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Project Officer: Adriana GODEANU METZ

Project Coordinator: Paolo Bergese (CSGI)

D5.2: Data Management Plan (DMP)

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Contributing partners: CSGI, HBM-LS

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Draft	
Final	X

Type		
R	Document, report	X
DEM	Demonstrator, pilot, prototype	
DEC	Websites, patent filling, videos, etc.	
OTHER		

Dissemination Level		
PU	Public	
CO	Confidential, only for members of the consortium (including the Commission Services)	X

Revision History		
Date	***Lead Author(s)***	***Comments***
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11/02/2019	CSGI, HBM-LS	Final version

Essential glossary	
Acronym	***Meaning***
DMP	Data Management Plan

This project has received funding from the European Union's Horizon2020 research and innovation program under grant agreement No. 801367.

The statements made herein do not necessarily have the consent or agreement of the evFOUNDRY consortium.

Table of Contents

1. Data Management Plan in the context of H2020

1.1 Introduction

The European Commission (EC) is running a flexible pilot under Horizon 2020 called the Open Research Data Pilot (ORD pilot). This pilot is part of the Open Access to Scientific Publications and Research Data Program in H2020. The ORD pilot aims to improve and maximize access to and re-use of the research data generated by Horizon 2020 projects and considers the need to balance openness and protection of scientific information, possible commercialization and Intellectual Property Rights (IPR) protection, privacy concerns, security as well as data management and preservation issues. According to the EC suggested guidelines, participating projects are required to develop a Data Management Plan (DMP). The DMP describes the types of data that will be generated or gathered during the project, the standards that will be used to generate and store the data, the ways how the data will be exploited and shared for verification or reuse, and how the data will be preserved. In addition, beneficiaries must ensure that their research data are Findable, Accessible, Interoperable and Reusable (FAIR).

This document provides the plan for managing the data generated and collected during the project. It covers: a) the handling of research data during and after the project, b) what data will be collected, processed or generated, c) what methodology and standards will be applied, d) whether data will be shared/made open and how and e) how data will be curated and preserved.

DMP of project evFOUNDRY will be set according to the article 29.3 of the Grant Agreement “Open Access to Research Data”. Project participants can deposit their data in a research data repository and take measures to make the data available to third parties. The third parties should be able to access, search, exploit, reproduce and disseminate the data. This should also help to validate the results presented in scientific publications. In addition, Article 29.3 suggests that participants will have to provide information, via the repository, about tools and instruments needed for the validation of project outcomes.

On the other hand, Article 29.3 incorporates the obligation of participants to protect results, security and to protect personal data and confidentiality prior to any dissemination. Article 29.3 concludes: “As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data if the achievement of the action's main objective, as described in Annex I, would be jeopardized by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.”

In line with this, the evFOUNDRY consortium will decide what information will be made public after and according to the analysis of aspects as potential conflicts against commercialization, IPR protection of the knowledge generated (by patents or other forms of protection), risk for obtaining the project objectives/outcomes, etc.

1.2 Scope of the document

This document is a deliverable of the evFOUNDRY project, which is funded by the European Union’s.

Horizon 2020 Programme under Grant Agreement number 801367. It describes what data the project will generate, how they will be produced and analysed. It also aims to detail how the data related to the evFOUNDRY project will be disseminated and afterwards shared and preserved. It covers:

I. the handling of research data during and after the project.

II. what data will be collected, processed or generated.

III. what methodology and standards will be applied.

IV. whether data will be shared/made open and how.

V. how data will be curated and preserved.

The DMP is not a fixed document. On the contrary, it will have to evolve during the lifespan of the project. This first version of the DMP includes an overview of the datasets to be produced by the project, and the specific conditions that are attached to them.

An updated version of the DMP will get into more detail and will describe the practical data management procedures implemented by the evFOUNDRY project.

1.3 Dissemination policy

The DMP for evFOUNDRY focuses on the security and robustness of local data storage and backup strategies, and on a plan for this repository-based data sharing, where and when appropriate and is based on the guidelines provided by the EU in the DMP template document.

Effective exploitation of evFOUNDRY research results depends on the proper management of intellectual property. A Consortium Agreement was signed by all the parties in order to inter alia specify the terms and conditions pertaining to ownership, access rights, exploitation of background dissemination of results, in compliance with the Grant Agreement. The Consortium Agreement is based on the DESCA Horizon 2020 Model with the necessary adaptations considering the specific context and the parties involved in the project.

In particular, the Ownership of the results and Access rights are governed by Grant Agreement Article 26.2 and Article 29.1 respectively with all additions and provisions in Consortium Agreement falling under their defined rules.

1.4 Information about the project

The table below provides synthetic information about the evFOUNDRY project.

Name	The Extracellular Vesicle Foundry
Acronym	evFOUNDRY
Project Objectives	Extracellular vesicles (EVs) are natural cell-derived nanoparticles containing bioactive proteins and RNAs, which are newly recognized as the universal agents of intercellular and inter-organismal communication, in both normal and pathological processes. EVs are reshaping our perspective on life sciences, environment and public health. They are under intensive investigation as early disease multi-biomarkers, while EV-based personalized therapeutic agents and vaccines have produced enticing results in early-phase clinical trials. However, EV exploitation is not supported by current manufacturing methods, which are inadequate in terms of purity and reproducibility or yield, time and cost. evFOUNDRY targets a breakthrough technology able to streamline production of high grade, therapeutic EVs from sustainable sources (such as bovine milk and Ascaris parasites cultures), drawing the baseline for future EV bioprocessing, which is necessary for effective EV medical translation

	Major objectives include: (i) to determine the compositional, structural and colloidal properties of EVs that control their interaction with surfaces; (ii) to engineer nanostructured surfaces integrated in microfluidic devices for separation of EV populations that are homogeneous in size and/or membrane properties; (iii) to design an integrated modular-system for the reproducible separation and analysis of these EVs under continuous flow; (iv) to implement a lab-scale prototype for the continuous production of quality compliant immune modulatory EVs.
Keywords	Molecular biology, Biotechnology (non-medical), bioreactors, applied microbiology, Colloid chemistry
Call	H2020-FETOPEN-1-2016-2017
Funding body	European Commission
Grant Agreement No	801367
Members of the consortium	1. CONSORZIO INTERUNIVERSITARIO PER LO SVILUPPO DEI SISTEMI A GRANDE INTERFASE (CSGI) 2. LUNDS UNIVERSITET (ULUND) 3. UNIVERSITY OF SOUTHAMPTON (SOUTHAMPTON) 4. AARHUS UNIVERSITET (AU) 5. UNIVERSITEIT UTRECHT (UU) 6. HANSABIOMED LIFE SCIENCES OU (HBM-LS)
Contact	Daniela Vullo evFOUNDRY@csgi.unifi.it
Contact's affiliation	CSGI
Duration	01.09.2018-31.08.2021

1.5 Data set description

In evFOUNDRY project, **Open Research Data Pilot** applies to two types of data:

- The data, including associated metadata, needed to validate the results presented in scientific publications (underlying data);
- Other data, including associated metadata, to be developed by the project.

Origin of data, the majority of them will from software used for experimental setups and equipment used. The format of the data and associated metadata will be mainly electronic, and will include lab measurements and records, schemes, technical protocols, SOPs, the datasheets and performances of the technological developments of the project, the validation results with the KPIs (Key Performance Indicators) used to evaluate the system performances, meeting presentations, demonstrator videos, pictures from set-upselaborated quality parameters and device design and validation and integration data. However, some primary data records can be also found handwritten as an example when beneficiaries use lab notes in a daily basis. evFOUNDRY project will ensure that all electronic files follow the FAIR policy as explained later.

More in detail, the project partners have identified the dataset that will be produced during different phases of the project. The list is provided below. This list is indicative and will be adapted if needed (addition/removal/modification of datasets) in the next versions of the DMP.

Data set name	Docs
Type of data	Documents
Format	.docx, .doc, .odt, .sxw, .rtf, .xlsx, .xls, .pptx, .ppt, .pdf, .xps, .txt
Source	These data come from: • Protocols elaborated by the partners • Project meetings (minutes, presentations, other supporting documents), exchange of ideas • Group meeting discussions transcribed to Word documents • Device designs and protocol schemes • Literature review; Word documents with search details (databases, strategies, results) and reviews • Computational and table files for underlying data and statistical analysis
Reuse and sharing	The partners share and reuse the Documents.
Archiving and preservation (including storage and backup)	The data will be stored by the partner collecting it (on their own computers and/or institutional servers).

Data set name	Video
Type of data	Video files
Format	.flv, .vob, .ogv, .ogg, .gif, .avi, .mov, .qt, .rm, .rmvb, .mp4, .m4p, .m4v, .mpg, .mp2, .mpeg, .mpe, .mpv, .flv .f4v .f4p .f4a .f4b
Source	These data come from:
Reuse and sharing	All partners have access to the video on demand. The files are used in publications and presented at meetings, as row data support validation and patent applications
Archiving and preservation (including storage and backup)	The data will be stored by the partner collecting it (on their own computers and/or institutional servers).

Data set name	Image
Type of data	Digital images
Format	.tif, .tiff, .gif, .jpeg, jpg, .jif, .jfif, .jp2, .jpx, .j2k, .j2c, .fpx, .pcd, .png, .pdf, .mvd, .psd, .bmp,
Source	These data come from: •
Reuse and sharing	Accessible to all the partners, shared at meetings, shared by email on request

Archiving and preservation (including storage and backup)	The data will be stored by the partner collecting it (on their own computers and/or institutional servers).

Every partner is responsible for the data he is collecting. The data will be collected, combined, stored and transmitted according to the relevant national, European and institutional regulations.

Expected **size of data** generated will be reasonable according to the normal practices of the beneficiaries' research well served by existent infrastructure for data management and storage. We do not expect to deal with large files.

2. FAIR data

2. 1. Making data findable, including provisions for metadata

The data will be standardized and, when possible, open standards will be adopted.

Partners agree on the following: project data are stored in a specific folder on local computers. The Content Management System (CMS) allows data to be stored in the restricted area of the evFOUNDRY website (http://www.evFOUNDRY.eu) accessible by login and password by each partner.

Whenever a set of data, a protocol or a project result is generated, an associated metadata/report will be made containing a set of information useful to make the associated data FAIR prior to data deposition and storage.

This will include:

Operator names; Report date; Report Main author; Report Number; Experiment dates; Type of experiment(s); Purpose of the experiment; Conclusions; Raw data storage (PC and Folder); Keywords.

Created metadata will include:

- **Experiment information** (project description, funding source, reference IDs etc),
- **Study design** (type of data, experimental design e.g. number and description of samples)
- **Methods** (SOPs, platforms, instrumentation details etc),
- **Data processing details** (methods for data processing, standardization method – open standards will be adopted when possible, incl. software, databases, methods for data analysis and annotations etc).

2.2. Making data openly accessible

Data will be made "as open as possible, as closed as necessary". Generated datasets will be primarily used by the Consortium to address the evFOUNDRY project objectives. After publication and prior filling for IP protection, the data (metadata) will be shared with community via public repositories, project web-site, publications etc. Final decisions on specific identification of closed data, or data subject to specific embargo related to IP policies will be taken in the updated DMP. Related access policies will be defined at due time.

The data, both row and metadata (as no ethical and privacy concerns exist) will be deposited in the public repositories such as Exocarta (for Proteomics/Proteins), NCBI (for transcriptomes).

2.3. Making data interoperable

Efforts will be made to make the data interoperable, allowing further data exchange and re-use. Well-established analytical pipelines will adhere to standard formats. In case of the incompatibility of the generated data with the available (open) software, the data will be converted to standard formats. Standard vocabularies will be used for data annotation. For example, the identified proteins will be assigned with e.g. Uniprot Accession, Uniprot ID (http://www.uniprot.org/), Gene Symbol (HGNC, http://www.genenames.org/); transcriptomics data are assigned with Probe Set ID (https://www.affymetrix.com);

2.4. Increase data re-use (through clarifying licences)

Licensing policies will be defined later when the general dissemination, IP protection and exploitation policies are more clearly drawn. Typically, a 6-12 months embargo after acceptance of relevant publications can be considered. Data will be made available and reusable through open data repositories for periods of 10 years.

3. Allocation of resources

Implementation of FAIR principles does not imply any additional costs to beneficiaries as all internal data management system is already established in loco. As for pursuing the open access to research data policy, the costs allocated to granting this are eligible and included in the project money as foreseen Horizon 2020 rules.

4. Data security

Internal data management system at beneficiary's sites are covered by existing infrastructure. All partners are equipped by IT systems adequate for the size of data generated (not big data) and pursue data backup regimens, granting reliability and quality. The project PIs will be responsible for the data management related aspects including data-wise management, data security and quality assurance. The efforts will be coordinated by the project coordinator.

5. Ethical aspects. The objectives and plan of evFOUNDRY project does not include any relevant Ethical aspects related to data use.

6. Other issues. DMP is compliant with all requirements of HORIZON2020, and is relying on well established procedures for data management established in partner institutions