Addressing Psychosocial and Lifestyle Risk Factors to Promote Primary Cancer Prevention: an integrated platform to promote behavioural change (IBeCHANGE)

Project Number: 101136840

D1.4 – Quality and risk assessment

Related Work Package	**WP1 – WP Project Management**
Related Task	**Task 1.4 – risk management**
Lead Beneficiary	IEO
Contributing Beneficiaries	All Partners
Document version	v1.0
Deliverable type	R
Dissemination level	PU
Due date	31/07/2024
Delivery date	31/07/2024
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Funded by the European Union

This project has received funding from the European Union's Horizon Europe research and innovation programme under the Grant Agreement Number 101136840.

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List of Abbreviations

Abbreviation	Explanation
AI	**Artificial Intelligence**
DMP	**Data Management Plan**
DPIA	**Data Protection Impact Assessment**
DPO	**Data Protection Officer**
EAB	**Ethical Advisory Board**
EC	**Executive Committee**
EM	**Ethics Manager**
GDPR	**General Data Protection Regulation**
IEAB	**Independent Ethical Advisory Board**
PI	**Principal Investigator**
PC	**Project Coordinator**
PM	**Project Manager**
PO	**Project Officer**
QM	**Quality Manager**
TSC	**Trial Supervision Committee**
WP	**Work Package**

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Executive Summary

The present deliverable, **D1.4 – Quality and Risk Assessment**, outlines the iBeChange quality and risk management plan, which is essential for ensuring the quality of the project outcomes and for monitoring the significant risks and corresponding mitigation measures. This document also serves as a guide for all project partners, detailing the policies and procedures that will be employed to manage quality and risks throughout the project lifecycle. Subsequently, this document is to be understood as a supplement to the Project Management Plan. (D1.1), and also this deliverable is based on the terms and conditions defined in the Grant Agreement and its Annexes and the specifications set in the Consortium Agreement. However, this is a dynamic document and will be updated as necessary throughout the project lifecycle.

1. Introduction

This report aims to deliver an in-depth overview of the quality and risk management plan for the iBeChange project. It is designed to complement the **project management plan** (**deliverable D1.1**) and serves as a reference for the procedures to be followed by all partners throughout the project's duration.

Two crucial aspects of project management that require special attention are **quality management** and **risk management**. Quality management involves ensuring that the project meets defined requirements and objectives, while risk management entails identifying potential threats and devising strategies to mitigate or avoid them.

In this report, we initially outline the roles and responsibilities of project stakeholders in executing the plan and monitoring its effectiveness. Following this, we delineate the primary objectives of the plan, and describe the processes and techniques that will be employed to manage quality and risks. This report, therefore, offers a detailed overview of our quality management goals, including the deliverables and milestones set for the project. We also examine the strategies and processes that will be utilized to manage quality throughout the project lifecycle, and the roles and responsibilities of project stakeholders in fulfilling these goals. In conclusion, the iBeChange risk management strategy is reported along with a summary of potential pre-identified risks and their respective mitigation strategy.

By implementing a robust quality and risk management plan, we aim to ensure that our project meets the specified requirements, is delivered on time and within budget, and adheres to the standards set by the European Union.

2. Project quality control

Integral part of the Project Management Plan is the quality assurance procedures that should provide the solid ground for successful, timely and quality implementation of the project activities. Therefore, the main purpose of this report is to define a consistent set of procedures, processes and guidelines that form a common standard to be applied and followed throughout the entire project lifetime. The quality assurance procedures defined in this document focus on:

- **Performance management**: assessing the progress of the work on a regular basis;
- **Communication management**: managing the interaction between partners during the work execution;
- **Documents / deliverables management**: overview and coordination of the exchange of documents among consortium and the submission of project deliverables to the European Commission.

2.1 Roles and responsibilities

The project management structure focuses on the coordination of resources and mechanisms to ensure efficient progress across all technical, administrative, and financial matters, thereby achieving the expected outcomes. The Grant Agreement defines the roles within the project organization, clarifying the responsibilities of the professionals involved, both individually and collectively. All consortium partners share mutual and equal responsibility for producing high-quality deliverables and project outcomes: they are expected to actively participate in setting and adhering to contingency rules and risk mitigation measures.

2.1.1. Project Coordinator and Project Manager

The **Project Coordinator** (PC), the European Institute of Oncology (IEO), is responsible for Project Management and Coordination. In accordance with the Grant Agreement and the Description of Action, the Project Coordinator oversees the overall project management and execution, ensuring the required quality throughout the project's duration.

Specifically, within the IEO team, Professor Gabriella Pravettoni, serving as the **Principal Investigator** (PI), acts as the scientific lead and primary liaison with the funding agency. She ensures the project's scientific integrity, progress, and successful completion. Her duties include chairing, coordinating, and administering the Executive Committee (EC) and other relevant bodies responsible for implementing decisions.

Giorgia Miale, serving as the **Project Manager**, coordinates team members, manages resources, mitigates risks, monitors the quality of procedures and deliverables, and ensures that all stakeholders remain aligned throughout the project lifecycle.

The aforementioned individuals, along with the project coordination team as a whole, have several responsibilities specific to quality management, including:

- **Defining quality standards and processes**: the PM and the PC team is tasked with establishing the quality standards and processes to be employed throughout the project, accordingly with the European Commission guidelines. This includes monitoring quality metrics related to deliverables and milestones, identifying quality control activities, and crafting a comprehensive quality assurance plan;
- **Ensuring quality requirements are met**: the PM is accountable for ensuring compliance with all quality requirements throughout the project. This involves conducting regular quality audits, monitoring quality control activities, and reviewing project deliverables to verify they meet the specified quality standards;

- **Communicating quality expectations**: the PM communicates quality expectations to all stakeholders, including the project team, EC, and partners. This includes clarifying quality metrics and standards, outlining the roles and responsibilities of the teams, and providing feedback on quality performance;
- **Managing quality risks**: the PM and PC team identify and manage quality risks throughout the project. This encompasses identifying potential quality issues, devising contingency plans, and implementing corrective measures as needed;
- **Continuous improvement of quality processes**: the PM and PC team ensures ongoing enhancement of the project's quality processes, implementing procedural improvements to elevate overall project quality.

2.1.2. Executive Committee

The **Executive Committee** (EC) comprises leaders and co-leaders from the Work Packages (WPs) representing IEO, UNIPA, POLIMI, ICO, EUT, SD, i-HD, and EAPM. Their role is to oversee coordination, planning, monitoring, and reporting within their respective domains. The EC's primary function is to ensure the timely submission of progress reports related to tasks, milestones, and deliverables.

Details on the composition and roles of the EC can be found in D1.1, par. 2.1.2.

2.1.3. Quality and Ethics Manager

Monica Casiraghi has been appointed as **Quality Manager** (QM) by IEO. Nathan Lea, representing i-HD, has been appointed as the **Ethics manager** (EM) by the Consortium.

The Quality and Ethics Managers play a pivotal role in upholding the integrity and credibility of research outcomes by ensuring rigorous adherence to quality standards, ethical guidelines, and regulatory requirements. Their oversight and guidance are essential for promoting research excellence and maintaining trust among stakeholders and the broader research community.

- **Setting Quality Standards**: this includes defining criteria for research methodologies, data collection, analysis, and reporting to ensure accuracy, reliability, and validity of findings;
- **Monitoring Compliance**: they oversee compliance with regulatory requirements, institutional policies, and ethical guidelines governing research practices. This involves conducting regular audits and reviews to assess adherence to standards and identify areas needing improvement;
- **Ethical Oversight**: specifically, the EM ensures ethical considerations are integrated into all aspects of the research. This includes obtaining necessary ethical approvals, monitoring participant welfare, and ensuring informed consent procedures are followed rigorously;
- **Training and Guidance**: they provide training and guidance to researchers and project staff on quality assurance protocols, ethical principles, and regulatory requirements, facilitating awareness and understanding of best practices to maintain high standards of research integrity;
- **Risk Management**: they proactively manage issues that could impact the reliability and credibility of research outcomes;
- **Reporting and Documentation**: they maintain comprehensive documentation of quality assurance activities, ethical approvals, and compliance measures;
- **Collaboration and Communication**: collaborating closely with PM, PI and other key stakeholders, they facilitate open communication and transparency regarding quality and ethical considerations throughout the project lifecycle.

2.1.4. Work Package and Task Leaders

Each WP will be overseen and coordinated by a designated **WP Leader**. It is the responsibility of these leaders to oversee, manage, and coordinate all activities within their respective work packages. WP Leaders will collaborate closely with **Task Leaders**, who are responsible for executing specific activities outlined in each WP according to the established work plan. Both WP and Task Leaders share the responsibility of providing general guidelines and fostering communication and coordination with other work packages or tasks. Their primary objective is to ensure that each work package is completed on time, within budget, and meets the required quality standards. As such, they have important responsibilities for quality management within their areas of responsibility, being specifically responsible for:

- **Ensuring compliance with quality standards**: this entails monitoring and controlling the quality of the work performed, and identifying and addressing any issues or deficiencies.
- **Conducting quality checks**: WP Leaders are accountable for conducting regular quality assessments to ensure that the work meets established standards. This involves reviewing work products and analyzing quality data to identify issues or trends, and implementing corrective and preventive actions as needed.
- **Reporting on quality performance**: WP Leaders are responsible for reporting the quality performance of their work packages to the PM and other stakeholders.

Details on the teams and individuals acting as WP leaders and Task Leaders, along with their responsibilities can be found in Deliverable D1.1, par. 2.1.3.

2.1.5. Technical and Clinical Leaders

The Consortium collectively agreed to appoint two additional figures for the Project Execution Bodies: the **Clinical Manager** and the **Innovation Manager**. Specifically, the Clinical Manager, appointed by ICO (Maria Serra Blasco), and the Innovation Manager, appointed by EUT (Carolina Migliorelli Falcone), will lead the Clinical and Technical teams respectively. Their roles include overseeing tasks related to the clinical or technical aspects of the project. These appointments were formalized during the Executive Committee meeting held on February 8th, 2024.
The Clinical and Innovation Managers play pivotal roles in leading the clinical and technical partners, ensuring effective coordination and quality management throughout the project. Their responsibilities are detailed below:

- **Monitoring Task Objectives**: They continuously monitor the achievement of objectives for each task. By keeping track of progress, they ensure that milestones are met and that the project stays on course.
- **Identifying Delays and Non-compliance**: In their oversight role, the Managers can identify any delays or non-compliance in the execution of tasks. They will promptly report these issues to the Project Coordinator, ensuring that corrective actions can be taken in a timely manner.
- **Scheduling Regular Meetings**: The Clinical and Innovation Managers are responsible for supporting the PM in the organization periodic meetings focused on project activities. Specifically, they draft the meeting agenda according to the needs of the project and the suggestions of the involved teams. These meetings serve as a platform for discussing completed tasks, planning upcoming activities, and ensuring alignment across all teams.
- **Producing Meeting minutes**: The Clinical and Innovation Managers produce detailed minutes respectively after each clinical and technical meeting. These reports document the

discussions, highlight any emerging issues, and facilitate the early identification of risks. The distribution of these reports ensures that all partners involved are informed and can contribute to risk mitigation strategies.

2.1.6. Ethical Advisory Board and Independent Ethical Advisory Board

Due to the significant ethical considerations inherent in the iBeChange project, meticulous oversight by highly specialized professionals is imperative. Following the recommendations outlined in the document "Ethics Advisors and Ethics Advisory Boards: Roles and Function in EU Funded Projects" (Version 2.0, 15 February 2023), an **Ethical Advisory Board** (EAB) has been set up in the first version of the project proposal. This board, comprised experts appointed by the project's ethical partner (i-HD), provides guidance and advice on scientific and clinical issues, trial design, recruitment strategies, and stakeholder engagement throughout the project lifecycle. They supervise operations to ensure compliance with regulatory frameworks and oversee the drafting of a **Data Management Plan** (DMP), submitted under Deliverable D7.1 (May 2024), and a **Data Protection Impact Assessment** (DPIA). Both documents aim to ensure compliance with data protection regulations and effective data management practices. The EAB has been then merged into the **Independent Ethical Advisory Board** (IEAB), appointed following the specific request of the European Commission delivered through the Ethics Summary Report dated 24/08/2023. This board will provide support on precise areas, entailing a specific expertise in cybersecurity, data protection, ethical and human-centered artificial intelligence.

More details on the appointment of the IEAB can be found in the Deliverable D9.1.

2.1.7. Trial Supervision Committee

The **Trial Supervision Committee** (TSC) will be composed by representatives from each participating clinical center, the sponsor (ICO, IEO, UMFCD), and an independent chairperson for overseeing the multicenter clinical trial. The constitution of the TSC is comprised under the WP5 Task 5.2 – *Studies Management and Supervision* and its appointment is scheduled for M16, in parallel with the first co-supervision meeting (refer to Milestone M5.1, led by ICO– *Trial Supervision Committee appointment and co-supervision meetings scheduled*). The TSC is planned to meet periodically, due closely monitoring the activity of the planned studies. Therefore, the role of this Committee will be to monitor the progress of the trial and ensure that it is being conducted in accordance with the protocol, regulatory requirements, and ethical standards.

The TSC's main responsibilities include reviewing safety and efficacy data, monitoring recruitment and retention of participants, ensuring that the study is conducted in compliance with applicable regulations and guidelines, and making recommendations regarding modifications to the protocol or the trial's conduct. The TSC will cooperate with ICO, leading the iBC/PS (pilot study) and iBC /CT (clinical trial) and IEO, the iBC/WS (pilot study with wearables) lead (refer to paragraph 2.3.4) and the IEAB to ensure the completion of the studies while maintaining the highest standard of scientific rigour and ethical conduct.

2.2 Quality Management objectives

Quality management is a critical aspect of any project, as it ensures that the specified requirements and objectives are met and that the project is delivered to the highest possible standard. The quality objectives for the iBeChange project are based on the Work Plan of the project (refer to deliverable D1.1) and in the Grant Agreement.

2.2.1 Deliverables and milestones

The primary objective of our quality management plan is to ensure that the project is delivered on time, within budget, and to the required quality standards. To achieve this objective, a set of deliverables and milestones has been established for each stage of the project; the deliverables are designed to monitor project progress and keep all stakeholders informed about the project's status, therefore it is mandatory to focus on them as part of the quality management objectives.

Milestones are typically defined as key management objectives that must be achieved at specific points in time, playing a crucial role in keeping the project on schedule. Several milestones have been settled as critical points for assessing progress and making necessary adjustments to stay aligned with our overall project goals. Additionally, these milestones are used to communicate progress to stakeholders, both internal and external, throughout the project's lifecycle.

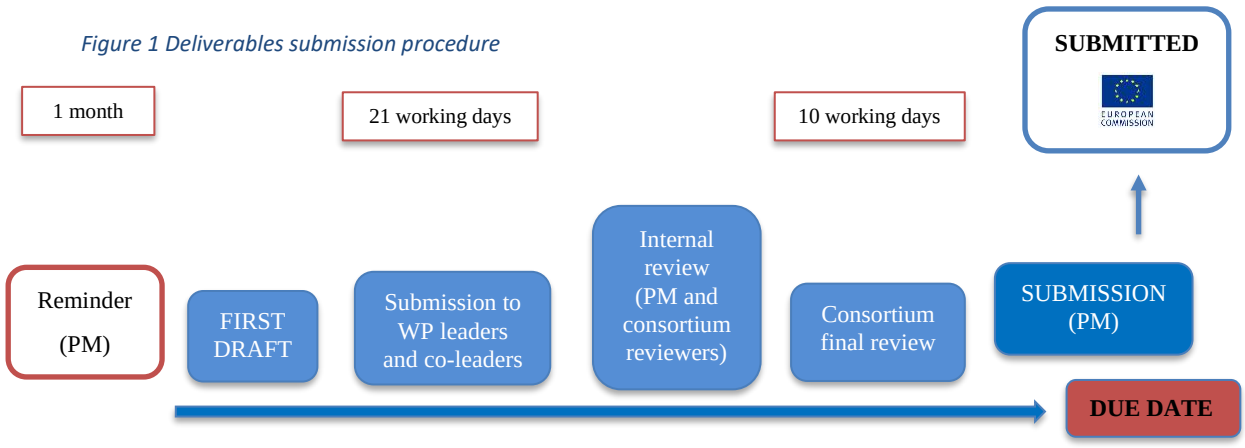
These tools have been defined in accordance with the Gantt chart, which is essential for planning and scheduling quality control activities. This allows us to monitor task status, identify any issues or delays, and take corrective action as needed. Additionally, visualizing the dependencies and interrelationships between tasks, we can identify areas where quality control activities may be impacted by other project tasks and take steps to mitigate these risks.

A comprehensive list of deliverables and milestones can be found in Deliverable D1.1.

A **deliverable acceptance plan** is a critical component of a quality management plan, as it outlines the criteria for determining whether a project deliverable meets the required standards and is acceptable for delivery. Each WP Leader and the PM are accountable for ensuring the quality of deliverables, including punctuality, adherence to templates and structure, and the relevance, completeness, clarity, and accuracy of content. The PM has established a specific submission procedure (refer to D1.1, section 3.1) and a management strategy for addressing delays (refer to D1.1, section 3.7.1).

The submission procedure for deliverables (reported in Figure 1) is a key component in the project's quality management system, providing a structured approach to monitor progress, analyze research outcomes, identify potential limitations, and develop risk mitigation strategies. Each deliverable undergoes a thorough review upon submission, where the achieved research outcomes are analyzed against the project's goals and objectives. Additionally, during the review process, the deliverables are assessed for any gaps, challenges, or deviations from the expected results. This scrutiny helps in identifying potential limitations or obstacles that may hinder project progress and permits the development of targeted strategies to address issues.

Figure 1 Deliverables submission procedure



Additionally, the PC provided templates for deliverables and PowerPoint presentations to be used and completed by each WP leader or responsible partner. By adhering to standardized templates and guidelines, all deliverables maintain a consistent level of quality, which is essential for clear communication and accurate assessment.

2.3 Quality assurance activities

Quality assurance is a proactive approach that prioritizes preventing quality problems before they occur. It involves developing procedures to prevent defects and errors and ensuring that products meet established quality standards.

2.3.1. Internal meetings

All consortium bodies meet regularly to coordinate, discuss, and assess the progress of the project and to exchange information. The organization of these internal meetings falls under WP1 (Project Management) and is the responsibility of the PM. During the first year of the project, the PM scheduled **bi-weekly clinical and technical meetings**. To facilitate interoperability among consortium members, **bi-monthly Consortium meetings** and **bi-monthly EC meetings** are also convened to address fundamental topics related to project execution and to resolve any issues that may arise. An annual in-person meeting among consortium members will serve as a checkpoint to evaluate the project's progress, exchange data and results, and address any encountered obstacles. After each meeting, minutes are prepared and shared with the relevant members.

More details on the meetings’ schedule can be found in D1.1, section 4.

Internal meetings play a critical role in the continuous monitoring and assessment of project quality. These meetings provide a structured forum for evaluating progress, addressing challenges, and ensuring alignment with project objectives. Specifically, they facilitate quality monitoring through:

- **Multidisciplinary Outcome Analysis**: Internal meetings enable the project team to analyze outcomes from a multidisciplinary perspective (e.g., enabling the convergence among clinical and technical expertise). This approach ensures that insights and feedback are integrated from various fields, fostering a holistic understanding of the project's progress and identifying areas for improvement.
- **Progress Monitoring**: Regularly scheduled internal meetings provide a consistent platform for monitoring project milestones and deliverables. This ongoing assessment ensures that the project remains on track and that any deviations are promptly addressed.
- **Continuous Improvement**: Feedback loops established during internal meetings foster a culture of continuous improvement. By regularly reviewing performance and implementing strategies previewed, the project team can enhance methodologies and processes, leading to better quality results.
- **Early Risk Identification**: By conducting joint analyses involving technical and clinical teams, internal meetings allow for the early identification of risks associated with the design and implementation of studies. This proactive approach helps in mitigating potential issues before they escalate, ensuring smoother project execution.

2.3.2. Adherence to European regulations in clinical studies and for the use of AI techniques

The primary aim of the iBeChange project is to develop an eHealth platform that monitors users' behaviour and provides responsive recommendations to promote behavioural change, as well as offering professional support.
Given the innovative nature of this intervention in the specific field of cancer prevention, it is essential to test its feasibility through a pilot study (**iBC/PS**) that will assess the deployment of the iBeChange platform in clinical settings, including the procedures for recruitment, management, intervention, and assessment. The data collected during the iBC/PS will be analyzed to identify potential implementation challenges for the main clinical trial (**iBC/CT**) and will provide valuable input for refining the intervention.
Recognizing that not everyone owns a smartphone or feels competent using one, we have included two pilot studies of an iBeChange version supported by wearables (**iBC/WS1** and **iBC/WS2**). These studies will enable professionals to unobtrusively collect data from users using a common consumer-grade wearable device.
To ensure the quality standards are met in the context of clinical studies and artificial intelligence (AI)-specific issues, the following aspects will be focused on: a) security, b) safety, c) legal considerations, d) ethics, e) privacy, and f) performance.
Given the complex nature of potential ethical issues and the importance of compliance with the European data protection framework, the iBeChange consortium holds relevant expertise in regulatory affairs, data management and protection (led by i-HD) and maintains robust connections with regulatory bodies. Measures to ensure that the iBeChange project maintains stringent ethical standards and upholds robust data protection practices throughout its operations have been planned:

- During the initial tasks, each study will be meticulously detailed in its respective protocols and circulated among clinical partners to standardize procedures and facilitate approval by their Ethics Committees and **Data Protection Officers** (DPOs) by slightly tailoring it to the particular logistics of each clinical center.
- Each DPO will actively contribute to crafting and implementing the clinical protocols, collaborating closely with the TSC.
- Participants will be required to sign an informed consent form, endorsed by their center's Ethics Committee, explicitly granting them access to their data.
- Digital platforms will prominently display General Data Protection Regulation (GDPR) and country-specific data protection regulations to users.
- Each clinical center will enter into a data access contract with technological partners to regulate the relationship between the "processor" and the "data controller."

Furthermore, all procedures involving human participants in the studies will be meticulously planned to align with the ethical standards set by institutional and/or national research committees, as well as with the principles outlined in the 1964 Helsinki Declaration and its subsequent amendments.
Each of the two study protocols will undergo approval by Ethical Committees and will be publicly registered in a platform including the ClinicalTrials.gov. This registration will include detailed timelines as proposed in the project plan to ensure compliance with all obligations.
In alignment with Horizon Europe requirements, the consortium will establish reporting obligations with these Committees, the open registry, and also the EC. **Midterm recruitment reports** and **reports on the status of posting results** will be submitted at strategically chosen intervals throughout the project timeline to fulfill these obligations. Moreover, reports from the IEAB will

be submitted as Deliverables during the project duration. These measures ensure transparency, compliance, and accountability throughout the iBeChange project.
Furthermore, all measures will be implemented through the iBeChange platform in compliance with the latest version of the **GDPR** (EC/2016/679). Each principal investigator from partner institutions will bear responsibility for ensuring ethical compliance as outlined in the DMP. They will maintain communication with their respective Ethics Committees and DPOs, incorporating guidance from ethics partners to ensure protocols are executed in adherence to ethical standards.
Measures have also been planned to ensure the availability of the iBeChange intervention throughout the entire implementation phase:

- **Technological and security measures**: security requirements will be determined through the DPIA process. In terms of human resources, the hiring of professionals necessary for developing and delivering the iBeChange intervention has been budgeted, in addition to the commitment of all researchers involved in the project proposal
- **Digital literacy and adherence**: a digital welcome and user support system will be implemented to promote participants' engagement with the iBeChange intervention. Digital literacy efforts will be emphasized to enable participants to effectively and safely interact with the intervention.

To further promote digital literacy among participants, additional steps can be taken:

- **Provide training and support**: conduct training sessions and provide materials to help participants acquire the necessary skills to use iBeChange and navigate the platform's features. This training can be offered in-person during study recruitment, through video conferences, or via online tutorials whenever participants encounter difficulties. Ongoing support throughout the study duration will also assist participants in troubleshooting any technical issues that may arise.
- **Educate participants about the iBeChange intervention**: ensure participants understand the purpose, benefits, and functionalities of the iBeChange intervention. Clear instructions and demonstrations will be provided as needed.
- **Ensure accessibility and convenience of the iBeChange program**: implement flexible scheduling options and consider telehealth appointments where feasible to make participation easier for participants. Extending the recruitment timeline will allow sufficient time to address any potential recruitment challenges, thereby enhancing recruitment efficiency.

3. Risk management

A comprehensive risk management strategy involves identifying potential risks, assessing their impact and likelihood, and implementing strategies to manage or mitigate those risks. The iBeChange project adopted a meticulous and systematic approach to develop **a risk mitigation strategy**, encompassing risk identification, risk assessment, and risk mitigation planning.
As part of our risk management process, we first identified potential risks. This was accomplished by conducting a thorough analysis of the project's objectives, scope, budget, and timeline, as well as considering external factors and historical data from previous projects. It is useful to categorize risks into types such as **technical**, **operational**, **financial**, **legal**, and **ethical**. Utilizing a probability and impact matrix helps evaluate the likelihood of each risk occurring and its potential impact on the project. This process helps prioritize the risks, focusing initially on those with the highest likelihood and impact. After evaluating the risks, we developed strategies to mitigate or respond to them.
iBeChange employs the following risk management strategies:

- **Risk avoidance**: avoiding activities that could potentially lead to a risk;
- **Risk reduction**: taking steps to reduce the likelihood or impact of a risk;
- **Risk acceptance**: accepting the risk and developing a contingency plan to address it if it occurs.

Accordingly, the following table summarizes the main elements of our risk management for the iBeChange project.

Table 1. List of critical risks, related WPs, Potential Impact and proposed mitigation strategies

Risk number	Description	Work Package (No)	Proposed mitigation measures
1	Delays in the Regulatory and Ethical clinical trial approval (medium risk)	WP1	To expedite approval, we will use the new centralized submission process defined by the EU regulation 536/2014. If delays shall be encountered at one or more centers, IEO and the country-delegated Contract Research Organization will make sure that all the required documents and certifications are submitted to the competent ethical boards as soon as possible. Further, all clinical centers of the consortium will provide synergetic and collaborative work in order to support each other during the design of the clinical trial protocol and the submission phase to each local ethical committee. Besides, the PC and the PM will work with the partner in charge of the ethical aspects to prevent potential ethical issues.
2	Administrative delays (low risk)	WP1	IEO has a solid internal administrative team that can handle managerial procedures and has extensive experience with clinical processes, agreements, and negotiations. A dedicated and experienced PM has been identified to support the Project Coordinator in the management of the iBeChange project. A management plan has

			been developed by the PM to define responsibilities and priorities of each beneficiary and the processes and activities to define, plan, monitor and coordinate the whole project.
3	Slow iBeChange clinical trial participant recruitment (low to medium risk)	WP5	Clinical staff and participants will work closely together to speed up recruitment as soon as conditions are favorable. The institutions have demonstrated in prior studies that they have stringent eligibility requirements and are equipped to handle any difficulties that may arise from the iBeChange initiative's real-world approach. In any case, throughout the entire clinical trial stage, the coordination will review recruitment on a monthly basis. Extra efforts will be made to ensure that clinical trial participant recruitment will be finalized as declared. In particular, if any problems with recruitment are found, new collaborators will be asked to join and help solve the issues, as well as other, national oncological centers nested in iBeChange clinical network. Besides, if necessary, the timeline of the clinical trial will be rescheduled and adapted accordingly to achieve the expected number of participants and to timely deliver results.
4	Attrition with questionnaires collection and analysis (medium risk)	WP3, WP2, WP1, WP5, WP4	The absence of longitudinal data on health-related psychosocial variables can lower accuracy and statistical power and introduce bias to the outcomes analyses. To overcome this risk, several activities are planned: i) communication material (infographics and animations) will be created to encourage participants' adherence, and ii) We will also create digital materials to guide participants throughout the process.
5	Challenges in collecting the data on social costs (medium-high risk)	WP6	The extended cost-effectiveness analysis aims to incorporate the social aspect to include expenses beyond the healthcare system. To gather this information, participants will be surveyed, but there is a risk of a low response rate. To mitigate this risk, we will supplement the analysis by gathering data on the social costs of breast, lung, and colorectal cancers reported in the literature and in public and free databases.
6	Data quality issues (low risk)	WP3, WP2, WP1, WP5, WP4	Datasets with lower data quality will be either excluded or compensated by increasing the data to effectively address the relevant questions, even if it comes with a lower data

			handling fee. Data problems can be resolved through various methods, such as the imputation of missing data. Also, IEO will coordinate partners in keeping similar approaches in data management and will share common internal suggestions to prevent data quality issues. Finally, a Data Management Plan was developed in WP7 to define quality check procedures and mitigation strategies to ensure data quality.
7	Sub-optimal dissemination of the results (low risk)	WP1, WP8	The EC, in collaboration with WP8 leader EAPM, will coordinate the planned program of results dissemination, which includes organized events (e.g., meeting participation), development of dissemination products (e.g., manuscripts in open access peer-reviewed journals, reports, articles), and social media features. The EC will evaluate the progress of the dissemination plan regularly and propose improvements based on new findings in the field. Finally, patients' associations will also be involved to support dissemination activities across the EU.
8	Lack of overall coordination (low risk)	WP1, WP8	Coordination requires communication strategies that are continuous and targeted. A management structure pillar provides effective management: i) IEO is responsible for project coordination; ii) communication strategies and procedures, tools, and events will ensure that coordination needs are met; iii) the majority of partners hold past and current experience in other projects. Thus, the coordinator and partners are fully prepared to identify and implement corrective measures in the event of an unforeseen event. However, if the PC and PM will not be enough to provide adequate coordination, an assistant to the PC will be allocated from its internal resources. Additionally, the EC will ensure adequate coordination and progress monitoring.
9	Ineffective overall financial management (low risk)	WP1	The mitigation of these risks will be the responsibility of the PC with the collaboration of the PM and IEO Administrative Office, which monitor all related critical situations. Mainly, IEO will schedule ongoing internal meetings to support the beneficiaries in the timely preparation and delivery of reports, providing templates, guidance, and support when needed.

10	Work Packages do not align to reach the expected objectives (low risk)	WP3, WP7, WP1, WP2, WP5, WP6, WP8, WP4	Adherence to consortium regulations and open communication between partners and collaborators will foster a collaborative work environment in which all team members contribute to their assigned tasks. If there are any disagreements or issues, they will be identified and resolved as soon as possible during the WP (work package) meetings. Any reasons for disagreements will be documented to ensure transparency. More in detail, during the project, the PC and PM will work with each beneficiary so that inadequate performance can be identified in early stages. The EC will also supervise WP activities ensuring that tasks, their results and deliverables are aligned to the directions of the iBeChange project. Successively (if it is needed), the risk status will be discussed with all beneficiaries to identify and to implement a shared intervention strategy to overcome the risks.

4. Conclusions

The present deliverable outlines the quality and risk management plan of the iBeChange project. By setting clear quality standards, implementing quality control procedures, and taking a proactive approach to risk management, we aim to minimize the likelihood of unexpected delays, budget overruns, and other issues that could impact the project's success. The quality assurance measures in place will guarantee that all deliverables meet the established standards, contributing to the overall excellence and reliability of the project outcomes. Through systematic risk identification, assessment, and mitigation strategies, we aim to minimize disruptions also related to ethical and technological matters.

Feedback from all the team members regarding the risk management process will be encouraged. We will adapt and refine our risk mitigation strategies based on this feedback and any new information that comes to light. Training sessions will be conducted if necessary for the team based on the understanding that it is essential that all team members are familiar with the quality standards and compliance requirements to ensure smooth implementation.

This proactive approach will facilitate the achievement of our project goals and ensure that all deliverables meet the expectations of our stakeholders.

Version history

Version	Description	Date completed
v1.0	First upload	31/07/2024
v2.0		