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D 7.7
Intermediate Data Management and Innovation Management

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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)	

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2	28/12/2020	Denise Amram, SSSA	First version of the DMP part of the Deliverable
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4	03/01/2021	Leonardo Ricotti, SSSA	Second revision of the Deliverable on DMP and drafting of the Innovation Management part
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1 Executive summary

This Deliverable reports the advancement in the Data Management Plan and the Innovation Management strategy.

The Intermediate Data Management Plan (IDMP) includes an update of the Initial Data Management Plan submitted under D7.4 and an integration of the updates that emerged within the project, in terms of data management, curation, and preservation-related rules. The IDMP updates the general strategy that the ADMAIORA consortium adopted to fulfill the Open Access Research Data Pilot and to create a FAIR ecosystem in light of the research data already produced and the ones the Consortium is going to develop in the next steps of the project life-cycle.

This part of the Deliverable confirms the strategy aimed at combining data management, dissemination activities and the overall management of the project, including the legal-ethical dimension of research data and it provides a more aware position of the Consortium towards Open Data.

The Innovation Management strategy describes how the priorities and initiatives of the Consortium have been orchestrated, thus to successfully pursue exploitation, dissemination and communication initiatives, also identifying appropriate limitations to the Open Access policy drafted in the DMP. This part of the Deliverable evaluates the efficacy of the Innovation Management strategy adopted so far in the project course and if it should be maintained or not in the second part of the ADMAIORA project.

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2 Introduction and applied methodology

The Data Management Plan and the Innovation strategy are strictly connected in terms of interests to be balanced, purposes to be achieved, and possible constraints to deal with. Their impact is significant for the ADMAIORA Consortium and stakeholders.

The Data Management Strategy Assessment included the following steps:

1. A call for contributions has been launched among partners to revise the Initial DMP and provide details for the Intermediate DMP. An excel file has been shared with the following instructions:

    i)   to verify whether the information included in the Initial DMP sheet was appropriate to describe how research data were managed, curated, and preserved in the first part of the project, highlighting any required updates/amendments.

    ii) to add any detail in the Intermediate DMP sheet regarding the research data that partners have produced or are planning to produce within the next months.

2. Contributions from partners have been analysed and standardized considering the Open Research Data Pilot.

3. A list of action points has been extracted to effectively address the Open Research Data Pilot in the next ADMAIORA activities.

4. Action points have been evaluated considering the innovation management strategy before being implemented in the Intermediate Data Management Plan.

5. The Intermediate Data Management Plan has been therefore drafted (*infra* 2.1.).

The Innovation Management strategy had the role to timely identify appropriate limitations to the Open access policy (especially those related to Intellectual property rights and possible commercial interests). In addition, it should avoid conflicts between dissemination/communication activities and exploitation-oriented ones. The assessment of this strategy was thus based on the evaluation of the outcomes produced in terms of exploitation, dissemination and communication, identifying if the orchestration of priorities and initiatives resulted effective or not, to this purpose. The ADMAIORA Innovation Management Strategy is therefore daily assessed by the Project Coordinator, Project Manager, Communication Manager, and Technical Project Manager within the daily management of the Consortium activities. The achievement of the planned results in terms of either patentability of the innovative concepts developed in ADMAIORA or timely enhancing the highest impact through dissemination and communication activities constitutes the ground of evaluation.

The continous balance of apparently conflicting interests, in fact, could daily affect the decision-making process with possible significant consequences on the scientific impact of the overall project.

2.1 The Intermediate Data Management Plan.

The ADMAIORA project opted for the Open access to Research Data Pilot (as described in Deliverable D7.4). Therefore, the ADMAIORA ecosystem is boosting FAIR principles in order to make data "as open as possible, and as close as necessary".

In the Initial Data Management plan, we identified four categories of research data. Considering the strategy assessment, we provided a revised version of the initial plan. In the table below, for each research data category, we addressed possible changes/updates/integration on the process of acquisition, collection, data storage and action points aiming at making them as Findable, Accessible, Interoperable, Reusable as possible.

Research Data	Initial DMP	FAIR Principles	Intermediate DMP
Deliverables as *per se* research information	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. If the Deliverable is "PUBLIC", it is 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 COVID-19 pandemic increased the offer of cloud services and platforms to share documents. In this regard, partners used Office 365 tools to allow simultaneous access to editable documents, although the general and official repositories remained the same ones. **FAIR principles involved:** accessibility and interoperability.	The Initial DMP shall be integrated by the following condition "other clouds and platforms can be used for the preparatory steps of the deliverables if: there is an institutional license, the cloud is GDPR compliant; the access is limited to authorized researchers with individual accounts, any copy is deleted after the Deliverable is submitted".
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 Open Access articles will also be 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	Open Access papers are also shared on the Coordinator's research group website (https://www.santannapisa.it/it/micro-nano-bio-systems-and-targeted-therapies-laboratory) and	The Initial DMP shall be integrated by the following condition "once that articles are published, according to the dissemination strategy of the project as well, authors are invited to share

Research Data	Initial DMP	FAIR Principles	Intermediate DMP
	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 more effective dissemination of the research products. The patentability of a research result constitutes a limitation to the Open Access policy. The patent content cannot be published in 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/	on the ResearchGate and LinkedIn profiles of many researchers involved in the project **FAIR principles involved:** accessibility and reuse.	them within the following channels: authors' personal accounts on ResearchGate and LinkedIn"
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 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 (like the pre-agreement under article 28 GDPR submitted at ESR assessment stage).	Within the D5.4 a data protection impact assessment has been performed in order to assess the IoT ADMAIORA ecosystem in development under article 35 GDPR. Additional conditions, mainly technical ones, to process personal data during clinical trials have been identified according to the ENISA standards. Specific clauses on data management will be included in the agreements to be submitted together with the protocol the competent ethical committee. **FAIR principles involved:** accessibility and reuse and corresponding limits.	The Initial DMP shall be integrated by the following condition: "within the IoT ADMAIORA ecosystem personal data collected in the trials can be processed only under the technical conditions identified under D5.4 and the organizational measures included in D8.1."

Research Data	Initial DMP	FAIR Principles	Intermediate DMP
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.	The COVID-19 pandemic increased the offer of cloud services and platforms to share documents. In this regard, partners used Office 365 tools to allow simultaneous access to editable documents, although the general and official repositories remained the same ones. **FAIR principles involved:** accessibility and interoperability.	The Initial DMP shall be integrated by the following condition "other clouds and platforms can be used for the experimental data if: there is an institutional licence, the cloud is GDPR compliant; the access is limited to authorized researchers with individual accounts, any copy is deleted after the Deliverable is submitted". All data that could not be directly included in a paper or Deliverables are made available on the "ADMAIORA Community" on Zenodo e.g. a first dataset has been shared at the following link: https://doi.org/ 10.5281/zenodo .4323047

Limits to the Open access policy have been re-assessed and confirmed as suitable and appropriate for the purposes of the project. In particular:

• 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). Further technical requirements have been added in light of the Data Protection Impact Assessment performed under article

35 GDPR on the IoT ADMAIORA ecosystem developed in WP5 by H&D Wireless and reported in D5.4.

• Public safety (misuse): whether during the development of the research the ethical issues related to possible misuse of the results might occur. No relevant issues have been identified so far.

• Intellectual property rights: for those aspects of the research which are patentable. In this regard, timely actions have been taken to protect the Consortium intellectual property rights, thanks to the Innovation Management procedures (see section 2.2).

• Commercial interests: for those profiles of the research which might be exploited as commercial activities. Also in this regard, specific examples of limitations have been applied based on Innovation Management actions that will continue monitoring the project activities, as specified in section 2.2.

2.2 The Innovation Management Strategy Assessment

During the first months on the project, SSSA developed an innovation management strategy aiming at monitoring all the project activities, establishing links with external actors, identifying in a timely manner the ones ready for entering a dissemination, communication, or exploitation (e.g., patenting) pathway and, in general, devising the innovation trajectory of the ADMAIORA outcomes. These activities were scattered throughout the whole project course.

This process was grounded on a close interplay between the Project Coordinator and the "first line of managers" of the project, appointed at SSSA, namely the Project Manager, the Technical Project Manager, and the Communication Manager. Almost daily interactions of these figures with the project partners and frequent short meetings/calls and ideas exchanges between these figures are allowing effective monitoring of all the project aspects and their correct addressing in the most effective pathways. The Innovation Management strategy pursued in ADMAIORA is thus a "top-down" approach, which is, however, constantly nurtured by "bottom-up" updates by the research personnel involved in the project.

This strategy was effective in timely identifying appropriate limitations to the Open access policy (especially those related to Intellectual property rights and, as a prospective, future constraints related to commercial interests). No conflicts emerged between dissemination/communication activities and exploitation-oriented ones, thus demonstrating the efficacy of this strategy, as confirmed by the external reviewer of the project who positively evaluated both the scientific impact of the project and the exploitation, dissemination, and communication strategies.

Such an Innovation Management strategy was facilitated by the outcomes of D7.3 (1st IP report and Consortium freedom to operate), submitted at month 5. Here, detailed IP landscape search and report (freedom to operate analysis) was prepared; this facilitated raising the attention of the Project Coordinator and the managers on the most delicate project aspects that might have larger margins for IP rights protection.

Following this strategy, protectable/exploitable results have been early identified and exploitation measures have been early adopted. On the other hand, results deemed particularly suitable for dissemination/communication have been enhanced, from this viewpoint.

For example, in the framework of WP5, Task 5.2 (Bioprinting handheld system), being aware of the IP landscape, and after several interactions between the researchers involved, from which different ideas and constraints emerged, the Project Coordinator and the managers oriented the research efforts towards a twofold approach (that was not originally expected in the DoA), thus to maximize both IP rights protection and the possible project success rate. In fact, it was decided to pursue two ways: a higher risk one, with a new concept that was immediately patented, and a lower risk one, which may be easier to be implemented and tested. Concerning the higher risk (patentable) solution, it was decided to apply a limitation to the Open Access policy to guarantee patentability of the concept (Italian patent filed on 09/10/2020). Concerning the lower risk solution, some aspects have been unveiled in the public Deliverable D5.3, while other aspects have been maintained confidential, in view of possible future commercial exploitation of these tools.

On the other hand, in the framework of WP3 (Development of nanocomposite hydrogels), the Project Coordinator and the managers, based on the outcomes of D7.3 and the bottom-up ideas generated by the Consortium, decided first to file a patent in the first months of the project related to the general ADMAIORA approach (International patent: WO 2020/174395), but then to not pursue patentability of the single materials and nanoparticles developed/functionalized in the project course, but rather to push as much as possible the dissemination and communication aspects, on these topics. This led to the preparation of several scientific papers and different communication initiatives centered on hydrogels and nanomaterials, which are allowing reaching a broad audience.

Furthermore, direct contacts with the Coordinators of other projects funded in the same ADMAIORA Call were established, to maximize the possible impact of such initiatives, especially in terms of overall dissemination power.Overall, the orchestration of priorities and initiatives resulted largely effective in successfully pursuing exploitation, dissemination and communication initiatives as well. Thus, the above-mentioned Innovation Management strategy will also be maintained in the second part of the ADMAIORA project.

3 Conclusions

The Data Management Plan is a living document. The Initial DMP has been draft at M7, implemented and updated during the overall development of the project. This Deliverable includes, in particular, those details emerging from an intermediate assessment of the data management strategy aimed at reaching the purposes of "as open as possible, as close as necessary" for each research data developed in the ADMAIORA ecosystem. At M49 we will submit the Final DMP. The overall ADMAIORA Data Management strategy has been integrated in order to further enhance the potentialities of the ADMAIORA ecosystem as a FAIR one, boosting the opportunity to develop research data "as open as possible and as close as necessary".

In this Deliverable, we assessed and compared the data management strategy with the innovation management one in order to address a fully alignment in the best interest of the project.

In particular, the innovation management strategy based on a top-down monitoring of the project activities by the Project Coordinator and the "first line of managers" (Project Manager, Technical Project Manager, and Communication Manager), nurtured by constant bottom-up updates by the research personnel involved in the project resulted largely effective in

orchestrating the priorities and initiatives of the Consortium, thus to successfully pursue exploitation, dissemination and communication initiatives and identifying, whenever necessary, appropriate limitations according to the Open Access policy of the DMP.

Such an overall approach will be confirmed in the second half of the ADMAIORA project.

4 References

The Intermediate Data Management Plan has been developed taking into account the following guidelines:

- 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

- EU Commission, Data governance and data policies at the European Commission, 2020, https://ec.europa.eu/info/sites/info/files/summary-data-governance-data-policies_en.pdf

- EU Commission, European Data Strategy, https://ec.europa.eu/commission/presscorner/api/files/attachment/862109/European_data_strategy_en.pdf.pdf

- EU Commission, Reproducibility of scientific results in the EU, https://op.europa.eu/en/publication-detail/-/publication/6bc538ad-344f-11eb-b27b-01aa75ed71a1#

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