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ultRAsound-mediated management of osteoarthritis

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D 7.4 Report on initial data management plan

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Deliverable author: [Denise Amram (SSSA), Leonardo Ricotti (SSSA), Irene

Bernardeschi (SSSA)]

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	Project co-funded by the European Commission within the H2020 programme							
	Dissemination Level							
PU	Public	X						
PP	Restricted to other programme participants (including the Commission Service)							
RE	Restricted to a group specified by the consortium (including the Commission Service)							
CO	Confidential, only for members of the consortium (including the Commission Service)							



Document History

Version	Date	Author	Summary of Main Changes
1	05/07/2019 Irene Bernardeschi, SSSA		First version of the template for project Deliverables
2	17/07/2019	Denise Amram, SSSA	First complete version of the Deliverable
3	23/07/2019	Gina Lisignoli, IOR	Integrations to the Deliverable
4	26/07/2019	Irene Bernardeschi, Denise Amram, SSSA	Revised version of the Deliverable
5	29/07/2019	Leonardo Ricotti, SSSA	Final version of the Deliverable



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1 Executive summary

This deliverable consists of the Initial Data Management Plan.

It describes the general strategy that the ADMAIORA consortium adopted to fulfil the Open Access Research Data Pilot and to create a FAIR ecosystem.

The deliverable refers to the chosen repository features, the interplay between data management, dissemination activities and the overall management of the project, taking into account the related legal-ethical issues, where the research data are personal ones.

The deliverable includes an introduction, the description of the data management strategy, the general rules to be applied to identified categories of research information, and the specific ones for each public deliverable produced in the project course.

Leader contractor: [SSSA]
Participant contractors: [BIU, IOR, VIMEX, IGT, PLASMACHEM, REGENTIS, HDW]



2 Introduction

Data are generated in order to achieve the ADMAIORA project purposes.

The ADMAIORA project opted for the Open access to research data. Consequently, research data (i.e. information, in particular facts or numbers, collected to be examined and considered and as a basis for reasoning, discussion, or calculation) will be available free of charge and reusable.

The ADMAIORA consortium agrees to deposit the data in a research data repository, which allows permanent access to datasets in a trustworthy environment, enabling search, discovery, and reuse. The Zenodo community has been chosen as repository: users may access, mine, exploit, reproduce and disseminate the uploaded data, free of charge.

coordinator of opened the project (leonardo.ricotti@santannapisa.it) and created an ADMAIORA community where research will data be updated under the Creative Common 4.0. https://zenodo.org/communities/admaiora/edit/ (Figure 1).





Figure 1 . Screenshot of the Zenodo community webpage.

File name: ADMAIORA_WP7_D7.4

Leader contractor: [SSSA]



Zenodo ensures to collect and store research data within the so-called *FAIR ecosystem*, according to which research data will be:

Findable: Metadata and data should be easy to find for both humans and computers;

Accessible: Once the user finds the required data, he/she needs to know how can they be accessed, possibly including authentication and authorisation;

Interoperable: The data usually need to be integrated with other data. In addition, the data need to interoperate with applications or workflows for analysis, storage, and processing;

Reusable: metadata and data should be well-described so that they can be replicated and/or combined in different settings (open licence).

As the Data Management Plan (DMP) is a living document, which is supposed to be updated in light of the development of the project, at this initial stage, it includes a planned general strategy for four categories of research data: (1) deliverables, (2) articles, (3) personal data and (4) side experimental data.

These four categories fully describe the lifecycle of the ADMAIORA project and the evolution of its implementation.

Each newly generated dataset in the project course will be evaluated and it will be either classified in one of the four categories above or defined as a new category of research data, to be added in the further DMP versions.

2.1 The Data Management Strategy

The Data Management strategy (Figure 2) is strongly connected to the dissemination plan (see D7.2 – Preliminary dissemination, communication and exploitation plan) and to the whole project management (D1.1 – Project management handbook) as the DMP is addressed both to partners (describing how to collect, store, process, curate, and disseminate research data) and to third parties (since it states the rules to implement and enjoy a FAIR ecosystem).

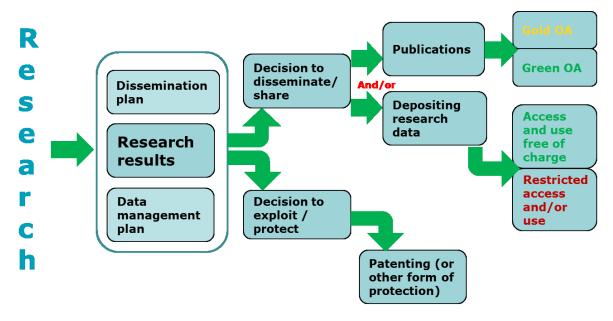


Figure 2. Data Management strategy

File name: ADMAIORA_WP7_D7.4 Leader contractor: [SSSA]



As stated, according to article 29.3 of the Grant Agreement the development of the ADMAIORA concept will produce research results that will be available in terms of open access publications and open access research data.

The Open access policy will be limited in these cases:

- Data protection issues: personal data belonging to the volunteers will be collected, stored, and processed following the procedures described under D8.1 (H Requirement No. 5), in compliance with the current EU and national legal framework (EU General Data Protection Regulation 2016/679 GDPR and the Italian Privacy Code Legislative Decree n. 196/2003, as amended by L.D. 101/2018, and the Italian Data Protection Authority Ethics code on data processing for statistical and scientific research purposes).
- Public safety (misuse): whether during the development of the research the ethical issues related to possible misuse of the results might occur.
- Intellectual property rights: for those aspects of the research which are patentable.
- Commercial interests: for those profiles of the research which might be exploited as commercial activities.

Unless the above-mentioned exceptions occur, research data will follow the FAIR principles under the CC BY NC 4.0 licence by which third parties may share (i.e. copy and redistribute the material in any medium or format) and adapt (i.e. remix, transform, and build upon) the material for any purpose, even commercially.

2.1.1 The Data Management Governance: General Rules.

The ADMAIORA Data Management Plan, the Dissemination Plan, and the Project Management Handbook play a fundamental role during the whole lifecycle of the project and their contents should be coherent with the specific strategies.

In order to better describe the information on how the ADMAIORA consortium will collect, structure, analyse, and publish data, we will consider the following research data that could be produced within one (or more) WP:

1) <u>Deliverables as per se research information</u>.

Deliverables, as they describe how a specific research output has been realized, are *per se* considered "research data" to be managed according to the project policy.

For each deliverable, contents are firstly included in word documents describing how the related tasks have been developed and which results have been achieved.

Each.doc file is shared between the ADMAIORA consortium (i.e. only within authorized persons) in the Dropbox Business shared folder (with servers sited in EU) while in progress.

Then, the final version is printed in .pdf format and submitted to the EU Commission Service. Size will be approximately included between 1M < x < 30 M.

The deliverable is stored in the Dropbox Business shared folder for all the duration of the project, including the reviews if it is not classified as a public deliverable. In that case, it could be either restricted to the other programme participants, or restricted to a group specified by the consortium, or CONFIDENTIAL (i.e. shared only for members of the Consortium), including in all cases the Commission Service.

File name: ADMAIORA_WP7_D7.4

Leader contractor: [SSSA]



If the deliverable is "PUBLIC", it will be uploaded in the Zenodo repository, under the ADMAIORA community https://zenodo.org/communities/admaiora/edit/, in order to fulfil the Open access research data pilot and on the dedicated section of the ADMAIORA website (www.admaiora-project.com) in the following section:

Download: https://www.admaiora-project.com/download/

The decision on the confidentiality, publicity, temporary confidentiality/postponed publicity of the results is determined according to the innovation management workflow (D1.1)

The table (see **Annex 1**) illustrates the details for each public deliverable.

At month 7, the following Deliverables have been issued:

- D1.1 and D7.2, which do not include further research data and can be classified as Deliverables as per se research information;
- D2.1 and D2.2, which include research data, as experiments and are not public at this stage;
- D7.1, which refers to the Project Website, built in Open source through CMS WordPress, adopting the CODEUS template to develop contents: https://themeforest.net/item/codeus-multipurposeresponsive-wordpresstheme/6906054;
- D7.4, which refers to the initial data management plan and describes the general strategy that the ADMAIORA consortium adopted to fulfil the Open Access Research Data Pilot and to create a FAIR ecosystem;
- D8.1 and D8.2, which concern the ethical-legal issues emerging from the ADMAIORA project and describe the plan aimed at achieving the full ethical-legal compliance of each sensitive research activity involving humans and animals.
- 2) <u>Articles</u>. Whether the research results converge in articles, each publication shall be readable, downloadable, and printable, following the gold policy as a priority.

The published work is made available in open access mode by the publisher immediately upon publication. Open access should be provided as soon as possible and in any case no later than six months after the official publication date.

References and OA articles will be also available in dedicated sections of the ADMAIORA website: Publications https://www.admaiora-project.com/papers/

Furthermore, Scuola Superiore Sant'Anna has an institutional Repository (IRIS), where research results by SSSA researchers will be available following the Open Access policy https://www.iris.sssup.it at least, as long as the author has an institutional SSSA account.

This will allow a more effective dissemination of the research products.

The patentability of a research result constitutes a limit to the Open Access policy.

The patent content cannot be published in a full form to not compromise the process. However, the metadata of the patent applications will be available on the ADMAIORA website, immediately after the patent filing Patents: https://www.admaiora-project.com/patents/

File name: ADMAIORA_WP7_D7.4

Leader contractor: [SSSA]



3) Personal data. Whether the research data refer to volunteers' personal data their collection, storage, and processing will follow the procedures identified in the D.8.1. In particular, according to the current applicable legal framework, only the partners appointed to the specific task 6.5 (i.e. SSSA and IOR) will have access to participants' personal data. They committed to provide a pseudonymization before processing personal data and to adopt all organizational and technical measures in order to protect and guarantee data subjects' rights. The key to re-identify participants will be kept by the principal investigator for the duration of the project in servers located in Italy, then it will be destroyed. Only researchers that will be instructed and committed to specific confidentiality clauses will be authorized to access to sensitive personal data (i.e. health data).

The informed consent documentation will be collected during tests and stored in folders in the involved institutions for 5 years after the end of the project. Access will be reserved to authorized employees of the partners involved in the specific tasks.

Data governance related to personal data is stated in specific agreements between the involved partners (further details in D8.1).

4) <u>Side experimental data</u>. To identify the state of the art concerning the biological and technological specifications some experiments have been already performed. Preliminary results (images, raw data, etc.) are shared within the partners involved in the specific tasks during projects meetings in the Dropbox shared folder.

These data, together with possible additional ones to be considered as functional to technical evolutions (that will result in Deliverable preparation), such as notes, schemes, technical drawings, etc., are considered confidential until they will be published in future papers/publications or included in public Deliverables. Then, they could be shared in the open repository.

2.1.2 The Online Data Management Plan.

The DMP (Figure 3) is created following the EC Guidelines and thanks to the support of the Open Access tool developed by the Digital Curation Centre (DCC), DMP Online tool, www.dmponline.dcc.ac.uk, recognized as fully compliant with the FAIR principles by the scientific community.

The Consortium created an ADMAIORA Plan directly connected with the ORCID ID of the Project Coordinator.

The initial DMP includes the above-mentioned rules identifying, in particular (see **Annex 2**):

- 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
- How to make data FAIR (Findable, Accessible, Interoperable, Re-Use)
- How the resources will be allocated for data management

File name: ADMAIORA_WP7_D7.4

Leader contractor: [SSSA]



Policy for sensitive data and other ethical aspects.

ADMAIORA



Figure 3. Structure of the initial ADMAIORA DMP.3



3 Conclusions

As stated, the Data Management Plan is a living document. This Initial DMP will be implemented and updated during the development of the project. Further details will be included at M24 (Intermediated DMP) and M48 (Final DMP).

References

This Initial Data Management Plan has been developed taking into account the following quidelines:

- EC's Guide on Open Access to Scientific Publications and Research Data in Horizon2020 (http://ec.europa.eu/research/participants/data/ref/h2020/grants-manual/hi/oa-pilot/h2020-hi-oa-pilot-guide-en.pdf)
- Guidelines included in the DMP Online tool developed by the Digital Curation Centre, available at www.dmponline.dcc.ac.uk
- Research Data Lifecycle by the UK Data Service (2017) (https://www.ukdataservice.ac.uk/manage-data/lifecycle)
- EC's Open Access Factsheet(https://www.openaire.eu/openaire-h2020-factsheets)
- FAIR Checklist (https://www.force11.org/fairprinciples)
- S. Hodsonet al., FAIR Data Action Plan Interim recommendations and actions from the European Commission Expert Group on FAIR data (https://zenodo.org/record/1285290#.XBEjSi8VRKM)
- S. Hodsonet al. Report of the Commission FAIR Data Expert Group (FAIR Data EG): Turning FAIR into reality (https://zenodo.org/record/1285272#.XBEjri8VRKM)
- Creative Commons License https://creativecommons.org

File name: ADMAIORA_WP7_D7.4 Leader contractor: [SSSA]

ANNEX 1

Lead Benefici ary	Task/D eliv./Ex perime nt	Name dataset	Types and formats of data generated/collected	During the research: where do you store your data	Specify if existing data is being re- used (if any)	Origin of the data	Expe cted size	To whom data will it be useful	Methods or software tools needed to access the data (if any)	Licence applied
SSSA	D1.1	Project manage ment handboo k	PDF file with a description of project management strategies and tools	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members	1 MB	General public, interested in details on the research project. Researchers interested in the project organization	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
REGENT IS	D3.1	PEG- fibrinoge n based hydrogel prototyp e develop ment	PDF file with a description and characterization of the hydrogel prototype. The document contains details such as composition, physical appearance, sterility, mechanical properties, storage handling.	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members	1 MB	Researchers interested in the ADMAIORA project activities.	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
REGENT IS	D3.2	Pluronic- fibrinoge n based hydrogel prototyp e develop ment	PDF file with a description and characterization of the hydrogel prototype. The document contains details such as composition, physical appearance, sterility, mechanical properties, storage handling.	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members	1 MB	Researchers interested in the ADMAIORA project activities.	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
SSSA	D4.1	Selected compon ents for the innovati ve LIPUS stimulati on set- ups	PDF file with a list of commercial and custom components and their main features	Dropbox folder shared with all ADMAIORA participants	Yes	Data derived from suppliers in paper and digital formats transmitted to the PI	10 MB	Researchers interested in ultrasonic systems	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License

SSSA	D4.2	Assembl ed innovati ve LIPUS stimulati on set- ups	PDF file with pictures of the final ultrasonic set-ups developed and a list of their measured performances. Short movie showing the system functionality.	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members	30 MB	Researchers interested in ultrasonic systems	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
H&D Wireless	D5.1	Prelimin ary software structur e	PDF file with the software architecture including flow charts and description of functions	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members	3 MB	Researchers interested in the ADMAIORA project activities.	Dropbox for internal use. Zenodo and project website (www.admaiora-project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
IGT	D5.2	Prelimin ary brace skeleton	PDF file with design and pictures of the prototype brace skeleton	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members	15 MB	Researchers interested in the ADMAIORA project activities.	Dropbox for internal use. Zenodo and project website (www.admaiora-project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
VIMEX	D5.3	Prelimin ary foot- controlle d pneumat ic flow for bioprinti nq	PDF file with design of foot-controlled pneumatic flow for bioprinting device	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members	3 MB	Researchers interested in endoscopy bioprinting of material	Dropbox for internal use. Zenodo and project website (www.admaiora-project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
SSSA	D5.10	Report on technolo gy integrati on	PDF file with a list of commercial and custom components and their main features and how they have been integrated. In the document the protocol planning for final validation tests will be also reported.	Dropbox folder shared with all ADMAIORA participants	Yes	Data derived from suppliers in paper and digital formats transmitted to the PI	7 MB	Researchers interested in OA treatment (medical doctors, orthopedic surgeons, patients), in ultrasonic systems, in regenerative medicine, in 3D bioprinting, in IoT technologies and in integration of mechatronic technologies	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License

SSSA	D7.1	Project website	PDF file with the description of the website and its structure	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the communication manager, by the partners and by a professional graphical designer	3 MB	General public interested in the ADMAIORA project activities.	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
SSSA	D7.2	Prelimin ary dissemin ation, commun ication and exploitat ion plan	PDF file with the description of the planned dissemination, communication and exploitation activities	Dropbox folder shared with all ADMAIORA participants	Yes	Information on public events (conference, fairs, etc.) found in the web. Data produced by the communication manager, by the partners and by a professional graphical designer. Information on patents relevant for ADMAIORA, provided by a professional patent attorney and found on public databases.	3 MB	General public interested in the non-specialistic ADMAIORA communicat ion activities. Researchers interested in the scientific dissemination activities. Companies and possible stakeholders interested in monitoring the project exploitation activities and patent portfolio.	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
SSSA	D7.4	Initial data manage ment plan	PDF file with a description of the data management plan	Dropbox folder shared with all ADMAIORA participants	Yes	Data derived from the Data Management Plan (DMP) used for the project.	1 MB	Researchers interested in getting in confidence with open access data policies in European projects	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
SSSA	D7.6	Report on 1st ADMAIO RA worksho p	PDF file with pictures of the event and a description of the agenda and scientific discussion carried out during the event.	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members. Public data derived from the conference/ev ent that hosts the workshop	1 MB	Researchers interested in the ADMAIORA project activities.	Dropbox for internal use. Zenodo and project website (www.admaiora-project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License

						(e.g. location, dates, etc.).				
SSSA	D7.7	Interme diate data manage ment and innovati on manage ment	PDF file with a description of an updated data management plan and a description of the innovation management strategy.	Dropbox folder shared with all ADMAIORA participants	Yes	Data derived from the Data Management Plan (DMP) used for the project. Data produced by the ADMAIORA participants on the innovation management procedures.	1 MB	Researchers interested in getting in confidence with open access data policies and in innovation managemen t strategies in European projects	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
SSSA	D7.8	Report on 2nd ADMAIO RA worksho p and other key commun ication events	PDF file with pictures of the event(s) and a description of the agenda and scientific/non-scientific discussions carried out during the events.	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members. Public data derived from the conference/ev ent that hosts the workshop and the other events (e.g. location, dates, etc.).	3 MB	Researchers and general public interested in the ADMAIORA project activities.	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
SSSA	D7.10	Report on 3rd ADMAIO RA worksho p	PDF file with pictures of the event and a description of the agenda and scientific discussion carried out during the event.	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members. Public data derived from the conference/ev ent that hosts the workshop (e.g. location, dates, etc.).	1 MB	Researchers interested in the ADMAIORA project activities.	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License
SSSA	D7.12	Final innovati on manage ment, 4th ADMAIO RA worksho p and other commun	PDF file with final description of the innovation management strategy and procedures, pictures of the event(s) and a description of the agenda and scientific/non-scientific discussions carried out during the events.	Dropbox folder shared with all ADMAIORA participants	Yes	Data produced by the project members. Public data derived from the conference/ev ent that hosts the workshop and the other events (e.g.	3 MB	Researchers and general public interested in the ADMAIORA project activities.	Dropbox for internal use. Zenodo and project website (www.admaiora- project.com) for accessing data by external people	Creative Common s 4.0 Internati onal License

	ication activities		location, dates, etc.).		

ANNEX 2

ADMAIORA

A Data Management Plan created using DMPonline

Creators: Denise AMRAM, Leonardo Ricotti

Affiliation: Other

Template: European Commission (Horizon 2020)

ORCID iD: https://orcid.org/0000-0001-8797-3742

Grant number: 814413

Last modified: 18-07-2019

ADMAIORA - Initial DMP

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

Data are generated in order to achieve the ADMAIORA project purposes.

For this reason, a proper description of datasets could be provided considering the lists of deliverables.

1. Deliverables as per se research information.

Deliverables, as they describe how a specific research output has been realized, are econsidered "research data" to be managed according to the agreed policy of the project

For each deliverable, contents are firstly included in word documents describing how the related tasks have been developed and which results have been achieved. Each file .doc is shared between the ADMAIORA consortium (i.e. only within authorized persons) in the Dropbox Business shared folder (with servers sited in EU) while in progress.

Then, the final version is printed in .pdf format and submitted to the EU Commission Service. Size will be approximately included between 1M <x <30 M.

The deliverable is stored in the Dropbox Business shared folder for all the duration of the project, including the reviews if it is not classified as a public deliverable. In that case, it could be either restricted to the other programme participants, or restricted to a group specified by the consortium, or CONFIDENTIAL (i.e. shared only for members of the Consortium), including in all cases the Commission Service.

If the deliverable is "PUBLIC", it will be uploaded in the Zenodo repository, under the ADMAIORA community https://zenodo.org/communities/admaiora/edit/, in order to fulfil the Open access research data pilot and on the dedicated section of the ADMAIORA website (www.admaiora-project.com) in the following sections: Download: https://www.admaiora-project.com/download/

The decision on the confidentiality, publicity, temporary confidentiality/postponed publicity of the results is determined according to the project management (D.1.1.)

At month 6, the following Deliverables have been issued.

D.1.1. and D.7.2. which do not include further research data and can be classified as Deliverables as per se research information;

D.2.1. and D.2.2. which include research data, as experiments and are not public at this stage.

D.7.1. which refers to the Project Website.

1. Articles. Whether the research results converge in articles, each publication shall be readable, downloadable, and printable, following the gold policy as a priority.

The published work is made available in open access mode by the publisher immediately upon publication. Open access should be provided as soon as possible and in any case no later than six months after the official publication date.

References and OA articles will be also available in dedicated sections of the ADMAIORA website:

Publications: https://www.admaiora-project.com/papers/

Furthermore, Scuola Superiore Sant'Anna has an institutional Repository (IRIS), where research results by SSSA researchers will be available following the Open Access policy https://www.iris.sssup.ita least, as long as the author has an institutional SSSA account.

This will allow a more effective dissemination of the research products.

The patentability of a research result constitutes a limit to the Open Access policy.

The patent content cannot be published in a full form to not compromise the process. However, the metadata of the patent applications will be available on the ADMAIORA website, immediately after the patent filing Patents: https://www.admaiora-project.com/patents/

1. Personal data. Whether the research data refer to volunteers' personal data their collection, storage, and processing will follow the procedures identified in the D.8.1. In particular, according to the current applicable legal framework, only the partners appointed to the specific task 6.5 (i.e. SSSA and IOR) will have access to participants' personal data. They committed to provide a pseudonymization before processing personal data and to adopt all organizational and technical measures in order to protect and guarantee data subjects' rights. The key to re-identify participants will be kept by the principal investigator for the duration of the project in servers located in Italy, then it will be destroyed. Only researchers that will be instructed and committed to specific confidentiality clauses will be authorized to access to sensitive personal data (i.e. health data).

The informed consent documentation will be collected during tests and stored in folders in the involved institutions for 5 yrs after the end of the project. Access will be reserved to authorized employees of the partners involved in the specific tasks.

Data governance related to personal data is stated in specific agreements between the involved partners (further details in D.8.1.).

1. Side experimental data. To identify the state of the art concerning the biological and technological specifications some experiments have been already performed. Preliminary results (images, raw data, etc.) are shared within the partners involved in the specific tasks during projects meetings in the Dropbox shared folder.

These data, together with possible additional ones to be considered as functional to technical evolutions (that will result in Deliverable preparation), such as notes, schemes, technical drawings, etc., are considered confidential until they will be published in future papers/publications or included in public Deliverables. Then, they could be shared in the open repository.

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

Open research data will be uploaded on the Zenodo ADMAIORA community which automatically generates the metadata.

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

Open research data will be uploaded on the Zenodo ADMAIORA community which ensures the open access under the applicable license: the CC By 4.0. one.

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 inter-disciplinary interoperability? If not, will you provide mapping to more commonly used ontologies?

Datasets are classified following the technical items common to the scientific panorama. In any case, the upload procedures on Zenodo allow to identify the standard vocabulary for each research information.

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

- $\bullet \quad \textbf{Specify how the data will be licenced to permit the widest reuse possible} \\$
- 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

Data re-use is addressed to all researchers interested in the project purposes. The upload on the Zenodo repository of the open research data and, where possible, on the ADMAIORA project website (results section) ensures the widest re-use of the data.

The consortium agreed for the CC by 4.0 licence for the open research data.

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

Annual licences to the Dropbox Business SSSA account for each researcher contributing to the project (~110€ per license per year).

Human Resources involved in the data management are:

- Project Coordinator;
- SSSA PM;
- SSSA Data Protection Officer.

4. Data security

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

SSSA acquired Dropbox Business Accounts with servers sited in EU (Germany) which is fully GDPR compliant.

According to the SSSA ICT security policy data processed with SSSA devices, tools and running on SSSA's servers are protected under the confidentiality, availability, and integrity perspectives.

From the organizational viewpoint, only instructed, therefore authorized researchers will have access to the research data stored in dedicated shared Dropbox Business account. Furthermore, all researchers are committed to specific confidential obligations and NDA.

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

See D.8.1, D.8.2.

6. Other

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

https://zenodo.org/communities/admaiora/edit/

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