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Project Acronym: BOW
Project Full Title: Biogenic Organotropic Wetsuits
Start date of the project: November 1st, 2020
Duration: 48 months
Project Coordinator: Paolo Bergese (CSGI)
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D5.2: Data Management Plan (DMP)

DELIVERABLE INFORMATION	
Deliverable N°	5.2
Deliverable Title	Data Management Plan
WP N°	WP5
Lead beneficiary	CSGI
Contributing partners	HBM, CNR
Type	Public deliverable
Due Submission Date:	30/04/2021
Actual Submission Date:	30/04/2021

TYPE		
R	Document, report, ORDP	☒
DEM	Demonstrator, pilot, prototype	☐
DEC	Websites, patent filing, videos, etc.	☐
OTHER		☐

DISSEMINATION LEVEL		
PU	Public	☒
PP	Restricted to other programme participants (including the Commission Services)	☐
RE	Restricted to a group specified by the consortium (including the Commission Services)	☐
CO	Confidential, only for members of the consortium (including the Commission Services)	☐

STATUS	
DRAFT	
FINAL	X

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REVISION HISTORY		
Date	**Authors and Contributors**	**Comments**
2021/04/12	Natasa Zarovni (HBM)	Draft version_v00
2021/04/15	Paolo Bergese (CSGI)	Draft version_v01
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2021/04/28	Paolo Bergese, Simonetta Tegliai, Patrizia Zitelli (CSGI), Antonella Bongiovanni (CNR)	Draft version_v03
2021/04/30	Paolo Bergese, Simonetta Tegliai, Andrea Zendrini, Patrizia Zitelli (CSGI)	FINAL VERSION

GLOSSARY OF TERMS	
TERM	**DEFINITION**
DMP	Data Management Plan
EVs	Extracellular vesicle
FAIR	Findable, Accessible, Interoperable, and Reusable
IPR	Intellectual Property Rights
KPIs	Key Performance Indicators
MBDs	Magnetic Bead Devices
ORD pilot	Open Research Data Pilot

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

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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 the BOW project will be set according to 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 before 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 BOW 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), the risk for obtaining the project objectives/outcomes, etc.

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1.2 Scope of the document

This document is a deliverable of the BOW project, which is funded by the European Union's Horizon 2020 Programme under Grant Agreement number 952183. It describes what data the project will generate, and how they will be produced and analysed. It also aims to detail how the data related to the BOW project will be disseminated and afterward 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 BOW project.

1.3 Dissemination policy

The DMP for BOW 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 BOW research results depends on the proper management of the intellectual property. A Consortium Agreement was signed by all the parties to *inter alia* specify the terms and conditions about 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 and Article 31 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 BOW project.

Name	**Biogenic Organotropic Wetsuits**
Acronym	**BOW**
Project Objectives	Extracellular vesicle (EVs) nanoparticles are the universal agents of intercellular and inter-organismal communication "made by cells for cells" to shuttle lipids, proteins, and nucleic acids. EVs mediate physiological processes and help to spread various diseases, including cancer and infections. Their innate navigation performances take origin in the unique structure and composition of their membrane (which is to date

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	inaccessible to synthetic mimics). The main goal of the BOW project is to explore and consolidate the technology able to impart biological surface precision, circulation, and targeting abilities of EVs to superparamagnetic nanodevices (Magnetic Bead Devices, MBDs) by "dressing" them with a single- or multi-layer "wetsuit" of EV membrane "fabric". This will prove and set a general, viable paradigm to recapitulate key biomimetic functions – including camouflage to the immune system and organ site/tumor-targeting – to any synthetic nanodevice while being disruptive as a first example of biogenic nanotechnology. If successful, such a non-incremental technology will promote the progress of implantable nanodevices and nanomaterials towards sustainable production and clinical translation, contributing to strengthen and keep in the lead position European biotechnology and impacting life quality for people. Major objectives include: (i) production of high-grade EVs with biomimetic and organotropic functions, (ii) synthesis and functionalization of MBDs, (iii) engineering a microfluidic device for streamlined fabrication of EV membrane coated MBDs (evMBDs) (iv) evaluation of evMBD biological performances and nanotoxicity in-vitro, ex-vivo and in-vivo.
Keywords	Biomaterials (as related to medical implants, devices, sensors), Biological Sciences, Nano-technology, Extracellular Vesicles, Magnetic Nanoparticles, Microfluidics, Organotropicity, Nanotoxicity, Biological Surface Science
Call	H2020-EIC-FETPROACT-2019
Funding body	European Commission
Grant Agreement No	**952183**
Members of the consortium	1. CSGI - Consorzio Interuniversitario per lo Sviluppo dei Sistemi a Grande Interfase (Italy) 2. CNR - Consiglio Nazionale delle Ricerche (Italy) 3. USC - University of Santiago of Compostela (Spain) 4. MPG - Max Planck Institute for Polymer Research (Germany) 5. ZAB - Zabala Innovation Consulting, S.A. (Spain) 6. HMGU - Helmoltz Zentrum Munchen (Germany) 7. ITS - Institute of Technology Sligo (Ireland) 8. ETHZ - Eidgenoessische Technische Hochschule Zuerich (Switzerland) 9. HBM - HansaBioMed Life Sciences, Ltd (Estonia) 10. BIO - Biodevice Systems (Czechia) 11. RR - Rigenerand S.r.l. (Italy)
Contact	Simonetta Tegliai & Patrizia Zitelli: bow@csgi.unifi.it Tel. +39 055457.3036 / 055457.3244
Contact's affiliation	CSGI - Consorzio Interuniversitario per lo Sviluppo dei Sistemi a Grande Interfase - Via della Lastruccia 3 - 50019 Sesto Fiorentino FI - Italy
Duration	01/11/2020-31/10/2024

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1.5 Data set description

In the BOW 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, most of them will come 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-up and elaborated quality parameters and device design and validation and integration data. However, some primary data records can also be found handwritten as an example when beneficiaries use lab notes daily. BOW 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 the 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: ● Experiments ● Protocols elaborated by the partners ● Project meetings (minutes, presentations, other supporting documents), exchange of ideas ● WP 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, and possibly share them with third parties in compliance with the Consortium Agreement
Archiving and preservation (including storage and backup)	The data will be stored by the partner collecting it (on their computers and/or institutional servers).

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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: • Experiments • Project meetings (minutes, presentations, other supporting documents), exchange of ideas • WP meeting discussions
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. Videos can be possibly shared with third parties in compliance with the Consortium Agreement
Archiving and preservation (including storage and backup)	The data will be stored by the partner collecting it (on their computers and/or institutional servers).

Dataset 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: • Experiments • Project meetings (minutes, presentations, other supporting documents), exchange of ideas • WP meeting discussions
Reuse and sharing	The partners share and reuse the Documents, and possibly share them with third parties in compliance with the Consortium Agreement.
Archiving and preservation (including storage and backup)	The data will be stored by the partner collecting it (on their computers and/or institutional servers).

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Every partner is responsible for the data he is collecting. The data will be collected, combined, stored, and transmitted according to this document while complying with the Consortium Agreement and the relevant national, European, and institutional regulations.

The expected **size of data** generated will be reasonable according to the normal practices of the beneficiaries' research well served by existing infrastructure for data management and storage.

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 Google Drive BOW Project.

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 before 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 BOW project objectives. After publication and prior filling for IP protection, the data (metadata) will be shared with the community via publications (primarily), public repositories - such as Exocarta (for proteomics) or NCBI (for transcriptomes), 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.

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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 licenses)

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 systems are 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 systems at beneficiary's sites are covered by existing infrastructure. All partners are equipped with 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.

BOW consortium will evaluate the toxicity and bioactive potential of EVs, MBDs, and evMBDs by *in vitro*, *ex vivo,* and *in vivo* tests. This will raise ethical issues regarding the use of human cells and animal models. We will address these issues always adhering to the highest ethical standards and complying with the applicable international, EU, and national law (in particular, EU Directive 2004/23/EC), according to Art. 5.1 of the Grant Agreement.

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.

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