2D BioPAD

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

D7.2 Data Management Plan, Version 1

Q-PLAN

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Executive Summary

This document constitutes the initial version of the **Data Management Plan (DMP)** and has been elaborated as a deliverable (D7.2) in the framework of the 2D-BioPAD project. 2D-BioPAD sets out to create a cost-effective, non-invasive point of care/self-testing tool for the early and accurate prognosis (assistive diagnosis) of Alzheimer's Disease (AD), with special focus on earlier stages such as Subjective or Mild Cognitive Impairment (SCI/MCI).

In this context, the initial version of the project's DMP sets out the overall methodological principles pertaining to the management of the data that will be collected, generated and/or re-used in the framework of 2D-BioPAD, safeguarding sound and ethical data management along the entire duration of the project. Moreover, it provides a first, yet still meaningful overview of 2D-BioPAD's data, as identified in this early stage of the project, along with information on the methodology pertaining to their management as well as to making them Findable, Accessible, Interoperable and Re-usable (FAIR).

The initial version of the DMP is the first of the three versions of 2D-BioPAD's DMP to be produced in the course of the project and will serve as a living document (D7.2 DMP – Initial Version delivered in M4 will be updated to D7.3 DMP, Version 2 in M24 and ultimately fixed as D7.4 DMP, Version 3 in M48). Along these lines, the DMP will be updated and further elaborated during the project to reflect an accurate, up-to-date and ultimately comprehensive plan for managing the data that will be collected, generated and/or re-used by the project across their entire life cycle, both during and after the completion of 2D-BioPAD.

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List of Terms and Definitions

Table 1: Terms and Definitions

Abbreviation	Definition
2D	two-dimensional
AB	Advisory Board
AD	Alzheimer's Disease
CA	Consortium Agreement
DCMI	Dublin Core Metadata Initiative
DMP	Data Management Plan
DOI	Digital Object Identifier
DPO	Data Protection Officer
EC or Commission	European Commission
EEA	European Economic Area
EU	European Union
FAIR	Findable, Accessible, Interoperable and Re-usable
FET	Field-Effect Transistor
GA	Grant Agreement
GDPR	General Data Protection Regulation
GFI	Graphene Flagship Initiative
HCP	Healthcare Professionals
HTML	Hypertext Markup Language
ICH	International Council for Harmonisation
IVD	in-vitro diagnostics
MCI	Mild Cognitive Impairment
MNPs	Magnetic nanoparticles
OAI	Open Archives Initiative
OAI-PMH	Open Archives Initiative Protocol for Metadata Harvesting
PC	Project Coordinator
PDB	Public database
PID	Persistent Identifier
PMS	Policy Monitoring System
PoC	Point-of-Care
PPI	Patient and Public Involvement
QA	Quality Assurance
QC	Quality Control
SCI	Subjective Cognitive Impairment
SIAB	Scientific and Industrial Advisory Board
SME	Small and Mid-size Enterprise
TBD	to be decided
TL	Task Leader
URL	Uniform Resource Locator
WP	Work Package
WTL	Work Task Leader
WPL	Work Package Leader

1. Introduction

The current document represents the initial version of 2D-BioPAD's Data Management Plan (DMP), which has received funding from the European Union's Framework Programme for Research and Innovation Horizon Europe under Grant Agreement No 101120706.

2D-BioPAD aims to **introduce a fast** and **cost-effective**, **non-invasive, reliable, digitally and graphene-enabled Point-of-Care** (PoC) ***in-vitro*** **diagnostics** (IVD) **system** for supporting the **early diagnosis** and **progression monitoring of Alzheimer's Disease** (AD) directly at primary healthcare settings. To achieve this, and tackle the scientific challenge, the technological and market gap of PoC IVD for AD, 2D-BioPAD leverages the unique properties of 2D materials, such as graphene and its derivatives. The 2D-BioPAD system and its impact will be demonstrated in 3 clinical centres in **Finland, Greece, and Germany**, under two clinical pilot studies, one retrospective with existing samples and one engaging up to 300 MCI/AD subjects in real-life clinical practice. In every step, and from the very beginning, 2D-BioPAD will go beyond current norms and involve a wide range of stakeholders, to identify the essential safety and ethical-by-design principles and guidelines that can accelerate uptake at primary healthcare settings and maximise acceptance and impact to both physical and digital supply chains.

To this end, the **consortium** of 2D-BioPAD brings together a complementary and interdisciplinary group of **11 partners across 8 different countries** within the EU, as presented in the **Table 2**.

Table 2: 2D-BioPAD partners

Partner Role*	Partner No	Partner Name	Partner Short name	Country
COO	1	UNIVERZITA PALACKEHO V OLOMOUCI - CATRIN	UP-CATRIN	CZECHIA
BEN	2	Q-PLAN INTERNATIONAL ADVISORS PC	Q-PLAN	GREECE
BEN	3	FUNDACIO INSTITUT CATALA DE NANOCIENCIA I NANOTECNOLOGIA	ICN2	SPAIN
BEN	4	GRAPHEAL	GRAPHEAL	FRANCE
BEN	5	ARISTOTELIO PANEPISTIMIO THESSALONIKIS	AUTH	GREECE
BEN	6	NOVAPTECH	NOVA	FRANCE
BEN	7	ITA-SUOMEN YLIOPISTO	UEF	FINLAND
BEN	8	ELLINIKI ETAIRIA NOSOY ALZHEIMER KAI SYGGENON DIATARACHON SOMATEIO	GAADRD	GREECE
BEN	9	EVNIA APS	EVNIA	DENMARK
BEN	10	ZENTRALINSTITUT FUER SEELISCHE GESUNDHEIT	ZI	GERMANY
BEN	11	UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN	NUID UCD/ CeADAR	IRELAND

All partners of 2D-BioPAD's consortium adhere to sound data management principles in order to ensure that the meaningful data collected, generated and/or re-used throughout the duration of the project are well-managed, archived and preserved, in line with the structure and guidelines of the Horizon Europe Data Management Plan Template[1].

The methodology of 2D-BioPAD for data management builds on know-how, tools and templates that were developed internally by Q-PLAN as well as on good practices and templates from the literature (such as the

[1] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/report/data-management-plan_he_en.docx

Horizon Europe Data Management Plan Template). As in previous EU-funded projects, tailored modifications to the methodology were implemented for 2D-BioPAD as well, in order to comply with the GA conditions and the particularities of the project. Along these lines, this deliverable presents the adjusted methodology as it was further developed and applied in the context of 2D-BioPAD, as well as presents the results from its application during the project.

Along these lines, this initial version of the DMP aims to achieve the following objectives:

- Describe the data management lifecycle for the data to be collected, generated and/or re-used in the framework of 2D-BioPAD, serving as the key element of good data management.
- Outline the methodology employed to safeguard the sound management of the data collected, and/or generated as well as to make them Findable, Accessible, Interoperable and Re-usable (FAIR).
- Provide information on the data that will be collected, generated and/or re-used and the way in which it will be handled during and after the end of the project along with the standards applied to this end.
- Describe details on how the data will be made openly accessible and searchable to interested stakeholders as well as its curation and preservation.
- Address the management of any research outputs other than data in line with FAIR principles.
- Present information on the resources to be allocated so as to make data FAIR clearly identifying responsibilities pertaining to data management, while addressing data security and ethical aspects.

With the above in mind, this initial version of the DMP is structured in 8 distinct chapters, as follows:

- **Chapter 1** provides introductory information about the DMP, the context in which it has been elaborated as well as its objectives and structure;
- **Chapter 2** presents a summary of the data to be collected/generated or re-used during the activities of 2D-BioPAD including its purpose as well as its types and formats. Additionally, it outlines its origin, expected volume and the stakeholders that may find it useful;
- **Chapter 3** describes the methodology that is applied in 2D-BioPAD in order to safeguard the effective management of data across their entire lifecycle, making it FAIR;
- **Chapter 4** presents the management of other research outputs that may be generated or re-used throughout 2D-BioPAD and provides sufficient details on making them FAIR;
- **Chapter 5** estimates the resources required for making the project's data FAIR, while also identifying data management responsibilities;
- **Chapter 6** outlines the data security strategy applied within the context of 2D-BioPAD along with the respective secure storage solutions employed;
- **Chapter 7** addresses ethical aspects as well as other relevant issues pertaining to the data collected/generated or re-used during the implementation of the project;
- **Chapter 8** concludes on the next steps foreseen in the framework of the project with respect to its data management plan.

Annexed in the document are (i) the project's Privacy Policy[2] (Annex I), the templates for the (ii) Informed Consent Form[3] (Annex II) and (iii) the Data Subject Request Form (Annex III) as well as (iv) the Record of Processing Activities (Annex IV), which will be used during the implementation of the project's activities to ensure compliance with relevant applicable EU and national regulation(s).

Note that the **DMP is not a fixed document**. It evolves during the lifespan of the project and **will be further elaborated and updated at least twice more throughout the duration of 2D-BioPAD** (**i.e., as D7.3 at M24 and D7.4 at M48**). Additional ad hoc updates may also be realised (if necessary), in order to include new data, better detail and/or reflect changes in the methodology or other aspects relevant to their management (such as costs for making data FAIR, size of data, etc.), changes in consortium policies and plans or other potential external factors. Q-PLAN is responsible for the elaboration of the DMP and with the support of all partners will update and enrich it when required.

Furthermore, the present version of the DMP does not delve into the data that will be handled through the two pilot studies. The protocol(s) (process, documents, etc.) for the data related to the pilot studies, namely the biological fluid samples, the subjects' profiles, etc., will be defined via the activities of T5.1 and will be documented in D5.1. Key aspects, will be incorporated in the second version of the DMP, i.e., **D7.3 at M24.**

[2] A tailored Privacy Policy will also be drafted later in the course of the project regarding the mobile app that will accompany the 2D-BioPAD device. The tailored version will be included in Version 2 of the Data Management Plan.
[3] A tailored Consent Form will also be drafted later in the course of the project to be shared with the subjects that will be included in the clinical pilot studies. The tailored version will be included in Version 2 of the Data Management Plan.

2. Data summary

2D-BioPAD will collect/generate or re-use meaningful non-sensitive data that do not fall into any special categories[4] of personal data as those are described within the General Data Protection Regulation[5] (GDPR). Sensitive data are also expected to be collected/generated during the clinical pilot studies by the clinical centres but will not be circulated to the consortium prior to their anonymisation or psedonymisation (more details about how sensitive data are expected to be handled by the clinical partners will be elaborated in D5.1). These data may be quantitative, qualitative or a blend of those in nature and will be analysed from a range of methodological perspectives with a view to producing insights that will successfully feed 2D-BioPAD's activities, enable us to deliver evidence-based results and ultimately achieve the objectives of the project. With that in mind, the second chapter of the DMP starts by explaining the purpose for which this data will be collected/generated and how it relates with 2D-BioPAD. It proceeds by describing the different types and formats of these data as well as their origin and expected volume, before concluding with an overview of potential stakeholders for whom they may prove useful for re-use.

2.1 Purpose of data collection/generation or re-use and its relation to the objectives of the project

In order to successfully meet its objectives and ensure the production of evidence-based results, 2D-BioPAD entails several activities during which data will be collected/generated or re-used. The purpose for which these data are collected/generated or re-used is interrelated with the objective of the activity during which they are produced.

In particular, these activities along with their objectives in the framework of 2D-BioPAD are as follows:

1. **Mapping and analysis of point-of-care AD solutions**, in order to delve deeper into the user-centred requirements, needs and challenges and to shed light on biomarkers for early detection of AD, clinical needs and challenges, technological solutions, key actors and socioeconomic perspectives for clinics and health systems.
2. **Analysis of the needs, challenges, and available solutions for reliable, cost-effective, safe, and ethical early diagnosis of AD**, in the context of introducing design guidelines for next-generation 2D-material-based PoC IVD systems and to also feed into the requirements and specification of the 2D-BioPAD framework.
3. **Cross-regional pilot studies evaluation and validation**, to evaluate and validate the results deriving from the clinical pilot studies through relevant performance criteria and metrics, the End-user survey and the wider survey addressed to key stakeholders.

[4] Special categories of personal data according to Regulation (EU) 2016/679 of the European Parliament (General Data Protection Regulation) include personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.

[5] Regulation (EU) 2016/679 of the European parliament and of the council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016R0679

4. **Regulatory Acceptability Activities, Plan, and Policy Recommendations**, in order to develop a User Requirements Specification Report and a Regulatory Acceptance Plan/Regulatory Strategy for the 2D-BioPAD solutions under development.
5. **Collaboration and Synergies with relevant projects and Initiatives**, in order to coordinate, develop and benefit from synergies with other relevant EU initiatives and to establish a close collaboration with Graphene Flagship Initiative.
6. **Setup and Operation of Scientific and Industrial Advisory Board (SIAB).** SIAB will be comprised of experts in diverse 2D-Materials, Nanotechnology, AI, and Neurosciences who provide strategic guidance in key stages of the project, contributing with their expertise and representing the views and interests of their stakeholder communities in order to better align the results of the project with them.
7. **Co-designing the 2D-BioPAD System Architecture**, involving a collaborative and iterative process to refine specifications, aligned with requirements from T1.1 and T1.2, for developing a cutting-edge biosensing platform, integrating paper-based microfluidics, graphene-based sensors, and magnetic nanoparticles, to achieve precise detection of Alzheimer's disease biomarkers, facilitating subsequent implementation activities in WP2-WP4 in
8. **Synthesis of Aptamers for AD protein biomarkers**, in order to choose 5 DNA aptamers per target.
9. **Evaluation of Aptamers**, in order to study the aptamers' characteristics and evaluate them via specific protocols to finally optimise them.
10. **Aptamer generation and optimization of aptamers**, to predict aptamer structures of high affinity, to optimise the length of aptamers and to propose new optimal aptamer sequences.
11. **Synthesis, characterization and evaluation of magnetic nanoparticles**, to synthesise magnetic nanoparticles that will be used for sample purification and that will act as flow control at different stages of the bioassay.
12. **Immobilization, Functionalization & Evaluation of Conjugated MNPs/Aptamers/Biomarkers**, in order to optimize the aptamers' immobilization efficiency on MNPs and the rate of MNPs-Aptamers/biomarkers, as well as to perform a systematic investigation of the binding capacity of conjugated MNPs/Aptamers with the selected biomarkers.
13. **Synthesis of conductive functionalized graphenes**, towards selectively and densely functionalized graphene derivatives via the chemistry of fluorographene. Attach out-of-plane binding sites for the biorecognition units. The functionalized graphenes should preserve their conductivity, electrochemical activity and keep the structure of ssDNA intact.
14. **Conjugation of functionalized graphenes with biorecognition ssDNA units,** to develop electrochemically active and conductive signal transducers, which will be selective for the AD biomarkers facilitated by the specific binding of the biomarkers to the graphene-immobilized ssDNA units.
15. **Synthesis of Janus type functionalized graphene**, to obtain graphene derivatives with only one basal plane with appropriate functionalities to conjugate the ssDNA biorecognition units, while retaining the other basal plane without or with different functionalization for improved interaction with the substrate of the sensor (e.g., the gate material of the FET sensor or the paper of the electrochemical sensor).
16. **Conjugation of Janus graphene with ssDNA for non-covalent functionalization of the FET graphene gate**, to conjugate the functionalized side of Janus graphene with ssDNA in mild conditions to provide selective recognition of the MNP/aptamers/biomarker complexes during the operation of the sensor.

The biorecognition units will be located on the one basal plane of graphene, while the second basal plane will remain pristine graphene for higher affinity to FET gate modification.

17. **Fabrication and Testing of the Graphene-based Electrochemical biosensor**, to develop reproducible PoC lateral flow electrochemical sensors, leveraging patented ICN2 techniques to print/stamp graphene-based electrodes on paper substrates, thereby enabling sensitive and selective biomarker detection in clinical scenarios.
18. **Fabrication and Testing of the Graphene-based FET biosensors**, to design and realize reproducible PoC FET sensors, leveraging GRAPHEAL designs (2D models and masks) to fabricate and integrate FET bio sensors in graphene/polymer films, to enable biomarker detection.
19. **Aptamer affinity prediction**, to train AI models to be able to predict aptamer affinity.
20. **Graphene Functionalization Optimization**, to create a multimodal AI capable of optimizing the functionalization by combining structural and tabular data.
21. **Advanced Microfluidics for Identifying Multiple Biomarkers**, to assess for the correct preparation, separation and delivery of the testing fluids on the sensors.
22. **Intelligent decision support module & User Interfaces,** to design and write programs and algorithms enabling data processing, data aggregation and fusion; as well as in-situ analysis and diagnostics.
23. **Casing prototyping and assembly**, to design and fabricate using CAD software and 3D printing technology the hardware surrounding the biosensor technology.
24. **Integration lab testing and fine tuning**, to ensure the correct acquisition, storage and analysis of the prelimiar data according to the requirements and compliance related to health data and EU requirements.
25. **Retrospective pilot study deployment and technical validation**, to ensure the technical validation of the 2D-BioPAD device.
26. **Prospective pilot study deployment and clinical validation**, to examine the feasibility of the device's usage in clinical practice in order to maximise its overall performance and end-users' experience, as well as to provide clinical validation of device.
27. **Monitoring and assessment of the dissemination, communication and stakeholder engagement activities** of 2D-BioPAD with a view to measuring their results and impact, fine-tune 2D-BioPAD's Dissemination and Communication Plan, as well as fulfil the project's reporting requirements towards the Commission.

The following section provides further details on the different types and formats of data collected/generated or re-used during the project's activities.

2.2 Types and formats of collected/generated or re-used data

2D-BioPAD is set to collect/generate or re-use data of various structures and formats. Along these lines, the data definition process used for this DMP is based on the source and the physical format of the data[6]. In particular, we define two main aspects: (i) the process under which the underlying data are created/captured which includes electronic text documents, spreadsheets, questionnaires and transcripts, among others and (ii) the storage format of quantitative and qualitative data. Examples of this aspect include easily accessible formats, such as postscripts (e.g., pdf, xps, etc.), machine readable formats (xml, html, etc.), spreadsheets,

[6] Jakobsson, U., Braukmann, R., Lundgren M., Expert Tour Guide on Data Management. Retrieved from https://www.cessda.eu/Research-Infrastructure/Training/Expert-Tour-Guide-on-Data-Management/1.-Plan.

(e.g., xlsx, csv, etc.), text documents (e.g., docx, rtf, etc.), compressed formats (e.g., rar, zip, etc.) or any other format required by the objectives and methodology of the activity within the framework of which it is produced.

Under this framework, special attention will be paid in using **open formats**[7] (such as csv, pdf, zip, etc.) and/or **machine-readable formats**[8] (such as xml, json, rdf, html, etc.) when possible, to enhance the **interoperability** and **re-use** of data. In doing so, we will be providing data that is **easily readable** and **freely usable in any software program** employed by third parties interested in utilizing the data.

The type and formats of the data collected/generated in the context of 2D-BioPAD can be divided into **3 categories**, namely (i) data collected/generated by direct input methods; (ii) data collected/generated through the design, implementation and use of the 2D-BioPAD System; and (iii) data collected/generated from dissemination, communication, stakeholder engagement activities, as described in the following subsections.

2.2.1 Data collected/generated through direct input methods

Direct input methods, under the scope of 2D-BioPAD, involve methodologies for collecting data through desk research and interactions between consortium partners and external stakeholders, with the latter providing data to the former. Along these lines, external stakeholders undertake the role of a data subject that is a natural person whose personal data are being processed[9]. In particular, the identification and selection of suitable data subjects are based on purposeful sampling according to which, external stakeholders are identified and selected by consortium partners based on their role regarding technical and clinical aspects of early detection and monitoring of Alzheimer's Disease (experts on biomarkers, aptamers, clinical needs, technological solutions etc.), as well as their personal or by proxy experience with the disease (patients, caregivers, health care practitioners) and the objectives of the respective activity for which data are collected. In this context, quantitative and qualitative data will be collected/generated during 2D-BioPAD[10]:

- **Quantitative data** are numerical and acquired through counting or measuring. Examples of quantitative data are the yearly turnovers of a business, the hourly compensation of a worker, the number of SMEs in Europe, etc. These data may be represented by ordinal, interval or ratio scales and lend themselves to statistical manipulation.
- **Qualitative data,** sometimes referred to as categorical data, is data that can be arranged into categories based on physical traits, gender, colours or anything that does not have a number associated with it. Moreover, written documents, interviews, and various forms of in-field observation are all sources of qualitative data. Examples of qualitative data are the preferences of learning, skillsets, country of origin, etc.

Additional details with respect to the different types and formats of data that will be collected through direct input methods under the frame of 2D-BioPAD are provided below.

[7] According to the Open Data Handbook: "*An open format is a file format with no restrictions, monetary or otherwise, placed upon its use and can be fully processed with at least one free/open-source software tool and it is not encumbered by any copyrights, patents, trademarks or other restrictions so that anyone may use it*".
[8] According to the Open Data Handbook: "*Machine readable formats are file formats that can be automatically read and processed by a computer. Machine-readable data must be structured data*".
[9] Regulation (EU) 2016/679 of the European parliament and of the council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016R0679.
[10] Neuman, W. L. (2014). Social research methods: Qualitative and quantitative approaches. Boston: Pearson.

Mapping and analysis of point-of-care AD solutions

The data that will be collected/generated here fall under Task 1.1 (Q-PLAN). The data will be quantitative and qualitative data on (i) biomarkers; (ii) clinical needs; (iii) technological solutions; (iv) key actors; and (v) socioeconomic perspectives for clinics and health systems. They will be collected through desk research, clinical and technical partners' expertise, interviews, and a wide online survey. The data collected through the survey will help to refine the interview research findings and identify new or extended information - focus on real-life application barriers and enablers. The collection methods are set up to involve (i) the clinical and technical consortium partners, (ii) key public and private stakeholders from the consortium ecosystem, and external entities, through the interviews, and (iii) citizens, HCPs, tech providers, and decision-makers through the survey. Clinical and technical partners have already started compiling short reports based on semi-structured templates provided by Q-PLAN to collect quantitative, and qualitative data on biomarkers and key technologies, respectively. Two main datasets will derive from this activity including the following: (1) Desk research and Interviews (Q-PLAN); and (2) Survey's results (EVNIA). The data storage formats will include Text documents and spreadsheets (.docx, .xlsx, .csv, .pdf).

Analysis of the needs, challenges, and available solutions for reliable, cost-effective, safe, and ethical early diagnosis of AD

The data to be collected/generated in the framework of this activity fall under Task 1.2 (EVNIA) and will be qualitative in nature. They will be used to identify and frame the current state of the art, unmet laboratory and clinical needs as well as the requirements for the compliant development of in-vitro diagnostics within the scope of this program. Data will be collected through desk research involving bibliographical searches and searches in resources of regulatory/bioethical nature that will be defined after the URS of the products have been finalized. A Safety/Ethics Guidelines Report will be prepared in alignment with GCP, EU/IVDR 746/2017, GDPR, ISO standards and Ethical crossroads. An Ethical Consideration Roadmap Plan (ECR-Plan) will be generated to serve as part of the design output documentation. The data storage formats will include text documents, spreadsheets, images, presentations (.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf).

Cross-regional pilot studies evaluation and validation

The data to be collected/generated here belong to Task 5.4 (ZI) and will refer to the evaluation and validation of the results from the clinical pilot studies. The data will include the results of (i) Relevant performance criteria and metrics, e.g. technical (e.g., accuracy, execution time, response time,), clinical (e.g., sensitivity, specificity), and ethical (e.g., fairness, accountability, security, safety, trustworthiness, transparency, privacy, and bias mitigation) aspects; (ii) the End-user survey that will be administered at the end of study to collect feedback in their overall experience throughout the project and (iii) wider survey addressed to key stakeholders, which will be conducted to further validate the key clinical pilot studies' findings over a wider target audience. Two main datasets will derive from this activity including the following: (1) Evaluation of performance criteria and metrics; (2) Satisfaction survey and validation survey. The data storage formats will include Text documents, Spreadsheets (.docx, .xlsx, .csv, .pdf).

Regulatory Acceptability Activities, Plan, and Policy Recommendations

The data to be collected/generated here belong to Task 6.4 (EVNIA). The data to be collected and synthesized for this task will result in:

i. the development of a User Requirements Specification Report. The data that will be generated are qualitative in nature and will define the requirements for a compliant development of in-vitro diagnostics within the scope of this program. Data will be collected through desk research involving bibliographical searches and searches in resources of regulatory nature including, but not limited to, European Regulations and international standards (e.g., EU/IVDR 746/2017, ISO standards, technical

reports etc.). The URS will serve as design output for the later stages of the products' development in terms of verification/validation testing activities and technical specifications based on regulatory acceptability.

ii. the development of a Regulatory Acceptance Plan/Regulatory Strategy for the 2D-BioPAD solutions under development. The data that will be generated are qualitative in nature and will define the requirements for a compliant development of in-vitro diagnostics within the scope of this program. Data will be collected through desk research involving bibliographical searches and searches in resources of regulatory nature including, but not limited to, European Regulations and international standards (e.g., EU/IVDR 746/2017, GDPR, ISO standards, clinical literature, vigilance data etc.). The Regulatory Strategy will serve as a guide for activities related to the product development, including, but not limited to, the clinical development and for potential, future regulatory submissions.

Two main datasets will derive from this activity including the following: (1) User Requirements Specifications; (2) Requirements for a compliant development of in-vitro diagnostics system. The data storage formats will include Text documents, Spreadsheets, Images, Presentations (.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf).

Collaboration and Synergies with relevant projects and Initiatives

The data to be collected/generated in the framework of this activity fall under Task 6.5 (Q-PLAN). The data to be collected include, but are not limited to photos, number of event participants and presentations, meeting minutes, past knowledge and good practises deriving from the partners' synergetic actions with Graphene Flagship Initiative, as well as other relevant EU initiatives and collaborations with sister projects. The synergies and how they will be forged to benefit the 2D-BioPAD project activities will be decided, per case, based on discussions with representatives of these projects. The data storage formats will include Text documents, Spreadsheets, Images, Presentations (.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf). Additionally, some information will be available online on 2D-BioPAD's and collaboration partners' websites and social media.

Setup and Operation of Scientific and Industrial Advisory Board

The data to be collected/generated here belong to Task 7.2 (GAADRD). The data regarding the setup of the 2D-BioPAD SIAB include personal information of candidate SIAB members (e.g., name and surname, gender, organisation, position, email, country of placement, brief description of professional profile). They will be collected by the consortium partners, under the guidance of GAADRD, following the process of retrieving information from online public sources (professional websites, etc). Each partner will be asked to identify 2-3 suitable relevant stakeholders from their own network (scientific, industrial, clinical and policy experts) and provide to the consortium information that is publicly available. The candidates will be assessed by a selection process and will be formally approached and invited to give their consent to become members of the SIAB. The SIAB will be comprised of 9 members, experts in diverse 2D-Materials, Nanotechnology, AI, and Neurosciences who provide strategic guidance in key stages of the project. The data will be qualitative and stored in text document, image and spreadsheet format (.docx, .xlsx, .pdf, .jpeg).

Data collected/generated through direct input methods will be **stored in formats which allow the documentation of information from various files and documents in a single location.** By doing so, it is possible to circulate raw data from transcripts, as well as text, images, and other objects from other files to one document file or multiple tabs of a single spreadsheet. Moreover, these formats can be immediately converted into open and machine-readable formats (e.g., .xml and .csv) boosting the interoperability and re-usability of the data produced in the framework of 2D-BioPAD.

2.2.2 Data collected/generated through the design, implementation and use of the 2D-BioPAD System

In the context of 2D-BioPAD, a PoC IVD device and an accompanying mobile app will be designed, tested and later will be made available to the clinical centres and used by them to perform the pilot studies.

The 2D-BioPAD PoC IVD system will be a fast and cost-effective, non-invasive, reliable, digitally and graphene-enabled device for supporting the early diagnosis and progression monitoring of AD directly at primary healthcare settings. The mobile app-based user interface will allow interoperable and secure connection with the PoC IVD device and the Cloud, while also offering user-friendly guidance and visualisation of the extracted results.

The following sections provide further details on data collected and/or generated from the design, implementation and use of the 2D-BioPAD System.

Co-designing the 2D-BioPAD System Architecture

The data that will be collected/generated here fall under Task 1.3 (ICN2) and will be quantitative and qualitative data on (i) the characterization of the flux of MNPs through the NC membrane (pore size of the membrane, size of the MNPs.); (ii) the production of graphene electrodes, their functionalization with ssDNA/aptamer and transfer onto paper; (iii) the gold deposition on MNPs and conjugation with MB-modified aptamers (test the sensing strategies - hidden sequence/aptamer “sandwich”); (iv) the testing of the control of MNPs/aptamers along the paper strip using a magnetic field (incubation, purification, and cleaning processes); (v) the creation of a device that monitors the magnetic field and takes electrochemical readings with the smartphone. The dataset that will derive from this activity will include the characterization of the materials that will be created to co-create the 2D-BioPAD system and the testing results of the 2D-BioPAD system. The data storage formats will include Text documents, Spreadsheets, Images, Presentations (.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf).

Synthesis of Aptamers for AD protein biomarkers

The data to be collected/generated here belong to Task 2.1 & Task 2.2 (NOVA & AUTH) and are related to the synthesis of up to 5 DNA aptamers per target, with the most robust properties, the evaluation for their binding properties and the specificity of chosen aptamers. The identification of aptamers for AD protein biomarkers will be done through literature review and search in databases for all the available sequences of DNA aptamers. The activity will also include data from the comparative study of their characteristics and evaluation of these aptamers. The data storage formats will include Text documents, Spreadsheets, Presentations (.docx, .xlsx, .csv, .ppt, .pdf).

Evaluation of Aptamers

The data to be collected/generated here belong to Task 2.1 & Task 2.2 (NOVA & AUTH). The activity Includes data that will derive from the following: (i) Comparative study of the aptamers’ characteristics together with binding and evaluation techniques proposed; (ii) Modified aptamers will be evaluated via SPR or BLI protocol; (iii) Evaluation and optimization of aptamers’ size. The data storage formats will include Text documents, Spreadsheets, Presentations (.docx, .xlsx, .csv, .ppt, .pdf).

Aptamer generation and optimization of aptamers

The data to be collected/generated here belong to Task 2.1, Task 2.2 & Task 3.5 (NOVA, AUTH & CeADAR). The data will derive from deep learning models: (i) the selected aptamers will feed deep learning models capable of predicting structures of high affinity; (ii) binding properties will be used as features to train a deep learning model aiding length optimization; (iii) AI generative models will be used to propose new optimal aptamer

sequences. The data storage formats will include Text documents, Spreadsheets, Presentations (.docx, .xlsx, .csv, .ppt, .pdf).

Synthesis, characterization and evaluation of magnetic nanoparticles

The data to be collected/generated here belong to Task 2.3 (AUTh). The data will derive from the synthesis of Magnetite (Fe3O4) MNPs of different sizes, their structural, morphological and magnetical (TEM, XRD, VSM) characterization, and their evaluation. The data storage formats will include Text documents, Spreadsheets, Presentations (.docx, .xlsx, .csv, .ppt, .pdf).

Immobilization, Functionalization & Evaluation of Conjugated MNPs/Aptamers/Biomarkers

The data to be collected/generated here belong to Task 2.4 (NOVA & UP-CATRIN). They include (i) **Immobilization data**: Aptamers immobilization protocols will be tested to optimize their immobilization efficiency on MNPs depending on the size of the MNP and of the aptamers; (ii) **Functionalization data**: Various conditions will be applied to optimize the rate of MNPs-Aptamers/biomarkers. This work will be multiplied by the number of biomarkers of our interest. ELISA and electrophoresis methods will be used to quantified conjugated and non-conjugated biomarkers and aptamers; (iii) **Evaluation data**: Systematic investigation of the binding capacity of conjugated MNPs/Aptamers with the selected biomarkers in simple and complex solutions (artificial CSF and plasma) will be performed. The main dataset that will derive from this activity will be titled “Immobilization and Functionalization of Conjugated MNPs/Aptamers/Biomarkers”. The data storage formats will include Text documents, Spreadsheets, Presentations (.docx, .xlsx, .csv, .ppt, .pdf).

Synthesis of conductive functionalized graphenes

The data to be collected/generated here belong to Task 3.1 (UP-CATRIN). Selectively and densely functionalized graphene derivatives will be synthesized via the chemistry of fluorographene. Bulk graphite fluoride (commercially available) is exfoliated (e.g., via sonication and high shear mixing in organic solvents), and nucleophile reagents are added at ~100 C. FG undergoes both defluorination and fluorine substitution, enabling selective and dense derivatization with both in-plane heteroatoms and/or out-of-plane functional groups. The collected data for this activity will be produced from chemical composition analysis of the synthesized derivatives and data analysis/interpretation (data tables, Origin Lab files, MS Excel files, images). The raw data are generated by the research equipment/dedicated software during the instrumental analysis. The data storage formats will include Text documents, Spreadsheets, Images, Presentations (.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf).

Conjugation of functionalized graphenes with biorecognition ssDNA units

The data to be collected/generated here belong to Task 3.1 (UP-CATRIN). Conducting functionalized graphene will be conjugated with ssDNA by a suitable chemistry in mild conditions. Graphene with spacer free azido groups can undergo click conjugation with an alkyne-ssDNA, graphene functionalized with propargyl amine can click-conjugate with an azide-ssDNA, and graphene acid can be conjugated via carbodiimide chemistry with an amino-ssDNA. The collected data for this activity will be produced from chemical composition analysis of the synthesized derivatives and data analysis/interpretation (data tables, Origin Lab files, MS Excel files, images). The raw data are generated by the research equipment/dedicated software during the instrumental analysis. The raw data analysis and interpretation is performed and recorded using data analysis and visualization software. The data storage formats will include Text documents, Spreadsheets, Images, Presentations (.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf).

Synthesis of Janus type functionalized graphene

The data to be collected/generated here belong to Task 3.2 (UP-CATRIN). Janus graphene will be synthesized for consecutive conjugation with ssDNA using the most suitable technique among named in the Task 3.2:

functionalization of fluorographene deposited on a substrate/template, fixed in a liquid-liquid interface, or stamping. The collected data for this activity will be produced from chemical composition analysis of the synthesized derivatives and data analysis/interpretation (data tables, Origin Lab files, MS Excel files, images). The raw data are generated by the research equipment/dedicated software during the instrumental analysis of the graphene derivatives that will be synthesized according to the previous methods. The data storage formats will include Text documents, Spreadsheets, Images, Presentations (.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf).

Conjugation of Janus graphene with ssDNA for non-covalent functionalization of the FET graphene gate

The data to be collected/generated here belong to Task 3.2 (UP-CATRIN). The functionalized side of Janus graphene will be conjugated with ssDNA in mild conditions to provide selective recognition of the MNP/aptamers/biomarker complexes during the operation of the sensor. Method described in Task 3.1 will be used. The collected data for this activity will be produced from chemical composition analysis of the synthesized derivatives and data analysis/interpretation (data tables, Origin Lab files, MS Excel files, images). The raw data are generated by the research equipment/dedicated software during the instrumental analysis. The data storage formats will include Text documents, Spreadsheets, Images, Presentations (.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf).

Fabrication and Testing of the Graphene-based Electrochemical biosensor

The data to be collected/generated here belong to Task 3.3 (ICN2). The data will derive from the following: (i) Fabrication of reproducible rGO@AuNPs on paper and PET; (ii) DNA-SH immobilization on rGO@AuNPs, Janus graphene immobilization (SH-FG-azide-ssDNA); (iii) Test of two sensing strategies with the electrodes. The dataset that will derive from this activity will include data on the fabrication and testing of the Graphene-based Electrochemical biosensor. The data storage formats will include Text documents, Spreadsheets, Images, Presentations (.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf).

Fabrication and Testing of the Graphene-based FET biosensor

The data to be collected/generated here belong to Task 3.4(GRAPHEAL). The data will consist in proprietary 2D models and mask (laser cut and screen printed biosensor assembly). The data storage formats will include Text documents, Spreadsheets (.docx, .xlsx, .csv, .pdf) as well as CAD files (dxf, Gerber, pdf, Postscript files).

Aptamer affinity prediction

The data to be collected/generated here belong to Task 3.5 (CeADAR) and will be the results of the process of AI models being trained with the purpose of predicting aptamer affinity. Part of the data will come from public databases (PDB) and part from the project experimental side (PDBx/mmCIF + experimental). The data storage formats will include Text documents, Spreadsheets (.docx, .xlsx, .csv, .pdf).

Graphene Functionalization Optimization

The data to be collected/generated here belong to Task 3.5 (CeADAR) and will be the results of the process of creating a multimodal AI capable of optimizing the functionalization by combining structural data and tabular data such as conductivity, defects, etc. Part of the data will come from public databases (PDB) and part from the project experimental side (PDBx/mmCIF + experimental). The data storage formats will include Text documents, Spreadsheets (.docx, .xlsx, .csv, .pdf).

Advanced Microfluidics for Identifying Multiple Biomarkers

The data to be collected/generated here belong to Task 4.1 (GRAPHEAL). The data to be generated will consist in Video files from vision camera identifying fluid flow, time logs of sensors values to assess for the correct preparation, separation and delivery of the testing fluids on the sensors. The data formats will include Text documents, Spreadsheets (.docx, .xlsx, .csv, .pdf) as well as image & video files (png, jpeg and mp4)

Intelligent decision support module & User Interfaces

The data to be collected/generated here belong to Task 4.2 (GRAPHEAL). The data will be collected during biosensor analysis and diagnostics and will consist in programs and algorithms enabling data visualization and processing. The data formats will include Text documents, Spreadsheets (.docx, .xlsx, .csv, .pdf) as well as images files (.png, .jpeg) and program files (python, C++ text files and compiled forms).

Casing prototyping and assembly

The data to be collected/generated here belong to Task 4.3 (GRAPHEAL). The data will be generated to fabricate the hardware surrounding the biosensor technology, using CAD software and 3D printing technology. The data formats will include Text documents, (.docx, .pdf) as well as 3D printing CAD files (STL).

Integration lab testing and fine tuning

The data to be collected/generated here belong to Task 4.4 (GRAPHEAL). The data will be generated to ensure the correct acquisition, storage and analysis of the preliminary data according to the requirements and compliance related to health data and EU requirements. The data formats will include Text documents, (.docx, .pdf) Spreadsheets (.xlsx, .csv, .pdf) and program files (python, C++ text files and compiled forms).

Retrospective pilot study deployment and technical validation

The data to be collected/generated here belong to Task 5.2 (UEF) and will derive from a retrospective pilot study based on existing fluid samples and related clinical data from clinical partners (UEF, GAADRD, ZI), e.g., biomarker data, demographics, diagnosis of cognitive disorder and related tests, comorbidities. The data will include the extracted reference values for the biomarkers, as well as the results of testing the envisioned functionalities both at sub-component level, but also at device level through several use cases. The data storage formats will include Text documents, Spreadsheets (.docx, .xlsx, .csv, .pdf).

Prospective pilot study deployment and clinical validation

The data to be collected/generated here belong to Task 5.3 (GAADRD) and will derive from assessing the feasibility of the device's usage in clinical practice (stage 1); clinical validation (stage 2). The data will include:

a) Biological fluid samples and relevant data of patients from the three clinical partners (UEF, GAADRD, ZI), e.g., biomarker data, demographics, diagnosis of cognitive disorder and related tests, comorbidities;
b) Quantitative and qualitative data on patients', caregivers' and health care practitioners' views and experiences (e.g., expectations, needs, concerns, trust, acceptance).

The data will be collected through survey(s) and by discussions (PPI) and semi-structured interviews with (i) people with MCI/AD and their caregivers as well as (ii) health care practitioners as a part of clinical pilot studies. The method and amount of data collected may vary between countries. Two main datasets will derive from this activity including the following: (1) Biological fluid samples and relevant data of patients from clinical partners; (2) Patients', caregivers' and health care practitioners' views and experiences. The data storage formats will include Text documents, Spreadsheets (.docx, .xlsx, .csv, .pdf).

More information regarding the 2D-BioPAD System and the data collected / generated through its use will be provided in future updates of the DMP, as its functionalities are further specified and developed in line with the findings stemming from the project's pilot studies and activities.

2.2.3 Data collected/generated from dissemination, communication and stakeholder engagement activities

The data deriving by monitoring and assessment of the dissemination and communication results of the project and by the stakeholder engagement with a view to measuring the impact of the relevant activities, fall under Task 6.1 (Q-PLAN) and include (i). Website analytics; (ii) social media statistics (including Twitter and LinkedIn); (iii). Data collected from project events; (iv). Newsletter subscriptions and (v). Data collected from dissemination and communication activities (e.g., participation in external events, participation in project workshops, etc.). The data will be identified through online analytics, utilising google analytics, SMAs, partners reporting, Mailchimp platform, etc. Q-PLAN is responsible for sending the necessary templates (.docx, .xlsx) to all partners, alongside with guidelines on how to fill them in, as well as for collecting input on an ad-hoc basis (i.e., each time a dissemination or stakeholder engagement action is performed). Q-PLAN is also responsible for preparing the necessary reports to evaluate the overall progress of dissemination and communication activities (measuring outcomes against pre-set KPIs) throughout the lifespan of the project. The storage format of the data to be collected during the project's duration, includes .csv, .docx, .xlsx, .pdf, .ppt, .jpeg and .png files.

Website analytics

The 2D-BioPAD website was developed during the first months of the project (it was launch on the 31/01/24 – M4) and will be the main dissemination channel of the project, hosting the deliverables and links to the tools, providing information about the project, partners, and regions, as well as sharing news with a dedicated section and a newsletter. Two sets of data will be collected within this category:

- Visitors' statistics (anonymised data), through Google Analytics;
- Newsletter subscribers, through MailChimp.

This type of information will be mostly used for reporting purposes. Data will be stored in spreadsheets (.xlsx) while the analysis of the results will be stored in a standard text document (.docx).

When people will visit the 2D-BioPAD website, it will (via cookies - as in the case of every online website) automatically collect information about the visitor's device used for accessing the website (e.g., web browser, IP address, time zone). Additionally, information will be captured on how visitors interact with the website itself. We refer to this, automatically collected, information as "Device Information".

Social Media statistics (including Twitter and LinkedIn)

These data will be collected/generated through a periodic monitoring of the project's social media statistics (i.e., Twitter and LinkedIn) with a view to measuring and assessing the performance and results of the project's social media activity in terms of dissemination and communication. With that in mind, the data will be both qualitative as well as quantitative in nature addressing the metrics reached on each channel (e.g., number of followers, tweets impressions on Twitter, number of people reached through posts, etc.). Additionally, these data will be followed by an analysis of the results stemming from them and possible ways to improve the results so as to reach the project's targets. All in all, the data will be stored in a spreadsheet (.xlsx) while at the same time the analysis of the results will be stored in a standard text document (.docx).

Newsletter subscriptions

In order to enhance the dissemination activities of the project, newsletter subscriptions are foreseen on the project's website. A subscription form hosted on the project's website will facilitate the collection of these data. Any interested stakeholder can voluntarily provide their contact details in a dedicated sign-up form, so as to receive the most up-to-date news and outcomes of the project. A newsletter will be sent to subscribers

once per 6 months. These data will be collected so as interested stakeholders can be informed about 2D-Bio PAD. Along these lines, the data will be comprised of a list of subscribers along with their email address. A copy of this contact list will be stored on MailChimp's (http://mailchimp.com) server, which is used for e-mail campaigns and newsletters distribution. All personal information included in this contact list is used and protected according to MailChimp's Privacy Policy.

Data collected from dissemination and communication activities and events

These data will be collected through the periodic monitoring of the project's miscellaneous dissemination activities such as publications in relevant journals, posts in blogs, the different events (e.g., trainings, project workshops, interviews, physical and virtual events, etc. organised by 2D-BioPAD, either alone or jointly with other projects or initiatives, consisting of the participants' lists that will enclose demographic information about the participants), the participation of 2D-BioPAD partners in relevant third party events in order to reach out and engage stakeholders (thus collecting general information about the events attended and their outreach, etc. The data will consist of a spreadsheet designed to keep track of any kind of communication and dissemination activity, including, but not limited to, press releases, social media posts, website articles, interviews, events (conferences, meetings, workshops, etc.), other publications, e-mails, presentations, informal discussions, seminars, etc. The purpose of collecting these data is to assess the outreach and efficiency of the dissemination activities during the implementation of the project. For this purpose, a template will be shared with all partners to recommend activities to be performed and log the activities they performed. The template will also be provided online so as the partners can directly update their input. Finally, the data will be both quantitative and qualitative in nature and all the data will be integrated into a single spreadsheet (.xlsx).

2.3 Origin of data and re-use of pre-existing data

In the context of 2D-BioPAD, **new data** will be collected/generated by partners as well as external stakeholders participating in the activities of the project and using the 2D-BioPAD Device and App. With that in mind and aside consortium partners, **external groups of stakeholders from which new data will originate include**:

- Experts in Biomarkers for Neurodegeneration/Dementia/Alzheimer's Diseases within and outside the EU;
- HCPs, caregivers and patients of AD;
- Business and Industrial community (producers with graphene-based expertise);
- Major European Initiatives (e.g., Graphene Flagship Initiative);
- Relevant Initiatives (EU projects focusing on 2D materials and/or Alzheimer's disease, relevant networks and working groups);
- Policy makers at regional, national and EU level and consultants (related to ethics on the creation of diagnostic devices for neurodegenerative diseases);
- Academic experts in the fields of Nanoparticles, Aptamers and Graphene (e.g., within academic institutions, non-university public research organisations, research and innovation organisations etc.).

Moreover, **pre-existing data** will be utilised within the context of 2D-BioPAD as well. In particular, outputs from EU-funded projects (e.g., active Horizon 2020 projects, Horizon Europe projects funded under HORIZON-CL4-2022-DIGITAL-EMERGING-02, projects that are part of the GFI etc.), national projects, institutions or other relevant initiatives as well as samples from clinical centres' biobanks will be used to provide a solid basis for 2D-BioPAD. The 2D-BioPAD consortium will strive to make the most of and advance the work and results of

these projects. Such activities include the analysis of the protein biomarkers for AD, the retrospective study of samples, the creation of sustainable business models etc. Finally, consortium partners' internal knowledge, experience and expertise from their participation in other projects and initiatives will directly and indirectly support the implementation of activities throughout the project.

2.4 Expected size of data

2D-BioPAD entails a series of activities aiming introducing a fast and cost-effective, non-invasive, reliable, digitally and graphene-enabled PoC IVD system for supporting the early diagnosis and progression monitoring of AD directly at primary healthcare settings. With that in mind, the table that follows presents the different activities implemented during the course of the project in which data are collected/generated, the types and formats of the data as well as the expected size of the data.

Table 3: Expected size of data

#	Name of activity	Dataset/Data	Type of data	Format of data	Expected size of data*
1	Mapping and analysis of point-of-care AD solutions	Desk research and Interviews	Text document	.docx, .pdf	100MB
2		Survey's results	Text documents, Spreadsheets	.docx, .xlsx, .csv, .pdf	100MB
3	Analysis of the needs, challenges, and available solutions for reliable, cost-effective, safe, and ethical early diagnosis of AD	Data from the State of the Art and regulatory resources	Text documents, Spreadsheets, Images, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	100MB
4	Cross-regional pilot studies evaluation and validation	Evaluation of performance criteria and metrics	Text documents, Spreadsheets	.docx, .xlsx, .csv, .pdf	100 MB
5		Satisfaction survey and validation survey	Text documents, Spreadsheets	.docx, .xlsx, .csv, .pdf	100 MB
6	Regulatory Acceptability Activities, Plan, and Policy Recommendations	Definition of User Requirements Specifications	Text documents, Spreadsheets, Images, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	100MB
7		Requirements for a compliant development of in-vitro diagnostics system	Text documents, Spreadsheets, Images, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	100MB
8	Collaboration and Synergies with relevant projects and Initiatives	Photos, number of event participants, presentations, joint activities	Spreadsheets, Images, Notes, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	About 50 MB
9	Setup and Operation of Scientific and Industrial Advisory Board	Information of candidate SIAB members (e.g., name and surname, mail, brief	Text documents, Spreadsheets, Images, Notes	.docx, .xlsx, .csv, .jpeg, .png, .pdf	200 MB

#	Name of activity	Dataset/Data	Type of data	Format of data	Expected size of data*
		description of professional profile, institution)			
10	Co-designing the 2D-BioPAD System Architecture	Characterization of the materials that will be created to co-create the 2D-BioPAD system	Text documents, Spreadsheets, Images, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	300MB
11	Synthesis of Aptamers for AD protein biomarkers	Synthetic protocols for Aptamers; functionalization; structural, chemical and physical characterization	Text documents, Spreadsheets, Presentations	.docx, .xlsx, .csv, .ppt, .pdf	20-200 MB
12	Evaluation of Aptamers	Evaluation of performance criteria and metrics; Selection of Aptamers	Text documents, Spreadsheets, Presentations	.docx, .xlsx, .csv, .ppt, .pdf	30-300 MB
13	Aptamer generation and optimization of aptamers	Synthetic protocols for Aptamers; conjugation of Aptamers with magnetic nanoparticles; structural, chemical and physical characterization of the conjugated structures.	Text documents, Spreadsheets, Presentations	.docx, .xlsx, .csv, .ppt, .pdf	200 MB
14	Synthesis, characterization and evaluation of magnetic nanoparticles	Synthetic protocols for magnetic nanoparticles; functionalization; structural, chemical and physical characterization	Text documents, Spreadsheets, Presentations	.docx, .xlsx, .csv, .ppt, .pdf	10-100 MB
15	Immobilization, Functionalization & Evaluation of Conjugated MNPs/Aptamers/Biomarkers	Immobilization and Functionalization of Conjugated MNPs/Aptamers/Biomarkers	Text documents, Spreadsheets, Presentations	.docx, .xlsx, .csv, .ppt, .pdf	30-300 MB
16	Synthesis of conductive functionalized graphenes	Synthetic protocols for graphene functionalization; structural, chemical and physical characterization	Text documents, Spreadsheets, Images, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	30-300 MB
17	Conjugation of functionalized graphenes with biorecognition ssDNA units	Synthetic protocols for conjugation of graphene with ssDNA; structural, chemical and physical characterization of the conjugated structures	Text documents, Spreadsheets, Images, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	30-300 MB
18	Synthesis of Janus type functionalized graphene	Protocols for Janus graphene synthesis; structural, chemical and physical characterization	Text documents, Spreadsheets,	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	30-300 MB

#	Name of activity	Dataset/Data	Type of data	Format of data	Expected size of data*
			Images, Presentations		
19	Conjugation of Janus graphene with ssDNA for non-covalent functionalization of the FET graphene gate	Synthetic protocols for conjugation of Janus graphene with ssDNA; structural, chemical and physical characterization of the conjugated structures.	Text documents, Spreadsheets, Images, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	30-300 MB
20	Fabrication and Testing of the Graphene-based Electrochemical biosensor	Fabrication and testing of the Graphene-based Electrochemical biosensor	Text documents, Spreadsheets, Images, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	200MB
21	Fabrication and Testing of the Graphene-based FET biosensor	2D models and mask design	Text images, Spreadsheets & CAD files	.dxf Gerbe pdf pngr	200MB
22	Aptamer affinity prediction	PDBx/mmCIF + experimental	Text documents, Spreadsheets	.xlsx, .csv, .pdf	500MB
23	Graphene Functionalization Optimization	PDBx/mmCIF + experimental	Text documents, Spreadsheets	.xlsx, .csv, .pdf	500MB
24	Advanced Microfluidics for Identifying Multiple Biomarkers	Fluid flow measurements, time logs of sensors	Text documents, Spreadsheets and video files	.docx, .xlsx, .csv, .png, jpeg and mp4	2GB
25	Intelligent decision support module & User Interfaces	Biosensing Data (time logs of sensor value), Program files (Text files)	Text documents, Spreadsheets	docx, .xlsx, .csv, .pdf,.png, jpe and program files (C++ Python)	500MB
26	Casing prototyping and assembly	Design files	CAD software and 3D printing files	.STL, .dxf	200MB
27	Integration lab testing and fine tuning	Biosensor data	Text documents, Spreadsheets and curves plots	.xlsx, .csv, .pdf, .png	500MB
28	Retrospective pilot study deployment and technical validation	Existing fluid samples and relevant data from clinical partners	Text documents, Spreadsheets	.docx, .xlsx, .csv, .pdf	100MB
29	Prospective pilot study deployment and clinical validation	Biological fluid samples and relevant data of patients from clinical partners	Text documents, Spreadsheets	.docx, .xlsx, .csv, .pdf	100MB

#	Name of activity	Dataset/Data	Type of data	Format of data	Expected size of data*
30		Patients', caregivers' and health care practitioners' views and experiences	Text documents, Spreadsheets	.docx, .xlsx, .csv, .pdf	200 MB
31	Monitoring and assessment of the dissemination, communication and stakeholder engagement activities	Website analytics	Text documents, Spreadsheets, Images, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	100MB
32		Social Media statistics (including Twitter and LinkedIn):	Text documents, Spreadsheets, Images, Presentations	.docx, .xlsx, .csv, .ppt, .jpeg, .png, .pdf	100MB
33		Newsletter subscriptions	Spreadsheets	.xlsx, .csv, .pdf	100MB
34		Data collected from dissemination and communication activities and events	Spreadsheets, Images	.docx, .xlsx, .csv, .jpeg, .png, .pdf	200MB

2.5 Data utility

The stakeholders that may find meaningful utility for the data to be collected/generated or re-used by the project (both within as well as outside of 2D-BioPAD's consortium) along with the benefits that could arise for them by utilizing these data, are concisely presented in the table that follows.

Table 4: Data utility

Stakeholder group	Data utility
Policy makers in the domain of biomedical applications	More specifically the project's generated data and results will offer policy makers the tools for better informed decision making regarding the use of 2D material-based (i.e., graphene) devices and systems for biomedical applications in the health domain. The project will help policy makers to identify current policy and regulatory limitations, challenges, and barriers and to create frameworks that could better prepare for and usher the new era for 2D-based systems for biomedical applications. Along these lines, data generated to this end, may be of great utility for experts who design, implement and/or fund relevant policies. Data generated on designated policy activities (policy briefs) will provide meaningful input that could be used to inform the design of policies targeted in 2D diagnostic systems around the world.
2D industry, advisors & investors	The data created/generated through 2D-BioPAD will provide insights on how to accomplish networking and stakeholder engagement to build the connections required to accelerate 2D innovation. The results of the project are expected to increase awareness regarding neurodegenerative devices and early diagnosis and its benefits and to provide useful feedback on a policy making level. To this end, data generated through 2D-BioPAD, may be of great utility for industry advisors and investors engaging in the implementation and funding of relevant policies. The industrial/commercial stakeholders, include technology solutions and services providers, industrial/commercial actors, medical device manufacturers, entrepreneurs, and investors, who would be interested in adopting 2D-BioPAD's solutions, develop their own solutions and applications based on 2D-BioPAD's results and/or who are engaging with 2D technologies and development of biomarkers.
Healthcare Professionals	The data created/generated through 2D-BioPAD could be useful for Healthcare Professionals including clinicians, doctors, nurses, who would be interested in adopting 2D-BioPAD's

Stakeholder group	Data utility
	solutions and would want a broad understanding of the bioethical aspects of the products within the context of the Good Clinical Practice.
Scientific community	In the frame of the 2D-BioPAD project, interdisciplinary research is performed that largely builds upon prior research efforts to generate insights on 2D material based diagnostic systems, biomarkers and AD. Additionally, clinical and technical stakeholders are engaged in the project's research and co-creation processes, mapping a plethora of perspectives regarding the state of play in PoC IVD systems for supporting the early diagnosis and progression monitoring of AD. Research data of the project that will be published in reports or peer-reviewed scientific journals as well as deposited in open repositories can be of great utility for scientists in the field, aggregating and classifying existing scientific knowledge on 2D technologies, medical devices and biomarkers related to AD and creating new knowledge and empirical open data on the application of the created devise and app in early diagnosis of AD.
Civil society	2D-BioPAD aims to engage caregivers and patients in its core activities in order to make sure that their perspective is taken into consideration in the creation of the diagnostics device, and to find more meaningful ways to shape the devise and application to address their needs. Open platforms and databases for sharing data might also be interested to host 2D-BioPAD's results.
Project partners	The data collected/generated during 2D-BioPAD are the cornerstone for project partners in order to produce evidence-based results and ultimately achieve the objectives of the project. Indeed, these data enable the co-creation, testing and validation of the 2D-BioPAD System (devise and app) that will help the early and cost-effective diagnosis of AD. At the same time, these data may be meaningful for project partners beyond the end of the project as well, enabling them to build and capitalise upon interesting ideas and opportunities that may emerge to ensure the long-term sustainability of the 2D-BioPAD methodology and tools.

3. FAIR data

The guidelines on Data Management Plan[11] of the Commission emphasise the importance of making the data produced by projects funded under Horizon Europe **Findable, Accessible, Interoperable as well as Reusable (FAIR)**, with a view to ensuring their sound management. This means using standards and metadata to make data discoverable, specifying data sharing procedures and which data will be open, allowing data exchange via open repositories as well as facilitating the reusability of the data. With that in mind, the following sections of the DMP lay out the methodology followed in the framework of 2D-BioPAD with respect to making data findable, accessible and interoperable as well as ensuring their preservation and open access, with a view to increasing their re-use.

3.1 Making data findable, including provisions for metadata

3.1.1 Data discoverability and identification mechanisms

2D-BioPAD places special emphasis on enhancing the discoverability of the data collected/generated or re-used during the course of its activities. **Open data produced during the implementation of the project will be locatable by means of a standard identification mechanism.** Indeed, 2D-BioPAD will be able to assign globally resolvable **Persistent Identifiers (PIDs)** on any open data (more information on open data as well as the respective repositories we plan on employing in the context of the project are provided in section 3.2). An

[11] https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

identifier is a unique identification code that is applied to a dataset, so that it can be unambiguously referenced. For example, a catalogue number is an identifier for a particular specimen and an ISBN code is an identifier for a particular book. PIDs are simply maintainable identifiers that allow for permanent reference to a digital object. In other words, PIDs are a way of giving digital resources, such as documents, images and data records, a unique and persistent reference number.

At the same time, data that are not open will be deposited in a searchable resource (i.e., the cloud web storage service of the project) and well-tailored identification mechanisms will be utilized as well, in the form of standard naming conventions that will safeguard their consistency and make them easily locatable for partners within the frame of the project. Along these lines, the following subsection provides further analysis on naming conventions and versioning.

3.1.2 Naming conventions and versioning

Following a consistent set of naming conventions in the development of the project's data files can greatly enhance their searchability. With that in mind, 2D-BioPAD creates consistent data file names that provide clues to their content, status and versioning, while also increasing their discoverability. In doing so, project partners as well as interested stakeholders can easily identify a file as well as classify and sort them.

According to the UK Data Archive (*UK Data Service, 2017b*), a best practice in naming convention is to create brief yet meaningful names for data files, that facilitate classification. The naming convention should avoid the utilisation of spaces, dots and special characters (such as & or !), whereas the use of underscores is endorsed, to separate elements in the data file name and make them understandable. At the same time, versioning should be a part of a naming convention to clearly identify the changes and edits in a file.

With that in mind and to facilitate the reference of the datasets that will be produced during its implementation, 2D-BioPAD employs a **standard naming convention that integrates versioning and takes into account the possibility of creating multiple datasets** during an activity that entails data collection/generation. Indeed, 2D-BioPAD's naming convention considers this issue and addresses it by employing a unique element that captures the number of datasets that are produced under the same activity.

In particular, the **naming convention employed by the project is described below**.

[Name of project] _ [Name of Study] _ [Number of dataset] _ [Issue Date] _ [Version number]

- **Name of project:** 2D-BioPAD
- **Name of Study:** A short version of the name of the activity for which the dataset is created.
- **Number of dataset:** An indication of the number assigned to the dataset.
- **Issue Date:** The date on which the latest version of the dataset was modified (YYYY.MM.DD.).
- **Version number:** The versioning number of a dataset.

With the above in mind, some **indicative examples** to showcase the naming structure that will be applied in the context of 2D-BioPAD are provided below:

- **2D-BioPAD_InterviewsUsercenteredRequirements_Dataset1_2024.01.31_v1 -** The first dataset generated from the interviews conducted with key public and private stakeholders from the consortium ecosystem, as well as external entities, to identify user-centred requirements, needs and challenges. This is the first version of the dataset that was last modified on the 31st of January 2024 (31/01/2024);

- **2D-BioPAD_ProspectivePilotStudy_Dataset2_2027.07.31_v2 –** The second dataset created in the process of the 2-stage prospective pilot study deployment and clinical validation, engaging HCPs and patients across the three clinical centres. The last modification of this dataset, which in this case produced the second version of the dataset, was on the 31st of July 2027 (31/07/2027).

Versioning of information makes a revision of datasets uniquely identifiable and can be used to determine whether and how data changed over time and to define specifically which version the creators/editors are working with. Moreover, effective data versioning enables understanding if a newer version of a dataset is available and which are the changes between the different versions allowing for comparisons and preventing confusion. In this context, **a clear version number indicator is used in the naming convention** of every data file produced during 2D-BioPAD in order to facilitate the identification of different versions.

3.1.3 Metadata allowing discovery

In addition to consistent naming conventions and versioning, the project also follows a metadata-driven approach so as to allow discovery and further increase the searchability of the data, while also facilitating its understanding and re-use. Metadata is defined as "data about data" or "information about information"[12]. It is usually structured textual information that describes the creation, content, or context of a digital resource – be it a single file, part of a single file, or a collection of many files. Metadata is the glue, which links information and data across the world wide web. It is the tool that helps people to discover, manage, describe, preserve and build relationships with and between digital resources [13].

In particular, three distinct types of metadata exist[14], as presented below:

- **Descriptive metadata** is used to identify and describe collections and related information resources. Descriptive metadata at the local level helps with searching and retrieving. In an online environment, descriptive metadata helps to discover resources. Most of the times, it includes information such as the title, author, date, description, identifier, etc.;
- **Administrative metadata** is used to facilitate the management of information resources. It is helpful for both short-term and long-term management and processing of data. This is information that will not usually be relevant to the public but will be essential for staff to manage collections internally. Such metadata may be location information, acquisition information, etc.;
- **Structural metadata** enables navigation and presentation of electronic resources. It documents how the components of an item are organized. Examples of structural metadata could be the way in which pages are ordered to form chapters of a book, a photograph that is included in a manuscript or a scrapbook or the JPEG and TIF files that were created from the original photograph negative, linked together.

With that in mind, **data produced/used during 2D-BioPAD is discoverable with metadata** suitable to its content and format. The project employs **metadata standards** to produce rich and consistent metadata with a view to supporting the long-term discovery, use and integrity of its data. More details on the metadata standards adopted by 2D-BioPAD are provided on the following subsection.

[12] Huxley, L., & Jacobs, N. (2004). Online information services in the Social Sciences. Oxford: Chandos.
[13] Foulonneau, M., & Riley, J. (2008). Metadata for digital resources: Implementation, systems design and interoperability. Oxford: Chandos.
[14] Caplan, P. (2003). Metadata fundamentals for all librarians. Chicago: American Library Association.

3.1.4 Standards for metadata creation

2D-BioPAD employs standards for creating metadata for data collected/generated by the project, with a view to describing it with **rich metadata** and thus improving their discoverability and searchability. In result, effective searching, improved digital curation and easy sharing will be realized. In addition, the metadata standards applied enable the integration of metadata from a variety of sources into other technical systems.

With that in mind, for **2D-BioPAD's openly available data** the metadata standards provided by **Zenodo will be used**. Zenodo (*https://zenodo.org/*) is an open repository developed under the European OpenAIRE programme and operated by CERN. The repository along with its metadata standards have been adopted and are being used by numerus research communities, enabling them to deposit research papers, datasets, software, reports as well as other research outputs. Along these lines, Zenodo creates metadata to accompany the datasets that are uploaded to the repository, extending their reach to a wider audience of interested stakeholders. These metadata can be exported in several standard formats, including open and machine-readable ones (such as MARCXML, Dublin Core, and DataCite Metadata Schema), following the guidelines of OpenAIRE and are stored by Zenodo in JSON-format according to a defined JSON schema[15].

Project **data not open, will also be annotated with open and machine-readable metadata** following the **Dublin Core Metadata standard**. The Dublin Core Metadata element set (certified with the ISO Standard 15836) is a standard which can be easily understood and implemented and as such, is one of the best-known metadata standards. It was originally developed as a core set of elements for describing the content of web pages and enabling their search and retrieval. Among the reasons for selecting this standard is also the fact that **Zenodo is compatible with Dublin Core metadata formats** and thus any initially closed data, that may become open at a later stage (e.g., due to a change in the consortium's policy), will not lose its metadata. With that said, the Dublin Core metadata standard is a simple yet effective set for creating rich metadata that will describe a wide range of resources. The fifteen element "Dublin Core" described in this standard is part of a larger set of metadata vocabularies and technical specifications maintained by the Dublin Core Metadata Initiative (DCMI)[16]. The full set of vocabularies also includes sets of resource classes, vocabulary encoding schemes, and syntax encoding schemes. **An online metadata generator will be used** to produce the different metadata elements required (*dublincoregenerator.com*).

3.1.5 Search keywords included in the metadata

The project's data will be provided with search keywords with a view to optimizing its findability as well as its ultimate re-use by interested stakeholders during its entire lifetime. With that in mind, the metadata standards employed by 2D-BioPAD provide opportunities for tagging the data collected/generated and its content with keywords. In general, keywords are a subset of metadata and include words and phrases used to name data. In the context of 2D-BioPAD, keywords are used to add valuable information to the data collected/generated as well as to facilitate the description and interpretation of its content and value.

Along these lines, the project's strategy on keywords is underpinned by the following principles:

- The who, the what, the when, the where, and the why should be covered;
- Consistency among the different keyword tags needs to be ensured;
- Relevant, understandable and clear keywording ought to be sought.

[15] For more information on the JSON format and the JSON schema visit the following website: http://json-schema.org/

[16] Retrieved from: https://www.dublincore.org/

In general, the keywords will comprise terms related to AD, MCI, nanoparticles, aptamers, biomarkers, etc. The keywords will accurately reflect the content of the datasets and avoid words used only once or twice within them.

3.1.6 Offering metadata that can be harvested and indexed

We know that the wild diversity of the metadata accompanying open data across the plethora of online repositories (e.g., disciplinary archives, institutional repositories, open access journals) can serve as barriers for their findability and sharing amongst different research communities. This is why in the context of 2D-BioPAD we have aligned our metadata creating approach with the **Open Archives Initiative (OAI)**, which promotes the use of a standard protocol for metadata harvesting, designed for better sharing and retrieval of data residing in distributed repositories. This protocol, namely the Open Archives Initiative Protocol for Metadata Harvesting (OAI-PMH)[17], promotes interoperability standards that facilitate efficient dissemination of data amongst diverse communities[18].

All structured **metadata linked to the project's open data will be offered in a way that can be exported and harvested** via the OAI-PMH thanks to the standards we adopt for metadata creation (see section 3.1.4). The same standards will also help us produce **metadata that facilitate indexing**. For instance, the use of the Dublin Core Metadata Standard (as further elaborated in section 3.3) provides a vocabulary of concepts with definitions in open-machine readable formats that enable easier indexing of metadata. Along these lines, there are several tools[19] which implement the Archives Initiative Protocol for Metadata Harvesting, such as **Arc source**, **EnhancedOAIServer** and **eprints.org**, and can be used for harvesting our data by different repositories.

2D-BioPAD's openly available data will be uploaded in Zenodo, which is in line with FAIR principles, including the "To be Findable" principle. Metadata of each record uploaded in Zenodo is indexed and searchable directly in Zenodo's search engine immediately after publishing. Metadata of each record is sent to DataCite servers during DOI registration and indexed there.

3.2 Making data accessible

3.2.1 Repository

The **data produced by 2D-BioPAD and deemed open for sharing and re-use, will be deposited to and securely stored by Zenodo** (*www.zenodo.org*), **which constitutes an open data repository** and has been specifically selected to enable access to the project's open data free of charge. In fact, Zenodo builds and operates a simple service that enables researchers, scientists, EU projects and institutions, among others, to share and showcase research results (including data and publications) that are not part of the existing institutional or subject-based repositories of the research communities. It accepts any file format, promotes peer-reviewed openly accessible research, allows the creation of own collections and it is available free of charge both for 2D-BioPAD to upload and share data as well as for other stakeholders to explore, download and re-use these data.

[17] Retrieved from: https://www.openarchives.org/pmh/

[18] Corrado, E.M. (2005) 'The importance of open access, open source, and open standards for libraries', Issues in Science and Technology Librarianship.

[19] For more information about the tools implementing the OAI-PMH: https://www.openarchives.org/pmh/tools/

Moreover, as a digital repository, Zenodo registers **Digital Object Identifiers (DOIs)** for all submitted data through DataCite[20], which is the leading global non-profit organisation that provides PIDs (and specifically DOIs) for research data and preserves these submissions using the safe and trusted foundation of CERN's data centre, alongside the biggest scientific dataset in the world, the LHC's 100PB Big Data store[21]. This means that the data preserved in Zenodo will be accessible for years to come, and the DOIs will function as perpetual links to the resources. DOIs remain valuable since they are future-proofed against Uniform Resource Locator (URL) or even protocol changes, through resolvers (such as DOI[22]). With that in mind, an example of a DOI retrieved from this open repository follows the structure illustrated in Figure 1.

Figure 1: Typical DOI created by Zenodo

3.2.2 Data

3.2.2.1 Openly available and closed data

2D-BioPAD, in line with FAIR principles of data management in the context of Horizon Europe, adopts the good practice of making data as open as possible and as closed as necessary. This calls for partners to disseminate their data that have the potential to offer long-term value to external stakeholders and do not harm the confidentiality and privacy of the stakeholders that contributed to the collection/generation of these data, maximising the beneficial impact of 2D-BioPAD.

Only anonymised and aggregated data will be made open (publicly available) to ensure that data subjects cannot be identified in any reports, publications and/or datasets resulting from the project. The relevant project partner in each case will **undertake all the necessary anonymisation procedures** to anonymise the data in such a way that the data subject is no longer identifiable (more details on data management responsibilities are provided in **Section 5.2**), in compliance with applicable European and National Regulations for personal data protection.

To this end, it is important to keep in mind that during the process of data anonymisation, data identifiers need to be removed, generalised, aggregated or distorted. Moreover, **anonymisation is different than pseudonymisation**, which falls under a distinct category in the GDPR - anonymisation theoretically fully and irreversibly prevents any backtrace of the subject's data, while pseudonymisation allows for the data subject to be re-identified with additional information. Along these lines, the table which follows provides a **list of good practices** for the anonymisation of quantitative and qualitative data derived from the tour guide on data management of the Consortium of European Social Science Data Archives (CESSDA).

Table 5: Good practices for data anonymisation

Type of data	Good practices
Quantitative data	• Remove or aggregate variables or reduce the precision or detailed textual meaning of a variable. • Aggregate or reduce the precision of a variable such as age or place of residence. As a general rule, report the lowest level of geo-referencing that will not potentially breach respondent confidentiality. • Generalise the meaning of a detailed text variable by replacing potentially disclosive free-text responses with more general text.

[20] For more information on DataCite: https://www.datacite.org/
[21] Retrieved from: https://www.software.ac.uk/tags/zenodo
[22] Retrieved from: http://dx.doi.org/

Type of data	Good practices
	• Restrict the upper or lower ranges of a continuous variable to hide outliers if the values for certain individuals are unusual or atypical within the wider group researched.
Qualitative data	• Use pseudonyms or generic descriptors to edit identifying information, rather than blanking-out that information. • Plan anonymisation at the time of transcription or initial write-up, (longitudinal studies may be an exception if relationships between waves of interviews need special attention for harmonised editing). • Use pseudonyms or replacements that are consistent within the research team and throughout the project. For example, using the same pseudonyms in publications and follow-up research. • Use 'search and replace' techniques carefully so that unintended changes are not made, and misspelt words are not missed. • Identify replacements in text clearly, for example with [brackets] or using XML tags such as <seg>word to be anonymised</seg>. • Create an anonymisation log (also known as a de-anonymisation key) of all replacements, aggregations or removals made and store such a log securely and separately from the anonymised data files.

Source: Tour guide on data management of the CESSDA[23]

With that in mind, the following table presents the data collected/generated during the course of the project that will be made openly available. In case certain data cannot be shared (or need to be shared under restrictions), a justification for that choice is provided.

Table 6: Data availability

#	Data	Availability	Notes
1	Mapping and analysis of point-of-care AD solutions - Desk research and Interviews	Open	N/A
2	Mapping and analysis of point-of-care AD solutions - Survey's results	Open & Closed	Data collected from the online survey will be available only to 2D-BioPAD consortium and the EU Commission. In case there is a need to share information for dissemination and communication purposes, GDPR requirements for personal data protection will be accounted for, and all personal information will be anonymised before being made openly available.
3	Analysis of the needs, challenges, and available solutions for reliable, cost-effective, safe, and ethical early diagnosis of AD	Closed	Data collected will be available only to 2D-BioPAD consortium and the EU Commission. In case there is a need to share information for dissemination and communication purposes, any sensitive information and identifiers related to the product development will be removed.
4	Cross-regional pilot studies evaluation and validation - Evaluation of performance criteria and metrics	Open & Closed	Where applicable, technical/other details requiring confidentiality will be closed
5	Cross-regional pilot studies evaluation and validation -	Open & Closed	Anonymized data can be open.

[23] Retrieved from: https://www.cessda.eu/Research-Infrastructure/Training/Expert-Tour-Guide-on-Data-Management/5.-Protect/Anonymisation

#	Data	Availability	Notes
	Satisfaction survey and validation survey		
6	Regulatory Acceptability Activities, Plan, and Policy Recommendations - User Requirements Specifications	Closed	Data collected will be available only to 2D-BioPAD consortium and the EU Commission. In case there is a need to share information for dissemination and communication purposes, any sensitive information and identifiers related to the product development will be removed.
7	Regulatory Acceptability Activities, Plan, and Policy Recommendations - Requirements for a compliant development of in-vitro diagnostics system	Closed	Data collected will be available only to 2D-BioPAD consortium and the EU Commission. In case there is a need to share information for dissemination and communication purposes, any sensitive information and identifiers related to the product development will be removed.
8	Collaboration and Synergies with relevant projects and Initiatives	Open	-
9	Setup and Operation of Scientific and Industrial Advisory Board	Open & Closed	Information about the candidate members will remain confidential between the consortium and personal data will be treated as expected by the GDPR. The final composition of the AB together with the terms of reference will be publicly available through the project's website.
10	Co-designing the 2D-BioPAD System Architecture	Open & Closed	Data collected from experimental measurements will be available only to 2D-BioPAD consortium and the EU Commission. Corresponding results will be shared for dissemination purposes via peer-review publications and presentations in scientific conferences. Selected overview results will be communicated to the public via social media.
11	Synthesis of Aptamers for AD protein biomarkers	Open & Closed	Data collected from experimental sequences will be available only to 2D-BioPAD consortium and the EU Commission. Corresponding results will be shared for dissemination purposes via peer-review publications and presentations in scientific conferences. Selected overview results will be communicated to the public via social media.
12	Evaluation of Aptamers	Open & Closed	Data collected from experimental sequences will be available only to 2D-BioPAD consortium and the EU Commission. Corresponding results will be shared for dissemination purposes via peer-review publications and presentations in scientific conferences. Selected overview results will be communicated to the public via social media.
13	Aptamer generation and optimization of aptamers	Open & Closed	Data collected from experimental sequences will be available only to 2D-BioPAD consortium and the EU Commission. Corresponding results will be shared for dissemination purposes via peer-review publications and presentations in scientific conferences. Selected overview results will be communicated to the public via social media. These data may have interesting exploitation prospects (IP to determine that).

#	Data	Availability	Notes
14	Synthesis, characterization and evaluation of magnetic nanoparticles	Open & Closed	Data collected from experimental sequences will be available only to 2D-BioPAD consortium and the EU Commission. Corresponding results will be shared for dissemination purposes via peer-review publications and presentations in scientific conferences. Selected overview results will be communicated to the public via social media.
15	Immobilization, Functionalization & Evaluation of Conjugated MNPs/Aptamers/Biomarkers	Open & Closed	Data collected from experimental sequences will be available only to 2D-BioPAD consortium and the EU Commission. Corresponding results will be shared for dissemination purposes via peer-review publications and presentations in scientific conferences. Selected overview results will be communicated to the public via social media.
16	Synthesis of conductive functionalized graphenes	Open & Closed	The data are accessible to the WP researchers and restricted to others to ensure delivery of publications or patents based on the WP results. If published in a scientific journal, the corresponding author of the manuscript may share the data upon motivated request or following the journal's policy.
17	Conjugation of functionalized graphenes with biorecognition ssDNA units	Open & Closed	The data are accessible to the WP researchers and restricted to others to ensure delivery of publications or patents based on the WP results. If published in a scientific journal, the corresponding author of the manuscript may share the data upon motivated request or following the journal's policy.
18	Synthesis of Janus type functionalized graphene	Open & Closed	The data are accessible to the WP researchers and restricted to others to ensure delivery of publications or patents based on the WP results. If published in a scientific journal, the corresponding author of the manuscript may share the data upon motivated request or following the journal's policy.
19	Conjugation of Janus graphene with ssDNA for non-covalent functionalization of the FET graphene gate	Open & Closed	The data are accessible to the WP researchers and restricted to others to ensure delivery of publications or patents based on the WP results. If published in a scientific journal, the corresponding author of the manuscript may share the data upon motivated request or following the journal's policy.
20	Fabrication and Testing of the Graphene-based Electrochemical biosensor	Open & Closed	The data are accessible to the WP researchers and restricted to others to ensure delivery of publications or patents based on the WP results. If published in a scientific journal, the corresponding author of the manuscript may share the data upon motivated request or following the journal's policy.
21	Fabrication and Testing of the Graphene-based FET biosensors	Open & Closed	The data are accessible to the WP researchers and restricted to others to ensure delivery of publications or patents based on the WP results. If published in a scientific journal, the corresponding author of the manuscript may share the data upon motivated request or following the journal's policy.
22	Aptamer affinity prediction	Open & Closed	Part from PDB, part from the project experimental side.

#	Data	Availability	Notes
23	Graphene Functionalization Optimization	Open & Closed	Part from PDB, part from the project experimental side.
24	Advanced Microfluidics for Identifying Multiple Biomarkers	Open & Closed	The data will be accessible to the WP researchers and restricted to others to ensure delivery of publications or patents based on the WP results. If published in a scientific journal, the corresponding author of the manuscript may share the data upon motivated request or following the journal's policy.
25	Intelligent decision support module & User Interfaces	Open & Closed	The data will be accessible to the WP researchers and restricted to others to ensure delivery of publications or patents based on the WP results Personal / Sensitive data will not be shared among the consortium. Only de-identified (or anonymised where applicable) data will be shared among the consortium where needed for performing necessary tests and evaluation activities.
26	Casing prototyping and assembly	Open & Closed	Design results will be shared in the form of photographs.
27	Integrations lab testing and fine tuning	Open & Closed	The data will be accessible to the WP researchers and restricted to others to ensure delivery of publications or patents based on the WP results Only de-identified (or anonymised where applicable) data will be shared among the consortium where needed for performing necessary tests and evaluation activities.
28	Retrospective pilot study deployment and technical validation	Open & Closed	Personal/Sensitive data will not be shared among the consortium. Only de-identified (or anonymised where applicable) data will be shared among the consortium where needed for performing necessary tests and evaluation activities.
29	Prospective pilot study deployment and clinical validation – Biological fluid samples and relevant data of patients from clinical partners	Open & Closed	Personal/Sensitive data will not be shared among the consortium. Only de-identified (or anonymised where applicable) data will be shared among the consortium where needed for performing necessary tests and evaluation activities. The number of participants, demographics, and diagnosis will be available in project's deliverables.
30	Prospective pilot study deployment and clinical validation - Patients', caregivers' and health care practitioners' views and experiences	Open & Closed	Research participant data: as per national regulations in at least one partner country this type of data cannot be made publicly available. The number of participants, group-level demographics, and diagnosis will be available in project's deliverables.
31	Website analytics	Open & Closed	Website analytics will be available only to 2D-BioPAD consortium and the EU Commission. In case statistics are shared, data will be aggregated and anonymised before being made openly available, while personal data will be treated as expected by the GDPR.
32	Social Media statistics	Open & Closed	Social media analytics will be available only to 2D-BioPAD consortium and the EU Commission. In case statistics are shared, data will be aggregated and anonymised before being made openly available, while personal data will be treated as expected by the GDPR.

#	Data	Availability	Notes
33	Newsletter subscriptions	Closed	Data from newsletter subscriptions will remain closed as it contains personal information and is useful only for internal reporting purposes.
34	Data collected from dissemination and communication activities and events	Open & Closed	Data collected from dissemination and communication actions will be available only to 2D-BioPAD consortium and the EU Commission. In case there is a need to share information for dissemination and communication purposes, any personal information will be anonymised before being made openly available.

It is important to note that **all personal data collected/generated will be considered as closed data prior to their anonymisation and aggregation** to safeguard the confidentiality of the data subjects.

More details about **the data related to the clinical pilot studies** will be documented in **D5.1**, due in M12.

3.2.2.2 Data accessibility and availability

Public access to the open data will be made available and free of charge through Zenodo, which will automatically link to OpenAIRE. The data will be fully accessible thanks to the included metadata and the search facility available on Zenodo. At the same time, closed data are intended to be stored and shared amongst authorised members of the consortium through cloud storage and file sharing providers which constitute structures that maintain and manage data and make these data accessible over a network, usually the internet (i.e., MS Teams). Before starting using these cloud services from providers situated both inside and outside the EEA, we have ensured that they comply with the relevant GDPR requirements.

The following table presents where data will be made accessible in the context of 2D-BioPAD.

Table 7: Data accessibility

#	Data	Accessibility notes
1	Mapping and analysis of point-of-care AD solutions - Desk research and Interviews	2D-BioPAD website
2	Mapping and analysis of point-of-care AD solutions - Survey's results	Zenodo
3	Analysis of the needs, challenges, and available solutions for reliable, cost-effective, safe, and ethical early diagnosis of AD	N/A (closed data)
4	Cross-regional pilot studies evaluation and validation - Evaluation of performance criteria and metrics	Zenodo & 2D-BioPAD website
5	Cross-regional pilot studies evaluation and validation - Satisfaction survey and validation survey	Zenodo & 2D-BioPAD website
6	Regulatory Acceptability Activities, Plan, and Policy Recommendations - User Requirements Specifications	N/A (closed data)
7	Regulatory Acceptability Activities, Plan, and Policy Recommendations - Requirements for a compliant development of in-vitro diagnostics system	N/A (closed data)
8	Collaboration and Synergies with relevant projects and Initiatives	2D-BioPAD website and the websites of the collaborative projects and initiatives
9	Setup and Operation of Scientific and Industrial Advisory Board	2D-BioPAD website

#	Data	Accessibility notes
10	Co-designing the 2D-BioPAD System Architecture	2D-BioPAD website & social media
11	Synthesis of Aptamers for AD protein biomarkers	Zenodo & 2D-BioPAD website & social media
12	Evaluation of Aptamers	Zenodo & 2D-BioPAD website & social media
13	Aptamer generation and optimization of aptamers	Zenodo & 2D-BioPAD website & social media
14	Synthesis, characterization and evaluation of magnetic nanoparticles	Zenodo & 2D-BioPAD website & social media
15	Immobilization, Functionalization & Evaluation of Conjugated MNPs/Aptamers/Biomarkers	Zenodo & 2D-BioPAD website & social media
16	Synthesis of conductive functionalized graphenes	Zenodo, Data sets for scientific publications may be available following the policy of the journal/publisher.
17	Conjugation of functionalized graphenes with biorecognition ssDNA units	Zenodo, Data sets for scientific publications may be available following the policy of the journal/publisher.
18	Synthesis of Janus type functionalized graphene	Zenodo, Data sets for scientific publications may be available following the policy of the journal/publisher.
19	Conjugation of Janus graphene with ssDNA for non-covalent functionalization of the FET graphene gate	Zenodo, Data sets for scientific publications may be available following the policy of the journal/publisher.
20	Fabrication and Testing of the Graphene-based Electrochemical biosensor	Zenodo & 2D-BioPAD website & social media
21	Fabrication and Testing of the Graphene-based FET biosensors	Zenodo & 2D-BioPAD website & social media
22	Aptamer affinity prediction	2D-BioPAD website
23	Graphene Functionalization Optimization	2D-BioPAD website
24	Advanced Microfluidics for Identifying Multiple Biomarkers	Zenodo & 2D-BioPAD website & social media
25	Intelligent decision support module & User Interfaces	Zenodo & 2D-BioPAD website & social media
26	Casing prototyping and assembly	Zenodo & 2D-BioPAD website & social media
27	Integration lab testing and fine tuning	Zenodo & 2D-BioPAD website & social media
28	Retrospective pilot study deployment and technical validation	Standard procedures will be put in place for secure access to de-identified data, subject to appropriate material/data transfer agreements. Personal/patient data (even de-identified) will not be made publicly available. Meta-data might become publicly available (TBD).
29	Prospective pilot study deployment and clinical validation - Fluid samples and relevant data from clinical partners	Standard procedures will be put in place for secure access to de-identified data, subject to appropriate material/data transfer agreements. Personal/patient data (even de-identified) will not be made publicly available. Meta-data might become publicly available (TBD).
30	Prospective pilot study deployment and clinical validation - Patients', caregivers' and health care practitioners' views and experiences	2D-BioPAD website & scientific journal (TBD). Standard procedures will be put in place for secure access to de-identified data, subject to appropriate material/data transfer agreements. Qualitative data (e.g., anonymised shorter quotes from interviews) and high-level statistics from the

#	Data	Accessibility notes
		clinical trials will be provided in scientific publications. Personal/patient data (even de-identified) will not be made publicly available. Meta-data might become publicly available (TBD).
31	Website analytics	2D-BioPAD website
32	Social Media statistics	2D-BioPAD social media
33	Newsletter subscriptions	N/A (closed data)
34	Data collected from dissemination and communication activities and events	2D-BioPAD website

3.2.2.3 Restrictions on use

By utilising Zenodo for sharing the project's openly available data, 2D-BioPAD can apply **different levels of accessibility** for these data taking into account any relevant issues (such as ethical, rules of personal data, intellectual property, commercial, privacy-related, security-related, etc.).

More specifically, **Zenodo offers the following levels of data accessibility**:

- **Open access**: Data remains available for re-use. Nevertheless, the level in which these data can be re-used is determined also by their accompanied licence for re-use (see subsection 3.4.3);
- **Embargoed status**: Access to the data will be restricted until the end of the embargo period, at which time, the content will automatically become publicly available;
- **Restricted access**: The data will not be made publicly available and sharing will be made possible only by the approval of the project partner that have the responsibility of the data;
- **Closed access**: The data are protected against unauthorized access at all levels and only members of the consortium have the right to access it.

Project partners will mainly use the open access level to disseminate the project's data amongst the interested stakeholders. Data that will not be available for re-use will be accessible only by authorised partners of 2D-BioPAD's consortium and/or authorised personnel from the funding authority of the project.

Moreover, **2D-BioPAD will ensure open access to all peer-reviewed scientific publications** that may be produced in the framework of the project. In particular, according to the Grant Agreement, 2D-BioPAD will:

- at the latest at the time of publication, a machine-readable electronic copy of the published version or the final peer-reviewed manuscript accepted for publication, is deposited in a trusted repository for scientific publications;
- immediate open access is provided to the deposited publication via the repository, under the latest available version of the Creative Commons Attribution International Public Licence (CC BY) or a licence with equivalent rights; for monographs and other long-text formats, the licence may exclude commercial uses and derivative works (e.g., CC BY-NC, CC BY-ND);
- information is given via the repository about any research output or any other tools and instruments needed to validate the conclusions of the scientific publication.

Beneficiaries (or authors) must retain sufficient intellectual property rights to comply with the open access requirements.

3.2.2.4 Identity ascertainment and data access committee

The identity of stakeholders who want to access the data on Zenodo is not necessary to be ascertained, as the uploaded on Zenodo data are publicly open and no authorization is needed. On the other hand, closed for the public data will be available only to authorized consortium partners through dedicated mechanisms provided by the cloud storage service employed by the respective partners in order to deposit the data.

The need for a data access committee to evaluate or approve access requests to personal data, is not foreseen because only authorized partners will have access to the project's closed data, accessible only by using their credentials (username/password), and no third-party will re-use them for their benefit.

3.2.3 Metadata

3.2.3.1 Availability and licences

Metadata of deposited publications generated in the context of 2D-BioPAD will be **open under a Creative Common Public Domain Dedication (CC 0)** or equivalent, in line with the FAIR principles for data management adopted by the project (in particular machine-actionable). Such **metadata will provide information, at least, about the following**:

- The publication at hand (author(s), title, date of publication, publication venue);
- Reference to the Horizon Europe funding;
- The name of the project, including its acronym and Grant Agreement number;
- Any particular licensing terms which may apply (depending on the chosen license);
- Persistent identifiers that have been attributed to the publication;
- Authors involved in the action, their organisations and the project itself.

Where applicable, the metadata will also include persistent identifiers for any research output or any other tools and instruments needed to validate the conclusions of the publication. The metadata will be available through Zenodo. It is quite unlikely that Zenodo will terminate its operation and stop providing its services, but in such a case, all data, metadata, code and documentation uploaded will be transferred and hosted to other suitable repositories without undue delay. In this respect, it is important to note that, since all of 2D-BioPAD's openly available data will make use of PIDs (i.e., DOIs), which is further elaborated in subsection 3.1.1, the links to the data will not be affected. In parallel, the project's data that will not be openly available for sharing will be deposited, together with their accompanying metadata, code and documentation (if necessary), to the cloud web storage service employed by the project.

3.2.3.2 Methods, Software tools and documentation to access the data

2D-BioPAD emphasises the accessibility of the data collected/generated during the project. With that in mind, no specialised method, software tool and/or documentation is expected to be needed at the moment, in order to access the data. Stakeholders will have the ability to access the data by simply using their web browser (e.g., Mozilla, Google Chrome, Internet Explorer, Safari, etc.) through their computers (either desktop or laptop), smartphones and/or tablets.

More specifically, they first need to access Zenodo through its webpage (following the link https://zenodo.org/) and utilise the search engine of the repository to search for interesting data. By typing

the name of the project (or any other relevant keyword connected to the 2D-BioPAD data) the search engine will direct the user to the project's data, ready to be explored and re-used. Moreover, since the data will be available in open formats, we will be ensuring that they can appropriately be read by a range of different software that are widely and freely accessible to all potential users of the data.

Closed data will only be accessed by authorised project partners through the usage of a cloud storage service. Again, no specialised method, software tool and/or documentation is needed to this end.

As it was further elaborated in subsection 3.2.1, if Zenodo terminates its operation and stops providing its services, in such a case all data, metadata, code and documentation uploaded will be transferred and hosted to other suitable repositories without undue delay.

Along these lines, this section has provided the methodology applied in the frame of 2D-BioPAD to ensure that its data are as openly accessible as possible by any stakeholder that may find them interesting for re-use. In this context, 2D-BioPAD also focuses on providing metadata standards and appropriate metadata vocabularies to increase data interoperability. The following section provides further details in this respect.

3.3 Making data interoperable

Data interoperability refers to the ability of systems and services that create, exchange and use data to have clear, shared expectations for the contents, context and meaning of that data[24]. With that in mind, 2D-BioPAD has adopted in its data management methodology the use of metadata vocabularies, standards and methods that will increase the interoperability of the data collected/generated through its activities.

More specifically, **the interoperability of the data that will not be publicly shared will be facilitated by the use of the Dublin Core Metadata standard.** This standard is a small "metadata element set", which accounts for issues that must be resolved in order to ensure that data meet traditional standards for quality and consistency, while remaining broadly interoperable with other data sources in the linked data environment. The fifteen elements of the standard provide a vocabulary of concepts with natural-language definitions (e.g., title, creator, author, etc.) that are instantly converted into open machine-readable formats (such as XML, HTML, etc.), enabling machine-processability. Each element is optional and may be repeated, while the standard itself offers ways exist for refining them, encouraging the use of encoding and vocabulary schemes. The vocabulary of the Dublin Core Metadata standard is presented in the following table[25]:

Table 8: Dublin Core Metadata standard vocabulary

No	Element	Element definition
1	Title	A name given to the resource.
2	Creator	An entity primarily responsible for making the content of the resource.
3	Subject	The topic of the content of the resource.
4	Description	An account of the content of the resource.
5	Publisher	An entity responsible for making the resource available.
6	Contributor	An entity responsible for making contributions to the content of the resource.
7	Date	A date associated with an event in the life cycle of the resource
8	Type	The nature or genre of the content of the resource.

[24] L. Steele & T. Orrell (2017). The frontiers of data interoperability for sustainable development. Publish What You Fund and Development Initiatives

[25] Sugimoto, S., Baker, T., & Weibel, S. L. (2002). Dublin Core: Process and Principles. Lecture Notes in Computer Science Digital Libraries: People, Knowledge, and Technology, 25-35.

No	Element	Element definition
9	Format	The physical or digital manifestation of the resource.
10	Identifier	An unambiguous reference to the resource within a given context.
11	Source	A reference to a resource from which the present resource is derived.
12	Language	A language of the intellectual content of the resource.
13	Relation	A reference to a related resource.
14	Coverage	The extent or scope of the content of the resource.
15	Rights	Information about rights held in and over the resource.

Along similar lines, **the interoperability of openly available data will be facilitated through Zenodo**, which adopts community- endorsed practices, since its metadata are stored internally in JSON format according to a defined JSON schema. This encloses HTML microdata that allows machine-readable data to be embedded in HTML documents in the form of nested groups of name-value pairs. Moreover, the JSON schema provides a collection of shared vocabularies in microdata format that can be used to mark-up pages in ways that can be understood by major search engines.

2D-BioPAD's data will offer qualified references to other data. A qualified reference is a cross-reference that explains its intent. For example, X is regulator of Y is a much more qualified reference than X is associated with Y, or X see also Y. Our goal is to create as many meaningful links as possible between (meta)data resources to enrich the contextual knowledge about the data, balanced against the time/energy involved in making a good data model. To be more concrete, our references will specify if one dataset builds on another data set, if additional datasets are needed to complete the data, or if complementary information is stored in a different dataset. The links between the datasets will also be described and, all datasets will be properly cited, including their persistent identifiers.

3.4 Increase data re-use

3.4.1 Documentation for validating data analysis and facilitating data re-use

By utilising Zenodo for sharing the project's openly available data, 2D-BioPAD ensures the facilitation of data access, validation and re-use, in compliance to the general policies of Zenodo regarding content, access and reuse. More specifically, the following principles are followed by Zenodo to make data re-useable according to the FAIR principles[26]:

- R1: (meta)data are richly described with a plurality of accurate and relevant attributes

Each record contains a minimum of DataCite's mandatory terms, with optionally additional DataCite recommended terms and Zenodo's enrichments.

- R1.1: (meta)data are released with a clear and accessible data usage license

License is one of the mandatory terms in Zenodo's metadata, and is referring to an Open Definition license. Data downloaded by the users is subject to the license specified in the metadata by the uploader.

- R1.2: (meta)data are associated with detailed provenance

[26] Retrieved from: https://about.zenodo.org/principles/

All data and metadata uploaded is traceable to a registered Zenodo user. Metadata can optionally describe the original authors of the published work.

- R1.3: (meta)data meet domain-relevant community standards

Zenodo is not a domain-specific repository, yet through compliance with DataCite's Metadata Schema, metadata meets one of the broadest cross-domain standards available.

3.4.2 License schemes to permit the widest use possible

Data will be made freely available in the public domain to permit the widest re-use possible. Moreover, the application of a licence to 2D-BioPAD's open data is a simple way to ensure that any interested third-party can re-use it. In this context, licences are the instrument which permit a third-party to copy, distribute, display and/or modify the project's data only for the purposes that are set by the licence. Licences typically grant permissions on condition that certain terms are met. While the precise details vary, three conditions are commonly found in licences which are the attribution, non-derivative, and non-commerciality.

Along these lines, 2D-BioPAD publishes openly available data under the **Creative Commons licencing scheme** to foster their re-use and build an equitable and accessible environment for them. Zenodo provides 2D-BioPAD the **opportunity to publish its open data under five Creative Common licences** as follows:

- **Creative commons Attribution-Share Alike 4.0** (CC BY-SA 4.0) according to which any third party can freely copy, distribute, display and modify the datasets for any purpose. Remix, transform, or built upon data, must be distributed under the same license as the original. Third parties must give appropriate credit, provide a link to the license, and indicate if changes were made.

Figure 28: CC BY-SA 4.0

- **Creative Commons Attribution 4.0 International** (CC BY 4.0) according to which any third party can freely copy, distribute, display and modify the datasets for any purpose. Third parties must give appropriate credit, provide a link to the license, and indicate if changes were made.

Figure 55: CC BY 4.0

- **Creative Commons Attribution-No Derivatives 4.0 International** (CC BY-ND 4.0) during which any third party can freely copy, distribute, display and modify the datasets for any purpose. Remix, transform, or built upon data, however, must not be distributed. Third parties must give appropriate credit, provide a link to the license, and indicate if changes were made.

Figure 82: CC BY-ND 4.0

- **Creative Commons Attribution-Non-Commercial 4.0 International** (CC BY-NC 4.0) based on which third parties can copy, distribute, display and modify the datasets for any purpose other than commercial unless they get a permission by project partners first. Third parties must give appropriate credit, provide a link to the license, and indicate if changes were made.

Figure 107: CC BY-NC 4.0

- **Creative Commons Attribution-Non-Commercial-No-Derivatives 4.0 International** (CC BY-NC-ND 4.0) according to which third parties can copy, distribute, display and modify the datasets for any purpose other than commercial unless they get a permission by project partners first. Remix, transform, or built upon data, however, must not be distributed. Third parties must give appropriate credit, provide a link to the license, and indicate if changes were made.

Figure 122: CC BY-NC-ND 4.0

Different licensing schemes may be selected to better fit the need of 2D-BioPAD's open data ensuring not only their long-term preservation and re-use but also the interests of the consortium along with the rights of individuals for whom the data are about. In such a case, this subsection of the DMP will be updated accordingly.

3.4.3 Availability for re-use

The re-use of data is a key component of 2D-BioPAD's methodology for making data FAIR. In fact, making data available for re-use ensures interested stakeholders, other than project partners, can benefit from these data, contributing towards maximising the impact of the project. **Rich metadata** created based on metadata standards that enable proper discovery as well as **appropriate licensing schemes facilitate the re-use of 2D-BioPAD's open data**, allowing them to find valuable utility even after the end of 2D-BioPAD project.

In principle, it is expected that data will become available for re-use no later than 120 days after the end of its processing in the framework of the project (i.e., collection, anonymisation, aggregation, etc.) to ensure that any additional data management activities required to this end do not compete with the timely delivery of the project's planned outputs.

With that in mind, the expected time that 2D-BioPAD's data will be made openly accessible and uploaded to Zenodo is indicatively provided in the following table:

Table 9: Expected time that data will be made open through Zenodo[27]

No	Data	Expected time for making data open	Notes
1	Mapping and analysis of point-of-care AD solutions - Desk research and Interviews	after M6, due date for D1.1, or after 1st midterm review	-
2	Mapping and analysis of point-of-care AD solutions - Survey's results	after M6, due date for D1.1, or after 1st midterm review	-
3	Analysis of the needs, challenges, and available solutions for reliable, cost-effective, safe, and ethical early diagnosis of AD	N/A	Closed data
4	Cross-regional pilot studies evaluation and validation - Evaluation of performance criteria and metrics	M48	-
5	Cross-regional pilot studies evaluation and validation - Satisfaction survey and validation survey	M48	-

[27] This timetable is based on expectations and may be modified during the course of the project taking into account any unforeseen risk that may occur.

No	Data	Expected time for making data open	Notes
6	Regulatory Acceptability Activities, Plan, and Policy Recommendations - User Requirements Specifications	N/A	Closed data
7	Regulatory Acceptability Activities, Plan, and Policy Recommendations - Requirements for a compliant development of in-vitro diagnostics system	N/A	Closed data
8	Collaboration and Synergies with relevant projects and Initiatives	-	M1 to M48 on 2D-BioPAD website and the websites of the collaborative projects and initiatives
9	Setup and Operation of Scientific and Industrial Advisory Board	N/A	Data will be open in 2D-BioPAD website
10	Co-designing the 2D-BioPAD System Architecture	N/A	Datasets for scientific manuscripts may be provided by the corresponding author of the manuscript upon reasonable request during years of scientific activity of the author.
11	Synthesis of Aptamers for AD protein biomarkers	after 1st midterm review	Datasets for scientific manuscripts may be provided by the corresponding author of the manuscript upon reasonable request during years of scientific activity of the author.
12	Evaluation of Aptamers	after 1st midterm review	Datasets for scientific manuscripts may be provided by the corresponding author of the manuscript upon reasonable request during years of scientific activity of the author.
13	Aptamer generation and optimization of aptamers	after 1st midterm review	Datasets for scientific manuscripts may be provided by the corresponding author of the manuscript upon reasonable request during years of scientific activity of the author.
14	Synthesis, characterization and evaluation of magnetic nanoparticles	after 1st midterm review	Datasets for scientific manuscripts may be provided by the corresponding author of the manuscript upon reasonable request during years of scientific activity of the author.
15	Immobilization, Functionalization & Evaluation of Conjugated MNPs/Aptamers/Biomarkers	after 1st midterm review	-
16	Synthesis of conductive functionalized graphenes	after 1st midterm review	Datasets for scientific manuscripts may be provided by the corresponding author of the manuscript upon reasonable request during years of scientific activity of the author.
17	Conjugation of functionalized graphenes with biorecognition ssDNA units	after 1st midterm review	Datasets for scientific manuscripts may be provided by the corresponding author of the manuscript upon reasonable request during years of scientific activity of the author.
18	Synthesis of Janus type functionalized graphene	after 1st midterm review	Datasets for scientific manuscripts may be provided by the corresponding author of the manuscript upon reasonable request during years of scientific activity of the author.
19	Conjugation of Janus graphene with ssDNA for non-covalent	after 1st midterm review	Datasets for scientific manuscripts may be provided by the corresponding author of the

No	Data	Expected time for making data open	Notes
	functionalization of the FET graphene gate		manuscript upon reasonable request during years of scientific activity of the author.
20	Fabrication and Testing of the Graphene-based Electrochemical biosensor	M36	Datasets for scientific manuscripts may be provided by the corresponding author of the manuscript upon reasonable request during years of scientific activity of the author.
21	Fabrication and Testing of the Graphene-based FET biosensors	M42	-
22	Aptamer affinity prediction	-	M36 - Data will be open in 2D-BioPAD website
23	Graphene Functionalization Optimization	-	M36 - Data will be open in 2D-BioPAD website
24	Advanced Microfluidics for Identifying Multiple Biomarkers	M42	-
25	Intelligent decision support module & User Interfaces	M42	-
26	Casing prototyping and assembly	M42	-
27	Integration lab testing and fine tuning	M42	-
28	Retrospective pilot study deployment and technical validation	-	M48
29	Prospective pilot study deployment and clinical validation - Fluid samples and relevant data from clinical partners	-	M48
30	Prospective pilot study deployment and clinical validation - Patients', caregivers' and health care practitioners' views and experiences	-	M48 In 2D-BioPAD website & scientific journal (TBD)
31	Website analytics	N/A	-
32	Social Media statistics	N/A	-
33	Newsletter subscriptions	N/A	Closed data
34	Data collected from dissemination and communication activities and events	N/A	-

3.4.4 Data provenance

Data provenance is the documentation of where a piece of data comes from and the processes and methodology by which it was produced. Put simply, provenance answers the questions of why and how the data was produced, as well as where, when and by whom[28]. Accurately recording data provenance is a cornerstone of good data management. 2D-BioPAD will use specific elements of the **Dublin Core Metadata**

[28] https://ardc.edu.au/resource/data-provenance/

Standards[29] and the **W3C Provenance Data Model**[30], to generate specific text files (e.g., README) that will accurately capture the history of each data entity throughout its versions (e.g., based on the DOI versioning Zenodo provides)[31].

3.4.5 Data quality assurance processes

Quality Assurance (QA) and **Quality Control** (QC) activities are an integral part of 2D-BioPAD's data management methodology and are implemented prior to the publication of any data to Zenodo, safeguarding the transparency, consistency, comparability, completeness and accuracy of the data.

QA is a planned system of review procedures conducted outside the framework of developing a dataset, by personnel not directly involved in the dataset development process[32]. In the context of 2D-BioPAD, it takes the form of **peer-reviews of methods and/or data summaries** to assess the quality of the dataset and identify any need for improvement, ensuring that the dataset correctly incorporates the scientific knowledge and data generated.

QC is defined as a system of checks to assess and maintain the quality of the dataset being compiled[33]. The relevant procedures of 2D-BioPAD are designed to provide routine technical checks as they measure and control data consistency, integrity, correctness and completeness as well as identify and address errors and omissions. In this context, QC checks cover everything from data acquisition and handling, application of approved procedures and methods, and documentation. Some of the general quality checks undertaken in the framework of the project include checking (i) for transcription errors in data input; (ii) that scale measures are within the range of acceptable values; and (iii) whether proper naming conventions are used.

[29] https://www.dublincore.org/resources/userguide/creating_metadata/#Provenance
[30] https://www.w3.org/TR/prov-dm/
[31] https://help.zenodo.org/
[32] 2006 IPCC Guidelines for National Greenhouse Gas Inventories, Vol. 1 General Guidance and Reporting, CHAPTER 6 Quality Assurance / Quality Control and Verification.
[33] 2006 IPCC Guidelines for National Greenhouse Gas Inventories, Vol. 1 General Guidance and Reporting, CHAPTER 6 Quality Assurance / Quality Control and Verification.

4. Other research outputs

At the moment of elaborating the initial version of 2D-BioPAD's Data Management Plan, the following "other research outputs" have been identified and are expected to be generated or re-used in the context of the project.

Table 10: Other research outputs

Task	WTL	Responsible Partner	Research output	Brief description	digital/physical	Reasons	Benefits/exploitation	Interested stakeholders	Format	Size (KB)	Repository	Open access	FAIR principles	Timing for making data available
Task 5.3	GAA DRD	GAA DRD	Serum, plasma, csf biological material	Biological samples from patients combined with demographic and diagnostic data.	physical	The samples and combined data will be stored in GAADRAD Biobank for future research projects	The samples and combined data will be stored in GAADRAD Biobank for future research projects	GAADRD and collaborated research laboratories and associations	.docx, .xlsx, .csv, .jpeg, .png, .pdf	100 MB	Clinical centres Biobanks	Open & Closed	Yes	By End of the project (M48)

5. Allocation of resources

5.1 Estimated costs for making data FAIR

The costs required for making the data collected/generated during 2D-BioPAD's activities FAIR are integrated into the budget of the project. With that in mind, the table which follows provides an overview of the estimated costs of making data FAIR as well as their budget source within the framework of 2D-BioPAD.

Table 11: Estimated costs for making data FAIR

#	Data Processing / Management Activity	Budget source	Total estimated effort in Person Months[34]	Total estimated cost in Euro[35]
1	Collection	Budget allocated to the WP under which the respective data are processed	40.18	216,463.25 €
2	Documentation	Budget allocated to the WP under which the respective data are processed	11.48	61,846.64 €
3	Storage	Budget allocated to the WP under which the respective data are processed	5.74	30,923.32 €
4	Access and security	Budget allocated to the WP under which the respective data are processed	5.74	30,923.32 €
5	Preservation	Budget allocated to the WP under which the respective data are processed	2.87	15,461.66 €
6	Availability and re-use	Budget allocated to the WP under which the respective data are processed	17.22	92,769.96 €
7	Overall data management	WP6	3.95	21,279.99 €
		Total	**87.18**	**469,668.15 €**

In order to produce the estimations of the costs for making data FAIR in the context of 2D-BioPAD, a series of **assumptions** were made, taking into account the respective **guidelines** provided by the Research Data

[34] The total estimated effort for each data processing/management activity reflects the cumulative effort for the implementation of the respective activity for all data collected/generated across the different WPs of 2D-BioPAD.
[35] The total cost of each data processing/management activity is calculated by multiplying the effort estimated for the respective activity with the weighted average cost of a person month in the framework of 2D-BioPAD.

Management Support, a multidisciplinary network of data experts within Utrecht University[36], as well as of the UK Data Service and its data management costing tool[37]. With that in mind, the estimated costs for making 2D-BioPAD's data FAIR cover **data-related activities and resources across the data lifecycle**, spanning from collection and documentation through storage and preservation over to sharing and re-use.

In particular, costs for **data collection** cover activities necessary for acquiring external datasets (if required), gathering/generating new data, transcribing (if applicable), formatting and organising these data as well as acquiring informed consent from data subjects. These data processing activity reflects the majority of the costs required for making data FAIR as the majority of 2D-BioPAD's data constitutes new data collected/generated over the course of the project. At the same time, **data documentation** costs address the effort required for describing data (e.g., marking data with variable and value labels, code descriptions, etc.) as well as creating well-defined metadata along with a meaningful description of the context and methodology of how data was collected/generated and processed (where necessary).

Costs for **data storage** include the resources required for ensuring adequate storage space for the data as well as the effort necessary for conducting data back-ups, while **data access and security** costs encompass costs related to ensuring access to the data as well as for protecting it from unauthorised access or use or from disclosure. Given that the storage of 2D-BioPAD's data will not require the procurement of additional space (other than what is already available to project partners) as well as that no special measures or software are required to access and secure the data (other than what is inherently built into the repositories of 2D-BioPAD's data), such costs are kept to a minimum.

Data preservation costs, on the other hand, are estimated relatively higher than data storage, access and security costs, as additional effort will be required in several cases in order to convert the collected/generated data from their original form (e.g., physical interview transcripts) to an open and/or machine-readable format suitable for long-term preservation (e.g., to an .xlsx format.). Adequate effort for **data availability and re-use** costs is also foreseen to safeguard the appropriate digitisation and anonymisation of the data as well as cover any resources required for data sharing and cleaning. Along the same lines, appropriate effort is foreseen for **overall data management** as well, in order to cover the effort related with the operationalisation of data management in the framework of 2D-BioPAD.

Finally, costs for **long-term preservation** in the framework of 2D-BioPAD are assumed to be negligible since the open data of the project will be hosted in the repository of Zenodo free of charge.

5.2 Data management responsibilities

For the effective, proper and secure handling of the data collected/generated in the frame of 2D-BioPAD, specific data management roles have been established within the data management methodology and procedures of the project. These responsibilities are outlined in this section of the DMP and are as follows.

Project Management Office (PMO): The PMO, Q-PLAN, is responsible for overall data management in the framework of 2D-BioPAD, including the elaboration of the DMP and its updates (when necessary, along with support of all partners). At the same time, the PMO is responsible for the elaboration of proper templates for

[36] Research Data Management Support. Guides: Costs of data management. Utrecht University. Retrieved from: https://www.uu.nl/en/research/research-data-management/guides/costs-of-data-management

[37] UK Data Service. Costing Data Management. Retrieved from: https://www.ukdataservice.ac.uk/manage-data/plan/costing

the Informed Consent Form and the Data Subject Request Form to be appropriately adjusted and utilised by project partners during the relevant activities of the project as well as for drafting the project's Privacy Policy that has been uploaded on the project's website. The PMO in collaboration with the relevant project partners (e.g., Task Leaders) will examine if additional specific privacy policies are required for certain project's tasks and will coordinate the elaboration of such privacy policies. Also, the PMO in collaboration with EVNIA and UEF will further examine regulatory and clinical aspects respectively. Finally, the PMO coordinates with Work Package Leaders, Task Leaders and Responsible Partners to determine whether and how the data collected/generated or re-used by the project are shared and become available for re-use, contributes to its quality assurance and uploads the project's openly available data to Zenodo.

Work Package Leaders (WPL): The WPL is responsible for coordinating the implementation of the data processing activities performed under the WPs they are leading. Moreover, they align with the PMO and the respective Work Task Leader on whether and how the data gathered/produced under the tasks that fall within the WP they are leading will be shared and/or re-used. This includes the definition of access procedures as well as potential embargo periods along with any necessary software and/or other tools which may be required for data sharing and re-use. Finally, the WPL are the main responsible for assuring the quality of the data stemming from the activities of the WP they are leading, including assessing their quality and indicating any need for improvement to the respective Work Task Leaders.

Work Task Leaders (WTL): WTLs are responsible for the data collected/generated or re-used in the frame of the tasks that fall under their leadership as well as for safeguarding their appropriate and timely processing. Moreover, they are responsible for properly adjusting the Informed Consent Form and Data Subject Request Form templates, to the needs and specificities of the activities carried out in the task they are leading. WTLs are responsible for identifying the need for a specific privacy policy regarding the task they are leading and collaborate with the PC for drafting and releasing it to the public. Finally, they undertake any necessary actions to prepare the data collected/generated or re-used through the tasks they are leading for sharing either within the consortium or openly (including the use of proper naming conventions, application of suitable anonymisation techniques, creation of appropriate metadata and documentation, etc.).

Partners: All project partners are tasked to collect, digitise, anonymise, store, destroy and/or otherwise process data for the specific purpose of the activity in which it has been collected/generated or re-used within the project. They are responsible for appropriately collecting the necessary consent for processing data as well as for ensuring that the Informed Consent Form and the Data Subject Request Form used to this end are properly adjusted to the needs of the activity they are participating (including references to the project's Privacy Policy and any other applicable specific privacy policies) and, in any particularities, applicable to their organisation while ensuring adherence to provisions of relevant national data protection legislation in their respective country. Moreover, they are responsible for managing the consents they have collected with a view to demonstrating their compliance with the relevant applicable EU and national regulation(s). Finally, they perform quality checks to assess and maintain the quality of the dataset(s) held within their records.

Data repositories: Data repositories are tasked with the storage and long-term preservation of the project's data. In this respect, Zenodo will maintain and preserve the openly available data of 2D-BioPAD, enabling its sharing and re-use. To this end, Zenodo assigns metadata and DOIs to the data, while also taking all necessary measures to securely back-up the data and restore it, safeguarding its long-term preservation.

In this context, the following table illustrates the allocation of data management responsibilities amongst the members of the 2D-BioPAD consortium per data collected/generated or re-used under each WP.

Table 12: Data management responsibilities of 2D-BioPAD's partners per data collected/generated under each WP

WP	WPL	Data	Tasks	WTL	Responsible Partners
WP1	ICN2	Mapping and analysis of point-of-care AD solutions	Task 1.1	Q-PLAN	ALL
		Analysis of the needs, challenges, and available solutions for reliable, cost-effective, safe, and ethical early diagnosis of AD	Task 1.2	EVNIA	UP-CATRIN, Q-PLAN, ICN2, GRAPHEAL, AUTH, UEF, GAADRD, ZI
		Co-designing the 2D-BioPAD System Architecture	Task 1.3	ICN2	ALL
WP2	AUTH	Synthesis of Aptamers for AD protein biomarkers	Task 2.1	NOVA	AUTH, CeADAR
		Evaluation of Aptamers	Task 2.1 & Task 2.2	NOVA	AUTH, CeADAR
		Aptamer generation and optimization of aptamers	Task 2.1, Task 2.2 & Task 3.5	NOVA	AUTH & CeADAR
		Synthesis, characterization and evaluation of magnetic nanoparticles	Task 2.3	AUTH	NOVA
		Immobilization, Functionalization & Evaluation of Conjugated MNPs/Aptamers/Biomarkers	Task 2.4	AUTH	UP-CATRIN, ICN2, NOVA
WP3	UP-CATRIN	Synthesis of conductive functionalized graphenes	Task 3.1	UP-CATRIN	ICN2, GRAPHEAL
		Conjugation of functionalized graphenes with biorecognition ssDNA units	Task 3.1	UP-CATRIN	ICN2, GRAPHEAL
		Synthesis of Janus type functionalized graphene	Task 3.2	UP-CATRIN	ICN2, GRAPHEAL
		Conjugation of Janus graphene with ssDNA for non-covalent functionalization of the FET graphene gate	Task 3.2	UP-CATRIN	ICN2, GRAPHEAL
		Fabrication and Testing of the Graphene-based Electrochemical biosensor	Task 3.3	ICN2	UP-CATRIN, GRAPHEAL, AUTH, NOVA
		Fabrication and Testing of the Graphene-based FET biosensor	Task 3.4	GRAPHEAL	UP-CATRIN, ICN2, AUTH, NOVA
		Aptamer affinity prediction	Task 3.5	CeADAR	UP-CATRIN, ICN2, and GRAPHEAL
		Graphene Functionalization Optimization	Task 3.5	CeADAR	UP-CATRIN, ICN2, and GRAPHEAL
WP4	GRAPHEAL	Advanced Microfluidics for Identifying Multiple Biomarkers	Task 4.1	GRAPHEAL	ICN2

WP	WPL	Data	Tasks	WTL	Responsible Partners
		Intelligent decision support module & User Interfaces	Task 4.2	GRAPHEAL	UP-CATRIN, Q-PLAN, ICN2, AUTH, UEF, GAADRD, EVNIA, ZI, CeADAR
		Casing prototyping and assembly	Task 4.3	GRAPHEAL	UP-CATRIN, ICN2
		Integration lab testing and fine tuning	Task 4.4	GRAPHEAL	UP-CATRIN, ICN2, AUTH, NOVA, UEF, GAADRD, EVNIA, ZI, CeADAR
WP5	UEF	Retrospective pilot study deployment and technical validation	Task 5.2	UEF	UP-CATRIN, ICN2, GRAPHEAL, AUTH, GAADRD, EVNIA, ZI
		Prospective pilot study deployment and clinical validation	Task 5.3	GAADRD	UP-CATRIN, ICN2, GRAPHEAL, AUTH, UEF, EVNIA, ZI
		Cross-regional pilot studies evaluation and validation	Task 5.4	ZI	UP-CATRIN, Q-PLAN, ICN2, GRAPHEAL, AUTH, NOVA, UEF, GAADRD, EVNIA
WP6	Q-PLAN	Monitoring and assessment of the dissemination, communication and stakeholder engagement activities	Task 6.1	Q-PLAN	ALL
		Regulatory Acceptability Activities, Plan, and Policy Recommendations	Task 6.4	EVNIA	UP-CATRIN, Q-PLAN, ICN2, GRAPHEAL, AUTH, UEF, GAADRD, EVNIA, ZI, CeADAR
		Collaboration and Synergies with relevant projects and Initiatives	Task 6.5	Q-PLAN	ALL
WP7	UP-CATRIN	Setup and Operation of Scientific and Industrial Advisory Board	Task 7.2	GAADRD	ALL

6. Data security

2D-BioPAD will securely handle any collected/generated or re-used data throughout its entire lifecycle as it is essential to safeguard these data against accidental loss and/or unauthorised access. To achieve this the project will apply appropriate technical and organisational measures based on a risk assessment of the relevant data that takes into account the impact and the likelihood of a potential data breach. With that in mind, the project's data security strategy aims at minimizing the probability that a data breach will occur during the course and after the completion of 2D-BioPAD, resulting either from human error or hardware failure, as well as inhibit any unauthorised access. Particularly, in case of personal data collection/generation it is crucial that these **data can only be accessible by those authorised to do so.**

Regarding the security and handling of **sensitive data** deriving **from the clinical trials**, a report on "Clinical Pilot Studies Initiation Package and Ethics check" (**D5.1**) will be created by M12, encapsulating all information and guidelines needed.

All project partners are responsible for processing[38] data using appropriate means, such as private servers or cloud service providers that adhere to the relevant legal data protection requirements (e.g., GDPR) and will ensure that these **data are protected,** and any **necessary data security controls have been implemented**, to minimize the risk of information leak and destruction. This case refers to the data that will be closed and therefore will not be shared and/or re-used within the framework of the project. In this case, to minimize the consequences of potential data losses, the data will be **backed up at regular time intervals based on change frequency and criticality. The backed-up files will be stored in appropriate storage media including external hard drives, flash drives, NAS devices and reputable cloud services**, so as to safeguard their preservation, while also enabling their recovery at any time. Moreover, **integrity checks**[39] will be carried out regularly ensuring that the stored data has not been changed or corrupted.

Access to closed data will only be permitted to authorised project partners. In case there is a **personal data breach**, the responsible **project partner will notify, without undue delay** and, where feasible, no later than **72 hours after having become aware of it, its competent national supervisory authority** (e.g., data protection authority) **as well as the data subject(s) that may be affected by the breach.** Moreover, the responsible partner will document any personal data breaches, including information such as the facts relevant to the breach, its effects and the remedial action(s) taken.

Identification and authentication access controls play an important role in the context of the project, as they help partners to protect the data collected/generated or re-used during 2D-BioPAD and especially personal data. To this end, each project partner is responsible for and committed to ensuring the application of appropriate access controls to the data they are processing. Finally, in order to safeguard the privacy of the users of the 2D-BioPAD website, a dedicated **privacy policy** will define the way in which this online space collects, processes and uses personal data, the security procedures followed, the users' rights as well as the cookies policy employed.

[38] Processing, according to Regulation (EU) 2016/679 of the European Parliament (General Data Protection Regulation), means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

[39] An integrity check is the process of comparing the current state of stored data and/or programs to a previously recorded state in order to detect any changes.

On another note, openly available data will be stored safely for long-term preservation on Zenodo, in the same cloud infrastructure as research data from CERN's Large Hadron Collider, using CERN's battle-tested repository software INVENIO, which is used by some of the world's largest repositories (such as INSPIRE HEP and the CERN Document Server). Along these lines, data are stored and backed-up in CERN's EOS service in an 18 petabytes disk cluster. Both data files and metadata are kept in multiple online replicas and independent replicas ensuring their long-term preservation as well as their recovery when necessary. Moreover, for each file two independent MD5 checksums are stored. One checksum is stored by INVENIO, used to detect changes to files made from outside of it whereas the other checksum is stored by EOS, and used for automatic detection and recovery of file corruption on disks. In this context, access control is applied by the different level of openness that Zenodo allows (i.e., open, restricted and closed).

7. Ethics and other issues

This Chapter addresses the ethical aspects of the 2D-BioPAD's Data Management Plan and the ethical compliance of the underlying data foreseen to be collected/generated or re-used under the project's activities. The project will process **data that is not included in any special category of personal data** (i.e., non-sensitive data), according to the relevant data protection legislation (e.g., GDPR), **whereas any sensitive personal data** related to the subjects and samples of the clinical pilot studies will be handled according to GDPR requirements and all, potential additional National regulations, by the clinical centres. **More information about the clinical studies will be elaborated under the activities of T5.1 and documented in D5.1 which is due M12 (September 2024).**

Non-sensitive data:

In accordance with the **Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (GDPR),** all personal data processed for project's activities shall be:

- processed lawfully, fairly and in a transparent manner in relation to the data subject;
- collected for specified, explicit and legitimate purposes relative to project's objectives and not further processed in a manner that is incompatible with those purposes;
- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed;
- accurate and, where necessary, kept up to date;
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed;
- processed in a manner that ensures appropriate security of the personal data (see section 6).

For all personal data processing activities within the framework of the project at least one lawful basis as of Art. 6 GDPR applies. Where informed consent is chosen as the lawful basis for processing, all relevant provisions of the data protection legislation (e.g., Art.7 GDPR) shall be fulfilled. Under this light, further details about the **scope of the activities that entail data collection/generation or re-use** in the frame of 2D-BioPAD along with the procedures for identifying/recruiting suitable stakeholders to take part in them as well as for obtaining their informed consent are defined by the respective WP Leaders (ICN2 for WP1, AUTH for WP2, UP-CATRIN for WP3, GRAPHEAL for WP4, UEF for WP5, Q-PLAN for WP6, UP-CATRIN for WP7). Moreover, **personal data processing carried out by partners are in line with relevant EU and national regulations**. The project's Privacy Policy[40] and the templates of the Informed Consent Form[41] and the Data Subject Request Form, used in the implementation of the project's activities, are compliant with the General Data Protection Regulation and annexed to this DMP (see Annex I, II and III). Last but not least, **no transfer of personal data outside the EU is foreseen as part of the project's implementation.** In case of data storage providers situated both inside and outside the EEA, partners are committed to ensure their compliance with the relevant GDPR requirements before they start using the data storage providers' services.

[40] A tailored Privacy Policy will also be drafted later in the course of the project regarding the mobile app that will accompany the 2D-BioPAD device. The tailored version will be included in Version 2 of the Data Management Plan.
[41] A tailored Consent Form will also be drafted later in the course of the project to be shared with the subjects that will be included in the clinical pilot studies. The tailored version will be included in Version 2 of the Data Management Plan.

It is important to highlight that **each partner is responsible for ensuring that the templates for the Informed Consent Form and Subject Data Request Form (including references to the project's Privacy Policy and any other applicable specific privacy policies) are appropriately adjusted** according to (i) the needs of the activity for which they are being used by them as well as to (ii) the relevant data protection laws and regulations applicable on European, national and organization level. **All partners should keep records to demonstrate that data subjects have consented to the processing of their personal data** and ensure that consent management mechanisms are in place according to Art. 7(3) of GDPR to make it easy for individuals to withdraw their consent.

Sensitive data:

In general, the consortium will carry out the action in compliance with:

- ethical principles (including the highest standards of research integrity) and
- applicable EU, international and national laws and regulations, including, but not limited to the EU Charter of Fundamental Rights, the European Convention for the Protection of Human Rights and Fundamental Freedoms[42] and its Supplementary Protocols, and the International Council for Harmonisation (ICH) principles[43] for quality, safety, efficacy and good clinical practice where applicable.

The consortium will also pay particular attention to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of persons, the right to non-discrimination, the need to ensure protection of the environment and high levels of human health protection. The beneficiaries will ensure that the activities under the action have an exclusive focus on civil applications. And that the activities under the action do not:

- aim at human cloning for reproductive purposes;
- intend to modify the genetic heritage of human beings which could make such modifications heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed);
- intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer, or
- lead to the destruction of human embryos (for example, for obtaining stem cells).

In addition, the beneficiaries will respect the **fundamental principle of research integrity** — as set out in the European Code of Conduct for Research Integrity[44]. This implies compliance with the following principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;

[42] https://www.echr.coe.int/documents/d/echr/convention_eng

[43] ICH principles:
- https://www.ich.org/page/ich-guidelines
- https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice-scientific-guideline

[44] https://allea.org/wp-content/uploads/2023/06/European-Code-of-Conduct-Revised-Edition-2023.pdf /

- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices including ensuring, where possible, openness, reproducibility and traceability and refrain from the research integrity violations described in the Code.

Activities raising ethical issues will comply with the additional requirements formulated by the ethics panels (including after checks, reviews or audits as described in Article 25 of the DoA). Before starting an action task raising ethical issues, the beneficiaries will have obtained all approvals or other mandatory documents needed for implementing the task, notably from any (national or local) ethics committee or other bodies such as data protection authorities. The documents will be kept on file according to European and national requirements for data storage and will be submitted upon request by the coordinator to the granting authority.

Personal data are expected to be handled **only by the clinical centres individually,** according to their European and National regulations, and will not be circulated to the consortium before anonymisation or pseudoanonymisation. More information about the personal data related to the clinical pilot studies will be elaborated during the activities of T5.1 and documented in D5.1, which is due M12. Key aspects will be incorporated in the next version of the DMP, i.e., D7.3 due M24.

Finally, regarding **other national/funder/sectoral/departmental procedures for data management** in the framework of 2D-BioPAD, at the moment of drafting this deliverable, **the following were identified and will be used in the framework of 2D-BioPAD**.

Table 13: Other Issues

Task	Responsible Partner	Other procedures for data management	Title	Description
3.1	UP-CATRIN	departmental	Raw data management	Centralized raw data management plan will be introduced at UP-CATRIN for traceability of sample synthesis and analysis.
3.2	UP-CATRIN	departmental	Raw data management	Centralized raw data management plan will be introduced at UP-CATRIN for traceability of sample synthesis and analysis.

8. Conclusions and way forward

This initial version of the 2D-BioPAD DMP aims at safeguarding the sound management of the data collected, processed and/or generated during the project's activities across their entire lifecycle, while also making them FAIR. It describes all the underlying processes of the 2D-BioPAD data management, collection, process and generation, in accordance with the GDPR guidelines, and sheds light on (i) the data being collected, processed, generated and/or re-used under the project activities, (ii) the specific objectives under which each dataset is collected, processed, generated and/or re-used, (iii) the management of the other research outputs of the project (iv) the allocation of resources and data management responsibilities and (v) the data security and ethical aspects of the data.

In the framework of 2D-BioPAD, the DMP is a living document and is updated throughout the course of the project, considering its latest developments and available results. It is expected to be further developed and updated at least twice by the end of the project (i.e., as D7.3 by M24 and as D7.4 by M48). If necessary, additional ad hoc updates may be released in order to include new data, better detail and/or reflect modifications in the methodologies applied or other aspects relevant to data management (such as costs for making data FAIR, size of data, etc.), changes in consortium policies and plans or other potential external factors.

9. Annexes

9.1 Annex I – Privacy Policy

PRIVACY POLICY

1. Who we are:

2D-BioPAD is a project funded by the European Union's Framework Programme for Research and Innovation Horizon Europe (GA 101120706). The project started in October 2023 and will last 48 months.

2D-BioPAD is developing **a fast, reliable, cost-effective**, **non-invasive, digitally and graphene-enabled Point-of-Care** (PoC) ***in-vitro*** **diagnostics** (IVD) **system** for **early Alzheimer's Disease** (AD) detection. To achieve this, and tackle the scientific challenge, the technological and market gap of PoC IVD for AD, 2D-BioPAD leverages the unique properties of 2D materials, such as graphene and its derivatives. The 2D-BioPAD system and its impact will be demonstrated in 3 clinical centres in **Finland, Greece, and Germany**, under two clinical pilot studies, one retrospective with existing samples and one engaging MCI/AD subjects in real-life clinical practice. The device will be accompanied by a user-friendly mobile app that will give real-time access to quantified results to healthcare professionals in primary healthcare settings. Along the way, Artificial Intelligence (AI) will be used for optimising the design and implementation of the 2D-BioPAD system.

The partners of the 2D-BioPAD consortium, listed below, process certain types of personal data for the purposes of the project. Each partner is responsible for the personal data they collect and process during their activities under the framework of the project:

- UP-CATRIN | UNIVERZITA PALACKEHO V OLOMOUCI - CATRIN, Czechia (Coordinator), *https://www.catrin.com/*
- Q-PLAN | Q-PLAN INTERNATIONAL ADVISORS PC, Greece, *https://qplan-intl.gr/*
- ICN2 | FUNDACIO INSTITUT CATALA DE NANOCIENCIA I NANOTECNOLOGIA, Spain, *https://www.icn2.cat/en/*
- GRAPHEAL, France, *www.grapheal.com*
- AUTH | ARISTOTELIO PANEPISTIMIO THESSALONIKIS, Greece, *https://www.auth.gr/en/*
- NOVA | NOVAPTECH, France, *https://novaptech.com*
- UEF | ITA-SUOMEN YLIOPISTO, Finland, *https://www.uef.fi/en*

- GAADRD | ELLINIKI ETAIRIA NOSOY ALZHEIMER KAI SYGGENON DIATARACHON SOMATEIO, Greece, *www.alzheimer-hellas.gr*
- EVNIA | EVNIA APS, Denmark, *https://www.evnia.dk/*
- ZI | ZENTRALINSTITUT FUER SEELISCHE GESUNDHEIT, Germany, *www.zi-mannheim.de*
- CeADAR | UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN, Ireland, *https://www.ceadar.ie/*

For further information, we can be contacted at: info@2d-biopad.eu.

2. How we collect your personal data

We collect personal data both directly and indirectly:

Directly. We obtain personal data directly from individuals in a variety of ways, including, but not limited to, the following cases:

- an individual subscribes to our newsletter/s;
- an individual registers to attend meetings and events we host and during attendance at such events;
- we establish cooperative relationships with an individual;
- we provide professional services pursuant to our contract with the European Commission;
- an individual participates in an interview or survey organized by us.

Indirectly. We obtain personal data indirectly about individuals from a variety of sources, including:

- our research partners;
- our networks and contacts;
- public and open data sources such as public registers, news articles and internet searches;
- social and professional networking sites (e.g., LinkedIn).

3. What types of data we collect?

We only collect the data that are necessary for the smooth implementation of our project. These data fall into the following categories:

- **contact details** (name/surname, e-mail address, street address, mobile phone number, land line phone number);
- **professional information** (job title, organization, field of expertise);
- **demographics** (e.g., age, gender, nationality);
- **information about what a person knows or believes;**
- **videos and photos** (from people that attend our events).

4. Bases of lawful processing

We process personal data on the following legal bases:

Legal obligations - for processing activities required for compliance both with applicable national and European legislation as well as with the specific legal and regulatory framework of the Horizon Europe Framework Programme for Research and Innovation of the European Union.

Consent – for processing activities such as organization of surveys and interviews, completing of questionnaires and dissemination of project's results.

Contractual obligations - for processing activities such as reporting to the European Commission and complying with project's publicity obligations.

5. What we do with your personal data

We process your personal data with the purpose of:

- Conducting research (e.g., interviews, surveys);
- Dissemination our project's results to different types of stakeholder;
- Sending invitations and providing access to guests attending our events and webinars;
- Administering, maintaining, and ensuring the security of our information systems, applications, and websites;
- Processing online requests or queries, including responding to communications from individuals;
- Complying with contractual, legal, and regulatory obligations.

6. How we secure your personal data when we process it

We continuously apply a personal data risk assessment process to identify, analyse, and evaluate the security risks that may threat your personal data. Based on the results of this risk assessment, we define and apply a set of both technical and organizational measures to mitigate the above security risks, including but not limited to:

- Data Protection Policies to guide our personnel when processing your data;
- Written contracts with organizations that process personal data on our behalf;
- Non-Disclosure Agreements with our personnel;
- Back up process, antimalware protection, access control mechanisms, etc.;
- Some of our partners have appointed a Data Protection Officer.

7. Do we share personal data with third parties?

We may occasionally share personal data with trusted third parties to help us deliver efficient and quality services. When we do so, we ensure that recipients are contractually bound to safeguard the data we entrust to them before we share the data. We may engage with several or all the following categories of recipients:

- Parties that support us as we provide our services (e.g., cloud-based software services such as Dropbox, Microsoft SharePoint, Google);
- Our professional advisers, including lawyers, auditors, and insurers;
- Dissemination services providers (e.g., MailChimp);

- Law enforcement or other government and regulatory agencies or other third parties as required by, and in accordance with applicable law or regulation;
- The European Commission according to our relevant contractual obligations.

8. Do we transfer your personal data outside the European Economic Area?

We do not own file servers located outside the European Economic Area (EEA). However, some partners may use cloud and/or marketing services from reputable providers such as SharePoint, DropBox, MailChimp, Google, etc., situated both inside and outside the EEA. We always check that such providers comply with the relevant GDPR requirements before start using their services.

9. Do we use cookies?

Our website, https://www.2d-biopad.eu, uses cookies. We use cookies to improve site navigation and to analyse our traffic. In the next paragraphs, you will learn what cookies are, what cookies we use and how you can disable their use.

Cookies are small alphanumeric characters files that are transferred from websites that you visit to your PC, smartphone, tablet or any other electronic device that you use for browsing. Cookies assign your computer with a unique ID, which in turn becomes your own identity each time you return to a website. Cookies do not damage your electronic equipment, nor can they read information from other files on your computer's hard drive.

Websites use cookies to "remember" for a period your actions and preferences such as language, font size and other display features. In this way, you are not required to enter these preferences each time you visit a website and navigate its pages. Furthermore, cookies help website owners to analyse how you are using their website and whether or not you are facing problems as you navigate them.

Personal Data Protection legislation states that we can store cookies on your device if they are strictly necessary for the operation of our website. For all other types of cookies, we need your consent. You can change or withdraw your consent at any time from the Cookies Settings on our website.

On our website, https://www.2d-biopad.eu, we use necessary, statistics and functional cookies. Some cookies are placed by third-party services (e.g., Google Analytics).

Without the necessary cookies, the website cannot perform its basic functions. These cookies are generally placed automatically either when a webpage is loaded or as a result of a user's request (that cannot be fulfilled without using a relevant cookie). Usually, necessary cookies expire when you close your browser.

Statistics cookies help us to measure our website's traffic and where it comes from so that we can improve its performance. Moreover, they collect information about which pages are more popular and how visitors use our website. None of this information can be used to identify you. It is all aggregated and, therefore, anonymized. This category includes cookies from third-party analytics services such as Google Analytics. Our website uses the following statistics cookies:

Name	Provider	Purpose	Cookie expires after
_ga	Google Analytics	This cookie is used to distinguish unique users by assigning a randomly generated number as a client identifier. It is included in each page request on a site and used to calculate visitor, session and campaign data for the site's analytics reports.	2 years
_gid	Google Analytics	This cookie stores and updates a unique value for each page visited. It is used to generate statistical data on how the visitor uses the website. It collects anonymized data including the number and origin of visitors and the websites they visited.	1 day
_gat	Google Analytics	This cookie is used to throttle the request rate, that is limiting the collection of data on high-traffic sites.	1 minute

Functionality cookies allow websites to remember the user's site preferences and choices they make on the site including username, region, and language. This allows the website to provide personalized features if you share your location. They are anonymous and do not track browsing activity across other websites.

You can delete cookies and stop them from being installed in your browser. There is no standardized way to remove cookies since different browsers clear cookies using different procedures. Please follow the instructions provided by each browser manufacturer on how to remove cookies.

If you wish to stop sending your information to Google Analytics, you may install in your browser the Google Analytics Opt-out Browser Add-on.

You may select and change the cookie settings (with the exception of the technically necessary cookies) by clicking on Cookie settings. By making a cookie active, you consent to its use according to the provisions of this Cookies Policy.

10. Your rights

You have the following rights regarding our processing of your personal data:

- **Right to withdraw consent** – You can withdraw consent that you have previously given to one or more specified purposes to process your personal data. This will not affect the lawfulness of any processing carried out before you withdraw your consent.
- **Right of access** – You can ask us to verify whether we are processing personal data about you and, if so, to have access to a copy of such data.
- **Right to rectification and erasure** – You can ask us to correct our records if you believe they contain incorrect or incomplete information about you or ask us to erase your personal data after you withdraw your consent to processing or when we no longer need it for the purpose it was originally collected.
- **Right to restriction of processing** – You can ask us to temporarily restrict our processing of your personal data if you contest the accuracy of your personal data, prefer to restrict its use rather than

having us erase it, or need us to preserve it for you to establish, exercise or defend a legal claim. A temporary restriction may apply while verifying whether we have overriding legitimate grounds to process it. You can ask us to inform you before we lift that temporary processing restriction.

- **Right to data portability** – In some circumstances, where you have provided personal data to us, you can ask us to transmit that personal data (in a structured, commonly used, and machine-readable format) directly to another entity.
- **Right to object –** You can object to our use of your personal data for direct marketing purposes, including profiling or where processing has taken the form of automated decision-making. However, we may need to keep some minimal information (e.g., e-mail address) to comply with your request to cease marketing to you.
- **Right to make a complaint to your local Data Protection Authority** (DPA) (see *https://ec.europa.eu/justice/article-29/structure/data-protection-authorities/index_en.htm*) regarding any concerns you may have about our data handling practices.

To ask us to do anything of the above, you can contact us by email: info@2d-biopad.eu. We will promptly examine your request against the relevant requirements of the laws and regulations governing privacy and personal data protection and we will answer the latest within 30 days after receiving your request. We will ask from you some kind of identification (e.g., photocopy of your identity card or passport) to avoid non-authorized reveal of your personal data. If, for reasons of complexity of the request or a multitude of requests, we are unable to respond promptly, we will notify you within 30 days of any delay, which in no case may exceed two months from the expiration of the 30-day deadline.

11. How long do we retain personal data?

We retain personal data to provide our services, stay in contact with you and to comply with applicable laws, regulations, and contractual obligations to which we are subject. Please note that we have an obligation to retain data concerning projects funded by the Horizon Europe Framework Programme for Research and Innovation of the European Union for up to five years after the end of the project (unless further retention is requested by auditors). After the expiry of the retention period, and unless further legitimate grounds for retention arise, we will dispose of personal data in a secure manner.

12. Disclaimer of liability for third party websites

Although our site may contain links to third-party sites, including the sites of the consortium partners, we are not responsible for the privacy practices or content of these sites, and we expressly disclaim any liability for any loss or damage that may be caused by the use of these links. We do not monitor the privacy practices or the content of these sites. If you have any questions about the privacy practices of another site, you should contact the site's responsible personnel. We suggest you read the privacy policy of each website you interact with, before allowing the collection and use of your personal data.

We may also provide social media features that allow you to share information on your social networks and interact with our project on various social media sites. The use of these social media features may result in the collection or sharing of information about you. We recommend that you check the privacy policies and regulations of the social networking sites you interact with, so that you can be sure that you understand what information may be collected, used, and disclosed by these sites.

13. Children

We do not knowingly collect, use, or disclose information from children under the age of 16. If we learn that we have collected the personal information of a child under 16, we will take steps to delete the information as soon as possible. Please immediately contact us if you become aware that a child under 16 has provided us with personal information.

14. Revisions of this Privacy Policy

This Privacy Policy is valid from 01/01/2024 and replaces any other previous notifications that we had issued in the past regarding our personal data management practices. We reserve the right to revise this Policy at any time. The current version will be always uploaded to our website indicating the date of entry into force, so you know when the most recent revision took place. If there are critical changes in this policy or our personal data practices change significantly in the future, we will notify you by posting the changes on our website.

It is important to note here that a **tailored Privacy Policy** will also be drafted later in the course of the project regarding the **mobile app** that will accompany the 2D-BioPAD device. The tailored version will be included in Version 2 of the Data Management Plan.

9.2 Annex II – Informed Consent Form

Text in red colour contains guidelines for adjusting this template and should be deleted.

Text in grey colour contains examples and should be adjusted to the context of each activity.

Text included in < > and/or highlighted with yellow should be replaced with content that is suitable to the context of each activity & project as well as to the organisation seeking to obtain the consent.

Before using this template take the time to carefully read and adjust it to the needs of the activity at hand as well as to any relevant regulations and particularities applicable to your country and organisation.

INFORMED CONSENT FORM

Who we are:

We are < Insert Partner Name > and we are contacting you in the framework of 2D-BioPAD a project funded by the European Union under the Horizon Europe Framework Programme for Research and Innovation. A detailed description on how 2D-BioPAD handles personal data is presented in the project's *Privacy Policy* available through the project's web page (www.2d-biopad.eu).

Project:

2D-BioPAD – Supple Graphene Bio-Platform for point-of-care early detection and monitoring of Alzheimer's Disease (GA Number 101120706).

Partner:

Organisation name: < Insert Partner Name >

Address: < Insert Partner Address >.

Phone: < Insert Partner Phone >.

E-mail: <Insert Partner Generic E-mail Address >

Responsible persons:

You may delete the line referring to the Data Protection Officer if your organisation does not have one.

#	Role	Name	E-mail
1	2D-BioPAD Project Manager	<Insert name of project manager from your organisation>	<Insert e-mail of project manager from your organisation >
2	Interviewer	<Insert name of interviewer from your organisation >	<Insert e-mail of interviewer from your organisation >

#	Role	Name	E-mail
3	Data Protection Officer	<Insert name of DPO from your organisation >	<Insert e-mail of DPO from your organisation >

What do we need from you?

Please explain in a brief paragraph (4-5 lines) the activity and its purpose under the frame of the project.

Example: We need you to participate in an interview that will be carried out by 2D-BioPAD with a view to identify the Point-of-care AD diagnostics' user-centred requirements, needs and challenges.

The interview is expected to last for no more than < Insert number of minutes > minutes. We will take written notes and we will be making a sound recording of the interview.

Please adapt the following text to accurately depict the type of personal data to be collected.

To effectively conduct this interview, we need to process some of your personal data:

- Your contact details (full name, email, phone number);
- Some basic demographics (age, gender);
- Your professional info (organization, job position, field of expertise);
- Your education info;
- Your opinions on the subject matter;
- Your photos.

Why do we need your data & what will we do with them?

We need your data to contact you in order to plan and carry out the aforementioned interview and to resolve any ambiguities, questions and other issues that may arise after and as a result of the interview. We also need to record your data to keep track of the interview process. The project's deliverables that will be derived by the interview will not include your personal data or any other information that could identify you. Your personal data will remain on our written notes (interview's transcript) and the sound recording we will make during the interview.

We will share your data with a few other 2D-BioPAD project partners that are also involved in this task and will participate in the drafting of the relevant deliverables. We are also obliged to grant access to your data to:

- EU officials such as our Project Officer for purposes related to project's evaluation;
- EU agencies and other authorities for project's auditing purposes.

We would also be very happy if you gave us your consent to contact you in the future to ask you to participate in other project's activities (e.g., surveys, interviews, project events etc.) and also to inform you about the project's progress (e.g., by sending you a newsletter or similar messages).

How can you withdraw your consent?

You should know that you can withdraw your consent at any time by communicating either on the phone or by email with the responsible persons listed in the previous page. With regards to the informational messages and newsletters you can always opt out by simply clicking the link ''Unsubscribe'' or something similar included at the end of all the relevant messages.

I hereby give my consent to the processing of my personal data needed for:

*(Please, tick the boxes below to confirm that you give us your consent for the respective subject. Any boxes left unticked mean that **you do not consent to the relevant subject**.)*

#	Consent Subject	Tick box
1	My participation in an interview that will be carried out by 2D-BioPAD to < insert key objective of the interview >	
2	My participation in future activities of 2D-BioPAD	
3	Receiving newsletters and messages regarding 2D-BioPAD activities	

_____ _____ _____

Name of participant Date Signature

It is important to note here that a **tailored Consent Form** will also be drafted later in the course of the project to be shared with the **subjects that will be included in the clinical pilot studies**. The tailored version will be included in Version 2 of the Data Management Plan.

9.3 Annex III – Data Subject Request Form

Text in red colour contains guidelines for adjusting this template and should be deleted.

Text included in < > and/or highlighted with yellow should be replaced with content that is suitable to the context of each activity & project as well as to the organisation seeking to obtain the consent.

2D-BioPAD

Data Subject Request form

You may delete the data referring to the Data Protection Officer if your organisation does not have one.

CONTACT

<Insert name of responsible Project Manager>	<Insert name of DPO > (Data Protection Officer)
<Insert email of responsible Project Manager>	<Insert e-mail of DPO >

DATA SUBJECT REQUEST FORM

This form should be used to submit a data subject request under the provisions of the European Union General Data Protection Regulation (GDPR).

Submitter Details

Title:			
Name:			
Address:			

TYPE OF REQUEST

Please select the type of request you are making:

☐	Consent Withdrawal
☐	Access request
☐	Rectification of personal data
☐	Erasure of personal data
☐	Restriction of processing of personal data
☐	Personal data portability request
☐	Objection to processing of personal data
☐	Request regarding automated decision making and profiling

PERSONAL DATA INVOLVED

REQUEST DETAILS

REQUEST REASON/JUSTIFICATION

Name: .....

Signature: .....

Date: .....

***

Once completed, this form should be submitted via e-mail to < Insert contact e-mail of Partner > or posted to:

< Insert Partner Name >

< Insert Partner Address >

9.4 Annex IV – Record of Processing Activities

Table 14: Record of Processing Activities

No	Project Activity / purpose	Data processing activity	Linked WP(s)	Linked Task(s)	Data subjects	Data source	Data category(-ies)	Responsible partner	Involved partner(s)	Type of involvement	Special category (Art. 9 GDPR)	Lawfulness of processing	Transfer to third countries (non EU-EEA)	Transfer to EU from third countries	Recipients	Comments
1	Mapping and analysis of point-of-care AD solutions	Interviews	WP1	Task 1.1	Interviewees	Data subject	Contact details, Professional information, Opinions, Demographics, Past experiences	Q-PLAN	EVNIA	Collection, Use	No	Art. 6(1)(a) - consent	No	No	-	-
2	Mapping and analysis of point-of-care AD solutions	Survey	WP1	Task 1.1	Survey participants	Data subject	Contact details Professional information, Opinions	EVNIA	Q-PLAN	Collection, Use	No	Art. 6(1)(a) - consent	No	No	-	-
3	Retrospective pilot study deployment and technical validation	Clinical practice	WP5	Task 5.2	Memory clinic patients	Data bases	Existing fluid samples and related data from clinical partners (UEF, GAADRD, ZI), e.g., biomarker	UEF	UEF, GAADRD, ZI	Collection, use	Yes	Art. 6(1)(a) - consent	No	No	Transfers may be conducted between clinical sites; fluid samples may also be transferred from clinical sites to selected technical	

No	Project Activity / purpose	Data processing activity	Linked WP(s)	Linked Task(s)	Data subjects	Data source	Data category(-ies)	Responsible partner	Involved partner(s)	Type of involvement	Special category (Art. 9 GDPR)	Lawfulness of processing	Transfer to third countries (non EU-EEA)	Transfer to EU from third countries	Recipients	Comments
							data, demographics, diagnosis of cognitive disorder and related tests, comorbidities.								partners where appropriate	
4	Prospective pilot study deployment and clinical validation	Clinical practice	WP5	Task 5.3	Memory clinic patients	Data subject	Biological fluid samples and relevant data of patients from clinical partners (UEF, GAADRD, ZI), e.g. biomarker data, demographics, diagnosis of cognitive disorder and related tests, comorbidities.	GAADRD	UEF, GAADRD, ZI	Collection, use	Yes	Art. 6(1)(a) - consent	No	No	Transfers may be conducted between clinical sites	

No	Project Activity / purpose	Data processing activity	Linked WP(s)	Linked Task(s)	Data subjects	Data source	Data category(-ies)	Responsible partner	Involved partner(s)	Type of involvement	Special category (Art. 9 GDPR)	Lawfulness of processing	Transfer to third countries (non EU-EEA)	Transfer to EU from third countries	Recipients	Comments
5	Prospective pilot study deployment and clinical validation	Interviews	WP5	Task 5.3	Patients, caregivers, health care practitioners	Data subject	Quantitative and qualitative data on patients', caregivers' and health care practitioners' views and experiences (e.g, expectations, needs, concerns, trust, acceptance).	GAADRD	UEF, GAADRD, ZI	Collection, use	Yes	Art. 6(1)(a) - consent	No	No	Transfers may be conducted between clinical sites	The data will be collected through survey(s) and by discussions (PPI) and semi-structured interviews with (i) people with MCI/AD and their caregivers as well as (ii) health care practitioners as a part of clinical pilot studies. The method and amount of data collected may vary between countries.
6	Cross-regional pilot studies evaluation and validation	Wide online survey	WP5	Task 5.4	Survey participants (key stakeholders)	Data subject	Contact details, Professional information, Opinions, Demographics, Experiences	ZI	UEF, Q-PLAN, EVNIA	Collection, use	No	Art. 6(1)(a) - consent	No	No	-	-
7	Cross-regional pilot studies evaluation and	Satisfaction Survey	WP5	Task 5.4	Survey participants (end-users involve	Data subject	Contact details, Professional information, Opinions, Demographi	ZI	UEF, Q-PLAN, EVNIA	Collection, use	No	Art. 6(1)(a) - consent	No	No	-	-

No	Project Activity / purpose	Data processing activity	Linked WP(s)	Linked Task(s)	Data subjects	Data source	Data category(-ies)	Responsible partner	Involved partner(s)	Type of involvement	Special category (Art. 9 GDPR)	Lawfulness of processing	Transfer to third countries (non EU-EEA)	Transfer to EU from third countries	Recipients	Comments
	validation				d at HCP or patient level)		cs, Experiences									
8	Monitoring and assessment of the dissemination, communication and stakeholder engagement activities	Dissemination of newsletter	WP6	Task 6.1	Newsletter subscribers	Data subject	Contact details	Q-PLAN	-	-	No	Art. 6(1)(a) - consent	No	No	-	-
9	Monitoring and assessment of the dissemination, communication and stakeholder engagem	Final Conference	WP6	Task 6.1	Event participants	Data subject	Contact details, Opinions, Demographics, Photos and visual materials	Q-PLAN	-	-	No	Art. 6(1)(a) - consent	No	No	-	-

No	Project Activity / purpose	Data processing activity	Linked WP(s)	Linked Task(s)	Data subjects	Data source	Data category(-ies)	Responsible partner	Involved partner(s)	Type of involvement	Special category (Art. 9 GDPR)	Lawfulness of processing	Transfer to third countries (non EU-EEA)	Transfer to EU from third countries	Recipients	Comments
	ent activities															
10	Monitoring and assessment of the dissemination, communication and stakeholder engagement activities	Conference workshop	WP6	Task 6.1	Workshop participants	Data subject	Contact details, Opinions, Demographics, Photos and visual materials	Q-PLAN	-	-	No	Art. 6(1)(a) - consent	No	No	-	-
11	Collaboration and Synergies with relevant projects and Initiatives	Networking	WP6	Task 6.5	GrapheneEU CSA project, and Related Networks and Initiatives' officials	Data subject	Contact details, Professional information, Demographics, Photos and visual materials	Q-PLAN	-	-	No	Art. 6(1)(a) - consent	No	No	-	-
12	Project management, meetings	Project management	WP7	Task 7.1, Task 7.3,	Project partners	Data subject	Contact details Professional information	UP-CATRIN	-	-	No	Art. 6(1)(b) - contract	No	No	-	-

No	Project Activity / purpose	Data processing activity	Linked WP(s)	Linked Task(s)	Data subjects	Data source	Data category(-ies)	Responsible partner	Involved partner(s)	Type of involvement	Special category (Art. 9 GDPR)	Lawfulness of processing	Transfer to third countries (non EU-EEA)	Transfer to EU from third countries	Recipients	Comments
	and reporting			Task 7.4			Videos and photos									
13	Project management, meetings and reporting	Project management	WP7	Task 7.1, Task 7.3, Task 7.4	Project partners	Data subject	Contact details Professional information Videos and photos	Q-PLAN	-	-	No	Art. 6(1)(b) - contract	No	No	-	-
14	Project management, meetings and reporting	Project management	WP7	Task 7.1, Task 7.3, Task 7.4	Project partners	Data subject	Contact details Professional information Videos and photos	ICN2	-	-	No	Art. 6(1)(b) - contract	No	No	-	-
15	Project management, meetings and reporting	Project management	WP7	Task 7.1, Task 7.3, Task 7.4	Project partners	Data subject	Contact details Professional information Videos and photos	GRAPHEAL	-	-	No	Art. 6(1)(b) - contract	No	No	-	-
16	Project management, meetings and reporting	Project management	WP7	Task 7.1, Task 7.3, Task 7.4	Project partners	Data subject	Contact details Professional information Videos and photos	AUTH	-	-	No	Art. 6(1)(b) - contract	No	No	-	-
17	Project management, meetings	Project management	WP7	Task 7.1, Task 7.3,	Project partners	Data subject	Contact details Professional information	NOVA	-	-	No	Art. 6(1)(b) - contract	No	No	-	-

No	Project Activity / purpose	Data processing activity	Linked WP(s)	Linked Task(s)	Data subjects	Data source	Data category(-ies)	Responsible partner	Involved partner(s)	Type of involvement	Special category (Art. 9 GDPR)	Lawfulness of processing	Transfer to third countries (non EU-EEA)	Transfer to EU from third countries	Recipients	Comments
	and reporting			Task 7.4			Videos and photos									
18	Project management, meetings and reporting	Project management	WP7	Task 7.1, Task 7.3, Task 7.4	Project partners	Data subject	Contact details Professional information Videos and photos	UEF	-	-	No	Art. 6(1)(b) - contract	No	No	-	-
19	Project management, meetings and reporting	Project management	WP7	Task 7.1, Task 7.3, Task 7.4	Project partners	Data subject	Contact details Professional information Videos and photos	GAADRD	-	-	No	Art. 6(1)(b) - contract	No	No	-	-
20	Project management, meetings and reporting	Project management	WP7	Task 7.1, Task 7.3, Task 7.4	Project partners	Data subject	Contact details Professional information Videos and photos	EVNIA	-	-	No	Art. 6(1)(b) - contract	No	No	-	-
21	Project management, meetings and reporting	Project management	WP7	Task 7.1, Task 7.3, Task 7.4	Project partners	Data subject	Contact details Professional information Videos and photos	ZI	-	-	No	Art. 6(1)(b) - contract	No	No	-	-
22	Project management, meetings	Project management	WP7	Task 7.1, Task 7.3,	Project partners	Data subject	Contact details Professional information	CeADAR	-	-	No	Art. 6(1)(b) - contract	No	No	-	-

No	Project Activity / purpose	Data processing activity	Linked WP(s)	Linked Task(s)	Data subjects	Data source	Data category(-ies)	Responsible partner	Involved partner(s)	Type of involvement	Special category (Art. 9 GDPR)	Lawfulness of processing	Transfer to third countries (non EU-EEA)	Transfer to EU from third countries	Recipients	Comments
	and reporting			Task 7.4			Videos and photos									
23	Setup and Operation of Scientific and Industrial Advisory Board	Desk research	WP7	Task 7.2	Potential SIAB participants	Online data bases	Contact details, Professional information, Demographics	GAADRD	All partners	Collection, Use	No	Art. 6(1)(a) - consent	No	No	-	All partners will support the process by providing candidate AB members to GAADRD.
24	Setup and Operation of Scientific and Industrial Advisory Board	Networking	WP7	Task 7.2	Potential SIAB participants	Data subject	Contact details, Professional information, Demographics	GAADRD	All partners	Collection, Use	No	Art. 6(1)(a) - consent	No	No	-	All partners will support the process by providing candidate AB members to GAADRD.

2D BioPAD

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

GA 101120706

Partners

CATRIN Czech Advanced Technology and Research Institute

Q-PLAN INTERNATIONAL

ICN2 Institut Català de Nanociència i Nanotecnologia

Grapheal

NOVAPTECH Think Aptamer

UNIVERSITY OF EASTERN FINLAND

ALZHEIMER Hellas

Evnia To Strive • To Seek • To Find

Zentralinstitut für Seelische Gesundheit

CeADAR Ireland's Centre for Applied AI

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