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 various open access repositories for publications and research data registries, and information on where to get help.

History of changes – October 2021:

- Alignment with Call 21 “Development of therapeutics and diagnostics combatting coronavirus infections” Open Access to research data requirements;
- Inclusion of specific IMI project assets to facilitate the fairification of data;
- Inclusion of specific resources for projects working on COVID-19, SARS-CoV-2 and related topics;
- Inclusion of an extensive list of European Research Infrastructures.

Peer-reviewed scientific research articles

What are the rules regarding open access to publications?

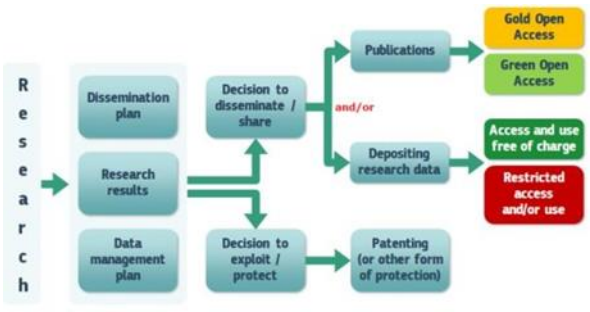
Article 29.2 of the IMI2 JU Grant Agreement details the obligations related to the provision of open access to peer-reviewed publications.

In a nutshell, you must ensure open access (free online access for any user) to all peer-reviewed publications relating to your results. In addition, you must include an acknowledgement of funding and a disclaimer clearly stating that the publication reflects only the author's view.

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 to disseminate them.

If you wish to commercially exploit your results, you will decide to protect your intellectual property rights (IPR). Otherwise, you should go down the open access route.



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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 your publication in a 'machine-readable' format. Access must be provided 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 the repositories (either of institutional or disciplinary nature) that are most appropriate for your subject and publication. See further down for 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 six 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 lifetime of the project.
- The European Commission guidelines encourage authors to retain their copyright and grant adequate licenses to publishers. Creative Commons offers useful licensing solutions (e.g. CC BY)[1]. This type of license 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)', 'Horizon2020' and 'EFPIA'. Also, if any, the name(s) of the associated partner(s) in the project;
    - 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 manually entering the full reference data.

[1] For instance, the Creative Commons Attribution 4.0 International Public License (CC BY 4.0) or a Creative Commons Public Domain Dedication (CC0 1.0) or a license with rights equivalent to the above.

- 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 IMI2 JU, and display the IMI2 JU and EFPIA (and Associated Partners, if any) logos and the EU emblem. According to Art. 29.4 of the IMI2 JU Grant Agreement, the formal acknowledgement of IMI2 JU'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 EFPIA [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 any articles that are not listed.
- Along with peer-reviewed publications, IMI2 JU 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 the repositories that are 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 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 is intended 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 that indexes 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 to 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 science 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 NucleotideArchive (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.

Research Data

FAIR data principles

IMI2 JU supports the FAIR 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.

FAIR principles do not impose openness on digital assets, but rather refer to the ways in which the digital assets are curated. For example, data can be fully in line with the FAIR principles even when access is restricted.

IMI project assets and FAIR-applied examples

FAIRsharing is a web-based, searchable portal containing manually curated descriptions of standards, databases and data policies in all disciplines, including life and medical sciences. It includes the IMI 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.

Created by IMI-funded data management professionals in the FAIRplus project, the FAIR Cookbook is an online resource for the life sciences with recipes that help you to make and keep data FAIR. It is presented as a collection of recipes on the FAIR components, the infrastructure needed, and a set of applied examples.

The FAIR Cookbook is a resource for 'FAIR doers', and recipes are added and improved, collaboratively and iteratively, in an open manner. See the links below for IMI projects applied examples:

1. Making omics data matrices FAIR
2. eTox - toxicity datasets
3. nd4bb - chemical activities datasets
4. Oncotrack - clinical cohort datasets
5. ReSOLUTE - transcriptomics datasets

What are the requirements for managing research data?

You are required to provide information on how you are planning to manage research data during the lifecycle 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). If you project belongs to IMI2 Call 21, you are subject to specific legal obligations.

1. Data Management Plan

A Data Management Plan (DMP) is a 'living' document that outlines 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 six 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 it should be 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.

To help you further with your DMP:

- ARGOS is an open, extendible service that simplifies the management, validation, monitoring and maintenance of Data Management Plans. It allows actors (researchers, managers, supervisors, etc.) to create actionable DMPs that may be freely exchanged among infrastructures for carrying out specific aspects of the data management process in accordance with the intentions and commitment of data owners.
- The Data Stewardship Wizard, developed by ELIXIR, is a tool for data management planning in which each data-related decision in a project acts to optimise the Findability, Accessibility, Interoperability and/or Reusability of the data.

2. Open Access to Research Data. Different rules for different IMI2 Calls

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 which IMI2 Call your project was awarded under, 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 of amending 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, with the option to opt out if duly justified.
- **For Call 21 funded projects,** you must deposit the digital research data generated in the action in a research data repository and take measures to make it possible for any third party to access, mine, exploit, reproduce and disseminate the data free of charge, at the latest within 30 days after

it has been generated. Exceptionally, if agreed by the IMI2 JU or the European Commission, your open access obligations can be replaced by special access rights to specific third parties that would need your research data to address a public health emergency.

Although we encourage you to remain part of the ORDP, you have the right to opt out if necessary (unless your project has been funded under IMI2 Call 21), under the following conditions:

- 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 concerns, 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.

Open access for projects working on COVID-19 and related topics

To address the outbreak of the coronavirus SARS-CoV-2, which causes COVID-19, there is a need to ensure that relevant research findings and data are shared as rapidly, openly and effectively as possible. Two paths apply:

- For Call 21, beneficiaries are subject to Article 29.3 (option 1c) of the IMI2 JU Model Grant Agreement. This means that you must make publicly available through open access the project´s quality-controlled research data and associated metadata that (i) has been generated in the course of the action and (ii) is relevant for the response to the public health emergency. You must do so at the latest within 30 days after the research data has been generated.

  As an exception, if agreed by the IMI2 JU or the European Commission, you can replace the open access obligations by special access rights for third parties who are in need of your research data to address a public health emergency.

  However, (i) this exceptional procedure must be described in the project DMP, and (ii) you are expected to share quality-controlled data in accordance with FAIR principles. We recommend for this purpose the use of harmonised protocols in collaboration with other actors.

- All IMI projects outside Call 21 with research outputs that - in any way - may be used to advance research on COVID-19 and topics related to the pandemic, are encouraged to provide immediate open access to relevant publications, data and any other output possible, in line with the specific guidance prepared by the European Commission (Horizon 2020 projects working on COVID-19, SARS-CoV-2, and related topics), thereby going beyond the current open access requirements of IMI2 as set out in the grant agreement.

Types of data covered by the Open Research Data Pilot

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 described in your DMP in a repository - 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.

In addition, for COVID-19 and pandemic-related research, the European Commission has partnered with the European Bioinformatics Institute (EBI) of the European Molecular Biology Laboratory (EMBL) and other partners to deliver a European COVID-19 Data Portal. The platform provides an open, trusted, and scalable European and global environment where researchers can store and share research datasets, starting initially with DNA sequences, protein structures, and other omics data, and subsequently expanding to include data from pre-clinical research and clinical trials, as well as epidemiological data.

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.

Directories of open access repositories

ELIXIR Deposition Database list compiles a list of recommended resources for the depositing 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. See also the Core Trust Seal certified repositories.

Make sure you check

- whether 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 certification that identifies the repository as a 'TrustworthyDigital Repository' with an explicit ambition to keep the data available in the long term[2].

Requirements for publishing results from clinical trials in the EU Clinical Trials Database

Transparency and public access to clinical trial results, whether positive or negative, are fundamental for the protection and promotion of public health. It assures trial subjects that their voluntary participation in clinical trials is useful and that the results have been collated and reported for the benefit of all.

In addition, for medicines that are placed on the market or used in further clinical trials, it allows patients and healthcare professionals, or any other citizen, to find out more information about medicines they might be taking or prescribing.

It is the responsibility of sponsors to ensure that the protocol information and results of all clinical trials is submitted in EudraCT; this information is publicly available through the EU Clinical Trials Register (EU CTR).

Since July 2014, sponsors are required to post results within one year of the end of a clinical trial (or six months for a paediatric trial). This information is also shared with the World Health Organization's International Clinical Trials Registry Platform (ICTRP), of which EU CTR is a primary registry.

[2] The following organisations carry out a certification of data depositories: **Core Trust Seal** (this list includes depositories certified bythe 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/

The following materials and tools can provide you with information and guidance on reporting trial results to EudraCT:

- Results information documentation
- Technical guidelines on the format of the data fields of results-related information on clinical trials.

Additional useful tools and resources

1. European Research Infrastructures

Whenever appropriate, you are encouraged to link with and make use of existing European Research Infrastructures such as:

- The European distributed infrastructure for life-science information, ELIXIR
- The European research infrastructure for bio-banking BBMRI-ERIC
- The European research infrastructure for multinational clinical research ECRIN-ERIC
- The European research infrastructure for translational medicine EATRIS-ERIC
- The European research infrastructure for structural biology INSTRUCT-ERIC
- The European research infrastructure for biological and biomedical imaging Euro- BioImaging
- The European research infrastructure for highly infectious emerging and remerging diseases ERINHA
- The European Virus Archive EVAg
- The vaccine research and development infrastructure network TRANSVAC.

2. Training and support

The EHDEN Academy, which stems from the IMI funded EDHEN project, is an online educational resource for anyone working in the domain of real-world data and real-world evidence - for all those who generate and utilise data, work technically with it, and are involved in methodological development and the use of standarised analytical tools.

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.

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
- H2020 Programme Guidelines on FAIR Data Management in Horizon 2020
- Horizon 2020 projects working on COVID-19, SARS-CoV-2, and related topics: Guidelines for open access to publications, data and other research outputs,. This document includes very detailed guidance and an extensive list of specific resources for projects working on COVID-19, SARS-CoV-2 and related topics.
- Guidelines on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak adopted on April 21 2020 by the European Data Protection Board.

See also: European IPR Helpdesk factsheet ‘Publishing vs. patenting’.