2D BioPAD

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

Ethical Consideration Roadmap

EVNIA

4 April 2024

Funded by the European Union

Document Information

Issued by:	EVNIA
Issue date:	04/04/2023
Due date:	31/03/2023
Work package leader:	Ruslan Alvarez, ICN2
Dissemination level:	Public

Document History

Version	Date	Modifications made by
1.0	04/04/2024	First release by ENVIA

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Executive Summary

The purpose of the Ethical Consideration Roadmap (ECR) is to detail ethics principles that must be applied in the project and that guides the project work to be performed in an ethically acceptable manner. Moreover, the roadmap describes forthcoming actions, and responsibilities to ensure that the ethics requirements and applicable regulations and guidelines are met and applied within the 2D-BioPAD project.

Ethical Self-Assessment offers a framework for consortium partners to review and document the ethics of the project activities throughout the research cycle. The Self-Assessment must cover all ethical considerations made and applied in the 2D-BioPAD project's design, development/experimentation, and deployment phases. The Self-Assessment provides a timely means to identify ethical issues for the research planned and conducted. EVNIA (with Efstathios Vassiliadis as WP1 Task Leader of T1.2) has the overall responsibility of keeping oversight of ethical considerations made and applied throughout the entire life cycle of project in accordance with the ECR.

2D-BioPAD will kick-off with a deep dive into the use of point-of-care devices for diagnosing and assessing progression of Mild Cognitive Impairment (MCI) to Alzheimer's Disease (AD), understanding in more detail the needs and challenges of targeted stakeholders (e.g., healthcare professionals, patients, caregivers, policymakers, etc.). The 1st step to this demand-driven analysis is a thorough desk research through existing knowledge (e.g., MDR, IVDR) in order to gather meaningful information to be used as a contextual baseline, going from general framework conditions to the specifics of the 2D-BioPAD system and clinical pilot studies. Key insights will be further refined through semi-structured interviews with key Clinical, 2D- and Nano material scientists and engineers, biologists, Medical Device experts, and Ethics experts' stakeholders, including patients' and citizens' representatives following well-established methodologies like the Patient and Public Involvement and Engagement (PPIE). Refined findings of these interviews will lead to a wider online survey that will target: (i) citizens (patients, caregivers, etc.), (ii) healthcare professionals, (iii) tech providers, and (iv) decision-makers/regulators; all target groups are accessible through the existing extended consortium networks (academic, industrial, commercial, clinical, regulatory, ethics, policy, etc.). The survey will be constructed to specifically collect data that can be used to complement and refine design input (User Requirement Specifications) as well as a preliminary clinical data to refine the unmet clinical need. As such performance and safety considerations will be covered within the survey and will be utilised as Real World Evidence (RWE) in guiding the intended use and support the device development. The results of these activities will offer profound insights to 2D-BioPAD, allowing a more accurate and high-performance design of the envisioned CRM-free, graphene-based, point-of-care device, but also introducing long-term impact to the AD community, targeting higher acceptance rates.

The 2D-BioPAD system and its impact will be demonstrated in three 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.

In relation to all of these project activities, the ECR outlines essential ethical points of attention in terms of the novelty of 2D-BioPAD system in combination with project activities involving human participants, human blood tissue, and processing of data related to these activities. The ECR outlines the following ethical principles to ensure research integrity in terms of incorporating: *Reliability* in ensuring the quality of research reflected

in the design, the methodology, the analysis and the use of resources, *Honesty* in developing, undertaking, reviewing, reporting and communicating research in a transparent and fair way, *Respect* for colleagues, research participants, society, ecosystems, cultural heritage and the environment, and *Accountability* for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts. Additionally demonstrating compliance with the fundamental ethical principles: (1) **Public Good** – ensuring the public good of research and statistics, (2) **Data Security and Confidentiality** maintaining confidentiality of data, (3) **Methodological Quality** – understanding the potential risks and limitations in research methods and technologies, (4) **Legal Compliance** – ensuring compliance with legal requirements, (5) **Public Views and Engagement** – considering public acceptability of the project, (6) **Transparency** – transparency in the collection, use and sharing of data.

The 2D-BioPAD consortium brings together a complementary and interdisciplinary group of 11 partners across 8 different countries within the EU, as presented in Table 1, that are responsible for ensuring that all research activities carried out under the 2D-BioPAD project are conducted in compliance with fundamental ethical principles throughout the duration of the project.

Table 1: 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	EVNIA	DENMARK
BEN	10	ZENTRALINSTITUT FUER SEELISCHE GESUNDHEIT	ZI	GERMANY
BEN	11	UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN	NUID UCD/ CeADAR	IRELAND

*BEN: Beneficiary; COO: Coordinator

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Table 2: Terms and Definitions

Abbreviation	Definition
AD	Alzheimer's Disease
ECR	Ethical Consideration Roadmap
ESC	Ethics Steering Committee
EU	European Union
FAIR	Findable, Accessible, Interoperable and Re-usable
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
hPSCreg	Human Pluripotent Stem Cell Registry
IPR	Intellectual Property Rights
IVD	In-Vitro Diagnostics
IVDR	In-Vitro Diagnostics Regulation
KERs	Key Exploitable Results
MCI	Mild Cognitive Impairment
MDR	Medical Device Regulation
PoC	Point-of-Care
PPIE	Patient and Public Involvement and Engagement
RWE	Real World Evidence
SCI	Subjective Cognitive Impairment
WMA	World Medical Association
WP	Work Package

1. Introduction

The Consortium hereby shares the ECR that has the purpose to detail the ethics management principles, forthcoming actions, and responsibilities to ensure that the ethics requirements are met within the 2D-BioPAD project. The ECR is a strategic document describing the fundamental ethical perspectives relevant to the 2D-BioPAD project and defining the procedures to be followed by Consortium partners and members working in the 2D-BioPAD project.

The ECR has been prepared using appropriate sections from the European Commission's guide "*EU Grants: How to complete your ethics Self-Assessment Version 2.0 13 July 2021*"[1] and adopting the ethical principles described by the UK Statistics Authority to guide the scope and methodology of ethics application in the 2D-BioPAD project. The ECR may be updated during the lifecycle of the project if needed, introducing further information as the project progresses and/or unexpected ethic issues arise.

The ECR has been prepared as part of the deliverable (D1.1) in the framework of the 2D-BioPAD project.

[1] Grants E. How to complete your ethics self-assessment Version 2.0, 13 July 2021: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf.

2. Ethics in the 2D-BioPAD Project

2.1 General Ethical Perspectives and Points of Attention

The 2D-BioPAD project 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 AD directly at primary healthcare settings.

To achieve this aim, 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 three 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.

Important ethical points of attention are the novelty of the 2D-BioPAD system in combination with project activities involving human participants, human tissue, and processing of data to validate and develop the 2D-BioPAD system as well as understanding the societal perspectives, clinical needs, and challenges to implement the 2D-BioPAD system.

2.2 European Code of Conduct for Research Integrity

All the 2D-BioPAD's consortium activities should be carried out in compliance with fundamental principles of research integrity described in "The European Code of Conduct for Research Integrity"[2] as follows:

- **Reliability** in ensuring the quality of research, reflected in the design, methodology, analysis, and use of resources.
- **Honesty** in developing, undertaking, reviewing, reporting, and communicating research in a transparent, fair, full, and unbiased way.
- **Respect** for colleagues, research participants, research subjects, society, ecosystems, cultural heritage, and the environment.
- **Accountability** for the research from idea to publication, for its management and organization, for training, supervision, and mentoring, and for its wider societal impacts.

[2] The European Code of Conduct for Research Integrity REVISED EDITION 2023: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf.

2.3 Applied Ethical Principles in the 2D-BioPAD Project

In addition to the above-mentioned Research Integrity principles, 2D-BioPAD's consortium activities shall be carried out in compliance with ethical principles developed by the UK Statistics Authority[3] that are the following (Figure 1):

- **Legal/regulatory compliance[3]:** adhere to laws and regulations during product design, development, validation, and use minimize the risks of ethical issues**.**
- **Public Good[3]:** the use of data has clear benefits for users and serves the public good.
- **Data Security and Confidentiality:** data processing methods transparent and according to recognized standards.
- **Methodological Quality[4]**: clinical activities shall be conducted in compliance with international and ethical- and scientific quality standards.
- **Public Views and Engagement[5]:** the views of the public are considered in light of the data used and the perceived benefits of the research.
- **Transparency[3]:** the access, use and sharing of data is transparent, and is communicated clearly and accessibly to the public.

Ethical perspectives and points of attention related to 2D-BioPAD project activities will be outlined in section 4 according to each of the ethical principles.

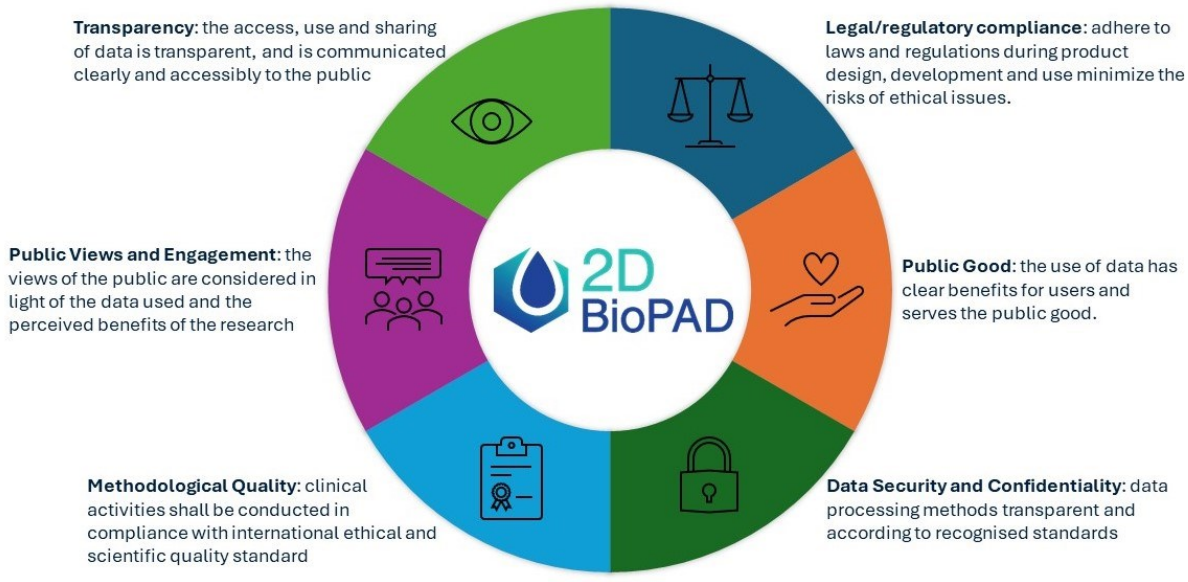

Figure 1: 2D-BioPAD's ethical principles.

[3] Statistics Authority UK. Ethical considerations associated with Qualitative Research methods: https://uksa.statisticsauthority.gov.uk/publication/ethical-considerations-associated-with-qualitative-research-methods/

[4] Vijayananthan A, Nawawi O. The importance of Good Clinical Practice guidelines and its role in clinical trials. Biomed Imaging Interv J. 2008;4(1):e5.

[5] Authority US. Considering public views and engagement regarding the use of data for research and statistics: https://uksa.statisticsauthority.gov.uk/publication/considering-public-views-and-engagement-regarding-the-use-of-data-for-research-and-statistics/pages/2/.

2.4 Ethical Requirements – Regulations and Guidelines

2.4.1 Global Requirements

All the 2D-BioPAD's consortium activities shall comply with:

- WMA Declaration Of Helsinki – Ethical Principles For Medical Research Involving Human Subjects[6].
- Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4 April 1997)[7].

2.4.2 European Requirements

European Regulations

All the 2D-BioPAD's consortium activities shall comply with the following European Regulations:

- 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 (General Data Protection Regulation)[8].
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[9].
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU[10].

European directives, standards, guidelines, conventions, and codes

In addition to the above-mentioned regulations, all the 2D-BioPAD's consortium activities will comply with the following European directive, standards, guidelines, conventions, and codes:

- The European Code of Conduct for Research Integrity[2].
- ICH E6 (R3) Guideline on good clinical practice (GCP)[11].

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[6] WMA Declaration Of Helsinki – Ethical Principles For Medical Research Involving Human Subjects: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

[7] Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164.

[8] 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 (General Data Protection Regulation): https://eur-lex.europa.eu/eli/reg/2016/679/oj.

[9] Regulation (Eu) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC : https://eur-lex.europa.eu/legal content/EN/TXT/?uri=CELEX%3A32017R0745&qid=1637490970264.

[10] Regulation (Eu) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0746&qid=1655725293918

[11] ICH E6 (R3) Guideline on good clinical practice (GCP): https://www.ema.europa.eu/en/documents/scientific-guideline/draft-ich-e6-r3-guideline-good-clinical-practice-gcp-step-2b_en.pdf.

- Charter of Fundamental Rights of the European Union 2012/C 326/02[12].
- European Convention on Human Right as amended by Protocols Nos. 11, 14 and 15; supplemented by Protocols Nos. 1,4, 6,7, 12,13 and 16[13].
- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[14].
- Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive)[15].
- Ethics By Design and Ethics of Use Approaches for Artificial Intelligence Version 1.0, 25 November 2021[16].
- ISO 14155:2020: Clinical investigation of medical devices for human subjects — Good Clinical Practice
- ISO 20916:2019: In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice.

2.4.3 National Requirements

Because the 2D-BioPAD research activities will be conducted in 3 clinical centres in Finland, Greece, and Germany, the corresponding activities will comply also with the following national requirements:

- **Finland:**
  - The ethical principles of research with human participants and ethical review in the human sciences in Finland, Finnish National Board on Research Integrity TENK guidelines 2019[17].
  - The Medical Research Act and Decree (488/1999)[18].
- **Greece**:
  - Law 3418/2005 Code of Medical Ethics, GG A. 287/28.11.2005 (Κώδικας Ιατρικής Δεοντολογίας)[19].

[12] Charter of Fundamental Rights of the European Union 2012/C 326/02: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT.

[13] European Convention on Human Right as amended by Protocols Nos. 11, 14 and 15; supplemented by Protocols Nos. 1,4, 6,7, 12,13 and 16: https://www.echr.coe.int/documents/d/echr/convention_ENG.

[14] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02004L0023-20090807.

[15] Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive): https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32022L2555&qid=1708615386705#d1e1272-80-1.

[16] Ethics By Design and Ethics of Use Approaches for Artificial Intelligence Version 1.0, 25 November 2021: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf

[17] The ethical principles of research with human participants and ethical review in the human sciences in Finland, Finnish National Board on Research Integrity TENK guidelines 2019: https://tenk.fi/sites/default/files/2021-01/Ethical_review_in_human_sciences_2020.pdf.

[18] The Medical Research Act and Decree (488/1999): https://www.finlex.fi/fi/laki/kaannokset/1999/en19990488.pdf.

[19] Law 3418/2005 Code of Medical Ethics, GG A. 287/28.11.2005 (Κώδικας Ιατρικής Δεοντολογίας): http://www.et.gr/idocs-

- **Germany:**
  - The Act on Medical Devices (Medical Devices Act) (Medizinproduktegesetz – MPG) (especially §§19-24)[20].
  - (Model) Professional Code for Physicians in Germany - MBO-Ä 1997 -The Resolutions of the 121st German Medical Assembly 2018 in Erfurt as amended by a Resolution of the Executive Board of the German Medical Association on 14/12/2018[21].

nph/search/pdfViewerForm.html?args=5C7QrtC22wHrZvzjsKBkq3dtvSoClrL87e_1TwhCA6l5MXD0LzQTLWPU9yLzB8V68knBzLCmTXKaO6fpVZ6Lx3UnKl3nP8NxdnJ5r9cmWyJWelDvWS_18kAEhATUkJb0x1LIdQ163nV9K--td6SIuShNcuKhBiRFLkjKDF2ovfg3HT3E7t8pK1PiSVF8gO4V.

[20] The Act on Medical Devices (Medical Devices Act) (Medizinproduktegesetz – MPG) (especially §§19-24): https://www.gesetze-im-internet.de/mpdg/.

[21] (Model) Professional Code for Physicians in Germany- MBO-Ä 1997 -The Resolutions of the 121st German Medical Assembly 2018 in Erfurt as amended by a Resolution of the Executive Board of the German Medical Association on 14/12/2018: https://www.bundesaerztekammer.de/fileadmin/user_upload/_old-files/downloads/pdf-Ordner/MBO/MBO-AE_EN_2018.pdf.

3. 2D-BioPAD Ethical Procedures and Responsibilities

3.1 General Assessment and Oversight – EVNIA

EVNIA (with Efstathios Vassiliadis as WP1 Task Leader of T1.2) has the overall responsibility of keeping oversight of ethical considerations made and applied throughout the entire life cycle of project in accordance with the ECR. Taking on this role EVNIA strives to provide leadership by promoting and supporting a culture that builds ethics and integrity consciousness into the project activities.

EVNIA's specific responsibilities in carrying out oversight are as follows:

- Request and remind all partners of 2D-BioPAD's consortium to read and review the ECR;
- Ensure relevant partners of 2D-BioPAD's consortium complete the Self-Assessment and continuously update status of Self-Assessments in the 2D-BioPAD Consortium SharePoint Site;
- Monitor and review the status of the ECR and its activities i.e., Self-Assessments provided by partners of the 2D-BioPAD's consortium;
- Evaluate possible emerged ethical issues during the project activities and advice on the necessary corrective actions;
- Provide status and general assessment of ethics in the project in Steering Committee meetings to ensure open discussion, priority of and handling of ethical related questions and issues raised during the project.

3.2 Self-Assessment – Consortium Members

The Self-Assessment process offers a framework for consortium partners to review and document the ethics of the project activities throughout the research cycle. The Self-Assessment must cover all ethical considerations made and applied in the 2D-BioPAD project's design, development/experimentation, and deployment phases. The Self-Assessment provides a timely means to identify ethical issues for the research planned and conducted.

The Self-Assessment is not intended to be performed by consortium members alone, but be performed as a group, discussed, and documented by each Task leader representing different partners in the Consortium. The Self-Assessment method does not resolve the ethical issues, however, strives to identify ethical risks and shape future discussions that enables prevention of ethical harms and improvement of ethics in project activities.

The Consortium Members' specific responsibilities in carrying out Self-Assessment are as follows:

- Complete the Self-Assessment per Task and archive in the 2D-BioPAD SharePoint Site for the EVNIA to review;
- React to emerged ethical issues during the project activities and communicate to the relevant responsible partner and EVNIA if needed.

In the stage of preparing D1.1 the Consortium Partners and Members are expected to read and comment on the ECR and to understand their responsibility in reporting ethical incidental findings that might compromise the security or integrity of the research and involved participants. The Self-Assessment should be performed in two timepoints per task by the relevant Consortium partner that is the main responsible for that task. In respect to timepoints, the first Self-Assessment per task should be made as an initial assessment in month 1-

4 after kick-off of the task focusing on the planned activities. The second Self-Assessment is a final assessment to be made when the task is finalized i.e., in the end of each task that will depict what was done in the conduct of the task e.g., provide the evidence/documentation for the activities. For tasks that comprise more than one delivery (or versions) per task only two Self-Assessments are required i.e., an initial assessment when initiating activities for the first delivery (or 1st version) and an end assessment when finalizing the last task/delivery (or 2nd or 3rd version). Table 3 below depicts an example of the tasks that require Self-Assessments including the planned timing of the task as well as the timepoint for performing the initial and final Self-Assessment.

Table 3: Self-Assessment Timeline

WP/Task	WP Task Leader	Planned timing for Task (project month)	Timing for INITIAL Self Assessment (project month)	Timing for FINAL Self Assessment (project month)
WPX ***Title of the WP***				
TX.n: *Title of the Task*	*Acronym of Lead Partner*	Mx-Mxx	Mxy-Mxz	Mxyz
WPZ: ***Title of the WP***				
TZ.n: *Title of the Task*	*Acronym of Lead Partner*	Mx-Mxx	Mxy- Mxz	Mxyz

4. 2D-BioPAD Main Ethical Principles

Ethical perspectives and guidance on points of attention will be outlined in the following sections and should be incorporated in 2D-BioPAD project activities that are depicted in the figure below and that should be followed by Consortium partners and members.

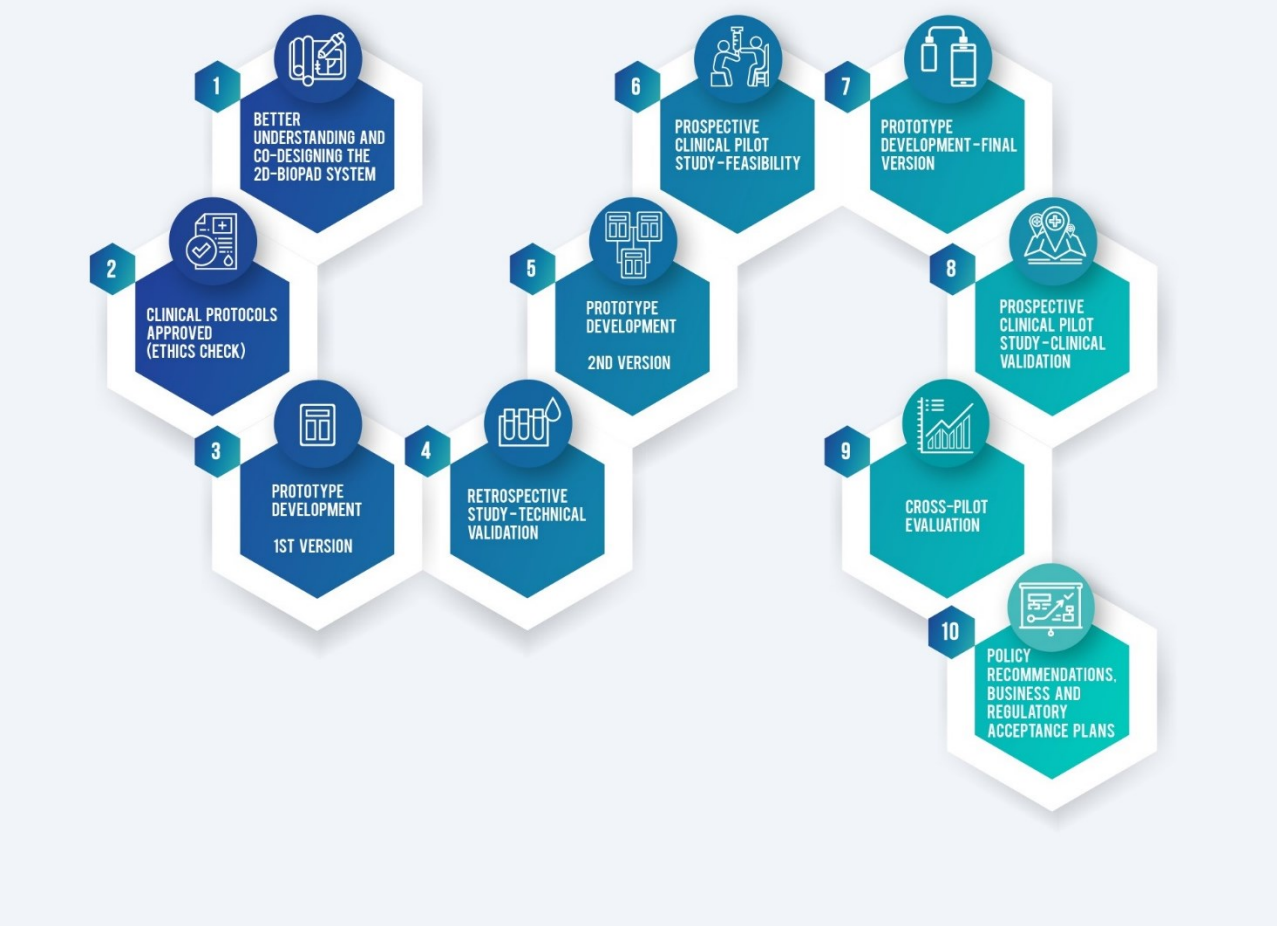

Figure 2: 2D-BioPAD project activities

4.1 Public Good

Main ethical scope

This principle focuses on ensuring the project will strive to serve the public good, is relevant to the communities involved, the project benefits outweigh the risks of the project and has objectives that are not harmful or prejudicial to participants. Thus, the project activities should ensure human rights, health, and safety and introduce minimal harmful environmental impact throughout the project.

Application of the principle in the 2D-BioPAD project

2D-BioPAD project activities aim to introduce a fast and cost-effective IVD system that strives to support the early diagnosis and progression monitoring of AD directly at primary healthcare settings reducing costs of screening processes and increasing the public accessibility. The 2D-BioPAD project activities plan to: (1) Provide and improve evidence bases that will support the development of healthcare service delivery, and (2) Guide critical decision-making with anticipated benefits for economy, society, and quality of people life.

In this context, the 2D-BioPAD project must strive to:

- Not use data or research outcomes to directly identify data subjects or specific populations.
- Provide a significant public good in line with best practice guidance.
- Apply public goods to the entire population.
- Present negligible potential harm to anyone involved, including the public.
- Identify in the planned methods any possible outcomes bias and mitigate them as far as possible.

2D-BioPAD project deliverables that incorporate the ethical principle:

- **Exploitation and Sustainability Plan** (WP6 D6.4) provides the outline of the use that the 2D-BioPAD consortium intends to make of its Key Exploitable Results (KERs) along with the respective action plans and time frame for exploitation. This includes any further activities aimed at the dissemination, use, and sustainability of 2D-BioPAD's KERs, along with any findings concerning IP issues. The plan envisages 2D-BioPAD final strategy for exploitation, management of Intellectual Property Rights (IPR) and sustainability, including also any selected commercialization path if applicable.
- **Clinical Study Protocol** (WP5 D5.1/D.5.2/D5.3/5.4) describes design, deployment, evaluation, and validation of clinical studies.

Ethics Self-Assessment in the 2D-BioPAD project

In order to ensure that 2D-BioPAD project comply with the principle of Public Good it is advised to evaluate the impact of the activities on people, communities, organisations, and companies.

To do that, the balance between the potential positive impact of projects (i.e., the public good benefit) and any potential risks (direct, or indirect) to groups or individuals that may arise from, or is related to, the project, will be evaluated throughout a Self-Assessment.

The self-assessment will evaluate:

- Voluntary participation, Informed consent and privacy of individual's information;
- Security in regard to identification of participants;
- Methodological quality in data collection, analysis, and outputs;
- Potential harm (including stigmatization) or distress related to a project and its outcomes for those who have participated in the research;
- Potential benefits of the project.

4.2 Data Security and Confidentiality

Main ethical scope

This principle focuses on the protection of data subject's identity (whether person or organisation), and on maintaining confidentiality and security of the data collected during the research project. Researchers should be transparent in their approach to data collection, validation of data collection methods, methods to secure data and ensure participants' confidentiality in data management and anonymity in reporting of results.

Application of the principle in the 2D-BioPAD project

All 2D-BioPAD project data collection and data management activities shall strive to ensure that personal data is:

- 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 in compliance with GDPR requirements.

Moreover, the Consortium members must pay 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.

2D-BioPAD project deliverables that incorporate the ethical principle:

In order to ensure that 2D-BioPAD project comply with the principle of Data Security and Confidentiality, a Data Management Plan (DMP) is available for all the consortium's partners. The 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 the project, safeguarding sound and ethical data management along the entire duration of the project. The DMP will be updated three times during the 2D-BioPAD project period to ensure that that all relevant data collection and data management aspects are planned and documented (i.e., project M3 v1, M24 v2, M48 v3).

- **Data Management Plan** (WP7 D7.2) describes:
    - 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.
    - The methodology employed is 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).
    - 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.
    - Details on how the data will be made openly accessible and searchable to interested stakeholders as well as its curation and preservation.
    - The management of any research outputs other than data in line with FAIR principles.
    - 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.

Ethics Self-Assessment in the 2D-BioPAD project

In addition, any potential risk related to data security and confidentiality that may arise from, or is related to, the project, will be evaluated throughout a Self-Assessment. Self-Assessment will evaluate potential risks related to:

- Processing of personal data;
- Informed Consent and privacy of individual's information;
- Bias, fairness and transparency in data collection, data management, data analysis, and outputs;
- Measures taken to avoid bias in input data and algorithm design where Artificial Intelligence will be used;
- Ethical standards in Cyber Security, put in place to ensure the trustworthiness, accuracy, and reliability of the systems and operations and to maintain data privacy and reduce the chances of a security breach.

4.3 Methodological Quality

Main ethical scope

This principle emphasizes the importance of ensuring suitable methodologies are applied in all research activities throughout the entire project phases while following applicable standards, and clinical guidelines, ensuring precision, reproducibility, and quality of research outputs, while also safeguarding the rights, integrity, and confidentiality of involved participants. From an organizational standpoint, this practice enhances resilience to public scrutiny and plays a crucial role in building public trust and confidence.

Application of the principle in the 2D-BioPAD project

2D-BioPAD project's activities shall strive to be:

- Conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with the applicable regulatory requirement(s) and the standards ISO 14155:2020, ISO 20916:2019 that address good clinical practices for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety and performance of medical devices and *in vitro* medical devices; and
- Initiated and continued only if the anticipated benefits justify the risks and if the rights, safety, and well-being of the involved subjects are the most important considerations and prevail over interest of science and society;
- Conducted by researchers skilled in the chosen methodology;
- Undergo a careful assessment of the chosen methods and subsequent analyses to ensure they effectively address the research questions and that methods are appropriately described in the study protocols;
- Supported by the available non-clinical- and clinical information available as state of the art;
- Conducted with products manufactured, handled, and stored in accordance with applicable Good Manufacturing Practice (GMP) and used in accordance with the approved protocol;
- Conducted in compliance with recognized standards of methodological integrity and quality and ensuring that research results are transparent by providing access to data, algorithms, or other results needed for replicating and validating findings.

2D-BioPAD project deliverables that incorporate the ethical principle:

- **Management and Quality Plan** (WP7 D7.1) defines the overall project management principles and procedures applied to 2D-BioPAD and the quality assurance (QA) provisions for safeguarding high-quality project outcomes. It describes the roles and responsibilities of each project participant, with emphasis on

work breakdown and management, progress reporting, financial monitoring, payment processes, risk identification and change management.
- **Data Management Plan** (WP7 D7.2) see Section 4.2.
- **Clinical Study Protocol** (WP5 D5.1/D.5.2/D5.3/5.4) describes design, deployment, evaluation, and validation of clinical studies.

Ethics Self-Assessment in the 2D-BioPAD project

Any quality risk that may arise from, or is related to, the project, will be evaluated throughout a Self-Assessment.

The self-assessment will evaluate:
- The application of ethical principles originating from regulations and standards;
- The application of clinical guidelines or other state of the art information;
- The quality of data;
- Methods used to collect, process and visualize the data, and any assumptions made during those processes;
- Validity of the conclusions;
- Potential bias in data collection, analysis, and outputs;
- Measures taken to avoid bias in input data and algorithm design where Artificial Intelligence will be used;
- Ethical standards in Cyber Security, put in place to ensure the trustworthiness, accuracy, and reliability of the systems and operations and to maintain data privacy and reduce the chances of a security breach;
- Research activities involving human cells or tissues;
- Staff required expertise to undertake the research specified;
- Quality of methods used to safeguard of research governance process and human oversight;
- The potential of the quality methods in realising research benefits or mitigate risks.

4.4 Legal/regulatory Compliance

Main ethical scope

Prior to commencing their research, researchers need to carefully consider any legal obligations pertinent to their work. These requirements may vary based on the nature of the research and the context in which it is conducted. For instance, different countries may impose distinct legal obligations that researchers must take these into account. All research activities should adhere to laws and regulations during product design, development, and use, minimize the risks of ethical issues.

Application of the principle in the 2D-BioPAD project

2D-BioPAD project activities shall strive to:
- Be conducted in compliance with Global requirements listed in Section 2.4.1;
- Be conducted in compliance with European requirements listed in Section 2.4.2;
- Be conducted in compliance with National requirements listed in Section 2.4.3;
- Follow harmonized protocols;
- Obtain the required approvals (i.e., ethics, legal, etc.).

2D-BioPAD project deliverables that incorporate the ethical principle:

- **Regulatory Affairs Plan** (WP6 D6.4) outlines the European requirements for the registration and approval of the 2D-BioPAD system;
- **Data Management Plan** (WP7 D7.2) see Section 4.2

Ethics Self-Assessment in the 2D-BioPAD project

Any legal/regulatory risk that may arise from, or is related to, the project, will be evaluated throughout a Self-Assessment.

The Self-Assessment will evaluate if:

- Project activities and methods applied have been cleared against all relevant legislation and requirements;
- Copies of ethics approvals (if required by law or practice) are available and properly recorded;
- Informed consent forms and information sheets are available and properly recorded.

4.5 Public Views and Engagement

Main ethical scope

This principle emphasizes the importance of considering the views of the public in light of the data used and the perceived benefits of the research. Taking into account public opinions on the utilization of their data for research and statistics is crucial for upholding public trust and acceptance in the research work and the data gathered and utilized. Efficiently understanding and anticipating public attitude can also aid in designing more efficient and inclusive methodologies for data collection.

Application of the principle in the 2D-BioPAD project

2D-BioPAD project activities shall strive to:

- Ensure project findings reflect the experiences and opinions of the participant group;
- Identify project's contribution to the already existing information.

2D-BioPAD project deliverables that incorporate the ethical principle:

- **Dissemination and Communication Plan** (WP6 D6.1) outlines the overall communication activities and awareness-raising, dissemination of project results, management of all relevant activities, and partners' responsibilities in this respect. It includes specific actions and activities that will be carried out by the 2D-BioPAD consortium members in order to ensure success and maximum publicity for the project and its results. The Dissemination and Communication Plan will be updated three times during the 2D-BioPAD project period to ensure that that all dissemination and communication activities are planned and documented (i.e., project M3 v1, M24 v2, M 48 v3).

Ethics Self-Assessment in the 2D-BioPAD project

Any public view and public engagement risk that may arise from 2D-BioPAD project activities will be evaluated throughout a Self-Assessment evaluating if:

- The research involves engagement with the public stakeholders;
- The public is supportive of the project.

4.6 Transparency

Main ethical scope

This principle focuses on the crucial importance for a researcher of upholding ethical standards by transparently communicating about the methodology of data collection, data management, data analysis, results, and decision-making processes employed in research projects. This transparency supports to assess the research and its procedures effectively.

Application of the principle in the 2D-BioPAD project

2D-BioPAD project's activities shall strive to:

- Enable participants to be able to ask questions throughout the research process to ensure that they are accurately informed, and researchers should seek to answer these questions quickly and clearly;
- Provide participants information that should be accessible and tailored appropriately to the individual;
- Give access soon after the work is complete to an explanation of the outputs and recommendations arising from the project and the researchers should consider how this can be effectively delivered to different audiences, for maximum impact;
- Provide access to data, algorithms, or other results needed for replicating and validating our findings;
- Consider the ethical implications of gaining consent from adults who have impaired decision making and consult with the appropriate individuals, such as caregivers or support workers if patients involved lack capacity to consent to their participation.

2D-BioPAD project deliverables that incorporate the ethical principle:

- **Dissemination and Communication Plan** (WP6 D6.1) see Section 4.5.
- **Data Management Plan** (WP7 D7.2) see Section 4.2.

Ethics Self-Assessment in the 2D-BioPAD project

Any transparency risk that may arise from 2D-BioPAD project activities will be evaluated throughout a Self-Assessment if:

- The research outcomes are openly available to the public;
- Both methods and tools are widely available to the public;
- Informed consent form and information sheets are written in a language and in terms participants can understand;
- Informed consent form and information sheets describe the aims, methods and implications of the project activity, the nature of the participation and any benefits, risks or discomfort that might ensue;
- Informed consent form and information sheets explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time and without any consequences;
- Informed consent form and information sheets state how biological samples and data will be collected, protected during the project and whether they will be destroyed or reused afterwards;
- Informed consent form and information sheets state what procedures will be implemented in the event of unexpected or incidental findings.

5. 2D-BioPAD Ethics Management Milestone Overview

Action Point	Description	Documentation	Timeline
1	Have workshop in the 2nd Semester Meeting to present and discuss the ECR	- 2nd Semester Meeting Agenda - PowerPoint ECR Presentation	17th and 18th of April 2024 project M7
2	Preparation of Ethics Plan (i.e., Ethical Consideration Roadmap) by Evnia.	Ethical Consideration Roadmap (i.e., this document)	Submission 19th of April 2024 (part of D1.1) project M7
3	Self-Assessment is be performed by each WP task leader representing different Consortium partners.	Self-Assessment Forms archived in the 2D-BioPAD SharePoint Site Ethical Self-Assessments - (See Appendix A: Self-Assessment)	Two Self-Assessments should be performed i.e., 1) initial assessment in month 1-4 after kick-off of the task focusing on the planned activities, 2) final assessment when the task is finalized i.e., in the end of each task.
4	Evnia ensures monitoring and follow-up on Self-Assessments	- Status overview in the 2D-BioPAD SharePoint Site.	Throughout the project.
5	Preparation of Dissemination and Communication Plan	- Dissemination and Communication Plan (WP6 D6.1)	Submission project M3 v1, M24 v2, M 48 v3
6	Preparation of Regulatory Affairs Plan	- Regulatory Affairs Plan (WP6 D6.7)	Submission project M48
7	Preparation of Exploitation and Sustainability Plan	- Exploitation and Sustainability Plan (WP6 D6.4)	Submission project M48
8	Preparation of Management and Quality Plan	- Management and Quality Plan (WP7 D7.1)	Submission project M3
9	Preparation of Data Management Plan	- Data Management Plan (WP7 D7.2)	Submission project M3 v1, M24 v2, M 48 v3

Appendix A: Self-Assessment

Purpose

The present Self-Assessment for the 2D-BioPAD offers a framework for Consortium partners to review the ethics of the project activities throughout the research cycle. The Self-Assessment must to cover all identified possible ethics issues identified for the 2D-BioPAD project's design, development/experimentation, and deployment phases. The Self-Assessment provides a timely means to identify ethical issues for the research conducted. The method does not resolve the ethical issues, however, strives to identify ethical risks and shape future discussions that enable prevention of ethical harms and improvement of ethics in project activities.

Responsibility

- The Self-Assessment is not intended to be performed by consortium members alone, but be performed as a group, discussed, and documented by each WP task leader representing different partners in the Consortium.
- WP/Task leaders are responsible to complete, and archive completed Self-Assessment form in the folder 2D-BioPAD SharePoint Site Ethical Deliverables.

Procedure

The Self-Assessment shall be read through and then completed with information regarding the name of the Organization, Country, WP task leader name, Work Package and Task numbers.

- Notes for the WP task leader:
    - All passages/text in italics and highlighted in grey are intended to support the WP Task leader during Self-Assessment preparation. These passages shall be deleted prior to delivery of the document so the Self-Assessment only comprises results of the Self-Assessment.
    - Where the answer is YES or NO, please tick NO if NOT APPLICABLE.
    - Where a specific document is requested to be kept on file and provided on request, please tick "Document available" check box if available.

1.1 Respondent of Self-Assessment

Organization	Country	WP/Task Leader	WP/Task	Date	Signature
			WPX / TY.Z		

1.2 Public Good

Public Good: evaluation of potential Risks and Benefits of the project		YES	NO	Description
Is there potential for your work to be used to make decisions about individuals (e.g., as may be the case with predictive modelling projects) or to identify individuals?		☐	☐	*Please specify and, for each risk identified, please report any possible mitigations that could be applied to minimise it.*
If **YES**	What ramifications may this have for these individuals?	*Please specify.*		
Is there potential for your work to be used to make decisions about, or to identify, particular groups or communities within society?		☐	☐	*Please specify and, for each risk identified, please report any possible mitigations that could be applied to minimise it.*
If **YES**	What ramifications may this have for them?	*Please specify.*		
Are there any potential data gaps in your work that could lead to harm, stigmatisation or distress for individuals or groups who are under-represented in your analysis (i.e., those who may be missing from your data)?		☐	☐	*Please specify and, for each risk identified, please report any possible mitigations that could be applied to minimise it.*
If **YES**	How could this be mitigated?	*Please specify.*		
Is there potential for harm, stigmatisation or distress for individuals or groups who are (a) included as data subjects in your project or (b) may be impacted as a result of the findings of the research (including social, environmental, economic, physical or mental health impacts)?		☐	☐	*Please specify and, for each risk identified, please report any possible mitigations that could be applied to minimise it.*
If **YES**	How can these risks be minimised?	*Please specify.*		
Is there potential for negative impacts for organisations who are (a) included as data		☐	☐	*Please specify and, for each risk identified, please report any possible mitigations that could be applied to minimise it.*

Public Good: evaluation of potential Risks and Benefits of the project		YES	NO	Description
subjects in your project or (b) may be impacted as a result of the findings of the research (including reputational impacts)?				
If **YES**	How can these risks be minimised?	*Please specify.*		
Is there potential for harm or distress to members of the research team, research facilitators, or other individuals involved in activities related to conducting the project?		☐	☐	*Please specify and, for each risk identified, please report any possible mitigations that could be applied to minimise it.*
If **YES**	How can these risks be minimised?	*Please specify.*		
Are there specific envisaged public benefits of your work?		☐	☐	*Please specify.*
If **YES**	How will you achieve these benefits?	*Please specify.*		
Is there any evidence-base behind your justification of potential benefits?		☐	☐	*Please specify.*
If **YES**	Is it peer-reviewed?	*Please specify.*		
	How confident are you that these benefits will be realised?	*Please specify.*		
Are there any limitations in your project approach that may limit the impact of potential benefits?		☐	☐	*Please specify.*
If **YES**	What are these and how have they been minimised?	*Please specify.*		
Is the work focused on enhancing trust in statistics or statistics producers (e.g., challenging or validating official statistics)?		☐	☐	*Please specify.*
If **YES**	By what means will it do this?	*Please specify.*		

Public Good: evaluation of potential Risks and Benefits of the project		YES	NO	Description
Is the work addressing a topic that requires urgent or timely data to aid decision-making?		☐	☐	*Please specify.*
If **YES**	What is the rationale for this?	*Please specify.*		
Is the work addressing data gaps in statistics?		☐	☐	*Please specify.*
If **YES**	Which ones?	*Please specify.*		
Will your work effectively communicate findings so that public benefit can be maximised across different audiences who may engage with your project results?		☐	☐	*Please specify.*
If **YES**	What communication methods and channels will you use to ensure this?	*Please specify.*		
Does your project approach uphold the principles of trustworthiness, quality and value in statistics?		☐	☐	*Please specify.*
If **YES**	In what way?	*Please specify.*		

1.3 Data security and confidentiality

Data security and confidentiality	YES	NO	Description	Document available	Document available (tick if yes)
Does your activity involve processing of personal data?	☐	☐	*Please provide information as requested below.* *1) Details of the technical and organizational measures to safeguard the rights and freedoms of the participants/data subjects. These may include:* • *Project specific data protection policy and/or the contact details of the data protection officer (these must be provided to the participants)* • *The security measures to prevent unauthorised access to personal data* • *Anonymisation /pseudonymisation techniques.* *2) Provide details of the informed consent procedures with regard to the data processing (if relevant).*	1) Informed consent forms and information Sheets (if relevant).	☐
				2) Data management plan (if relevant).	☐

Data security and confidentiality		YES	NO	Description	Document available	Document available (tick if yes)
				3) Provide explanation as to how all of the processed data is relevant and limited to the purposes of the project ('data minimisation' principle) *4) Provide justification of why personal data will not be anonymised/ pseudonymised (if relevant).* *5) Provide details of the data transfers (type of data transferred and country to which data are transferred).*	3) Data protection impact assessment (if relevant).	☐
If **YES**	Does it involve the processing of special categories of personal data (e.g. sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)?	☐	☐	*1)Provide justification for the processing of special categories of personal data (if relevant).* *2) Provide justification to why the project objectives cannot be reached by processing anonymised/ pseudonymised data (if applicable).*		

Data security and confidentiality			YES	NO	Description	Document available	Document available (tick if yes)
	If **YES**	Does it involve processing of genetic, biometric or health data?	☐	☐		1) Declaration confirming compliance with the laws of the country where the data were collected.	☐
	Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?		☐	☐	*1) Provide Details of the methods used for tracking, surveillance or observation of participants.* *2) Provide details of the methods used for profiling.* *1) Provide assessment of the ethics risks related to the data processing operations.* *2) Provide explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded and harm will be prevented.* 3) *Provide explanation as to how the data subjects will be informed of the existence of the profiling, its possible consequences and how their*	1) Opinion of the data controller on the need for conducting data protection impact assessment under art 35 GDPR. (if relevant).	☐

Data security and confidentiality		YES	NO	Description	Document available	Document available (tick if yes)
				fundamental rights will be safeguarded.		
Does your activity involve further processing of previously collected personal data (including use of pre-existing data sets or		☐	☐	*1) Provide details of the database used or of the source of the data.* *2) Provide details of the data processing operations.*	1) Confirmation that the data controller has a lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects.	☐

Data security and confidentiality	YES	NO	Description	Document available	Document available (tick if yes)
sources, merging existing data sets)?			*3) Provide explanation as to how the rights of the participants/data subjects will be safeguarded.* *4) Provide explanation as to how all of the processed data is relevant and limited to the purposes of the project ('data minimisation' principle)* *5) Provide justification of why the data will not be anonymised/ pseudonymised (if relevant).*	2) Permission by the owner/manager of the data sets (e.g. social media databases) (if applicable).	☐
				3) Informed Consent Forms + Information Sheets + other consent documents (if applicable).	☐
Is it planned to export personal data (data transfer) from the EU to non-EU countries?	☐	☐	*1) Provide details of the types of personal data and countries involved.* *2) Provide explanation as to how the rights and freedoms of the participants/data subjects will be safeguarded*	1) Confirmation that data transfers will be made in accordance with Chapter V of the General Data Protection Regulation 2016/679.	☐
Is it planned to import personal data (data transfer) from non-EU countries into the EU or from a non-EU country to another non-EU country?	☐	☐	*1) Provide details of the types of personal data and countries involved. 1) Confirmation of compliance with the laws of the country in which the data was collected.*	1) Confirmation of compliance with the laws of the country in which the data was collected.	☐

Data security and confidentiality		YES	NO	Description	Document available	Document available (tick if yes)
Is it planned to use Artificial Intelligence in your project/activity?		☐	☐	1) *Provide details of type of data artificial intelligence will be processed by AI* 2) *Provide mathematical, technical, and functional details of the AI models, software infrastructure. Different use cases, limitations of the AI models and how to avoid pitfalls.*	1) Study protocols or DMP (or both).	☐
If **YES**	Are you going to inform participants about the use of AI?	☐	☐	1) *Provide explanation on how the participants and/or end-users will be informed.* 2) *Provide details on the content of the documentation provided to end-users.*	1) Informed Consent Forms + Information Sheets + other consent documents (if applicable).	☐
	Is there any measure taken to avoid bias in input data and algorithm design?	☐	☐	1) *Provide details on how AI system will be developed and on the type of training data.* 2) *Provide details on the analysis of measure distribution, noise, data generality of training data.*		☐
	Will the AI model contain data and parameters sensitive to people's personal and	☐	☐	1) *Provide details on type of data.*	1) Study protocol and DMP.	☐

Data security and confidentiality		YES	NO	Description	Document available	Document available (tick if yes)
	professional life?					
	Have you assessed the main ethical risks for the use of AI technology?	☐	☐	1) *Provide details on the ethical risks foreseen for the use of AI technology.* 2) *Provide details on how the risks are mitigated.*	1) Risk Management documents, Study protocol and DMP.	☐

1.4 Methodological Quality

Methodological Quality	YES	NO	Description	Documents to be kept on file and provided on request	Document available (tick if yes)
Is the activity conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).	☐	☐	*1) Details on applicable requirements.*		
Is the activity supported by non-clinical and clinical information available as state of the art and acquired during the first steps of the project?	☐	☐	*1) Provide a summary of available data*		
Is the activity conducted with products manufactured, handled and stored in accordance with applicable Good Manufacturing Practice (GMP) and used in accordance with the approved protocol.	☐	☐	*1) Provide a list of products used within the process*	1) A Material Safety Data Sheet (MSDS), Certificate of Analysis (COA), Study protocol or any other applicable.	☐
Is the activity conducted in compliance with recognised standards of data integrity and quality.	☐	☐	*1) Provide details on the applicable standards*		
Is the activity conducted by researchers skilled in the chosen methodology.	☐	☐	*1) Provide name and job title of the team members involved in this activity*	1) Team members Curricula Vitae.	☐
Does your activity involve interventions (physical also including imaging technology, behavioural treatments, tracking	☐	☐	*1) Specify which type of intervention*		

Methodological Quality		YES	NO	Description	Documents to be kept on file and provided on request	Document available (tick if yes)
and tracing, etc.) on the study participants?						
Does your activity involve the use of human cells or tissues?		☐	☐	*Provide details on type of human cells or tissue and how they are going to be used*		
If **YES**	Are they available commercially?	☐	☐	*1) Details on cell types and provider (company or other).*	1) Copies of import licences (if relevant).	☐
	Are they obtained within this project?	☐	☐	*1) Details on cell types including the source of the material, the amount to be collected and the procedure for collection.* *2) Details on the duration of storage and what will be done with the material at the end of the activity.* *3) Confirmation that informed consent has been obtained.*	1) Copies of ethics approvals.	☐
					2) Informed consent forms and information sheets.	☐
	Are they obtained from another project, laboratory or institution?	☐	☐	*1) Details on cell types.* *2) Country where the material is stored.* *3) Details of the legislation under which material is stored.* *4) Details on the duration of storage and what will you do with it at the end of the project?* *5) Name of the laboratory/institution.* *6) Country where the laboratory/institution is located.*	1) Authorisation by primary owner of cells/tissues (including references to ethics approvals).	☐
					2) Copies of import licences (if relevant).	☐

Methodological Quality		YES	NO	Description	Documents to be kept on file and provided on request	Document available (tick if yes)
				7) Confirm that the material is fully anonymised or that consent for secondary use has been obtained.	3) Statement from the primary laboratory/institution that informed consent has been obtained.	☐

1.5 Legal/regulatory compliance

Legal/regulatory compliance	YES	NO	Description
Are the activity and methods employed consistent with Global legal requirements set up in ECR?	☐	☐	*1) Specify which are the Global requirements applicable to the activity.*
Are the activity and methods employed consistent with European legal requirements set up in ECR?	☐	☐	*1) Specify which are the European requirements applicable to the activity.*
Are the activity and methods employed consistent with National legal requirements set up in ECR?	☐	☐	*1) Specify which are the National requirements applicable to the activity. If not applicable put N/A*

1.6 Public Views and Engagement

Public Views and Engagement		YES	NO	Description
Is the public widely supportive of the project aim and method?		☐	☐	
If **YES**	Does the research involve regular engagement with the public and/or stakeholders?	☐	☐	*1) Specify how the research involve engagement with the public and/or stakeholders.*
	Do activities' findings reflect the experiences and opinions of the participant group?	☐	☐	*1) Specify how findings reflect the experiences and the opinions of the participant group.*

1.7 Transparency

Transparency		YES	NO	Description of the required characteristic	Documents to be kept on file and provided on request	Document available (tick if yes)
Does your activity involve human participants?		☐	☐			
If **YES**	Are they volunteers?	☐	☐	*1)Provide details on recruitment, inclusion and exclusion criteria and informed consent procedures.* *2)Provide details on unexpected findings policy.*	1) Copies of ethics approvals (if required by law or practice).	☐
					2) Informed consent forms and information sheets.	☐
	Are they healthy volunteers for medical studies?	☐	☐	*1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.* *2) Details on incidental findings policy.*	1) Copies of ethics approvals (if required by law or practice).	☐
					2) Informed consent forms and information sheets.	☐
	Are they patients for medical study?	☐	☐	*1) Details on the disease/condition /disability* *2) Details on the recruitment, inclusion and exclusion criteria and informed consent procedures.*	1) Copies of ethics approvals (if required by law or practice).	☐
					2) Informed consent forms and information sheets.	☐

Transparency		YES	NO	Description of the required characteristic	Documents to be kept on file and provided on request	Document available (tick if yes)
				3) Details on incidental findings policy		
	Are they potentially vulnerable individuals or groups?	☐	☐	*1) Details on the type of vulnerability.* *2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.* *3) Procedures to ensure participants are not subject to any form of coercion and undue inducement.*	1) Copies of ethics approvals.	☐
					2) Informed consent forms and information sheets.	☐
Are informed consent form and information sheet required for your activity?		☐	☐			
If **YES**	Are they written in a language and in terms involved persons can fully understand?	☐	☐			
	Do they describe the aims, methods and implications of the project activity, the nature of the participation and any benefits, risks or	☐	☐			

Transparency		YES	NO	Description of the required characteristic	Documents to be kept on file and provided on request	Document available (tick if yes)
	discomfort that might ensue?					
	Do they explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences?	☐	☐			
	Do they state how biological samples and data will be collected, protected during the project and whether they will be destroyed or reused afterwards?	☐	☐			
	Do they state what procedures will be implemented in the event of unexpected or incidental findings?	☐	☐			
	Are there other persons unable to give informed consent?	☐	☐	*1) Details on the procedures for obtaining consent from the guardian/legal representative.* *2) Procedures to ensure participants are not subject to any form of coercion and undue inducement.*		
Will research outcomes be openly available to the public?		☐	☐			
If **YES**	How will research outcomes be disseminated?			*1)Details on activity's dissemination plan*		

1.8 Need for self-assessment revision/addition

Need for self-assessment revision/addition	YES	NO	Reason for self-assessment revision/addition	Expected timepoint
Do you expect to make an ethics self-assessment again at a later stage in the project i.e., revision/addition to the ECR.?	☐	☐		

2D BioPAD

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

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