IMI2 project guidelines for open access to publications and research data

This guide provides an overview of the rules related to open access to publications and research data management that apply to IMI2 projects. It also includes useful information on open access repositories for publications and research data registries, and information on where to get help in case of further questions.

## What are the requirements of the binding open access to publications rules?

> Article 29.2 of the IMI2 JU Grant Agreement details the obligations related to the provision of open access to peer-reviewed publications.
>
> In a nutshell, you must ensure open access (free, online access for any user) to all peer-reviewed publications relating to your results.
>
> You can find further explanations in the IMI2 JU Annotated Model Grant Agreement.

As the decision tree in the graph shows, your first decision should be whether you want to commercially exploit the results of your research or if you want to disseminate them.

In the first case, you will decide to protect your IPR, and in the second case, you should go down the open access route.
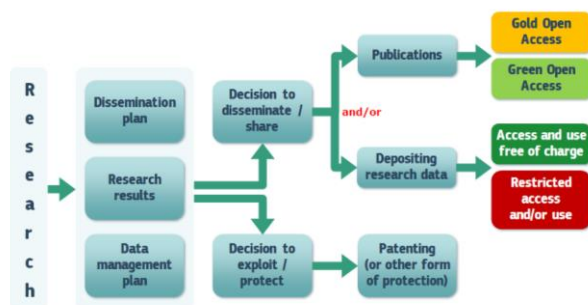
Source: European Commission

If you chose to publish your results in a peer-reviewed publication as a means of dissemination, the open access to publications mandate comprises two steps:

1. depositing publications in repositories (online archive);
2. providing open access to publications and related bibliographic metadata.

Step 1. Depositing publications in repositories (online archive)

- You need to provide access to you publication in a 'machine-readable' format – either to the published version or to the final peer-reviewed manuscript accepted for publication. Scanned versions of printed publications do not fulfil this requirement.

- Depositing is mandatory regardless of the open access mode selected. It must be done as soon as possible and at the latest upon publication.

- You are free to deposit your peer-reviewed publications in those repositories (either of institutional or disciplinary nature) most appropriate for your subject and publication. See below some suggested resources.

Step 2. Providing open access to publications and related bibliographic metadata

- Both open access routes are equally valid, although a mixed strategy of green/gold open access is highly recommended. The article should be made public immediately if you chose 'gold open access' or within 6 months if you chose 'green open access'.

- To monitor any embargo periods, you must provide the publication date and embargo period.

- You can claim the cost of article processing charges since there are eligible costs, provided they were incurred during the duration of the project.

- The European Commission guidelines encourage authors to retain their copyright and grant adequate licences to publishers. Creative Commons offers useful licensing solutions (e.g. CC BY). This type of licence is a good legal tool for providing open access in its broadest sense.

- The bibliographic metadata must be in a standard format and must include all of the following:

  - the terms 'Innovative Medicines Initiative 2 Joint Undertaking', 'European Union (EU)', 'Horizon 2020', and [insert names of the JU members other than the EU] [and [insert name(s) of the associated partner(s)]]';

  - the name of the action, acronym and grant number;

  - the publication date, and length of embargo period if applicable, and;

  - a persistent identifier.

In addition, please consider the following points.

- You must continuously report all publications related to your project via the Participants Portal in one of the following three ways:

  1. by registering the publication in the Open Access Infrastructure for Research in Europe (OpenAIRE). Each project has its own page on OpenAIRE, featuring project information, related project publications and data sets, and a statistics section;

  2. by encoding the publication's Digital Object Identifier (DOI), or;

  3. by entering manually the full reference data.

- You should also report joint publications coming from private/public project participants with public/private organisations outside the consortium if they are related to the funded project.

- Make sure that all your publications consistently specify that the project has received funding from IMI, and display the IMI JU and EFPIA (and associated partners) logos and the European Union emblem. According to Art. 29.4 of the IMI2 JU Grant Agreement, the formal acknowledgement of IMI's support should read:

  'This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No [Number]. The JU receives support from the European Union's Horizon 2020 research and innovation programme and [insert names of the JU members other than the EU] [and [insert names of the Associated Partners]].'

  The reference to JU funding and support from the EU and JU members (and associated partners) must be included even when the dissemination of the project result is combined with other data.

- Remember to include a disclaimer when disseminating a project result, clearly stating that it reflects only the author's view and that the JU is not responsible for any use that may be made of the information it contains.

- Check whether the list of your project publications in OpenAIRE is complete, and that all are open access. Please notify OpenAIRE of articles not listed.

Along with peer-reviewed publications, IMI encourages you to provide open access to other types of scientific publications such as monographs, conference proceedings or grey literature.

Useful resources

Lost in the current heterogeneous landscape of repositories? Below you will find some resources to help you identify repositories most relevant for you.

For publisher policies

RoMEO is a searchable database of publisher's policies regarding the self-archiving of journal articles on the web and in open access repositories. RoMEO's own database covers over 22 000 journals and it is supplemented by feeds from the British Library's *Zetoc* service, *DOAJ*, and *Entrez*. Each entry provides a summary of the publisher's policy, including what version of an article can be deposited, where it can be deposited, and any conditions that are attached to that deposit.

Directories of open access publications repositories

OpenAIRE is an EU-funded initiative that acts as an aggregator of publications that have been deposited to institutional repositories (also harvesting from several subject-specific repositories such as Europe PMC and arXiv), and intends to link the aggregated research publications to the accompanying research and project information, data sets and author information.

OpenDOAR is a directory of open access publication repositories. It enables the identification, browsing and search for international repositories, based on a range of features, such as location, software or type of material held.

ROAR is a registry of open access publication repositories indexing the creation, location and growth of these repositories and their contents. ROAR works on self-registration only.

The Directory of Open Access Journals is a service that indexes high quality, peer reviewed open access research journals, periodicals and their articles' metadata with more than 12 000 journals covered. The Directory aims to be comprehensive and cover all open access academic journals that use an appropriate quality control system. It is not limited to particular languages, geographical region, or subject areas.

Repositories

For life sciences articles, books, patents and clinical guidelines the recommended repository is Europe PubMed Central. It provides links to relevant records in databases such as Uniprot, European Nucleotide Archive (ENA), Protein Data Bank Europe (PDBE) and BioStudies.

Zenodo is an EC-co-funded multi-disciplinary repository that allows researchers to deposit both publications and data, while providing tools to link them.

What are the requirements to manage research data?

IMI supports the 'FAIR data principles', i.e. *findable, accessible, interoperable and re-usable.* This means that research data should be:

- identified in a persistent manner using community conventions, and described using sufficiently rich metadata;
- stored in such a way that they can be accessed by humans and machines;
- structured in such a way that they can be combined with other data sets;
- licensed or have terms-of-use that spell out how they can be used by others.

You are requested to provide information on how you are planning to manage research data during the life cycle of your project through the Data Management Plan and, if your project belongs to Call 11 onwards, through your participation in the Open Access to Research Data Pilot (ORDP).

Data Management Plan

A Data Management Plan (DMP) is a 'living' document outlining how research data collected or generated will be handled during and after a research project. The first version of the DMP should be submitted within the first 6 months of the project. You can find here the annotated Horizon 2020 DMP template for Health projects.

The DMP should gain substance as the project progresses. You should update it whenever significant changes occur, but at a minimum in line with project reviews.

Costs for data management are eligible for reimbursement for the duration of the grant agreement. To make an estimate of the cost associated with data management, the University of Utrecht compiled a Data Management Cost Guide.

Open Access to Research Data Pilot

Article 29.3 of the IMI2 JU Grant Agreement details the obligations related to the provision of open access to research data.

You can find further explanations in the IMI2 JU Annotated Model Grant Agreement.

Depending on under which IMI2 Call your project was awarded, different rules related to open access to research data apply.

- From Call 1 to 10, participation in the Open Access to Research Data Pilot was optional. If you did not opt-into the pilot at the time, you have the possibility to amend your grant agreement at any time during the project to request a partial or total opt-in, if you so wish.
- From Call 11 onwards, all IMI2 projects participate by default in the Horizon 2020 Open Research Data Pilot, covered by Article 29.3 of the IMI2 Grant Agreement.

Although we encourage you to remain part of the ORDP, you have the right to opt-out if necessary.

- When: at any stage, that is during the application phase during the grant agreement preparation phase and after the signature of the grant agreement.
- What: some or all of your data sets from the ORDP at any time.
- How: by providing via an amendment a written justification to the IMI2 JU Programme Office following a consortium decision. You would have to set out valid and specific reasons for the exclusion and take into account the scope and aim of your call topic, e.g. for intellectual property rights (IPR) concerns, privacy/data protection concerns, national security concern, if it would run against the main objective of the project or for other legitimate reasons.

The key principle to bear in mind is to be 'as open as possible, as closed as necessary'. If you plan to keep some data sets closed, you need to justify these decisions in your Data Management Plan.

Types of data covered by ORDP

The types of data covered by ORDP are as follows:

- the data (and metadata) needed to validate results in scientific publications.
- other curated and/or raw data (and metadata) specified in the DMP.

What are the requirements of the Open Research Data Pilot?

1. You must deposit the research data generated by your project, preferably in a subject specific repository, if available. For life sciences articles, books, patents and clinical guidelines the recommended repository is Europe PubMed Central. Alternatively, you can use the institutional repository at your host institution or a general-purpose repository such as Zenodo.
2. As far as possible, you must take measures to enable third parties to access, mine, exploit, reproduce and disseminate (free of charge for any user) this research data.

Useful resources

Directories of open access publications repositories

ELIXIR Deposition Database list compiles a list of recommended resources for the deposition of experimental data.

To help you identify the most relevant home for your data, re3data provides an extensive overview of research data depositories across all disciplines. See here a demonstration of searching for research data repositories using the Re3data directory.

FAIRsharing is a web-based, searchable portal containing both in-house and crowdsourced manually curated descriptions of standards, databases and data policies relevant to the life sciences. It includes the eTRIKS Standards Starter Pack, which reflects the set of terminologies, data formats and databases selected by the IMI-funded eTRIKS project, to provide guidance and recommendations for data harmonisation in the field of translational research.

Make sure you check:

- if the repository matches your particular data needs (e.g. formats accepted, mixture of open and restricted access);

- whether the data will remain findable (via the use of a persistent and globally unique identifier for sustainable citations and to links to particular researchers and grants), as well as accessible and re-usable;

- whether the repository specifies a license governing access and re-usability of the data;

- whether the depository stores the data in a safe way. Look for the certification as a 'Trustworthy Digital Repository' with an explicit ambition to keep the data available in long term[1].

IMI catalogue of project tools

We have started building a catalogue of accessible tools generated by our projects. Send us a link to the research resource/tool you would like to make available to the research community together with a very short description. Please also indicate the access conditions to the resource and we will publish it on the IMI website.

Useful links

The following resources prepared by the European Commission provide further guidance on open access to scientific publications and research data.

- H2020 online manual open-access and dissemination
- Guidelines to the Rules on Open Access to Scientific Publications and Open Access to Research Data
- European IPR Helpdesk factsheet 'Publishing vs. patenting'.
- H2020 Programme Guidelines on FAIR Data Management in Horizon 2020

Training and support

OpenAIRE has local representatives in all EU countries: the National Open Access Desks, or NOADs, that can be contacted via the helpdesk system at www.openaire.eu. It also provides webinars and workshops on the DMP and open access.

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[1] The following organisations carry out a certification of data depositories: **Core Trust Seal** (this list includes depositories certified by the Data Seal of Approval and accredited by the World Data System): https://www.coretrustseal.org/why-certification/certified-repositories/,**Nestor seal** (DIN-Norm 31644): http://www.dnb.de/Subsites/nestor/EN/Siegel/siegel.html, **ISO 16363 certified depositories**: http://www.iso16363.org/iso-certification/certified-clients/