



Discussion of the key issues at the stage of planning

Korbinian Bösl

Data management coordinator

ELIXIR Norway



elixir.no

Life cycle



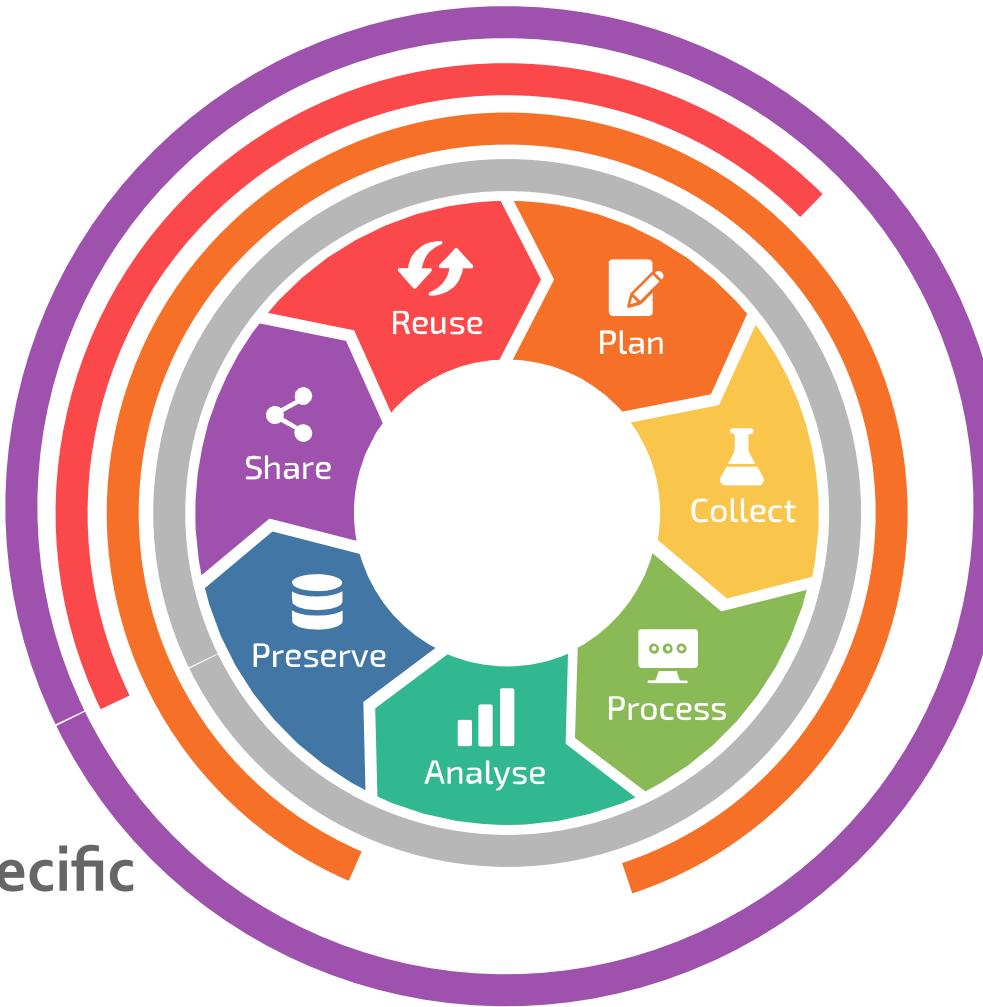
Requirements

Funder

Project
& Domain specific

Ethical & Legal

Institutional



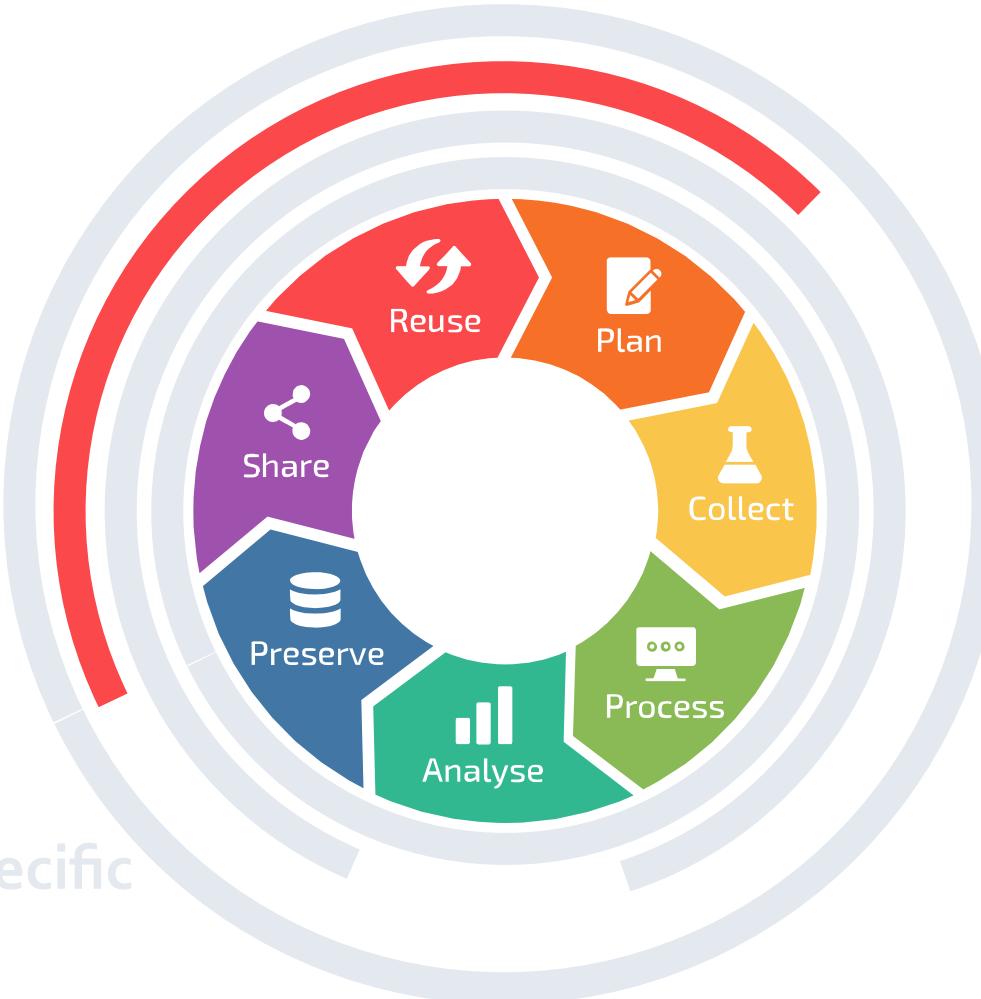
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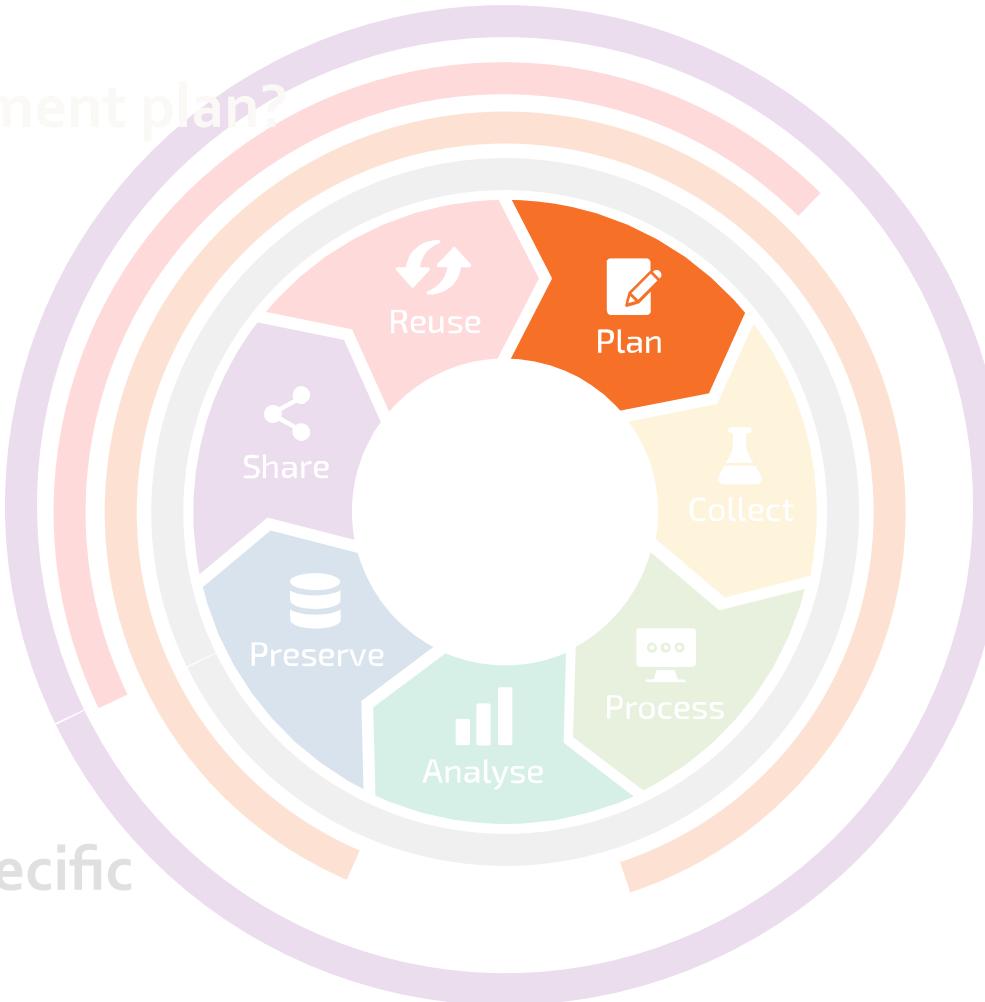
Data Management plan?

Funder

Project
& Domain specific

Ethical & Legal

Institutional

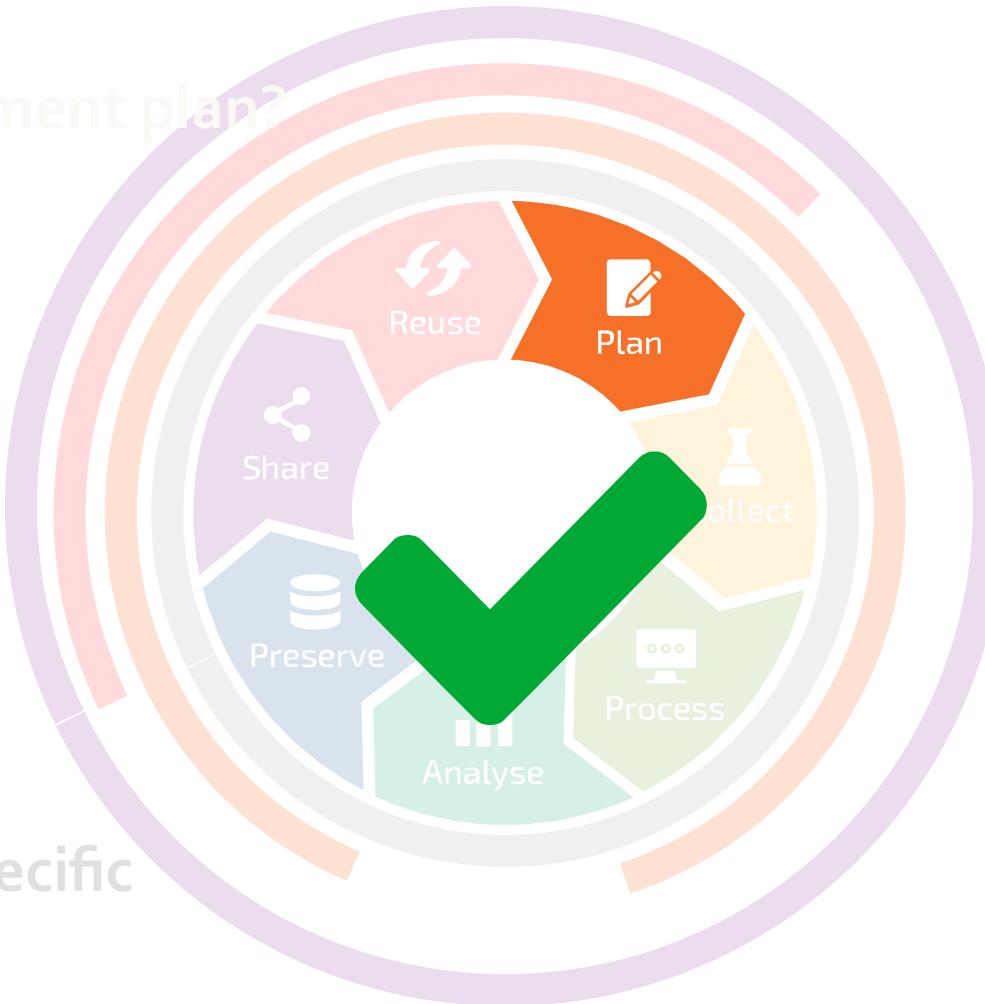


Data Management plan?

Funder



Project
& Domain specific



Ethical & Legal

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



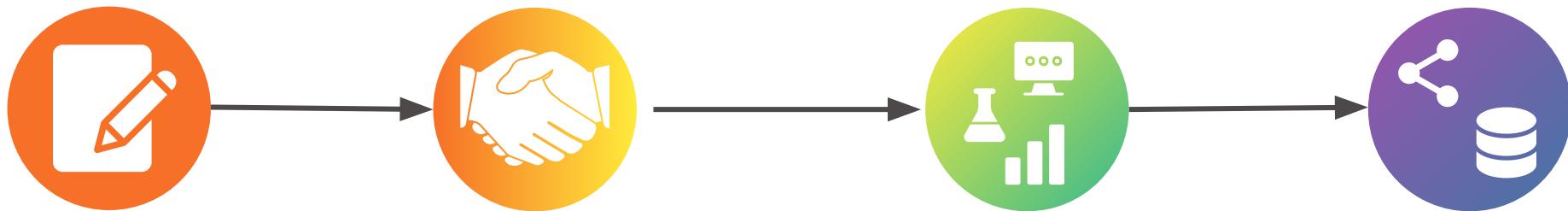
1. Introduction
2. Project Personnel
3. Quality System
4. Documentation
 - 4.1. Data Management Files
 - 4.2. Protocol
 - 4.3. Database Specification Document
5. Electronic Data Management Systems
 - 5.1. Oversight of Data Acquisition Tools
 - 5.2. Data Flow Diagram
6. DAT Design
 - 6.1. CRF and Patient-Reported 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

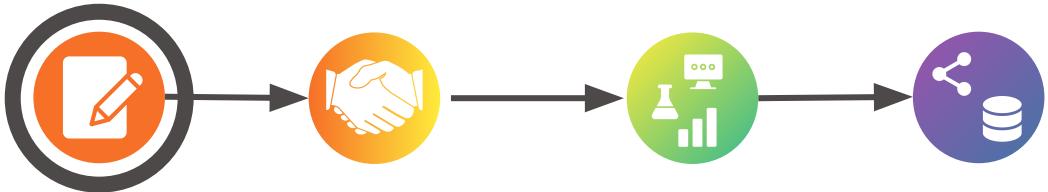
+ Your local funder



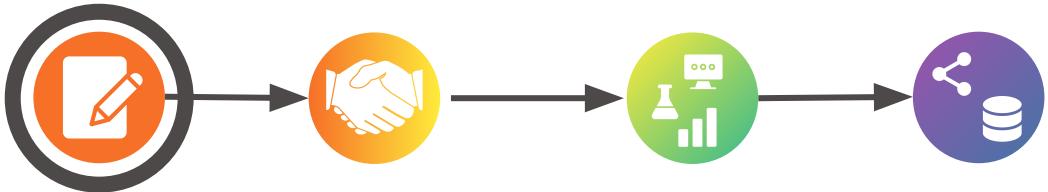


Applicants must clearly describe:

- 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

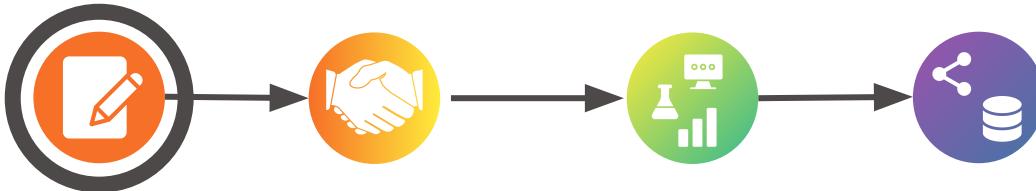


No full DMP required (- but helpful)

You should consider:

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

https://www.eppermed.eu/wp-content/uploads/EPPerMed_JTC2026_CARMEN2026_GuidelinesApplicants.pdf



§§Ethical and Legal issues

REK approval necessary (for sharing of data?)

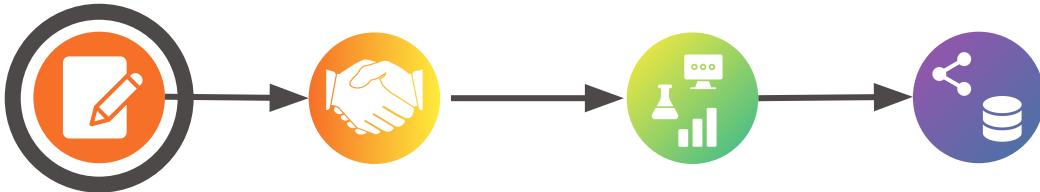
GDPR considerations

IPR aspects

Which Research Ethical Guidelines apply for this project?

RRI

https://www.eppermed.eu/wp-content/uploads/EPPerMed_JTC2026_CARMEN2026_GuidelinesApplicants.pdf

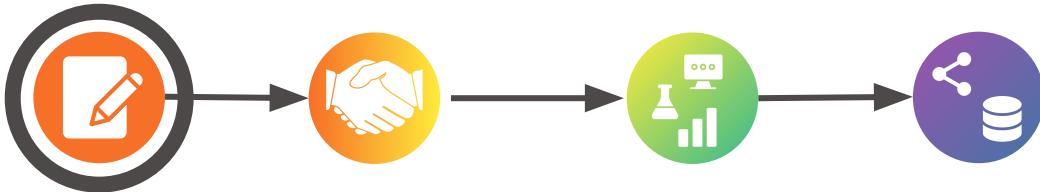


Storage and Computing

Is access to computing/storage secured?

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

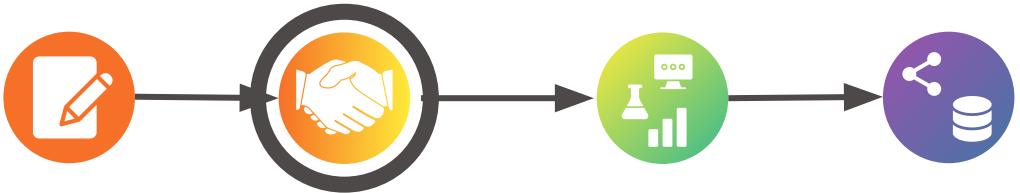
How will data be accessed & transferred?



👤 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?

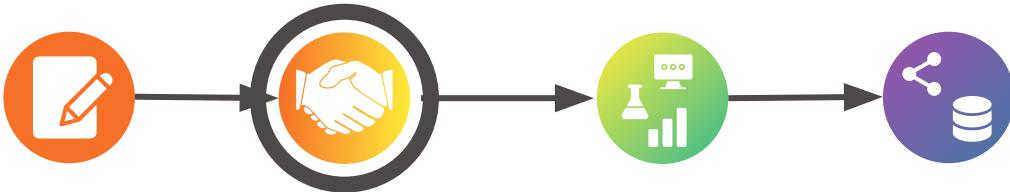


When awarded funding

Full DMP required

3 month after project start

https://www.eppermed.eu/wp-content/uploads/EPPerMed_JTC2026_CARMEN2026_GuidelinesApplicants.pdf



When awarded funding

Full DMP required

Documentation, formats, volume

Quality assurance including Metadata standards

Backup during project

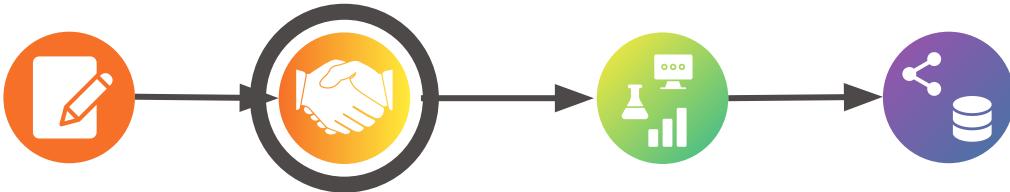
Sharing & Preservation

Ethical and Legal aspects - including IPR

Who is responsible in the project?

To which trustworthy repository will the data be submitted?



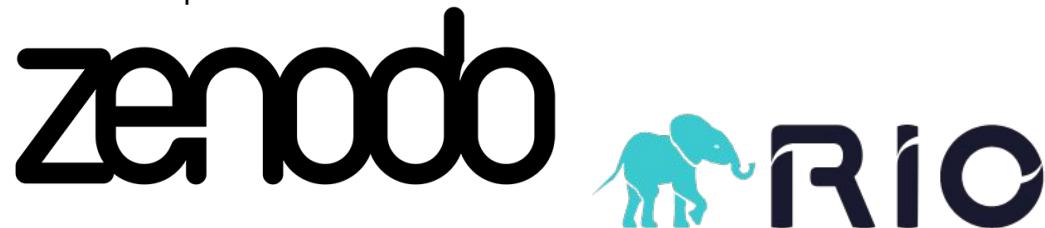


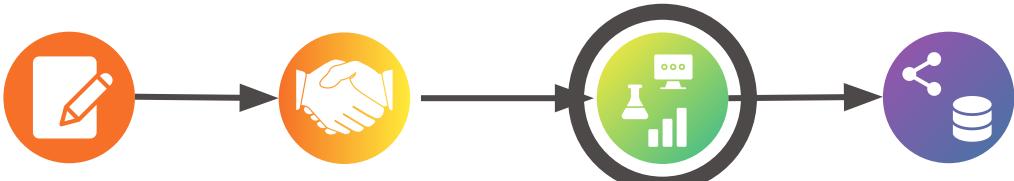
EP PerMed
European Partnership
for Personalised Medicine

Full DMP required

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

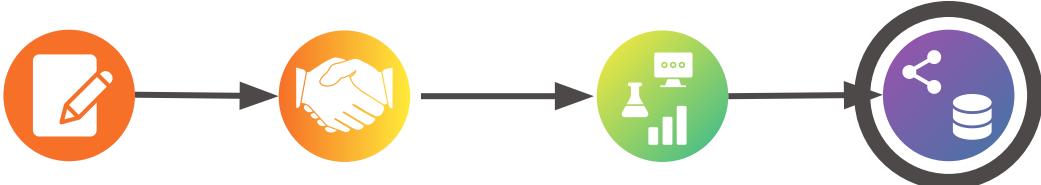
Different possibilities:





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

https://www.eppermed.eu/wp-content/uploads/EPPerMed_JTC2026_CARMEN2026_GuidelinesApplicants.pdf



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.*”

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf

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

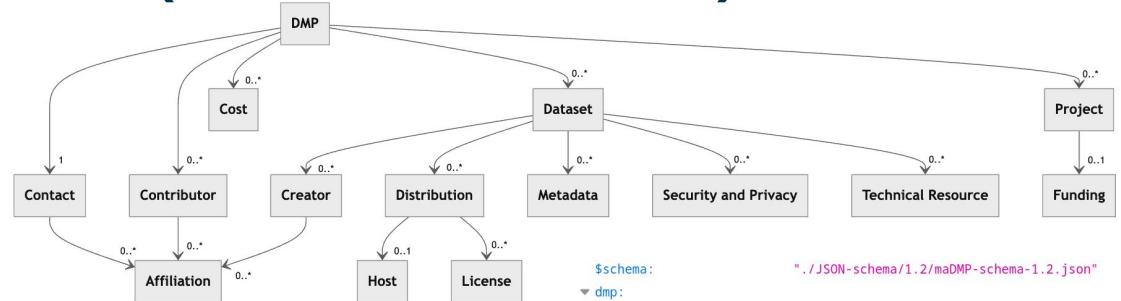
Exchange format
Usually in JSON

Enables re-use of information for:

Storage quotas

Permissions setup

Adding datasets to your DMP



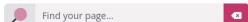
```
$schema: ..//JSON-schema/1.2/maDMP-schema-1.2.json"
  dmp:
    title: "Minimal DMP"
    contact:
      contact_id:
        identifier: "0000-0000-0000-0000"
        type: "orcid"
        mbox: "cc@example.com"
        name: "Charlie Chaplin"
        created: "2018-07-23T10:10:23.6Z"
    dmp_id:
      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.



Your tasks
Compliance monitoring & measurement
How to measure compliance to data management regulations and standards.

Your tasks
Costs of data management
Budgeting and costing for data management

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

Your tasks
Data analysis
How to make data analysis FAIR.

Your tasks
Data brokering
Information on brokering data to data repositories on behalf of data producers.

Your tasks
Data deletion
How to properly delete data

Your tasks
Data discoverability
How to make data discoverable

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

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:



DTL |

GOFAIR



<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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