2D BioPAD

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

D6.4 Exploitation and Sustainability Plan, Version 1

Q-PLAN

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Executive Summary

In the context of 2D-BioPAD, managing innovation and Intellectual Property Rights (IPR) is crucial for effectively exploiting the project's results beyond its end. Therefore, the partners of 2D-BioPAD have strategically underpinned the implementation of 2D-BioPAD with a tailored strategy and methodology for IP management, carefully planning and working towards exploitation and sustainability. Along these lines, this report is elaborated as the interim version of the Exploitation and Sustainability Plan of 2D-BioPAD providing an overview of the project's Innovation and IPR Management strategy as well as the methodology and results of its application by this stage of implementation.

In particular, the report sheds light on the objectives of IP management in the framework of 2D-BioPAD, presenting an overview of key concepts and terms towards creating better awareness amongst the partners of the consortium. At the same time, it lays down the main components of our strategy and methodology in this respect before ultimately, describing the results of our work, in terms of Background as well as Key Exploitable Results (KERs) identified so far by the partners. The outline of 2D-BioPAD's KERs is presented in this report together with the partners' preliminary plans and actions for post-project exploitation. In particular, specific exploitation plans were crafted per partner and each identified KER, including target groups that stand to benefit from their use, key exploitation routes, necessary protection measures, as well as actions required for advancing the exploitation readiness and potential of each KER by the end of the project and beyond.

The current report on Exploitation and Sustainability will be further elaborated and updated as the project progresses. An updated version will be delivered by M24 (i.e., D6.5), whereas the final version is foreseen to be delivered by M48 (i.e., D6.6), reflecting the final results of the consortium concerning exploitation planning, to guide post-project exploitation of 2D-BioPAD's key exploitable results.

The updated versions will also include information related to the 2D-BioPAD innovation roadmap, following the guidance from the GrapheneEU CSA project, aligning with the activities of the Graphene Flagship Initiative.

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List of Terms and Definitions

Table 1: Terms and Definitions

Abbreviation	Definition
AD	Alzheimer's Disease
AI	Artificial Intelligence
CA	Consortium Agreement
CC	Creative Commons
EM	Exploitation Manager
EUIPO	European Union Intellectual Property Office
EUTM	EU Trade Mark
GA	Grant Agreement
KER	Key Exploitable Result
IP	Intellectual Property
IPR	Intellectual Property Rights
NDA	Non-Disclosure Agreement
TRL	Technology Readiness Level
WIPO	World Intellectual Property Organisation

1. Introduction

The development of meaningful project results that can sustainably be exploited beyond the end of the grant is both a priority as well as a commitment of 2D-BioPAD's partners. To this end, Intellectual Property (IP

) management plays a key role and underpins the implementation of 2D-BioPAD throughout its course, paving the way for the smooth exploitation of its results.

Our approach to IP management considers: (i) the existing guide "Your Guide to IP in Horizon 2020", since the tips and recommendations it provides remain valid and helpful for Horizon Europe projects; (ii) the new guide "Your Guide to Intellectual Property Management in Horizon Europe" which focuses on Horizon Europe collaborative projects; and (iii) the guide "Successful Valorisation of Knowledge and Research Results in Horizon Europe", which explains how to boost the impact of a project through effective communication, dissemination and exploitation.

With that in mind, the current document constitutes the **initial version of 2D-BioPAD's Exploitation and Sustainability Plan (Version 1)**, which lays down the strategy and basic principles of the project in this respect. This initial version of the Exploitation and Sustainability Plan will serve as the basis for the activities to be implemented in the framework of Task 6.2 towards sound innovation management as well as towards exploitation and sustainability of the project's results after the end of the grant.

Along these lines, the remaining of the document comprises of the following sections:

- **Section 2** provides an overview of IP management in the context of 2D-BioPAD, defining objectives and clarifying key concepts and terms (including IP protection measures).
- **Section 3** outlines the IP management strategy of the project and its underlying stages of applications during the different stages of 2D-BioPAD's implementation.
- **Section 4** introduces the methodology and tools used to capture the Background and key exploitable results of 2D-BioPAD, as well as to craft an exploitation plan for each one.
- **Section 5** offers an updated overview of 2D-BioPAD's Background and Key Exploitable Results (KERs) along with a brief description of each one.
- **Section 6** describes the exploitation plans crafted per KER, including the actions which are currently foreseen as necessary for the KERs to be effectively exploited.
- **Section 7** outlines the individual exploitation plan set out by each of the members of the 2D-BioPAD consortium at this stage of the project.
- **Section 8**. Finally, this report concludes with the next steps foreseen in the context of the project towards the exploitation of its KERs.

The methodology of 2D-BioPAD for exploitation and sustainability builds on know-how, tools and templates that were developed internally by Q-PLAN as well as on good practices from the literature (such as guides developed by the IPR Helpdesk for H2020 and Horizon Europe). As in previous EU-funded projects, tailored modifications to the methodology were implemented for 2D-BioPAD as well, in order to comply with the conditions of the Grant Agreement (GA) and the particularities of the project. Along these lines, this deliverable presents the adjusted methodology as it was further developed and applied in 2D-BioPAD as well as presents the results from its application during the project.

2. Objectives and Key Concepts Overview

2.1 Objectives

The overall purpose of 2D-BioPAD's IP management is to appropriately protect all the results that (will) stem from the project during its life span, handle and manage them effectively, ensuring exploitation and dissemination of Key Exploitable Results (KERs).

To this end, the main objectives of the Exploitation and Sustainability Plan are to:

- develop a common understanding among 2D-BioPAD's partners concerning key terms and issues revolving around IP, Background, KERs as well as access rights.
- assess and conceptualise a strategy along with a framework for managing IP that can be employed for each identified KER of 2D-BioPAD.
- establish common guiding routes and actions within the consortium to safeguard the smooth implementation of IP management.
- describe the IP management methodology to be followed within the context of 2D-BioPAD for the identification and exploitation of results.

In this section, we start by providing definitions and key information on important terms and issues with an eye on developing a shared understanding among 2D-BioPAD partners around them. We also facilitate the protection of IP stemming from 2D-BioPAD by providing helpful information on available protection measures and relevant concepts.

2.2 Key Concepts

In general, the key concepts to consider for designing the Exploitation and Sustainability Plan of Horizon Europe projects are the following:

- Background
- Results and ownership of results
- Key Exploitable Results (KERs)
- Access rights and rights to use

Therefore, the following subsections aim to clarify the main terms concerning the key elements of IPR management, representing key aspects of our IP management procedures.

2.2.1 Background and Access Rights to Background

Background means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that is: (a) held by the beneficiaries before they acceded to the Consortium Agreement and (b) needed to implement the action or exploit the results[1].

According to 2D-BioPAD's Consortium Agreement (CA), the background needed to carry out the project activities must be accessible to the other project partners on a **royalty-free basis** unless otherwise agreed previously. All project partners must identify the background pertinent to the project actions and grant the

[1] See Article 16, "Intellectual property rights (IPR) — background and results —access rights and rights of use", in the Terms and Conditions of the 2D-BioPAD Grant Agreement

respective access rights[2]. The background is determined and agreed upon within the CA after the internal evaluation of pre-existing knowledge. During the project, partners can add background if needed after they give written notice to the other partners and if the Steering Committee approves the addition[3].

2.2.2 Results and Ownership of Results

Result means any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights[4].

According to 2D-BioPAD's Grant Agreement (GA), project results are owned by the partners that generate them. Given the collaborative nature of the project, some results can be jointly developed by several partners. In this case, joint ownership can arise among the contributing partners, with the share of each joint owner and the terms of the exercise of their joint ownership agreed upon between the involved parties[5]. In principle, each joint owner can use their jointly owned results (i) for non-commercial research and teaching activities on a royalty-free basis or (ii) for other exploitation purposes after providing fair and reasonable compensation to the remaining joint owners[6].

2.2.3 Key Exploitable Results (KERs)

Key Exploitable Result (KER) means an identified main interesting result, which has been selected and prioritised due to its high potential to be "exploited" – meaning to make use and derive benefits- downstream the value chain of a product, process or solution, or act as an important input to policy, further research or education[7].

Overall, exploitation refers to using a result produced in an EU project in further activities (other than those covered by the project), such as performing other research activities or developing, creating and marketing a product, process or service. Among the various results generated and which could potentially be exploited, some are distinguished as KERs.

Usually, there are many results as project outcomes, and the purpose is to distinguish the few KERs, meaning those that can really "make a difference"[8]. Selecting and prioritising results as KER can be based on degree of innovation, exploitability and impact potential[7].

[2] See Attachment 1 in the Consortium Agreement for a detailed description of the 2D-BioPAD background and the access rights granted in principle for the consortium.
[3] See Section 9.3, "Access Rights for Implementation", of the 2D-BioPAD Consortium Agreement
[4] See Article 16, "Intellectual property rights (IPR) — background and results —access rights and rights of use", in the Terms and Conditions of the 2D-BioPAD Grant Agreement
[5] See "Intellectual property rights (IPR) — background and results — access rights and rights of use (— article 16)" in Annex 5 of the 2D-BioPAD Grant Agreement
[6] See Article 8, "Results", of the 2D-BioPAD Consortium Agreement
[7] European IP Helpdesk, Introducing the Horizon Results Platform and Horizon Results Platform TV, Horizon Results Platform, Bulletin No. 4 – Horizon Europe
[8] EU Science and Innovation (2023), Horizon Results Platform: Opportunities for ERC Beneficiaries, https://www.youtube.com/live/MA9k6j9zWBs?si=1Fghc4_ysmFJcD77&t=767

2.2.4 Access Rights and Rights to Use

Access rights refer to rights to use the project results or background[9]. They are required if carrying out some project tasks or exploiting the results would be impossible without them (or if project implementation would be significantly delayed or require significant additional financial or human resources)[10]. The granting of access rights within a collaborative Horizon Europe project follows specific rules pre-defined in the GA and the CA. Depending on their purpose of use, access rights within 2D-BioPAD can be depicted in the following table.

Table 2: Access Rights[11]

Purpose for Access	Access to Background (Article 16 in Annex 5 of 2D-BioPAD's GA)	Access to Results (Article 16 in Annex 5 of 2D-BioPAD's GA)
Project Implementation	• Royalty-free • Unless otherwise agreed by participants before accession to the GA	• Royalty-free
Exploitation of Own Results	• Subject to individual agreement • Granted under fair and reasonable conditions	

The European Commission (EC) does not own the results produced under 2D-BioPAD. However, for policy, information, communication, dissemination and publicity purposes, the EC has the right to use non-sensitive information and other materials and documents relating to the project, such as deliverables, pictures or audio-visual material, on a royalty-free basis, both during the project implementation and afterwards[12].

2.3 Protection of Results

When considering IP protection, it must be noted that IP can be protected by several types of IPR, and consequently, the most appropriate protection strategy must be chosen. The selection of the most suitable form of IP protection depends on the nature and specific characteristics of the results under consideration and the objectives of the IP owner.

A few key terms concerning IP protection are the following:

- Copyrights and creative commons licenses;
- Non-disclosure and confidentiality agreements;
- Trade and service marks;
- Trade secrets;
- Patents and utility models;
- Industrial designs.

Short definitions and key elements of these terms are provided in the following subsections.

[9] European Commission (2023), AGA — Annotated Grant Agreement: V1.0 DRAFT, EU Grants, EUFunding Programmes 2021-2027

[10] Section 1, "Definitions", of the 2D-BioPAD Consortium Agreement

[11] European Commission, European Innovation Council and SMEs Executive Agency, Your guide to intellectual property management in Horizon Europe, Publications Office of the European Union, 2022,

[12] See Article 16, "Intellectual property rights (IPR) — background and results —access rights and rights of use", in the Terms and Conditions of the 2D-BioPAD Grant Agreement

2.3.1 Copyright and Creative Commons Licenses

2.3.1.1 Copyright

Copyright[13] (or author's right) is the term used to describe the rights that creators have over their literary, scientific and artistic works.

An exhaustive list encompassing works eligible for copyright protection does not exist. Nevertheless, there are typically several types of works internationally recognised and covered by copyright, including the following:

- literary works such as novels, poems, plays, newspaper articles;
- computer programs, databases;
- films, musical compositions, and choreographies;
- artistic works such as paintings, drawings, photographs, and sculptures;
- architecture; and
- advertisements, maps, and technical drawings.

According to the European IP Helpdesk, in the European Union, copyright protection is automatically granted upon creating a work without the need for registration or other formalities. While registration is not a prerequisite for establishing the right, it can prove beneficial in certain situations, such as resolving disputes over ownership or creation and facilitating financial transactions. In practice, including a copyright notice on the work is common, such as "all rights reserved" or the symbol © along with the year of creation. This informs others about the existence of copyright, reducing the likelihood of infringement.

Copyright encompasses both economic and moral rights. Economic rights empower right holders to control the use of their works, allowing them to sell or license the works to others. Meanwhile, moral rights include the author's right to claim authorship and object to any distortion or mutilation of their work. These dual aspects of copyright provide a comprehensive framework for authors to protect their creative endeavours.

2.3.1.2 Creative Commons Licenses[14]

The Creative Commons (CC) licenses are a free, simple, and standardised way that every person and organisation in the world can use to grant copyright permissions for creative and academic works. They are free of charge and do not require creators or other rights holders to register with Creative Commons organisation to assign a CC license to their work.

According to Creative Commons, CC licenses are copyright licenses and depend on the existence of a copyright to work. Also, as they are built on copyright, CC licenses work worldwide and last as long as applicable copyright lasts. In practice:

- creators who want to preserve their copyright and make their work available to the public for limited kinds of uses shall consider using CC licenses;
- instead, if they want to reserve all of their rights under copyright law, they should not use CC licenses.

[13] European Commission (2019), Your guide to IP in Europe, Publications Office, Executive Agency for Small and Medium-sized Enterprises
[14] Creative Commons (2024), Frequently Asked Questions

In November 2013, CC published the version 4.0 license suite. These licenses are briefly presented in the following table.

Table 3: The most up-to-date licenses offered by CC15

License buttons	Description of the license
	**Attribution (CC BY).** This license lets others distribute, remix, adapt, and build upon your work, even commercially, as long as they credit you for the original creation. This is the most accommodating of licenses offered and recommended for maximum dissemination and use of licensed materials.
	**Attribution-ShareAlike (CC BY-SA).** This license lets others remix, adapt, and build upon your work, even for commercial purposes, as long as they credit you and license their new creations under identical terms. This license is often compared to "copyleft" free and open-source software licenses. All new works based on yours will carry the same license, so any derivatives will also allow commercial use. This is the license used by Wikipedia and is recommended for materials that would benefit from incorporating content from Wikipedia and similarly licensed projects.
	**Attribution-NoDerivs (CC BY-ND).** This license lets others reuse the work for any purpose, including commercially; however, it cannot be shared with others in adapted form, and credit must be provided to you.
	**Attribution-NonCommercial (CC BY-NC).** This license lets others remix, adapt, and build upon your work non-commercially, and although their new works must also acknowledge you and be non-commercial, they don't have to license their derivative works on the same terms.
	**Attribution-NonCommercial-ShareAlike (CC BY-NC-SA).** This license lets others remix, adapt, and build upon your work non-commercially as long as they credit you and license their new creations under identical terms.
	**Attribution-NonCommercial-NoDerivs (CC BY-NC-ND).** This license is the most restrictive of our six main licenses, only allowing others to download your works and share them with others as long as they credit you, but they can't change them in any way or use them commercially.

The CC buttons (i.e., the pictures in the first column of the table above) are a shorthand way to convey the basic permissions associated with material offered under CC licenses. Creators and owners who apply CC licenses to their material can download and apply those buttons to communicate the permissions granted in advance to users.

Deliverable authors and other result creators can simply mark their work with a statement such as **"This work is licensed under the Creative Commons** [mention which license you wish to apply to your work from the table above] **license**. Or they can insert the applicable license buttons with the same statement[15].

[15] Creative Commons (2024). About Cc Licenses.

2.3.2 Non-disclosure and Confidentiality Agreement

A **Non-disclosure agreement** (NDAs) is a legally enforceable agreement between parties that is used to ensure that certain information will remain confidential[16].

NDAs are often used to protect trade secrets (such as know-how), client lists, and financial data in business settings. Similar to NDAs, Confidentiality Agreements aim to ensure that information will remain confidential as well. However, they are typically devised in employment or personal situations instead[17]. In any case, the subject of an NDA or a Confidentiality Agreement, is legally protected and can only be a piece of information that is (i) not known by the public, (ii) not already known by the receiving party, and (iii) not made public in ways other than breaking the confidentiality rules[18]`.

In collaborative projects, such as 2D-BioPAD, maintaining confidentiality is important for organisations involved, from the initial setup of the project to the stages of implementation and exploitation[19]. For this reason, 2D-BioPAD's CA foresees that, throughout the project and for five years after its end, partners will uphold the confidentiality of any data, documents, or other materials deemed confidential in connection to the project's execution[20].

2.3.3 Trade mark

A **trade mark**[13] is an exclusive right over the use of a sign in relation to the goods and services for which it is registered. Trade marks consist of signs capable of distinguishing the products (either goods or services) of a trader from those of others.

According to the World Intellectual Property Organization (WIPO)[21], a trademark can comprise a single word, a group of words, letters, or numbers. It can also include drawings, symbols, three-dimensional aspects like the shape and packaging of products, or even specific colours used to stand out. There are countless possibilities for what a trademark can be. A trademark owner can stop others from using similar signs for the same or related products and/or services unless they get permission first.

In order to protect a trademark in a specific country or region, you can do so by registering it. This involves submitting an application to the relevant national or regional trademark office and paying the necessary fees. At the EU level, you can obtain an EU trade mark (EUTM) at the European Union Intellectual Property Office (EUIPO) [22].

[16] Thomson Reuters (2022), 4 things you should know about non-disclosure agreements
[17] Bloomberg Law (2024), Confidentiality and Nondisclosure Agreements Explained
[18] European Commission (2020), Your guide to IP and contracts – Stay ahead of the innovation game, Executive Agency for Small and Medium-sized Enterprises, Publications Office
[19] European IP Helpdesk, Non-Disclosure Agreement (Template)
[20] Section 10, "Non-disclosure of information", of the 2D-BioPAD Consortium Agreement
[21] WIPO, Trademarks
[22] European Union Intellectual Property Office (2024), Trade marks

2.3.4 Trade Secret

A **trade secret**[13] can be considered any confidential business information providing a competitive advantage to an enterprise. The information must be secret (meaning that it is not generally known), have commercial value due to its secrecy and have been subject to reasonable measures to keep it secret.

A broad spectrum of information qualifies for protection as a trade secret. This encompasses diverse categories, ranging from know-how and technical knowledge to business and commercial data like customer lists, business plans, recipes, or manufacturing processes.

According to WIPO, various measures are employed to safeguard a trade secret. These can involve securely storing confidential information, entering into NDAs when discussing trade secrets with business partners, and incorporating non-disclosure clauses into various agreements such as employment agreements and consortium agreements. This is particularly important in situations where the exchange of confidential information is highly likely or deemed necessary. If someone who has to keep information secret shares it without permission, it's considered a violation of the agreement. In such instances, the trade secret holder can pursue remedies for the breach.[23]

2.3.5 Patent and Utility Models

A **patent**[13] is an exclusive right granted to protect inventions (products or processes) that offer a new technical solution or facilitate a new way of doing something.

According to the European IP Helpdesk, the patent holder is granted the exclusive right to prevent third parties from commercially exploiting the invention for a limited time. In exchange, the patent holder is obligated to disclose the details of the invention in the patent application, making it public knowledge. Permission for others to use the invention can be granted through a mutually agreed-upon arrangement, known as a patent licensing agreement. Alternatively, the patent owner has the option to sell the patent, transferring ownership to another entity.

Overall, according to WIPO, patent rights are applicable and enforceable within the geographical boundaries of the country or region where they are officially registered. Upon the expiration of a patent, the protection it provides ceases, and the invention becomes part of the public domain. Subsequently, the invention becomes available for commercial exploitation by others, free of charge.[24]

Similar to a patent, a Utility Model grants an exclusive right for the protection of an invention. The criteria for obtaining a utility model are less strict than patents, and the associated fees for acquiring and sustaining a utility model are typically more affordable. Additionally, the duration of protection granted to a utility model is shorter than that afforded to a patent.

[23] WIPO, Frequently Asked Questions: Trade Secrets
[24] WIPO, Frequently Asked Questions: Patents

2.3.6 Industrial Designs

An **industrial design**[13] is the outward appearance of the whole or part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation.

According to WIPO, industrial designs are used on many different products, ranging from packages and containers to furniture, household items, jewellery, electronics, and textiles. Essentially, if someone has a registered industrial design, they can stop others from making, selling, or bringing in products that look very similar to the protected design, especially when these actions are done for business purposes[25].

[25] WIPO, Industrial Designs

3. Strategy

The strategy for Intellectual Property (IP) management we employ in 2D-BioPAD is founded on the 6 pillars of IP management in Horizon Europe (as depicted in the figure included below), with the aim of addressing the diverse IP issues that typically arise at different stages of a collaborative Horizon Europe project (from its start, over to its end and beyond).

Figure 1: The pillars on which 2D-BioPAD's IP management strategy is founded[26]

At the start of the project, it is crucial to identify and agree on which existing IP is to be shared among partners and under what terms and conditions (Background), for use during the project (implementation) and after its end (exploitation) if needed (Pillar 1: IP used).

As the project progresses, the results born from its implementation need to be captured and defined, while decisions are to be made about their owners that will be managing them (Pillar 2: IP created). Along the way, the exploitability potential of the results for commercial or research applications is assessed in order to identify key exploitable results (Pillar 3: IP assessment) as well as appropriate measures for their protection (Pillar 4: IP protection).

Towards the end of the project, as the final results of the project become available and planning of exploitation routes becomes more important, our strategy focuses on fine-tuning dedicated action plans for exploitation (with alternative pathways if needed) towards the long-term sustainability of the project's results (Pillar 5: IP dissemination and exploitation).

The exploitation plans consider the period after the end of the project by design, including any requirements for continuing to disseminate and/or exploit results identified at that time as well as any potential IP transfers or agreements (Pillar 6: IP post-project management).

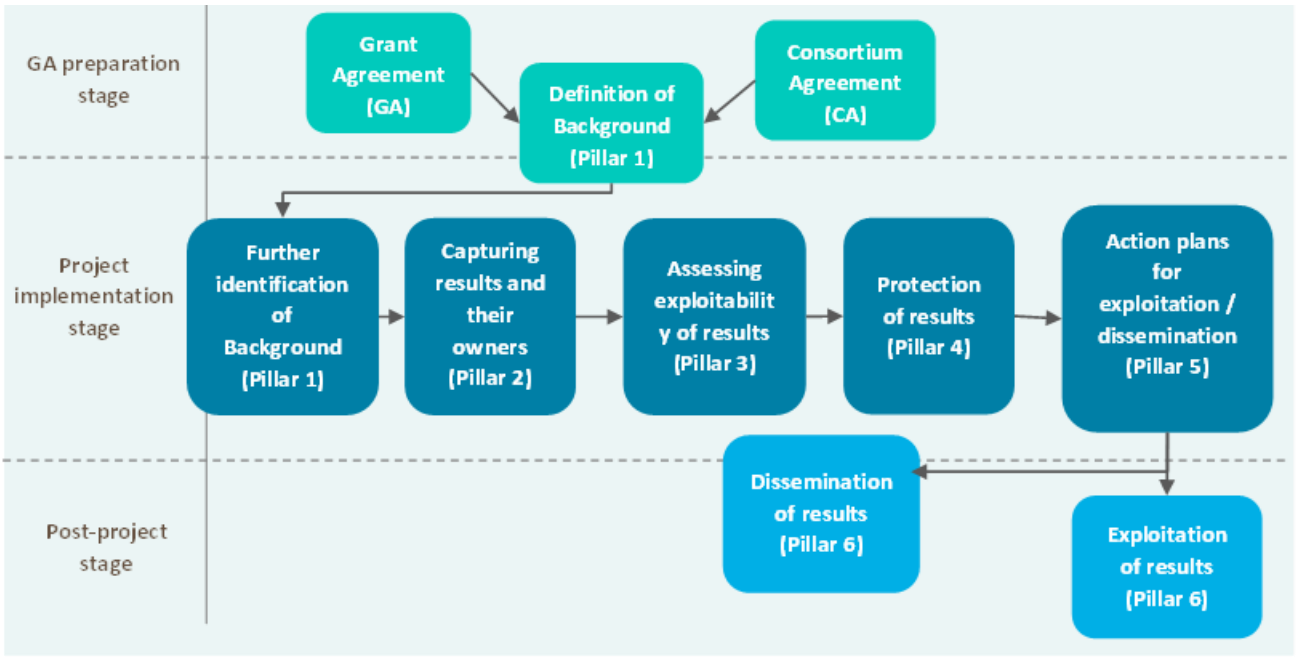
[26] European Commission (2022), Webinar: IP Management in collaborative Horizon Europe projects

Along these lines, 2D-BioPAD's IP management strategy lays out a comprehensive **framework** which distinguishes the **IP management processes** across the following stages:

- GA preparation stage;
- Project implementation stage;
- Post-project stage.

The following figure provides a more illustrative overview of the different IP management stages, as they are considered within the framework of 2D-BioPAD's respective strategy.

Figure 2: 2D-BioPAD's IP Management Stages



More details about these stages are presented in the sub-sections that follow.

3.1 Grant Agreement Preparation Stage

Both **the Grant Agreement (GA) and the Consortium Agreement (CA) constitute documents that describe several issues related to Intellectual Property Rights (IPR)**. Their provisions are a reference point for IPR issues, underpinning the implementation of our IP management strategy. Any further advancements regarding IPR actions put in place by partners will be facilitated under the underlying provisions of the GA and the CA.

3.1.1 Grant Agreement

The GA constitutes a contract which sets out the key rules and conditions of the project and is conducted between the EC and the partners of 2D-BioPAD[27]. It represents the main contractual basis for 2D-BioPAD, while its main points and sections referring to IPR are included in **Section 2 "Rules for carrying out the**

[27] See the respective section of the IPR helpdesk glossary for a definition of Grant Agreement

action"[28]. Under this scheme, the management of the 2D-BioPAD IP is regulated, whereas access rights and obligations related to the background are set. In addition, the GA defines issues concerning the ownership and protection of the project's generated results, as well as their exploitation and dissemination. Finally, transferability and access rights to results are also defined in 2D-BioPAD's GA.

3.1.2 Consortium Agreement

The CA constitutes a contract among the partners of the 2D-BioPAD consortium, which defines rights and obligations during the partnership for the purposes of carrying out the activities foreseen by the project[29]. The CA minimises the probability of later disputes as it provides rules and responsibilities during the project as well as defines the access rights to be granted to the partners concerning the project. In addition, rights and responsibilities are outlined among the consortium members concerning IP issues.

The main points and respective sections of 2D-BioPAD's CA which refer to IPR are included in:

- **Section 8 "Results"**, which sets out key provisions on ownership and joint ownership of results, as well as on their transfer and dissemination.
- **Section 9 "Access Rights"**, that clarifies the principles governing access rights for implementation as well as for exploitation and dissemination purposes. It also states specific provisions for access rights to software.
- **Attachment 1 "Background included"** presents an initial list of usable Background.

3.2 Project Implementation Stage

During the implementation stage of 2D-BioPAD, IP handling procedures are foreseen to be applied among partners to organise the sound management of the project's results. As the implementation of the project advances, the focus shifts from capturing and assessing the exploitability of the results over to **defining Key Exploitable Results (KERs)** and agreeing on their owners and protections measures. Ultimately, the focus is placed on putting in place and working towards suitable **action plans for exploitation and dissemination**.

Along the way, 2D-BioPAD's IPR management emphasizes the establishment of robust handling procedures for IPR issues that are of strategic importance to the project in order to facilitate the exploitation of its KERs.

Therefore, partners should focus on two different points:

- **Providing access rights to their knowledge** that is needed for other partners to carry out their work on the project.
- **Establishing procedures for the early identification of key exploitable results** with a view to timely designing actions plans for protecting and exploiting them.

In this respect, the following sub-sections cover key IP-related issues that are addressed by the IP management strategy of 2D-BioPAD during the course of the implementation stage.

[28] See Article 16, "Intellectual property rights (IPR) — background and results —access rights and rights of use", in the Terms and Conditions of the 2D-BioPAD Grant Agreement

[29] See the respective section of the IPR helpdesk glossary for a definition of Consortium Agreement.

3.2.1 Further Identification of Background

Partners may **identify, if necessary, further essential knowledge, know-how, or data** complementary to those outlined in the CA, which may need to be added to the Background of the project. The Background can be attached to the results of the project, which, eventually, will help out to determine access rights, ownership and protection measures.

3.2.2 Capturing Results, Assessing Exploitability and Defining Owners

A core process of 2D-BioPAD's IP management strategy is effectively capturing the results of the project and carefully assessing their exploitability, all with a view to creating a concrete mapping of the project's KERs, with the potential to enhance 2D-BioPAD's IP portfolio, along with the owner(s) of each one. Thus, all **valuable IP stemming from 2D-BioPAD must be identified, listed, named, described and analysed in a systematic way**.

To this end, all partners are asked to elaborate further on the provisions of the CA with regards to the results born from their work in the context of the project and their ownership (through 2D-BioPAD's IPR management tools, as described in Section 4 of this report). Overall, **KERs are owned by the beneficiary(-ies) that generates them**. Due to the strong collaborative work that Horizon Europe projects entail, typically two or more partners may jointly contribute to the creation of an individual result. Thus, in the framework of our strategy, **special attention is being paid to handling joint ownership issues**.

Information regarding the ownership of KERs needs to be reported to the EC by the end of the project. In particular, partners are required to elaborate a "**Results Ownership List**" and include it within the final (periodic) report of the project[30]. This list will include all identified KERs of the project and clearly indicate which partner(s) is ultimately responsible for protecting, exploiting and, by extension, managing, each one beyond the end of the project[31].

3.2.3 Protection of Results

Effective exploitation of the new knowledge developed within the frame of 2D-BioPAD requires the **protection of the project's KERs**. Thus, each partner must carefully examine the possibility of protecting its KER(s) and must adequately protect them across an appropriate **period of time** and with proper **territorial coverage** if: (i) the KER can reasonably be expected to be commercially or industrially exploited; and (ii) protecting the KER is possible, reasonable as well as justified (given the circumstances at the time of the decision)[32].

In this respect, when considering IP protection for the KER(s) they own, 2D-BioPAD's **partners must consider their own interests along with the interests of the entire consortium**. Partners must safeguard the identified KER(s) with adequate protection measures, which will offer a decent protection period within a suitable geographical territory. The following table indicatively illustrates protection instruments that may be applied to various subjects.

[30] See Annex 5 "Specific Rules" of the 2D-BioPAD Grant Agreement and in particular the Section "Intellectual Property Rights – Background and Results – Access Rights and Rights of Use (Article 16)"

[31] Scherer, J., Weber, S., Alveen, P. et al. (2022), European IP Helpdesk – Successful valorisation of knowledge and research results in Horizon Europe – Boosting the impact of your project through effective communication, dissemination and exploitation, European Commission, European Innovation Council and SMEs Executive Agency, Publications Office of the European Union

[32] European Commission (2022), Webinar: IP Management in collaborative Horizon Europe projects

Table 4: Indicative Protection of Results

Subject Matter	Copyright	Trade mark	Trade secret	Patent	Industrial design
Promotional and advertising material	X				
Scientific articles and technical reports	X				
Computer software, databases	X				
Appearance of technical devices					X
Design of product packaging		X			X
Company or technology logo		X			
Client lists			X		
Business plans			X		
Industrial processes			X	X	
New technologies			X	X	

Overall, IP protection constitutes a tool to create value through the licensing, sale or commercialisation of IP in the form of products and services. Moreover, its utilisation is vital for prospective commercial or industrial exploitation as it can contribute to supporting the branding of products and services both to customers and investors.

The decision on whether to seek protection for intellectual property rights is made before deciding whether or not to publish results. For instance, when aiming at patent protection, research results can only be published after the patent application has been filed. Therefore, the protection of research results and their commercial exploitation is promoted[31].

3.2.4 Exploitation of Results

2D-BioPAD's KER(s) will be effectively exploited for research, commercial or other relevant use. In particular, partners will seek to find and seize exploitation opportunities of the project's results in: (i) further research activities, (ii) developing, creating or marketing a product or process, (iii) creating and providing a service, (iv) using them in standardisation activities or other use scenarios such as to inform policy or for educational purposes.

Along these lines, following the successive phases of identifying and assessing results as well as defining owners and protection measures, further actions will run, including:

- **Outlining potential exploitation routes** foreseen for each of 2D-BioPAD's KERs beyond the end of the project.
- **Elaboration of 2D-BioPAD's Exploitation and Sustainability Plan** to serve as the road map for exploitation actions.

All project partners are obliged to take measures to ensure the exploitation of their KER(s) up to four years after the completion of the project[11]. Exploitation may occur directly or indirectly by another legal entity (e.g., through transfer and licensing of results). As formalised in the GA, "*If, despite a beneficiary's best efforts, the results are not exploited within one year after the end of the action, the beneficiaries must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to*

exploit the results"[33]. The Horizon Results Platform is hosted at the Funding &Tenders Portal of the EC. It is a free tool that partners can use to disseminate their KER to targeted users and seize opportunities for exploitation through successful matchmaking.

3.2.5 Dissemination of Results

2D-BioPAD's partners are set to select appropriate means for the dissemination of the project's KERs (e.g., scientific publications, publication on websites, conferences, open access, etc.), according to the conditions set forth in the GA and the CA[34], as well as to any confidentiality agreements that might arise to maintain confidentiality during and after the project. In this context, **all partners should be aware that they should first ensure the protection of a project's KER and then proceed to dissemination actions of the underlying result**.

Overall, 2D-BioPAD follows the **"Open Science"** approach, taking any steps required for spreading knowledge as soon as it is available using digital and collaborative technology. Open access to research data follows the principle "*as open as possible, as closed as necessary*"[35]. Thus, partners make their scientific publications and data available with open access. They may decide not to provide open access to research data only if it goes against their legitimate interests or for other justified reasons (e.g., confidentiality or security concerns). In such a case, a justification is included in the 2D-BioPAD Data Management Plan[31].

3.3 Post Project Stage

Dissemination and exploitation of KER(s) take place even after the project ends. Thus, **2D-BioPAD's IP management continues after the end of the project**, for example, to protect KERs (if needed), manage any agreements related to IP (e.g., licences) or potential costs and revenue sharing. In preparation for the post-project stage, the 2D-BioPAD consortium will:

- **Discuss and agree on (joint) exploitation strategies and pathways**. As some of the KERs are built on the combined knowledge of several partners, partners work on shared strategies for managing, protecting, and exploiting them.
- **Look at possible IP ownership arrangements and related responsibilities** (e.g., on maintenance costs). This requires the definition of the relative contributions of joint owners.
- **Explore, if needed, potential agreements (e.g., licensing) and remuneration options** for the use of IP stemming from 2D-BioPAD and choose what fits better to the circumstances[11].

With the above in mind, at the project's conclusion, the final version of the project's Exploitation and Sustainability Plan will provide the final outline of the use that the 2D-BioPAD consortium intends to make of its KERs along with the respective action plans and time frame for exploitation. This includes any further activities aimed at the dissemination, use, and sustainability of 2D-BioPAD's KERs, along with any findings concerning IP issues. In result, the deliverable will envisage our final strategy for exploitation, management of IPR and sustainability, also including any selected commercialisation pathways if applicable.

Finally, **if there is any request from the EC, partners will have to report their progress towards exploiting their KERs, including any needs or obstacles they may have faced after the end of the project**. Such a request

[33] See Annex 5 "Specific Rules" of the 2D-BioPAD Grant Agreement and in particular the Section "Intellectual Property Rights – Background and Results – Access Rights and Rights of Use (Article 16)"
[34] See Section 8.4, "Dissemination", of the 2D-BioPAD Consortium Agreement
[35] European Commission, Directorate-General for Research and Innovation (2024), Open Science

may come two years after the end of 2D-BioPAD, and the requested information may be asked in the form of a structured questionnaire incorporated into the System for Grant Management (SyGMa) of the EC[11].

3.4 Main roles

The IP management strategy of the project constitutes an integral priority for 2D-BioPAD's management structure. **Roles, with clear responsibilities and expected contributions**, have been established to put in place a continuous IP monitoring mechanism that can help ensure that IP information is reliable and timely captured, along with tailored procedures under which newly generated/identified KERs are handled within the lifespan of 2D-BioPAD.

The key roles established in this context are concisely outlined below.

3.4.1 Exploitation Manager

The **Exploitation Manager (EM) of 2D-BioPAD leads the definition, implementation, monitoring and fine-tuning of the project's IPR management strategy**, ensuring that novel knowledge and results which arise during the project are properly assessed and managed.

In this framework, the EM is responsible for screening any newly identified KERs, handling any corresponding IP issues that may arise during the project's lifespan. To this end, the EM directs partners to commonly establish the most adequate and efficient exploitation route(s) based on the nature of their KERs and the purposes of the 2D-BioPAD consortium concerning their exploitation. This includes a **crucial mediation role in case of IP conflicts**, guiding involved partners to find mutually agreeable solutions (including written agreements whenever necessary) and always in line with the provisions of 2D-BioPAD's CA (see Article 12.8 of the CA).

Along the way, the EM closely cooperates with the Project Coordinator and the Steering Committee across the duration of the project to exchange information born from advancing project activities and to determine adequate handling and protection of KERs. Finally, the EM coordinates the **development of the project's Exploitation and Sustainability Plan**, including the elaboration of the respective deliverables (initial and updates).

3.4.2 All partners

Efficient management of IP in 2D-BioPAD is achieved through the adoption of a participatory process, based on which **all partners are actively contributing to the timely identification and assessment of the IP being born from their work** under the framework of the project.

Along these lines, **each partner is responsible for**: (i) identifying the IP they are bringing as Background for the implementation of the project and/or exploitation of its results; (ii) capturing and assessing the exploitability of the results stemming from their work in the project; (iii) protecting their results when meaningful; and ultimately (iv) safeguarding their exploitation by identifying and taking any necessary actions during or after the project (e.g. deciding on ownership issues, making any needed IP agreements, maintaining protection measures, etc.).

It is good practice for **partners to inform and consult with the EM** before deciding whether to protect a KER stemming from their activities or not – particularly if the partner is considering a potential joint IP scheme. **In case that the Work Package Leaders identify a new result generated under their respective Work Package, the EM must be informed**.

In order to facilitate the implementation of our IP management strategy, while supporting each partner to carry out their role in its framework, a dedicated methodology with respective tools have been customised for use in 2D-BioPAD, as outlined in the section that follows.

4. Methodology

4.1 Methodological Steps and Tools

The implementation of 2D-BioPAD's IP management strategy is realised through the utilisation of a tailored methodology along with a suite of IP management tools which aim at supporting all partners of the project to identify, protect and manage their Key Exploitable Results (KERs) in a way that paves the way for successful exploitation beyond the end of the project.

In particular, our **methodology** is aligned with the different IP management stages of our strategy and can be broken down into **4 distinct but interconnected steps,** as follows:

- **Step 1**: Identify any further **background** required for implementation or exploitation.
- **Step 2**: Assess project results and **define KERs** along with their owners.
- **Step 3**: Outline **exploitation routes** for KERs and decide on **protection measures**.
- **Step 4**: Craft **action plans for exploitation** (and commercialisation, if applicable).

In order to allow for the implementation of these methodological steps, the tools employed by partners in the context of 2D-BioPAD encompass (in brief) are the following:

- **Background identification/modification form**, which is to be used by partners to notify the Exploitation Manager in the case that they identify any further own Background required for implementation or exploitation of results as well as in the case that modifications to any already identified own Background need to take place.
- **Exploitability assessment and planning templates**, that partners can employ in order to capture and convey key information required for assessing the exploitability of the results stemming from their work in the project as well as to outline owners with their contributions, appropriate protection measures and potential exploitation routes.

At this stage of the project, an initial application of our methodology has been completed with the results outlined in the present report. During the later stages of the project, the Exploitation and Sustainability Plan will be updated twice more to capture and integrate the updated and final evolution of the identified KERs, ensuring that any access rights required (either for implementation or exploitation) are in place, as well as our plans for their exploitation (e.g. ownership amongst project partners, IP agreements or further actions required for making the KERs ready for exploitation, etc.).

With that in mind, the structure of our methodological tools along with the data that each one is designed to capture is concisely outlined in the sub-sections of this report that follow below.

4.2 Background Identification/Modification Form

In this context of 2D-BioPAD's IP management methodology, the background identification/modification form (see table below) is designed to **collect crucial information about the Background of partners**, **beyond of what is documented and agreed in the CA** of the project. In particular, the form serves a dual purpose as it can be used to: (i) identify any additional Background, on top of the Background already identified in the CA, along with its specific restrictions and/or conditions for implementation/exploitation; and (ii) to modify any previously identified Background and its respective restrictions and/or conditions if applicable.

Table 5: Background identification/modification form

Owner(s)	
Description	
Specific restrictions and/or conditions for implementation	
Specific restrictions and/or conditions for exploitation	
Connected KER(s)	

To this end, the form calls partners to identify the owner of the Background, provide a concise description of the Background as well as to clearly specify any restrictions and/or conditions for the use of the Background by the other partners for implementation or the exploitation of results. A direct reference to any connected KERs is also required if relevant. The form is completed on an ad hoc basis, when the need arises during the project, and is provided to the EM. The EM will then assess the proper course of action, following the relevant provisions of the project's CA and in cooperation with the proper management bodies of the consortium.

The **Background required for implementation and exploitation of 2D-BioPAD's results**, as identified by project partners by M6, is **outlined in Section 5** of this report. The background identification/modification form is included in its Annex (see Annex I).

4.3 Exploitability Assessment and Planning Templates

The exploitability assessment and planning templates of our IP management methodology are designed to **facilitate the work of the partners that is required to identify the KERs of the project as well as to carefully plan and act towards their sustainable use** (be it for research, commercial or other use) during and after the end of 2D-BioPAD. They are accordingly comprised of templates dedicated for exploitability assessment of results, exploitation planning per KER and exploitation planning per partner, as described below.

4.3.1 Exploitability assessment template

The exploitability assessment template aims at supporting partners towards identifying and **assessing the exploitation potential and readiness of results**, while also pin pointing and elaborating on **key aspects pertaining to exploitation and IP**, as depicted in the table below.

Table 6: Exploitability Assessment Template

Brief Description	
Creator(s) and relevant background (if applicable)	
Intended users and expected benefits	
Intended Exploitation route(s)	
IP Protection Measures	

In particular, besides a brief description of the KER identified, partners are also required to reflect on the following aspects which are important for the exploitation of the result at hand:

- **Creators and relevant background** (if applicable): The partners that were principally involved in the development of the key exploitable result are captured here and, if possible, the way each one contributed to this end. If applicable, any background used in order to create the key exploitable result along with its owner is recorded here too.
- **Intended users and expected benefits**: The main stakeholder groups that are expected to use the key exploitable result are listed in this part of the template. This includes consortium partners as well as external stakeholders if applicable (such as SMEs, corporates, research institutes, public authorities, citizens, etc.). Partners are also asked to describe why each of the aforementioned groups is expected to use the key exploitable result, highlighting the benefits to be derived from its use.
- **Intended exploitation route(s)**: This part of the template captures the main exploitation route foreseen for the key exploitable result along with any alternatives if applicable (e.g. exploitation in future research projects, commercialization, open access dissemination, etc.). Attention is given (to

the degree possible depending on the stage of the project) on how the key exploitable result will be provided to its target users (where they will find it, how they will access it, under what terms, etc.).

- **IP protection measures**: Partners are asked to define in this part of the template the measure considered (or measures if alternatives are to be considered) in order to protect the key exploitable result as well as the rationale behind their selection(s).

The main partner responsible for each KER is tasked with the completion of this template (in cooperation with other partners contributing to the creation of the specific result), which serves as the basis for discussing, agreeing and ultimately defining the exploitation plan for each KER of the project, along with the necessary actions required to make it a reality.

4.3.2 Exploitation planning per KER template

The purpose of the exploitation planning template in the framework of our IP management methodology is to lay out a road map for exploitation with concrete actions and a specific timeline for each KER, guiding all involved partners on the road to their selected exploitation route(s). An outline of the exploitation planning template is depicted in the table which follows.

Table 7: Exploitation Planning per KER Template

Action	What?	By Whom?	By When

This template calls for partners to consider and document the main points that need to be addressed to **ensure that 2D-BioPAD's KER(s) are ready and on the way for exploitation**. These points may include **key dimensions** ranging from **ownership** (e.g. decision on owners and/or terms of use for each involved partner, preparation of IP agreements) and **IPR** (such as the selection of proper protection measures and the preparation for any applications needed) over to the **actions needed to advance the exploitation readiness and prospect** of the KER (e.g. development, testing and/or validation, design of business model or plan). Such actions may also pertain to the **definition of appropriate dissemination measures** (such as finding a proper repository for the longer-term accessibility of the KER) as well as the **exploration of different alternatives for exploitation** (e.g. discussing and aligning with other consortium partners or organisations outside of the consortium for licensing or transferring the result, agreeing on costs sharing) if applicable for the chosen exploitation route of the KER.

For each of the identified points, partners are required to define the actions that need to take place in order to address them and advance towards their exploitation route as well as which partner needs to take action and by what time, creating a **clear (joint) action plan** to this end. The completion of the template for each KER is led by the main partner responsible for the respective KER and implemented in cooperation with other partners of the consortium contributing to the creation of the KER with guidance from the EM when needed.

4.3.3 Exploitation planning per partner template

The third and final template of our exploitability assessment and planning template package (see table below), aims at outlining the **individual exploitation plan of each 2D-BioPAD partner**, identifying which of 2D-BioPAD's KERs will fit in this context and how, while also facilitating the identification of potential synergies and joint exploitation pathways at the same time.

Table 8: Exploitation Planning per Partner Template

< Partner Short Name >	KER of main interest: KER1, KER2, …, KERX

Along these lines, through this template, each partner is required to indicate the project's **KERs that are of main interest** to their organisation in terms of exploitation and/or dissemination beyond the end of 2D-BioPAD. Moreover, they are asked to provide a concise **narrative that elaborates on how the exploitation routes of their selected KERs align and will be integrated within the current or future trajectory of their work**. With that in mind, this template is completed by each partner (starting with information from the GA if available) and is **gradually enriched and fine-tuned as the project progresses** in order to deliver the final individual exploitation plan of each partner by the end of 2D-BioPAD.

The **2D-BioPAD KERs** which were identified via the applications of our methodology and tools by this stage of the project, are **presented in Section 5**, while at the same time the **exploitation plans crafted per KER and per partner are outlined in section 6 and 7** respectively. The respective templates are annexed to this report (Annex II).

5. Background and Key Exploitable Results

5.1 2D-BioPAD's Identified Background

The Background required for the implementation of 2D-BioPAD and/or the exploitation of its results, as it has been identified by partners by this stage of the project, is presented by the following table.

#	Owner	Brief description	Specific restrictions and/or conditions for implementation	Specific restrictions and/or conditions for exploitation	Connected KER
1	UP-CATRIN	Data, results and expertise involving the chemical derivatization of fluorographite for the synthesis of graphene derivatives.	This background knowledge can be freely used within the project towards the goals	The background can be exploited only as a novel/innovative IP resulting from the project, under an ad-hoc agreement amongst the parties for a fair and reasonable remuneration.	KER#1

5.2 2D-BioPAD's Key Exploitable Results

The results of 2D-BioPAD, which have been assessed and considered as KERs by partners at this stage of the project, are listed in the table which follows along with a brief description.

Table 9: 2D-BioPAD's Key Exploitable Results

KER	Description	Main Partner(s) Responsible	Envisioned TRL
1	Graphene Derivatives	UP-CATRIN	5
2	Electrochemical biosensing module	ICN2	5
3	GFET biosensing module	GRAPHEAL	6
4	Aptamers for AD protein biomarkers	NOVA	5
5	MNPs as enablers and amplifiers	AUTH	6
6	Advanced Microfluidics	GRAPHEAL	5
7	AI for material sciences design	CeADAR	5
8	Clinical Pilot Studies Protocol	UEF	N/A
9	Regulatory Acceptability Plan	EVNIA	N/A
10	2D-BioPAD Business Models and Plan	Q-PLAN	N/A
11	Best Practices, lessons learnt, and recommendations	ZI	N/A
12	2D-BioPAD System	ICN2 & GRAPHEAL	7

More information regarding each 2D-BioPAD KER, along with the exploitation plan crafted for each one at this stage of the project, is provided in the next section of this report.

6. Exploitation plan per Key Exploitable Result

In this section of the Exploitation and Sustainability Plan, the main 2D-BioPAD KERs are described, along with the main contributors to their development. Information is also provided on who their intended users are, the benefits they stand to gain from exploiting that asset, as well as potential exploitation routes and IP protection measures. At the same time, any actions that may be needed to facilitate the KER intended exploitation route(s) are also identified, concisely outlining what needs to be done, when and by whom towards this end.

Along these lines, the above information is presented in two tables for each KER:

- One table summarises the exploitation assessment and plan of the specific KER.
- A second table summarises any actions needed for its exploitation or dissemination.

Each KER is presented in a different sub-section of this section, as follows.

6.1 Graphene Derivatives

Table 10: Exploitation plan for the Graphene Derivatives

Brief Description	Graphene derivatives which are i) electrochemically active, ii) ionically or electronically conductive, iii) with chemical modifications for improved immobilization of bioreceptors (for instance aptamers, peptides or antibodies) or other elements contributing to improving the sensing properties of the sensor
Creator(s) and relevant background (if applicable)	**Main:** UP-CATRIN **Contributors:** ICN2, AUTH, NOVA, GRAPHEAL, NUID UCD - CeADAR [Background #1]
Intended users and expected benefits	**Consortium Partners:** ICN2, GRAPHEAL: 1) ICN2 and GRAPHEAL may test UP-CATRIN's graphene derivatives to verify and confirm possible merits and advantages of its use as novel/innovative IP which are intended to be: graphene platforms for sensor performance. 2) ICN2 and GRAPHEAL may incorporate the graphene derivatives into the implementation of their biosensing modules (KER #2 and #3), during the project. Novel IP is expected to be generated. **Other stakeholders outside the consortium:** 1) Private companies active on the i) production of graphene and graphene derivatives, ii) production of graphene-based sensors, iii) use of biosensors. 2) Public bodies such as research institutes and universities interested in utilizing the graphene derivatives for testing in similar applications.
Intended Exploitation route(s)	1) Potential future research projects, 2) creating novel intellectual property, 3) commercialization, 4) publications in scientific research journals, 5) dissemination through social media and international conferences.
IP Protection Measures	1) In the project, we will seek to protect results as soon as they emerge, by means of patent protection. For this activity, UP-CATRIN will coordinate the

	IP protection with the institute's TTO (Dr. Jiri Navratil), Lawyer (Mrs. Linda Lososova) and, with external patent attorneys (Dr. Katerina Hartvichova).

Table 11: Actions needed for the exploitation of the Graphene Derivatives

Action	What?	By Whom?	By When
Intellectual property rights	Patent	UP-CATRIN, ICN2, GRAPHEAL	As soon as exploitable results are produced and identified
Development, testing and validation	i) Graphene derivatives ii) sensor device using graphene derivatives	UP-CATRIN (preliminary testing and characterization), ICN2 and GRAPHEAL testing after integration in the sensor.	By the end of the project
Ownership	IP rights	UP-CATRIN, ICN2, GRAPHEAL	-
Dissemination	Research results on the properties of graphene derivatives connected to the operation of the sensor	UP-CATRIN, ICN2, GRAPHEAL, Q-PLAN	After securing IP protection, or when result obtained if does not require IP protection.

6.2 Electrochemical biosensing module

Table 12: Exploitation plan for the Electrochemical biosensing module

Brief Description	The Electrochemical Biosensing Module is a crucial component of the 2D-BioPAD system designed for point-of-care early diagnosis of Alzheimer's Disease (AD). This module combines paper-based microfluidics with graphene-based electrochemical sensors to provide an automated and sensitive biosensing platform employing aptamers as recognition element and magnetic nanoparticles to enhance sample purification, minimize non-specific signals, and control flow during various stages of the bioassay. The architecture resembles a lateral flow bioassay, but it employs electrochemical readout instead of traditional optical methods.
Creator(s) and relevant background (if applicable)	**Main:** ICN2 **Contributors:** UP-CATRIN (graphene derivative for electrodes modified with DNA) AUTH (MNPs conjugated with aptamers) NOVA (aptamers selection)
Intended users and expected benefits	**Consortium Partners:** the final device will be provided to the clinical centers for clinical validation and use, targeting mainly HCPs. **Other stakeholders outside the consortium:** 1) **Clinical Laboratories**: Facilities performing diagnostic testing that can integrate the 2D-BioPAD system into their workflow for efficient and reliable AD screening.

	2) **Diagnostic Device Manufacturers**: Companies involved in the production of diagnostic devices, seeking to incorporate the Electrochemical Biosensing Module into their product portfolios. 3) **Research Institutions**: Academic and research organizations interested in advancing AD diagnostics, leveraging the capabilities of the Electrochemical Biosensing Module for their studies.
Intended Exploitation route(s)	1) **Research Collaborations**: Establish collaborations with research institutions and biotechnology companies to further optimize and validate the Electrochemical Biosensing Module. Collaborative efforts can bring diverse expertise and resources for rigorous testing and refinement. 2) **Clinical Trials**: Initiate clinical trials in collaboration with healthcare institutions and professionals to validate the module's performance in real-world scenarios. Collecting data from patient samples will strengthen the module's reliability and effectiveness. 3) **Commercialization Partnerships**: Seek partnerships with companies specializing in medical devices and diagnostics for manufacturing, distribution, and market penetration. Collaborate with established players to leverage their market reach and infrastructure. 4) **Licensing and Technology Transfer**: Explore opportunities for licensing the technology or entering into technology transfer agreements with established organizations. 5) **Regulatory Approvals**: Work closely with regulatory bodies to obtain necessary approvals for the Electrochemical Biosensing Module. Comply with international standards to ensure the module meets regulatory requirements for global acceptance. 6) **Public and Private Funding**: Pursue funding opportunities from both public and private sources to support further development, manufacturing scale-up, and market entry. Grants, venture capital, and public-private partnerships can provide crucial financial backing. 7) **Publications in scientific research journals**. 8) **Dissemination** through social media and international conferences.
IP Protection Measures	1) **Patent Filings**: File patents for novel aspects of the Electrochemical Biosensing Module, including unique configurations, sensor technologies, and integration methods. This will provide legal protection against unauthorized use or replication. 2) **Trade Secrets**: Identify critical aspects of the module's design and manufacturing process as trade secrets. Implement robust internal controls and confidentiality agreements to safeguard these trade secrets from unauthorized disclosure. 3) **Non-Disclosure Agreements (NDAs)**: Engage in partnerships, collaborations, and discussions with third parties under the protection of NDAs. This ensures that sensitive information about the Electrochemical Biosensing Module is not disclosed without legal consequences. The ownership of any intellectual property that arises from the work done in ICN2 will be owned by ICN2 and will be managed according to ICN2 policies.

Table 13: Actions needed for the exploitation of the Electrochemical biosensing module

Action	What?	By Whom?	By When
Intellectual property rights	Apply for a patent	ICN2	End of the project
Development, testing and validation	Further development will be needed to reach a higher TRL	ICN2	After the end of the project
Ownership	Establishment of a spin-off for commercialisation	ICN2 with the support of UP-CATRIN	After the end of the project
Dissemination	Promotional campaign to promote the new research findings to a wider audience	ICN2, Q-PLAN	After IPRs secured, during (ICN2, Q-PLAN) and after (ICN2) the project.

6.3 GFET biosensing module

Table 14: Exploitation plan for the GFET biosensing module

Brief Description	The GFET biosensing module is a crucial component of the 2D-BioPAD system designed for point-of-care early diagnosis of Alzheimer's Disease (AD). This module consists of sensitive graphene field effect transistors (GFETs) with high conductivity and mobility. The module will employ aptamers as recognition element for AD biomarkers and magnetic nanoparticles to enhance sample purification, minimize non-specific signals, and control flow during various stages of the bioassay. The architecture resembles a lateral flow bioassay, but it employs electrochemical readout instead of traditional optical methods.
Creator(s) and relevant background (if applicable)	**Main:** GRAPHEAL **Contributors:** UP-CATRIN (graphene derivative for electrodes modified with DNA) AUTH (MNPs conjugated with aptamers) NOVA (aptamers selection)
Intended users and expected benefits	**Consortium Partners:** the final device will be provided to the clinical centers for clinical validation and use, targeting mainly HCPs. **Other stakeholders outside the consortium:** 1) **Diagnostic Device Manufacturers**: Companies involved in the production of diagnostic devices, seeking to incorporate the GFET Biosensing Module into their product portfolios. 2) **Research Institutions**: Academic and research organizations interested in advancing AD diagnostics, leveraging the capabilities of the GFET Biosensing Module for their studies.
Intended Exploitation route(s)	1) **Research Collaborations**: Establish collaborations with research institutions and biotechnology companies to further optimize and validate the GFET Biosensing Module. Collaborative efforts can bring diverse expertise and resources for rigorous testing and refinement.

	2) **Clinical Trials**: Initiate clinical trials in collaboration with healthcare institutions and professionals to validate the module's performance in real-world scenarios. Collecting data from patient samples will strengthen the module's reliability and effectiveness. 3) **Licensing and Technology Transfer**: Explore opportunities for licensing the technology or entering into technology transfer agreements with established organizations. 4) **Regulatory Approvals**: Work closely with regulatory bodies to obtain necessary approvals for the GFET Biosensing Module. Comply with international standards to ensure the module meets regulatory requirements for global acceptance. 5) **Public and Private Funding**: Pursue funding opportunities from both public and private sources to support further development, manufacturing scale-up, and market entry. Grants, venture capital, and public-private partnerships can provide crucial financial backing. 6) **Dissemination** through social media and international conferences/events.
IP Protection Measures	1) **Patent Filings**: File patents for novel aspects of the GFET Biosensing Module, including unique configurations, sensor technologies, and integration methods. This will provide legal protection against unauthorized use or replication. 2) **Trade Secrets**: Identify critical aspects of the module's design and manufacturing process as trade secrets. Implement robust internal controls and confidentiality agreements to safeguard these trade secrets from unauthorized disclosure. The ownership of any intellectual property that arises from the work done in GRAPHEAL will be owned by GRAPHEAL and will be managed according to GRAPHEAL policies.

Table 15: Actions needed for the exploitation of the GFET biosensing module

Action	What?	By Whom?	By When
Intellectual property rights	Apply for a patent	GRAPHEAL	End of the project
Development, testing and validation	Further development will be needed to reach a higher TRL	GRAPHEAL	After the end of the project
Ownership	Introduce a new “product” to GRAPHEAL’s existing portfolio	GRAPHEAL with the support of UP-CATRIN	After the end of the project
Dissemination	Promotional campaign to promote the new research findings to a wider audience	GRAPHEAL, Q-PLAN	After IPRs secured, during (GRAPHEAL, Q-PLAN) and after (GRAPHEAL) the project.

6.4 Aptamers for AD protein biomarkers

Table 16: Exploitation plan for the Aptamers for AD protein biomarkers

Brief Description	Aptamers which will serve as biorecognition/specificity module of sensors proposed by other consortia members. The aptamers selected/identified here, will serve as probes for targeting the AD-biomarker proteins. Aptamers are highly selective towards their target, and hence careful consideration regarding the target form, easy commercial availability, and further maintaining the testing conditions is crucial to get specific aptamers and accurate testing. The aptamers are short single-stranded DNA/RNA molecules capable of forming unique three-dimensional folds. This 3D-shape also imparts specificity to the aptamers towards their targets.
Creator(s) and relevant background (if applicable)	**Main**: NOVA **Contributors**: ICN2, AUTH, CeADAR
Intended users and expected benefits	**Device manufacturers** The DNA aptamers are easy to modify with different functional groups, linkers, reporter dyes, etc., and hence can be used as probe in sensing devices. **Pharmaceutical R&D** The AD-biomarker specific aptamers will be of direct interest to different groups/companies working on Alzheimer diagnosis.
Intended Exploitation route(s)	Collaboration through commercialization partnerships with interested players.
IP Protection Measures	**Patent Protection:** The aptamer sequence will not be disclosed (rather no patent will be applied).

Table 17: Actions needed for the exploitation of the Aptamers for AD protein biomarkers

Action	What?	By Whom?	By When
Intellectual property rights	Aptamer sequence will not be disclosed	NOVA	During and after the project
Development, testing and validation	Rigorous testing of selected aptamers using SPR and BLI Truncation of full-length aptamers will be tried without compromising binding affinity.	NOVA	During and after the project
Ownership	Introduce a new “product” to NOVA’s existing portfolio	NOVA	After the end of the project
Dissemination	Promotional campaign to promote the new research findings to a wider audience	NOVA, Q-PLAN	During (NOVA, Q-PLAN) and after (NOVA) the project.

6.5 MNPs as enablers and amplifiers

Table 18: Exploitation plan for the MNPs as enablers and amplifiers

Brief Description	Magnetic nanoparticles (MNPs) to enhance sensitivity and amplification of the electrochemical signal of 2D-BioPAD sensor for the detection of Alzheimer's disease biomarkers. These are bi-phasic (Magnetite/Au) MNPs where magnetite will serve as focus for MNPs via external field drive, while Au will assure electric conduction with graphene substrate. The MNPs will also aim to enhance the stability of the sensor response by preventing non-specific interactions and improving the overall robustness of the sensor platform.
Creator(s) and relevant background (if applicable)	**Main:** AUTH will synthesize the MNPs and try to find optimum conjugation process with selected aptamers. **Contributors**: **NOVA** will select adequate aptamers for effective implementation of sensor. **ICN2** will examine sensor operation and signal acquisition.
Intended users and expected benefits	Potential intended users and main stakeholders for MNPs in AD diagnostics: 1) **Medical Professionals:** Neurologists, radiologists, and other healthcare professionals involved in diagnosing and treating Alzheimer's Disease are primary users of MNP-enabled diagnostic tools. Clinical partners participating in 2D-BioPAD also will also benefit. 2) **Diagnostic Laboratories:** Facilities specializing in medical imaging, genetic testing, and biomarker analysis may adopt MNP technologies to improve the efficiency and accuracy of their diagnostic workflows for Alzheimer's Disease. 3) **Medical Device Manufacturers:** Companies that develop diagnostic imaging systems, laboratory equipment, and data analysis software are stakeholders in the MNP ecosystem for AD diagnostics. 4) **Pharmaceutical Companies:** Biopharmaceutical firms involved in developing drugs and therapies for Alzheimer's Disease have a vested interest in accurate and early diagnosis of the condition. 5) **Technology Partners:** Companies specializing in hardware, software, and cloud computing infrastructure provide the technological foundation for MNP-enabled diagnostic solutions.
Intended Exploitation route(s)	1) For **research projects**, target users, including academic researchers, clinicians, and industry scientists, would access the key exploitable result through scientific publications, conference presentations, and collaborative research networks. 2) For **commercialization**, target users, including healthcare providers, diagnostic laboratories, and pharmaceutical companies, would access MNPs-based diagnostic products through commercial partners, distributors, and online marketplaces. 3) For **open access dissemination**, target users, including researchers, educators, and policymakers, would access MNPs-related resources through open-access repositories, scientific databases, and collaborative platforms. Access to this KER would typically be provided under terms specified by the relevant licensing agreements, open-access policies, or data sharing protocols. These terms may include provisions related to attribution, redistribution, modification, and

	commercial use, depending on the specific licensing arrangements and IPRs associated with the KER.
IP Protection Measures	1) **Patent Protection:** Patent protection offers legal rights and exclusivity for inventions related to MNPs, such as novel compositions, synthesis methods, functionalization techniques, diagnostic applications, and medical devices. 2) **Trade Secret Protection:** Trade secret protection safeguards confidential and proprietary information related to MNPs, such as proprietary manufacturing processes, formulation techniques, or quality control methods. 3) **Confidentiality Agreements and Non-Disclosure Agreements (NDAs):** Confidentiality agreements and NDAs provide legal safeguards for confidential information exchanged between parties involved in MNPs-related collaborations, partnerships, or technology transfer activities. 4) **Material Transfer Agreements (MTAs):** Material transfer agreements govern the transfer and use of MNPs-related materials, such as nanoparticles, reagents, cell lines, or biological samples, between research institutions, commercial entities, and academic collaborators. These measures collectively provide a comprehensive framework for protecting the key exploitable result of MNPs as enablers and amplifiers in AD diagnostics, safeguarding IPRs, promoting innovation, and facilitating collaboration and technology transfer in the field.

Table 19: Actions needed for the exploitation of the MNPs as enablers and amplifiers

Action	What?	By Whom?	By When
Intellectual property rights	Patent protection may cover inventions related to the synthesis, functionalization, characterization, and diagnostic applications of MNPs in AD diagnostics.	AUTH, Q-PLAN, ICN2	36th-48th month
Development, testing and validation	Development of MNPs-based Diagnostic Assays involving designing and synthesizing magnetic nanoparticles optimized for use in AD diagnostics.	AUTH, ICN2	36th-48th month
Ownership	Ownership of the KER may be subject to negotiation, legal agreements, and contractual arrangements among the parties involved. Clear delineation of ownership rights is essential to facilitate technology transfer, commercialization, and collaborative partnerships aimed at advancing MNPs-based diagnostic technologies for AD.	AUTH, ICN2	36th-48th month
Dissemination	Upon successful development, testing, and validation, MNPs-based diagnostic assays can be transferred to commercial partners for manufacturing, distribution, and commercialization. Technology transfer may involve licensing agreements, collaborations, or partnerships with industry partners, diagnostic companies, or healthcare	AUTH, Q-PLAN, ICN2	36th-48th month

	providers. Commercialization strategies include market entry, product launch, and post-market surveillance to ensure widespread adoption and continued improvement of MNPs-based diagnostic technologies for AD.	

6.6 Advanced microfluidics

Table 20: Exploitation plan for the Advanced microfluidics

Brief Description	Advanced microfluidics are employed to allow better treatment of biological fluids as well as detection of five biomarkers simultaneously. Different approaches will be employed for the electrochemical and GFET biosensing modules.
Creator(s) and relevant background (if applicable)	**Main:** GRAPHEAL, ICN2
Intended users and expected benefits	1) **Medical Device Manufacturers:** Companies that develop diagnostic imaging systems, laboratory equipment, and data analysis software are stakeholders in the MNP ecosystem for AD diagnostics. 2) **Pharmaceutical Companies:** Biopharmaceutical firms involved in developing drugs and therapies for Alzheimer's Disease have a vested interest in accurate and early diagnosis of the condition. 3) **Technology Partners:** Companies specializing in hardware, software, and cloud computing infrastructure provide the technological foundation for MNP-enabled diagnostic solutions.
Intended Exploitation route(s)	1) **Research Collaborations**: Establish collaborations with research institutions and biotechnology companies to further optimize and validate the Electrochemical Biosensing Module. Collaborative efforts can bring diverse expertise and resources for rigorous testing and refinement. 2) **Licensing and Technology Transfer**: Explore opportunities for licensing the technology or entering into technology transfer agreements with established organizations. 3) **Public and Private Funding**: Pursue funding opportunities from both public and private sources to support further development, manufacturing scale-up, and market entry. Grants, venture capital, and public-private partnerships can provide crucial financial backing. 4) **Publications in scientific research journals**. 5) **Dissemination** through social media and international conferences.
IP Protection Measures	1) **Patent Filings**: File patents for novel aspects of the Electrochemical Biosensing Module, including unique configurations, sensor technologies, and integration methods. This will provide legal protection against unauthorized use or replication. 2) **Trade Secrets**: Identify critical aspects of the module's design and manufacturing process as trade secrets. Implement robust internal controls and confidentiality agreements to safeguard these trade secrets from unauthorized disclosure.

Table 21: Actions needed for the exploitation of the Advanced microfluidics

Action	What?	By Whom?	By When
Development, testing and validation	Development, testing and validation	Development, testing and validation	Development, testing and validation
Further development will be needed to reach a higher TRL	Further development will be needed to reach a higher TRL	Further development will be needed to reach a higher TRL	Further development will be needed to reach a higher TRL

6.7 AI models for material sciences design

Table 22: Exploitation plan for the AI models for material sciences design

Brief Description	AI model design and training as a source of academic knowledge and technological development for specific applications on material science, aligned to the goals of the 2D-BioPAD project.
Creator(s) and relevant background (if applicable)	**Main:** NUID UCD - CeADAR. The background provided by this partner is the technical knowledge to process experimental laboratory data in order to train AI architectures capable of extract the main feature relationships to achieve the goals of creating a viable PoC IVD and architectures capable of generating new aptamer candidates to be synthesized and tested experimentally. **Contributors**: NOVA (supporting the selection of aptamers) UP-CATRIN, ICN2, GRAPHEAL (supporting the graphene's design)
Intended users and expected benefits	**Consortium stakeholders:** UP-CATRIN, ICN2 and GRAPHEAL are expected to benefit from the output of CeADAR's research by obtaining new aptamer structures that will support the optimization of their graphene biosensor creation. Besides the structures, AI-based optimal functionalization of graphene data will be provided. **External stakeholders:** Research institutions and companies interested in the development of biosensors for different biomarker applications or aptamer binding to graphene.
Intended Exploitation route(s)	**Academic exploitation:** Preparation of scientific publications, attendance to conferences and high-level dissemination. Use of the generated technologies as background for posterior projects, either directly or tangentially related to the aims of 2D-BioPAD. Offer of licensing the use and outputs of generative models to stakeholders interested in their exploitation.
IP Protection Measures	Patent or technology protected by NUID UCD - CeADAR.

Table 23: Actions needed for the exploitation of the AI models for material sciences design

Action	What	By Whom	By When
Intellectual Property Rights	Patent or protect generative models.	NUID UCD - CeADAR	By the end of the project.

Action	What	By Whom	By When
Development, testing and validation	Experimental confirmation of usability and reliability of results.	NUID UCD - CeADAR and consortium partners (GRAPHEAL, ICN2, UP-CATRIN, AUTH).	During the project, in the respective WP months.
Ownership	NUID UCD - CeADAR offering licensing.	NUID UCD - CeADAR	By the end of the project.
Dissemination	Scientific publications, conference participation, social network and/or traditional press.	NUID UCD – CeADAR and consortium partners (previously cited).	Along the project as partial results appear. At the end of the project as well.

6.8 Clinical pilot studies protocol

Table 24: Exploitation plan for the Clinical pilot studies protocol

Brief Description	Clinical pilot study protocol published in an international peer-reviewed journal as a source of academic knowledge for informing future study designs
Creator(s) and relevant background (if applicable)	**Main:** UEF **Contributors:** GAADRD, ZI
Intended users and expected benefits	**Consortium stakeholders:** The clinical study protocol design will benefit technical partners by supporting current and next steps that need to be taken towards future medical device registration. **External stakeholders:** Research institutions and companies interested in clinical pilot testing of devices for blood-based biomarkers.
Intended Exploitation route(s)	**Academic exploitation:** Preparation of open-access scientific publications, attendance to conferences and high-level dissemination. Use of the clinical study protocol as background for posterior projects, either directly or tangentially related to the aims of 2D-BioPAD. Protocol registration on relevant public registry, e.g. ClinicalTrials.gov or equivalent
IP Protection Measures	Copyright

Table 25: Actions needed for the exploitation of the Clinical pilot studies protocol

Action	What	By Whom	By When
Intellectual Property Rights	Copyright	UEF, GAADRD, ZI	By the end of the project.
Development and ethical approval	Finalising the protocol, obtaining ethical approval	UEF, GAADRD, ZI	Before starting recruitment of study participants

Action	What	By Whom	By When
Dissemination	Scientific publications, registration in relevant clinical study registry, conference participation, social network and/or traditional press.	UEF, GAADRD, ZI and consortium partners	Throughout the project after ethical approval is obtained.

6.9 Regulatory Acceptability Plan

Table 26: Exploitation plan for the Regulatory acceptability plan

Brief Description	Development of a Regulatory Acceptability Plan that will guide consortium partners how to meet regulatory requirements applicable for the 2D-BioPAD system. The Regulatory Acceptability Plan will outline non-clinical and clinical evidence requirements for a future CE-mark assessment with a focus on risk acceptability in terms of design, usability and performance thresholds. Within this context, the 2D-BioPAD system's classification, applicable standards, and required testing for verification and validation purposes will be determined. A strategy for a future pivotal clinical investigation will be proposed. The primary aim of the Regulatory Acceptance Plan will be to outline the criteria that enable European regulators to approve the use of the 2D-BioPAD system in a real-world setting (used by Alzheimer's patients and healthcare professionals). With that in mind, applicable requirements throughout the lifecycle of the 2D-BioPAD system will be described.
Creator(s) and relevant background (if applicable)	**Main:** EVNIA
Intended users and expected benefits	**Consortium partners:** The Regulatory Acceptability Plan will outline the regulatory requirements applicable for the 2D-BioPAD system that must be taken into account by the partners of the project for a future CE-mark assessment. Each partner of the project will be referring to different sections of the Regulatory Acceptability Plan based on their contribution to the solution's development. The Regulatory Acceptability Plan will be connected mainly with KER#9. **External stakeholders** Technology providers for PoC IVD devices. Key insights from the Regulatory Acceptability Plan could potentially be communicated to external stakeholders, including but not limited to 1) Academia and Research Institutions, 2) Healthcare Professionals, 3) Clinical Laboratories, and 4) MedTech manufacturers, to support regulatory strategies of stakeholders involved in the research, development and production of similar 2D-material ecosystems.

Intended Exploitation route(s)	The Regulatory Acceptability Plan could be potentially exploited in the following routes. The list is not exhaustive and could be updated with more routes during the progress of the project 1) CE-marking of the 2D-BioPAD system: the primary route of exploitation is a future CE-marking application for the regulatory approval of the 2D-BioPAD system in Europe under EU Regulation 2017/745 (MDR) 2) Research projects for further optimization of the 2D-BioPAD system's technology and/or development of new, similar applications 3) Licensing and Technology Transfer, Commercialization through the establishment of partnerships with MedTech stakeholders and/or Academia/Research Organizations 4) Publications in scientific research journals 5) Dissemination through social media and international conferences
IP Protection Measures	**Non-Disclosure Agreements (NDAs):** For the engagement in partnerships, collaborations, and discussions with third parties, such as MedTech manufacturers, Academia and Research Institutions, and Clinical Laboratories. This will ensure that sensitive information about the 2D-BioPAD system will not be disclosed.

Table 27: Actions needed for the exploitation of the Regulatory acceptability plan

Action	What	By Whom	By When
Design verification and preliminary testing	Partners will develop and verify the design of the 2D-BioPAD system. The User Requirements Specifications and the intended purpose of the 2D-BioPAD system will be proposed	All Consortium Partners	By the end of the project.
Dissemination & Communication	As above	EVNIA with the support from all Consortium Partners	After securing IP protection and signing of NDAs where applicable.

6.10 2D-BioPAD Business Models and Plan

Table 28: Exploitation plan for the 2D-BioPAD Business Models and Plan

Brief Description	Design of business models and a business plan for the commercial exploitation of the 2D-BioPAD assets.
Creator(s) and relevant background (if applicable)	**Main:** Q-PLAN **Contributors:** UP-CATRIN, ICN2, AUTH, GRAPHEAL, NOVA, EVNIA
Intended users and expected benefits	**Consortium partners:**

	The business models and the business plan will focus on elaborating a sustainable commercialization pathway for the 2D-BioPAD system. The complete business plan will be connected mainly with KER#12. **External stakeholders** Technology providers for PoC IVD devices. Key insights from the business modelling activity will (potentially) be communicated to external stakeholders to support business-oriented knowledge diffusion to the 2D-material ecosystem.
Intended Exploitation route(s)	The business models and plan will be part of the exploitation route of KER#12, i.e., the 2D-BioPAD system, supporting its potential commercialization. Key findings will also be used to support roadmap activities of the GFI.
IP Protection Measures	Copyright under appropriated Creative Commons license and/or trade secret.

Table 29: Actions needed for the exploitation of the 2D-BioPAD Business Models and Plan

Action	What	By Whom	By When
Testing, validation and fine-tuning	Partners will develop, assess, refine and validate business models in order to elaborate the business plan for the MIPs.	Q-PLAN with the support from all partners	During and after the duration of the project.
Dissemination & Communication	Presentation of the Business Models & Plans to potentially interested companies.	Q-PLAN with the support from all partners	During and after the duration of the project.

6.11 Best Practices, lessons learnt and recommendations

Table 30: Exploitation plan for the Best Practices, lessons learnt and recommendations

Brief Description	The best Practices, lessons learnt and recommendations will be part of the "D5.4 Cross-pilot Comparative Assessment" and will elaborate on the main findings of the 2D-BioPAD clinical pilot studies. Forming a set of guidelines, these insights will summary the best of the 2D-BioPAD outcomes leading future research in 2D-materials for biomedical applications such neurodegenerative diseases, e.g., Alzheimer's Disease.
Creator(s) and relevant background (if applicable)	**Main:** UEF, GAADRD, ZI **Contributors:** UP-CATRIN, ICN2, AUTH, NOVA, GRAPHEAL, EVNIA, Q-PLAN, NUID UCD - CeADAR.
Intended users and expected benefits	**External stakeholders:** - Healthcare professionals - Neurodegenerative diseases' researchers - Health system owners/decision makers - Patients and Caregivers - Technology providers

	Benefits: - Promote research in blood-based biomarkers using 2D-materials such as graphene
Intended Exploitation route(s)	Generated insights will be made publicly available as D5.4, scientific publications, and policy briefs. They will also be used to fuel future research activities, including other projects and initiatives in fluid-derived biomarkers for brain disorders, and beyond.
IP Protection Measures	The produced report and results will be protected via copyright. Similarly, any publications generated based on the insights of the clinical pilot studies will be also protected via copyright under appropriated Creative Commons license.

Table 31: Actions needed for the exploitation of the Best Practices, lessons learnt and recommendations

Action	What	By Whom	By When
Clinical pilot studies completion	To extract insights the clinical pilot studies should be completed with adequate data to allow for constructive analysis.	UEF, GAADRD, ZI/All partners	End of the project.
Dissemination	Promotion through the project channels as well as key European events and platforms.	ZI/All partners	Final semester of the project and beyond.

6.12 2D-BioPAD System

Table 32: Exploitation plan for the 2D-BioPAD system

Brief Description	A digitalised PoC IVD device based on the integration of KERs#1-#7 capable of analysing blood samples and detecting up to 5 protein biomarkers for early detection and progression monitoring of Alzheimer's Disease. For each biomarker, the device will wirelessly send quantitative data about its concentration to a mobile app. The mobile app will then offer this information along cut-off values and other relevant information to the healthcare professional to assist in their decision making.
Creator(s) and relevant background (if applicable)	**Main:** UP-CATRIN, ICN2, AUTH, GRAPHEAL, NOVA, CeADAR **Contributors:** GAADRD, UEF, ZI, EVNIA, Q-PLAN [Background #1]
Intended users and expected benefits	Users: 1) Healthcare professionals 2) Healthcare systems owners 3) Pharmaceuticals 4) Biotech providers 5) Policy makers

	6) Researchers (e.g., neurologists, biochemists, biologists, geneticists, etc.) Benefits: • Support low-cost blood testing for AD biomarkers • Early detection of AD • Screening for treatment options for AD (and potentially other diseases) • Progression and/or treatment effect monitoring • Further research on blood biomarkers
Intended Exploitation route(s)	1) Future **research projects** – the consortium will seek to engage if further research activities to progress the TRL of the system and seek knowledge on other uses (e.g., other bodily fluids, other biomarkers, etc.) 2) **Commercialisation**: before the end of the project the consortium will decide if the IP will be exploited via a newly established or an established company from the consortium institutions. This will be further explored during the project along with the respective IP Agreement.
IP Protection Measures	**Patent** or technology protected by the consortium. This will depend on the IPRs of KERs#1-7. **Trademark** for the protection of the brand.

Table 33: Actions needed for the exploitation of the 2D-BioPAD system

Action	What	By Whom	By When
Business Modelling and Planning	Detailed Business plan to outline the commercialisation pathway.	Q-PLAN/All partners	By the end of the project.
Intellectual Property Rights	IPR Agreement and Patent application. The patent application will also depend on the IPRs of KER#1-7.	Q-PLAN/All partners	The IPR Agreement will be finalized by the end of the project. The patent application will be sought right after.
Development, testing and validation	Further development, testing, and clinical validation to ensure high accuracy and reliability.	NUID UCD - CeADAR and consortium partners (GRAPHEAL, ICN2, UP-CATRIN, AUTH).	During the project, in the respective WP months.
Ownership	Newly or already established company(-ies), based on the IPR agreement.	All partners	Within the first year after the end of the project.
Regulatory approval	Initiative process for regulatory approval in US and Europe.	EVNIA/All partners	Within 3 years after the end of the project.
Dissemination	**Scientific:** Scientific publications, conference participation, social	All partners	During and after the end of the project. Commercial promotion will kick-off after the

	network and/or traditional press. **Commercial:** Social media campaigns.	trademark has been established.

7. Exploitation Plans per Partner

This section summarises, in tabular format, the assets of the 2D-BioPAD project that each partner is currently interested the most to exploit, as well as how they intend to proceed to this end.

Table 34: Individual exploitation plans per partner

UP-CATRIN	KERs of main interest: KER#1, KER#2, KER#3, KER#11, KER#12
UP-CATRIN actively engages with research and development on nanomaterials, nanotechnologies for various applications, including sensing. Therefore UP-CATRIN is interested in (i) integrating results into existing research practice to develop new components for biosensing solutions that go beyond what is planned in the project; (ii) elaborating new scientific publications with improved impact and visibility in the academic community; (iii) improving and updating teaching material to train high-level engineers and scientists; (iv) transferring new technology to industrial/commercial partners via contractual research & development projects, through spin-offs or licensing to a third party); (v) leveraging the collaborations and visibility forged during the project to open up new R&I avenues; and (vi) leveraging the obtained expertise, know-how and IP for initiating new activities for attracting funding.	
Q-PLAN	**KERs of main interest: KER#8, KER#9, KER#10, KER#11, KER#12**
Q-PLAN is interested in exploiting the above KERs in a twofold way. First, QPL will use them to broaden and enhance its services portfolio and in particular the business support services directed to healthcare technology providers, healthcare professionals, health system owners and policy makers. By broadening its services portfolio, Q-PLAN aims to also investigating new clients and collaborations in the healthcare sector as the fields cross-cutting the 2D-BioPAD project (2D-materials, nanotechnology, neurosciences, medical devices, PoC IVD, etc.) are of strategic interest to Q-PLAN. Second, Q-PLAN will use the 2D-BioPAD results to new proposals and projects within the Horizon Europe framework and beyond. The tools can be used as background knowledge to the creation of new products and services or further research activities in future projects and other research and innovation endeavours. Finally, Q-PLAN is interested to explore and support a joint exploitation for KER#12, i.e. the 2D-BioPAD system.	
ICN2	**KER of main interest: KER#2, KER#12**
ICN2 is interested in leading the critical task of co-designing the 2D-BioPAD system requirements and architecture, with a focus on both functional and non-functional aspects. The primary objective is to create a reliable, time-efficient, and cost-effective point-of-care solution for the early diagnosis of Alzheimer's Disease (AD). Specifically, ICN2 is interested in (i) co-designing the 2D-BioPAD system for early AD diagnosis; (ii) collaboration with all stakeholders for effective implementation and support; (iii) integration of paper-based microfluidics with graphene-based electrochemical sensors using aptamers as recognition elements; (iv) allowing an electrochemical readout, digitized via a mobile app; (v) using MNPs for sample purification and flow control; (vi) integrating results into research practices, new scientific publications, updating teaching material, technology transfer to partners, opening new R&I avenues, and leveraging expertise for funding activities; (vii) maximizing impact, contributing beyond project scope, and fostering innovation in biosensing solutions.	
GRAPHEAL	**KER of main interest: KER#3, KER#6, KER#12**
GRAPHEAL will elaborate on their individual exploitation plan in the second version of this report (i.e., D6.5). The exploitation pathway described in the GA remains relevant.	
AUTH	**KER of main interest: KER#5**
The key exploitable results that would be of interest to AUTH, an organization focused on promoting research and innovation in the field of magnetic nanoparticles (MNPs) for medical applications, could include: **Novel Synthesis Methods:** Development of novel synthesis methods for manufacturing magnetic nanoparticles with tailored properties, such as size, shape, composition, and surface functionalization.	

Biosensors and Assays: Design and fabrication of biosensors and diagnostic assays based on magnetic nanoparticles for the detection of biomarkers associated with various diseases, including infectious diseases, cancer biomarkers, and neurodegenerative markers in AD. **Theranostic Platforms:** Development of theranostic platforms integrating diagnostic and therapeutic functionalities using magnetic nanoparticles. **Regulatory Approvals and Commercialization:** Successful regulatory approvals and commercialization of MNPs-based medical products and technologies, including drug delivery systems, imaging agents, and diagnostic assays. **Intellectual Property Portfolio:** Establishment of a strong intellectual property portfolio encompassing patents, trademarks, and trade secrets related to MNPs-based innovations. **Collaborative Partnerships:** Formation of collaborative partnerships with academia, industry, and healthcare organizations to advance research, development, and commercialization of MNPs-based medical technologies. These key exploitable results align with AUTH's mission to promote research, innovation, and collaboration in the field of applications, contributing to advancements in healthcare and patient well-being.
NOVA — **KER of main interest: KER#4, KER#7**
NOVA is interested in integrating results into current research practices with a view to further enriching their portfolio of services and products, while also leveraging expertise for future funding activities. Knowledge acquired will also lead to enriching NOVA's inhouse capability and technology to develop aptamers against different AD biomarker proteins (and beyond). In addition, NOVA is interested in further capitalizing the potential of AI for the design of novel aptamers with improved capabilities. Main relevant findings from 2D-BioPAD will be incorporated to existing scientific work to integrate AI technologies to the design and production pipeline of aptamers.
UEF — **KER of main interest: KER#8, KER#11**
The exploitation pathways that would be of interest to UEF, an organization focused on promoting research and innovation in the field of dementia-related diseases, could include: **Clinical study protocol:** the UEF Brain Research Unit is interested in both development and implementation of innovative clinical study designs for research on dementia diseases **Best practices, lessons learnt and recommendations**: relevant for future projects connecting clinical study designs with healthcare implementation and regulatory aspects **Collaborative Partnerships:** Formation of collaborative partnerships with academia and industry in both medical and technical fields to advance dementia-related research and development
GAADRD — **KER of main interest: KER#8, KER#11, KER#12**
The exploitation pathways that would be of interest to GAADRD, an organisation focused on the needs of people with dementia and related diseases and their families in a multidisciplinary approach, could be: - **Clinical study protocol**: GAADRD has a great research experience and is always interested in innovative protocol development and implementation for research purposes regarding Dementia. - **Best practices, lessons learnt and recommendations**: The project will promote the research on blood based biomarkers and provide a valuable input for future research attempts. - **Collaborative Partnerships**: Collaboration in a multidisciplinary consortium, with Academic and Industrial leaders promotes the research and the knowledge derived during the process. - **2D-BioPAD System**: To test the device during the project and use it in future research protocols and hopefully, in the everyday clinical practice as an indicator of early diagnosis biomarker driven.
EVNIA — **KER of main interest: KER#9**
Evnia is interested in exploiting the Regulatory Acceptability Plan to: - broaden and enhance its client portfolio and in particular the provision of regulatory and clinical support services to MedTech manufactures, healthcare technology providers, health system owners and regulatory policy makers at the fields of 2D-materials; nanotechnology materials, medical devices, PoC IVDs, etc;

- participate in new projects within the Horizon Europe framework and beyond by using the Regulatory Acceptability Plan as background knowledge for the development of new products and services at the fields mentioned above; - explore and support a joint exploitation for KER#12, i.e. the 2D-BioPAD system.	
ZI	**KER of main interest: KER#8, KER#11**
The exploitation pathways that would be of interest to ZI could include: **Clinical study protocol:** ZI is interested in both development and implementation of innovative clinical study designs for research on dementia diseases **Best practices, lessons learnt and recommendations**: relevant for future projects connecting clinical study designs with healthcare implementation and regulatory aspects **Collaborative Partnerships:** Formation of collaborative partnerships with academia and industry in both medical and technical fields to advance dementia-related research and development	
NUID UCD - CeADAR	**KER of main interest: KER#4, KER#7**
CeADAR's exploitation plan in terms of the KERs' of interested is aligned with its goals of academic contribution and technology innovation. In particular: - **Intellectual property**: AI models for intelligent material design. These include: predictive models for physical properties (optimal graphene functionalization, optimal aptamer length for high affinities) and generative models (aptamer structure candidate generation). - **Licensing**: Use and byproducts (in case of generative AI) for stakeholders, within 2D-BioPAD and external clients after the project is finalized. - **Academic/Research portfolio**: Leverage acquired and built project for scientific publications, dissemination, and as background for future projects within the scope of CeADAR activities.	

8. Conclusions and Way Forward

The report on the initial version of the 2D-BioPAD's Exploitation and Sustainability Plan has highlighted the main principles of the project's strategy, methodology and tools for IP management, as these have been adjusted, adopted and applied within the framework of 2D-BioPAD. More importantly, the report presented the results from their application in practice, reflecting the work of the partners so far in terms of assessing the exploitability of the project's results, identifying Key Exploitable Results (KERs), defining their owners and eventually planning the way towards their exploitation.

Along these lines, this report also provided an overview of the project's Background and Key Exploitable Results (KERs) as they have been identified at this stage of the project. A plan for each KER has been crafted and reflected within this version of the report, including exploitation routes and concrete actions towards this end. From here on out, partners will be working on their exploitation plans (per KER as well as per partner). 2D-BioPAD's Exploitation and Sustainability Plan will be updated again during the project (i.e. by M24 and M48), depicting the latest status in terms of exploitation planning.

The next version of this report will also elaborate on joint exploitation activities or related material as will emerge from the Graphene Flagship Initiative and the 2D-BioPAD's synergies (e.g., MUNASET), in view of the innovation roadmap required.

The EM is responsible for updating the Exploitation and Sustainability Plan. In collaboration with all partners, the EM will monitor the activities of the project as they evolve in order to capture and assess any new results (not already identified), pave the way towards the exploitation of the already identified KERs as well as to resolve any potential conflicts that may arise along the way, with a view to jointly fostering smooth post-project exploitation of results in a sustainable manner.

ANNEX

Annex I - Background Identification/Modification Form

According to the Grant Agreement[36], Background is defined as "data, know-how or information (…) that is needed to implement the Action or exploit the results". Partners must identify and agree amongst them on the Background for the project. In this context, the purpose of this form is to identify: (i) any additional Background, on top of the Background already identified in the Consortium Agreement of the project along with its specific restrictions and/or conditions for implementation/exploitation; as well as (ii) the need to modify any previously identified Background along with its specific restrictions and/or conditions for implementation/exploitation.

< Insert title of Background >	
Owner(s)	Please specify the owner of the Background.
Description	Please elaborate here a brief description of the Background.
Specific restrictions and/or conditions for implementation[37]	Please list here any restrictions and/or conditions for accessing and using the particular Background for the implementation of the project.
Specific restrictions and/or conditions for exploitation[37]	Please list here any restrictions and/or conditions for accessing and using the particular Background for exploitation of project results.
Connected Key Exploitable Result(s)	Please list here any Key Exploitable Result(s) for which the Background is required in the context of implementation and/or exploitation.

[36] See Article 16.1, "Background and access rights to background", of the Grant Agreement

[37] See Article 16.4, "Specific rules on IPR, results and background", of the Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action"

Annex II - Exploitability Assessment and Planning Templates

Exploitability Assessment Template

(to be completed by the main partner responsible for each KER)

< Insert title of Key Exploitable Result >	
Brief description	Please enter here a brief description of the key exploitable result that further elaborates on the initial description included in the DoA.
Creators and relevant background (if applicable)	Please list here the partners that were principally involved in the development of the key exploitable result and, if possible, the way each one contributed to this end. If applicable, clearly state any background used in order to create the key exploitable result along with its owner.
Intended users and expected benefits	Please list here the main stakeholder groups that are expected to use the key exploitable result. This includes consortium partners as well as external stakeholders if applicable (such as SMEs, corporates, research institutes, public authorities, citizens, etc.). Briefly describe why each of the aforementioned groups is expected to use the key exploitable result, highlighting the benefits to be derived from its use.
Intended exploitation route(s)	Please list here they key exploitation route(s) (e.g. exploitation in future research projects, commercialization, open access dissemination, etc.) foreseen for the key exploitable result, highlighting how it will be provided to its target users (where they will find it, how they will access it, under what terms will they be able to use it, etc.).
IP protection measures	Please mention the measure selected to protect the key exploitable result as well as the rationale behind its selection (concisely). e.g., copyright (and respective license), NDA, Trade mark, Trade secret, Patent, Utility Model, Industrial Design, other…

Exploitation Plan per KER Template

(to be completed by main partner responsible for each KER)

Actions needed to make the key exploitable result ready for use			
Action	**What?**	**By Whom?**	**When?**
Intellectual property rights			
Development, testing and validation			
Ownership			
Dissemination			
…			

Exploitation Plan per Partner Template

(to be completed by each partner for the main KERs which they intend to use)

< Insert Partner Short Name >	**KER of main interest:** XXX, XXX and XXX
Please mention here the main key exploitable results that are of interest to your organisation in terms of exploitation beyond the end of the grant. Explain how they fit with your current work and/or future plans, describing how you plan on exploiting each one.	

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

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