CHANGER
CHALLENGES AND INNOVATIVE CHANGES IN RESEARCH ETHICS REVIEWS

D1.1: Report on all project structures and processes, critical risks, and management processes

Grant Agreement ID	101131683	Acronym	CHANGER
Project Title	Challenges and Innovative Changes in Research Ethics Reviews		
Start Date	01/01/2024	**Duration**	36 Months
Project URL	TBA		
Contractual due date	31/03/2024	**Actual submission date**	
Nature	R = Document, report	**Dissemination Level**	PU = Public
Author(s)	V. Mollaki (NCSR-D), X. Gialia (NCSR-D), V. Karkaletsis (NCSR-D)		
Contributor(s)	E. Galifianaki (NCSR-D)		
Internal Reviewer(s)	T. Spranger (UBO), I. Manos (UM)		

Document Revision History *(including peer reviewing & quality control)*

Version	Date	Changes	Contributor(s)
V1.0	01/02/2024	Initial complete draft	V. Mollaki, X. Gialia, V. Karkaletsis, E. Galifianaki
V1.1	06/03/2024	Second version sent to internal reviewers	V. Mollaki, X. Gialia
V1.2	19/03/2024	Third version after internal review	V. Mollaki, X. Gialia, V. Karkaletsis
V1.3	27/03/2024	E-submission to Participant Portal. Pending Review by EC	X. Gialia

Executive Summary

In accordance with the objectives of Work Package 1, this deliverable is dedicated to describing the conduction of continuous project structures and processes for the operation of the project and the production of its scientific and technical results. Task 1.1 is concerned with the management of the quality of the produced deliverables and other project outputs throughout the project's lifespan. Moreover, the current deliverable examines potential risks and management procedures.

Risk management is considered as an aspect of quality, since risks that are unforeseen or remain unmanaged can severely affect both technical and scientific progress, let alone its quality. The project risk management methodology includes the steps for conducting risk identification, risk assessment, determination of risk response strategies and risk monitoring processes. The objectives of project risk management are to decrease the probability and impacts of events or circumstances adverse to the project success. Risks are identified and assessed by all partners, while the risk management process is orchestrated by the Project Coordinator. Every identified risk is evaluated and tagged with a probability and impact and is accompanied by a specific avoidance and/or mitigation plan. A Risk Management Registry is created and updated throughout the project's lifespan to systematically document the identified risks together with their assessment and mitigation strategies.

The procedures described in the present document are in line with current best practices in project management and they are well suited to the project, i.e., they are effective and do not require excessive quality control overheads.

The document describes how the CHANGER project will be managed. In particular, it presents the structure of the consortium, by explaining the consortium partners and their individual or group roles and responsibilities in the project to achieve the objectives set. It also outlines the management procedures in terms of communication and dissemination, meetings, planning and overall coordination, in detail.

Table of Contents

List of Figures

List of Tables

List of Terms & Abbreviations

Abbreviation	Definition
GA	Grant Agreement
CA	Consortium Agreement
WP	Work Package
PC	Project Coordinator
DoA	Description of Action
EC	European Commission
KPIs	Key Performance Indicators

1   Introduction

The deliverable will detail the administrative and management processes to be enabled during the implementation of the project, including the ways that progress is monitored, conflicts are resolved, and risks are recognized and mitigated.

1.1   Purpose and Scope

This deliverable presents the Project Structures and Processes, Critical Risks and Management Processes of the CHANGER project. 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). The deliverable does not cause any changes to legal obligations.

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

This is a deliverable of Task T1.1 Administration, quality, financial, and risk management, which aims to coordinate and manage administrative, legal, and contractual matters. Another, subsequent deliverable (D1.4 Data Management Plan, M6) will analyse in detail the ways that data will be managed in the context of CHANGER in accordance with all relevant regulations as well as ethical, openness and FAIRness principles. It will also include the Ethical, Gender, Legal and Security Compliance Framework that will be mobilized in the context of the project. This is a living document that may be reviewed and revised throughout the lifespan of the project in order to take into account new information and modified requirements.

1.3   Methodology and Structure of the Deliverable

In accordance with the requirements, rules and guidelines set in the CHANGER Grant Agreement and Consortium Agreement, the deliverable defines the project organisation, roles and responsibilities, details the processes for deliverables submission, and project reporting along with the internal reviewing process. It also provides information on the tools used for project coordination and collaboration, such as the mailing list, the repositories for deliverables and reports, the templates to be used for all project documents and deliverables.

1.4   Relation to the Work Packages and Deliverables

The present deliverable describes the CHANGER processes and structures, as well as management processes and thus, cross-cuts horizontally all WPs of the project and defines rules and procedures for the preparation, review and submission of all deliverables.

2 Project Structures and Processes

2.1 Project Structures

2.1.1 General Assembly

Objectives: The General Assembly is the ultimate decision-making body of the consortium and the highest level of management in CHANGER. It is responsible for the overall management, planning and control of the project such as: potential changes of project's technical scope, contractual matters, budget, timeline, deliverables, milestones, (re-)allocation of resources, accession/recession of partners, intellectual property rights. It also monitors the overall progress of the project in accordance with the Description of Action (DoA).

Composition: The General Assembly comprises of one Representative from each consortium partner or a delegated person, and is chaired by the NCSR-D Project Coordinator (PC) unless decided otherwise in a meeting of the General Assembly. The General Assembly is formally empowered by the CA to take important high-level decisions affecting the implementation of the project. Each General Assembly Member is deemed to be duly authorised to deliberate, negotiate and decide on all matters discussed in the meeting. The Members agree to abide by all decisions of the General Assembly. All General Assembly Members participate in a cooperative manner in the meetings.

At the time of writing this Deliverable, the CHANGER General Assembly is composed of members described in Table I.

Table I. Members of the General Assembly. *

General Assembly Members	
Member	**Delegated person**
Vangelis Karkaletsis	Vicky Mollaki
Tina Garani-Papadatos	-
Ana Marusic	Antonija Mijatovic
Jeanne Bonnici	Marina Markellou
Marjo Rauhala	-
Matthias Kaiser	Ellen-Marie Forsberg
Constantin Vica	Alexandra Zorila
Ljupco Risteski	Eda Starova Tahir
Alfonso Alfonsi	-
Tade Spranger	Luciano d'Andrea
Pascal Borry	Phaedra Locquet
Hella von Unger	Nevien Kerk
Ioannis Manos	Georgia Rina
Alexander Bagattini	Michael Schmidt
Carla Barbosa	-
Edward Dove	-

* At the time of writing this Deliverable Ben 16 UNIRIO is in the process of applying for national funds to fund their participation in CHANGER. Thus, Ben 16 UNIRIO has not signed the CA and has not appointed a General Assembly representative, since the Brazilian government will only answer their application and announce the budget in July 2024. Therefore, they cannot be liable until then and they will sign the CA when they secure the national funding.

Meetings: The General Assembly meets at least once a year, and meetings may also be held by tele- or videoconference, or other telecommunication means. The chair (NCSR-D PC) gives written notice of a General Assembly meeting to each partner as soon as possible and no later than 45 calendar days preceding the meeting. The PC prepares and sends an agenda of the General Assembly meeting to all partners no later than 21 calendar days preceding the meeting, and any partner may add an item to the original agenda by written notice to all of the other General Assembly Members up to the minimum 14 calendar days preceding the meeting. During a meeting the General Assembly Members present or represented can unanimously agree to add a new item to the original agenda. The PC produces minutes of each meeting, which are the formal record of all decisions taken. The draft minutes are being sent to all Members of the General Assembly within 10 calendar days of the meeting and are considered as accepted if, within 15 calendar days from receipt, no Member has sent an objection by written notice with respect to the accuracy of the draft of the minutes by written notice. The PC sends the accepted minutes to all General Assembly Members.

2.1.2 Executive Board

Objectives: The Executive Board is the supervisory body for the execution of the Project, which shall report to and be accountable to the General Assembly. It also monitors the overall progress of the project in accordance with the DoA.

Meetings: The Executive Board meets at least every 6 months and meetings may be held by tele- or videoconference, or other telecommunication means. The PC provides written notice of an Executive Board meeting no later than 20 calendar days preceding the meeting and any Executive Board Member may add an item to the original agenda. The PC produces minutes of each meeting, which are the formal record of all decisions taken. The draft minutes are being sent to all Members of the Executive Board within 10 calendar days of the meeting and are considered as accepted if, within 15 calendar days from receipt, no Member has sent an objection by written notice with respect to the accuracy of the draft of the minutes by written notice. The PC sends the accepted minutes to all Executive Board Members.

Composition: At the time of writing this Deliverable, the CHANGER Executive Board is composed of members described in Table II.

Table II. Members of the Executive Board.

Executive Board Members	
Vangelis Karkaletsis	WP1
Ana Marusic	WP2
Marjo Rauhala, Matthias Kaiser	WP3
Pascal Borry	WP4
Jeanne Mifsud Bonnici, Alfonso Alfonsi	WP5

2.2   Decision-Making Procedures

The decision-making process is structured in multiple tiers as described herein. The following processes are defined with regards to the decision-making process (more details are outlined in the CA):

- The General Assembly is the ultimate decision-making body of the consortium (see also section 2.1.1). Decisions are only binding once the relevant part of the minutes has been accepted.
- Decisions without a meeting: Decisions may also be taken without a meeting if a) the PC circulates to all Members of the General Assembly a suggested decision with a deadline for responses of at least 10 calendar days after receipt by a Party and, b) the decision is agreed by 2/3 of all Parties (see CA Section 6.2.2.8). The decision will be binding after the Coordinator sends a notification to all Members.

2.3   Project Coordinator

The PC is the legal entity acting as the intermediary between the Parties and the Granting Authority. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the GA and the CA.

 Acting in this role, the Coordinator will:

- Set up an effective and ongoing communication within the Consortium, keeping the address list of Members and other contact persons updated and available.
- Ensure that the Consortium is properly represented in all communications with the European Commission (EC) through being the intermediary.
- Chair the General Assembly during its meetings.
- Monitor compliance by the Parties with their obligations under this Consortium Agreement and the Grant Agreement.
- Manage and support all plans, tasks and activities assigned to the partners.
- Coordinate the smooth operations of the project and safeguard the objectives.
- Oversee the project's progress quality-wise and monitor the proper implementation of the action.
- Protect the Consortium's rights and ensure the partners' compliance and devotion to their obligations.
- Tackle any conflicts that might arise, by adopting mechanisms for corrective resolution.
- Collect, review to verify consistency and submitting reports, other deliverables (including financial statements and related certifications) and specific requested documents to the Granting Authority.
- Transmit documents and information connected with the Project to any other Parties concerned.
- Administer the financial contribution of the Granting Authority and fulfil the financial tasks.
- Arrange any necessary amendments, decided upon by the General Assembly, to the Grant Agreement with the Granting Authority.

2.4 Work Package Leaders

For easier and more efficient coordination, CHANGER is divided in five Work Packages (WPs), each one aiming at specific objectives. Each one of them is led by one partner of the Consortium, who also has a number of responsibilities, among which, the following:

- To plan the work within the WP and divide tasks to the partners involved.
- To ensure compliance with the project's as well as the individual WP's timeframes.
- To detect deviations and take corrective measures.
- To create and submit the required reports to the PC.
- To safeguard the quality and accurate and timely achievement of the WP's objectives, deliverables and milestones.

2.5 Ethics and Gender

As part of WP1, NCSR-D provides ethics support to the project, with the involvement of all Partners (Task 1.2), because the CHANGER consortium consists of ethics experts, ethicists and lawyers who can ensure compliance with the applicable international conventions, EU and national legal provisions.

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 in not restricted to: 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 is the main ethical and integrity reference is followed in the project.

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. We are 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, based on gender balance and inclusivity.

Personal data protection: Personal data collection and processing will comply with the General Data Protection Regulation (2016/679, EU GDPR) and any applicable special derogations in the respective countries. Only personal data necessary to accomplish the project activities will be processed, in particular taking into account the principles enshrined in Art. 5 GDPR.

A Data Protection Officer has been assigned to the project: Dr. Alexandros Nousias, with a background in law (alexandros.nousias@gmail.com). Another, subsequent deliverable (D1.4 Data Management Plan, M6) will analyse in detail data management in accordance with relevant regulations as well as ethical standards, openness and FAIRness principles.

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 European Commission (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.

3 Critical Risks

3.1 Introduction

For the purpose of this deliverable, the term "risks" refers to potential risks concerning the advancement of activities and the progress of the project. Risks describe the impact on the project such as, diminished quality of the project results and outcomes, increased costs, delivery delays, or failure. Risk management withing the project incorporates the following activities:

- assessing continuously what could go wrong (risks),
- determining which risks are important to deal with, and
- implementing strategies to mitigate those risks.

Risks caused by the project, such as risks for the personal data of participants, are within the objective of deliverable D1.4 Data Management Plan, to be submitted in M6.

3.2 Risk Identification, Assessment and Mitigation

The project will continuously monitor and assess identified risks and pay specific attention to risks identified as having high and medium exposure/impact. Throughout the project lifetime, task level risks are being monitored and if necessary, the respective controls to mitigate their impact on the work plan will be taken. The main purpose of this action is constant monitoring for timely problem identification and the implementation of necessary adjustments and contingency action, on a case-by-case basis.

CHANGER has foreseen a risk management process that encompasses risk planning (identification, assessment, analysis, mitigation planning) and risk abatement (mitigation plan implementation, tracking, risk reassessment), in an iterative cycle until the end of the project, to ensure that risks are identified in a timely manner and handled proactively. Following risk identification, the impact of risks is assessed as to whether the risk level is higher than the risk that could be accepted for the project. In case that a risk exceeds the acceptable levels, a risk analysis activity will be instantiated that will define the required actions, in order to set the risk within acceptable levels. This can be accomplished through reduction in likelihood, reduction in consequences, or a combination of both. It includes the specifics of what should be done, when it should be accomplished, who is responsible, and the resources required to implement the risk mitigation plan.

Critical implementation risks and mitigation actions have already been included in Part A of the GA. At the time of writing this Deliverable, the risk management strategy as described in the DoA (Critical risks & risk management strategy) was re-evaluated in light of the project start and the kick-off meeting between all project partners (January 2024). No new risks have been identified for the project, and the mitigation measures as described in the DoA are still relevant and timely.

4   Management Processes

4.1   Preparation of Deliverables and Reports

4.1.1   Reviewing Duty

Throughout the project, all internal reviewers per deliverable are named for all the deliverables of a semester, by M1 of each semester at the latest. When assigning internal reviewers to each deliverable, care has been taken to:

- Assign deliverables to partners that have personnel capable of carrying out the review.
- Assign deliverables to partners that have a minor-to-no role in the deliverable under review, with the aim to ensure an independent view on the deliverable.
- Distribute reviewing duty evenly so as to avoid requiring excessive numbers of reviews by the same partner.

The internal reviewers must provide their input within two (2) weeks.

4.1.2   Deliverable preparation Processes

The plan for preparing, internally reviewing and submitting deliverables is shown in Figure 1. Eight (8) weeks before the official deadline of each deliverable, the drafting of the deliverable is initiated, whereas four (4) weeks before the deadline the deliverable under consideration is released to internal reviewers for further internal guidance and comments who provide their input within two (2) weeks. Final edits and revisions then take place following internal reviewing, taking into consideration any proposed corrections for the specific deliverable.

One (1) week before the official deadline the final version of the deliverable will be sent to the PC who is responsible for its e-submission to the European Commission's Participant Portal no later than the last working day of the Due Month as stated in the GA.
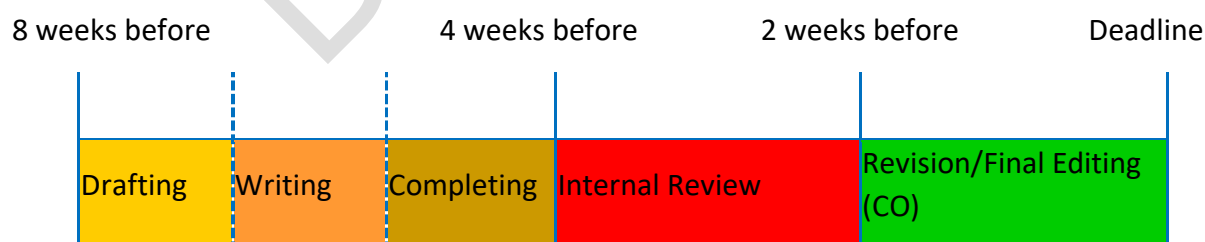

Figure 1: Deliverable preparation process

4.1.3 Project Reporting

The PC must submit to the Commission official technical and financial reports as defined in the GA. The PC must submit a periodic report within 60 days following the end of each reporting period. All other deliverables shall be submitted according to the deadlines set in the GA.

The project reviews according to the GA are as follows:

- RV1: month 18 (First Periodic Review)
- RV2: month 36 (Final Review)

In addition to the Reporting Periods in months 18 and 36, the PC shall collect information at months 9 and 27 on the progress of the project such as estimations of effort, budget and a summary of the technical part of the project. These reports are an informal procedure to monitor the whole consortium regarding the project implementation.

4.1.4 Key Performance Indicators

Key Performance Indicators (KPIs) will be used as a tool to measure and evaluate the impact of the CHANGER project activities. To verify achievements, a set of measurable success indicators have been established in relevant Tasks, where applicable. KPIs include:

- At least 20 interviews in stakeholder consultations cross-country (T2.3).
- A cross-country and cross-disciplinary focus group study with at least 10 focus groups (T.2.4).
- At least 5 different novel methodologies for ethics review will be developed (T3.1).
- Pilot tests of novel ethics review approaches in up to 7 RECs, covering regions of Europe from North to South and East to West (T3.1)
- One ethics assessment tool for AI (T. 3.3)
- One benchmarking tool for AI to be used by RECs (T3.4).
- Four MOOCs in the areas of e-consent, AI, organoids and gene editing (T4.2).
- Intensive course for at least 250 Framework Programme ethics appraisal scheme experts (T4.3).
- At least five Dialogue Events, involving globally from 50 to 70 people (T5.1).
- A Research Ethics Playbook (T5.2).

Additionally, details on the KPIs that will be used to measure the actions and achievements particular to dissemination and communication, will be presented in D1.5 (M18).

4.2   Coordination and Collaboration Tools

The CHANGER consortium will use an array of widely used online tools for coordinating work and facilitating collaboration between its members.

4.2.1   Internal Communication (other Communication tools)

Partners as an internal audience, require easy to use, daily communication within the partnership, mainly via digital means. To ensure smooth interaction and safe exchange of information within the consortium, partners have agreed, and the coordinator has established, internal communication channels -as early as the kick-off meeting- which include:

$\Rightarrow$ Dedicated project mailing list for ease of communication within the partnership.

$\Rightarrow$ Specialised WP-related mailing lists for WP partners to communicate amongst them without spamming the whole partnership.

$\Rightarrow$ To facilitate the sharing of information and collaboration among partners, it was essential to put in place a document management infrastructure that facilitates synchronous access to all documents. A shared virtual space has been set-up (Google Drive folder acting as a repository) (documents, meeting minutes, templates, presentations, deliverables, video recordings, visual material etc.) and accessibility of information from all partners (Figure 2). Simultaneously, a repository for more sensitive data that will be produced during the project has been set up in Next Cloud at NCS-RD's servers.

$\Rightarrow$ Weekly meetings between CHANGER-engaged colleagues at NCSR-D (project coordinator) take place to discuss project progress and address potential areas of concern which are then followed up with partners.

$\Rightarrow$ Teleconference facilities have been enabled, with a dedicated Zoom account, to facilitate partner discussions online. To enable all partners to keep abreast of updates in the project, monthly plenary teleconferences have been set up with regular updates across all Work Packages. Additional WP-related meetings take place on a monthly basis.

$\Rightarrow$ Frequent face-to-face plenary meetings will be organised to provide partners with the opportunity to meet and discuss in more detail and agree next steps for each WP (one already organised, kick-off in Athens, in January 2024).
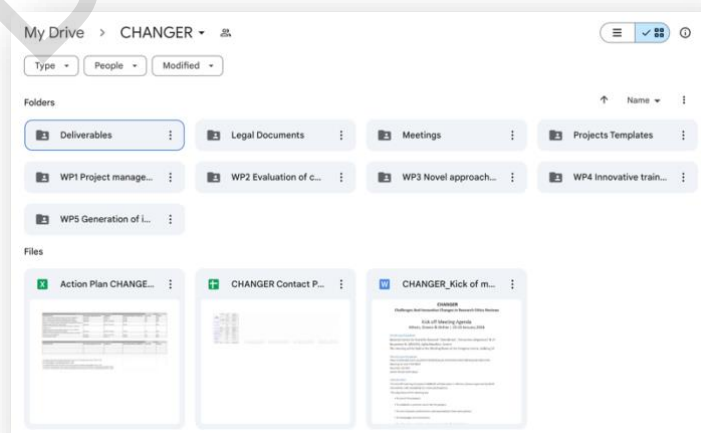

Figure 2: Google Drive Folder - CHANGER project repository

4.2.2 CHANGER visual material: Project Logo | Templates | Banners

The CHANGER project logo has been created by a professional graphic designer at NCSR-D to create a unique and memorable logo which will constitute the branding of the project. Different logo options were prepared by NCSR-D and were put up for virtual voting during the kick-off meeting (January 2024). The selected logo is shown in the Figure 3 and was designed to demonstrate the "change" that will result from the activities of the project in the field of the research ethics reviews and practices. The logo is a smart, simple, and intuitive design that includes the project's full name. It provides an easily recognised project trademark to be used throughout all communication activities (project website, presentations, flyers, Press releases etc.) to help enhance brand continuity and raise awareness.

Figure 3: The CHANGER project logo

To embed the project's brand identity across communications, several project templates (Figure 4 and 5) have been produced to ensure consistency across partner usage including:

- A PowerPoint presentation.
- Meeting agenda & minutes.
- Templates for Deliverables.

The templates were made available on the common GDrive folder for ease of access by all partners since the very start of the project.
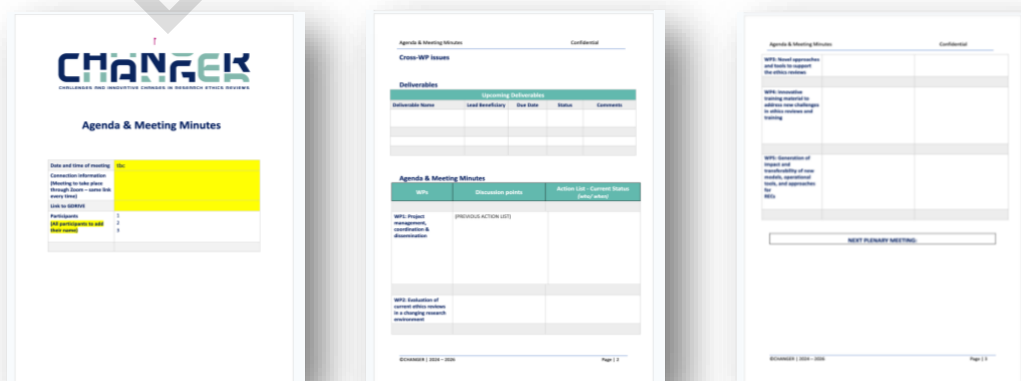

Figure 4: Agenda & Minutes template

Figure 5: Powerpoint presentation template

A series of electronic banners have been created to help promote the project online, bearing the project's brand identity, logo and colours (Fig. 6). These banners are freely available for partners to use on their social media, organisational websites, announcements about the project etc. This material will be also available on CHANGER website under the Media kit section for use by journalists or other stakeholders.

Figure 6: Branded electronic banners for general use

A virtual background has been created for online meetings and presentations with external stakeholders and at events to enhance the professional look and feel of the project (Figure 7).

Figure 7: CHANGER ZOOM background

Finally, the CHANGER project website, which is currently in preparation phase and is soon to be available online under the URL www.changerproject.eu will carry all the information about the project, its partners and its results (Figure 8).
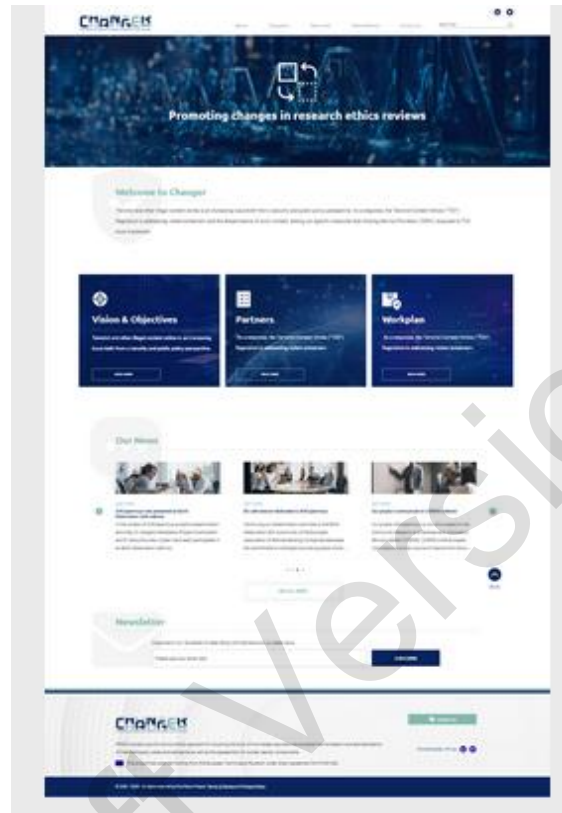

Figure 8: CHANGER project website

5 Conclusions

The present deliverable has established detailed guidelines for the management of the project. It describes how the project is organised according to what was presented in the DoA. It also describes how deliverables and reports will be prepared from a quality perspective, ensuring that processes and procedures are defined, and their execution is continuously monitored and improved as necessary. Finally, it includes the dissemination and communication material produced in the frame of the project by communication professionals at NCSR-D.

This is a living document that may be reviewed and revised throughout the lifespan of the project in order to take into account new information and modified requirements.

------End of Document------