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INTERNAZIONALE SALUTE

Piano di Formazione Nazionale

Modulo 4 - “Laboratorio per scrivere un progetto di ricerca clinica in Horizon Europe”

Annex Clinical Trials

21/09/2023

FIORELLA GUADAGNI
IRCSS SAN RAFFAELE

If your application includes clinical trials, please note that the European Union (EU) pharmaceutical legislation known as the Clinical Trials Regulation No 536/2014 entered into application on 31 January 2022, repealing the Clinical Trials Directive (EC) No. 2001/20/EC and national implementing legislation in the EU Member States, which regulated clinical trials in the EU until the Regulation's entry into application.

As a result, from 31 January 2023, all initial clinical trial applications in the European Union (EU) must be submitted via the Clinical Trials Information System (CTIS). CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data.

Transition period: The Clinical Trials Regulation foresees a three-year transition period, from 2022 to 2025. By 31 January 2025, all ongoing trials that were approved under the Clinical Trials Directive will be governed by the new Regulation and will have to be transitioned to CTIS.

NEWS

Clinical Trials Information System mandatory in EU

Use of the Clinical Trials Information System is now mandatory for new clinical trial applications in the EU, says the European Medicines Agency.

From 31 January 2023, all initial clinical trial applications in the European Union (EU) must be submitted via the Clinical Trials Information System (CTIS).

According to the European Medicines Agency (EMA), CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data.

This follows a one-year transition, during which sponsors could choose whether to apply for a new clinical trial in the EU/EEA in line with the Clinical Trials Directive or under the new Clinical Trials Regulation (CTR), which entered into application on 31 January 2022.

https://www.europeanpharmaceuticalreview.com/news/179088/clinical-trials-information-system-mandatory-in-eu/

Clinical Trials Information System

The future of clinical trial applications in the EU

The new regulation streamlines the processes for the application and supervision of clinical trials, and their public registration. All clinical trial sponsors will now use the same system and follow the same procedures to apply for the authorisation of a clinical trial. Location and which NCA or national ethics committee sponsors are dealing with will not be taken into consideration.

The CTR foresees a three-year transition period, from 2022 to 2025. In the next two years, by 31 January 2025, all ongoing trials approved under the Clinical Trials Directive will be governed by the new Regulation and will have to be transitioned to CTIS.

Ultimately, the application of the CTR strengthens Europe's position as an attractive location for clinical research, the EMA asserted.

https://www.europeanpharmaceuticalreview.com/news/179088/clinical-trials-information-system-mandatory-in-eu/

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Development of the Clinical Trials Information System

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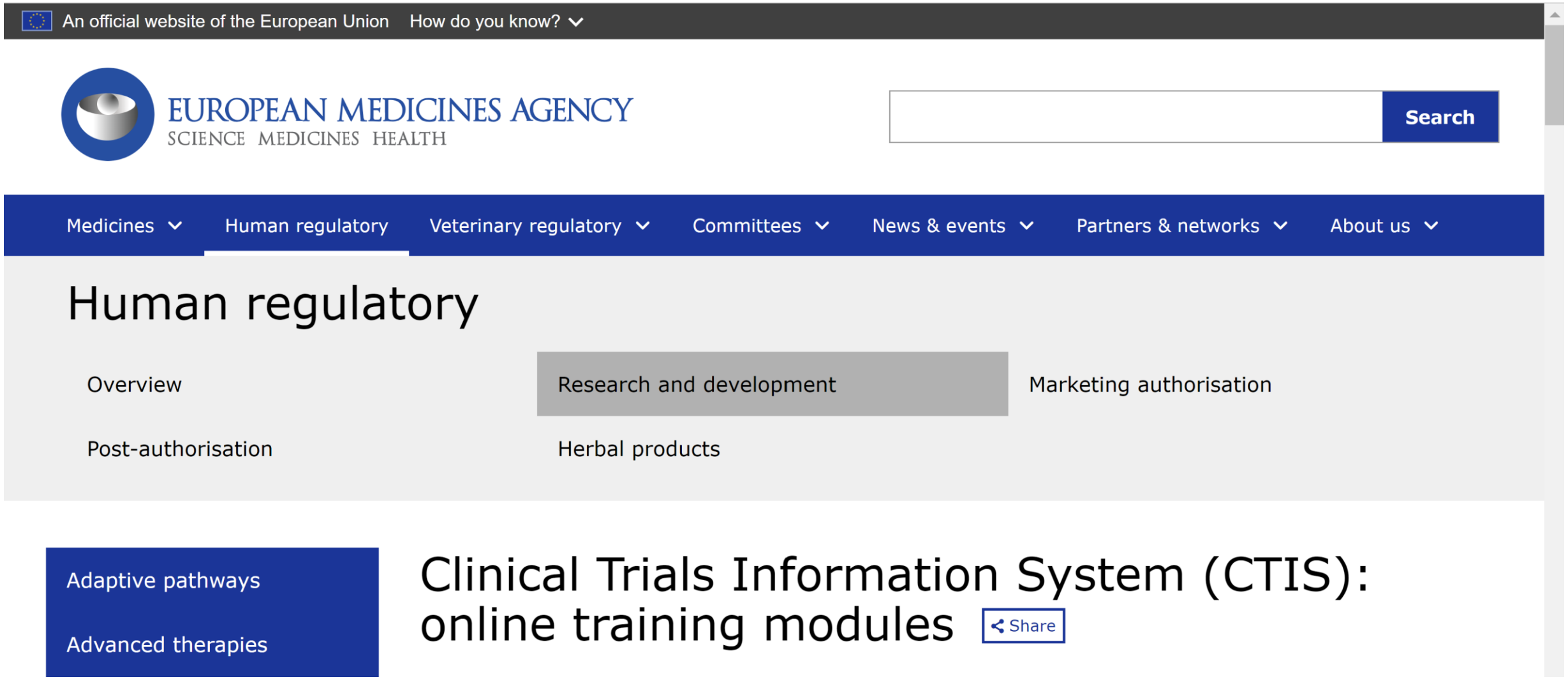
The European Union (EU) Member States and European Economic Area (EEA) countries, European Commission and European Medicines Agency (EMA) launched the Clinical Trials Information System (CTIS) on 31 January 2022.

At the same time, EMA launched a searchable public website enabling anybody to view information on clinical trials in the EU and EEA contained in the CTIS database.

CTIS serves to implement EU pharmaceutical law set out in the Clinical Trials Regulation (Regulation (EU) No 536/2014).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Introduction to CTIS

Expand section | Collapse section

- Introduction to the Clinical Trials Regulation (Regulation (EU) No 536/2014) (Module 01)
- High-level overview of CTIS workspaces and common system functionalities (Module 02)

27.5.2014 EN Official Journal of the European Union L 158/1

I

(Legislative acts)

REGULATIONS

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

This Regulation applies to all clinical trials conducted in the Union.

It does not apply to non-interventional studies.

Article 2

Definitions

1. For the purposes of this Regulation, the definitions of 'medicinal product', 'radiopharmaceutical', 'adverse reaction', 'serious adverse reaction', 'immediate packaging' and 'outer packaging' set out in points (2), (6), (11), (12), (23) and (24), respectively, of Article 1 of Directive 2001/83/EC apply.

2. For the purposes of this Regulation, the following definitions also apply:

(1) 'Clinical study' means any investigation in relation to humans intended:

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;

(b) to identify any adverse reactions to one or more medicinal products; or

(c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products;

with the objective of ascertaining the safety and/or efficacy of those medicinal products;

(2) 'Clinical trial' means a clinical study which fulfils any of the following conditions:

(a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned;

(b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or

(c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

Article 3

General principle

A clinical trial may be conducted only if:

(a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests; and

(b) it is designed to generate reliable and robust data.

High safety standards and streamlined procedures for EU clinical trials

SUMMARY OF:

Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

WHAT IS THE AIM OF THE REGULATION?

- The regulation aims to simplify and speed up procedures authorising **clinical trials** to ensure that the European Union (EU) remains an attractive centre for clinical research. It also aims to foster multinational clinical trials conducted both by commercial and non-commercial entities to deliver innovative medicines to patients and improve treatments using existing medicines.
- It repeals Directive 2001/20/EC, but a transition period is in place until 31 January 2025 (see section '**From when does the regulation apply?**' below).

KEY POINTS

General principle

A clinical trial may be held only if:

- the **rights, safety, dignity and well-being of participants** are protected and prevail over all other interests; and
- it is designed to generate **reliable and robust data**.

Rules

1. Less bureaucracy ('red tape'). Sponsors of clinical trials will only need to submit a single application for approval irrespective of where in the EU the trial is to be held. There will be less red tape.

2. Shorter authorisation times. The timeline to authorise clinical trials is set at 60 days. If no decision is taken within this period, the trial may go ahead ('tacit approval'). Decisions on applications for substantial modifications of clinical trials must be taken within 49 days. Where no decision is issued, the authorisation is considered to be given.

3. Vulnerable groups. Applications for the authorisation of clinical trials must be assessed on the basis of appropriate expertise. Specific expertise must be used to assess clinical trials involving participants in emergency situations, minors, those who are incapacitated, pregnant and breast-feeding women and, where appropriate, certain other groups, such as older people or those suffering from rare and extremely rare diseases.

4. Ethical review. All trials are subject to scientific and ethical review. The ethical review must be performed by an ethics committee in accordance with the law of the EU Member State concerned. However, the procedures and the timelines for the ethical review must be compatible with the authorisation procedure stipulated by this regulation.

5. Informed consent. Prior to the trial, participants must be given clear information about their rights (including the right to withdraw); conditions, duration, nature, objectives, implications, risks and inconveniences of the trial; possible treatment alternatives; and the possible damage compensation system.

6. Publicly accessible EU database on clinical trials. The European Medicines Agency set up a database named Clinical Trial Information System containing information on all clinical trials held in the EU, whether successful or not.

7. Safety assessments. The cooperation between Member States in the assessment of safety information reinforces clinical trials in generating high quality data and improves the safety of current and future medicines on the EU market. An implementing act, Implementing Regulation (EU) 2022/20, sets out the rules for cooperation between Member States when assessing safety information reported in accordance with Regulation (EU) No 536/2014.

8. Member State inspections. Member States must appoint inspectors to supervise compliance with the regulation and ensure that those inspectors are adequately qualified and trained. Implementing Regulation (EU) 2017/556 sets out the detailed arrangements for good clinical practice inspection procedures.

FROM WHEN DOES THE REGULATION APPLY?

Regulation (EU) No 536/2014 has applied since 31 January 2022, 6 months after the publication of the notice referred to in Article 82(3) stating that an independent audit report verified that the EU portal and the EU database have achieved full functionality (see Decision (EU) 2021/1240). The existing legislation in the field (Directive 2001/20/EC) will be repealed following a 3-year transition period from that date.

BACKGROUND

The Commission's former good manufacturing practice directive has been repealed by the new Commission good manufacturing practice directive, Directive 2017/1572, on the date of entry into application of the regulation on clinical trials.

The guidelines for the application of clinical trials directive can be found in EudraLex, Volume 10.

For further information, see:

- Clinical trials (European Commission).

MAIN DOCUMENT

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, pp. 1–76).

Successive amendments to Regulation (EU) No 536/2014 have been incorporated into the original text. This consolidated version is of documentary value only.

RELATED DOCUMENTS

Commission Implementing Regulation (EU) 2022/20 of 7 January 2022 laying down rules for the application of Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards setting up the rules and procedures for the cooperation of the Member States in safety assessment of clinical trials (OJ L 5, 10.1.2022, pp. 14–25).

Commission Decision (EU) 2021/1240 of 13 July 2021 on the compliance of the EU portal and the EU database for clinical trials of medicinal products for human use with the requirements referred to in Article 82(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council (OJ L 275, 31.7.2021, pp. 1–2).

Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council (OJ L 80, 25.3.2017, pp. 7–13).

Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use OJ L 238, 16.9.2017, pp. 44–50)

Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections (OJ L 238, 16.9.2017, pp. 12–21).

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, pp. 34–44).

INFORMATION ON CLINICAL STUDIES

(For calls that involve clinical studies[1], project participants must add this document to the application and ***upload it as separate annex to the proposal part B in the Submission System.)***

Clinical studies have a number of methodological, operational and regulatory specificities. Information on these issues is crucial for evaluators to assess the scientific quality and operational feasibility of the proposal. The following set of section headings guide applicants to provide essential information on clinical studies in a standardised format.

[1] *Clinical study covers clinical studies/trials/investigations/cohorts and means, for the purpose of this document, any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).*

Applicability:

For **HE collaborative research and innovation:**

Single-stage and stage-2 proposals: The use of this template is mandatory for single-stage or stage-2 proposals, if the application includes a clinicalstudy[1]AND it concerns a topic including clinical studies[1].
For these topics, you will have the possibility to **upload the completed template as a separate part of your application in the submission system.**

Stage-1 proposals: In the limited frame of a stage-1 proposal, not all methodological details of clinical studies can be fully elaborated. Depending on the characteristics of the study, however, key aspects of clinical study have to be convincingly addressed already at stage 1. **This template cannot be uploaded as a separate document at stage 1, but relevant aspects of this information should be integrated in part B of the stage 1 proposal template.**

[1] *For proposals containing clinical studies submitted to topics not foreseeing clinical studies, you may use the section headings of this template as an orientation and provide the related information in sections B.1 and B.3 of the proposal, if the submission system does not provide the possibility to upload the template.*

[1] If the proposal contains more than one clinical study, each study should be described separately, e.g. study A, study B, etc.

For each[1] clinical study performed within the scope of the proposal, essential information according to the below structure **should be provided and compiled into one single document per proposal**. Each section must be addressed briefly and concisely. In case one or more sections do not apply to a particular study, please provide a short explanation.

When the requested information is currently not available (e.g. a clinical study is planned for a later stage of the project and it will be based on or influenced by future results of other studies), the source and the collection of the relevant input should be described.
Information provided in this template does not need to be repeated elsewhere in the proposal but can be referred to.

There are no page limitations for this template, but explanations should be as concise as possible.

[1] *If the proposal contains more than one clinical study, each study should be described separately, e.g. study A, study B, etc.*

Information **outside the scope** of this template will not be taken into account in the proposal evaluation.

No other chapters or annexes (containing e.g. complete study protocols) can be added to this template.

Section headings should not be changed.

Ethics considerations have to be addressed in the appropriate section of the proposal.

Similarly, **risks and mitigation measures** have to be addressed in the respective section of the proposal (part B.3.1 and table 3.1e) and not in this template!

The below three **mandatory deliverables** apply to each clinical study included in the proposal:

1. Study initiation package (before enrolment of the first study participant) including:

   - Registration number of the clinical study in a registry meeting WHO Registry criteria[4] (see also references given in subheading 1.1 of this template)
   - Final version of study protocol as approved by the regulator(s) / ethics committee(s)
   - Regulatory and ethics (if applicable, institutional) approvals required for the enrolment of the first study participant (In case of multicentre clinical studies, submission of approvals for the first clinical site is sufficient.)

2. Midterm recruitment report

   This report is due when 50% of the study population is recruited. The report shall include an overview of the number of recruited participants by clinical sites, any problems in recruitment and, if applicable, a detailed description of implemented and planned measures to compensate for any incurred delays.

3. Report on the status of posting results

Irrespective of the successful completion of the clinical study, summary results must be posted in the applicable registry/ies (where the study was registered) even if the timing of posting of results falls outside of the grant period. The report is to be scheduled for the time results posting is expected or for the last months of the project, whichever comes earlier.

1 Description of the clinical study

1.1 Title, acronym, unique identifier (e.g. EudraCT Number[5], or identifier from ISCRTN[6], ClinicalTrials.gov[7] if available) of the clinical study

[insert text]

1.2 Study rationale

Please provide the overall rationale for conducting the proposed study.

[insert text]

1.2.1 Extent and evaluation of current knowledge directly linked to the scientific question(s) to be answered by the clinical study

[insert text]

1.2.1.1 Outcomes (efficacy, safety) of completed and number of ongoing clinical studies utilising the same intervention in the same indication (including review of public registers)

[insert text]

1.2.1.2 Level of evidence related to the mechanism of action of the intervention in the planned clinical study population

[insert text]

1.3 Objective(s) of the clinical study

Please differentiate between primary and secondary objective(s)

5 Please note that from 31.1.2023 all applications for clinical trials in the EU will need to be submitted through the Clinical Trials Information System (CTIS) as per the Clinical Trials Regulation (536/2014): https://euclinicaltrials.eu/

1.4 Characteristics of the study population (size, age group, sex distribution, inclusion and exclusion criteria; all items with justification!)

[insert text]

1.4.1 Details on sample size and power calculation

[insert text]

1.5 Design of the clinical study (controlled / uncontrolled; randomised; open / blinded; parallel group / cross over / other; please justify the appropriateness of the selected design)

[insert text]

1.6 Type of intervention (medicinal product / advanced therapy medicinal product / medical device / in vitro diagnostic medical device / surgical or other invasive procedure / other medical intervention, including, e.g., counselling)

[insert text]

1.7 Description and timing of study procedures

Please provide an overview, preferably in a tabular format, about the schedule of study procedures. Please give a simple statement on how long individual patients or healthy volunteers participate in the clinical study.

[insert text]

2 Preparedness status

2.1 Development of the clinical study protocol

Please describe how the below aspects have been or will be addressed in developing the clinical study protocol (if applicable):

2.1.1 Scientific advice from regulatory and health technology assessment bodies

[insert text]

2.1.2 Clinical efficacy, safety, and methodological guidelines (including guidelines on statistics)

[insert text]

2.1.3 Involvement of citizens / patients, carers in drawing up the clinical study protocol

[insert text]

2.2 Regulatory intelligence to ensure timely regulatory approval and ethics clearance of the clinical study in all jurisdictions where its implementation is planned

Please provide information on the following regulatory and ethics aspects:

2.2.1 How the consortium will ensure access to regulatory expertise necessary to get advice on, and management of, regulatory affairs activities in all concerned jurisdictions?

[insert text]

2.2.2 How the consortium will ensure access to ethics expertise necessary to get advice on current proceedings and documentation requirements of all concerned ethics committees?

2.3 How the scientific and operational governance of the clinical study will be ensured?

2.3.1 Please give details about the sponsor(s) (name, type of entity, seat or country of residence).

[insert text]

2.3.2 Please describe the composition, the role and the functioning of the planned board(s), governing bodies.

[insert text]

3 Operational feasibility

3.1 Please describe how the availability of the intervention(s) (including comparators) is secured throughout the entire implementation phase (give details on manufacturing, packaging / labelling operations, storage, logistical, import/export issues, etc.)

[insert text]

3.2 Please describe how the study population will be recruited

Please give details on the recruitment strategy, monitoring of progress and potential mitigation measures

3.2.1 How many clinical sites will contribute to the recruitment of the study population in which countries? Are these clinical sites part of an established clinical trial network? Please also describe the selection criteria of the clinical sites.

[insert text]

3.2.2 Will recruitment of the study population be of competitive nature between the clinical sites? (Please describe how underperformance of individual clinical sites in recruitment will be managed.)

[insert text]

3.2.3 What evidence supports the ability of the individual clinical sites to recruit the required number of study participants within the planned timeline (e.g. documented performance in previous clinical studies of similar complexity targeting very similar study population)?

[insert text]

3.3 Please describe what additional supply (e.g. an electronic device for remote data capture, a specific instrument for administering the investigational product, etc.) is necessary to carry out the required study procedures and how this supply will be made available to the clinical sites

[insert text]

3.4 Please provide plans on data management aspects (data standards, type of data capture, verification of data, central data collection, cleaning, analysis, reporting, security)

[insert text]

3.5 Please give details on how reporting obligations (regarding study initiation, safety of study participants, ethical concerns, quality issues, integrity of data, study results) to regulatory bodies and ethics committees will be met.

3.6 Please list all items of the sponsor's responsibilities (e.g. monitoring clinical sites, meeting regulatory obligations, data management, etc.) that will be supported by entities that are not part of the sponsor's organisation. Please describe how the sponsor will ensure oversight of these activities.

[insert text]

3.7 What are the plans for major study milestones and what evidence supports its feasibility?

Please describe a realistic plan (based on prior experience) detailing the time necessary for (i) compiling the required regulatory and ethics submission package, (ii) receipt of regulatory and ethics approval, (iii) initiation of clinical site(s), (iv) completion of recruitment of the study population, (v) final assessment of all study participants, (vi) analysis and reporting of the study results.

[insert text]

ANNEX CLINICAL TRIALS

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Modulo 4 - “Laboratorio per scrivere un progetto di ricerca clinica in Horizon Europe”

Open Science, Open Access, Open Data, DMP, Ethics and GDPR

29/06/2023

FIORELLA GUADAGNI
IRCSS SAN RAFFAELE

The Partnership should align with EU-wide initiatives on open access and FAIR data[222].

In the context of the work programme 2023-2024 of cluster 1 'Health', FAIR data are data which meet principles of findability, accessibility, interoperability, and reusability. Data can include exploitation of information and data from European data infrastructures and programmes such as Copernicus, European Space Agency and the GEO initiative. For further details, see the FAIR principles website [13], the FAIR cookbook [14] and the guides for researchers on how to make your data FAIR.[15]


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FAIR Principles

In 2016, the '**FAIR Guiding Principles for scientific data management and stewardship'** were published in *Scientific Data*. The authors intended to provide guidelines to improve the **F**indability, **A**ccessibility, **I**nteroperability, and **R**euse of digital assets. The principles emphasise machine-actionability (i.e., the capacity of computational systems to find, access, interoperate, and reuse data with none or minimal human intervention) because humans increasingly rely on computational support to deal with data as a result of the increase in volume, complexity, and creation speed of data.

A practical "how to" guidance to go FAIR can be found in the **Three-point FAIRification Framework**.

- FAIR Principles
  - F1: (Meta) data are assigned globally unique and persistent identifiers
  - F2: Data are described with rich metadata
  - F3: Metadata clearly and explicitly include the identifier of the data they describe
  - F4: (Meta)data are registered or indexed in a searchable resource

Findable

The first step in (re)using data is to find them. Metadata and data should be easy to find for both humans and computers. Machine-readable metadata are essential for automatic discovery of datasets and services, so this is an essential component of the **FAIRification process**.

F1. (Meta)data are assigned a globally unique and persistent identifier

F2. Data are described with rich metadata (defined by R1 below)

F3. Metadata clearly and explicitly include the identifier of the data they describe

F4. (Meta)data are registered or indexed in a searchable resource

- FAIR Principles
  - F1: (Meta) data are assigned globally unique and persistent identifiers
  - F2: Data are described with rich metadata
  - F3: Metadata clearly and explicitly include the identifier of the data they describe
  - F4: (Meta)data are registered or indexed in a searchable resource

What does this mean?

Principle F1 is arguably the most important because it will be hard to achieve other aspects of FAIR without globally unique and persistent identifiers. Hence, compliance with F1 will already take you a long way towards publishing FAIR data (see **10 ways identifiers can help with data integration**).

Globally unique and persistent identifiers remove ambiguity in the meaning of your published data by assigning a unique identifier to every element of metadata and every concept/measurement in your dataset. In this context, identifiers consist of an internet link (e.g., a URL that resolves to a web page that defines the concept such as a particular **human protein**). Many data repositories will automatically generate globally unique and persistent identifiers to deposited datasets. Identifiers can help other people understand exactly what you mean, and they allow computers to interpret your data in a meaningful way (i.e., computers that are searching for your data or trying to automatically integrate them). Identifiers are essential to the human-machine interoperation that is key to the vision of **Open Science**. In addition, identifiers will help others to properly cite your work when reusing your data.

- FAIR Principles
  - F1: (Meta) data are assigned globally unique and persistent identifiers
  - F2: Data are described with rich metadata
  - F3: Metadata clearly and explicitly include the identifier of the data they describe
  - F4: (Meta)data are registered or indexed in a searchable resource

Examples of globally unique and persistent identifiers

- One particular person on planet earth has this globally unique and persistent identifier: **https://orcid.org/0000-0001-8888-635X**
- Here is an identifier that uniquely links to the results of a study estimating the FAIRness of different data repositories: **doi:10.4121/uuid:5146dd06-98e4-426c-9ae5-dc8fa65c549f**
- The human polycystin-1 protein has a globally unique and persistent identifier given by the UniProt database: **http://www.uniprot.org/uniprot/P98161**
- Polycystic kidney disease Type 1 has a globally unique and persistent identifier given by the OMIM database: **http://omim.org/entry/173900**
- The number 163483 refers to the undergraduate student ID of **Mark Wilkinson**, the NCBI gi number for a bovine protease, and a part number for a Singer sewing machine. Hence, this is a poor example of F1 !

- A1.1: The protocol is open, free and universally implementable
- A1.2: The protocol allows for an authentication and authorisation procedure where necessary
- A2: Metadata should be accessible even when the data is no longer available

Accessible

Once the user finds the required data, she/he/they need to know how they can be accessed, possibly including authentication and authorisation.

A1. (Meta)data are retrievable by their identifier using a standardised communications protocol

A1.1 The protocol is open, free, and universally implementable

A1.2 The protocol allows for an authentication and authorisation procedure, where necessary

A2. Metadata are accessible, even when the data are no longer available

- I1: (Meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation
- I2: (Meta)data use vocabularies that follow the FAIR principles
- I3: (Meta)data include qualified references to other (meta)data

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.

I1. (Meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.

I2. (Meta)data use vocabularies that follow FAIR principles

I3. (Meta)data include qualified references to other (meta)data

- R1: (Meta)data are richly described with a plurality of accurate and relevant attributes
- R1.1: (Meta)data are released with a clear and accessible data usage license
- R1.2: (Meta)data are associated with detailed provenance
- R1.3: (Meta)data meet domain-relevant community standards

Reusable

The ultimate goal of FAIR is to optimise the reuse of data. To achieve this, metadata and data should be well-described so that they can be replicated and/or combined in different settings.

R1. (Meta)data are richly described with a plurality of accurate and relevant attributes

R1.1. (Meta)data are released with a clear and accessible data usage license

R1.2. (Meta)data are associated with detailed provenance

R1.3. (Meta)data meet domain-relevant community standards

This topic aims to provide funding to adaptive clinical platform trials that may be implemented routinely outside of an epidemic or pandemic context, but that are designed to be ready for the timely assessment of novel diagnostics, therapeutics or vaccines in the face of an epidemic or pandemic.

Proposals should develop the wide range of elements needed to sustain multi-country adaptive platform trials, including the trial implementation capacity, laboratory analysis capacity, and a harmonised approach to the collection, storage, sharing and analysis of FAIR[163] data.

- The scientific and clinical community make wide use of newly established and where relevant open access databases and/or integrate them with existing infrastructures for storage and sharing of collected data according to FAIR [174] principles, thereby encouraging further use of the data.

The proposals should adhere to the FAIR data[243] principles and adopt data quality standards, GDPR-compliant data sharing, access and data integration procedures based on good practices developed by the European research infrastructures. In relation to the use and interpretation of data, special attention should be paid to systematically assess for bias and/or discrimination (sex/gender, ethnic, minority and vulnerable groups aspects). Proposals are invited to consider adopting recommendations for in-silico models construction and validation.[244]

The proposals should address all of the following activities:

- Identification of the barriers to health data integration and access as needed for the selected use cases, and of specific existing tools, technological solutions and coordination and standardisation agreements addressing those barriers. Issues to be covered include semantic ontologies, data standards and formats, data quality, data storage, management and access modalities, as well as enhanced findability of relevant datasets through improved metadata standards and data catalogues.

- New approaches to assemble large, easily findable and lawfully accessible high-quality datasets integrating multiple types of health data leading to improved clinical outcomes (e.g. new care solutions, personalised disease management, advanced diagnostic tools), taking into account data FAIRification[245] and inter-operability needs.

The proposals should address all of the following activities:

- New techniques, support tools, mechanisms and modalities to enable GDPR compliant access to sensitive personal data, including genomics, allowing for their re-use across borders and integration of different types of data relevant to human health. Legal and ethical frameworks should duly consider the heterogeneity in national and sectorial rules and procedures for data access and re-use.

- Data management approaches for cross-border distributed data storage and processing, enabling remote collaboration, electronic consent management, data provenance tracking, and scalability of data management resources, ensuring data privacy and security, and resulting in robust support to advanced, innovative clinical workflows. Joint data governance is expected to be piloted among several clinical centres across Europe.

The proposals should address all of the following activities:

- Development of a data analytics platform applying distributed learning and artificial intelligence approaches to query and aggregate efficiently, effectively and securely data from multiple sources for multiple use cases (groups of diseases), to monitor patients' health status, analyse causal inference, support diagnosis and health policymakers, and establish recommendations for patients and other stakeholders.

OpenAIRE Services Support Open Science In Europe About SIGN IN

Written on Jun 26, 2018.

In a press release the European Commission published its proposal for Horizon Europe, an ambitious €100 billion research and innovation programme that will succeed Horizon 2020.

Compared with Horizon 2020, it includes several new features including the establishment of a **European Innovation Council** (**EIC**) aimed at helping the EU become a frontrunner in market-creating innovation. **New missions** will also focus EU-wide research and innovation efforts to tackle global societal challenges and strengthen industrial competitiveness. The principle of **'open science'** will become the modus operandi of Horizon Europe, requiring open access to publications and data, supported by infrastructure across Europe. This will assist market uptake and increase the innovation potential of results generated by EU funding.. Horizon Europe will intensify its **openness to the world** by extending association possibilities to a wider range of third countries.

Furthermore, the strategic plan identifies European co-programmed and co-funded partnerships, as well as the EU missions and contains orientations regarding cross-cutting elements of Horizon Europe related to **areas for international cooperation**, and key **specific issues**, such as **gender, social sciences and humanities integration, key enabling technologies**, **ethics**, **open science practices**, as well as **social innovation** and the **EU taxonomy.**

5. Implement open science practices

Horizon Europe (HORIZON)

Programme Guide

Open science practices are addressed and evaluated under 'excellence' as they are considered a part of the methodology. However, open access in particular also results in the broad dissemination of knowledge and is relevant in the context of dissemination.

Providing open access to peer-reviewed publications is mandatory in Horizon Europe, when peer-reviewed publications are produced. Open access to generated research data is required under the premise 'as open as possible as closed as necessary', meaning that there can be exceptions to this. Data management plans are mandatory for all projects generating or reusing data. Additionally, we recommend that you provide open access to research outputs beyond publications and data and share them as early and openly as possible.

Please consult the relevant sections under 'open science' for guidance on all of the above and the Annotated Grant Agreement for further guidance regarding the requirements.

16. Open science

Open science in Horizon Europe

Open science is an approach based on open cooperative work and systematic sharing of knowledge and tools as early and widely as possible in the process. It has the potential to increase the quality and efficiency of research and accelerate the advancement of knowledge and innovation by sharing results, making them more reusable and improving their reproducibility. It entails the involvement of all relevant knowledge actors.

Horizon Europe moves beyond open access to open science for which it features a comprehensive policy implemented from the proposal stage to project reporting. The Horizon Europe Regulation sets the legal basis for the open science obligations and incentives that apply to Horizon Europe beneficiaries. The Annotated Grant Agreement provides guidance on how to comply with the open science obligations required in the Model Grant Agreement. **The present guide complements the information provided in the Annotated Grant Agreement, with a particular focus on the preparation of proposals.**

In Horizon Europe, open science practices are considered in the evaluation of proposals, under 'Excellence' and under the 'Quality and efficiency of implementation'.[16] There are mandatory open science practices, which are required for all projects through the Model Grant Agreement and/or through the work programme or call conditions, and recommended practices (all open science practices that are not mandatory). Recommended open science practices are incentivised through their the evaluation at the proposal stage. Proposers should be aware of both mandatory and recommended practices and integrate them into their proposals.

Open science practices include early and open sharing of research (for example through preregistration, registered reports, pre-prints, or crowd-sourcing); research output[17] management; measures to ensure reproducibility of research outputs; providing open access to research outputs (such as publications, data, software, models, algorithms, and workflows); participation in open peer-review; and involving all relevant knowledge actors including citizens, civil society and end users in the co-creation of R&I agendas and contents (such as citizen science).

These practices are explained and relevant resources provided in a separate section further below (open science practices and resources).

Mandatory open science practices

- Some open science practices are **mandatory for all beneficiaries per the grant agreement.** They concern:
    - open access to scientific publications under the conditions required by the grant agreement;
    - responsible management of research data in line with the FAIR principles of 'Findability', 'Accessibility', 'Interoperability' and 'Reusability', notably through the generalised use of data management plans, and open access to research data under the principle 'as open as possible, as closed as necessary', under the conditions required by the grant agreement;
    - information about the research outputs/tools/instruments needed to validate the conclusions of scientific publications or to validate/re-use research data;
    - digital or physical access to the results needed to validate the conclusions of scientific publications, unless exceptions apply;
    - in cases of public emergency, if requested by the granting authority, immediate open access to all research outputs under open licenses or, if exceptions apply, access under fair and reasonable conditions to legal entities that need the research outputs to address the public emergency[18].

These obligations are described in the Model Grant Agreement (Article 17) and detailed guidelines on complying with them are provided in the Annotated Grant Agreement (Article 17).

- Some open science practices are **mandatory per specific work programmes or call conditions,** which may provide for additional obligations to adhere to open science practices.

Recommended open science practices

These are open science practices beyond the mandatory ones, such as involving all relevant knowledge actors, including citizens, early and open sharing of research, output management beyond research data, open peer-review. This is a non-exhaustive list of practices that proposers are expected to adopt when possible and appropriate for their projects. Finally, certain work programme topics or call conditions may encourage specific additional open science practices.

Evaluation of open science practices

Open science practices are evaluated under the **'Excellence'** criterion (in particular under methodology) and under the '**Quality and efficiency of implementation'** award criterion. Proposers should address open science practices in the relevant section on open science under methodology[19].

Proposers will have to provide concrete information on **how** they plan to comply with the **mandatory open science** practices. Failure to sufficiently address this, will result in a lower evaluation score.

A clear explanation of how they will adopt **recommended practices**, as appropriate for their projects, will result in a higher evaluation score.

Under the 'Excellence' part of their proposals, in the section on methodology, proposers should describe how open science practices (mandatory and recommended, as appropriate) are implemented as an integral part of the methodology and show how their implementation is adapted to the nature of their work, therefore increasing the chances of the project delivering on its objectives. Information relevant to the specific area of the proposal should be provided in no more than one page. If open science practices are not applicable to the proposal, justifications should be provided sp that, if evaluators agree, open science will not be taken into consideration in the evaluation. Additionally, proposers generating or reusing data should outline in a maximum of one (additional) page their plans for data management.

Under 'Capacity of participants and consortium as a whole', proposers should describe how the consortium brings together the necessary disciplinary and inter-disciplinary knowledge. Proposers should show how this includes expertise and/or track record in open science practices, relevant to what is planned for the project. If justification has been provided that open science practices are not relevant for their projects, it is not necessary to demonstrate track record and expertise.

Finally, in **Part A of their proposals**, proposers are asked to list up to five relevant publications, widely used datasets or other achievements of consortium members that they consider significant for the action proposed. Open access is expected for publications, in particular journal articles, while datasets are expected to be FAIR and 'as open as possible, as closed as necessary'. If publications are not open access, proposers are strongly encouraged to deposit them retroactively in repositories and provide open access to them when possible. The significance of publications will not be

How should you address open science practices in your proposal?

Make sure to read the Annotated Grant Agreement on the mandatory open science practices in combination with this guide[20].

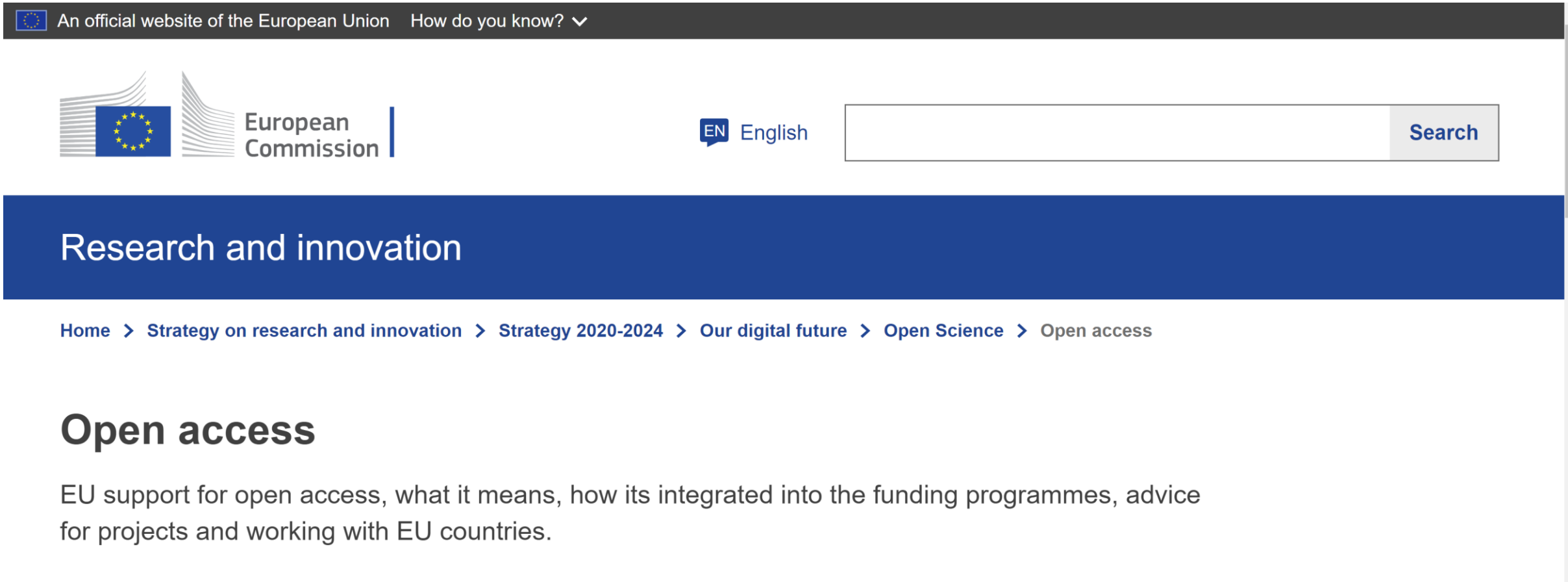
Early and open sharing: Provide specific information on whether and how you will implement early and open sharing and for which part of your expected output. For example, you may mention what type of early and open sharing is appropriate for your discipline and project, such as preprints or preregistration/registration reports, and which platforms you plan to use.

Research data management (RDM): RDM is mandatory in Horizon Europe for projects generating or reusing data. If you expect to generate or reuse data and/or other research outputs (except for publications), you are required to outline in a maximum of one page how these will be managed. Further details on this are provided in the proposal template in the relevant section on open science. A full data management plan (DMP) is not required at submission stage. For those work programmes that require the use of the European Open Science Cloud (EOSC) federated repositories, proposers should explicitly discuss the use of such repositories in their proposals. By exception, in cases of a public emergency and if the work programme requires so, you should submit a full DMP already with submission of proposals or at the latest by the signature of the grant agreement. A template for a DMP is provided under the reporting templates in the Funding & Tenders Portal Reference Documents page.

Open access: Offer specific information on how you will meet the open access requirements, that is deposition and immediate open access to publications and open access to data (the latter with some exceptions and within the deadlines set in the DMP) through a trusted repository, and under open licenses. You may elaborate on the (subscription-based or open access) publishing venues that you will use. You may also elaborate on the trusted repository/repositories through which open access to publications and research data will be provided (article 17). Open access to research data and other research outputs should be addressed in the section on research data management of your proposal. Research data should be open as a default, unless there are legitimate reasons for keeping them closed. On open access to data and the legitimate reasons for restricting access, consult the AGA (article 17).

As a general rule, open access to other research outputs such as software, models, algorithms, workflows, protocols, simulations, electronic notebooks and others is not required but strongly recommended. Access to 'physical' results like cell lines, biospecimens, compounds, materials, etc. is also strongly encouraged.

Open peer review: Anytime it is possible, you are invited to prefer open peer review for your publications over traditional ('blind' or 'closed') peer review. When the case, you should provide specific information regarding the publishing venues you envisage to make use of, and highlight the venues that would qualify as providing open peer review.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How do you know?
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Open access
EU support for open access, what it means, how its integrated into the funding programmes, advice for projects and working with EU countries.

EU support for open access

Open access is the practice of providing online access to scientific information that is free of charge to the user and is reusable.

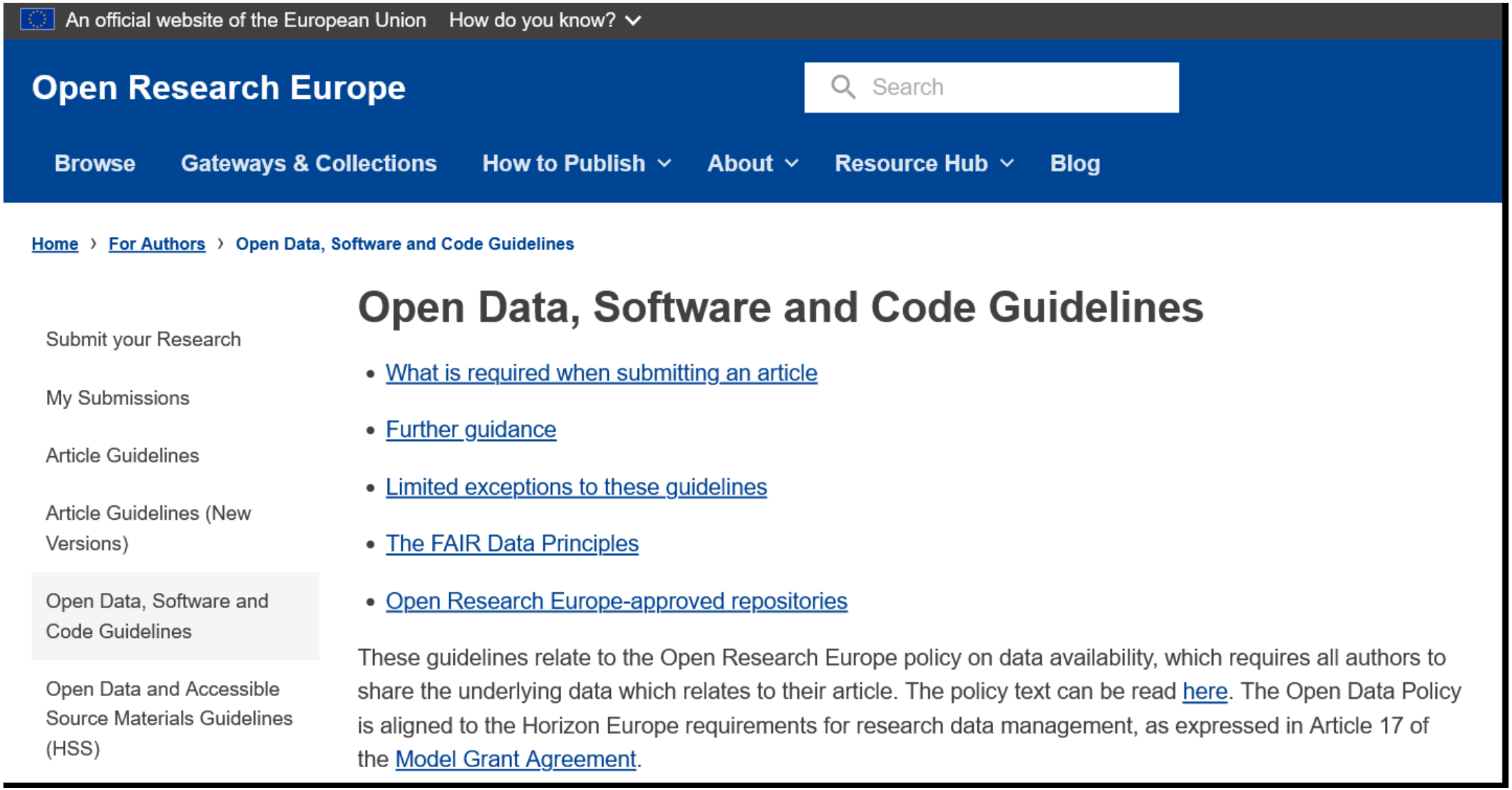
It is now widely recognised that making research results more accessible to all contributes to better and more efficient science, and to innovation in the public and private sectors

The Commission supports open access, specifically in its funding programmes.

Open access to scientific information in research and innovation refers to 2 main categories

- peer-reviewed scientific publications (primarily research articles published in academic journals)
- scientific research data: data underlying publications and/or other data (such as curated but unpublished datasets or raw data)

Background note EN ••• that provides more information on open access to scientific publications and research data at the EU and national level.



An official website of the European Union How do you know?

Open Research Europe

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Home › For Authors › Open Data, Software and Code Guidelines

Submit your Research

My Submissions

Article Guidelines

Article Guidelines (New Versions)

Open Data, Software and Code Guidelines

Open Data and Accessible Source Materials Guidelines (HSS)

Open Data, Software and Code Guidelines

- What is required when submitting an article
- Further guidance
- Limited exceptions to these guidelines
- The FAIR Data Principles
- Open Research Europe-approved repositories

These guidelines relate to the Open Research Europe policy on data availability, which requires all authors to share the underlying data which relates to their article. The policy text can be read here. The Open Data Policy is aligned to the Horizon Europe requirements for research data management, as expressed in Article 17 of the Model Grant Agreement.

All articles should include citations to trusted repositories that host the data underlying the results, together with any information needed to replicate, validate, and/or reuse the results/ your study and analysis of the data – as part of the Data Availability Statement. This includes details of any software, instrument or other tool used to process results and, where relevant, the raw data. Importantly, publishing your data will allow you to track its provenance and ensure that those responsible for its generation are adequately credited for their work. Other who then reuse your data for their own studies can cite your date (which can be cited separately from your article if appropriate). Failure to openly provide data for publication without good justification will result in your article being rejected.

Open Research Europe requires open access to research data supporting articles under the principle 'as open as possible, as closed as necessary', according to the policy of Horizon Europe.

Exceptions: We recognize that openly sharing data may not always be feasible. Exceptions to open access to research data underlying publications in Open Research Europe are permitted according to the relevant policy of Horizon Europe. These consider the obligation to protect results, confidentiality obligations, security obligations, the obligation to protect personal data and other legitimate constraints. For Horizon Europe grants, these exceptions should be noted in the associated Data Management Plan. Where open access is not provided to the data needed to validate the conclusions of a publication that reports original results, authors should provide the relevant access needed to validate the conclusions to the extent their legitimate interests or constraints are safeguarded.

If your data must be restricted for legal, ethical, or other reasons, please see below for further information on what should be included in your data availability statement. For more information on each of the requirements, please see Further Guidance.

Before you begin, please closely consult any Data Management Plan completed in relation to the research. For additional help and resources please refer to the guidelines on research data management in the Horizon Europe Programme Guide.

Open Research Europe

Open Research Europe is a scholarly publishing platform available to Horizon 2020 and Horizon Europe beneficiaries. It comes at no cost to them, has a rigorous and open peer review process, and the open access model enables everyone to access the results.

- Open Research Europe website
- Infographic EN | •••

What is it?

A **SCIENTIFICALLY RIGOROUS PUBLISHING SERVICE** for researchers involved in Horizon 2020 and Horizon Europe projects

An **OPTIONAL** service

Allows researchers to **COMPLY WITH OPEN ACCESS OBLIGATIONS**

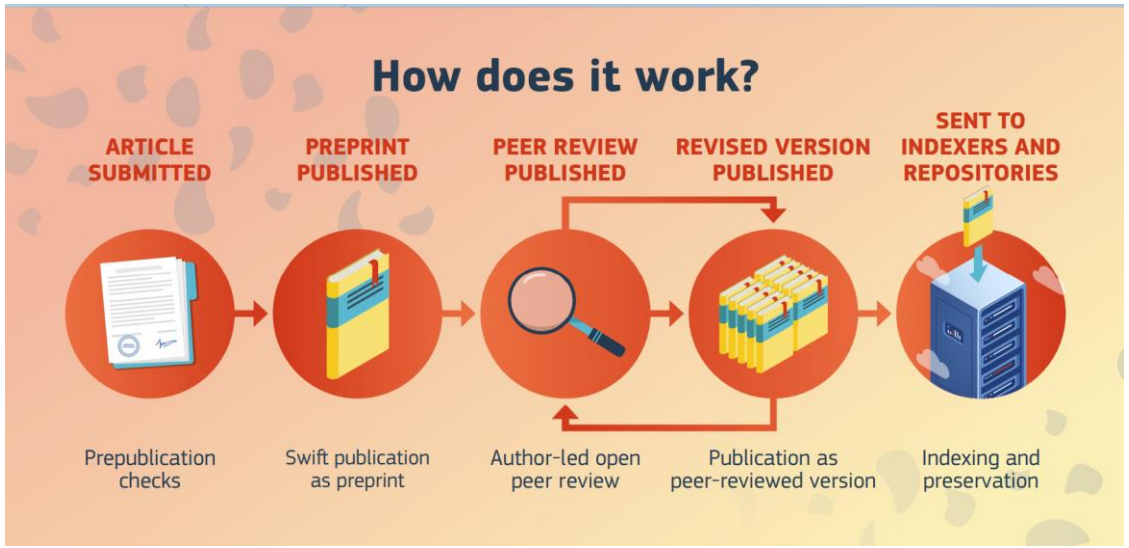
NO COST to researchers

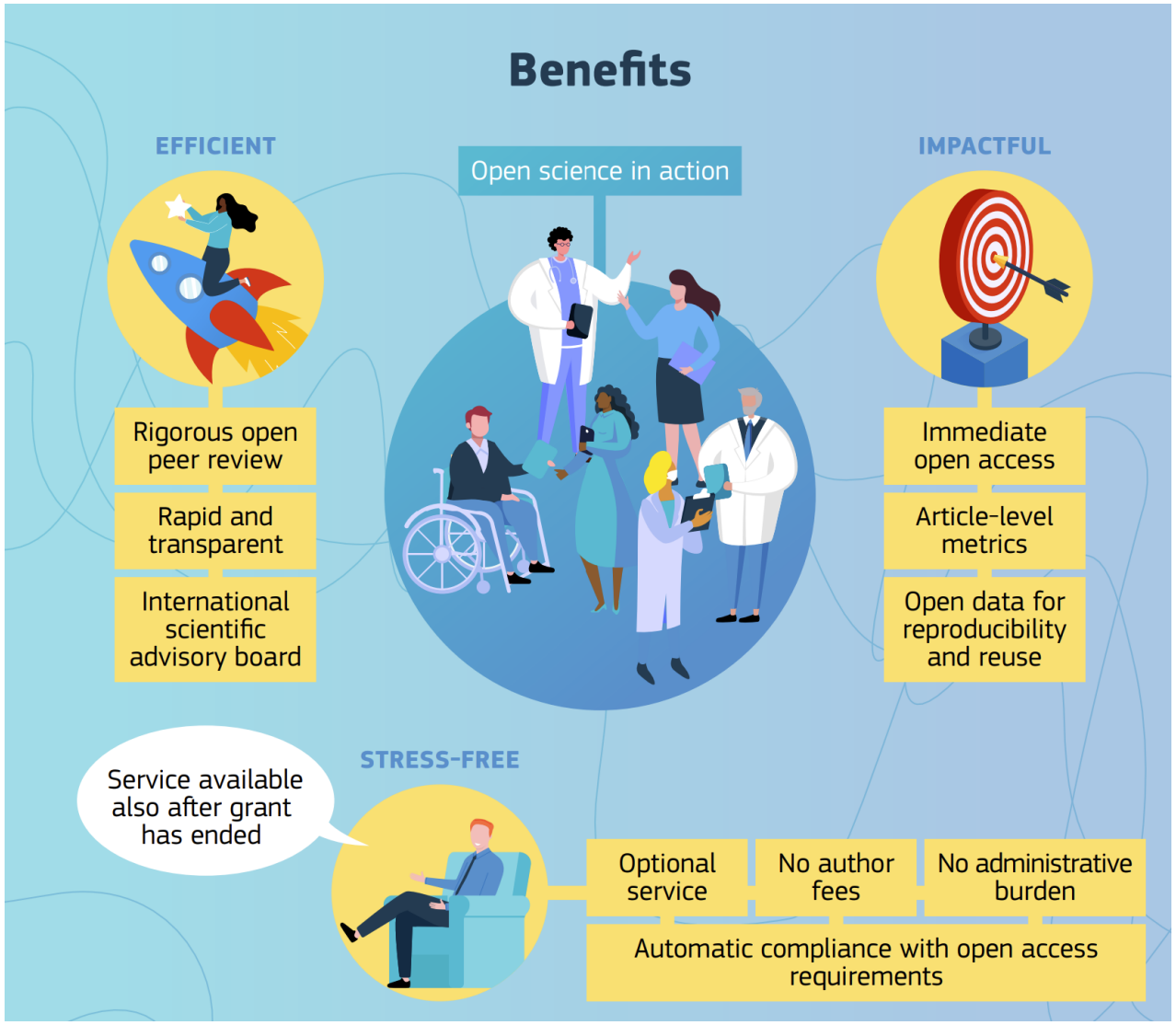
Who can publish?

Authors involved in **HORIZON 2020** and **HORIZON EUROPE** projects

Publications in **ALL SUBJECT AREAS** funded by Horizon 2020 and Horizon Europe

Submission of **ORIGINAL ARTICLES** stemming from projects


How does it work?
ARTICLE SUBMITTED
PREPRINT PUBLISHED
PEER REVIEW PUBLISHED
REVISED VERSION PUBLISHED
SENT TO INDEXERS AND REPOSITORIES
Prepublication checks
Swift publication as preprint
Author-led open peer review
Publication as peer-reviewed version
Indexing and preservation


Benefits
EFFICIENT
Open science in action
IMPACTFUL
Rigorous open peer review
Rapid and transparent
International scientific advisory board
Immediate open access
Article-level metrics
Open data for reproducibility and reuse
Service available also after grant has ended
STRESS-FREE
Optional service
No author fees
No administrative burden
Automatic compliance with open access requirements

Data management plans (DMPs) are a cornerstone for responsible management of research outputs, notably data and are mandatory in Horizon Europe for projects generating and/or reusing data (on requirements and the frequency of DMPs as deliverables consult the AGA article 17). A template for a DMP is provided under the reporting templates in the reference documents of the Funding and Tenders portal of the European Commission. Its use is recommended but not mandatory. DMPs are formal documents that outline from the start of the project all aspects of the research data lifecycle, which includes its organisation and curation, and adequate provisions for its access, preservation, sharing, and eventual deletion, both during and after a project. Writing a DMP is part of the methodology of the project, since good data management makes the work more efficient, saves time, contributes to safeguarding information and to increasing the value of the data among the beneficiaries themselves and others, during and after the research. DMPs are thus a key means of support when planning and conducting a research project, and, ideally, filling in a DMP should be started prior to the beginning of the project.

DMPs play a key role in helping researchers to adequately manage research outputs other than data and publications, also in line with the FAIR principles. Such research outputs may be physical or digital, and include original software created during the project, workflows, protocols, new materials such as samples, cell-lines, antibodies, among many others. DMPs should reflect an adequate management strategy for such outputs as well.

A DMP should be a living document, which is updated and enriched as the project evolves. Such updates might occur after attaining milestones related e.g. to the generation of new data or to reflect changes related to the original planning, changes in data/output access provisions or curation policies, changes in consortium practices *(e.g. new innovation potential, decision to file for a patent)*, changes in consortium composition, etc.

A good practice regarding DMPs is to register them as a non-restricted public deliverables to make them openly accessible, unless legitimate reasons exist to keep them confidential. An additional good practice is to publish the DMP in specialised journals or publishing platforms such as RIO etc., or to deposit them in DMP-specific public repositories such as DMPOnline and others.

As practices with regard to data management, storage, and sharing differ widely across disciplines, the DMPs should reflect common disciplinary practices. In addition to domain specificities, DMPs across the board should address an overarching set of data-related requirements including those aspects related to making the data FAIR. Common aspects that need to be addressed in all DMPs include[23]:

[23] These aspects are broadly in line with the requirements set forth in Science Europe's Practical Guide to the International Alignment of Research Data Management: https://www.scienceeurope.org/media/4brkxxe5/se_rdm_practical_guide_extended_final.pdf

- **Data set description**: a sufficiently detailed description of the data generated or re-used, including the scientific focus and technical approach to allow association of their data sets with specific research as well as information on data types and an estimate of the data set's size.

- **Standards and metadata**: the protocols and standards used to structure the data (i.e. fully reference the metadata) so that other scientists can make an assessment and reproduce the dataset. If available, a reference to the community data standards with which their data conform and that make them interoperable with other data sets of similar type.

- **Name and persistent identifier for the data-sets**: a unique and persistent identification (an identifier) of the data sets and a stable resolvable link to where the data sets can be directly accessed. Submission to a public repository normally provides this; many institutional repositories provide similar services.

- **Curation and preservation methodology**: information on the standards that will be used to ensure the integrity of the data sets and the period during which they will be maintained, as well as how they will be preserved and kept

accessible in the longer term. A reference to the public data repository in which the data will be/is deposited with relevant consideration on whether the chosen repository meets the requirements of a trusted repository.

- **Data sharing methodology**: information on how the data sets can be accessed, including the terms-of-use or the license under which they can be accessed and re-used, and information on any restrictions that may apply or relevant security and privacy considerations. It is also important to specify and justify the timing of data sharing. On open access to research data *see below relevant section on open access*.

- **Output management, for research outputs other than data and publications**: The section on output management should show efforts to manage outputs in line with the FAIR principles, including a detailed description of the output, consider relevant metadata standards and the provision of PIDs when depositing the output, or its digital representation if it is physical. The plan should further detail the deposition, curation and preservation methodology foreseen, identifying the right home for the output, and it should set out an approach likely to maximise the re-use and adoption of the output by the wider research community. If the output is physical, the plan should indicate how it would be made available to potential users.

- **Costs and personnel related to RDM**: An estimation of costs related to RDM such as costs for data collection, data documentation, data storage, data access and security, data preservation, data availability and reuse as well as the person/team responsible for data management and quality assurance processes.

DMP

- A template for the Horizon Europe DMP is provided A template for a DMP is provided under the reporting templates in the reference documents of the Funding and Tenders portal of the European Commission.
- The RDA FAIR Data Maturity Model Working Group delivers a detailed annotated list of indicators to address when increasing the FAIRness of data.
- For developing DMPs: The DMPONLINE tool (supports the development of project DMPs); ARGOS (online tool); the Data Stewardship Wizard, a joint ELIXIR CZ and ELIXIR NL tool, helps researchers understand what is needed for FAIR-oriented data stewardship, and build their own Data Management Plans.
- The Science Europe Practical Guide to the International Alignment of Research Data Management contains detailed guidance for drafting and evaluating DMPs.

4. Data security

What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)?

Is the data safely stored in certified repositories for long term preservation and curation?

The Horizon Europe strategic plan defines four **key strategic orientations:**

- **Promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains** to accelerate and steer the digital and green transitions through human-centred technologies and innovations.
- **Restoring Europe's ecosystems and biodiversity, and managing sustainably natural resources** to ensure food security and a clean and healthy environment.
- **Making Europe the first digitally enabled circular, climate-neutral and sustainable economy** through the transformation of its mobility, energy, construction and production systems.
- **Creating a more resilient, inclusive and democratic European society**, prepared and responsive to threats and disasters, addressing inequalities and providing high-quality health care, and empowering all citizens to act in the green and digital transitions.

Ethics and data protection

Data protection is both a central issue for research ethics in Europe and a fundamental human right. It is intimately linked to autonomy and human dignity, and the principle that everyone should be valued and respected. For this principle to guide the development of today's information society, data protection must be rigorously applied by the research community.

The right to data protection is enshrined in the EU Charter of Fundamental Rights and the Treaty on the Functioning of the European Union, which give effect to individuals' right to privacy by providing them with control over the way information about them is collected and used.[1]

In research settings, data protection imposes obligations on researchers to provide research subjects with detailed information about what will happen to the personal data that they collect. It also requires the organisations processing the data to ensure the data are properly protected, minimised, and destroyed when no longer needed.

While individual EU-funded research projects processing personal data must comply with EU and national data protection laws, the objective of this guidance note is to ensure that, in addition to respecting legal obligations, all projects are guided by ethical considerations and the values and principles on which the EU is founded.

Particular attention should be paid to research involving special categories of data (formerly known as 'sensitive data'), profiling, automated decision-making, data-mining techniques, big-data analytics and artificial intelligence, as such processing operations may pose higher risks to the rights and freedoms of data subjects (see Table 1). The increasing impact of these and other new technologies on our everyday lives and activity is reflected in the letter and spirit of the EU's 2016 General Data Protection Regulation GDPR).

While the EU's ethics review process is primarily concerned with ethics issues, your project must demonstrate compliance with the GDPR. However, the fact that your research is legally permissible does not necessarily mean that it will be deemed *ethical*.

Crucially, if your research proposal involves the processing of any personal data, whatever method is used, you – and all of your partners, collaborators and service providers – must, if called upon, be able to demonstrate compliance with both legal and ethical requirements. Such requests could come from data subjects, funding agencies or data protection supervisory authorities.

When developing and implementing your proposal, it is your responsibility to identify the appropriate legal provisions and ensure compliance. All EU projects processing personal information about identifiable human research subjects are subject to the GDPR. The principle of accountability is central to the GDPR and requires data processors to establish and document data protection compliance processes. Comprehensively addressing data protection issues in your research proposal, which will become part of your contract if selected for funding, can make an important contribution to the accountability of the project.

Note that in addition to the GDPR, national legislation or related EU measures could also apply to your research:

- if your proposal uses data processed or provided by authorities responsible for preventing, investigating, detecting or prosecuting criminal offences, Directive (EU) 2016/680 may also apply;
- if your project uses personal data generated or processed by electronic networks (e.g. data relating to 'cookies', internet usage or electronic network traffic), the EU's e Privacy Directive (currently under revision) may also apply;
- EU Member States have laid down their own rules on data processing, e.g. the processing of special categories of data (such as genetic, biometric and/or health data) may be subject to additional national legal requirements, such as prior notification of regulators or data protection authorities. It is your responsibility to ensure that your research complies with the data protection laws in all the Member States in which your research data are processed, as well as the GDPR.[3]

[3] See in particular Articles 9(4), 8 and 89(3) GDPR.

[Box 1] Key issues, concepts and definitions

'**Personal data'** are defined extremely broadly and include **'any information relating to an identified or identifiable natural person'**. An **'identifiable natural person'**, or **'data subject'**, is **'one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person'** (Article 4(1) GDPR).

Personal data include data such as internet protocol (IP) addresses (unique identifiers that can be used to identify the owner of devices connected to the internet) and data from 'smart meters' monitoring energy usage by addresses linked to identifiable persons.

'Special categories of personal data' (formerly known as 'sensitive data') are subject to more stringent data-protection safeguards. They include ' **personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation'**(Article 9(1) GDPR).

If your project involves the processing of special categories of data, it is more likely to raise significant ethics issues. You must therefore justify the inclusion of this kind of data in your project.

The definition of **'data processing'** is very broad. It includes **'any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction'** (Article 4(2) GDPR).

It is highly likely that if your project involves any data about identifiable persons, even if they are not directly participating in the research, you are processing personal data and must comply with EU and national law. Only data that have been fully and irreversibly anonymised are exempt from these requirements. Importantly, while **pseudonymisation** can provide individual data subjects with a degree of protection and anonymity, pseudonymised data still fall within the scope of personal data because it is possible to re-identify the data subject (see below).

Even if your project is using only **anonymised data**, the origin or acquisition of the data may still raise significant ethics issues.

Even if your project is using only **anonymised data**, the origin or acquisition of the data may still raise significant ethics issues.

The GDPR places obligations on both:

- the **'data controller'**, which **'alone, or jointly with others, determines the purposes and means of the processing of personal data'**; and
- the **'data processor'**, which **'processes personal data on behalf of the controller'**.

You must ensure that any partners, contractors or service providers that process research data at your request and on your behalf comply with the GDPR and the H2020 ethics standards. Where you share with consortium partners the responsibility for processing personal data collected in the course of your research project, your project may have **joint data controllers**. In this case, you and your partners must set out your respective responsibilities in an agreement available to data subjects and provide them with a single point of contact.

[Table 1] Indicators of data processing operations that may entail higher ethics risks

Types of personal data	* racial or ethnic origin * political opinions, religious or philosophical beliefs * genetic, biometric or health data * sex life or sexual orientation * trade union membership
Data subjects	* children * vulnerable people * people who have not given their explicit consent to participate in the project
Scale or complexity of data processing	* large-scale processing of personal data * systematic monitoring of a publicly accessible area on a large scale * involvement of multiple datasets and/or service providers, or the combination and analysis of different datasets (i.e. big data)

[Table 1] Indicators of data processing operations that may entail higher ethics risks

Data-collection or processing techniques	* privacy-invasive methods or technologies (e.g. the covert observation, surveillance, tracking or deception of individuals) * using camera systems to monitor behaviour or record sensitive information * data mining (including data collected from social media networks), 'web crawling' or social network analysis * profiling individuals or groups (particularly behavioural or psychological profiling) * using artificial intelligence to analyse personal data * using automated decision-making that has a significant impact on the data subject(s)
Involvement of non-EU countries	* transfer of personal data to non-EU countries * collection of personal data outside the EU

If your research entails higher-risk data processing, you must provide a detailed analysis of the ethics issues raised by your project methodology. This should comprise:

- an overview of all planned data collection and processing operations;
- identification and analysis of the ethics issues that these raise; and
- an explanation of how you will mitigate these issues in practice.

You must ensure that these issues are duly included and addressed in the research protocol that you submit to your research ethics committee. You may also be required to conduct a data protection impact assessment (DPIA) in line with Article 35 GDPR and supplementary guidance on DPIAs (see below).

If your institution has appointed a data protection officer (DPO), you should involve them in all stages of your project and seek their advice on data privacy issues. This will help in the implementation of your proposal and grant agreement (EU grants are subject to full compliance with data privacy rules).

Where complex, sensitive or large-scale data processing is envisaged or data are to be transferred outside the EU, you should consult the DPO on the compatibility of the data protection arrangements with the host institution's policies and applicable legislation.

You should include the opinion and/or advice of the DPO in your proposal. If your host institution does not have a DPO, it is recommended that you seek the advice of a suitably qualified expert.

III. Pseudonymisation and anonymisation

One of the best ways to mitigate the ethical concerns arising from the use of personal data is to anonymise them so that they no longer relate to identifiable persons. Data that no longer relate to identifiable persons, such as aggregate and statistical data, or data that have otherwise been rendered anonymous so that the data subject cannot be re-identified, are not personal data and are therefore outside the scope of data protection law.

However, even if you plan to use only anonymised datasets, your proposal may still raise significant ethics issues. These could relate to the origins of the data or the manner in which they were obtained. You must therefore specify the source of the datasets you intend to use in your proposal and address any ethics issues that arise. You must also consider the potential for misuse of the research methodology or findings, and the risk of harm to the group or community that the data concern.

Where it is necessary to retain a link between the research subjects and their personal data, you should, wherever possible, pseudonymise the data in order to protect the data subject's privacy and minimise the risk to their fundamental rights in the event of unauthorised access. Pseudonymisation and anonymisation are not the same thing and it is important that you are aware of the difference between them, as the GDPR requires you to use them wherever possible or feasible (Article 89 GDPR).

[Box 2] Pseudonymisation and anonymisation: understanding the difference

Pseudonymisation entails substituting personally identifiable information (such as an individual's name) with a unique identifier that is not connected to their real-world identity, using techniques such as coding or hashing. However, if it is possible to re-identify the individual data subjects by reversing the pseudonymisation process, data protection obligations still apply. They cease to apply only when the data are fully and irreversibly anonymised.

Anonymisation involves techniques that can be used to convert personal data into anonymised data. Anonymisation is increasingly challenging because of the potential for re-identification.

Re-identification is the process of turning pseudonymised or anonymised data back into personal data by means of data matching or similar techniques.

While anonymised data are no longer considered personal data, anonymisation processes are challenging, particularly where large datasets containing a wide range of personal data are concerned. This is because it is very difficult to create fully anonymous datasets that retain the granular information needed for research purposes.[4] As far as your research proposal is concerned, if there is a significant prospect of re-identification of persons whose data have been collected, the information should be treated as personal data. It is difficult to assess the risk of re-identification with absolute certainty and you should always err on the side of caution. A growing body of case studies and research publications in which individuals are identified from 'anonymous' datasets has demonstrated the fundamental constraints to anonymisation as a technique to protect the privacy of individuals.

In some instances, your host institution, funding body or publisher may require you to keep the raw data for auditing, accountability or research integrity purposes. There may be other scenarios in which a host institution has a raw dataset which it makes available to its researchers and partners in anonymised form. In these instances, while the recipients of the anonymised data may – subject to the mitigation of the risk of re-identification – be exempt from data protection requirements, the host institution is still processing personal data and must therefore ensure appropriate protection for the raw (personal) data. This includes technical and organisational measures to protect the data

IV. Data protection by design and default

To innovate ethically and responsibly, researchers and developers have long been encouraged to apply the concept of 'privacy by design', which provides a framework for focusing the design of systems, databases and processes on respect for data subjects' fundamental rights. A wider concept of 'data protection by design', now included in the GDPR, requires data controllers to implement appropriate technical and organisational measures to give effect to the GDPR's core data-protection principles (articles 5 and 25 GDPR). Data protection by design is one of the best ways to address the ethics concerns that arise from your research proposal at the design stage of your project.

In a research and development context, measures to achieve data protection by design could include:

- the pseudonymisation or anonymisation of personal data;
- data minimisation (see Box 3);
- applied cryptography (e.g. encryption and hashing);
- using data-protection focused service providers and storage platforms; and
- arrangements that enable data subjects to exercise their fundamental rights (e.g. as regards direct access to their personal data and consent to its use or transfer).

You must apply the principle of data protection by design where it could mitigate the ethics risks raised by the data processing in your research project, and explain in your research proposal how this will be achieved. This approach is underscored by the principle of data protection by default. **Wherever you have the possibility to enhance the level of data protection afforded to your research subjects, you should apply such measures by default rather than just considering them or making them available as an optional extra.**

Where your research involves complex, sensitive or large-scale data processing, your proposal should include a description of the measures you will take to apply the principles of data protection by design and default, and/or to enhance security so as to prevent unauthorised access to personal data or equipment.

[Box 3] Data minimisation

Data processing must be lawful, fair and transparent. **It should involve only data that are necessary and proportionate** to achieve the specific task or purpose for which they were collected (Article 5(1) GDPR).

You should therefore **collect only the data that you need to meet your research objectives**. Collecting personal data that you do not need for your research project may be deemed unethical and unlawful.

If you are in any doubt as to whether you actually need all of the data you intend to collect, you should **conduct a data minimisation review**. This should be designed and conducted by the research team to ensure that data are collected on a **'need to know' basis**, i.e. the data are required for a specific purpose that is relevant and limited to your project's objectives and methodology.

[Box 3] Data minimisation

Data minimisation applies not only to the amount of personal data collected, but also to the extent to which they may be accessed, further processed and/or shared, the purposes for which they are used, and the period for which they are kept. You must minimise the processing as far as possible.

If you are unable fully to identify the purpose of the data processing at the time of data collection or you need to keep the data beyond the duration of your project, **you must explain and justify the data collection and retention arrangements**.

You must also explain how you will apply the principles of data minimisation and data protection by design in practice. In particular, you must ensure that:

- you pseudonymise or anonymise the data wherever possible (see Box 2);
- the data are securely stored; and
- where appropriate, policies and procedures are established to limit the use of the data and protect the fundamental rights of the data subjects.

V. Informed consent to data processing

Informed consent is the cornerstone of research ethics. It requires you to explain to research participants what your research is about, what their participation in your project will entail and any risks that may be involved. Only after you have conveyed this information to the participants – and they have fully understood it – can you seek and obtain their express permission to include them in your project (Articles 4(11) and 7 GDPR).[5]

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5 For research involving clinical trials, data processing should also comply with Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

You must keep records documenting the informed consent procedure, including the information sheets and consent forms provided to research participants, and the acquisition of their consent to data processing. These may be requested by data subjects, funding agencies or data protection supervisory authorities.

For consent to data processing to be 'informed', the data subject must be provided with detailed information about the envisaged data processing in an intelligible and easily accessible form, using clear and plain language. As a minimum, this should include:

- the identity of the data controller and, where applicable, the contact details of the DPO;
- the specific purpose(s) of the processing for which the personal data will be used;
- the subject's rights as guaranteed by the GDPR and the EU Charter of Fundamental Rights, in particular the right to withdraw consent or access their data, the procedures to follow should they wish to do so, and the right to lodge a complaint with a supervisory authority;
- information as to whether data will be shared with or transferred to third parties and for what purposes; and
- how long the data will be retained before they are destroyed.

VII. Use of previously collected data ('secondary use')

As noted above, some of the most high-profile breaches of ethics standards have concerned the use of data collected for one purpose and then used for other research or targeting processes, without the knowledge or consent of the data subject. If you are processing personal data in your research without the express consent of the data subjects, you must explain how you will obtain the data, justify their use in your project and ensure that the processing is fair to the data subject.

If the collection or use of data raises specific ethics issues (e.g. as regards consent and transparency, privacy and the rights and expectations of the data subjects), you must provide a detailed overview of the planned data collection and processing operations and **explain how the ethics concerns will be mitigated**.

If you are using data that are publicly available, you must provide details of the source(s) and confirm that the data are openly and publicly accessible and may be used for research purposes. You must also do this where the data you intend to use have been manifestly made public by the data subject (see Box 4).

[Box 4] Using 'open source' data

The fact that some data are publicly available does not mean that there are no limits to their use.

On the contrary, **if you take 'open source' personal data about identifiable persons and create new records or files/profiles, you are processing personal data about them** and must have a lawful/legitimate basis for doing so.

You must ensure that the data processing is fair to the data subject and that their fundamental rights are respected.

If your research project uses **data from social media networks** and you do not intend to seek the data subjects' explicit consent to the use of their data, you must assess whether those persons actually intended to make their information public (e.g. in the light of the privacy settings or limited audience to which the data were made available).

It is not enough that the data be accessible; they must have been made public to the extent that the data subjects do not have any **reasonable expectation of privacy**. **You must also ensure that your intended use of the data complies with any terms and conditions published by the data controller**.

If you are in any doubt as to what you can and cannot do with this kind of data, you should seek advice from your DPO or a suitably qualified expert and include their opinion in your proposal.

VIII. Data protection impact assessments

The risk-based approach to data processing upon which the GDPR is predicated can help researchers with complex, sensitive or large-scale data processing requirements to identify and address the ethics issues that arise from their methods and objectives.

The DPIA is a process designed to assess the data-protection impacts of a project, policy, programme, product or service and, in consultation with relevant stakeholders, to ensure that remedial actions are taken as necessary to correct, avoid or minimise the potential negative impacts on the data subjects.

Under the GDPR, a DPIA is mandatory for processing operations that are likely to 'result in a high risk to the rights and freedoms of natural persons' (art.35). These include in particular:

- a 'systematic and extensive' analysis of personal data in the context of automated processing, including profiling, where this has a significant effect on the data subject;
- large-scale processing of 'special categories' of personal data, or of personal data relating to criminal convictions and offences; or
- a systematic monitoring of a publicly accessible area on a large scale.

If your research objectives and methods require you to conduct a DPIA in accordance with the GDPR, then provision for this must be made in your proposal. This includes details of how, when and by whom the assessment will be conducted.

Crucially, if the DPIA indicates that the envisaged processing would result in a high risk to people's rights and freedoms in the absence of measures taken by the controller to mitigate the risk, you must seek the advice of your data protection supervisory authority as to whether the envisaged processing is permissible (art.36 GDPR).This may in turn have a significant bearing on the viability of your research proposal and must therefore be addressed in your risk assessment.

Regardless of whether a DPIA is required or conducted, if the data processing that you envisage raises significant ethics concerns, you must provide a thorough evaluation of those risks in your proposal. As a minimum, this should include the risk of unethical conduct or harm to the wellbeing or interests of research participants at both individual (e.g. research participants, their associates or other third parties) and group level (e.g. the potential for adverse impacts on the community that the data concern).

When assessing the ethical issues arising from your research, you must consider the risk of discrimination, stigmatisation, data breaches (i.e. exposing the identity or sensitive data of individuals or damaging their reputation through a breach of confidentiality), threats to the safety or security of participants and the potential for misuse of the research methodology or findings.

[Box 5] Scenarios in which you should conduct a data protection impact assessment

WP29 considers that **processing operations raising multiple data-protection concerns are more likely to present a high risk to the rights and freedoms of data subjects, and therefore require a DPIA**, regardless of the measures, which the controller intends to adopt. The Article 29 guidance note[10] gives the following examples:

Examples of processing	Possible Relevant criteria	DPIA likely to be required?
A hospital processing its patients' genetic and health data (hospital information system).	- Sensitive data or data of a highly personal nature - Data concerning vulnerable data subjects - Data processed on a large-scale	Yes
The use of a camera system to monitor driving behaviour on highways. The controller envisages to use an intelligent video analysis system to single out cars and automatically recognise license plates	- Systematic monitoring. - Innovative use or applying technological or organisational solutions	Yes
A company systematically monitoring its employees' activities, including the monitoring of the employees' work station, internet activity, *etc*.	- Systematic monitoring - Data concerning vulnerable data subjects	Yes

[Box 5] Scenarios in which you should conduct a data protection impact assessment

WP29 considers that **processing operations raising multiple data-protection concerns are more likely to present a high risk to the rights and freedoms of data subjects, and therefore require a DPIA**, regardless of the measures, which the controller intends to adopt. The Article 29 guidance note[10] gives the following examples:

Examples of processing	Possible Relevant criteria	DPIA likely to be required?
The gathering of public social media data for generating profiles.	- Evaluation or scoring - Data processed on a large scale - Matching or combining of datasets - Sensitive data or data of a highly personal nature	Yes
An institution creating a national level credit rating or fraud database.	- Evaluation or scoring - Automated decision making with legal or similar significant effect - Prevents data subject from exercising a right or using a service or a contract - Sensitive data or data of a highly personal nature	Yes
Storage for archiving purpose of pseudonymised personal sensitive data concerning vulnerable data subjects of research projects or clinical trials	- Sensitive data - Data concerning vulnerable data subjects. - Prevents data subjects from exercising a right or using a service or a contract	Yes

X. Data security

Whenever and however you collect personal data, you have both ethical and legal obligations to ensure that participants' information is properly protected. This is fundamental to safeguarding their rights and freedoms, and minimising the ethics risks related to the data processing.

The GDPR requires all data controllers and processors to implement appropriate technical and organisational measures to ensure a level of data security that is commensurate to the risks faced by the data subjects in the event of unauthorised access to, or disclosure, accidental deletion or destruction of, their data (art.32 GDPR).

Your proposal should provide details of the technical and organisational measures that will be implemented to protect the personal data processed in the course of your research, e.g. with reference to your host institution's and research partners' data protection and information security policies. Such measures may include the pseudonymisation and encryption of personal data, and policies and procedures to ensure the confidentiality, integrity, availability and resilience of processing systems.

[Box 7] Data security: 10 do's and don'ts

Do

- ✓ use GDPR-compliant tools to collect, process and store research subjects' personal data;
- ✓ take communications security seriously, and devise and implement dedicated protocols for your project as necessary;
- ✓ check the terms and conditions of all of the service providers you use (software, applications, storage, etc.) to process personal data within your project, in order to identify and mitigate risks to the data subjects;
- ✓ encrypt your research data and/or the devices on which they are stored, and ensure that keys/passwords are appropriately protected; and
- ✓ consult your DPO or a suitably qualified expert for advice on how to achieve a level of data security that is commensurate to the risks to your data subjects.

[Box 7] Data security: 10 do's and don'ts

Don't

- ✘ collect data on a personal device such as a smartphone without ensuring that they are properly protected (e.g. consider the implications of automatic back-ups to the cloud, and the device's security features);
- ✘ use free services that may use your participants' data for their own purposes in lieu of payment, or collect data or communicate with research participants via social media platforms without first assessing the data protection implications;
- ✘ use unencrypted email, SMS or insecure 'voice over IP' platforms to communicate with vulnerable participants or those who may be subject to state surveillance;
- ✘ expose personal data to unauthorised access or use when accessing them remotely (e.g. by using insecure wifi connections) or travelling to countries where your devices may be inspected or seized; and
- ✘ assume that your research partners, collaborators or service providers have appropriate information security and data protection policies without checking that this is the case.

XI. Transfer of personal data to non-EU countries

Sending participants' personal data to partners, collaborators or service providers outside the EU raises ethical and legal issues that can be difficult to address in practice. Researchers based outside the EU may be subject to different ethical rules and their treatment of the data may fall short of EU standards.

Few non-EU countries have received an 'adequacy determination' from the European Commission indicating that they have a data protection framework offering a level of protection equivalent to that provided under EU law.[13] This means that your research subjects' data may not be adequately protected or may even be used in ways that undermine their fundamental rights. The EU requires that its ethics standards apply to all of the research it funds, regardless of the country in which it takes place. The transfer of personal data from non-EU countries is subject to strict data protection requirements under Chapter V GDPR.

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13 The list of countries covered by a Commission adequacy determination is available at: https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/adequacy-protection-personal-data-non-eu-countries_en

XII. Collection of personal data outside the European Union

Collecting personal data from research subjects in non-EU countries raises similar ethical issues, but these may be amplified by the need to ensure that the participants are:

- wholly comfortable with being part of a research project conducted by researchers from outside their own country;
- aware of what will happen to their data; and
- not subject to any undue pressure to participate.

As noted above, the EU's ethics requirements apply to all EU-funded research, irrespective of where it takes place. Similarly, the GDPR applies to all data-processing operations conducted by data controllers based in the EU, irrespective of where the processing takes place. This means that, even if you are collecting personal data outside the EU, you must still ensure and be able to demonstrate compliance with EU law.

It is your responsibility to determine what legal obligations apply to any research you conduct outside the EU and to take whatever action is necessary to comply with them. You must also be able to demonstrate compliance upon request. Again, if you are unsure as to how to handle issues related to international data transfers, you should seek the advice of your host institution's DPO, or a suitably qualified expert, and include their opinion in your proposal.

[Box 8] Checklist: international data transfers

Transferring personal data out of the EU

- ✓ ensure that any international data transfers fulfil at least one of the relevant conditions in Chapter V GDPR;
- ✓ check that any third-party services you intend to use (e.g. survey tools, data analytics, cloud storage, etc.) are incorporated in an EU Member State or legally represented in the EU in accordance with the GDPR;
- ✓ adopt legally binding and enforceable agreements with partners or service providers prior to data transfers;
- ✓ prohibit the onward transfer of personal data by members of your consortium and any other recipients outside the framework of such agreements; and
- ✓ implement appropriate organisational and technical measures to ensure that personal data are transferred securely.

[Box 8] Checklist: international data transfers

Collecting personal data in non-EU countries

- ✓ ensure that processing, notification, consent and accountability provisions meet GDPR standards;
- ✓ identify any further data protection requirements in applicable laws in the country in which data are to be collected and explain in your proposal how you will comply with them;
- ✓ if applicable, ensure that research participants understand and consent to the export of the personal data they provide to an EU Member State or an non-EU country;
- ✓ use pseudonymisation or anonymisation techniques to minimise the risk to data subjects;
- ✓ implement appropriate organisational and technical measures to ensure that personal data are transferred securely.

XIV. Data protection officers and other sources of help

If your institution has appointed a DPO, it is recommended that you seek their advice as to your data protection obligations and how to meet them. You must ensure that the DPO's contact details are made available to all the data subjects involved in your research.

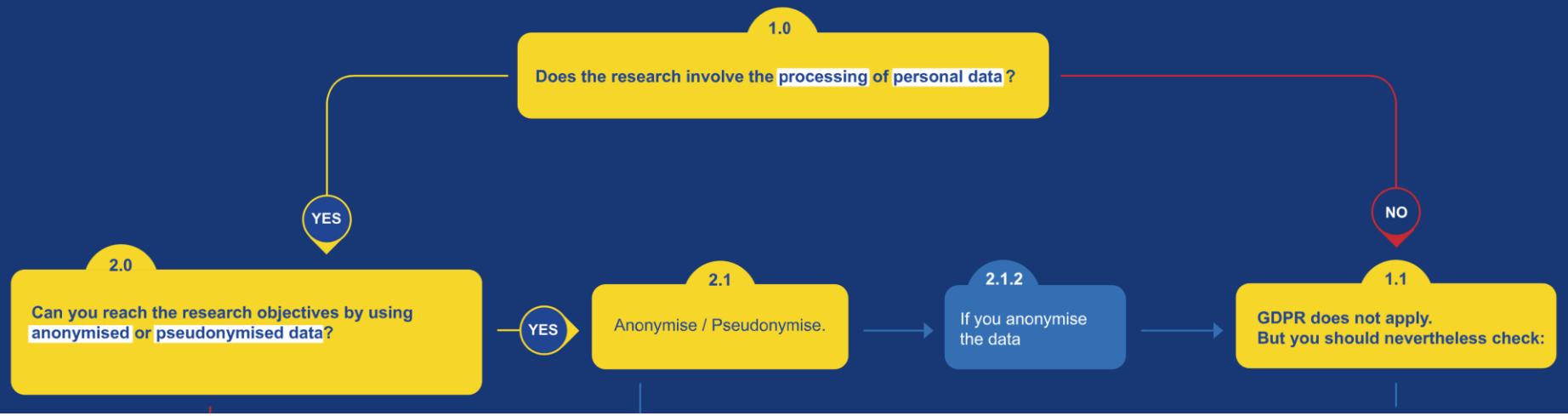
If you are uncertain about any aspects of ethics in your research, you should consider appointing an ethics advisor or engaging an ethics mentor to provide advice, oversee the ethical concerns in your research and ensure that it is fully ethically compliant.

The Ethics and Data Protection Decision Tree can further support you in identifying and addressing potential ethics issues related to the data processing activities in your project.

Ethics and Data Protection Decision Tree

THE FOLLOWING QUESTIONS ARE INTENDED TO :

1. Support the identification of potential ethics risks related to the data processing activities of your proposal/project
2. Facilitate compliance with the data ethics requirements aimed at safeguarding the fundamental human rights and freedoms of the research participants
3. Foster the application of the 'ethics by design' principles



https://ec.europa.eu/assets/rtd/ethics-data-protection-decision-tree/index.html