****

A blue hexagons on a dark background

Description automatically generated

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

**3rd Project Meeting Minutes**

**Online**

*24-25/10/2024*

Logo

Description automatically generatedA picture containing text, clipart

Description automatically generatedLogo, company name

Description automatically generated

Project Information

|  |  |
| --- | --- |
| **Title** | Supple Graphene Bio-Platform for point-of-care early detection and monitoring of Alzheimer’s Disease (GA Number 101120706) |
| **Start Date** | 01 October 2023 |
| **Duration** | 48 months |
| **Website** | <https://2d-biopad.eu/> |
| **Coordinator** | UNIVERZITA PALACKEHO V OLOMOUCI (UP-CATRIN) |
| **Project Overview** | The 2D-BioPAD project aims to introduce a fast and cost-effective, non-invasive, reliable, digitally-enabled Point-of-Care In-Vitro Diagnostic system based on graphene for supporting the early diagnosis and monitoring the progress of AD directly in primary healthcare settings. |

Document Information

|  |  |
| --- | --- |
| **Issued by:** | UNIVERZITA PALACKEHO V OLOMOUCI (UP-CATRIN)  Q-PLAN |
| **Issue date:** | 07/11/2024 |
| **Work package leader:** | UP-CATRIN |
| **Dissemination level:** | Confidential |

Document History

|  |  |  |
| --- | --- | --- |
| Version | Date | Modifications made by |
| 0.1 | 30/10/2024 | First draft elaborated by Q-PLAN and shared with partners |
| 0.2 | 04/11/2024 | Comments received by partners |
| 1.0 | 07/11/2024 | Final version released by UP-CATRIN & Q-PLAN and shared with partners |

Authors

|  |  |
| --- | --- |
| Name(s) | Beneficiary |
| Lucie Hrabalíková, Aris Bakandritsos | UP-CATRIN |
| Aristotelis Folas, Apostolos Tsolakis | Q-PLAN |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Disclaimer**

Funded by the European Union under GA no. 101120706. Views and opinions expressed are however those of the authors only and do not necessarily reflect those of the European Union or CNECT. Neither the European Union nor the granting authority can be held responsible for them.

© **2D-BioPAD Consortium, 2023 - 2027**

Reproduction is authorised provided the source is acknowledged.

Table of Contents

[1. Introduction and scope of the document 4](#_Toc181875639)

[2. Project Overview 5](#_Toc181875640)

[3. Decisions taken during each session of the meeting 6](#_Toc181875641)

[3.1 Biomarkers binding and quantitative analysis (WP2) │ AUTH 6](#_Toc181875642)

[3.2 Workshop WP3 & WP4 “Collaboration towards the Joint development of the 2D-BioPAD electrochemical & GFET biosensors” │ UP-CATRIN & GRAPHEAL 7](#_Toc181875643)

[3.3 Clinical Pilot Studies Design, Deployment, Evaluation & Validation (WP5) │ UEF 9](#_Toc181875644)

[3.4 Dissemination, exploitation and communication (WP6) │ Q-PLAN 10](#_Toc181875645)

[3.4.1 T6.4 Workshop/Discussion: “2D-BioPAD as a Diagnostic Aid under the IVDR” 11](#_Toc181875646)

[3.5 Project management and coordination (WP7) │ UP-CATRIN 12](#_Toc181875647)

[4. Action List 13](#_Toc181875648)

[5. Annexes 19](#_Toc181875649)

[**5.1** Annex I – List of Participants 19](#_Toc181875650)

[5.2 Annex II – Agenda of the meeting 23](#_Toc181875651)

List of Figures

[Figure 1: Current project status in terms of timing 5](#_Toc181875618)

List of Terms and Definitions

| Abbreviation | Definition |
| --- | --- |
| **Aβ** | Amyloid Beta |
| **AD** | Alzheimer's Disease |
| **AI** | Artificial Intelligence |
| **D** | Deliverable |
| **DMP** | Data Management Plan |
| **EC** | European Commission |
| **ECR** | Ethical Consideration Roadmap |
| **EU** | European Union |
| **GDPR** | General Data Protection Regulation |
| **GFAP** | Glial Fibrillary Acidic Protein |
| **GFET** | Graphene field effect transistor |
| **GFI** | Graphene Flagship Initiative |
| **HCPs** | Healthcare Professionals/Practitioners |
| **IVD** | In-Vitro Diagnostics |
| **IVDR** | In-Vitro Diagnostics Regulation |
| **LOD** | Limit of Detection |
| **MCI** | Mild Cognitive Impairment |
| **MDR** | Medical Device Regulation |
| **MNPs** | Magnetic Nanoparticles |
| **NFC** | Near-Field Communication |
| **NFL** | Neurofilament Light |
| **PC** | Project Coordinator |
| **PoC** | Point-of-Care |
| **QA** | Quality Assurance |
| **SCI** | Subjective Cognitive Impairment |
| **SIAB** | Scientific and Industrial Advisory board |
| **tau** | Tau protein |
| **WP** | Work Package |

1. Introduction and scope of the document

The current document is entitled “3rd Project Meeting Minutes” and aims to provide an overview of the 3rd Project Meeting of the 2D-BioPAD project. The meeting was held remotely on the 24th and 25th of October 2024.

The core aims of the meeting were to:

* Present and discuss the progress made in the active tasks of the project during the second semester of the project (April 2024 – September 2024).
* Carefully plan and stimulate the work to be carried out during the third semester of the project (October 2024 – March 2025) to timely complete all the work foreseen in its framework.
* Discuss the various administrative, and financial aspects of the project.

The document at hand emphasises on the critical discussions and decisions that project partners jointly made during all the sessions of the meeting, as presented in the Agenda in Annex II. It also presents in brief the content of the workshops and other sessions that took place during the meeting.

Finally, the “3rd Project Meeting Minutes” include the action list, which was developed and agreed by all partners, focusing on the 3rd semester of the project, as well as the participants’ list for the two days of the meeting (Annex I).

|  |
| --- |
| *Q-PLAN, as the PMO of 2D-BioPAD, prepared the initial version of the 3rd Project Meeting Minutes and shared them with all partners of the consortium to receive their comments and feedback. The current document constitutes the final version of the 3rd Project Meeting Minutes, incorporating the comments and feedback received from the partners of the 2D-BioPAD consortium.* |

1. Project Overview

The Project Coordinator (PC/UP-CATRIN) presented a quick overview of the project’s current status. The PC stressed the importance of this stage of the project, during which the consortium is advancing towards the development of the 2D-BioPAD biosensors.

The following figure provides an overview of where the project is currently positioned in terms of timing.

Figure 1: Current project status in terms of timing

|  |
| --- |
|  |

1. Decisions taken during each session of the meeting

## Biomarkers binding and quantitative analysis (WP2) │ AUTH

The discussion during this session revolved around the aptamer identification / selection for targeting specific AD biomarkers, alternatives to aptamers (i.e. antibodies) and the progress on the MNP synthesis and their conjugation with aptamers. Key progress points included:

* NOVA has completed the selection of aptamers for GFAP. NOVA provided the full-length aptamer sequences (two sequences) for GFAP to partner.
* The selection for NfL is ongoing.
* Further support is required for the Selection of aptamers for Αβ and p-tau targets. Ongoing communications initiated from several partners (UP-CATRIN, ICN2, AUTH, GRAPHEAL, NOVA) with various stakeholders (e.g., University of Wurzburg and University of Nicosia, Cyprus) to get access to p-tau peptides and knowledge on how to approach the case of Aβ.
* AUTH has already completed the synthesis protocol for the MNPs to be used in the project and has sent a first batch to ICN2 for experimentation.
* AUTH has completed the conjugation of the syntehsised MPNs with a thrombin aptamer.

An extended discussion focused on the solutions proposed to tackle the challenges related (i) with the commercial availability of p-tau 217 proteins, (ii) aggregation of Aβ monomers into oligomers and polymers, which make it difficult for the aptamers to bind to the targeted analytes.

Along these lines, the **decisions** that stemmed from this session of the meeting can be summarised as follows:

#### **Main decisions:**

* Biomarkers to be targeted are: **Αβ40**, **Αβ42**, **p-tau217**, **GFAP**, and **NfL** (additional option **p-tau181**). **Partners should exhaust all available options on these biomarkers** (peptides/ full protein biomarkers, aptamers/ antibodies etc.).Partners will also prepare **a plan as a mitigation measure** to present in the review meeting (April/ May 2025), if aptamers’ raising for some biomarkers is not successful. Decision to be made in **February 2025**.
* **UP-CATRIN will support with the identification of the aptamers’ binding site(s), through simulations.** This activity is out of the project tasks, and resources outside the project will be provided voluntarily**.** In parallel, **CeADAR** will develop an AI/ML model that can identify the binding site using open data from the thrombin protein/aptamer. The first results of the model are expected by the end of December 2024.
* **NOVA** will provide the **truncated/optimized aptamer sequences for GFAP** to ICN2 by the 22nd of November.
* **ΝOVA** expects to **finalise the selection of the NfL aptamer** by the 30th of November. Additional 3 weeks will be required to truncate/optimize the aptamer (if the selection is successful).
* **NOVA** will proceed with the option of **p-tau217 peptides** for the aptamer selection process, instead of the full length protein. The timeline depends on the procurement.
* **UP-CATRIN** will send an email requesting **support on Aβ40 and Aβ42[[1]](#footnote-2)** and request peptide synthesis services to the colleague from Nicosia University Cyprus to arrange a meeting within November (Similar to the email sent to University of Wurzburg).
  + Meeting has been arranged for the 6th of November.
* **UP-CATRIN**, **AUTH**, **NOVA** and **GRAPHEAL** will jointly communicate (putting each other in cc) with other suppliers offering p-tau217 peptides (Sinobio, Biolegend, etc.).
  + If not possible to include others in CC, partners should inform the consortium accordingly.
* **NOVA, UP-CATRIN and AUTH** to exchange the **p-tau 217 sequences** and **antibodies** with AUTH and UEF to verify that these sequences are currently used at lab testing (ELISA, SIMOA, …) by the **31st of October 2024**.
* **AUTH** will evaluate the **binding affinity and specificity of the conjugated MNP-aptamer** for thrombin in complex environments by the **30th of January 2025.**
* **NOVA will provide the sequence of the aptamers to AUTH, ICN2 and GRAPHEAL who will procure them directly from third-party suppliers** for further developing the biosensor. If needed, support from other partners can be provided, however it should be communicated as early as possible.

#### **Discussion on Deliverables:**

* **D2.3** first full version should be shared with all partners by **the end of February 2025** (one month before due).

|  |
| --- |
| *A detailed list of actions was prepared for WP2 and is included in the Action List of the project (see Section 4 of the current document). The WP2 PowerPoint presentations are included in the dedicated project’s cloud storage (i.e., SharePoint).* |

## Workshop WP3 & WP4 “Collaboration towards the Joint development of the 2D-BioPAD electrochemical & GFET biosensors” │ UP-CATRIN & GRAPHEAL

UP-CATRIN, as the leader of WP3, presented the overview of WP3 (which has started on M7 with T3.1 and T3.2), with ICN2 & GRAPHEAL following on the current status of the electrochemical biosensor and GFET biosensor, respectively (T3.3 & T3.4). In particular, UP-CATRIN introduced the current status on the graphene derivatives. UP-CATRIN progresses in functionalization of graphenes for the electrochemical biosensor (T3.1) towards achieving the functionalization targets set in the GA. The asymmetric double functionalization as an improved solution for attaching bioprobe on the graphene channel in GFET sensors is not required by GRPHEAL any longer. But WP3 partners consider useful the symmetric double functionalization, and UP-CATRIN works towards this direction, as explained in the internal semester report.

ICN2 presented their status of T3.3: ICN2 the started to detect DNA sequences in low nM range in order to test their rGO@AuNPs electrodes. ICN2 will start to functionalize rGO electrodes (also using graphene derivatives sent by UP-CATRIN) with antibodies, apart from aptamers.

GRAPHEAL presented the aptamer testing concept in a similar platform and will soon start working on the GFET device development (T3.4), based on the full-length aptamer sequence for GFAP (sent by NOVA). GRAPHEAL informed that the “testing” of an aptamer may take from 6 weeks to 6 months depending on several factors.

Finally, CeADAR presented briefly the approach to be followed later in the project (M18) regarding the use of AI under T3.5.

Following, the workshop extended discussions for the next steps of the development of the biosensors. The **decisions** during the discussion that followed includes below points:

#### **Main decisions:**

* **All partners** agreed to work towards a **clear and persuasive strategy towards biosensing of up to 5 biomarkers,** to present in the upcoming review meeting (April/ May 2025), with a view on delivering **a functional prototype** of the biosensors for the retrospective clinical study **by September 2025.**
* **GRAPHEAL** will initiate the implementation of the GFET biosensor without integrating the graphene derivatives from UP-CATRIN and the MNPs from AUTH because it was concluded as much more important to proceed with mitigation measures. GRAPHEAL will consider the use of derivatices and MNPs, at a later stage. To be confirmed by the end of January 2025.
* **GRAPHEAL and UP-CATRIN** will proceed with the **procurement of the full aptamer and antibody for GFAP** and GRAPHEAL will start working on them towards the **GFET sensor** development**.** Preliminary results are expected by the **end of December.** 
  + UP-CATRIN will purchase the GFAP aptamer, GFAP protein, and NfL antibody and protein. The latter as mitigation measure if NfL aptamer identification will delay.
* **GRAPHEAL** will work in parallel with an antibody for NfL . Preliminary results are expected by the **end of January.**
* **ICN2** will proceed with the **procurement of Aβ40** and **Aβ42** **peptides** to identify a strategy for testing with antibodies. Decision on which peptides will be procured after the discussion with the various “suppliers” early November.
* **ICN2** will work with the truncated **GFAP aptamer** (after NOVA has provided the updated sequence) for the electrochemical biosensor (mid-end November)**. ICN2 is expected to purchase the truncated GFAP sequence by mid-December.** Preliminary results are expected by the **end of February 2025.**
* **ICN2** and **GRAPHEAL** will check if the ***Biosafety Level 2* clearance allows them to handle blood and/or plasma samples** at their lab **by the end of December.**
* **UP-CATRIN, ICN2, and GRAPHEAL** to provide a list of data generated (type, format, volume) during the design, synthesis and characterization of graphene-based prototypes by the end of November 2024, so that **CeADAR** cananalyse what models can be trained for the activities of T3.5. A clear plan is expected by the end of **December 2024**.
* **GRAPHEAL** will organise a **WP4 meeting** with all involved partners to showcase progress and collaborations/expectations/input with/from other partners by **the end of November 2024.**

Α roadmap with additional information on the sequences for the GFAP aptamer and the p-tau217 peptide has been consolidated by UP-CATRIN and can be found in the presentations of the meeting **here**, along with other information.

#### **Discussion on Deliverables:**

**D3.1 first full version should be shared with all partners by the end of February 2025** (one month before due).

|  |
| --- |
| *A detailed list of actions was prepared for WP3 & WP4 and is included in the Action List of the project (see Section 4 of the current document). The WP3 and WP4 PowerPoint presentations are included in the dedicated project’s cloud storage (i.e., SharePoint).* |

## Clinical Pilot Studies Design, Deployment, Evaluation & Validation (WP5) │ UEF

UEF presented an overview of WP5, focusing on the questions and issues that need to be addressed for applying the clinical protocol for the retrospective and prospective clinical pilot studies, starting next year in October 2025.

Ethical Committee (EC) approvals have been secured by UEF and GAADRD in September 2024, whereas no EC approval has been provided by ZI. An update from ZI was provided through an e-mail with relevant information, stating that (i) the application for the retrospective study has already been submitted and a response from the Ethical Committee is expected; and (ii) the application for the prospective vote is underway and will be completed by end of October with a response expected by the end of November 2024.

Along these lines, the **decisions** that were made during this session may be summarised as follows:

#### **Main decisions:**

* **ZI** will finalise the **submission of the prospective clinical study documents to their Ethical Committee** by the **31st of October 2024.**
* **ZI** willinform UEF and UP-CATRIN **upon receiving responses** from their Ethical Committee or **in case of delays** for both the retrospective and prospective studies by the end of November 2024.
* **EVNIA** will arrange a meeting with **UEF** by end of November to discuss the approach to be followed with FIMEA regarding regulatory aspects of the clinical protocol.
  + As communicated by GAADRD and ZI, regulatory approval of the clinical study protocol is not required for Greece and Germany (the ethical committee approval is sufficient).
* **UEF will prepare a legal agreement template by end of December 2024**, about the Materials and Data Transfer Agreement between the clinical centres (UEF, GAADRD, ZI) and technical partners (ICN2, GRAPHEAL). UEF will share the template with GAADRD, ZI, ICN2 & GRAPHEAL.
* **UEF** will arrange **a meeting with FIMEA** to discuss the regulatory-compliant clinical study protocol, by **end of December 2024**. Support from other partners (i.e., EVNIA, ICN2, GRAPHEAL) may be requested.
* **UEF** will share the most updated clinical study protocol **with the SIAB at the beginning of March 2025** for feedback.
* **GAADRD** and **UEF** agreed to try to involve HCPs for the clinical pilot studies that are not directly involved in the 2D-BioPAD project. If not possible, HCPs will need to carefully tackle potential bias in the process.
* **UEF** willberesponsible for the benchmarking of all the samples from the 300 subjects. **GAADRD** and **ZI** are expected to transfer/ship their samples to UEF for the benchmarking

#### **Discussion on Deliverables:**

Not applicable.

|  |
| --- |
| *A detailed list of actions was prepared for WP5 and is included in the Action List of the project (see Section 4 of the current document). The WP5 PowerPoint presentation is included in the dedicated project’s cloud storage (i.e., SharePoint).* |

## Dissemination, exploitation and communication (WP6) │ Q-PLAN

The WP6 session started with the dissemination and communication activities of the project, including the synergies with other projects and initiatives, such as the GFI. Q-PLAN asked all partners for stronger support in the Dissemination and Communication actions.

Following, Q-PLAN presented the plan for the market analysis (T6.3), including the products to focus (2D-BioPAD device and data) as well as the next steps for discussing the exploitation of Key Exploitable Results (T6.2). Q-PLAN is planning interviews to support the market analysis, apart from the secondary market search. available promotional material and activities.

Finally, Q-PLAN provided updates on the synergies and the plan for next workshops and webinars in the context of GF, towards achieving more collaboration with projects.

Along these lines, the **decisions** that were made during this session may be summarised as follows:

#### **Main decisions:**

* All partners are expected to **interact more on social media (reposting, tagging the project)** and **report their Dissemination and Communication activities**, in the dedicated spreadsheet available [**here**](https://upolomouc.sharepoint.com/:x:/r/sites/2D-BioPAD/Sdilene%20dokumenty/General/06.WPs/WP%206/T6.1_D%26C/Reporting%20templates/2D-BioPAD%20D%26C%20Reporting.xlsx?d=w6dc879d3dc4a4a71be57683291c1815b&csf=1&web=1&e=1mxndm). Any outreach events or actions can be included in the file. It is recommended to collect evidence related to 2D-BioPAD for these activities (photos, agendas, etc.). Q-PLAN kindly requested to be informed beforehand by partners about participating in an event.
* **Q-PLAN** willorganise **interviews with all partners** to update and refine information regarding the exploitation of the projects Key Exploitable Results, as well as Individual exploitation plans per partner. The interviews are expected to commence in November 2024 and complete by the end of February 2025.
* The **market analysis** under T6.3 will focus on the below 2D-BioPAD (potential) **products**:
  + 2D-BioPAD Decision Support Tool (as a Device)
  + Designing a Decision Support Tool (as a Service)
  + Data (Real-world data from the clinical pilot activities)
* **Each partner will identify at least 1 key interviewee for the market research interviews by the 8th of November** (T6.3). Q-PLAN will arrange the interviews between November 2024 and February 2025, based on semi-structured questionnaires.
* **Q-PLAN** will collaborate with **MUNASET** for the market analysis regarding the methodologies for market research and the analysis on the common markets (IVD, market segments etc.). No sensitive info will be shared or discussed.
* **Q-PLAN** will investigate a synergy with the **SAFARI** project as per the suggestion from **UP-CATRIN**.
* **Q-PLAN** will investigate a synergy with the **2D-PL** project, as they are working with GFETs for biomedical applications. More information to be shared with the partners in December 2024.
* **Q-PLAN** willinitiate a synergy with the **GRAPHERGIA** project, in the form of a joint promotional article. Preliminary discussions will take place in **November 2024**. More information to be shared with the partners in December 2024.
* **Q-PLAN** willinvestigate a synergy with the **GIANCE** project in view of applying their LCA/LCC approach to the 2D-BioPAD biosensors. Initial contact has been made. More information to be shared with the partners in December 2024.
* **Q-PLAN** will explore the organisation of a workshop with all PPs/AMs linked with 2D-BioPAD within December 2024 or January 2025. More information to be available by **mid-November**.
* **Partners** can make more suggestions on synergies [here](https://upolomouc.sharepoint.com/:x:/r/sites/2D-BioPAD/Sdilene%20dokumenty/General/06.WPs/WP%206/T6.5_Synergies/2D-BioPAD%20Synergies%20List%20v0.1.xlsx?d=wfb572d8cbbfd40d1a0f8bab12ed6111b&csf=1&web=1&e=JskCe5) and inform Q-PLAN for any action required.
* **Regarding upcoming workshops and webinars** (in collaboration with the GFI)**:**
  + **EVNIA will organise an online Workshop related to MDR and IVDR in February 2025.** 
    - Suggestedby EVNIA to prepare questions on expectations from partners for this workshop. Q-PLAN suggested to extend to GF partners. EVNIA to come back on this by the **end of November 2024** with a date and plans.
  + **Webinar on Clinical Applications of Graphene-based solutions, by UEF in April 2025. UEF** supported by **Q-PLAN** to **plan by end of December 2024** about the outline of webinar and the target audience**.** Q-PLAN to support. To invite speakers from other GF projects that work on medical applications / brain disorders.
  + **Webinar on AI for 2D Material Sciences, by CeADAR in June / July 2025:** CeADAR, supported by Q-PLAN, will plan for a webinar on AI for 2D Material Sciences for June/July 2025. 2D-BioPAD to lead the outline of the webinar. To ask GF partners who has interest in participating as speakers in such a webinar. **CeADAR** to follow up with **Q-PLAN** within **December 2024.**
* 2D-BioPAD **to accept all proposed PP/AMs** (partnering projects/ associated members) in the GF context but is free to set limits in the collaboration areas.

### T6.4 Workshop/Discussion: “2D-BioPAD as a Diagnostic Aid under the IVDR”

EVNIA led the discussion for the regulations of 2D-BioPAD as a Diagnostic Aid / Decision Support Tool under the IVDR.

#### **Main decisions:**

* An update of the 2D-BioPAD devise description was presented and approved and should be used in all project disseminations when describing the 2D-BioPAD device:

**Intended Purpose:**

2D-BioPAD is a non-invasive, near-patient blood test, intended as a decision support tool to assist clinicians in the diagnostic assessment of AD,

**Intended Population:**

2D-BioPAD is intended for adults

**Intended User:**

2D-BioPAD is intended for healthcare professionals qualified to make diagnostic assessments of AD

**Indication (medical condition):**

2D-BioPAD is indicated for patients with cognitive impairment and/or dementia, suspected of AD

**Intended Clinical Benefit:**

2D-BioPAD supports the diagnostic assessment of AD by indicating biomarkers related to tau

phosphorylation, neurodegeneration and inflammation

* EVNIA will arrange a meeting with ICN2 & GRAPHEAL by end of November to discuss **what is the data/ evidence required to collect during the implementation of the device** (sensitivity, specificity etc.), to support **towards regulatory compliance.**

|  |
| --- |
| *A detailed list of actions was prepared for WP6 and is included in the Action List of the project (see Section 4 of the current document). The WP6 PowerPoint presentation(s) are included in the dedicated project’s cloud storage (i.e., SharePoint).* |

## Project management and coordination (WP7) │ UP-CATRIN

This session of the meeting was focused on discussing the management and coordination aspects of the project and was guided by the respective presentation given by UP-CATRIN.

The **decisions** which emerged through the course of this session are:

#### **Main decisions:**

* **All partners to share first draft version of deliverables one month before due date. For D2.3 and D3.1, first version should be available at the end of February 2025.**
* Next version of DMP (Data Management Plan) to include info on data from the clinical pilot study.
* Next **monthly project meeting** is on **5th November (link** [**here**](https://teams.microsoft.com/l/meetup-join/19%3ameeting_Mzk4ZDI2MGQtMGZhNS00ZGRmLWI3MWEtNjI3MDcyZDlhMWQ5%40thread.v2/0?context=%7b%22Tid%22%3a%220792fd97-b4b9-4f63-9459-1be9d4004149%22%2c%22Oid%22%3a%2225851c07-8567-4ccd-8227-db51957531f7%22%7d)**),** to discuss on progress for aptamers & biomarker proteins and peptides.
* **NOVA will examine possibility for Next Project Meeting in Bordeaux, in March 2025**.
* **UP will contact the PO** by **end of January**, about the **date and location of the review meeting in 2025.** Q-PLAN will support the communication (if needed).

#### **Discussion on Deliverables:**

No WP7 deliverables in the 3rd semester. D7.3 - Data Management Plan, Version 2 (due date M24, September 2025) to be updated to include info on data from the clinical pilot study.

|  |
| --- |
| *A detailed list of actions was prepared for WP7 and is included in the Action List of the project (see Section 4 of the current document). The WP7 PowerPoint presentation is included in the dedicated project’s cloud storage (i.e., SharePoint).* |

1. Action List

| **WP.Task. #** | **Action point** | **Partner** | **Deadline** | **Comments** |
| --- | --- | --- | --- | --- |
| **WP2** | | | | |
|  | Identify the sequence for the p-tau217 peptide | NOVA / AUTH / UP-CATRIN | 31/10/2024 |  |
|  | Identification of the aptamers’ binding site(s), through simulations. | UP-CATRIN | TBD |  |
|  | Meeting with the University of Nicosia to discuss availability / procurement of Aβ and p-tau peptides | UP-CATRIN / NOVA | 6/11/2024 |  |
|  | Contact to Shanghai company for p-tau protein peptides with NOVA in cc | GRAPHEAL | 8/11/2024 |  |
|  | Follow up with the University of Wurzburg (Dr. Maric) for p-tau and Aβ | NOVA | 8/11/2024 |  |
|  | Communicate with other companies offering p-tau 217 (Sinobio, Biolegend, etc.). | GRAPHEAL / NOVA / AUTH/ ICN2 | 8/11/2024 |  |
|  | Provide the truncated/optimized aptamer sequences for GFAP | NOVA | 22/11/2024 |  |
|  | AI/ML model for binding site identification | CeADAR | 20/12/2024 | Start with open available data from Thrombin (and other known proteins) |
|  | Contact SIAB to get insight on the procurement form for Aβ | NOVA / AUTH | 29/11/2024 | TBC |
|  | Finalise the selection of aptamers for NfL | NOVA | 29/11/2024 |  |
|  | MNP conjugation with Thrombin aptamer | AUTH | 29/11/2024 |  |
|  | Initiate Selection for p-tau217 | NOVA | November / December 2024 | Depending on availability of peptides |
|  | Initiate Selection for Aβ40 | NOVA | November / December 2024 | Depending on availability of peptides |
|  | Initiate Selection for Aβ42 | NOVA | November / December 2024 | Depending on availability of peptides |
|  | Provide the truncated/optimized aptamer sequences for NfL | NOVA | 20/12/2024 | (Assuming 3 weeks from previous step) |
|  | Decision on mitigation plan for targeted biomarkers | All partners | 04/02/2025 | Current biomarkers  Αβ40, Αβ42, p-tau217, GFAP, and NfL  (p-tau181 backup) |
|  | First draft of D2.3 for Quality Review | AUTH | 28/2/2024 |  |
|  | Quality Review available | GRAPHEAL, ZI | 14/3/2024 |  |
|  | Final version of D2.3 available for submission | AUTH | 30/3/2024 |  |
| **WP3** | | | | |
|  | Purchase of the GFAP aptamer and protein and the NfL antibody and protein | UP-CATRIN | 15/11/2024 | To be sent to GRAPHEAL directly |
|  | Purchase of Αβ40 & Αβ41 for experimentation and testing | ICN2 | 15/11/2024 |  |
|  | Graphene derivatives' SYNTHESIS for the electrochemical biosensor | UP-CATRIN | 29/11/2024 |  |
|  | Send Graphene derivatives to ICN2 to plan integration in the device | UP-CATRIN | 29/11/2024 |  |
|  | Provide a list of data generated (type, format, volume) during the design, synthesis and characterization of graphene-based prototypes | UP-CATRIN, ICN2, and GRAPHEAL | 29/11/2024 | To support CeADAR’s work |
|  | Preliminary results on GFAP with GFET biosensor | GRAPHEAL | 20/12/2024 |  |
|  | Evaluate the conjugated MNPs- aptamers sent by AUTH | ICN2 | 20/12/2024 |  |
|  | Confirm Biosafety Level 2 clearance | ICN2 & GRAPHEAL | 20/12/2024 |  |
|  | Work on dual functionalisation of graphene for the electrochemical biosensor | UP-CATRIN | 20/12/2024 |  |
|  | Preliminary results on Nfl with GFET biosensor | GRAPHEAL | 31/01/2025 |  |
|  | Preliminary results on GFAP with electrochemical biosensor | ICN2 | 28/2/2025 | Truncated version |
|  | Meeting for data/ evidence of the device towards regulatory compliance. Identify data to collect during the implementation of the device (sensitivity, specificity etc.). | EVNIA/ ICN2 / GRAPHEAL | 29/11/2024 |  |
|  | First draft of D3.1 for Quality Review | UP-CATRIN | 28/2/2024 |  |
|  | D3.1 Quality Review | NOVA, CeADAR | 14/3/2024 |  |
|  | Final version of D3.1 available for submission | UP-CATRIN | 30/3/2024 |  |
| **WP4** | | | | |
| 4.2.1 | Organise meeting to identify contribution/collaboration | GRAPHEAL | 15/11/2024 |  |
| 4.2.2 | Firmware development for the 2D-BioPAD decision support tool | GRAPHEAL | 20/12/2024 |  |
| 4.2.3 | App Mock-ups available for the 2D-BioPAD decision support tool | GRAPHEAL | 31/01/2025 |  |
| **WP5** | | | | |
| 5.1.1 | Submit the prospective clinical study documents for ethical approval | ZI | 31/10/2024 |  |
| 5.1.2 | Inform about approval status for both the retrospective and prospective clinical pilot study documents | ZI | 30/11/2024 |  |
| 5.1.3 | Meeting about the regulatory aspects of the clinical protocol | EVNIA / UEF | 30/11/2024 | Support for reaching out to FIMEA – no need to prepare a regulatory compliant protocol (yet) |
| 5.1.4 | Materials and Data Transfer agreement template | UEF | 20/12/2024 | To be shared with GAADRD, ZI, ICN2 & GRAPHEAL |
| 5.1.5 | Finalise the Materials and Data Transfer agreement template | UEF, GAADRD, ZI, ICN2 & GRAPHEAL | 29/01/2025 |  |
| 5.1.6 | Arrange a meeting with the Finnish medicine agency to discuss the regulatory-compliant clinical study protocol | UEF / EVNIA | 20/12/2024 |  |
| 5.1.7 | Share the Protocol with members of the SIAB for comments | UEF / GAADRD | 14/03/2025 | In whatever status the protocol is |
| **WP6** | | | | |
| 6.1.1 | Promo articles | Q-PLAN, NOVA, CeADAR | 30/11/2024 | Aptamer Article pending NOVA’s approval. Q-PLAN to share draft to CeADAR |
| 6.1.2 | Social media campaigns - partners asked to interact (re-post, share, comment) | Q-PLAN / Support by all | Ongoing |  |
| 6.1.3 | Website content update with educational material | Q-PLAN / Support by all | Ongoing |  |
| 6.1.4 | Press Releases for GW24 & 3rd PM | Q-PLAN | 8/11/2024 |  |
| 6.1.5 | GW24 Video Interview from ICN2 | Q-PLAN / ICN2 | 20/12/2024 |  |
| 6.2.1 | Organise interviews for discussing exploitation pathways | Q-PLAN / ALL | 15/11/2024 | Nov24 – Feb 25 |
| 6.2.2 | Update the exploitation plan | Q-PLAN | 30/03/2025 |  |
| 6.3.1 | Initiate market analysis in the context to T6.3 | Q-PLAN | 10/10/2024 |  |
| 6.3.2 | Organise interviews for discussing market analysis and business with a key stakeholder from each partner | Q-PLAN / ALL | 30/11/2024 |  |
| 6.3.3 | Finalise interviews for market analysis, with selected interviewees | Q-PLAN | 28/02/2025 |  |
| 6.3.4 | Aggregated results from the market analysis | Q-PLAN | 30/03/2025 |  |
| 6.3.5 | Present results to 4th Project Meeting | Q-PLAN | March-April 2025 |  |
| 6.4.1/6.5.1 | Regulatory Workshop / Webinar | EVNIA /  Q-PLAN | February 2025 |  |
| 6.5.2 | Explore synergies with GRAPHERGIA | Q-PLAN / UP-CATRIN | 30/11/2024 | Communication initiated. |
| 6.5.2 | Explore synergies with SAFARI | Q-PLAN / UP-CATRIN | 30/11/2024 |  |
| 6.5.3 | Explore synergies with GIANCE | Q-PLAN / UP-CATRIN | 30/11/2024 | Communication initiated. |
| 6.5.4 | Explore synergies with 2D-PL | Q-PLAN / UP-CATRIN | 30/11/2024 |  |
| 6.5.5 | Explore workshop with PPs/Ams | Q-PLAN / UP-CATRIN | 29/11/2024 | To be discussed during the GF D&C meeting on the 14th of November |
| 6.5.6 | Organise Webinar on Clinical Applications of Graphene-based solutions | UEF / Q-PLAN | 20/12/2024 | Identify theme and speakers (webinar for April 2025) |
| 6.5.7 | Organise Webinar on AI for 2D Material Science, within GF | CeADAR / Q-PLAN |  | Identify theme and speakers (webinar for Jun/Jul 2025) |
| 6.5.8 | Initiate collaboration with MUNASET on market analysis, etc. | Q-PLAN | Jan/Feb 2025 |  |
| **WP7** | | | | |
| 7.1.1 | [Partners update KPIs list here](https://upolomouc.sharepoint.com/sites/2D-BioPAD/Sdilene%20dokumenty/Forms/AllItems.aspx?csf=1&web=1&e=OQAhqr&cid=83b0e86a%2D62e4%2D4604%2D846d%2D954a8d0ed099&FolderCTID=0x012000C5B60DBA2DB3734093B440FDE5610EFF&id=%2Fsites%2F2D%2DBioPAD%2FSdilene%20dokumenty%2FGeneral%2F06%2EWPs%2FWP%207%2FT7%2E1%5FCoordination%5Fand%5Fquality%5Fmanagement&viewid=fa0c46b7%2D2996%2D4d87%2D8277%2Dd9150ecab5b2) | Q-PLAN | 4/11/2024 |  |
| 7.1.2 | [Partners update KPIs requested by the GFI here](https://upolomouc.sharepoint.com/:x:/r/sites/2D-BioPAD/_layouts/15/Doc.aspx?sourcedoc=%7B35404C22-66D2-4713-A526-0FB80D26F98E%7D&file=HE%20GF%20Common%20KPIs.xlsx&action=default&mobileredirect=true) | Q-PLAN/ ALL | 4/11/2024 |  |
| 7.3.1 | Align the DMP with the Clinical Pilot Study Protocol | Q-PLAN / UEF / EVNIA | April 2025 |  |
| 7.4.1 | Partners provide input on 1st & 2nd Semester internal progress report | ALL | 25/10/2024 | GRAPHEAL, ZI pending |
| 7.4.2 | Semester internal reporting finalise | Q-PLAN/ ALL | 15/11/2024 | Fine-tuning |
| 7.4.3 | Financial report -partners' fill template & send to UP | ALL | 31/10/2024 |  |
| 7.4.4 | Q-PLAN shares the 3rd project meeting minutes with partners | UP-CATRIN / Q-PLAN | 01/11/2024 |  |
| 7.4.5 | Partners provide feedback to the meeting minutes | ALL | 04/11/2024 |  |
| 7.4.6 | Final Project Meeting minutes shared with partners | UP-CATRIN / Q-PLAN | 08/11/2024 |  |
| 7.4.7 | Hold digital monthly meetings (agenda, moderation, minutes, etc.) | UP & Q-PLAN/ ALL | 5/11/2024 |  |
| 7.4.8 | Planning for 4th Project meeting in Bordeaux (tbc) in March 2025 | NOVA/ UP-CATRIN / Q-PLAN | Nov-Dec 2024 |  |
| 7.4.9 | Contact with PO for review arrangements | UP-CATRIN | Jan 2025 |  |
| 7.4.10 | Initiate the 1st Period Reporting (activity reporting will be initiated a bit earlier) | UP-CATRIN, Q-PLAN / ALL | 1/4/2025 |  |
| 7.4.11 | Submit report to the EC | UP-CATRIN, ALL | TBD |  |

1. Annexes

## Annex I – List of Participants

**List of Participants – DAY 1 (24/10/2024)**

| No | Organisation | Country | Participant |
| --- | --- | --- | --- |
|
| 1 | **UNIVERZITA PALACKEHO V OLOMOUCI (UP)** | Czechia | Aristeidis Bakandritsos |
| Lucie Hrabalikova |
|  |
| 2 | **Q-PLAN INTERNATIONAL ADVISORS PC (Q-PLAN)** | Greece | Alexandra Gkouma |
| Aristotelis Folas |
| Apostolos Tsolakis |
|  |
| 3 | **FUNDACIO INSTITUT CATALA DE**  **NANOCIENCIA I NANOTECNOLOGIA (ICN2)** | Spain | Marianna Rossetti |
| Ronaldo Valentin Challhua Reynoso |
| Sebastián Acebal Colli |
|  |
| 4 | **GRAPHEAL** | France | Vincent Bouchiat |
| 5 | **ARISTOTELIO PANEPISTIMIO**  **THESSALONIKIS (AUTH)** | Greece | Mavroeidis Angelakeris |
| Anastasia Pantazaki |
| George Katsipis |
| Antonios Makridis |
| Eleni Tzekaki |
| 6 | **NOVAPTECH (NOVA)** | France | Jean-Jacques Toulmé |
| Sandeep Kumar |
| 7 | **ITA-SUOMEN YLIOPISTO (UEF)** | Finland | Alina Solomon |
| Mervi Issakainen |
| Kaisa Paldanius |
| 8 | **ELLINIKI ETAIRIA NOSOY ALZHEIMER KAI**  **SYGGENON DIATARACHON SOMATEIO (GAADRD)** | Greece | Magda Tsolaki |
| Anthoula Tsolaki |
| Foteini Pikouli |
| 9 | **EVNIA APS (EVNIA)** | Denmark | Gitte Holst |
| Angeliki Koukoura |
| Vaso Basinou |
| Kyriaki Antonopoulou |
| Eirini Papadaki |
| 10 | **ZENTRALINSTITUT FUER SEELISCHE**  **GESUNDHEIT (ZI)** | Germany | Lutz Froelich |
| 11 | **UNIVERSITY COLLEGE DUBLIN, NATIONAL**  **UNIVERSITY OF IRELAND, DUBLIN (CeADAR)** | Ireland | Polat Goktas |
| Cristian Bosch Serrano |

**List of Participants – DAY 2 (25/04/2024)**

| No | Organisation | Country | Participant |
| --- | --- | --- | --- |
|
| 1 | **UNIVERZITA PALACKEHO V OLOMOUCI (UP)** | Czechia | Aristeidis Bakandritsos |
| Lucie Hrabalikova |
| - |
| 2 | **Q-PLAN INTERNATIONAL ADVISORS PC (Q-PLAN)** | Greece | Alexandra Gkouma |
| Aristotelis Folas |
| Apostolos Tsolakis |
| Petros Papadionisiou |
| 3 | **FUNDACIO INSTITUT CATALA DE**  **NANOCIENCIA I NANOTECNOLOGIA (ICN2)** | Spain | Marianna Rossetti |
| - |
| 4 | **GRAPHEAL** | France | Vincent Bouchiat |
| 5 | **ARISTOTELIO PANEPISTIMIO**  **THESSALONIKIS (AUTH)** | Greece | Mavroeidis Angelakeris |
| Anastasia Pantazaki |
| George Katsipis |
| Antonios Makridis |
| Eleni Tzekaki |
| 6 | **NOVAPTECH (NOVA)** | France | - |
| Sandeep Kumar |
| 7 | **ITA-SUOMEN YLIOPISTO (UEF)** | Finland | Alina Solomon |
| Mervi Issakainen |
| Kaisa Paldanius |
| 8 | **ELLINIKI ETAIRIA NOSOY ALZHEIMER KAI**  **SYGGENON DIATARACHON SOMATEIO (GAADRD)** | Greece | Magda Tsolaki |
| Anthoula Tsolaki |
| Foteini Pikouli |
| 9 | **EVNIA APS (EVNIA)** | Denmark | Gitte Holst |
| Angeliki Koukoura |
| Vaso Basinou |
| Kyriaki Antonopoulou |
| Eirini Papadaki |
| 10 | **ZENTRALINSTITUT FUER SEELISCHE**  **GESUNDHEIT (ZI)** | Germany | - |
| 11 | **UNIVERSITY COLLEGE DUBLIN, NATIONAL**  **UNIVERSITY OF IRELAND, DUBLIN (CeADAR)** | Ireland | Polat Goktas |
| Cristian Bosch Serrano |

## Annex II – Agenda of the meeting

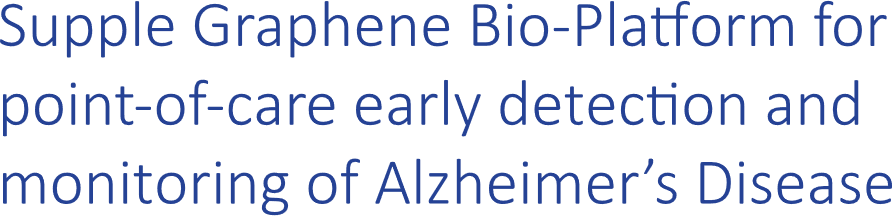
Day 1 – Thursday 24th of October 2024

|  |  |  |
| --- | --- | --- |
| **Time (CEST)** | **Topic** | **Responsible Partner(s)** |
| 10:00 - 10:15 | **Welcome and Project Overview** | **UP** |
| 10:15 – 10:30 | **WP2 – Οverview**  *(brief update on WP2 approach and current results)* | **AUTH** |
| * Overview on current status and tasks activities * Key Highlights of D2.1 |
|  |
| 10:30 – 11:15 | **WP2 - Aptamers and alternatives for AD biomarkers**  *(Presentation of the challenges and collaboration on aptamer selection. Discussion and planning of next actions)*   * Presentation of current status, challenges, alternatives, timeline, etc. * External Consultation - Feedback from the SIAB and experts * AI support for Aptamer selection * Decisions on Next Steps and Critical Milestones for 3rd Semester | **NOVA**  (CeADAR) |
| 11:15 – 11:45 | **WP2 - MNPs progress and conjugation with AD Aptamers**   * Presentation of current status and challenges * Decisions on Next Steps and Critical Milestones for 3rd Semester | **AUTH**  (NOVA) |
| 11:45 - 12:00 | *Short coffee break* |  |
| 12:00 - 12:15 | **WP3 & WP4 – Status Overview and current results** *(brief update on WP3 approach and current results)* | **UP** (ICN2,  GRAPHEAL, CeADAR) |
| * WP3 Update on the graphene derivatives, electrochemical and GFET biosensors * WP4 Update on the software of 2D-BioPAD: firmware development and mobile app (T4.2) |
| 12:15 - 13:00 | **Workshop: “Collaboration towards the Joint development of the 2D-BioPAD electrochemical & GFET biosensors”- Part 1** *(Presentation of the Time plan, challenges and collaboration on developing the common features of the biosensors. Discussion and planning of next actions)*   * Biosensor current status and collaboration with partners * Implementation Challenges and Barriers * Time plan of actions towards 1st prototype available for testing * Decisions on Next Steps and Critical Milestones for 3rd Semester | **ICN2-GRAPHEAL** (UP, CeADAR) |
| 13:00 - 14:00 | *Lunch break* |  |
| 14:00 - 14:30 | **Workshop Part 2 and Discussion on criteria & KPIs of the biosensing technology for clinical pilots** *(collaboration on developing the common features of the biosensors. Discussion and planning of next actions)*   * Biosensor current status and collaboration with partners * Implementation Challenges and Barriers * Time plan of actions towards 1st prototype available for testing * Decisions on Next Steps and Critical Milestones for 3rd Semester * Criteria of 2D-BioPAD biosensing technologies for clinical pilots (blood processing/microfluidics, plasma separation, quantity needed) | **ICN2-GRAPHEAL** (UP, CeADAR) |
| 14:30 - 14:45 | *Short coffee break* |  |
| 14:45 – 15:30 | **2D-BioPAD as a Diagnostic Aid under the IVDR**   * Relevant IVDR specifications for 2D-BioPAD * Guidelines for documents and evidence tracking * Planning for adhering to IVDR | **EVNIA** |
| 15:30 - 15:45 | **Wrap up and conclusions of the 1st day** | **ALL** |
| 15:45 - 16:00 | **Consortium meeting photo** | **ALL** |

Day 2 – Friday 25th of October 2024

|  |  |  |
| --- | --- | --- |
| **Time** | **Topic** | **Responsible Partner(s)** |
| 10:15 - 10:45 | **WP5 - Clinical Pilot Studies Design, Deployment, Evaluation & Validation** *(update on WP5 approach, discussion and planning of next actions)*   * Protocols for the clinical studies and key highlights of D5.1 * Update on the national Ethical Committees decisions, comments and approval. * Update on the Regulatory-compliant Clinical Protocol. | **UEF** (GAADRD, ΖΙ) |
| 10:45 - 12:00 | **WP6 - Dissemination, exploitation and communication** *(update on WP6 approach, discussion and planning of next actions)*   * Updates on Dissemination and communication activities; Exploitation & IP Management, Business modelling and planning * Networking & joint activities with relevant initiatives * Update on GFI activities – Looking back to GW24 * Action plan for the 3rd semester (activities, important deadlines, responsible partners, etc.) | **Q-PLAN** (UP) |
| 12:00 - 12:15 | *Coffee break* |  |
| 12:15-13:00 | **WP7 - Project management and coordination** *(update on WP7 approach, discussion and planning of next actions)* | **UP** (Q-PLAN) |
| * Project overview * Project KPIs monitoring & GF KPIs * Internal semester reporting * Overview of action plan for the next 6 months (M13 – M18) * Planning for the next project meeting |
| 13:00-13:15 | **Wrap up and end of the 3rd project meeting** | **ALL** |





GA 101120706

Partners



A blue hexagon with white letters

Description automatically generated



Member of the:

1. Proposed by UEF: <https://www.stressmarq.com/pffs/amyloid-beta/> [↑](#footnote-ref-2)