



# Extracellular vesicles from a natural source for tailor-made nanomaterials

VES4US

## [D6.4] Data Management Plan

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DISSEMINATION LEVEL		
PU	Public	<input checked="" type="checkbox"/>
PP	Restricted to other programme participants (including the Commission Services)	<input type="checkbox"/>
RE	Restricted to a group specified by the consortium (including the Commission Services)	<input type="checkbox"/>
CO	Confidential, only for members of the consortium (including the Commission Services)	<input type="checkbox"/>



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## 1. INTRODUCTION

VES4US aims at developing a radically new platform for the efficient production and functionalisation of Extracellular Vesicles (EVs) obtained from a renewable source, which will enable their exploitation as tailor-made products in the fields of nanomedicine, cosmetics and nutraceuticals.

The main aim of Work Package 6 (WP-6) as part of VES4US is to consider core management and good research practice aspects to deliver high quality outcomes, to ensure their adequate dissemination and to guarantee cross-fertilisation of ideas and skills via integrated training actions at all levels of the consortium structure.

The present report constitutes the VES4US Data Management Plan (DMP - deliverable 6.4). VES4US acknowledges the importance of good research data management to ensure that outputs are findable, accessible, interoperable and reusable (FAIR). This Data Management Plan (DMP) will be hence compiled, over the duration of the project, on a structure recommended by the Digital Curation Centre (DCR) as detailed on the EU OpenAIRE online platform. This document details at the time of its submission (month 06) the framework to be considered amongst the consortium members within VES4US for a range of activities related to data acquisition, storage, sharing and dissemination. Efforts will be made to make the data available to the broader research community, stakeholders and policy makers. The options for publication of peer-reviewed articles will also be carefully considered in the context Green and Gold publication routes and the use of Open Access Data Repositories.

## 2. DATA SUMMARY

**What data will be collected or created ?** Quantitative and qualitative datasets, protocols and different purified EV fractions samples will be obtained via Ves4US. Efforts will be made to process the data generated from multiple instrumentation platforms and sources so that data sharing and long-term access is enabled. A harmonised structure for data collection and a common lab notebook format will be agreed upon between the partners. The consistency and quality of the data collected will be revised periodically. Data with long-term value will be identified on an on-going basis and steps taken with respect to making them accessible.

**How will the data be collected or created ?** Various scientific methods, protocols and instruments will be used in VES4US. Many will be based on well-established approaches which are detailed in the scientific literature and are already part of in-house procedures used in the laboratory of the Principal Investigators (PIs) within the consortium. Some experiments will use commercially available kits which are batch numbered and manufactured with Quality Control checks. New frontier research will also be carried out in VES4US, for which protocols have not been developed, and could be considered further for potential licencing. A harmonised structure for data storing (file naming, folder structure) has been agreed between the PIs and shared templates for generated data sets are being finalised. Time will be made for reviewing periodically the consistency and quality of the data collected (review of data or representation, adequacy of calibration, measurement repeatability), which will be documented by the PIs, Task Leaders and Work Package Leaders within VES4US.

**To whom might it be useful ?** The data generated throughout the project will be used by the consortium members and may be of interest to the European Commission services and European Agencies, EU National Bodies, the specialist niche and broader scientific community as well as the general public. The data produced



as part of VES4US will also be of use to a variety of industrial actors affiliated to the therapeutic medicine, cosmetic, nutraceutical and instrumentation manufacturing sectors.

### 3. DOCUMENTATION AND METADATA

**What documentation and metadata will accompany the data ?** Rigorous data documentation will be carried out so as to prevent misuse, misinterpretation or confusion by secondary users and to facilitate understanding and reusing data. This will include basic details such as:

- who created or contributed to the data,
- data set title,
- date of creation
- conditions under which specific data can be accessed,
- Details on the methodology used,
- analytical and procedural information,
- definitions of variables,
- units of measurement,
- assumptions made,
- format and file type of the data,
- data published or not (if so, link to be added)

The information will be captured at the end of planned experiments and recorded and stored by the PIs, Task Leaders and/or Work Package Leaders. Metadata files will be created as 'readme' text file to help secondary users with data localisation and description. The use of metadata standards will be considered based on the quality of the results; the catalogue of disciplinary metadata standards maintained by the internationally-recognised centre of expertise Digital Curation Centre (DCC) will be considered to this effect.

The assignment and management of persistent identifiers (PIDs) to the data will be assessed in the course of the project. A naming convention has been agreed upon for metadata, datasets and templates and could consist of three parts separated by an underscore: 1) a prefix indicating whether the file is a dataset, metadata or a template, 2) a root composed of a short description of the file content and name of file provider and 3) a suffix indicating the date of the last updated version. An example could look like the following : VES4US\_dataset\_EVdistribution\_CNR\_Palermo\_ABed140219.

**Where will the data/metadata be located ?** Until a data repository centre is chosen, all key files pertaining to data sets or publication material will be stored in dedicated folders on the Google Drive account shared by the VES4US consortium. Selected information will also be made publicly available on the VES4US website.

### 4. ETHICS AND LEGAL COMPLIANCE

**How will ethical issues be managed ?** Consent or anonymisation will not be needed as no human personal data will be used or generated. The use of human cell lines is standard practice in many research and 3<sup>rd</sup> level institutions. Moreover, the use of an invertebrate model as *C. elegans* has few ethical concerns for the public and is highly supported by the E.U. (Resolution on the protection of animals used for scientific purposes,

5/05/2009). The foreseen experiments on human cells and animals (mice and rats) will be carried out according to the appropriate ethical requirements, as detailed in part B (chapter 5) of the Grant agreement. As described in the same section, all related documentation (including copies of authorisations for the supply of animals and the animal experiments and copies of training certificates/personnel licences of the staff involved in animal experiments) are stored and will be provided upon request.

**How will copyright and Intellectual Property Rights issues be managed ?** No specific plan for licensing the data is anticipated as of now; this will be further explored as part of the exploitation plan of VES4US (D.7.3 and D.7.7). This might be revised depending on the results generated and discussions amongst the VES4US consortium members. To that end, specific data sharing might be postponed or partially restricted to protect proprietary information should licensing or the filing of patents be considered.

## 5. STORAGE AND BACK UP

**How will the data be stored and backed up during the research ?** Electronic files will be stored on computers, external storage devices and hard drives but, most importantly, also placed on shared drives within the host institution networks, which are automatically backed up periodically and reviewed by IT services staff. Specifically, a backup of the Google Drive shared files is periodically (once a week) created on an external hard drive by the VES4US coordinator. Hard copies of key data will also be kept within laboratory log-books. Relevant files suitable for sharing will also be made available via access on the Google Drive specifically set up for the project.

**How will access and security be managed ?** No sensitive confidential data in terms of personal information is associated with VES4US; data privacy risk is therefore not a key issue. Basic security management will be adhered to via the use of password-protected computers and instruments in restricted access rooms. Key data files and folders will also be password-protected on a case-by-case basis. Sensitive data will be identified by PIs, Task Leaders and/or Work Package Leaders and placed in a dedicated folder on the shared Google Drive prior to considering their suitability for patenting or publishing.

## 6. SELECTION AND PRESERVATION

**Which data are of long-term value and should be retained, shared, and/or preserved ?** No data are anticipated to be subjected to destruction for contractual, legal or regulatory purposes. Key data generated through the Work Packages will be selected for long-term retention. This will be informed by the data deemed suitable for publication or which would be needed as foundation or validation work for future spin-off experiments. It is anticipated that data/protocols could be translated and re-used as part of some of the teaching programmes in place in some of the partner institutions within VES4US. All staff members involved in VES4US will be required to prepare data and other files for sharing and preservation for facilitating data access by secondary users.

**What is the long-term preservation plan for the dataset ?** Some of the data will be preserved beyond the period of funding. For example, some strains might be deposited in international culture collections or biomass/extracts kept in freezers for future validation by third parties. Key data will be deposited for long-

term storage in repository centres so that a 'persistent identifier' is associated with the data for easy discoverability; the search for the most relevant centres will be investigated during the project (eg. Zenodo) using specific online tools (eg. Re3data). Some are free or have reasonable rates, the expenses for which would be covered by the VES4US budget.

## 7. DATA SHARING

**How will the data be shared ?** Potential data users will be informed about the type of data available and their location upon dissemination (peer-reviewed publications, international conferences, national symposia) and outreach activities (workshop, secondary school visits, social media platforms). This information will also be present on the relevant VES4US webpages as well as the final theses of the postgraduate students recruited, which will be made available via inter university library loans. As per general practice, published data will be made available within 6 months of publication and 'green-gold routes' given consideration. This specific aspect will be discussed in more depth during Steering Committee meetings. Open Access peer reviewed manuscripts and data sets will also be uploaded onto scientific networking platforms (*e.g.* ResearchGate) for sharing. Requests for access to data will be handled directly during the lifetime of the project. Thereafter, selected data files will be accessible via specific repositories (yet to be decided upon). Conditions (eg. acknowledging the reuse of the data) will be made onto potential users depending on the type, size, complexity and sensitivity of the data sought. Specific data sharing might also be postponed or partially restricted to protect proprietary information should licensing or the filing of patents be considered.

## 8. RESPONSIBILITIES AND RESOURCES

**Who will be responsible for data management ?** The implementation of the DMP (data capture, metadata production, data quality, storage and backup, data archiving and data sharing) will be the responsibility of the VES4US steering committee, which will periodically review progress. All contributors to the Tasks, Milestones and Deliverables of VES4US will help compiling data sets and outputs and specifying the level of sharing associated with such activities.

**What resources will be required to deliver the Data Management Plan ?** Scrutiny into the level of resources to commit towards the full implementation of the DMP in VES4US will be reviewed during year-2 of the project, especially when a suitable data repository centre has been identified.

## 9. CONCLUSION

VES4US is committed towards the training of a highly qualified workforce to meet the future needs of the European society and to develop a knowledge-based economy. Adherence to the FAIR principles of data findability, accessibility, interoperability and reusability is seen as essential to sustain the continuum of data generation and interpretation amongst EU-funded projects with finite life-cycles. VES4US will hence make the data, publications and/or outcomes generated throughout its duration (and after its completion) accessible to a variety of relevant end-users such as European Agencies, National Bodies, the specialist niche and broader scientific community as well as the general public and industrial actors.

