

Discussion of the key issues at the stage of planning

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Data management coordinator

ELIXIR Norway



elixir.no

Life cycle



Requirements

Funder

Ethical & Legal

Project
& Domain specific

Institutional



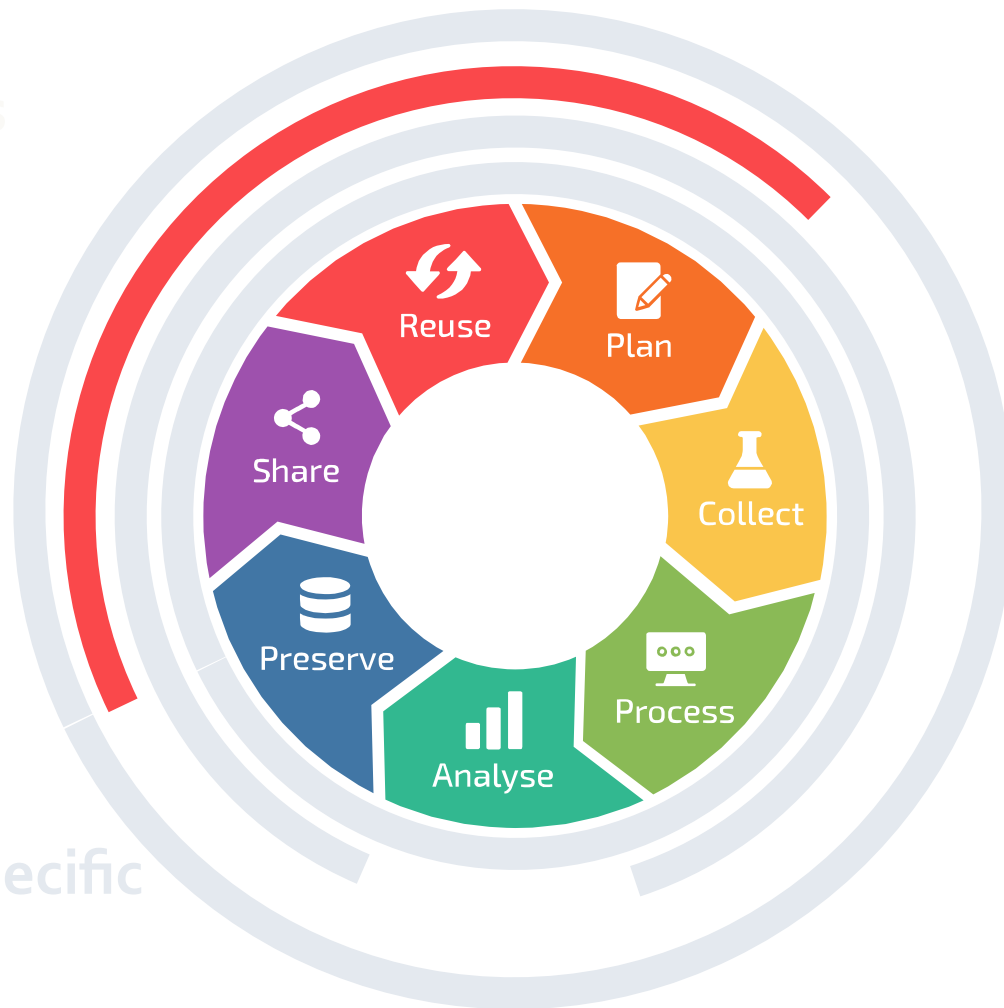
Requirements

Funder

Ethical & Legal

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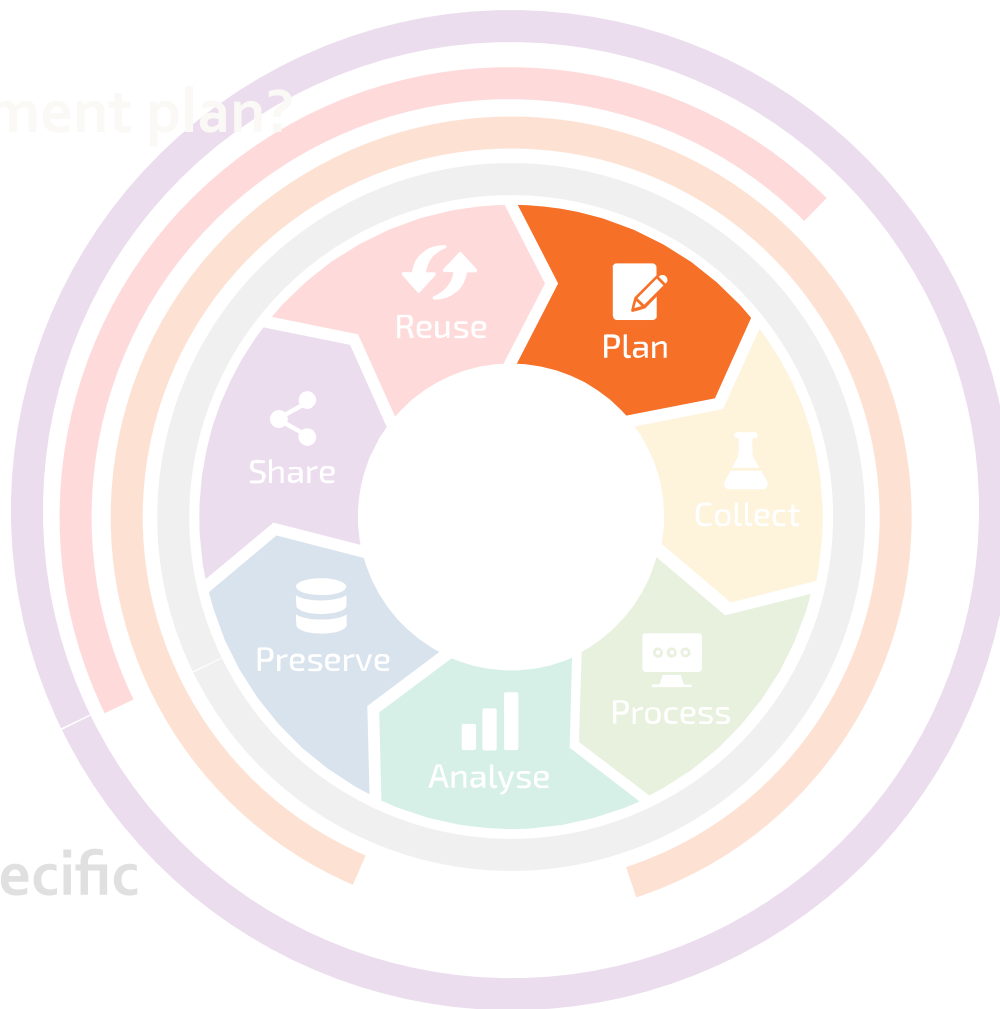
Data Management plan?

Funder

Ethical & Legal

Project
& Domain specific

Institutional



Data Management plan?

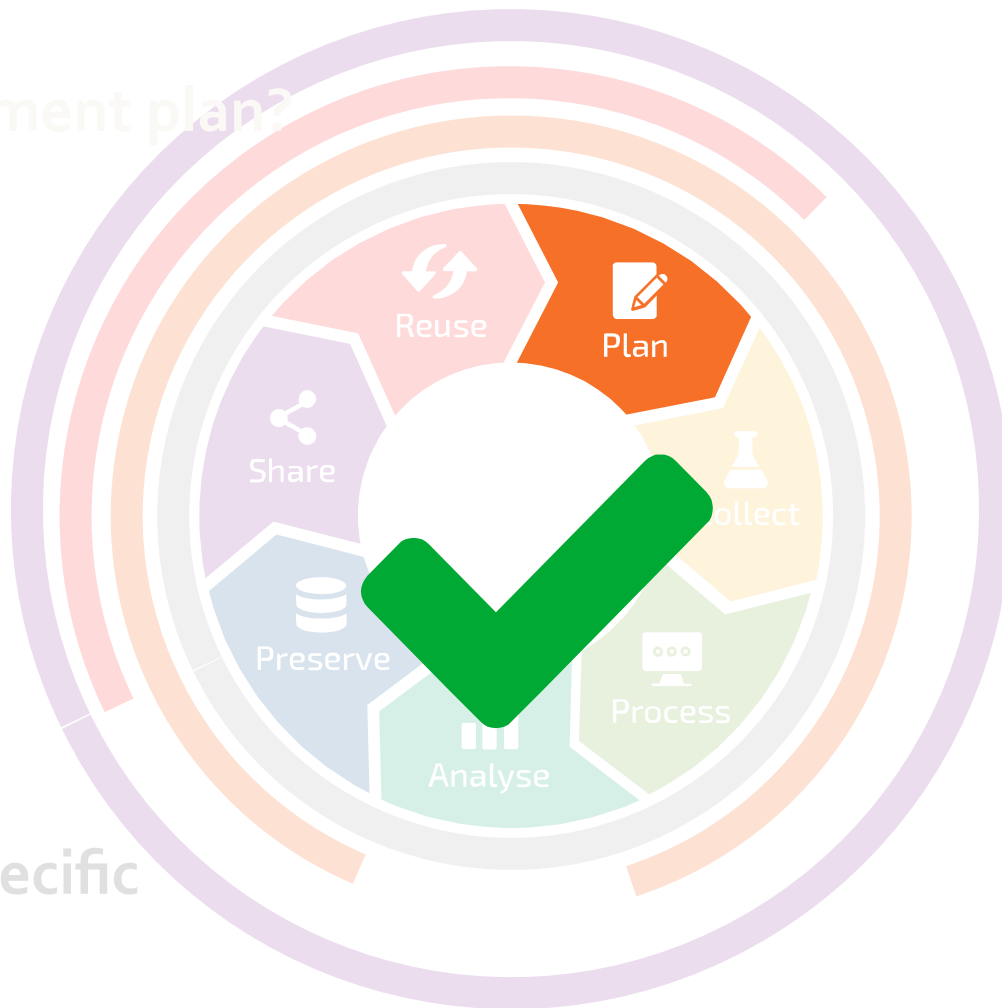
Funder



Ethical & Legal

**Project
& Domain specific**

Institutional



Clinical trials DMPs



ICH Topic E 9 Statistical Principles for Clinical Trials (CPMP/ICH/363/96)

ICH E6 (R3) Guideline for good clinical practice (GCP) Step 5
section 2.10, 2.11, 2.13, 4.9, 5.5, 5.15

Guideline on computerised systems and electronic data in clinical trials

This is not your scientific DMP (some information might be the same)

Clinical trials DMPs



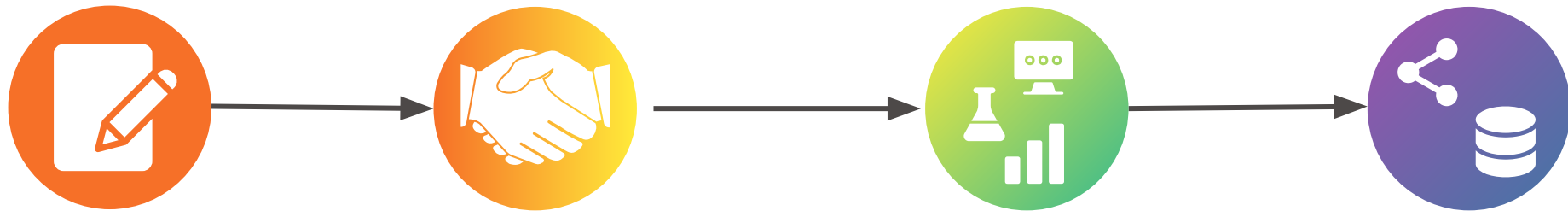
1. Introduction
2. Project Personnel
3. Quality System
4. Documentation
 - 4.1. Data Management Files
 - 4.2. Protocol
 - 4.3. Database Specification Document
5. Electronic Data Management Systems
 - 5.1. Oversight of Data Acquisition Tools
 - 5.2. Data Flow Diagram
6. DAT Design
 - 6.1. CRF and Patient-Reported Outcome Measures (PROM)
 - 6.2. Annotated CRF
 - 6.3. User Acceptance Testing
 - 6.4. Approval
 - 6.5. Changes to the DAT(s)
7. Randomisation and Blinding
 - 7.1. Randomisation
 - 7.2. Measurements to Ensure the Safeguarding of the Blinding
 - 7.3. Systems for Unblinding
8. Training for Site Personnel

9. Data Entry
 - 9.1. Data Entry Instruction
 - 9.2. Corrections to Data Entered by the Participant
 - 9.3. Self-Evident Corrections
 - 9.4. Derived Data
10. Data Quality Control
 - 10.1. Data Verification
 - 10.2. Data Validation
11. Review of Data and Metadata
12. Protocol Deviations
13. Reconciliation of Serious Adverse Events (SAE)
14. Data from External Sources
 - 14.1. Laboratory Data
 - 14.2. Other Data from External Data Sources
15. Coding of Medical Terms
16. Interim Analysis/Data Monitoring Committee
17. Database Lock
 - 17.1. Database Unlock
18. Unblinding
19. Database Export
20. Audit
21. Retention and Archiving
22. Data Management Report



EP PerMed
European Partnership
for **Personalised Medicine**

+ Your local funder



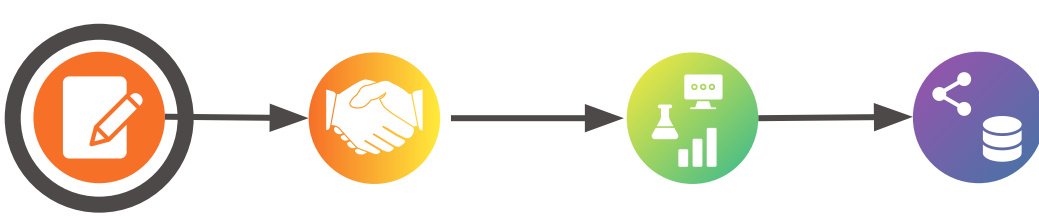


Applicants must clearly describe:

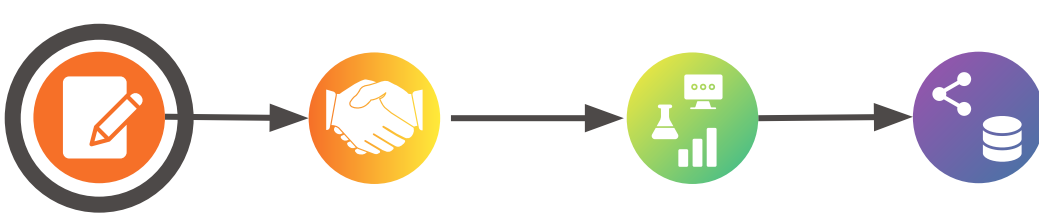
all tools, technologies, and digital supports to be used in the project.

how data from different sources (such as different institutions) will be combined,

how different data streams will be merged and how the primary outcomes will be meaningful across different institutions.



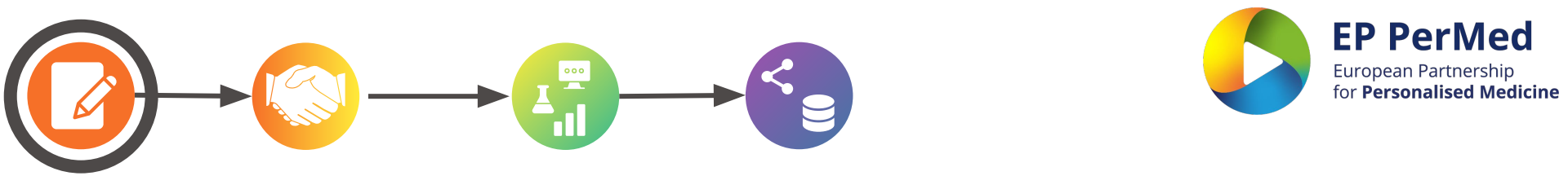
How outputs will be maintained after the project end and would be available (findable, accessible, interoperable and re-usable) or communicated to the wider research community, during and after the end of the project period



No full DMP required (- but helpful)

You should consider:

- §§ Ethical and Legal issues
- 💾 Storage and computing (budgeting?)
- 👤 Budgeting for RDM-personnel & time effort



§§ Ethical and Legal issues

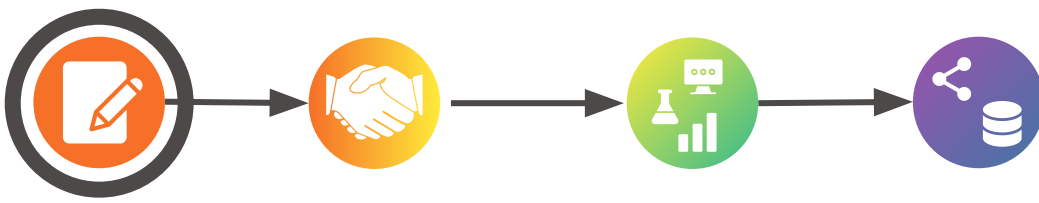
REK approval necessary (for sharing of data?)

GDPR considerations

IPR aspects

Which Research Ethical Guidelines apply for this project?

RRI

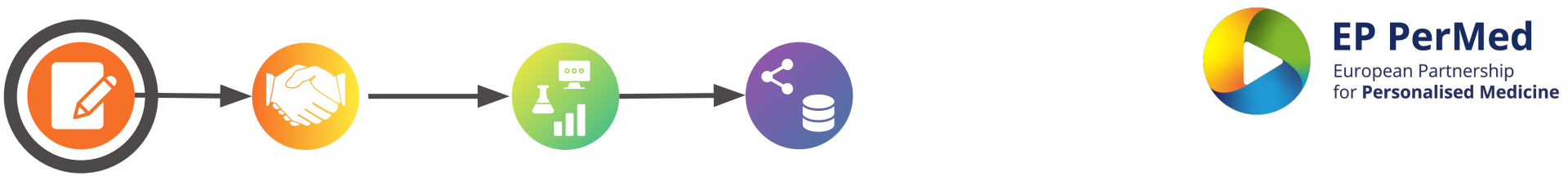


Storage and Computing

Is access to computing/storage secured?

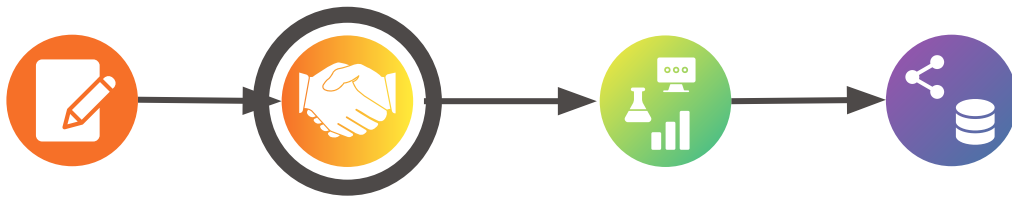
Will we have to pay for data storage (of sensitive data?)

How will data be accessed & transferred?



Budgeting for RDM-personnel & time effort

Will we need help from a Data Steward (and budget for this)?
Will we need with data analysis, data warehousing or deposition?

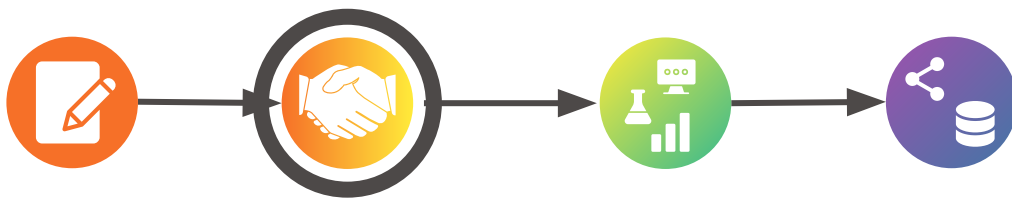


EP PerMed
European Partnership
for **Personalised Medicine**

When awarded funding

Full DMP required

3 month after project start



EP PerMed
European Partnership
for **Personalised Medicine**

When awarded funding

Full DMP required

Documentation, formats, volume

Quality assurance including Metadata standards

Backup during project

Sharing & Preservation

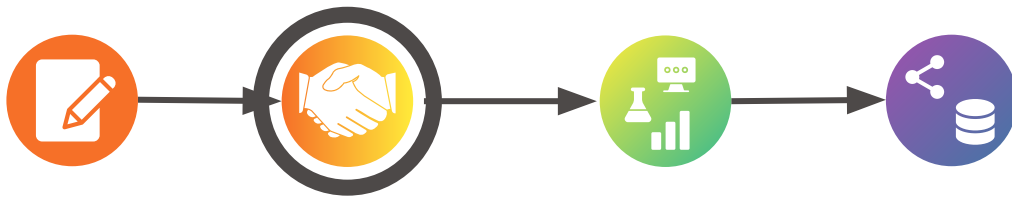
Ethical and Legal aspects - including IPR

Who is responsible in the project?

To which trustworthy repository will the data be submitted?



https://www.eppermed.eu/wp-content/uploads/EPPERMed_JTC2026_CARMEN2026_GuidelinesApplicants.pdf



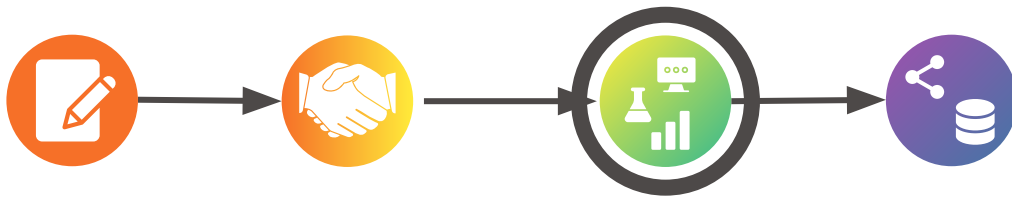
Full DMP required

Some Funders require Data management plans are to be made public and openly accessible.

Different possibilities:

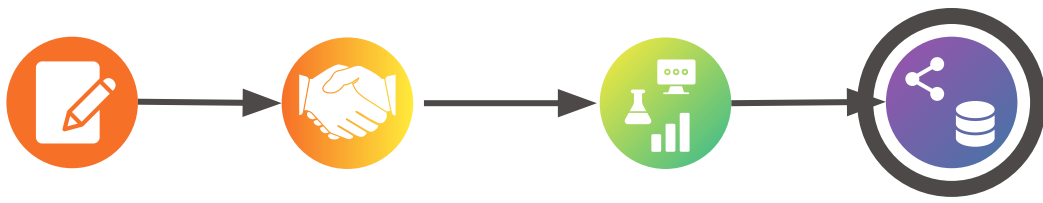
zenodo





DMP is constantly updated

Compliance with or updates of the DMP, must be reported in each annual scientific project progress report



Final version of the data management plan in connection with the final report scientific report.

Data is deposited to trustworthy repository



Horizon Europe

Open Science (OA, RDM, citizens engagement etc.) **embedded throughout HE**

14. Dissemination and exploitation of research results &

16. Open science

- *"Open science practices are addressed and evaluated under 'excellence' as they are considered a part of the methodology."*
- *"Data management plans are mandatory for all projects generating or reusing data and should be aligned with the D&E plan."*

RDA DMP Common Standard for machine-actionable Data Management Plans (RDA DCS maDMP)

Exchange format

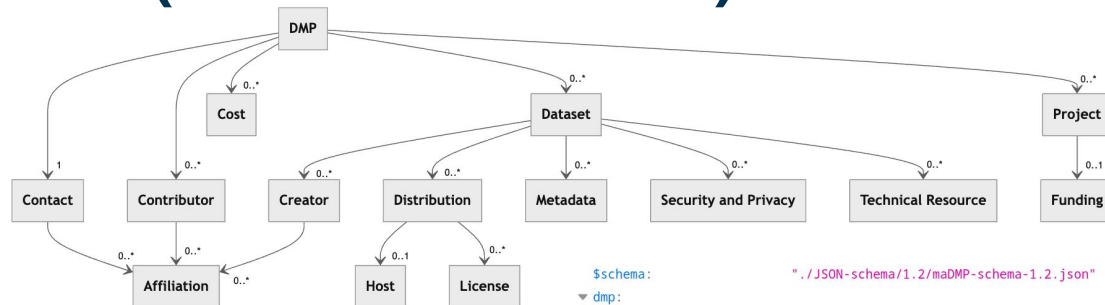
Usually in JSON

Enables re-use of information for:

Storage quotas

Permissions setup

Adding datasets to your DMP



```
$schema: "/JSON-schema/1.2/maDMP-schema-1.2.json"
dmp:
  title: "Minimal DMP"
  contact:
    contact_id:
      identifier: "0000-0000-0000-0000"
      type: "orcid"
    mbox: "cc@example.com"
    name: "Charlie Chaplin"
    created: "2018-07-23T10:10:23.6Z"
  dmp_id:
    identifier: "10.0000/00.0.1234"
    type: "doi"
  dataset:
    0:
      dataset_id:
        identifier: "10.0000/00.0.5678"
        type: "doi"
      title: "Placeholder dataset"
      personal_data: "unknown"
      sensitive_data: "unknown"
      ethical_issues_exist: "unknown"
      language: "eng"
      modified: "2019-02-06T15:30:42.1Z"
```



Your tasks

In this section, information is organised around regular research data management tasks or challenges. You will find:

- Best practices and guidelines for each data management task.
- A list of all the considerations to be taken into account when performing a specific data management task.
- Links to task-specific training materials.
- Links to tool assemblies implemented by others to address specific data management challenges.
- Links to a Data Stewardship Wizard for your DMP and to step-by-step instructions to make your data FAIR.
- A summary table of tools and resources relevant for the specific task and recommended by communities.

Find your page...

Your tasks

Compliance monitoring & measurement

How to measure compliance to data management regulations and standards.

Your tasks

Data analysis

How to make data analysis FAIR.

Your tasks

Data discoverability

How to make data discoverable

Your tasks

Costs of data management

Budgeting and costing for data management

Your tasks

Data brokering

Information on brokering data to data repositories on behalf of data producers.

Your tasks

Data interlinking

Best practices to interlink datasets from a multi-omics study deposited in technology-specific repositories.

Your tasks

Creating a data-flow diagram

Best practices to capture your planned data-flow in a diagram.

Your tasks

Data deletion

How to properly delete data

Your tasks

Data management plan

How to write a Data Management Plan (DMP).

Data management

Data life cycle >

Your role >

Your domain >

Your tasks >

Compliance monitoring

Costs of data management

Creating a data-flow diagram

Data analysis

Data brokering

Data deletion

Data discoverability

Data interlinking

Data management coordination

Data management plan

Data organisation

Data security

Data sensitivity

Data provenance

Data publication

Data quality

Data storage

Data transfer

Documentation and metadata

Ethical aspects

Existing data

GDPR compliance

Identifiers

Licensing

Machine actionability

Tool assembly >

National resources >

All tools and resources

All training resources

Your tasks

Data management plan

What should you write in a Data Management Plan (DMP)?

Description

A DMP should address a broad range of data management aspects, regardless of funder or institution specific templates. It is important to be aware of the current best practices in DMPs before starting one. For more generic information about data management planning, see also our [Planning page](#).

Considerations

Common topics of a DMP are:

- General information about the project.
- Description of the datasets that will be used and generated.
- Description of metadata, ontologies and data documentation.
- Storage solutions, data security and preservation strategy that will be adopted during and after the project.
- How, when and where data will be shared and published.
- Costs and resources needed for data management.
- Ethical and legal issues, such as privacy, intellectual property and licences.

Solutions

- This website includes best practices and guidelines about the different aspects of research data management that should be covered in a DMP.
- Core requirements for DMP have been described by [Science Europe](#).
- Consider the [DMP Common Standard](#) from the Research Data Alliance as a reference data model for organising the different topics.

What template should you use to draft your DMP?

Description

A number of DMP templates are currently available, originating from different funding agencies or institutions. Moreover, there are ongoing efforts to develop templates for machine-actionable DMPs.

Considerations

- Each funding agency could require or recommend a specific DMP template.
- Your institution could require and recommend a DMP template.
- Template could be presented as list of questions in text format or in a machine-actionable format.

Solutions

 https://rdmkit.elixir-europe.org/data_management_plan

Filled questionnaire → **Template** → **DMP in various formats**
once per funding body .docx, .tex, .html, .json, incl. maDMP



Full compliance:



The Data Stewardship Wizard is provided by:



<https://ds-wizard.org>
<https://github.com/ds-wizard>

Recommended by





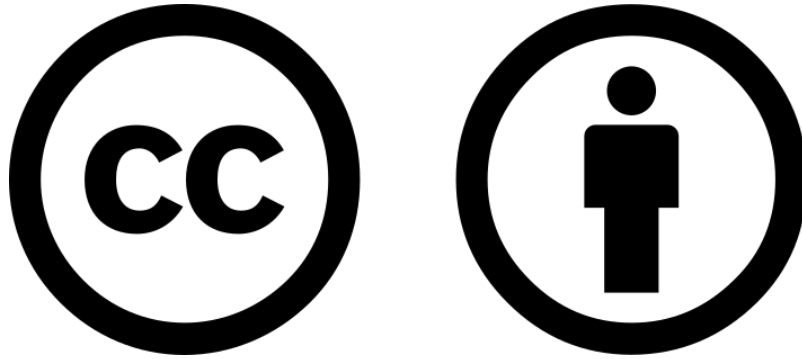
Production (also for later use)

researchers.dsw.elixir-europe.org

Testing (your DMP might disappear)

dsw-test.elixir.no

Use LS Login (registration for test environment necessary)



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