Develop Child and Orphan Device Evaluation support

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Symbols, abbreviations and acronyms

D	Deliverable
DMP	Data management plan
EC	European Commission
M	Month
MS	Milestone
UT	University of Twente
WP	Work Package

Abstract

The DeCODe project aims to catalyse innovation and addressing the unique healthcare needs of people living with a rare disease, with a specific focus on children. The consortium, comprising experts in multiple essential domains, will accellarate the development of innovative solutions by providing tailored support for researchers and developers. This will enhance the quality of care for children living with rare diseases.

In order to execute the project successfully, various data will be collected, analysed, transferred, stored and presented between the partners and society. Therefore, it is important to consider and find an agreement how to handle data throughout the execution, and after the end, of our project. This deliverable describes the DeCODe data management plan (DMP). The DMP is generated using the online tool DMPonline.

It is important to emphasize that the DMP is a dynamic document and will be updated as needed during the project.

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Introduction

Task 1.3 – Data management aims to outline data management needs and create a Data Management Plan for project datasets. The current DMP is generated using the online tool DMPonline. The DMP details data handling, methodologies, standards, and post-project preservation. It may involve engaging with users and stakeholders for data reuse. The document specifies data collection, storage, management, use, and protection requirements. The DMP references and describes datasets, along with partner responsibilities, conditions, and technical measures to ensure data confidentiality, privacy, security, and proprietary rights.

Data management Plan

The DeCODE data management plan can be found on the next pages. The PDF is generated using the online tool DMPonline.

DeCODe data management plan

Data Summary

Will you re-use any existing data and what will you re-use it for?

No

What types and formats of data will the project generate or re-use?

CMV, excel

What is the purpose of the data generation or re-use and its relation to the objectives of the project?

Three types of data are generated:

- information on initiatives and incentives for orphan device development;
- information on experts in orphan device development;
- information on a critical path for orphan device development;
- information on best practices.

These different data types will be useful for orphan device developers of different nature, being academics, SMEs, patient-led initiatives

What is the expected size of the data that you intend to generate or re-use?

1 MB

What is the origin/provenance of the data, either generated or re-used?

The data will come from different sources:

- from discussion with consortium members and external experts via a Delphi;
- via a survey;
- via a (grey) literature search.

To whom might your data be useful ('data utility'), outside your project?

These different data types will be useful for orphan device developers of different nature, being academics, SMEs, patient-led initiatives, to support their development trajectory.

FAIR data

2.1. Making data findable, including provisions for metadata: Will data be identified by a persistent identifier?

All data will be registered with metadata in the institutional repository of the University of Twente

2.1. Making data findable, including provisions for metadata: Will rich metadata be provided to allow discovery? What metadata will be created? What disciplinary or general standards will be followed? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.

For the list of initiatives, the following metadata is used:

- Name
- type of tool
- source
- Location
- Technology relevance
- purpose of tool
- lifecycle stage the tool is most relevant to
- Specificities for orphan and paediatric device developers
- Opportunities and risks associated with the tool
- License associated with using the tool?
- Costs associated with using the tool?
- cost estimates
- reference

For the list of experts, the following metadata is used:

- Name
- stakeholder type
- individual or organisation
- reference
- enrollment
- location
- technology relevance
- rare disease focus
- support that can be provided to the OPD developer
- lifecycle stage the support is most relevant to
- costs associated with engaging with the stakeholder

For the critical path, the following metadata will be used:

- different development steps
- different initiatives used
- different stakeholders consulted
- checklist at every step

For the best practices, the following metadata will be used;

- Best practice example
- location best practice example
- type of best practice example

2.1. Making data findable, including provisions for metadata: Will search keywords be provided in the metadata to optimize the possibility for discovery and then potential re-use?

Yes; as the data will be stored in a database, the above-indicated metadata will be used so that it is possible to search for this

2.1. Making data findable, including provisions for metadata: Will metadata be offered in such a way that it can be harvested and indexed?

Yes

2.2. Making data accessible - Repository: Will the data be deposited in a trusted repository?

Yes; the data is deposited in an online web-based depository on the DeCODe website. It will also be deposited in the UT repository for back-up.

2.2. Making data accessible - Repository: Have you explored appropriate arrangements with the identified repository where your data will be deposited?

Yes

2.2. Making data accessible - Repository: Does the repository ensure that the data is assigned an identifier? Will the repository resolve the identifier to a digital object?

Yes, the repository will have a digital object identifier

2.2. Making data accessible - Data:
Will all data be made openly available? If certain datasets cannot be shared (or need to be shared under restricted access conditions), explain why, clearly separating legal and contractual reasons from intentional restrictions. Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if opening their data goes against their legitimate interests or other constraints as per the Grant Agreement.

Yes, all data will be made openly available, as they will be depositied in an online database

2.2. Making data accessible - Data:
If an embargo is applied to give time to publish or seek protection of the intellectual property (e.g. patents), specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible.

There is no embargo

2.2. Making data accessible - Data:
Will the data be accessible through a free and standardized access protocol?

the data will be freely accessible

2.2. Making data accessible - Data:
If there are restrictions on use, how will access be provided to the data, both during and after the end of the project?

there are no restrictions on use of the data

2.2. Making data accessible - Data:
How will the identity of the person accessing the data be ascertained?

It is not possible to know the identity of the person accessing the data

2.2. Making data accessible - Data:
Is there a need for a data access committee (e.g. to evaluate/approve access requests to personal/sensitive data)?

No, there is no need for a data access committee

2.2. Making data accessible - Metadata:
Will metadata be made openly available and licenced under a public domain dedication CC0, as per the Grant Agreement? If not, please clarify why. Will metadata contain information to enable the user to access the data?

Yes, the metadata will be openly available on the DeCODe website

2.2. Making data accessible - Metadata:

How long will the data remain available and findable? Will metadata be guaranteed to remain available after data is no longer available?

The data will be available and findable for the full duration of the project and five years following the project.

2.2. Making data accessible - Metadata:

Will documentation or reference about any software be needed to access or read the data be included? Will it be possible to include the relevant software (e.g. in open source code)?

There is no specialized software needed to access the data

2.3. Making data interoperable:

What data and metadata vocabularies, standards, formats or methodologies will you follow to make your data interoperable to allow data exchange and re-use within and across disciplines? Will you follow community-endorsed interoperability best practices? Which ones?

Whenever possible, specific metadata vocabularies will be used, such as the MeSH, ICD and others.

2.3. Making data interoperable:

In case it is unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies? Will you openly publish the generated ontologies or vocabularies to allow reusing, refining or extending them?

NA

2.3. Making data interoperable:

Will your data include qualified references[1] to other data (e.g. other data from your project, or datasets from previous research)?

[1] ***A qualified reference is a cross-reference that explains its intent. For example, X is regulator of Y is a much more qualified reference than X is associated with Y, or X see also Y. The goal therefore is to create as many meaningful links as possible between (meta)data resources to enrich the contextual knowledge about the data. (Source: https://www.go-fair.org/fair-principles/i3-metadata-include-qualified-references-metadata/)***

No

2.4. Increase data re-use:

How will you provide documentation needed to validate data analysis and facilitate data re-use (e.g. readme files with information on methodology, codebooks, data cleaning, analyses, variable definitions, units of measurement, etc.)?

Yes, we will provide documentation to validate the data collection and analysis in the dedicated research outputs

2.4. Increase data re-use:

Will your data be made freely available in the public domain to permit the widest re-use possible? Will your data be licensed using standard reuse licenses, in line with the obligations set out in the Grant Agreement?

Yes, the data will be made publicaly available via the DeCODe website

2.4. Increase data re-use:

Will the data produced in the project be useable by third parties, in particular after the end of the project?

Yes, the data will be useable by third parties

2.4. Increase data re-use:
Will the provenance of the data be thoroughly documented using the appropriate standards?

Yes, the provenance of the data will be documented in three dedicated research outputs.

2.4. Increase data re-use:
Describe all relevant data quality assurance processes.

All data curated will be verified by two experts within the consortium. In addition, outside experts will be asked to verify the data.

2.4. Increase data re-use:
Further to the FAIR principles, DMPs should also address research outputs other than data, and should carefully consider aspects related to the allocation of resources, data security and ethical aspects.

Other research outputs, such as the publication on best practices, will be made available.

Other research outputs

In addition to the management of data, beneficiaries should also consider and plan for the management of other research outputs that may be generated or re-used throughout their projects. Such outputs can be either digital (e.g. software, workflows, protocols, models, etc.) or physical (e.g. new materials, antibodies, reagents, samples, etc.).

The workflow of support-giving will be included in the publication on best practices

Beneficiaries should consider which of the questions pertaining to FAIR data above, can apply to the management of other research outputs, and should strive to provide sufficient detail on how their research outputs will be managed and shared, or made available for re-use, in line with the FAIR principles.

The publication on best practices will also be openly accessible and posted in different databases, such as researchgate.

Allocation of resources

What will the costs be for making data or other research outputs FAIR in your project (e.g. direct and indirect costs related to storage, archiving, re-use, security, etc.) ?

The data will be designed fair by design. No additional costs are needed to make the data FAIR after the project.

How will these be covered? Note that costs related to research data/output management are eligible as part of the Horizon Europe grant (if compliant with the Grant Agreement conditions)

There are no specific costs dedicated to the data management, all costs needed are part of WP1, project management

Who will be responsible for data management in your project?

The University of Twente is responsible for data management.

How will long term preservation be ensured? Discuss the necessary resources to accomplish this (costs and potential value, who decides and how, what data will be kept and for how long)?

The data will be kept for 5 years after the project, after which it will either need to be re-curated or is out of date.

Data security

What provisions are or will be in place for data security (including data recovery as well as secure storage/archiving and transfer of sensitive data)?

The data that are collected are not sensitive. In case of an incidence, data security is ensured because of daily back ups that are kept at least 28 days

Ethics

Are there, or could there be, any ethics or legal issues that can have an impact on data sharing? These can also be discussed in the context of the ethics review. If relevant, include references to ethics deliverables and ethics chapter in the Description of the Action (DoA).

Yes. The information on stakeholders should be verified and stakeholders should be asked if they want to be included in the dataset.

Will informed consent for data sharing and long term preservation be included in questionnaires dealing with personal data?

Yes, informed consent for data sharing and long-term preservation be included in the questionnaires dealing with personal data

Other issues

Do you, or will you, make use of other national/funder/sectorial/departmental procedures for data management? If yes, which ones (please list and briefly describe them)?

No

Planned Research Outputs

Publication - "Best practices for orphan device development "

Best practices coming from the support provided by the DeCODe project to 5 different orphan device developers.

Publication - "The Orphan Device Development guidance"

Overview of the critical path analysis of orphan device development

Publication - "A Horizon Scan of the Initiatives, Platforms, Datasets and Tools available to support the Development of Child and Orphan Devices in the European Union "

Overview of the data on initiatives and experts in orphan device development

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Planned research output details

Title	DOI	Type	Release date	Access level	Repository(ies)	File size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Best practices for orphan device development		Publication	Unspecified	Open	None specified		Creative Commons Attribution 4.0 International	None specified	No	No
The Orphan Device Development guidance		Publication	Unspecified	Open	None specified		Creative Commons Attribution 4.0 International	None specified	No	No
A Horizon Scan of the Initiatives, Platforms, Data ...		Publication	Unspecified	Open	None specified		Creative Commons Attribution 4.0 International	None specified	No	No

Conclusion

This deliverable described the data management plan of the DeCODe project. The DMP is considered as a dynamic document and will be updated whenever needed.