



D1.4: Data Management Plan and Reports of the Project's Ethical Management Responsibilities

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Executive Summary

The present deliverable describes the Data Management Plan (DMP) that will be followed in the course of the project. In more detail, the report: a) presents an overview of the datasets collected and used by the project; b) specifies the FAIR criteria to achieve for the methods, tools and data produced by CHANGER; lists the data management activities in accordance with the applicable regulatory requirements, namely the General Data Protection Regulation (GDPR), and to the extent applicable, Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union.

By default and by design, CHANGER does not involve any processing of *special categories* of personal data (previously known as *sensitive data*). Only processing of non-sensitive personal data is planned and as such, the DMP will be a living document that will be regularly updated by the Coordinator leading WP1 as well as the project partners, in order to align with the project's needs and the emerging regulatory and sociotechnical requirements. As such, updated versions of this document will be provided during M18 and M36 (in time with the periodic evaluation/assessment of the project), updating all the necessary sections in light of the needs and findings of the project.

The present deliverable also describes the project's Ethical Management procedures and how the project will comply with ethical principles and standards.

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List of Terms & Abbreviations

Abbreviation	Definition
DMP	Data Management Plan
GDPR	General Data Protection Regulation
FAIR	Findable, Accessible, Interoperable, Reusable
RDF	Resource Description Framework
CC	Creative Commons
NDA	Non-Disclosure Agreement
REC	Research Ethics Committee
NEC	National Ethics Committee
DPO	Data Protection Officer
GA	Grant Agreement
CA	Consortium Agreement

1 Introduction

1.1 Purpose and Scope

The purpose of deliverable **D1.4: Data Management Plan and Reports of the Project's Ethical Management Responsibilities** is to describe the data management lifecycle for the data to be collected, processed and/or generated by the CHANGER project in the context of the WPs, as well as the management of ethics issues that are raised by the project activities. As part of making research data findable, accessible, interoperable and reusable (FAIR), the project's DMP includes information on the handling of research data during and after the end of the project; what data will be accessed, collected, processed and/or generated; which methodology and standards will be applied; whether data will be shared/made open access; how data will be curated and preserved (including after the end of the project); and the GDPR compliance scheme.

The information in this document does not supersede the rules and conditions laid out in the CHANGER Grant Agreement (GA) and those in the CHANGER Consortium Agreement (CA).

1.2 Approach for Work Package and Relation to other Work Packages and Deliverables

From an organisational point of view, the present D1.4 deliverable is a direct outcome of T1.2: Project Data Management, Legal & Ethical Support. However, its scope extends horizontally to all major CHANGER activities across the WPs following D1.1: Report on all project structures and processes, critical risks and management processes. Its purpose is to ensure that data generated and published within the project are lawfully obtained and processed, adequately described, contextualised and documented, appropriately shared, openly accessible as much as possible, and are in compliance to applicable EU and national regulations related to data confidentiality, integrity and availability (CIA).

As activities of the project evolve, all aforementioned aspects will be clarified or modified if necessary. To accommodate this reality, the DMP will be a living document, regularly reviewed and revised if necessary to incorporate and manage any changes of data usage and production in the project and the actions carried out thereof.

1.3 Methodology and Structure of the Deliverable

The deliverable is structured in accordance with the template and guidelines provided by the European Commission (EC), and is organised in the following sections: Section 2 provides a data summary addressing issues regarding the purpose of the data access/collection/generation and its relation to the objectives of the project, the types and formats of data the project will generate/collect, the origin of data, the expected size of data, and the data utility (i.e., to whom might data be useful). Section 3 reports on the measures and directions to be adopted to ensure compliance of CHANGER with FAIR data principles. Section 4 summarises the allocation of resources and a preliminary cost coverage plan in the context of the project, in order to serve the aforementioned measures. Section 5 discusses the main concerns regarding data security and privacy and the proposed approaches to face them, taking into account wider ethical and legal aspects related to the data involved in the project. Section 6 describes the Ethical Management Responsibilities.

2 Data Summary

The DMP adheres to and complies with the “H2020 Data Management Plan – General Definition” given by the EC online, where the DMP is described as follows:

“A DMP describes the data management life cycle for the data to be collected, processed and/or generated by a Horizon 2020 project. As part of making research data findable, accessible, interoperable and reusable (FAIR), a DMP should include information on:

- The handling of research data during and after the end of the project;*
- What data will be collected, processed and/or generated;*
- Which methodology and standards will be applied;*
- Whether data will be shared/made open access; and*
- How data will be curated and preserved (including after the end of the project)”.*

Qualitative analysis lies at the project's research core. Synching secondary desk research with ‘field results’ allow the production of knowledge in the form of papers, articles and further qualitative assessments as per the scope and the deliverables of CHANGER. As a matter of principle, being a project that embraces open knowledge, the policy for the project's outputs and publications is free/open-access by default. More specifically, the project's deliverables, such as research reports, handbooks and digital outputs, are freely distributed through the Embassy of Good Science and the project's website under Creative Commons licenses, with the exception of the internal deliverables, which concern the project's ethics and management. Respectively, for the project-related scientific publications the available open-access options will be selected, including both gold and green open access depending on the case.

These policies are compliant with the official FAIR guidelines¹ [1] (findable, accessible, interoperable and re-usable) as, and to the extent possible, adopted by CHANGER.

In respect of research data, we note that CHANGER is not about developing, merging, mining datasets but is rather about qualitative analysis following interpretive methods. The project comprises primarily of qualitative case study research and participatory action research, following a participatory design approach. As such, the analysis and respective research outcomes do not involve quantitative processing of large datasets. It rather relies upon qualitative, small-n research to explore, examine and assess a set of innovative ethics review methodologies, views and best practices in the emerging data driven and automated era. To put this in context, the project's “ground truth” lies on the aggregation, analysis and sharing of anonymous views and overall feedback, as obtained by the participants as described in WP2, WP3, WP4 and WP5. The data obtained from direct interaction of the participants through interviews and focus groups will be transcribed by Task leaders, and the recordings will be deleted soon after transcription.

Data generated as part of interviews and focus groups are considered as unstructured data. Since no structured datasets are necessary to achieve the project objectives, no metadata directly linked to

¹ H2020 Programme Guidelines on FAIR Data Management in Horizon 2020
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf.

the obtained raw data are provided, thus making related licensing concerns of no relevance. As such, neither a respective catalogue of relevant legal and regulatory data models nor a strategy for a homogenisation of the data sources needs to be provided.

2.1 Purpose of data collection/generation and relation to the project objectives

At the core of CHANGER's objectives and ambition is to: a) evaluate current approaches in ethics review and identify best practices, b) develop new approaches, c) enhance knowledge and expertise, and d) identify policy implications. As such, the data processing activities will be subject to data protection law principles, including purpose limitation, data minimisation and lawfulness, while fully excluding processing of special categories of personal data (under art. 5 of the GDPR).

2.2 Types of data/formats that will be generated/collected by the project

Data to be collected come in very limited volumes in a raw and analogue rather than structured electronic formats. No further data transformation takes place, no metadata attached and no relevant metadata schema deployed. Thus, preferred types for generated data that favour interoperability, like, indicatively Resource Description Framework (RDF) in its different serializations are not relevant in the present context.

Table 1. Identified data types, with respect to their **meaning**.

Name	Description	Format
Interviews/Focus groups/Dialogue Events	Name, contact details, (email address), participants' image and voice (video recordings) participant's feedback (views, opinions, positions).	Paper, electronic format, audio, video, reporting
	Report drafting	Deliverables & Reports in electronic format
Secondary desktop research	Journals, archives, portals	Online publications, project deliverables in electronic format
e-Newsletter Subscription	Contact details	Electronic format on CHANGER website

Table 2. Identified data types, with respect to their **openness**.

Name	Description
Private of partners	Available solely to the partner who owns it
Available to partners	Not public, only available to the partners. No Non-Disclosure Agreement (NDA) is necessary and the Consortium Agreement suffices
Published as Open Data	Publicly available with an open license
Open Access/Public	Publicly available with no further clarifications. Secondary uses may not be allowed or permissions to be required
Public Domain	Public with no legal restrictions, distributed under a CC0 license

2.3 Data publicly available reused by the CHANGER project

Publicly available data from relevant EU projects, such as pro-Ethics, iRECS, SOPs4RI, TechEthos, etc., published scientific papers, reports or other public research sources will be re-used to enrich the research framework and the development of the deliverables and related policy roadmaps.

2.4 The origin of the data used in the project

The present section is directly linked to section 2.1. and involves the following origins of data:

- The CORDIS database for relevant EU projects research (publicly available).
- Secondary desktop research through journals and archives (publicly available).
- Field data produced directly from the observation points (including, interviews, focus groups and other participatory events).

2.5 To whom the data will be useful

2.5.1 Within the CHANGER project

CHANGER partners will have access to the datasets that have been assigned to them, in line with their responsibilities as defined by tasks as described in individual WPs. Specific connections between WPs will be developed:

- Datasets produced in WP2 will be useful to WPs 3, 4 and 5;
- Datasets produced in WP3 will be useful to WPs 4 and 5;
- Datasets produced in WP4 will be useful to WP5;
- Datasets produced in WP5 will be useful for the wider objectives of CHANGER.

Data obtained from interviews and focus groups will be transcribed and pseudonymized (coded) at the site/centre where they take place. All data will be shared in a pseudonymised (coded) form and solely between institutions in accordance with the CHANGER ethics approvals, and only for the

purposes of CHANGER research, while maintaining compliance with the GDPR, in particular within the country in which the data have been generated, between centres having received ethics approval. Either way, to the extent personal data are involved all related processing activities are subject to the existing Consortium Agreement.

2.5.2 Outside CHANGER project

The following groups are identified:

- Ethics Review Experts;
- Chairs or members of Research Ethics Committees (RECs), members or scientific officers of National Ethics Committees (NECs);
- Researchers in research integrity and ethics, policy advisors to different bodies such as the EC;
- The community of researchers and practitioners of humanities, social and political studies.

The data that will be shared with non-EU countries will be limited to Brazil, Norway, North Macedonia and the UK, subject to the appropriate safeguards for international data transfers, like binding corporate rules, derogations and adequacy decisions. Both the UK and Norway have an adequacy decision on data protection by the European Commission (on the basis of article 45 of Regulation (EU) 2016/679). No personal data will be shared with non-EU collaborators.

2.5.3 Publications

CHANGER data and information will not be directly publicly available as raw datasets, but rather indirectly as derivative and processed knowledge, in the form of publications, reporting and project deliverables. The general principle is that all publications will be made available through the dedicated area on the project website as well as through official repositories such as the Open Aire platform and the Embassy of Good Science.

3 FAIR Principles

As one of the main objectives of CHANGER is the promotion and facilitation of the usage of CHANGER output and assets, it is critical to ensure that project data results adhere to the FAIR principles, that is they are Findable, Accessible, Interoperable and Reusable through different means. Additionally, and as described in the previous sections, CHANGER to some extent will try to rely on input data (outside the project's sphere of control) that also adhere as much as possible to the FAIR principles. The following subsections describe the main actions and directions that will be examined in order to ensure that FAIRness is fulfilled to the maximum possible extent for data generated in the context of CHANGER.

3.1 Making data findable, including provisions of metadata

As explicitly stated, there are two principal types of data, quantitative raw data aggregated through the participatory events, and secondary judgments, evaluations, conclusions and recommendations. Raw data will be maintained at the level of the participating institutions solely for the purposes of the deliverables. Processed data (anonymized and pseudoanonymised) will be stored and available via CHANGER's website in the form of publications and reports which in turn will use Digital Object Identifiers (DOI) and metadata vocabularies and schema inherent to the hosting environment.

3.2 Making data openly accessible

In principle, data shall be transformed to information and knowledge expressed and publicly available in the form of publications, articles, papers and CHANGER communication channels. This processed data may be made publicly available, subject to privacy or random limitations, constraints and restrictions as expressed via the consent forms and CHANGER's ethics approvals, solely in the context of publications, reports and deliverables. Furthermore, agreement amongst the partners collecting or generating the data is needed before the data will be made available, for example on which data (individual / aggregated / metadata) will be made available

All data, reports and publications are made publicly available in the sense of Open Access. CHANGER publishes its assets on the Embassy of Good Science and the project's website. Furthermore, assets receive a DOI to make citation and identification easier. Licenses will be represented in a machine-readable form, using common metadata descriptor (e.g. dct:license) pointing to standard URL licenses as inherent to the hosting environments.

3.3 Making data interoperable

As stated previously, no structured datasets will be generated. Hence, no incorporation of standards and widely used schemas, ontologies and vocabularies for describing and representing such data assets will be used. For the rest of the CHANGER assets and general knowledge open access requirements apply.

3.4 Increase data reuse (through clarifying licenses)

Unless CHANGER partners deem otherwise (i.e. confidentiality) CHANGER assets are open by default, using permissive licenses like the CC-BY license (Creative Commons 4.0 Attribution International) or restrictive licenses like CC-BY-NC (Creative Commons 4.0 Attribution Non-Commercial International) unless this hampers the project's operational model. As the case may be, a hybrid licensing scheme may be applied. Raw data generated from interviews and focus groups will undergo a quality check and will be deleted 3 years after the termination of the project. Publications and reports will enjoy long time preservation on the project's repos or third-party environments; they will undergo a quality check in order to analyse their plausibility and consistency, making sure that others can directly use it to perform assessments and validate the results produced by the project.

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4 Allocation of Resources

Per the project's work plan, data management activities are the main responsibility of Task 2.1, led by NCSR-D, where usage requirements and consequently data needs are defined. In any case, effort on Data Management will be also dedicated in the context of Work Packages 2, 3, 4 and 5 where the actual data collection, processing and generation primarily takes place. Regarding additional costs emerging from the adopted approach for data and knowledge publishing, the following table provides a high-level summary.

Table 3: Associated costs with data management activities.

Issue	Action
Costs for making non-patented data, methods and other CHANGER assets FAIR	<ul style="list-style-type: none">– Fees associated with the publication of scientific articles containing project's research data in "Gold" Open access journals. The cost sharing, in case of multiple authors, shall be decided among the authors on a case-by-case basis.– Project Website operation: to be determined.– Data archiving at OPENAIRE: free of charge.– Data archiving at Embassy of Good Science: free of charge.– Copyright licensing with Creative Commons: free of charge.
Partner responsibilities	Every partner is responsible for the data they produce. Any fee incurred for Open Access through scientific publication of the data will be the responsibility of the data owner (authors) partner(s) in compliance with the CA, Article 8.4.2.1: During the Project and for a period of 1 year after the end of the Project, the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 29.1 of the GA.
Long-term preservation	Data preservation of at least 1 year after the project is required by the GA (Article 31.3). The associated costs for dataset preparation for archiving will be covered by the project itself. Proprietary and confidential datasets of any type will remain the property of the owners.

5 Data Security, Protection & Ethics Design

5.1 Security scope in the context of CHANGER

CHANGER uses established platforms and execution spaces that already adopt state-of-the-art security, authentication and authorization mechanisms. All personal data in raw form are part of the material which will be used for deliverables and publications. As such, no personal data are published or communicated with the public. Collected data will be stored on involved partners' (Task leading partners) premises, on secure disposal, where only members of the research team will have access under need-to-know restrictions and overall supervision. The data will be used only within and by the project, and will not be made accessible to any third party or the public.

All confidential information including the personal data at hand enter the CHANGER ecosystem via interviews, focus groups and desktop research managed by the WP leaders and partners involved in the research activities, and are subject to the following security controls:

- Appointment of a Data Protection Officer (DPO);
- Access on a need-to-know basis;
- Information Security.

5.2 Data protection and GDPR compliance

It is important to highlight at this stage that the central concept of CHANGER remains the collective knowledge, rather than the individual. No behavioural patterns are identified on an individual level whatsoever. The endgame is to gather information linked to wider collective perceptions, opinions, positioning and choices, generated by individual observation and interview. Any personal data involved is the raw material for wider conclusions and secondary knowledge generation, with no individual involvement or interest. That said CHANGER will pay particular attention to the protection of personal data, to maximize its utility in compliance with applicable legislation relating to the protection of personal data. CHANGER shall ensure that no data will be shared and processed without ensuring legal compliance and calculating legal risks. In particular, the CHANGER project shall ensure that personal data are protected according to the GDPR and that the use cases and field events adhere to the GDPR.

Either way, a full scale GDPR process is developed. Appointing a DPO at the coordinator NCSR is the starting point and appropriate technical and organisational measures and safeguards are deployed throughout the personal data lifecycle as met within the project subject to the methodology in place.

By default and by design, CHANGER does not involve any processing of special categories of personal data. In the unlikely event there is such data disclosure during the interviews and/or focus groups, these data will not be transcribed and will be subject to the appropriate guidelines of the DPO.

5.3 Ethics Design

Towards its ethical and legal compliance subject to the safeguards and controls in place, CHANGER caters an inclusive character and design. To that end:

- Researches and wider actions conducted in the context of WP2, WP3, WP4 and WP5 neither involve any particular vulnerable participants nor address any highly sensitive topics.
- Data processing activities are not personal data oriented. In any case, CHANGER keeps track for future associations that may tag data as '*identifiable*' or entail properties of an individual, thus classify it as personal.
- CHANGER partners involved in personal data processing activities in the context of the CHANGER tasks are the joint controllers. No Controller - Processor data flows and data sharing agreements apply at this stage.
- Main purposes of processing:
 - Scientific Research;
 - CHANGER deliverables and asset generation;
- Legal basis:
 - Consent (appropriated consent forms per processing activities);
 - Public Interest as the project aims at providing useful scientific insights related to the practice of research ethics and the RECs operational model.
- Data Source:
 - Publicly available sources, mainly under open licenses;
 - Directly from Individuals.
- Data types:
 - Personal data *stricto sensu* are limited both in scale and in scope. In the identified processes, data are no longer gathered about one specific individual, but rather as general knowledge. Data are analysed on the basis of patterns and group mainly focused on research ethics models and structures.
 - Biometric data: It refers to all data captured via audio/visual recording and/or photographs. GDPR Recital 51 states that: "The processing of photographs should not systematically be considered to be processing of special categories of personal data as they are covered by the definition of biometric data only when processed through a specific technical means allowing the unique identification or authentication of a natural person. The same goes retrospectively for audio and video as the processing described herein does not aim to uniquely identify natural persons. Thus, voice and image in the context of CHANGER do not refer to related voice and image recognition patterns, through sophisticated algorithms, but rather to static information captures with no further analysis/processing whatsoever. On top of that any processing of that sort is under the legal basis of informed consent, hence satisfying the lawfulness requirements.

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- Web analytics data: CHANGER website analytics including number of accesses per year and number of individuals/organizations registered to receive project updates.
- Data transfers to non-EU countries: YES, solely in pseudonymised format where the key is kept at the EU partner and subject to the international data transfer rules as mentioned.
- Data transfers from non-EU countries: YES. In compliance with the relevant national laws in each non-EU country.

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6 Ethical Management Responsibilities

6.1 Introduction

As part of WP1, the coordinator NCSR-D provides ethics support to the project (see also D1.1), with the involvement of all partners. The CHANGER consortium consists of ethics experts, ethicists and lawyers who have long experience and can ensure compliance with international ethics standards, as well as the applicable international conventions, EU and national legal provisions.

6.2 Research involving human participants

The project activities raising ethics issues are related to the involvement of human participants in social sciences/humanities research, and CHANGER takes full awareness of all ethical issues addressed in the guides "Guidance Notes on Ethics in Social Science and Humanities" and "Ethics and Data Protection", published respectively in October and November 2018 (and updated in 2021) by panels of experts at the request of the European Commission.

For the work involving human participation in social sciences/humanities research, all necessary ethics approvals/opinions and/or authorisations will be obtained prior to the start of the research activities. The CHANGER team is aware of differing practices of review of social sciences/humanities research and expect that in some countries in the consortium ethics approvals/opinions are not required or are waived for that type of research. All participants will be selected in an unbiased manner, including based on gender balance and inclusivity.

6.3 Data Protection

The collection and processing of personal data will be conducted according to the procedures described in detail in Section 2, and in accordance with the applicable international, EU and national laws and regulations, and after previous written informed consent by the individual. The Consortium will process data committing to the highest standards of data security and protection, in order to ensure the integrity, confidentiality and control of the data (see Section 2).

6.4 Involvement of non-EU countries

CHANGER will perform activities and collect data from non-EU countries, namely the UK, Norway and Brazil. Research and data collection will be performed under the same conditions as in EU countries except if justified by local requirements that do not contradict the spirit of ethical guidelines. Request for approval of all study activities will be submitted to the local ethics committees in compliance with relevant requirements.

We confirm that the research that will be held in non-EU countries would be allowed in all EU Member states.

6.5 Gender aspects and inclusivity

CHANGER encourages a balanced participation of all genders at all levels of the management structure and research activities aligned with the EC 2016 checklist. In addition, the CHANGER consortium will ensure that project activities including interviews, focus groups and training will be gender-balanced and inclusive. Beyond the project, CHANGER is expected to have an impact on ensuring gender balance and diversity in research by promoting methodologies and in ethics reviews that incorporate ethics-by-design and inclusive research practices. All project activities are designed in line with an age, gender and diversity inclusive approach, and aim to promote gender equality and bridge gaps through dedicated sessions and emphasis on gender analysis, equal participation and representation in decision-making. At the time of writing this Deliverable, the CHANGER consortium is consisted of >60% females.

6.6 Compliance with ethical principles and relevant legislations

The work in the CHANGER project is led by relevant EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out. The legal and ethics framework includes but is not restricted to the following:

- The Universal Declaration of Human Rights;
- The European Convention on Human Rights;
- The Charter of Fundamental Rights of the European Union;
- The General Data Protection Regulation.

The European Code of Conduct for Research Integrity (ALLEA – revised edition 2023) is the main ethical and integrity reference followed in the project.

7 Conclusions

The present report describes the data management lifecycle for the data to be collected, processed and generated in the context of CHANGER. As part of the pursue to make research data findable, accessible, interoperable and re-usable (FAIR), it focuses on the handling of research data during & after the end of the project; what data will be collected, processed and/or generated; which methodology and standards will be applied; whether data will be shared/made open access; how data will be curated and preserved (including after the end of the project). On top of that an actionable ethical design warrants relevant and up to date ethical compliance.

The current deliverable is the initial version of the project's DMP, which will be treated as a live document from hereon; as the project evolves, the report will be revised and updated providing further details and - if needed - amendments and corrections to make sure that all data-related aspects of CHANGER are covered thoroughly and in accordance with the guiding principles of FAIRness, security and privacy.

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