
Plan Overview

A Data Management Plan created using DMPonline

Title: Reliable and accessible information on cell and gene-based therapies

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Project abstract:

Cell and gene-based therapies have the potential to treat many debilitating diseases and conditions. However, the pace of their clinical development does not meet public expectations. They face difficulties reaching patients because inter alia the complexity and costs of product development, regulatory hurdles and the non-harmonized procedures for reimbursements. In addition, there are concerns over patient safety due to the use of unproven treatments. Proposals should offer well-structured and detailed strategies to convey accurate and up-to-date information on cell and gene-based therapies using multiple contemporary modalities, including a website. The consortium should consist of diverse actors and could include experts in science communication, patients' representatives, industry, SMEs, clinical and academic researchers as well as the major European learned societies in the field. They should provide expertise across the field of human stem cells, regenerative medicine, genome-editing and gene therapy.

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Reliable and accessible information on cell and gene-based therapies - Initial DMP

Manchester Data Management Outline

1. Will this project be reviewed by any of the following bodies (please select all that apply)?

Question not answered.

2. Is The University of Manchester collaborating with other institutions on this project?

Question not answered.

3. What data will you use in this project (please select all that apply)?

Question not answered.

4. Where will the data be stored and backed-up during the project lifetime?

Question not answered.

5. If you will be using Research Data Storage, how much storage will you require?

Question not answered.

6. Are you going to be working with a 3rd party data provider?

Question not answered.

7. How long do you intend to keep your data for after the end of your project (in years)?

Question not answered.

Questions about personal information

Personal information, also known as personal data, relates to identifiable living individuals. Special category personal data is more sensitive information such as medical records, ethnic background, religious beliefs, political opinions, sexual orientation and criminal convictions or offences information. If you are not using personal data then you can skip the rest of this section.

Please note that in line with [data protection law](#) (the General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de-identified) as soon as practically possible. You must obtain the appropriate [ethical approval](#) in order to use identifiable personal data.

8. What type of personal information will you be processing (please select all that apply)?

Question not answered.

9. Please briefly outline how you plan to store, protect and ensure confidentiality of the participants' information.

Question not answered.

10. If you are storing personal information (including contact details) will you need to keep it beyond the end of the project?

Question not answered.

11. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester?

Question not answered.

12. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?

Question not answered.

13. Are you planning to use the personal information for future purposes such as research?

Question not answered.

14. Who will act as the data custodian for this study, and so be responsible for the information involved?

Question not answered.

15. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).

Question not answered.

1. Data summary

Provide a summary of the data addressing the following issues:

- **State the purpose of the data collection/generation**
- **Explain the relation to the objectives of the project**

- **Specify the types and formats of data generated/collected**
- **Specify if existing data is being re-used (if any)**
- **Specify the origin of the data**
- **State the expected size of the data (if known)**
- **Outline the data utility: to whom will it be useful**

No data will be collected. This project aims at diffusing information on stem cell therapies.

2. FAIR data

2.1 Making data findable, including provisions for metadata:

- **Outline the discoverability of data (metadata provision)**
- **Outline the identifiability of data and refer to standard identification mechanism. Do you make use of persistent and unique identifiers such as Digital Object Identifiers?**
- **Outline naming conventions used**
- **Outline the approach towards search keyword**
- **Outline the approach for clear versioning**
- **Specify standards for metadata creation (if any). If there are no standards in your discipline describe what metadata will be created and how**

N/A

2.2 Making data openly accessible:

- **Specify which data will be made openly available? If some data is kept closed provide rationale for doing so**
- **Specify how the data will be made available**
- **Specify what methods or software tools are needed to access the data? Is documentation about the software needed to access the data included? Is it possible to include the relevant software (e.g. in open source code)?**
- **Specify where the data and associated metadata, documentation and code are deposited**
- **Specify how access will be provided in case there are any restrictions**

N/A

2.3 Making data interoperable:

- **Assess the interoperability of your data. Specify what data and metadata vocabularies, standards or methodologies you will follow to facilitate interoperability.**
- **Specify whether you will be using standard vocabulary for all data types present in your data set, to allow interdisciplinary interoperability? If not, will you provide mapping to more commonly used ontologies?**

N/A

2.4 Increase data re-use (through clarifying licenses):

- **Specify how the data will be licenced to permit the widest reuse possible**
- **Specify when the data will be made available for re-use. If applicable, specify why and for what period a data embargo is needed**
- **Specify whether the data produced and/or used in the project is useable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why**
- **Describe data quality assurance processes**
- **Specify the length of time for which the data will remain re-usable**

N/A

3. Allocation of resources

Explain the allocation of resources, addressing the following issues:

- Estimate the costs for making your data FAIR. Describe how you intend to cover these costs
- Clearly identify responsibilities for data management in your project
- Describe costs and potential value of long term preservation

No resources will be available to partners.

4. Data security

Address data recovery as well as secure storage and transfer of sensitive data

N/A

5. Ethical aspects

To be covered in the context of the ethics review, ethics section of DoA and ethics deliverables. Include references and related technical aspects if not covered by the former

N/A

6. Other

Refer to other national/funder/sectorial/departmental procedures for data management that you are using (if any)

N/A