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Data management plan - 2

Work Package 6

Project management and coordination

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1 INTRODUCTION

This document is the second version of the Data Management Plan (DMP) of OrChESTRA, created for the half way of the project (month 18). It outlines what datasets the project generates and compiles, how the research data collected or generated within OrChESTRA are handled and describes the data management life cycle for the data collected, processed, generated, and made available. It also describes measures that have been taken to safeguard and protect sensitive data and emphasizes that the produced results must be easily located and accessible.

As part of making research data findable, accessible, interoperable, and re-usable (FAIR), the DMP defines the methodologies and standards to be applied to data and includes information on:

- what data will be collected, processed and/or generated;
- which methodology & standards will be applied;
- whether data will be shared/made open access; and
- how data will be curated & preserved (including after the end of the project).

This document will be reviewed and updated over the course of the project whenever significant changes arise, such as (but not limited to):

- new data being gathered;
- generation of periodic reports;
- development of final report;
- changes in consortium policies;
- changes in consortium composition and external factors (e.g. new consortium members joining or old members leaving).

2 ORCHESTRA PROJECT

The OrChESTRA Twinning Action, funded under Horizon Europe Programme, aims to promote new opportunities for ODTÜ MEMS, TU/e, IMEC and UFR via development of productive and sustainable links among them for higher levels of excellence in the field of organ-on-a-chip platforms, with a major focus on enhancing the range of competences of the coordinator, ODTÜ MEMS.

The main scope of OrChESTRA is to create a collaborative framework around ODTÜ MEMS in the field of organ-on-a-chip platforms via sharing specialised knowledge, outlining a common roadmap for future collaborations, brainstorming for new research avenues and elaborating business-oriented research and technology development activities. A number of activities are proposed which include mainly best practice sharing, mentoring, training, networking, and public outreach and awareness activities as well as a common research component. In scope of research component of OrChESTRA, it is aimed to develop a novel organ-on-a-chip platform integrated with sensors for in situ and real-time measurements of biophysical and biochemical parameters in response to stimuli such as drugs.

Thus, the project activities are designed to ensure sustainability, evolution, and continuation of the activities including the cooperation among the partners well beyond the 3-year funding period.

3 DATA SUMMARY

OrChESTRA is a Coordination and Support Action (CSA), in scope of which the purposes of data collection and/or generation are focused on administration and organisation of the project activities. As a twinning action, OrChESTRA will follow a series of well-formulated and interlinked coordination and support measures like strategic planning, mobility, training, organising summer/winter schools and other events, best practice sharing, communication, and networking in order to attain expected impacts at institutional, consortium, national and European level. In addition, a research component (Work Package 3 – WP3) is involved in this twinning project in order to strengthen the commitment and the engagement of the twinning partners, bringing new opportunities for integrating smaller research activities.

At this stage in OrChESTRA, three main data types have been collected and/or generated within the context of the project activities:

- **Project management data** – data about the project partners, data generated during the consortium meetings, reporting data related to project management.
- **Project activities data** – data that originates from the project's activities, which mainly include best practice sharing, benchmarking activities, mobility, mentoring, training, communication, networking, and public outreach and awareness activities.
- **Research data** – the scientific results and outcomes of the research component (WP3 which aims to develop a novel organ-on-a-chip platform integrated with sensors) and other joint research activities initiated in scope of the project.

3.1 Project management data

Project management data involves data provided by the project partners with the purpose of monitoring the progress of the project implementation and preparing project progress reports. ODTÜ MEMS, as the coordinator, is the main responsible from collection, analysis and storage of the project management data generated under the relevant tasks of WP6 Project management and coordination.

The datasets generated under project management data are as follows:

- Data about the project partners: Contact names and info, mailing lists, address, bank account etc.
- Data generated during the consortium meetings: Data generated during the kick-of-meeting, periodic consortium meetings and other internal meetings organised as needed.
- Reporting data related to project administrative/financial management: Data on usage/reallocation of budget resources, progress of project activities against relevant tasks, milestones and deliverables, data on actual performance against project objectives and KPIs.

Formats to be used: These data are collected in various forms (e.g. electronic documents, pen and paper, photos, videos) in MS Office format (docx, xlsx, pptx), Adobe Portable Document format (.pdf), as well as images (svg, png, jpg), videos (mp4) etc. formats.

Data storage and sharing: The datasets used in the project management and all relevant reporting data and documents are shared electronically by the project partners and stored in the dedicated project files under

the project's "OrChESTRA-Shared" Dropbox folder. These datasets will be stored for a 5-year period after the end of the project.

Exploitation / data access policy: The project management datasets are maintained to support the administration activities, and therefore they are unlikely to be needed to be made available for any wider use. All data collected from the project partners will be kept confidential. The dissemination level of the "D6.1 Progress report" and project governance plans (i.e. "D6.2 Quality management plan", and "D6.3 Risk and contingency plan") are defined as sensitive.

3.2 Project activities data

Project activities data involves data that originates from the project's activities, which mainly include best practice sharing, benchmarking activities, mobility, mentoring, training, communication, networking, and public outreach events and awareness activities as well as data collected from and/or about people involved in OrChESTRA project activities. The responsible task leaders under WP1, WP2, WP4 and WP5 as well as ODTÜ MEMS are in charge of collection of the data. All partners are involved in data analysis, and ODTÜ MEMS, as the coordinator, is responsible from the storage of the project activities data.

The datasets identified under project activities data are as follows:

- Training/meeting materials: Materials, presentations and video files that originates from the training sessions, webinars, summer schools, project workshops, meetings with stakeholders etc.
- Data collected for carrying out the project tasks: Datasets collected by the partners for the purposes of carrying out a project task (activities and events) including lists of lecturers/speakers and participants, agendas of the workshops, lists of mentors-mentees, data on the short-term staff exchanges, short-term expert visits, registration data (i.e. name, name of organisation, role in the organisation, and contact data) of the participants attending workshops, meetings and other events, business-related contacts, contact information related to dissemination etc.
- Derived data regarding the project tasks: Datasets created by the partners via processing the output of the project task (activities and events), including guidelines, procedures, reports on participation in international conferences, communication report, results of interviews with the stakeholders, results of surveys etc.

Formats to be used: These data are collected/generated in various forms (e.g. electronic documents, pen and paper, photos, videos) in MS Office format (docx, xlsx, pptx), Adobe Portable Document format (.pdf), as well as images (svg, png, jpg), videos (mp4) etc. formats.

Data storage and sharing: The data sets collected/generated in scope of the project activities are shared electronically by the project partners and stored in the dedicated project files under the project's "OrChESTRA-Shared" dropbox folder. The relevant datasets relating to the project activities will be stored in dedicated databases for a 5-years period after the end of the project. The project deliverables will be submitted to the EC via the Funding & Tenders Portal. The public deliverables will be published under the "Publications" tab on the project website.

Personal data collection is limited to what is needed for the completion of tasks. Any personal data that is collected and which is not necessary for the completion of tasks will be destroyed as soon as task/activity will be completed. Personal data are stored only for as long as necessary to achieve the goals and objectives

of the project, and stored personal data are reviewed by partners annually with a view to determining its ongoing relevance to current and future tasks.

Exploitation / data access policy: These data are used for developing the related public deliverables of the project and for communication and dissemination purpose. The protection and procedures about the use of IPRs are applicable to outputs explicitly resulting from the project twinning activities. The reports and other related deliverables on the twinning activities are public but only include non-sensitive data. Personal data of the project team personnel are for internal use only. Original personal data and information are not shared with third parties without additional permission.

3.3 Research data

Research data of the OrChESTRA project refers to the scientific results and outcomes of the research component (WP3 which aims to develop a novel organ-on-a-chip platform integrated with sensors) and other joint research activities initiated in scope of the project via exchange of scientific knowledge and data. The foreground knowledge/IP expected from the results of WP3 are “electrochemical biosensor”, “organ-on-a-chip device (gut-on-a-chip)” and “whole platform including OoC and the biosensor”.

Formats to be used: Data generated during research activities are primarily electronic, including data tables in various formats (MS Excel file xlsx, GraphPad Prism file pzfx, etc.) and images (tiff, jpg). The raw characterization data (such as FTIR, XPS, Absorbance, etc.) are transferred to Origin 2022, where they are plotted and saved as tiff files. The electrochemical data obtained via Methrohm software Nova 2.1 are stored within the program itself. The selected data are exported to Origin 2022 for further investigation. The electrochemical experiments are conducted using the Autolab PGSTAT 128N device located in the METU MEMS Center BioMEMS laboratory infrastructure. Thanks to the software of the device, the electrochemical data obtained is suitable for analysis and reuse by project personnel and researchers in any format needed (.txt, Excel, etc.). The data and the information driven from these data are reported in research publications in peer-reviewed journals, as well as conference papers/proceedings, websites, social networks and other means as PDF (.pdf) files.

Data storage and sharing: The data sets collected/generated in scope of the WP3 activities are shared electronically by the project partners and stored in the dedicated project files under the project’s “OrChESTRA-Shared” Dropbox folder. The relevant datasets relating to the project activities are stored in dedicated databases for a 5-years period after the end of the project. The project deliverables are submitted to the EC via the Funding & Tenders Portal. The public deliverables are published under the “Publications” tab on the project website. During the production of electrochemical sensors, the MEMS fabrication notes and microscope images obtained during the production steps, as well as chip-die photographs, have been stored using the METU MEMS Center Eflatun infrastructure. All related notes and photographs are backed up by the project personnel (scholar) responsible for the work package to encrypted work computers provided by the METU MEMS Center after the completion of each MEMS production. The notes kept during MEMS productions and images at the chip-die level are saved in ".jpg" and ".tif" file formats using the high-resolution camera and microscope images in the cleanroom. These file formats can be easily viewed using image viewing programs available on each computer. The electrochemical experiments conducted throughout the project were carried out using the Autolab PGSTAT 128N device located in the METU MEMS Center BioMEMS laboratory infrastructure. Each measurement taken was stored on the computer connected to the device in folders named according to the date of the experiment. Additionally, for the purpose of

examining the experiment data obtained at the end of each completed experiment set, the relevant data was backed up by the project scholars on the personal encrypted computers provided by the Center at the MEMS Center. The experiment data obtained is saved as ".NOX" extension files and can be opened and examined using the free software "NOVA" specific to the device. The results of the analyses conducted in the METU Central Laboratory were obtained on CDs and backed up on highly secured computers provided by the METU MEMS Center to the personnel. For the further studies, the data obtained will be stored in the ODTU MEMS Center Eflatun infrastructure, while the produced chips and particles will be stored in the restricted access BioMEMS laboratory.

Exploitation / data access policy: These data are used for developing the related public deliverables of the project and for communication and dissemination purpose. The protection and procedures about the use of IPRs are applicable to outputs explicitly resulting from the project twinning activities. The reports and other related deliverables on the twinning activities are public but only include non-sensitive data. Some of the data already obtained has started to be shared through international publications and conferences. In the future, data from the current period will also be shared in a similar manner through international publications and conferences.

4 FAIR DATA

OrChESTRA follows FAIR principles to promote the accessibility and reusability of the data and processes developed in the project in a manner sensitive to partners' local regulatory and security/privacy needs. This ensures **find-ability, accessibility, interoperability and reusability of data** as per the EU guidelines. FAIR data efforts take into account data privacy requirements. In particular, personal data are kept confidential and processed in accordance with the EU General Data Protection Regulation 2016/679.

4.1 Making data findable, including provisions for metadata

Regarding findability of data/research outputs; the existing cloud server maintained by the consortium are used to store data. Data declassified will be sent to OpenAIRE, thus ensuring public availability and findability.

Research publications and information on the website/social media will be provided with search keywords to optimize reuse possibilities and ensure the availability of OrChESTRA data. Clear version numbers will be added to each document by each consortium organization. Descriptive, structural and administrative metadata will be produced for datasets to make the data findable.

Open access data sources will be discoverable and identifiable using standard identification mechanisms. All partners agreed to provide relevant metadata and keywords so that their data can be easily discovered. Research publications will enclose Digital Object Identifiers (DOI) linked to the associated open data. To maximize access to the data, project activity data will be assigned by the activity number (deliverable), project acronym and number, file content name, date. For open access publications, standard naming conventions will be applied according to the editors of scientific journals.

4.2 Making data accessible

The OrChESTRA twinning action project has been producing strategy planning documents, forecasts, monitoring reports, scientific research reports, conference proceedings, presentations, materials for social networks and other materials that are disseminated via partially open publication. Restricted material

distribution will be confidential through confidentiality agreements with research partners, and where research results could affect a project partner's business plans. Dissemination level of the "D6.1 Progress report", project governance plans (i.e. "D6.2 Quality management plan", and "D6.3 Risk and contingency plan"), "D2.2 Institutional capacity enhancement report" and the deliverables of the research component work package (WP3: D3.1, D3.2 and D3.3) are defined as sensitive, i.e. available only for members of the consortium (incl. the Commission Services). Personal data are secured in accordance with GDPR. The raw data files are stored in consortium member institutions and are accessible to other partners upon request.

OrChESTRA consortium supports open and openly available free access to scientific information. The project partners intend to make the joint scientific publications that result from the OrChESTRA project available for the public as early and widely as possible through commonly agreed formats, but only after the end of the embargo period (after the necessary steps for ensuring the protection of IPRs have been made). Data will be accessible using freely available widely used standard software (e.g. PDF).

Open Access will be provided to peer-reviewed papers published by the consortium partners, either in an open access journal repository ("gold standard" model) or for instance using the OpenAIRE repository. The full text articles will also be accessible in OrChESTRA web-page, journals web-page and related sites to enable making the data accessible for other researchers and public. In this regard, the Management Committee will identify how the non-restricted data and the deliverables other than having an "sensitive" dissemination level can be made available for Open Access sharing and Preprint Servers. The specific journal or conference will be selected based on the suitability of the topic and the expected target audience, considering maximisation of the potential exploitation impact. Open access platforms such as Open Research Europe (ORE), European Open Science Cloud, Projekt DEAL, as well as preprint servers such as bioRxiv, ChemRxiv and medRxiv will be considered.

Accessibility of research outputs will be ensured within a period of 1 year from generation of data to ensure IP protection. The internal process has been defined as follows: (1) Every new result is evaluated during the internal progress meetings and classified as potential IP or public. (2) Results classified as public can be released immediately. Results classified as potential IP are kept until the activity progresses. (3) A patent is prepared for data that are considered commercially interesting. If no patent is initiated within a 6-month period of the results then data are re-evaluated with possibility to declassify.

More details on the accessibility of the data will be provided in the next DMP versions. The consortium partners will determine which data will be explicitly made available and which data cannot be shared (or needs to be shared under the restriction). Details of the repository, data access methods and tools will also be included in the future versions of the DMP. The consortium aims to use the project website (https://orchestra-project.eu/) as a repository for public data, facilitating access to anyone interested.

4.3 Making data interoperable

Provisions have also been taken to make open access data produced in the OrChESTRA project interoperable, facilitating the exchangeability and reusability of data across research institutions, organizations, etc. Data are presented in standard formats (e.g. .doc, .xls, .jpg, .pdf) compatible with open software applications to enable unrestricted data exchange between researchers, institutions, organizations, countries, and others. The interdisciplinary interoperability of data will be ensured by a standardized and organized controlled vocabulary for metadata description.

4.4 Making data reusable

The decision on the use and reusability of data by third parties will be made after communication and agreement among the consortium member(s) and the data owner(s), taking into account the intellectual property rights regulations. Background IP will be royalty-free access basis for carrying out the project; fair and non-discriminatory for use. Project results will be owned by the partners that have contributed to their production. Access to knowledge will be royalty-free for execution of the project, except for possible new contractors; preferential or at market conditions for use. Data that are eventually under IP protection will be handled by the consortium and licensed to external users. Open access data will be made available as soon as possible for open access under a CC license, after embargo period of maximum 1 year.

Long-term storage of scientific data throughout the project are provided by the coordinator and consortium members. The project partner institutions will store the data for five years after the end of the OrChESTRA project. Open access publication data will be available for the entire journal and/or repository lifetime. Public content made available through the project website will be downloadable and reusable without any restrictions or embargoes. Data quality is primarily under the responsibility of data creators and is ensured by the project partners via evaluating accuracy, relevance and completeness. All data obtained for WP3 are and will be made available to the consortium members. The characterization results are and will be transferred to Origin 2022. The electrochemical data can also be transferred to .txt or Excel formats, as well as Origin 2022, all of which can be reused upon sharing.

5 ALLOCATION OF RESOURCES

Data collection and storage costs are covered under the budget allocated to the project activities. Peer-reviewed publications costs related to open access to research data are eligible as part of the Horizon Europe grant, therefore will be covered by OrChESTRA project budget. Costs for long-term preservation of open access papers will be covered before publication in a journal. Responsibility for managing the data underlying OrChESTRA activities lies with the partners managing the work packages and the authors of individual research studies or outputs.

Curation and storage/preservation costs: The partners have their own cloud servers that are actively maintained and backed up to ensure data safety. These are used as the main data storage repositories.

6 DATA SECURITY

ODTÜ MEMS as the coordinator of the project is the main responsible for the data management. Nevertheless, the consortium as a whole decides relevant aspects of data management. Data creator(s) are responsible for data quality.

During the implementation of the OrChESTRA project, data are collected in various forms, e.g. electronic documents, pen and paper, photos, videos. These data are stored by each partner for project documentation purposes. For this, the relevant corporate rules and regulations of each partner regarding data storage and security apply. The data of participants in activities are collected by coordinator securing the correspondence to data protection strategy and its ensuring compliance with GDPR requirements. All data are stored and transferred according to applicable national, EU and international legislation for data security regulations.

General procedures for data handling, management and storage are applied. None of the project outcomes will have any dual use. No military activity will be carried out in the project.

Personal contact data collected during the project activities are stored internally. Each partner is responsible for ensuring that those data are stored safely and securely in full compliance with European Union data protection laws. All collected personal data will be deleted from the project's data store five years after the end of the project.

7 ETHICAL ASPECTS

All OrChESTRA activities are carried out in accordance with the national legal and ethical requirements of the countries where it is carried out, namely, Türkiye, the Netherlands, Belgium and Germany. In addition, the consortium confirms that compliance with applicable international and EU law in the implementation of research activities are ensured and the ethical concerns raised by the project activities are handled rigorously following the recommendations provided in the European Commission Ethics Self-Assessment Guidelines. OrChESTRA complies with the Horizon Europe ethical standards and guidelines and the provisions of the General Data Protection Regulation 2016/679 for the collection and processing of personal data in meetings, communication and dissemination activities. Informed consent for data sharing and long-term storage will be included in questionnaires regarding personal data.

8 CONCLUSION

This updated version of the DMP underscores our commitment to the principles set for the OrChESTRA's data management ensuring the sound management of the data produced/used during the project's activities. Moving forward, we remain dedicated to reviewing and refining our data management approaches to support the dynamic needs of our research community and stakeholders. The next release of the Data Management Plan will be delivered at M36.