PLAN	M1	M48
T6.3	Business modelling and planning	Q-PLAN	M13	M48
T6.4	Regulatory Acceptability Activities, Plan, and Policy Recommendations	EVNIA	M1	M48
T6.5	Networking & joint activities with relevant initiatives	Q-PLAN	M1	M48
WP7	**Project Management & Coordination**	**UP**	**M1**	**M48**

Activities per Work package		Leader	Start	End
T7.1	Coordination and quality management	UP	M1	M48
T7.2	2D-BioPAD Industrial Advisory Board	GAADRD	M1	M48
T7.3	Data Management	Q-PLAN	M1	M48
T7.4	Project Meetings and Reporting	UP	M1	M48

Table 7. List of Deliverables

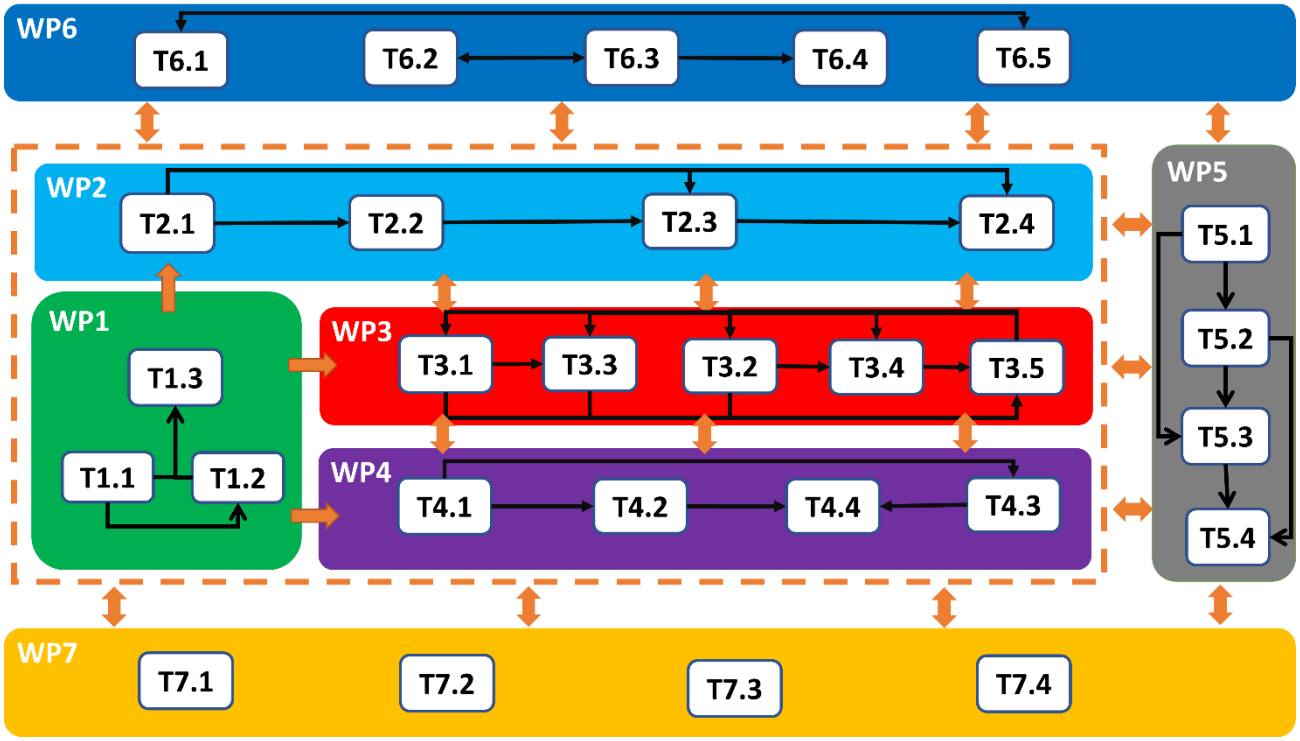
Del. No	Deliverable name	WP	Lead partner	Type	Diss. Level	Due Date
1.1	MCI to AD Biomarker Deep Dive Analysis for Early Diagnosis	1	Q-PLAN	R	PU	M6
1.2	System Architecture, Version 1	1	ICN2	R	PU	M9
1.3	System Architecture, Version 2	1	ICN2	R	PU	M24
2.1	Conjugated MNPs/Aptamers Design, Synthesis, and Selection, Version 1	2	AUTH	OTHER	SEN	M12
2.2	Conjugated MNPs/Aptamers Design, Synthesis, and Selection, Version 2	2	AUTH	OTHER	SEN	M24
2.3	Conjugated MNPs/Aptamers Binding to AD Biomarkers evaluation, Version 1	2	AUTH	R	PU	M18
2.4	Conjugated MNPs/Aptamers Binding to AD Biomarkers evaluation, Version 2	2	AUTH	R	PU	M30
3.1	Functionalized graphene synthesis and ssDNA conjugation, Version 1	3	UP	OTHER	SEN	M18
3.2	Functionalized graphene synthesis and ssDNA conjugation, Version 2	3	UP	OTHER	SEN	M30
3.3	Fabrication and testing of Graphene-based biosensors, Version 1	3	ICN2	OTHER	SEN	M24
3.4	Fabrication and testing of Graphene-based biosensors, Version 2	3	ICN2	OTHER	SEN	M36
3.5	AI for 2DM-based PoC IVD Design	3	CeADAR	OTHER	PU	M36
4.1	Advanced microfluidics for 2DM-based PoC IVD	4	GRAPHEAL	OTHER	SEN	M36
4.2	2D-BioPAD integrated system, Version 1	4	GRAPHEAL	OTHER	SEN	M24
4.3	2D-BioPAD integrated system, Version 2	4	GRAPHEAL	OTHER	SEN	M38
4.4	Integration, Stress-testing, and Fine-tuning, Version 1	4	GRAPHEAL	OTHER	SEN	M30
4.5	Integration, Stress-testing, and Fine-tuning, Version 2	4	GRAPHEAL	OTHER	SEN	M42
5.1	Clinical Pilot Studies Initiation Package and Ethics check	5	UEF	R	PU	M12
5.2	Pilot Studies Deployment, Version 1	5	UEF	R	PU	M30
5.3	Pilot Studies Deployment, Version 2	5	UEF	R	PU	M42
5.4	Cross-pilot Comparative Assessment	5	ZI	R	PU	M48
6.1	Dissemination and Communication Plan and Activities, Version 1	6	Q-PLAN	R	SEN	M3
6.2	Dissemination and Communication Plan and Activities, Version 2	6	Q-PLAN	R	SEN	M24
6.3	Dissemination and Communication Plan and Activities, Version 3	6	Q-PLAN	R	SEN	M48

Del. No	Deliverable name	WP	Lead partner	Type	Diss. Level	Due Date
6.4	Exploitation and Sustainability Plan, Version 1	6	Q-PLAN	R	SEN	M6
6.5	Exploitation and Sustainability Plan, Version 2	6	Q-PLAN	R	SEN	M24
6.6	Exploitation and Sustainability Plan, Version 3	6	Q-PLAN	R	SEN	M48
6.7	Regulatory Acceptability Plan and Policy Recommendations	6	EVNIA	R	SEN	M48
7.1	Management and Quality Plan	7	UP	R	SEN	M3
7.2	Data Management Plan, Version 1	7	Q-PLAN	R	PU	M4
7.3	Data Management Plan, Version 2	7	Q-PLAN	R	PU	M24
7.4	Data Management Plan, Version 3	7	Q-PLAN	R	PU	M48

Table 8. List of Milestones

MS No	Milestone title	Related WP(s)	Lead Beneficiary	Delivery Date	Means of verification
1	Deep Dive Results, Requirements and Design Principles for 2D-BioPAD Available	1	Q-PLAN	6	D1.1 Available
2	System Architecture and Use Cases Available	1	ICN2	9	D1.2 Available
3	Clinical Pilot Studies Protocols available and approved	5	UEF	12	D5.1 Available
4	First prototype of (i) conjugated MNPs/Aptamers and (ii) functionalised graphenes conjugated with ssDNA	2,3	UP	18	D2.3, D3.1 Available
5	Final System Architecture, Final Pilot Studies designs, and First 2D-BioPAD prototype device available	1,2,3,4,5	UP	24	D1.3, D2.2, D3.3, and D4.2 Available
6	Preliminary Business models & Exploitation plans available	6	Q-PLAN	24	D6.5 Available
7	Second prototype of (i) conjugated MNPs/Aptamers and (ii) functionalised graphenes conjugated with ssDNA. Preliminary retrospective study results available	3,4,5	UP	30	D2.4, D3.2, and D5.2 Available
8	First complete 2D-BioPAD system prototype available, Enrolment of patients on the prospective pilot study	4	GRAPHEAL	36	D3.4, D3.5, D4.1, Available & System Available for Clinical Testing
9	Fully operational 2D-BioPAD system prototype available and Preliminary Prospective Study Results Available	4,5	GRAPHEAL	42	D4.5 Available
10	2D-BioPAD Evaluation completed. Lessons Learnt, Best Practises, Recommendations and Business and Regulatory Acceptance Plans presented	5,6	Q-PLAN	48	D5.4, D6.6, and D6.7 Available
11	Ethics Check	5	UP	12	D5.1 Available

Figure 4: Overview of the work plan - PERT chart



Annex IV – Distribution of Deliverables Quality Reviews amongst Partners

Table 9. Reviewers assigned to each deliverable

Del. No	WPL	Lead partner	Due Date	Quality Reviewer No 1	Quality Reviewer No 2
1.1	ICN2	Q-PLAN	M6	UEF	ICN2
1.2	ICN2	ICN2	M9	GRAPHEAL	Q-PLAN
1.3	ICN2	ICN2	M24	GRAPHEAL	Q-PLAN
2.1	AUTH	AUTH	M12	ICN2	UEF
2.2	AUTH	AUTH	M24	ICN2	UEF
2.3	AUTH	AUTH	M18	GRAPHEAL	ZI
2.4	AUTH	AUTH	M30	GRAPHEAL	ZI
3.1	UP	UP	M18	NOVA	CeADAR
3.2	UP	UP	M30	AUTH	CeADAR
3.3	UP	ICN2	M24	Q-PLAN	AUTH
3.4	UP	ICN2	M36	Q-PLAN	AUTH
3.5	UP	CeADAR	M36	EVNIA	NOVA
4.1	GRAPHEAL	GRAPHEAL	M36	ICN2	NOVA
4.2	GRAPHEAL	GRAPHEAL	M24	UP	ICN2
4.3	GRAPHEAL	GRAPHEAL	M38	UP	ICN2
4.4	GRAPHEAL	GRAPHEAL	M30	Q-PLAN	CeADAR
4.5	GRAPHEAL	GRAPHEAL	M42	Q-PLAN	CeADAR
5.1	UEF	UEF	M12	GAADRD	ZI
5.2	UEF	UEF	M30	GAADRD	ZI
5.3	UEF	UEF	M42	GAADRD	ZI
5.4	UEF	ZI	M48	GAADRD	UEF
6.1	Q-PLAN	Q-PLAN	M3	AUTH	UP
6.2	Q-PLAN	Q-PLAN	M24	AUTH	EVNIA
6.3	Q-PLAN	Q-PLAN	M48	AUTH	CeADAR
6.4	Q-PLAN	Q-PLAN	M6	GRAPHEAL	NOVA
6.5	Q-PLAN	Q-PLAN	M24	GRAPHEAL	NOVA
6.6	Q-PLAN	Q-PLAN	M48	GRAPHEAL	NOVA
6.7	Q-PLAN	EVNIA	M48	GRAPHEAL	UEF
7.1	UP	UP	M3	GAADRD	UEF
7.2	UP	Q-PLAN	M4	UP	EVNIA
7.3	UP	Q-PLAN	M24	UP	EVNIA
7.4	UP	Q-PLAN	M48	UP	EVNIA

Annex V – Terms of Reference for the 2D-BioPAD Scientific and Industrial Advisory Board (SIAB)

Terms of Reference

Introduction

You have been invited to the 2D-BioPAD Scientific and Industrial Advisory Board (SIAB). The current document outlines the Terms of Reference that will help you understand what this involves before you decide to participate. Please take the time to carefully read this document and ask for any clarifications you may require.

2D-BioPAD in a nutshell

2D-BioPAD is a 4-year Research and Innovation Action running from October 2023 to September 2027, funded by the European Union under the Horizon Europe Research and Innovation program.

2D-BioPAD aims to introduce a fast and cost-effective, non-invasive, reliable, digitally and graphene enabled Point-of-Care (PoC) in-vitro diagnostics (IVD) system for supporting the early diagnosis and progression monitoring of Alzheimer's Disease (AD) directly at primary healthcare settings.

To achieve this, and tackle the scientific challenge, the technological and market gap of PoC IVD for AD, 2D-BioPAD leverages the unique properties of 2D materials, such as graphene and its derivatives. Towards that direction, 2D-BioPAD goes beyond the state-of-the-art of its 2D Materials' pioneer consortium to deliver a graphene-based PoC IVD system that will (i) introduce a versatile surface chemistry that combines nano and DNA technologies towards improved biocompatibility, stability, as well as high sensitivity and specificity for enhanced (bio-)sensing; (ii) be able to reliably identify and quantify in real-time and simultaneously up to 5 AD biomarkers in blood samples effectively supporting healthcare professionals in early diagnosis; (iii) offer an easy to use and understand digital interface with key metrics and insights regarding the measured results; and (iv) employ Artificial Intelligence (AI) to improve the overall system implementation.

The 2D-BioPAD system and its impact will be demonstrated in 3 clinical centres in Europe (Finland, Greece, and Germany) under two clinical pilot studies. In every step, and from the very beginning, 2D-BioPAD will go beyond current norms and involve a wide range of stakeholders, starting from the clinic itself, and led by industrial partners, to identify the essential safety and ethical-by-design principles and guidelines that can accelerate uptake at primary healthcare settings and maximise acceptance and impact to both physical and digital supply chains.

In this context, the SIAB of 2D-BioPAD is comprised of experts in diverse 2D-Materials, Nanotechnology, AI, and Neurosciences who provide strategic guidance in key stages of the project, contributing with their expertise and representing the views and interests of their stakeholder communities in order to better align the results of the project with them.

Project Partners – Consortium

The consortium of 2D-BioPAD brings together a consortium of **11 partners across 8 different countries**:

- **UNIVERZITA PALACKÉHO V OLOMOUCI - CATRIN (UP) | Czechia**

The Czech Advanced Technology and Research Institute (CATRIN) at Palacký University is a cutting-edge scientific hub dedicated to advancing research in the fields of nanotechnology, biotechnology, and

biomedicine. At its core, CATRIN boasts outstanding scientific teams, featuring international researchers. CATRIN emphasizes interdisciplinarity, fosters global collaborations, and works to translate our research findings into practical applications. CATRIN-RCPTM, a part of CATRIN, focuses on the development of nanomaterials and nanotechnologies for energy conversion and storage, environmental applications, catalysis, and applications in biomedicine. The research covers a wide range of low-dimensional carbon materials, 2D nanostructures, quantum dots, and metal-based nanomaterials with unique magnetic, optical, electronic, or biological properties.

For more information visit https://www.catrin.com/

- **Q-PLAN INTERNATIONAL ADVISORS PC (Q-PLAN) | Greece**

Q-PLAN is an innovation and management consulting company based in Thessaloniki, Greece. It focuses on design, management and implementation of Research and Innovation projects as well as studies; support of private or public organisations of different types and sizes to (re)design, implement, audit and accredit/ certify their management systems and processes; and support services for businesses to make the most out of available funding and financing opportunities. Q-PLAN has been involved in over 55 EU-funded projects and policy studies.

For more information visit: https://qplan-intl.gr/

- **FUNDÀCIO INSTITUT CATALÀ DE NANOCIÈNCIA I NANOTECNOLOGIA (ICN2) | Spain**

The Institut Català de Nanociència i Nanotecnologia, acronym ICN2, is a non-profit international research institute located close to Barcelona (Catalonia, Spain). It is devoted to the generation of knowledge, materials and devices in the broad fields of ICT, health, energy and the environment.

The expertise of the ICN2 lies at the nanoscale, where new properties, interactions and ways to exploit them in everyday life are being discovered. Among its goals is to bring together scientists from diverse backgrounds in the pursuit of better science, better training and better outreach to society, while also seeking out new ways to engage with local and global industry.

For more information visit www.icn2.cat

- **GRAPHEAL S.A.S. (GRAPHEAL) | France**

Grapheal realizes flexible bioelectronic sensors, digital by design, minimalistic in components, with capabilities to detect and dose molecular biomarkers & pathogens with mobile technologies. Grapheal integrates the entire design value chain from synthesis of sensing nanomaterials to complete sensor integration with wireless connectivity, embedded data analysis, and software development. Through its original platform, Grapheal provides competitively priced solutions without the need to purchase a dedicated reader, while collecting digital results in a few minutes.

For more information visit https://www.grapheal.com/

- **ARISTOTELIO PANEPISTIMIO THESSALONIKIS (AUTH) | Greece**

Aristotle University of Thessaloniki (AUTH) (https://www.auth.gr/en) is the largest Higher Education Institution in Greece and one of the largest in Southeastern Europe. It is known as the most interdisciplinary university of the country with a wide range of offered services in basic and applied research, as well as in research on humanities and social sciences. It comprises 10 faculties which consist of 40 schools and 1 single-

School Faculty. Its strategic objectives, in the framework of its vision/mission, remain high and consistently oriented to the continuation of its tradition; namely, to be a pioneer institution, standing out among Greek and many foreign Universities on all levels: education, research, culture, connection with society. AUTH is committed to perform high quality research in pioneering topics aiming at quality and excellence promotion. Due to its wide range of scientific actions AUTH can implement research, technological, educational, and training projects at almost all scientific fields.

For more information visit http://magnacharta.physics.auth.gr/

- **NOVAPTECH S.A.S. (NOVA) | France**

Novaptech is a biotech company internationally renowned for its expertise in aptamers – synthetic oligonucleotides displaying antibody-like properties. Novaptech carries out R&D projects for its customers worldwide, in the pharma and life sciences areas, for therapeutic and diagnostic applications. It also designs aptamer-based biosensors and tests in the frame of its in-house R&D programs.

In the frame of the EU-funded project 2D-BioPAD, Novaptech will select, characterize, optimize and functionalize aptamers to Alzheimer's Disease (AD) biomarkers, hence participating in the development of a fast and cost-effective, non-invasive, reliable Point-of-Care (PoC) in-vitro diagnostics (IVD) system for supporting the early diagnosis and progression monitoring of AD directly at primary healthcare settings.

For more information visit https://novaptech.com/

- **ITA-SUOMEN YLIOPISTO (UEF) | Finland**

UEF is the most multidisciplinary university in Finland, established in 2010 following the merger of University of Joensuu (est. 1969) and University of Kuopio (est. 1972). The high standards of interdisciplinary research and education respond to global challenges and build a sustainable future. UEF strategic research is focused on four profile areas: ageing, lifestyles and health; environmental change and sustainable use of natural resources; cultural encounters, mobilities and borders; and diversifying learning and interaction. The 2D-BioPAD UEF team reflects the close collaboration between the Brain Research Unit at the School of Medicine, Faculty of Health Sciences, and the Neuro-Ethics and Law Research Group at the School of Law, Faculty of Social Sciences and Business Studies.

For more information visit https://www.uef.fi/en

- **ELLINIKI ETAIRIA NOSOY ALZHEIMER KAI SYGGENON DIATARACHON SOMATEIO (GAADRD) | Greece**

The Greek Association of Alzheimer's Disease and Related Disorders (Alzheimer Hellas) is a non-profit organization that was founded in 1995, by relatives of patients with Alzheimer's Disease as well as by doctors of all specialties. Alzheimer Hellas operates two Day Care Centers in Thessaloniki, one in Katerini, a Day center for caregivers, a Home care unit, and an inpatient facility for End-stage Dementia patients. Alzheimer Hellas, since 2000, has organized Pan-Hellenic Interdisciplinary Conferences in addition to informative lectures and seminars.

It participates in Greek, European, and international research projects, Pharmaceuticals, and Nutraceuticals trials. Since 1995, It has been an active member of the International and European Alzheimer's Associations and participates in every major conference on the field of dementia. 11 Pan-Hellenic Inter-Scientific Alzheimer Conferences have been carried out until now along with the 13th European Alzheimer Conference in Thessaloniki and the 25th International Conference.

For more information visit http://www.alzheimer-hellas.gr

- **EVNIA APS (EVNIA) | Denmark**

Evnia was founded in 2015 in Copenhagen with the vision to become the missing link between manufacturers, regulators and investors for the time-effective commercialization of innovative medical devices and in-vitro diagnostics. Headquartered in Denmark, the company currently has offices in the UK, Greece and Italy and is servicing life-science clients globally. It has been certified under ISO 9001:2015 as a clinical and regulatory affairs consultancy within the life science industry.

Evnia offers a cluster of services from the early stages of a medical device's lifecycle until its post-market adulthood. EVNIA supports healthcare innovation and patient safety by providing services in the fields of Due Diligence, Regulatory Strategy, Clinical Development Strategy, Post-Market Surveillance, Real World Evidence, Market Access and Reimbursement, EU and UK Representation Services (AR & UKCA)

EVNIA's full-value-chain services are supported by a cross-functional team of medical writers, doctors, usability engineers, biostatisticians, biocompatibility experts and regulatory affairs executives.

For more information visit https://www.evnia.dk/

- **ZENTRALINSTITUT FUER SEELISCHE GESUNDHEIT (ZI) | Germany**

The Central Institute of Mental Health stands for internationally outstanding research and pioneering treatment concepts in psychiatry and psychotherapy, child and adolescent psychiatry, psychosomatic medicine and addiction medicine. Their four clinics guarantee psychiatric care for the population of Mannheim. Mentally ill people of all ages can rely on the most advanced treatment based on international standards of knowledge.

In psychiatric research we are one of the leading institutions in Europe. We work closely with the University of Heidelberg and the Mannheim Medical Faculty of the University of Heidelberg and we are part of the German Center for Psychiatry as well as the Heidelberg Mannheim Health & Life Science Alliance.

For more information visit www.zi-mannheim.de.

- **UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND (NUID-UCD/CeADAR) | Ireland**

NUID-UCD/ CeADAR, as Ireland's national centre for AI, offers a comprehensive service in all aspects of innovation and applied R&D in AI, Machine Learning and Data Analytics. CeADAR has no-charge proofs-of-concept, market-ready solutions, and supports companies in finding funding and investment. We also deliver training and upskilling courses for beginners to advanced practitioners and for business decision-makers. Our ecosystem of hundreds of companies provides access to a vibrant network of multinational companies, SMEs and startups in Ireland and throughout Europe.

CeADAR is a creative AI powerhouse and Ireland's only European Digital Innovation Hub (EDIH) in AI focused on delivering value and sustained competitive advantage through accelerated research, development and deployment of AI and data analytics technology and innovation into business. For more information visit https://ceadar.ie/.

Role and benefits

Role

The SIAB is set up and operated to share their knowledge and expertise with the consortium of the project in key implementation stages. The role of the SIAB in the context of the project may be summed up as follows:

- act as a **consultation body for the 2D-BioPAD consortium** by providing strategic guidance aimed to support project activities that will explore in-depth the necessary design principles for cutting edge 2D material-based point-of-care diagnostic systems for biomedical applications;
- **support the preparation and approval** of the protocols for the 2D-BioPAD clinical pilot studies;
- **suggest actors in the PoC IVD sector for neurodegenerative diseases such as AD** (e.g., technology providers, academics, public authorities, advisors, NGOs, healthcare professionals, health program owners, etc.) to participate in project activities;
- **support the evaluation, assessment, and validation of the 2D-BioPAD solutions,** by participating in validation activities, as well as the elaboration of guidelines, best practices and recommendations;

To fulfil this role, it is envisaged that the SIAB, during the course of the project, will participate mostly in digital meetings/events and occasionally in physical activities of the project as well as provide advice on ad-hoc basis if deemed necessary.

- **Semi structured Interviews:** In order to better grasp the needs, challenges, and opportunities of PoC IVD for AD, 20 semi-structured interviews will be organised early in the project's duration. SIAB members will be considered as key stakeholders to be interviewed, towards providing valuable insight to the 2D-BioPAD co-design activities.
- **Online Surveys:** Two online surveys are foreseen in the project targeting 150 responses each. With a focus on the eight consortium countries (i.e., Czechia, Denmark, Finland, France, Germany, Greece, Ireland, and Spain), SIAB members will be requested to promote the online surveys to their networks and contacts in the regions and target groups of interest.
- **Co-creation workshops:** Three co-creation workshops are expected during the 2D-BioPAD lifecycle for co-designing and refining the 2D-BioPAD system architecture. Following a participatory co-design approach, selected interdisciplinary teams, from industrial and healthcare stakeholders and members from our SIAB, will be formed. These teams will be engaged in a series of co-creative exercises that will support an iterative process into defining the 2D-BioPAD functional and non-functional requirements, based on the expected functionalities and clinical pilot studies' scenarios studies envisioned.
- **Policy workshops:** A total of 2 policy workshops are foreseen with key policymakers, regulatory bodies, including members of the SIAB, to (i) identify the current policy and regulatory limitations, challenges, and barriers, towards better designing its overall clinical strategy so that it is properly aligned, in view of the intended purpose; (ii) make recommendations for the future policies and standards required for such applications.
- **Final conference**: The SIAB will have the opportunity to meet during 2D-BioPAD' Final Conference, a dedicated event planned at the end of the project with a view to sharing the results of 2D-BioPAD and engage with an international audience of stakeholders, further promoting their uptake.
- **Ad-hoc interactions:** If deemed necessary, the support of the SIAB (either of the entire board or of specific members based on their particular expertise) will be requested for ad hoc needs such as:

- Suggest additional key experts and stakeholders to participate in the project activities (e.g., interviews, surveys, co-design workshops, training, etc.).
- Provide feedback to functional and non-functional system requirements for the 2D-BioPAD system architecture.
- Provide access to (open) data, platforms, and solutions that may support the development of the 2D-BioPAD system.
- Participate in the evaluation, assessment, and validation of the 2D-BioPAD system.
- Provide feedback on guidelines and recommendations based on the project outcomes towards increasing the uptake of the 2D-BioPAD solutions.
- To participate in other key events (physical or digital) organized by the project to extend the reach of the consortium to stakeholder communities and to facilitate the exchange, networking, and dissemination.

Benefits

The project **provides several benefits** to its SIAB members, such as:

- Sharing **expertise** and **knowledge** by participating in the co-design and validation of the 2D-BioPAD solution for digitalised PoC IVD for early diagnosis and monitoring of AD.
- **Networking opportunities and visibility** as an expert stakeholder in a large multi-stakeholder community in the Biotech domain, with emphasis in graphene and nanomaterials.
- **First access to meaningful insights, knowledge**, **and open data** generated exclusively within the context of the project and its activities.

Terms of Membership and Management

Terms of membership

The SIAB shall be composed of eminent experts coming from diverse backgrounds to offer a blend of expertise that represents various groups of stakeholders from 2D-materials, nanotechnology, neuroscience, and ethics experts. These experts will provide 2D-BioPAD with valuable feedback aimed at aligning the project's outcomes with the needs of users and stakeholders.

Along these lines, at the beginning of the project, 9 members will be selected to form the SIAB. The SIAB will be open to new members in the future in order to draw from additional expertise and increase the outreach of 2D-BioPAD. New members could be appointed to the SIAB when necessary and as the project evolves.

Although members of the SIAB may be selected because of their affiliations with key organizations, they serve on the SIAB in their **individual capacity** to represent the interests and views of their stakeholder communities. **Members of the SIAB may not delegate another person to carry out the role expected from them** or be replaced by any other person without prior written agreement with the 2D-BioPAD consortium. Members of the SIAB are appointed for the entire duration of the project (48 months, from 1 October 2023 to 30 September 2027). If due to job changes or attrition, an SIAB member loses links to important networks or constituencies, the consortium may decide to fill in this gap by appointing additional members.

The contribution of SIAB members is **on a pro bono basis**, apart from the cases in which physical travel is involved and a specific budget for their reimbursement is foreseen in the framework of the project. In such

cases, the travel and accommodation expenses of SIAB members will be reimbursed by the project. Moreover, participation in the SIAB is **entirely voluntary**. There will be no adverse consequences if an SIAB member decides not to participate or to withdraw at any stage. In fact, SIAB members may withdraw their participation at any time by informing the SIAB Manager (see Section 4 of the current document). They may also request for their data to be withdrawn without giving a reason and without prejudice. Anonymous data already collected will be used because this information cannot be traced back to a specific person, but no further data or input will be collected, nor any other procedure will be carried out in relation to the specific member.

Management

The SIAB is managed by the **SIAB Manager** (see Section 4 below) who facilitates the communications and interactions between the SIAB and the consortium, ensuring that SIAB members are not overloaded. The SIAB Manager will also ensure that for each task requiring input from the SIAB, the partners have beforehand prepared an action plan and all necessary briefings and material. Only then, will the SIAB manager introduce a partner who may directly communicate with the SIAB in order to achieve the expected goals at each time.

Contact Point

Any enquiry, complaint, or concern about any aspect of your experience as a member of the Industrial Advisory Board can be addressed to the **2D-BioPAD Scientific and Industrial Advisory Board Manager** that oversees the set up and manages the SIAB. The contact details of the SIAB Manager are provided below:

2D-BioPAD Scientific and Industrial Advisory Board **Manager**: GAADRD

Contact Person: Sanna Laaksonen

Email: sanna-laaksonen@alzheimer-hellas.gr

Project website: https://2d-biopad.eu

Declaration of Acceptance

(for individuals appointed as members of the 2D-BioPAD Scientific and Industrial Advisory Board in their individual capacity)

I, the undersigned, _____ certify that I have read and agree to abide by the 2D-BioPAD Scientific and Industrial Advisory Board Terms of Reference.

I pledge that I will participate in the 2D-BioPAD Scientific and Industrial Advisory Board in my individual capacity and as such I may not delegate another person to carry out the work or be replaced by any other person without prior written agreement with the 2D-BioPAD consortium.

I certify that no conflict of interest exists that could be considered prejudicial to my independence in acting as a member of the 2D-BioPAD Scientific and Industrial Advisory Board.

I undertake not to divulge any information given in the context of the work of the Experts Advisory Board unless the 2D-BioPAD consortium agrees to release me from this obligation and to respect the confidentiality requirements.

I declare to accept entirely and with no reservations my appointment as 2D-BioPAD Scientific and Industrial Advisory Board member as described in the Terms of Reference.

I consent that any input or contribution I provide as a member of the 2D-BioPAD Scientific and Industrial Advisory Board may be used by the 2D-BioPAD consortium for reporting purposes or to align the services and tools offered by the 2D-BioPAD project with the needs of end-users to ensure that they make the most out of its value propositions.

I consent to the publication, on the project website and any documentation related to the project, of my name, picture and short biography as a member of the 2D-BioPAD Scientific and Industrial Advisory Board and to the publication of written reports that are produced by the 2D-BioPAD consortium partners.

Name and Surname:

Place:

Date:

Signature:

Annex VI – Scientific and Industrial Advisory Board's Status

The initial pool of nominated members for the 2D-BioPAD's Scientific and Industrial Advisory Board is presented in the following table (presented in alphabetical order):

No.	Name	Organisation	Position	Type of Organisation	Country
1	Bobby Soni	BioInnovation Institute	Chief Business Officer	Industrial	Denmark
2	Charlotte Teunissen	Amsterdam UMC	Professor	Academic	Netherlands
3	Dianna Gove	Alzheimer Europe	Director for Public Involvement and Ethics	Association	Luxembourg
4	Fabiana Arduini	University of Rome Tor Vergata	Professor	Academic	Rome/Italy
5	Firat Güder	Imperial College	Professor	Academic	London/UK
6	Graham Armitage	EIT Health	Managing Director	Association	Dublin, Ireland
7	Justin Gooding	University of New South Wales	Professor	Academic	Sydney/Australia
8	Martin Pumera	Central European Institute of Technology	Professor	Academic	Brno/CZ
9	Mercè Boada	Fundacion ACE	Chief Medical Officer	Academic	Barcelona, Spain
10	Montserrat Rivas	University of Oviedo / IEEE Magnetics	Professor	Academic	Oviedo/Spain
11	Oliver Smith	Oliver Smith	Independent Advisor	Commercial	Madrid, Spain
12	Oliviero Gobbo	Trinity College	Senior Researcher	Academic	Dublin, Ireland
13	Oskar Hanson			Academic	
14	*Representative of the GFI*	*TBD*	*TBD*	*TBD*	*TBD*

The consortium has initiated the process for onboarding experts to the SIAB based on specific criteria (e.g., expertise) and availability, targeting a composition of **9 experts** to commit to participating in the activities of the SIAB. All the members of the SIAB will be made available on the project's website.

One of the members has already been nominated to be covered by an expert from the GraphenEU project, to strengthen the ties with the Graphene Flagship Initiative and allow smoother communication among relevant stakeholders.

It is important to note that **the 2D-BioPAD Scientific and Industrial Advisory Board (SIAB) will be open for new members across the entire duration of the project**, allowing for further additional expertise and knowledge to flow into the project, while extending its reach out to key stakeholder groups across Europe.

Annex VII – 2D-BioPAD Project Management (PM) Guidelines

This document provides you with key guidelines regarding the main tools and processes for the effective management of the 2D-BioPAD project.

Mailing list(s)

The following mailing lists are currently available in 2D-BioPAD:

2D-BioPAD@qplan-intl.gr (for all consortium members)

All partners should adhere to the following:

1. The mailing list moderator is Q-PLAN (i.e., Apostolos Tsolakis).
2. UP-CATRIN should also be included in the communication of mailing list edits so that all project documents are updated accordingly.
3. Every partner should be aware at all times of their members included in the mailing list (it's primarily the partners' responsibility to keep the mailing list up to date).
4. At least two people from each organisation should be included in the mailing list.
5. Every new member who will actively participate in project activities should be included in the mailing list. Partners should send an e-mail to Q-PLAN (i.e., Apostolos Tsolakis) and UP-CATRIN (i.e., Lucie Hrabalikova) with the contact details of the new person and their role in the project.
6. An updated copy of the mailing list is kept here.

If there is a need to establish a new mailing list (e.g., for a WP), please send a request to Q-PLAN (i.e., Apostolos Tsolakis) and UP-CATRIN (i.e., Lucie Hrabalikova) to coordinate accordingly.

Online Repository (SharePoint via MS Teams)

The 2D-BioPAD online repository is set up using SharePoint at UP-CATRIN's infrastructure. The repository can be accessed through the following link:

https://upolomouc.sharepoint.com/sites/2D-BioPAD

1. Every partner is responsible for ensuring that they have access to the repository. If you don't have access, please contact UP-CATRIN (i.e., Lucie Hrabalikova).

Internal Communication

MS Teams

Intra-consortium communication is based on MS Teams.

1. The #general channel is used frequently to share information about day-to-day project activities.
2. All partners are kindly requested to have access to the MS Teams system to facilitate communication among partners.
3. There are multiple channels per WP and per project activity. If you do not have access, please contact UP-CATRIN (i.e., Lucie Hrabalikova) to invite you.
4. Partners have the capacity to create channels. However, you are kindly required to keep it as concise as possible to avoid confusion.

The above-mentioned guidelines will be updated, when necessary, to be in line with the project's requirements and progress.

2D BioPAD

Supple Graphene Bio-Platform for point-of-care early detection and monitoring of Alzheimer's Disease

GA 101120706

Partners

CATRIN Czech Advanced Technology and Research Institute

Q-PLAN INTERNATIONAL

ICN2 Institut Català de Nanociència i Nanotecnologia

Grapheal

NOVAPTECH Think Aptamer

UNIVERSITY OF EASTERN FINLAND

Alzheimer Hellas

Evnia To Strive • To Seek • To Find

Zentralinstitut für Seelische Gesundheit

CeADAR Ireland's Centre for Applied AI

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