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WP1 Project Management

D1.2 Data Management Plan

***VOCORDER**: Towards the ultimate breath analysis -based continuous healthcare*

VOCORDER CONSORTIUM

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Project title	Towards the ultimate breath analysis -based continuous healthcare
Project acronym	VOCORDER
Starting date	1 October 2023
End date	31 March 2027
Contract no.	101115442
Project Coordinator	MITERA
Deliverable no.	D1.2
Document name	VOCORDER_D1.2.pdf
Deliverable name	Data Management Plan (DMP)
Work Package	1
Nature[1]	R
Dissemination[2]	PU
Lead Beneficiary	7 NEURATECH
Contributing beneficiary / beneficiaries	ALL
Reviewed by	AIDEAS, MITERA
Approved by	MITERA
Due date	31 March
Actual submission date	29/03/2024

[1] **R** = Document, Report, **DMP** = Data Management Plan, **OTHER** = Other
[2] **PU** = Public, **SEN** = Sensitive, limited under the conditions of the Grant Agreement

Contents

ABBREVIATIONS

Term	Explanation
DMP	Data Management Plan
DPO	Data Protection Officer
OMB	Office of Management and Budget

EXECUTIVE SUMMARY

This report focuses on the preparation of the Data Management Plan (DMP) for VOCORDER project. DMP provides an analysis of the main elements of data management policy that will be used throughout the project with regard to all datasets that will be generated. In particular, DMP will define how this data will be managed and shared by the project partners, and also, how this information will be curated during the project, as well as preserved after the project ends. The first version of the DMP is delivered in Month 6 of the project, when the first data sets are identified. More detailed version of the DMP will be delivered at later stages of the project if applicable and at the end of the project as a final DMP report.

1. INTRODUCTION

The amount of data generated is continuously increasing, while use and re-use of data to derive new scientific findings is relatively stable. This information would be useful in

the future if the data is well documented according to accepted and trusted standards which enable the recognition of suitable data by negotiated agreements on standards, quality level and sharing practices. For this purpose, DMP defines strategies to preserve and store data over the defined period of time in order to ensure their availability and re-usability after the end of VOCORDER project. The procedures that will be implemented for data collection, storage, access, sharing policies, protection, retention and destruction will be according to the requirements of the national legislation of each partner and in line with the EU standards.

1.1 VOCORDER Data management plan objectives

The purpose of this document is to set the DMP for the VOCORDER project. It contains guidelines that will be used for the development of a DMP which will include an analysis of the main elements of the data management policy that will be used by the VOCORDER consortium with regards to all the data that will be generated by the project. In accordance with Guidelines on FAIR Data management in Horizon 2020[i], the objectives of the DMP are:

- To identify the datasets that VOCORDER will produce.
- To define how these datasets will be made 'FAIR' (Findable, Accessible, Interoperable and Reusable).
- To define procedures for data security (including data recovery as well as safe storage) during the project and for long term preservation.
- To define the allocation of resources (responsibility) for data management during and after the project.
- Provide details on how the VOCORDER consortium plans to address the Ethical issues (if any) related to data which will be collected during the Project timeframe

The DMP will not be a fixed document, but it will evolve and will gain more precision and substance during project implementation. New versions of the DMP will be created whenever important changes to the project occur due to inclusion of new data sets, changes in consortium policies or external factors.

The first version of this DMP is delivered within the first six months of the project and is based on DMP template provided by the European Commission and in line with its

‘’guidelines to the Rules on Open Access to Scientific Publications and Open Access to Research Data in Horizon 2020’’[ii].

2. DATA SETS

2.1 Define research Data

One definition of research data is: "the recorded factual material commonly accepted in the scientific community as necessary to validate research findings."[iii]. Research data covers a broad range of types of information, and digital data can be structured and stored in a variety of file formats. Note that properly managing data (and records) does not necessarily equate to sharing or publishing that data.

Some examples of research data include:

- Documents (text, Word), spreadsheets
- Laboratory notebooks, field notebooks, diaries
- Questionnaires, transcripts, codebooks
- Audiotapes, videotapes
- Photographs, films
- Spectra
- Test responses
- Slides, artefacts, specimens, samples
- Collection of digital objects acquired and generated during the process of research
- Database contents (video, audio, text, images)
- Models, algorithms, scripts
- Contents of an application (input, output, logfiles for analysis software, simulation software, schemas)
- Methodologies and workflows
- Standard operating procedures and protocols

In addition to the other records to manage, some kinds of data may not be sharable due to the nature of the records themselves, or to ethical and privacy concerns. As defined by the OMB, this refers to:

- Preliminary analyses
- Drafts of scientific papers
- Plans for future research
- Peer reviews
- Communications with colleagues

Research data also do not include:

- Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published or similar information which is protected under law.
- Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

The following research records may also be important to manage during and beyond the life of a project:

- Correspondence (electronic mail and paper-based correspondence)
- Project files
- Grant applications
- Ethics applications
- Technical reports
- Research reports
- Signed consent forms

2.2 Data Sets

The specific Data Sets for the VOCORDER project need to be identified and described with the contribution of all project partners. A short description of the data, which will be generated in the research project (e.g. samples, physical collections, software, curriculum materials, and other materials to be produced during the course of the project) must be provided. Additionally, an estimation of the amount of data and content of the data (if possible) must be included.

For this reason, the following template will be filled by the WP leaders in order to collect information regarding data sets according to the following template:

WORK PACKAGE (Mention the VOCORDER Work Package this dataset belongs) TASKS (Mention the VOCORDER TASK this dataset belongs)	
Data Identification	
Dataset description	(Description, Source of data, creation of data)
Source	(Data derives from…)
Partners activities and responsibilities	
Partner owner dataset	
Partner in charge of data collection	
Partner in charge of data analysis	
Partner in charge of data storage	
Standards	
Info about metadata	
Standards, Format	(standard if any, word, excel, design etc.)
Data exploitation and sharing	
Data exploitation	(purpose/use of the data analysis)
Data sharing, re-use and distribution	(Data shared with…, Use of data by…)
Archiving and preservation (including storage and backup)	

Data storage (including backup)	Storage and backups of the relevant materials … first level of storage and backup. e.g. Google Drive folder - second level of storage A third level of storage and accessibility will be the members section in the VOCORDER website (Private documents).

In addition to the above, the following table will also be filled by the WP leaders in order to provide adequate information regarding data sets according to the following issues:

Are you generating the data or sourcing it from somewhere else under certain terms and conditions?
Is the data digital or non-digital, or both?
How will the data be created or collected? What instruments or tools will be used to produce the data?
What transformations will the data undergo? What software or file formats will you use as you work with the data?
Will the data be updated or become redundant as you make revisions and produce subsequent versions?
Is the data sensitive or confidential?
Is there ethics approval, or is ethics approval required?

From the information that will be gathered the roles of the partners and the use of the data will be identified. As a result, for each type of research data it will be defined who will be providing the data and who will be using/analysing the data.

Additionally, the file formats that will be used are an important issue. The formats that will be used should be the best for long-term preservation and continued access of data. Formats most likely to be accessible in the future are:

- Non-proprietary and not tied to a specific piece of software
- Open, documented standard
- Common, used by the research community
- Standard representation (ASCII, Unicode)
- Unencrypted
- Uncompressed

2.3 Descriptive information and Metadata

The DMP defines what documentation and metadata will accompany the data. Metadata is structured information describing the characteristics of a resource; for example, the dates associated with a dataset or the title and author of a book. Metadata supports discovery, re-use and long-term preservation of resources. Metadata needs to vary across scientific fields, but typically cover the following:

- General descriptive and access of metadata
- Data characteristics
- Archive terms and access policies

A metadata record consists of a set of predefined elements that define specific attributes of a resource. Each element can have one or more values; for example, a dataset may have multiple creators. Documenting data enables other researchers to discover your data. Metadata about the nature of the files is also critical to the proper management of digital resources over time. All the partners will agree on specific issues regarding for example:

- The way that the data will be organized or formatted so that everyone working on it now and in the future knows the origins of the data.

- The way that each file will be named (File Naming Conventions). The use of the following format is proposed for each file/document: "Date (yyyymmdd)_project_company_filename_author_version".
- Providing adequate metadata within the dataset (e.g. field labels or column headings) in order to be easy to interpret the data. Other examples of information that the data need to contain include:
    - Reference period
    - Project funding information: European Union logo and information about Grant Agreement and the action/program that funds the project
    - Release policy including dissemination rules and purposes
    - Information about data collection (source, frequency and adjustments)
    - Keywords (Keywords or phrases describing the subject or content of the data)
    - Geographic coverage of the dataset (if applicable)
    - File formats
    - Comments
- Ways to identify different versions. It is proposed in each data set to include a versioning table, additionally to use the prefix ". v1" in each file/document name relevant to the versioning table. For versioning the rule that will be followed will be the use of a sequentially numbered system: v1, v2, v3, etc. and "Final" for the final version. If changes need to be done in the final version, then the name of the document will change including the relevant sequential version number, ensuring that the document with the "Final" prefix is indeed the final one.

At a minimum, metadata records should be kept in a fielded form, such as a spreadsheet, CSV file, or tab-delimited file. Auxiliary information necessary to interpret the metadata - such as explanations of codes, abbreviations, or algorithms used - should be included as accompanying documentation. A brief description of the Data sets identified for the VOCORDER project are included in Annex 1.

2.4 Ownership (IPR)

In the DMP issues regarding copyright and Intellectual Property Rights of the data are included. These issues are set in the Consortium Agreement and the Grant Agreement of the VOCORDER project regarding all the results of the project. Thus, the DMP follows

the Consortium Agreement and the Grant Agreement that is signed by all project partners regarding Ownership issues.

Any type of results generated under the VOCORDER Project will be disseminated in accordance with the Consortium Agreement.

2.5 Storage and Access

The long-term storage of data is a main issue of the project. Not only the data will be stored. The computers, the recording tools should be stored in order to confirm, validate, reproduce the experimentations. All data and their associated metadata will be stored anonymously in the project's database repository, adhering to all privacy and security measures for data protection.

Brief descriptions of the platforms and repositories chosen for the VOCORDER data storage and dissemination will be included in this section.

3. ETHICAL AND LEGAL ISSUES

3.1 Research Ethics Compliance

The VOCORDER project is subject to compliance with the ethical principles and relevant national, Union and international legislation, as set out in Article 14 of the Grant Agreement (GA), which, among other, states that all activities must be carried out in compliance with:

(a) Ethical principles, including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct.

(b) Applicable international, EU and national law, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.

The VOCORDER consortium is specially compromised to ensure the respect of n 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 partners have also been committed to the basic EU values, such as but not limited to respect for human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities.

In Task 2.3 and D 2.1. ethics approvals, along with the study registration in the ClinicalTrials.gov data system will be managed. In Task 6.1 and D 6.1. the assessments of legal and ethical aspects including, informed consent, beneficence and non-maleficence will follow. Ethics check should be performed at M24 to assure that ethical approvals for the clinical trials have been obtained in all five participating countries before e any patients are recruited. Copies of the approvals should be submitted to the Commission by M22. This section will offer updates on the implementation of measures identified in D 2.1 and D 6.1, as well as introduce any additional measures required to address emerging ethical risks and requirements throughout the project. As the project unfolds, any new legal and ethical challenges arising from VOCORDER's research activities will be integrated into this section.

3.1.1 Opinions/ approvals by ethics committees and/or competent authorities

When necessary, and always before starting an action or task raising ethical issues, the beneficiaries must have obtained all approvals or other mandatory documents needed for implementing the task, notably from any (national or local) ethics committee or other relevant bodies such as data protection authorities. More specifically, obtaining ethical approvals for clinical trials in all five participating countries should precede the recruitment of patients. An Ethics check should be performed at M24 to assure that ethical approvals have been acquired.

Copies of the approvals should be submitted to the Commission by M22. All documents must be kept on file and be submitted upon request by the coordinator to the granting authority. If they are not in English, they must be submitted together with an English summary, which shows that the documents cover the action tasks in question and includes the conclusions of the committee or authority concerned. The EC recommends that partners request the assistance of ethics experts, research ethics departments/committees and their organisation's DPO[3]. The relevant partners will need

[3] European Commission. (2021). EU Grants AGA – Annotated Model Grant Agreement. EU Funding Programmes 2021-2027; Available here.

to demonstrate that the opinions/authorisations/notifications cover the tasks to be undertaken in the context of the action.

This subsection will provide a record of all the activities requiring approvals during the project and report on the approvals and opinions obtained by each partner.

Partner	Ethical committee	Approval

3.1.2 Incidental findings policy

The occurrence of incidental findings constitutes another issue that needs to be taken into account at the evaluation of compliance of research activities with ethics. Incidental findings are defined as results that arise outside the original purpose for which the test or procedure was conducted. Secondary findings are findings that arise and are actively sought but they do not represent the primary objective of the test or the procedure. 'Anticipated' incidental findings are discoveries that are recognized to be linked with a particular test or procedure. These findings need not be frequent or probable. What defines them is the awareness of the possibility of encountering them. Conversely, 'unanticipated' incidental findings are those that could not have been predicted based on current scientific understanding. Researchers cannot prepare for such findings in advance. Nonetheless, researchers can contemplate in advance how they might respond if a specific type of unexpected discovery emerges, such as one that could have actionable or life-saving implications.

The EU Commission explicitly acknowledges the potential for incidental findings in its guidance titled "How to Complete Your Ethics Self-Assessment."[4] The policy on incidental findings is outlined in the ethics issues checklist published by the EU Commission, particularly in section 2 (humans). It is therefore inferred that this ethical responsibility pertains to research involving human participants. In cases of human subject research, procedures to be followed in the event of unexpected incidental findings should be clearly delineated. Specifically, researchers must outline whether participants have the right to be informed of such findings or to remain unaware. Researchers are obliged to anticipate the possibility of discovering incidental findings and preemptively describe the protocol to be followed in such instances. This involves proactive measures, such as obtaining consent from participants, as well as subsequent

[4] European Commission. (2021). EU Grants, How to complete your ethics self-assessment; Available here.

actions, such as maintaining confidentiality and communicating findings to research participants.

In VOCORDER the project's activities will be governed by the following minimum set of rules regarding the incidental findings.

Frist of all, these incidental findings will be immediately referred the project's responsible partner for the clinical trials (MITERA) and only if necessary to the Advisory Board members and the Internal Ethics Committee. They will be responsible for assessing their ethical ramifications and determining the appropriate course of action.

The incidental findings will be governed by the following guidelines:

a. Participants will provide informed consent to participate in the clinical trial.

b. MITERA, the Advisory Board and the Internal Ethics Committee will consider the deletion of any incidental findings.

The responsible partner for inspecting as well as guiding the consortium's partners regarding the project's ethical requirements/aspects will be VUB. These requirements may be revised and adjusted throughout the lifetime of the VOCORDER project.

3.1.3 Informed consent forms and information sheets

Ensuring the attainment of a valid, written informed consent from research participants is of utmost importance. Participation in the VOCORDER research will be entirely voluntary for all individuals, with the right to withdraw from any stage of the research activities without facing any repercussions or penalties. A comprehensive information sheet outlining the purpose, procedure, risks, etc., of the VOCORDER research will be furnished to participants along with the consent form. A protocol and draft templates for information consent forms will be added into this subsection, following the principles set under Work Package (WP) 2, 6 and 7, and more specifically stated on Task 2.3 and D 2.1., Task 6.1 and D 6.1. and D 7.3 concerning Ethical and GDPR requirements.

vocorder

MITERA
Responsibility for life
MEMBER OF HHG GROUP

Informed Consent Form for VOCORDER

[Informed Consent form for VOCORDER participants]

This informed consent form is written for patients suffering from lung cancer, gastric and colon cancer, breast cancer, kidney insufficiency or infections - pneumonia (community-acquired and hospital-acquired) and for healthy controls of both sexes, aged between 20 to 75 years, who do not suffer from these diseases.

Name of Principal Investigator: Kontopidou Flora
Name of Organization: MITERA Hospital
Name of Project: VOCORDER - HORIZON-EIC-2022-PATHFINDERCHALLENGES-01-04

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

You are cordially invited to participate in the clinical study conducted within the project VOCORDER. Prior to making your decision regarding participation in the project's clinical study, it is essential that you comprehend the project's nature and your role within it. Kindly take the time to thoroughly review the following information. If you decide to participate in our study, we would like to thank you in advance. However, you are totally free to decline our invitation to take part in the project.

VOCORDER is a European funded project with duration of 3 years and 6 months, which was initiated in October 2023. The clinical study will take place under the premises of the MITERA hospital and run by MITERA research team. It will be decomposed into a baseline and an intervention phase. This clinical study is going to address the correlation analysis between breath VOCs profiles as detected by the VOCORDER breath analyser and electronic medical data as collected by medical professionals.

Purpose of the clinical study

The objectives of the study could be summarised as follows:

- providing a solution for easy-to-use breath analysis able to monitor the health of any individual at any setting and offering life-long health status monitoring and elements of predictive medicine with methodologies grounded in existing scientific evidence;
- developing a health monitoring apparatus people can easily integrate into their everyday life, paying attention to minimising false positives that can occur in the real world and ensuring a clinically acceptable solution amendable to successful evaluation under common Health Technology Assessment (HTA) methodologies;
- developing and demonstrating the beyond state-of-the-art technologies needed to implement the breath analysis apparatus;

- prioritising the development of AI-enhanced predictive models that address specific conditions in the continuum of a patient and enabling AI-breath analysis for identification of health conditions.

Type of Study Intervention
You will be asked to fill in a questionnaire with demographic and medical-history data. Moreover, an interview will be conducted with the responsible personnel. Afterwards, at least 2-3 breath samples are expected to be obtained by you on different days at the same time of day and further analysed.

Participant selection
Patients suffering from lung cancer, gastric and colon cancer, breast cancer, kidney insufficiency or infections - pneumonia (community-acquired and hospital-acquired) and healthy controls of both sexes, aged between 20 to 75 years, who do not suffer from these diseases are invited to participate in the clinical study.

Voluntary Participation
Your involvement is entirely voluntary. It is entirely your choice whether to participate or not. You are free to withdraw your participation at any time, without providing reasoning and without further consequences.

Duration
The clinical study will be conducted in two phases:

- 1st Phase: Baseline phase (June-December 2024)
- 2nd Phase: Intervention phase – VOCORDED technology validation (May-December 2026).

Depending on the phase of the clinical study you will take part in and during that time, it will be necessary for you to come to the hospital 2 days at the same time for each day.

Side Effects
No side effects are anticipated from this clinical study.

Risks and Benefits
This clinical study is not interventional so there has been no reasonably foreseeable risk, discomfort or disadvantages identified in the context of your participation in the clinical study of VOCORDER. On the contrary, the method applied in VOCORDER for sample breath collection is one of the least intrusive. The benefits stemming from the results which may reasonably be expected from the research output include the provision of an easy-to-use breath analysis, enabling each individual to monitor their health at any setting. The obtained results are expected to have importance for tailoring the technology of breath analysis in the VOCORDER breath analyser toward the early detection of diseases of interest timely.

Reimbursements
No reimbursement is provided by the clinical study.

Data collected and analysed
In order to perform the clinical study, personal information will be collected upon the consent of the individuals. The collected data according to their purpose within the project, will consist of:

a) Name and surname
b) Age
c) Gender
d) Contact details (address, phone number, email address)
e) Medical data (medical history, medical record and questionnaire to be filled by the participant)

Processing and Storage of Data

Your data will be processed in accordance with the General Data Protection Regulation (GDPR), Clinical Trials Regulation (CTR) and the applicable national legislation. The data will be collected by the MITERA project team and stored in a computerised working folder within the hospital. The folder is only accessible to the MITERA project team. The patient-related data is then anonymised and entered into a specially developed database that is shared with the other partners - authorised users. All information will be kept strictly confidential. By March 2027, at the conclusion of the project, your personal data will be either deleted or destroyed. Processed data, however, may persist beyond the project's duration as it could be incorporated into scientific publications and other dissemination activities, as outlined below. The sole purpose of storing your data is for project activities.

Data Protection, Confidentiality and Privacy
All the necessary measures have been adopted for ensuring data protection, confidentiality and privacy in VOCORDER. More specifically, Data protection and privacy concerns have been addressed and compliance with the requirements posed by the relevant legislation has been achieved. Specific guidelines have been communicated to the involved beneficiaries. Confidentiality obligations have been agreed between the partners as well.

Dissemination of the Results
The stored data will be used for research purposes, which encompass, among others, publications, intellectual property management and further types of sharing of information and relevant events. It is important to note that in all instances, the data will be presented in an anonymised manner. The results will not be shared with the participants since the VOCORDER breath analysis method will till the end of the project remain an experimental one.

Incidental Findings
Any incidental findings will be deleted. If the findings render necessary for the purposes of immediately referred to MITERA, the project's responsible partner for the clinical trials and only if necessary to the Advisory Board members and the Internal Ethics Committee will assess their ethical ramifications and proceed to the appropriate course of action.

Data Sharing and Re-use
Your data will be not sent to third parties or to countries outside of the European Union. The stored data will be utilised for activities only associated with VOCORDER, including their processing for research purposes and dissemination activities. Rest assured that your data will not be sold or be freely provided to any third party under any circumstances.

Data Breach
In the event of a data breach, each partner will promptly notify the Project Coordinator (MITERA). They will together take all the essential measures to mitigate any potential adverse effects. Since your contact information is included in the collected data, you will receive a notification as soon as possible regarding the nature of the data breach, the information compromised, and the steps being implemented to prevent or reduce any possible harm.

Data Subjects' Rights
You have the right to request the correction and/or deletion of your data, as well as to restrict the processing of your data, as outlined in Articles 15-21 of the GDPR. In addition, you maintain the right to withdraw your consent at any time, in accordance with Article 6(1) and Article 9(2) of the GDPR, without facing any adverse consequences, by simply sending an email at [EMAIL]. If needed, your local supervisory authority will furnish you with information on how to exercise your rights, as prescribed in Article 57(e) of the GDPR. To assert your rights or to address any further inquiries concerning the exercise of your data subject rights, you can reach out to MITERA, the project's coordinator, at [EMAIL]. Please be aware that you have the option to lodge a complaint within your national data protection authority regarding the handling of your personal data, or with another competent supervisory authority as per the GDPR.

Who to Contact
Each beneficiary of VOCORDER adheres to its respective ethical guidelines, in compliance with the national legislation of the country they reside at. If you have any specific inquiries concerning the research activities conducted within VOCORDER and/ or your rights, please direct your question to the project's Coordinator, MITERA, at [EMAIL].

This proposal has been reviewed and approved by the Scientific Council of MITERA, which is a committee whose task is, among others, to verify the compliance of the study with ethical principles and legal obligations.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Consent Form

Thank you for your interest in taking part in the clinical study of the VOCORDER project. Before you agree in participating, the medical personnel organising the study and gathering your information is obliged to provide an explanation of the project to you. At any case, please review the VOCORDER Information Sheet for further details. If anything is not clear to you, please refer to the personnel for further inquiries. Based on the information provided and after reviewing the VOCORDER Information Sheet and being offered the explanations by the research team,

□ **I confirm that I comprehend the nature of the project. I have also been afforded the opportunity to pose questions, and they have been addressed and answered to my satisfaction.**

□ **I understand that my participation is voluntary and that I am free to withdraw my consent at any time, without providing reasoning and without further consequences.**

□ **I have been informed that my data will be stored in a secure manner and for a duration not exceeding the length of the project.**

□ **I understand that my information will be treated as strictly confidential and handled in accordance with the provisions prescribed in the applicable EU legislation, mainly in General Data Protection Regulation and Clinical Trials Regulation.**

I consent to voluntarily participate as a participant in this clinical study and to the processing of my personal data for the assessment the purposes of VOCORDER.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
1. The participants will fill in a questionnaire and breath samples will be collected by them.
2. The data provided will be securely stored, anonymised and used for the purposes of VOCORDER till the finalisation of the project.
3. No result or incidental finding will be communicated to the participants.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

3.1.4 Appointment of contact persons for legal and ethical matters

Every partner, regardless of whether they have designated a Data Protection Officer (DPO), has provided the contact information for the individual responsible for legal and ethical matters within the framework of VOCORDER. Consequently, if a partner has designated a DPO, their contact information will be utilized. In cases where the partner does not have a DPO, the details of an individual within the organization will be provided for legal and ethical matters.

A table containing the aforementioned information will be added in this subsection.

Partners	Assigned DPO or person responsible for legal and ethical matters	Contact details

3.2 Privacy and Confidentiality

Ensuring privacy and confidentiality is essential for research activities to adhere to ethical standards. The European Textbook on Ethics by the EU Commission highlights the close connection between privacy and confidentiality, noting that historically, privacy has been regarded as the fundamental interest[5]. Given that privacy and confidentiality concerns can emerge in all types of research involving human participants, it is imperative for VOCORDER partners to prioritize adherence to both principles.

3.2.1 Privacy

Defining privacy proves challenging due to various references across official legal documents, such as, but not limited to the 1948 Universal Declaration of Human Rights, the European Convention on Human Rights, and the Charter of Fundamental Rights of the EU. In an attempt to amalgamate existing definitions, the EU Commission has introduced at the following comprehensive and inclusive definition of privacy, which essentially encompasses the protection of:

• Control over personal information;

• Control over access to oneself, encompassing physical and mental aspects;

• Control over the ability to make significant decisions about family matters, fostering self-expression and the cultivation of diverse relationships[6].

In VOCORDER adequate and careful consideration is given to all potential ethical and legal issues that could arise, related especially to privacy. User privacy will be adequately considered, monitored and protected, while privacy and security measures will be adopted.

[5] European Commission. (2010). European Textbook on Ethics in Research; Available here.
[6] Ibid. p. 78-79; Judith DeCew. (1997). In Pursuit of Privacy: Law, Ethics, and the Rise of Technology. Ithaca: Cornell University Press.

3.2.2 Confidentiality

Confidentiality is another critical aspect to consider during research endeavors. It entails an obligation that arises when an individual gains access to another person's information, either through a contractual agreement or within a specific relationship context (such as the doctor-patient relationship). The Commission outlines three parameters that define confidentiality and distinguishes it from privacy.

Unlike to privacy, confidentiality pertains solely to information.

- The obligation of confidentiality arises specifically within particular relationships or agreements. Confidentiality duties are applicable when information is provided with the understanding that it will not be disclosed without consent. This contrasts with the broader duty to respect privacy, which extends to everyone.

- Privacy respect imposes limitations on how researchers (and others) gather information about their subjects, whereas confidentiality concerns how they communicate information they already possess.

In VOCORDER all partners must keep any data, documents or other material confidential during the implementation of the project and for four years after end of the project in accordance with Article 13 of the GA. Further detail on confidentiality can be found in the aforementioned provision.

3.3 Data Security and Protection

The protection of personal data is enshrined as a fundamental principle in both the Charter of Fundamental Rights and the Treaty on the Functioning of the European Union. In the realm of research, privacy concerns arise whenever data pertaining to individuals are gathered and processed. Safeguarding participants' right to privacy emerges as a significant challenge for researchers, as they must strike a delicate balance between processing and sharing participants' personal data for research purposes while also shielding them from unauthorized access.

Regulation 2016/679 (GDPR)[7] serves as the primary legislative framework governing the protection of personal data, and researchers are expected to conduct their research in accordance with its provisions. Particularly in cases involving the collection and

[7] 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/ GDPR).

processing of special categories of personal data, such as health data, the GDPR imposes stricter conditions that must be adhered to for the research to maintain ethical compliance with individuals' right to data protection.

Within this context, when personal data processing is anticipated in research, participants should be provided with comprehensive information at all stages of the research process. This information should include details about the types of data being collected, the purposes for which they are being collected, the duration of data storage, procedures for data destruction when no longer necessary, the identity and contact information of the data processor, methods for data access by the data subject, and the data subject's right to be forgotten etc.

Simultaneously, researchers should implement technical and organizational measures to safeguard the rights of research participants. This includes adopting security measures to prevent unauthorized access and employing techniques such as anonymization or pseudonymization to protect participant data.

3.3.1 Personal Data in VOCORDER

Researchers collecting personal data ("data about individuals") must adhere to the relevant data protection pieces of legislation. Thus, the core GDPR terminology when handling personal data will be summarised. In general, four categories of personal data can be identified, namely:

• **Personal data** are defined broadly, encompassing "any information relating to an identified or identifiable natural person" (Article 4 GDPR). Put simply, personal data enable the identification of individuals either directly or indirectly based on the data. Under the term both direct identifiers and indirect identifiers, referring to any other information linked or linkable to an individual are meant.

• **Special categories of personal data**, also known as ‘sensitive data’ refers to information deemed riskier to individuals and thus warranting enhanced protection. This category includes "personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, as well as the processing of genetic data, biometric data for uniquely identifying a person, data concerning health, or data concerning a person's sex life or sexual orientation" (Article 9(1) GDPR). Processing such special categories of data is prohibited by default, with only a limited number of conditions under which such processing renders lawful (Article 9(2) GDPR).

• **Pseudonymised data** are data that have undergone pseudonymisation. Pseudonymisation is called the processing of personal data in a manner that renders it impossible to attribute to a specific individual without additional information, provided that this additional information is kept separate and is subject to technical and organizational measures to prevent attribution to an identified or identifiable person (Article 4(5) GDPR). Despite being pseudonymised, such data are still considered personal data, and as such, the GDPR remains fully applicable.

• **Anonymised or Anonymous data** are regarded as "data that do not (or no longer) relate to identifiable individuals." The (re-)identification of the individuals involved is made impossible, and this inability is permanent, extending even to the researchers conducting the study. Such data do not qualify as personal data under GDPR and thus fall outside the scope of data protection laws.

In VOCORDER, demographic data will be collected both from patients and from healthy individuals. The term refers to all of the non-clinical data about a patient or a healthy person, including their name, date of birth, sex, race, contact details, etc. Among them personal and special categories of data can be included, which will be collected through a questionnaire and an interview of the involved parties.

Additionally, data on the clinical status, including information about comorbidities, long-term diseases, and in general information relating to the health situation of a person will be collected. Health data as such is considered sensitive data and is subject to particularly strict rules and can only be processed by health professionals who are bound by the obligation of medical secrecy.

3.3.2 De- personalisation in VOCORDER

As already mentioned in the previous subsection, anonymisation constitutes a processing activity aiming at removing all identifying elements from a set of personal data to ensure the data subject cannot be identified. For data to be considered anonymous, no elements should remain in the information that could, with reasonable effort, be used to re-identify the involved individuals. Once data have been effectively anonymised, they cease to be classified as personal data. In cases achieving complete anonymization is not technically feasible due to the inability to suppress the risk of re-identification, pseudonymisation will be implemented along with necessary technical and

organizational measures. Even then, anonymisation can be considered as a protective measure.

On the contrary, pseudonymisation is a processing activity designed to mitigate risks to the data subject by rendering their identification impossible without the use of supplementary information. Unlike anonymisation, it does not render a data subject unidentifiable; therefore, it remains subject to the legal data protection framework.

Under the context of VOCORDER, anonymisation of the data is impossible since it would be necessary to reidentify the participants so as to draw conclusions on the effectiveness of the medical device on identifying diseases and monitoring the health status on the individuals. Instead, pseudonymization of the data will be performed in order for the re-identification of the participants to be feasible.

Therefore, data collection will be performed in a pre-defined way based on the relevant SOPs under the premises of MITERA. Informing the participants and the granting their consent will precede the collection. Personal data safety issues will also be considered. The data and their associated metadata will be stored anonymously in the VOCORDER's database repository, adhering to all privacy and security measures for data protection. User privacy, ethics, gender and GDPR issues will be adequately considered, monitored and protected, while any data shared with 3rd parties for dissemination reasons, will only be shared after explicit permission and consent and without revealing personal or other sensitive information. Their processing by other VOCORDER partners rather than the medical ones will occur after their de-personalisation, using pseudonimysation and encryption techniques.

Taking the above into consideration, since personal data are, after all, processed by the consortium, it will be made sure that the GDPR framework will be implemented and that the data subjects' rights will be respected throughout the project's duration. In this context, legal compliance, including compliance of the project's data processing activities with the GDPR, will be closely monitored. Relevant compliance issues will be addressed in Task 2.3 and D 2.1., Task 6.1 and D 6.1. Partners are bound under Article 15 of GA and will be fully accountable for the data processing operations.

3.3.3 Data Security

In the context of data security, all partners will provide feedback on the security measures they intend to apply to ensure security of their dataset. They will use state-of-the-art

technologies for secure storage, delivery, and access to their datasets, and for the management of the rights of the users. This section will report on the technical and organization measures adopted by the project partners for data security purposes, including data recovery, secure storage or archiving and the access to and transfer of sensitive data.

In this section, a table will be included with the assigned DPOs by the partners. If there are no assigned DPOs, their Privacy Policy will be included along with a statement of compliance regarding the processing of personal data.

Partner	Assigned DPO/ Privacy Policy / Declaration of compliance

4. CONCLUSIONS

The document presented the Data Management and Open Access strategy for the VOCORDER project. The initial VOCORDER Data Management Plan comprises the identification of the initial Data Sets by all partners. The DMP will be revised and updated during the entire duration of the project. The DMP will be updated at least by the mid-term and final review to fine-tune it to the data generated and the uses identified by the consortium since not all data or potential uses are clear from the start. New versions of the DMP will be created, whenever important changes to the project occur due to inclusion of new data sets, changes in consortium policies or external factors.

5. ANNEXES

5.1 Annex 1. VOCORDER Data Sets

5.1.1 WP1

WORK PACKAGE: **WP1** Project Management (MITERA) **WP1** data sets will be further defined and amended later in to the project

5.1.2 WP2

WORK PACKAGE: **WP2** Specifications of the components, overall architecture and application use cases (ARGOS) TASKS **T2.1** – Literature Review on VOCs and other volatile compounds in breath, related to health conditions (ETH)	
Data Identification	
Dataset description	List of VOCs biomarkers and their correlation to diseases
Source	Literature research, papers, publications
Partners activities and responsibilities	
Partner owner dataset	WP2 partners
Partner in charge of data collection	ETH
Partner in charge of data analysis	ETH, with the help of MITERA
Partner in charge of data storage	MITERA (through SharePoint)
Standards	
Info about metadata	TBD
Standards, Format	Excel (.xlsx)
Data exploitation and sharing	

Data exploitation	Data used to select VOCs and biomarkers that correlate to diseases. List of target VOCs will be used as input identification of target wavelengths for spectroscopic analysis VOCs.
Data sharing, re-use and distribution	Data shared with all WP2 partners
Archiving and preservation (including storage and backup)	
Data storage (including backup)	Data stored on MITERA's SharePoint and on ETH's internal server.

In addition to the above table, the following table also provided adequate information regarding the data sets for WP2.

Are you generating the data or sourcing it from somewhere else under certain terms and conditions? Data sourcing from publications and clinical studies
Is the data digital or non-digital, or both? Digital
How will the data be created or collected? What instruments or tools will be used to produce the data? Data collected through literature research.
What transformations will the data undergo? What software or file formats will you use as you work with the data? Data gathered on Excel and then used in Deliverable D2.2 (Word + pdf formats)
Will the data be updated or become redundant as you make revisions and produce subsequent versions? Yes (the spreadsheet will be updated as long as the technical specifications are not completed).
Is the data sensitive or confidential? Confidential

Is there ethics approval, or is ethics approval required? No

For the WP2 there are additional data sets from the ALPES as shown in the table below:

WORK PACKAGE: **WP2** Specifications of the components, overall architecture and application use cases (ARGOS) TASKS **T2.2** - Specifications of individual components & key technologies (ALPES)	
Data Identification	
Dataset description	Spreadsheet summing up all technical specifications of individual components used in the VOCORDER
Source	Inputs from Partners involved in T2.2
Partners activities and responsibilities	
Partner owner dataset	WP2 partners
Partner in charge of data collection	ALPES
Partner in charge of data analysis	ALPES, with the help of ARGOS
Partner in charge of data storage	MITERA (through SharePoint)
Standards	
Info about metadata	TBD
Standards, Format	Excel (.xlsx)
Data exploitation and sharing	
Data exploitation	Data used to build the technical specifications of individual components

	used in the VOCORDER, and that serve as an input for Deliverable D2.2.
Data sharing, re-use and distribution	Data shared with all WP2 partners
Archiving and preservation (including storage and backup)	
Data storage (including backup)	Data stored on MITERA's SharePoint and on ALPES' internal server.

In addition to the above table, the following table also provided adequate information regarding the data sets for WP2.

Are you generating the data or sourcing it from somewhere else under certain terms and conditions? Data generated by all WP2's partners.
Is the data digital or non-digital, or both? Digital
How will the data be created or collected? What instruments or tools will be used to produce the data? Data collected through common work with the VOCORDER's SharePoint.
What transformations will the data undergo? What software or file formats will you use as you work with the data? Data gathered on Excel and then used in Deliverable D2.2 (Word + pdf formats)
Will the data be updated or become redundant as you make revisions and produce subsequent versions? Yes (the spreadsheet will be updated as long as the technical specifications are not completed).
Is the data sensitive or confidential? Confidential
Is there ethics approval, or is ethics approval required? No

5.1.3 WP3

WORK PACKAGE: **WP3** Building the VOCORDER - Key enabling technologies & components (EUL) TASKS **T3.1** - QCL and ICL arrays (ALPES)	
Data Identification	
Dataset description	- Design & simulation of QC chips - Mechanical layouts of items developed within VOCORDER - Photolithography masks used for processing of QCLs - Process sheets of fabricated QCLs - Results of characterization measurements undertaken during the fabrication of QCLs - Reports of final characterization measurements of fabricated QCLs - Pictures of QCLs developed during the project
Source	- ALPES' simulation software - Mechanical design software - Commercial mask design tools - Subcontractors' characterization setups - ALPES' characterization setups - Cameras
Partners activities and responsibilities	
Partner owner dataset	ALPES
Partner in charge of data collection	ALPES
Partner in charge of data analysis	ALPES
Partner in charge of data storage	ALPES

Standards	
Info about metadata	TBD
Standards, Format	.csv .gds .xlsx .tif .jpeg .pdf
Data exploitation and sharing	
Data exploitation	Data used to develop QCLs used in the frame of VOCORDER.
Data sharing, re-use and distribution	No sharing excepted: - Reports of final characterization measurements of fabricated QCLs - Pictures of items developed in the frame of VOCORDER
Archiving and preservation (including storage and backup)	
Data storage (including backup)	ALPES' internal server

In addition to the above table, the following table also provided adequate information regarding the data sets for WP3.

Are you generating the data or sourcing it from somewhere else under certain terms and conditions? No
Is the data digital or non-digital, or both? Digital & non-digital
How will the data be created or collected? What instruments or tools will be used to produce the data? Data created through simulation software, characterization setups or cameras.

What transformations will the data undergo? What software or file formats will you use as you work with the data? dwd
Will the data be updated or become redundant as you make revisions and produce subsequent versions? No
Is the data sensitive or confidential? Confidential
Is there ethics approval, or is ethics approval required? No

5.1.4 WP4

WORK PACKAGE: **WP4** Artificial intelligence towards identification of health conditions (AIDEAS) TASKS T4.1 Annotation of EMR data (AIDEAS) T4.2 Annotation of spectral data (ICCS) T4.3 AI-based identification of correlation between spectral and EMR/health data (AIDEAS)	
Data Identification	
Dataset description	Risk factors based on questionnaire, EMR and biomarkers from gas analysis
Source	Data derives from Matera's Pilot Study from baseline phase and validation phase
Partners activities and responsibilities	
Partner owner dataset	MITERA and ETH
Partner in charge of data collection	MITERA
Partner in charge of data analysis	ETH, AIDEAS, ICCS and NEURALTECH
Partner in charge of data storage	MITERA

Standards	
Info about metadata	Digital raw data will be accompanied by descriptive textual descriptions (meta-data)
Standards, Format	Possible formats include JSON, CSV and Excel spreadsheets.
Data exploitation and sharing	
Data exploitation	Identifying early disease detection biomarkers, developing of artificial intelligence models and interpreting the outputs from machine learning models.
Data sharing, re-use and distribution	Utilizing data supplied by Mitera and ETH for knowledge extraction and developing artificial intelligence models.
Archiving and preservation (including storage and backup)	
Data storage (including backup)	Storage and backups of the relevant materials: First level of storage and backup locally in Mitera's server. Second level of storage in cloud server with security mechanisms. A third level of storage and accessibility will be the members section in the VOCORDER website (Private documents).

In addition to the above table, the following table also provided adequate information regarding the data sets for WP4.

Are you generating the data or sourcing it from somewhere else under certain terms and conditions? We source the data from our partner, Mitera, under specific terms and conditions.
Is the data digital or non-digital, or both? At the stage of WP4, the data exists in a digital format.
How will the data be created or collected? What instruments or tools will be used to produce the data? In WP 4, there will be no creation of new data; instead, data from other work packages will be utilized as input.
What transformations will the data undergo? What software or file formats will you use as you work with the data? The data will undergo various transformations such as cleaning, normalization, and analysis to prepare it for further use. During these processes, we might employ software like Python 3.9 for scripting and data manipulation, SPSS for statistical analysis, and Excel for data organization and preliminary analysis. The data will be stored and handled in file formats such as CSV, JSON, or Excel spreadsheets, depending on the requirements of the specific analysis or phase of the project.
Will the data be updated or become redundant as you make revisions and produce subsequent versions? • Physical data (gasses) will not become redundant after the initial analysis. They will be possible to be processed in phases. • Digital data: During processing, new versions of the original files will be created, always maintaining the integrity and respect for the original data.
Is the data sensitive or confidential? The data are sensitive and confidential, but we will be using anonymized versions, which will be designated as confidential within the involved partnership.
Is there ethics approval, or is ethics approval required? Ethics approval is required and has been arranged by Mitera.

5.1.5 WP5

WORK PACKAGE: **WP5** Primary integration of components and laboratory testing TASKS **T5.1** – Integration of optoelectronics components, electronics & software (ARGOS)

T5.2 - Integration with cloud-based data analytics (AIDEAS) **T5.3** - Laboratory environment device testing and validation against gold standard (EMPA)	
Data Identification	
Dataset description	Result of research activities: testing of specifications, integration testing,
Source	Laboratory experiments
Partners activities and responsibilities	
Partner owner dataset	ARGOS, AIDEAS, EMPA
Partner in charge of data collection	ARGOS, AIDEAS, EMPA (WP-task leaders)
Partner in charge of data analysis	ARGOS, AIDEAS, EMPA
Partner in charge of data storage	MITERA (through SharePoint)
Standards	
Info about metadata	TBD
Standards, Format	Excel (.xlsx), (*.pdf), (*.pptx)
Data exploitation and sharing	
Data exploitation	Data used to validate the successful development of individual modules and successful integration of modules into VOCORDER device prototype. Data will be used as input for Deliverables D5.1 and D5.2.
Data sharing, re-use and distribution	Data shared with all WP2 partners
Archiving and preservation (including storage and backup)	

Data storage (including backup)	Data stored on MITERA's SharePoint and on partners' internal server.

Are you generating the data or sourcing it from somewhere else under certain terms and conditions? Data will be generated by individual partners by laboratory experiments.
Is the data digital or non-digital, or both? Digital
How will the data be created or collected? What instruments or tools will be used to produce the data? Data will be created by laboratory equipment (such as oscilloscope, spectral analysers, power meters, IR-camera)
What transformations will the data undergo? What software or file formats will you use as you work with the data? Data gathered will be evaluated and documented in Office-documents and then used in Deliverable D5.1 and D5.2 (Word + pdf formats)
Will the data be updated or become redundant as you make revisions and produce subsequent versions? Yes (the documents will be updated as long as the partners work on it).
Is the data sensitive or confidential? Confidential
Is there ethics approval, or is ethics approval required? No

5.1.6 WP6

WORK PACKAGE: **WP6** High-level integration, demonstration and validation (MITERA) **WP6** data sets will be further defined and amended later in to the project

5.1.7 WP7

WORK PACKAGE: **WP7** Communication, Dissemination, Training and Exploitation of the results (NEURALTECH) TASKS **T7.1** – Dissemination plan & high impact collateral (NEURALTECH) **T7.2** - Business models and exploitation plans (NEURALTECH) **T7.3** - IPR management and patenting (VUB)	
Data Identification	
Dataset description	Data generated will be digital for Website, Innovation Management Strategy, Plans for Exploitation and Dissemination of results, DMP Questionnaire, Deliverables and Publications (hard copies may also be sent for journal & conference publications), and hard copies in the case of VOCORDER leaflet and poster.
Source	Data generated during project duration, data from other deliverables, data collected form partners, research data generated, data taken also form the GA
Partners activities and responsibilities	
Partner owner dataset	According to the ownership model
Partner in charge of data collection	NEURALTECH – METIS -VUB
Partner in charge of data analysis	NEURALTECH – METIS -VUB
Partner in charge of data storage	MITERA (through SharePoint)
Standards	
Info about metadata	TBD
Standards, Format	Format of data generated will be .xls, .ppt, .pdf, .doc and .cdr files and emails.
Data exploitation and sharing	
Data exploitation	Data used to disseminate, communicate and exploit VOCORDER's results
Data sharing, re-use and distribution	Data shared with all partners.

	Publications, posters or leaflets for dissemination and communication activities based on dissemination rules.
Archiving and preservation (including storage and backup)	
Data storage (including backup)	Data stored on MITERA's SharePoint and on partners' internal server.

Are you generating the data or sourcing it from somewhere else under certain terms and conditions? Data will be generated by individual partners
Is the data digital or non-digital, or both? Both
How will the data be created or collected? What instruments or tools will be used to produce the data? Data will be created by individual partners and will be collected through emails
What transformations will the data undergo? What software or file formats will you use as you work with the data? Word + pdf formats
Will the data be updated or become redundant as you make revisions and produce subsequent versions? Yes (the documents will be updated as long as the partners work on it).
Is the data sensitive or confidential? Confidential
Is there ethics approval, or is ethics approval required? No

5.1.8 WP8

WORK PACKAGE: **WP8** Portfolio Activities (MITERA) **WP8** data sets will be further defined and amended later in to the project

5.1.9 WP9

WORK PACKAGE: **WP9** Ethics requirements (MITERA)
WP9 data sets will be further defined and amended later in to the project

REFERENCES

[i] "Guidelines on FAIR Data Management in Horizon 2020"- European Commission, 2016

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

[iii] Office of Management and Budget (OMB), Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organisations, CIRCULAR A-110 REVISED 11/19/93 As Further Amended 9/30/99**,** https://www.whitehouse.gov/omb/circulars_a110#36