Release of the Data Management plan

Deliverable 10.2

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

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Executive summary

This Deliverable provides the UPGRADE Data Management Plan (DMP). This first version of the DMP describes the different data that will be generated during UPGRADE action and describe how they will be preserved and shared during and beyond the project lifespan. The DMP will be revised every year during the project.

This document has been prepared according to the guidelines provided by the H2020 Participant Portal (http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm).

This version of the UPGRADE DMP fulfils the project deliverable D10.2 month 6 by responsible partner FONDAZIONE TELETHON (FTELE).

1 What is the Open Research Data Pilot

The Open Research Data Pilot of the European Commission enables open access and reuse of research data generated by Horizon 2020 projects. There are two main pillars to the Pilot: developing a Data Management Plan (DMP) and providing open access to research data, if possible.

As a Horizon 2020 project participating in the pilot, UPGRADE is going to:

- Develop (and keep up-to-date) a Data Management Plan (DMP)

- Deposit the data in a research data repository

- Ensure that third parties can freely access, mine, exploit, reproduce and disseminate it (where applicable)

- Provide additional information to facilitate the use of the raw data

The ORD Pilot applies to:

1. the data (and metadata) needed to validate results in scientific publications,
2. other curated and/or raw data (and metadata) that is specified within this DMP.

2 Data summary

The purpose of this data collection is to give support to the generation novel AMPs stringently validated in preclinical disease models and enabling knowledge to set the stage for their prompt translation into gene therapy trials for diseases affecting large patient populations. This relates with the main objective of UPGRADE of overcoming the current limitations of gene therapy strategies, improving the safety, efficiency, genome precision and in vivo delivery of advanced medicinal products (AMPs) based on genome editing and targeting technologies.

In the context of this DMP, data are here defined as:

- Mathematical models
- DNA sequences
- Immunofluorescence images

The project UPGRADE includes twelve work packages from which nine of them (WP1 to WP9) will result in relevant information to be shared with academy, research, physicians and private sector. The purpose of the DMP is to support the data management life cycle for all data that will be collected, processed or generated by the UPGRADE project.

Throughout the project, data will be produced and reused to support the development of research and innovation activities focusing on:

- expanding our toolbox of editing technologies and increasing genome editing efficiencies by recruiting and forcing selected DNA repairs pathways (WP1);

- converting two major viral gene transfer platforms into site-specific integrating machineries (WP2);

- developing advanced methodologies to detect any unintended genetic and epigenetic changes induced by the editing technologies (WP3);

- retargeting tropism of viral and non-viral platforms towards selected cell types or tissues (WP4);

- developing strategies to make AMPs immune-stealth (WP5);

- developing strategies for selection, expansion and non-genotoxic engraftment of edited hematopoietic stem cells to broaden application from in situ correction of inherited mutations to one-size-fits-all targeted transgene delivery into a safe genomic harbour (WP6);

b) preventing muscle wasting in aging and disease conditions via targeted gene therapy (WP7);

c) developing genome editing strategies to treat retinal degenerations (WP8);

d) broadening application of liver-directed gene therapies to include pediatric patients and treat hypercholesterolemia (WP9).

3 FAIR data

3.1 Making data findable, including provisions for metadata

In order to ensure UPGRADE data to be findable and traceable, all open data and publications will be deposited in a dedicated Zenodo community (*UPGRADE H2020 Project Community*). Zenodo has been selected as repository platform since it is free and is integrated into reporting lines for research funded by the European Commission via OpenAIRE. More importantly, Zenodo assigns all publicly available uploads a Digital Object Identifier (DOI) to make the upload uniquely citable.

Moreover, a specific section in the restricted area of the project website will be dedicated to the allocation of the data and project material.

FTELE will be responsible for uploading data and other items in ZENODO. Each partner will provide the datasets and publications to be integrated in the ZENODO repository to the project management team. For publications subject to embargo periods (due to the publishers' policies), FTELE will upload them in ZENODO as soon as the embargos are finished.

3.2 Making data openly accessible and interoperable

Data will be openly available in a variety of easily accessible formats, including Post Script (PDF, XPS), Excel (XLSX, CSV), Word (DOC, RTF), Power Point (PPT), image (JPEG, PNG, GIF, TIFF), source code (C, CSS, JavaScript, Java, MATLAB, etc), and database (MS Access, MySql, Oracle, etc.).

3.3 Increase data re-use (through clarifying licences)

Open data availability will occur as soon as possible in UPGRADE while respecting the authors' publication targets.

UPGRADE activities will include filing applications for orphan drug designation for new AMPs for rare diseases, and filing patents covering the innovative technologies and treatment modalities developed by the Consortium. As the new technologies are validated, we expect to engage in collaboration with potential partners for their further development into AMPs and eventual commercialization. Potential avenues will be collaborative research agreements with biotech companies, licensing deals with pharma, and the creation of innovative startup companies. The successful commercialisation of new ideas generated in UPGRADE will result in tangible benefits when utilized, satisfying market/stakeholders needs, and will require careful management that ranges from the original generation of ideas to distribution of the product or service.

The Partners will always work in close coordination with the Innovation Management Committee (IMC) for the timely assessment of patentability and exploitation opportunities: as Foreground IP is created, the IMC will facilitate the assessment of its potential commercial value, its protection accordingly and any decisions on the route for its exploitation and/or dissemination.

The partners expect the data to have immense value in medium to long term to foster new fundamental research interrogating gene function and regulation also in previously intractable cells and tissues, and to trigger new investments in the biotechnological space aimed at capturing and exploiting their novel R&D potential. The methodology and data products developed in the project are expected to have a large impact in this field, through generalised application at European and other international sites.

Even more importantly, UPGRADE will provide proof-of-principle of several new therapeutic strategies developed and validated in paradigmatic disease models that could be expanded upon suitable adaptation to the treatment of many more disease entities.

4 Allocation of resources

PIs are responsible for data management and the coordinator is responsible for storage and re-use of the data. Quality control of the data is the responsibility of the relevant responsible partner who generates the data. The data will be preserved indefinitely (minimum of 5 years).

The ZENODO repository of UPGRADE results will ensure data availability, backup and versioning. Long term preservation will be guaranteed for the lifetime of the ZENODO repository (https://zenodo.org/policies). This is currently the lifetime of the host laboratory CERN, which currently has an experimental programme defined for the next 20 years at least. After the end of that period, the data will only be kept at the data owners' servers and repositories.

Publications featuring the data will be produced in the project and will be made available through open access (using open access journals or journals selected for a short embargo period).

Long-term archiving in ZENODO and a backup of all UPGRADE data will be guaranteed by the Coordinator, as responsible for the Data Management Plan.