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

Project Number: 101136840

D1.1 – Project management plan

Related Work Package	**WP1 – Project management and coordination**
Related Task	**Task T1.1 – Project coordination**
Lead Beneficiary	IEO
Contributing Beneficiaries	ALL PARTNERS
Document version	v1.0
Deliverable type	R
Dissemination level	PU
Due date	31/05/2024
Delivery date	18/06/2024
Authors	Giorgia Miale (IEO)
Contributors	Gabriella Pravettoni (IEO), Marianna Masiero (IEO), Chiara Marzorati (IEO)
Reviewers	all partners

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.

Disclaimer

Table of Contents

List of Abbreviations

Abbreviation	Explanation
AI	Artificial Intelligence
BC	Behaviour change
CA	Consortium Agreement
DoA	Description of the Action
EAB	Ethical Advisory Board
EC	Executive Committee
EM	Emotional Management
GA	Grant Agreement
IEAB	Independent Ethical Advisory Board
PM	Project Manager
PI	Principal Investigator
PO	Project Officer
RCT	Randomised Controlled Trial
KoM	Kick-off Meeting
WP	Work Package

List of Tables

List of Figures

Executive Summary

This document summarises the primary rules, conventions, and methodologies to be employed by the partners for inter-project coordination and management of structures and procedures within the iBeChange project.
WP1 focuses on coordination and communication with WP leaders and on project implementation procedures, encompassing scientific, ethical, and technical management. The key objectives of WP1 include monitoring and supervising project progress, facilitating information exchange between WPs, ensuring execution of partners’ contractual duties, and offering guidance on compliance with EU regulations and contractual-legal requirements.
IEO implemented actions, instruments and strategies revolving around scheduling and prioritizing tasks, monitoring expenses, upholding agreed-upon quality standards, identifying, assessing, and mitigating potential risks, and fostering effective communication among team members.
The instruments and strategies devised to monitor activity completion status and ensure timely submission of expected deliverables are detailed within this document.
Additionally, this document provides an explanation of the Consortium's organisational structure, decision-making procedures, roles, and responsibilities.

1. Introduction

The iBeChange project aims to support individuals in modifying their unhealthy behaviours to promote primary cancer prevention, aligning with various EU strategic objectives, policies, and plans. iBeChange seeks to assist individuals in reducing their cancer risk by encouraging adherence to the recommendations outlined in the **European Code Against Cancer** through the implementation of a user-friendly digital tool. The project's objective is to develop a personalised and adaptive behavioural change platform that leverages artificial intelligence (AI) techniques to tailor interventions for each user. This platform will address areas such as nutrition, exercise, smoking, alcohol consumption, as well as psychosocial care and emotional management (EM; e.g., depression, anxiety, and social support). The project employs a co-design methodology by involving all relevant stakeholders in the creation and development of the platform. Additionally, various professionals will participate in activities such as literature reviews, retrospective studies, pilot studies, and clinical trials, ensuring the adoption of a comprehensive interdisciplinary approach. The diversity of the team relies on experts in healthcare research, health services research, innovation, social science, ethics assessment and other relevant areas.

The project leverages on 12 partners' expertise, acquired from previous research and EU-funded projects on digital interventions, cancer prevention, decision support tools for prevention, and behavioural change (BC).

Below is a table detailing the iBeChange Consortium partners.

Table 1. List of iBeChange partners.

LIST OF PARTNERS			
Role	**Short name**	**Legal name**	**Country**
Coordinator	IEO	Istituto Europeo di Oncologia	Italy
Beneficiary	EUT	Fundació Eurecat	Spain
Beneficiary	ICO	Institut Català d'Oncologia	Spain
Beneficiary	POLIMI	Politecnico di Milano	Italy
Beneficiary	SD	SporeData OÜ	Estonia
Beneficiary	UNIPA	Università degli Studi di Palermo	Italy
Beneficiary	I-HD	The European Institute for Innovation through health data	Belgium
Beneficiary	TU/e	Technishe Universiteit Eindhoven	Netherlands
Beneficiary	EAPM	European Alliance for Personalised Medicine	Slovenia
Beneficiary	SIMAVI	Software Imagination & Vision SRL	Romania
Beneficiary	UMFCD	Universitatea de Medicina si Farmacie Carol Davila	Romania
Associated Partner	ECANCER	The eCancer Global Foundation	United Kingdom

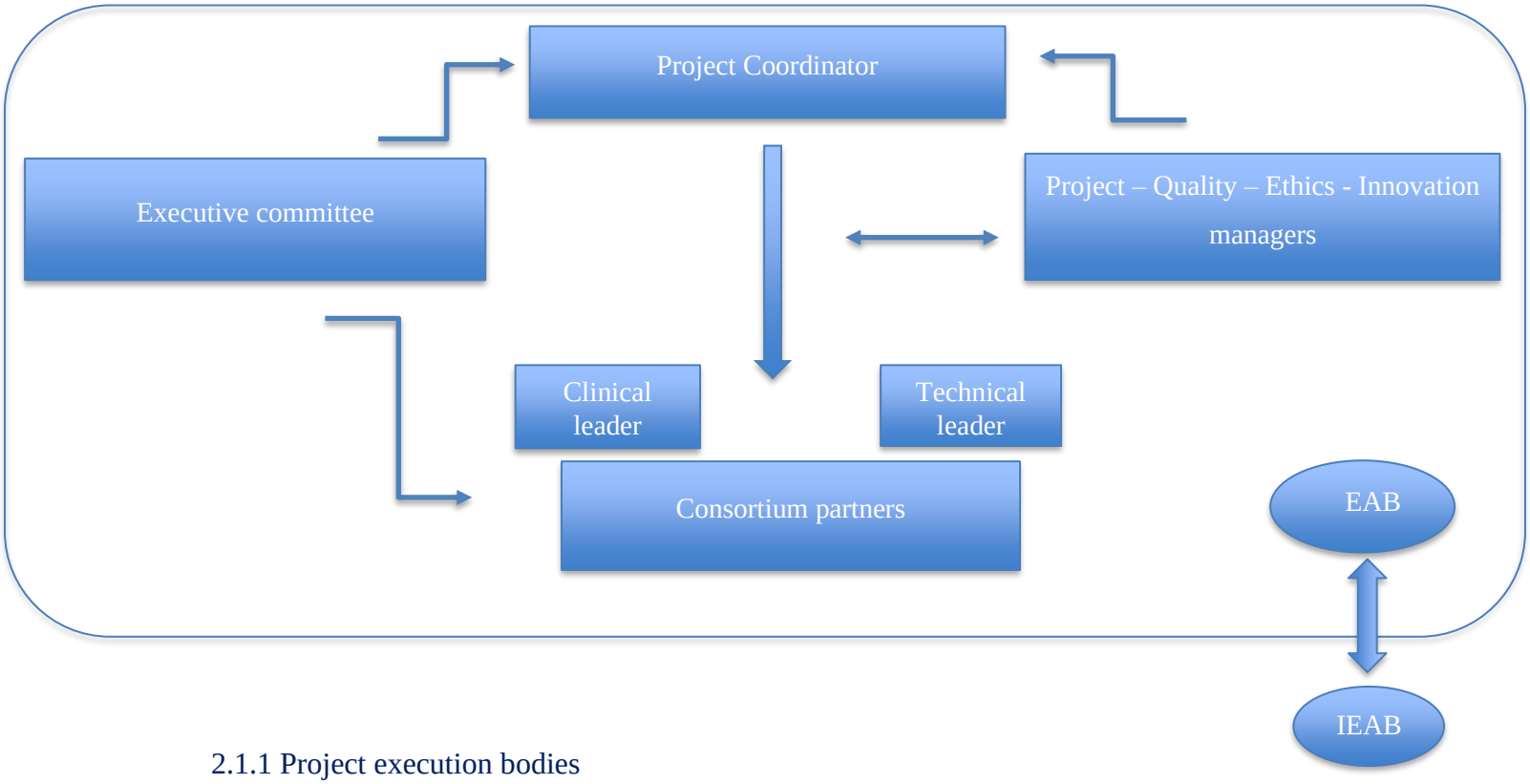
2. Project structure overview

As delineated in the **Description of the Action** (DoA), the primary objective of project management is to ensure the successful execution of the project in order to achieve its objectives. The rules for composition, organisation and decision making of the Project's governing bodies are outlined in the **Consortium Agreement** (CA) and the **Grant Agreements** (GA).

2.1 Roles and responsibilities

The **project structure** (see *Figure 1*) has been designed to foster project advancement and to promote collaboration and communication among the consortium. Specific roles and corresponding responsibilities have been assigned as illustrated in the graph below.

Figure 1. Project Structure Overview.



2.1.1 Project execution bodies

Professor **Gabriella Pravettoni** (IEO), serving as the **Principal Investigator** (PI), acts as the scientific lead and primary liaison with the funding agency for the project, ensuring its scientific integrity, progress, and successful completion. Her duties encompass chairing, coordinating, and administering the EC and other relevant boards responsible for overseeing the implementation of decisions. Supporting her in these endeavours are the Project (IEO), Quality (IEO), Innovation (EUT), Clinical (ICO) and Ethics (i-HD) managers.

A **Project Manager** (PM; Giorgia Miale) was designated by IEO starting from January 2024. PM's responsibilities encompass coordinating team members, managing resources, mitigating risks and ensure that stakeholders involved stay aligned throughout the project lifecycle.
The other aforementioned figures have been appointed in accordance with the indications and preferences of the involved partners. Specifically, the **Quality, Clinical, Innovation** and **Ethics managers** were designated during the Consortium Meeting held on April 17th. Monica Casiraghi has been appointed as Quality Manager by IEO. Nathan Lea, representing i-HD, has been appointed as the Ethics manager and will collaborate with the Independent Ethical Advisory Board (IEAB).
Furthermore, the Consortium had collectively agreed upon the appointment of two additional figures for the Project Execution Bodies: the **Clinical** and **Innovation Managers**.
Specifically, the Clinical Manager and the Innovation Manager will serve as leaders for the Clinical and Technical teams, respectively, overseeing tasks related to the clinical or technical aspects of the project. These appointments, designated by ICO (Maria Serra Blasco) and EUT (Carolina Migliorelli Falcone), were formalized during the Executive Committee meeting held on February 8th, 2024.

Table 2. Contact details of the project execution bodies.

Name	Institution	Role	Email address
Gabriella Pravettoni	IEO	Principal Investigator	gabriella.pravettoni@ieo.it
Giorgia Miale	IEO	Project Manager	giorgia.miale@ieo.it
Monica Casiraghi	IEO	Quality Manager	monica.casiraghi@ieo.it
Nathan Lea	I-HD	Ethics Manager	nathan.lea@i-hd.eu
Maria Serra Blasco	ICO	Clinical Manager	mariaserrab@iconcologia.net
Carolina Migliorelli Falcone	EUT	Innovation\technical Manager	carolina.migliorelli@eurecat.org

2.1.2 Executive Committee

The **Executive Committee** consists of Work Package (WP) leaders and co-leaders (IEO, UNIPA, POLIMI, ICO, EUT, SD, i-HD, EAPM), responsible for overseeing coordination, planning, monitoring, and reporting within their respective domains. The EC's function is to ensure the punctual submission of progress reports concerning tasks, milestones, and deliverables. The principal responsibilities of the EC include defining the project's scientific management, scope, objectives, and overall direction based on the Project Coordinator's proposal. Furthermore, the EC plays a crucial role in supporting the development of the project's technical roadmap, ensuring effective coordination and monitoring. The members of the EC were formally confirmed during the **iBeChange Kick-Off meeting** held on **January 22nd – 23rd 2024**.

Table 3. Contact details of the Executive Committee team.

Name	Institution	Email address
Marianna Masiero	IEO	marianna.masiero@ieo.it
Dario Monzani	UNIPA	dario.monzani@unipa.it
Emilia Ambrosini	POLIMI	emilia.ambrosini@polimi.it
Maria Serra Blasco	ICO	mariaserrab@iconcologia.net
David Suñol Moreno	EUT	david.sunol@eurecat.org
Ricardo Pietrobon	SD	ricardo@sporedata.com
Nathan Lea	I-HD	nathan.lea@i-hd.eu
Denis Horgan	EAPM	denishorgan@euapm.eu

2.1.3 Work packages and task leaders

Each **Work Package** will be overseen and coordinated by a designated **Work Package Leader** (see paragraph 3.1). It is the responsibility of these leads to manage and coordinate all activities within their respective work packages, including monitoring performance and progress, facilitating the transfer of information, and promptly reporting any issues to the PM and the PI. Furthermore, WP Leaders will collaborate closely with **Task Leaders** (see paragraph 3.3); Task Leaders are appointed with preparing and executing activities within their assigned tasks according to the established work plan. Both Work Package and Task Leaders share the responsibility of providing general guidelines and facilitating communication and coordination with other work packages or tasks. Their overarching aim is to ensure the timely delivery of results required as input for tasks to be performed in other work packages.

2.1.4 Ethical Advisory Board and Independent Ethical Advisory Board

The iBeChange Project involves the collection of sensitive data from a large number of vulnerable individuals, including participants at risk of cancer some of which will test positive for cancer screening. This presents potential risks such as stigmatization, discrimination, misuse, and data monetization. The project encompasses both retrospective and prospective studies, where data on socio-demographic variables, behavioural habits, psychosocial and environmental risk factors, as well as other physical and clinical information, will be gathered and analysed. Due to the significant ethical considerations inherent in the project, meticulous oversight by highly specialized professionals is imperative.

In accordance with 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 established. This board comprises three experts who periodically report to the Commission and its appointment has been tailored to the specific needs of the project, considering the number, severity, and complexity of the ethical issues raised by the proposal. This appointment was clearly explained and justified in the Ethics Summary Report.

Currently with the verification of the Grant Agreement and associated with the document REF.ARES (2023)5782926 - 24/08/2023, the European Commission requested the appointment of an additional board, the **Independent Ethical Advisory Board** (IEAB). The IEAB, with specific expertise in cybersecurity, data protection, ethical and human-centered artificial intelligence, will:

a. advise on the primary ethical and potentially legal challenges and uncertainties that may arise;
b. help the project navigate the ethical challenges that arise when applying novel technologies and using sensitive and personal health related and cancer management data; c. provide an additional layer of support when working with potentially vulnerable participants; d. ensure compliance in a shifting regulatory framework; e. help consider emerging security challenges and reaching a level of assurance that is required for participants and the wider European citizenry.

In line with the requirements specified in Deliverable D9.1 under WP9, the IEAB was appointed by IEO (the lead beneficiary of this task) in close collaboration with i-HD. The actions taken to appoint the IEAB are outlined in detail in Deliverable D9.1.

3. Project work plan

The **iBeChange's work plan** is structured around nine distinct WP encompassing a series of essential actions pivotal for attaining the anticipated objectives.
Within each WP, a detailed roster of tasks is outlined, strategically designed to drive progress and ensure alignment with overarching objectives. These tasks are deeply interconnected seamlessly, forming a cohesive roadmap that guides the project lifecycle, facilitating the segmentation of our project into manageable phases.
Central to the efficacy of the work packages are the deliverables and milestones they encompass. By defining specific objectives within each work package, these deliverables and milestones offer a holistic view of our project's trajectory, serving as tangible markers of progress, providing clear benchmarks against which our achievements can be measured.

3.1 Deliverables and milestones management

With a keen focus on achieving all established objectives within the agreed-upon timeframes outlined in the Grant Agreement, IEO, as the Coordinator Centre, adopts a proactive approach to supervision. One of the key strategies employed by IEO involves optimising communication channels and protocols. Recognising that many tasks necessitate collaborative efforts with other project partners, IEO ensures that communication flows seamlessly among all stakeholders. This may involve regular meetings, progress updates, and feedback sessions to address any challenges and foster a collaborative environment (as explained in the following paragraphs).
Moreover, IEO takes on the responsibility of managing timelines and deadlines effectively. Through timely reminders and updates, IEO keeps partners informed of impending milestones and deliverables.
The IEO team established guidelines for deliverable submission, which were shared and discussed among consortium partners during the Kick-Off Meeting (KoM).
Given the substantial number of documents and products to be delivered throughout the project's duration, the timeline for deliverables, tasks, and milestones has been shared with the consortium, and deadlines are regularly emphasized by the IEO PM.
The Project Coordinator has developed a **comprehensive review** and **submission procedure** to ensure both the quality and timely submission of deliverables, in accordance with the deadlines set in the Grant Agreement. The **submission procedure** is structured as follows:

- **STEP1:** One month before the deliverable's due date, a reminder will be sent by the IEO PM to the responsible partners.
- **STEP2:** Each deliverable must be submitted to the Work Package Leader and Co-Leader at least 21 working days before the deadline for revisions.
- **STEP3:** All deliverables undergo internal review by the PM and two or three reviewers selected from the consortium team based on their expertise.
- **STEP4:** The revised version is circulated to the Consortium at least 10 working days before the deadline of the deliverable, due collecting eventual inputs and providing a final revision and approval.
- **STEP6:** The deliverable is uploaded on the *EU funding and tenders* portal by IEO's PM.

A deliverable template has been developed and shared among the Consortium members (further details on this topic can be found in section 5.2).

3.2 Work Packages' overview

The nine WP's have the following objectives and responsibilities:

- WP1 – IEO: *Project management and coordination*

The main goal is to guarantee the achievement of the results within the expected timeframe and resources of the proposal by (1) ensuring continuous and smooth communication and organisation between the consortium and the EU; (2) overseeing the whole execution of the project, including the monitoring and coordination of its technical, scientific, clinical, ethical, and exploitation aspects; (3) ensuring the quality of the final results and deliverables.

- WP2 – IEO: *Design of the integrated platform using Behaviour Change Techniques and User-Centred Design Approach*

With a focus on a user-centred co-creation approach, the overall aim of this WP is to theoretically design an ontological model that incorporates Behavioural Change Techniques (BCTs) and strategies that will feed the Behavioural Change Platform developed under WP4. First, it will focus on the identification of: 1) traditional (e.g., self-reported measures) and unobtrusive measures (e.g., application, wearables, sensors) of the targeted behavioural, physiological, and psychological factors; 2) the most effective BCTs to target the considered lifestyles; 3) the best digital interventions to provide psychological support to end users. The results of this WP will serve as input for WP3 and WP4. It will work closely with WP7 to ensure that regulatory aspects are effectively considered and designed from the outset.

- WP3 – POLIMI: *Novel approaches for interaction through a Virtual User Model*

WP3's aim is to implement smart, ecological and personalised strategies to gather user information and to interact with the user in order to maximise acceptance and adherence. Retrospective and publicly available data will be exploited to study the relationship between cancer onset and BCs, so as to inform the iBeChange Platform (WP4). A Virtual user AI-based data-driven model will be designed to support the identification of personalised interventions. Finally, personalised interfaces to improve the user experience will be developed.

- WP4 – EUT: *Intelligent Reinforcement Learning-based Personalized Behaviour Change Platform*

The overall aim of this WP is to design and develop the iBeChange Platform to deliver highly personalised BC recommendations and digital psychological support to users based on the ontological model constructed in WP2. In accordance with the Virtual-User model (T3.3), high-risk behavioural patterns, psychosocial risk factors, and previous interactions with the system, it will adjust the language, timing, and content of the delivered recommendations. This WP will focus on the research of technical approaches to promote long-term, sustainable BC, converting the findings from WP2 and the data collected in WP3 into an application ready to be tested by the final users.

- WP5 – ICO: *Deployment of the Recommendation System to the population*

The primary aim of this WP is to design and conduct the prospective studies to assess the feasibility and impact of the iBeChange platform. The WP will begin with a pilot study (iBC/PS) to test the

feasibility of the recruitment, management, intervention and assessment procedures at clinical sites. Following the pilot, a multicentre randomised controlled trial (RCT) will be conducted (iBC/CT) to assess the implementation and effectiveness of the recommendation system. The secondary objectives of this WP include informing an update of the Recommendation System after the iBC/CT to produce the definitive version of the iBC platform; and testing the usage of wearables to collect behavioural and psychosocial data on a subsample of the study.

- WP6 – SD: *Impact assessment*

The main objective of this WP is to conduct a series of assessments regarding the impact of the iBeChange's system.

- WP7 – i-HD: *Ethical, Privacy, and Data Protection*

The goal of this WP is to identify, analyse and develop safeguards for the ethical and legal issues surrounding the development of the integrated platform, with a particular focus on data protection and privacy legislation, ethics, regulations applied to new technologies, medical devices where appropriate and clinical trials legislation. In parallel, partners will be assisted in developing their ethics approvals for their work and submission to the appropriate Independent Review Boards. Additionally, this WP will oversee the selection and appointment of an independent panel of experts to serve as an Ethical Review Board (EAB). This EAB will oversee the ethical and compliance conduct of the project and report every eighteen months on its progress and adherence, providing guidance and direction where ethical challenges may arise. WP7 and the EAB will oversee the conduct of the Ethics Manager and specify the tasks required by the role. We will further inform and address challenges and requirements around data quality and throughout the project directly support all WPs in matters around regulatory compliance and ethics, working closely with the leads and partners.

- WP8 – EAPM: *Policy Alignment/Implementation, dissemination, and communication*

The aim of this WP is to create the framework for an overarching support tool for policymakers for decision-making as well as effective communication and dissemination with all key stakeholders. Specifically, we will focus on: 1) the development of a governance model to address challenges at regional, national and European levels related to the use of big data for BC and EM; 2) allowing constant feedback on the real needs of public health Policy Makers; 3) the evaluation of opinions and attitudes of citizens towards prevention policy strategies; and 4) the development of structures and processes for dissemination and communication activities.

- WP9 – IEO: *Ethics requirements*

This WP was specifically requested for the appointment of an Independent External Advisory Board (IEAB) (see sub-paragraph 2.1.4).

3.3 WP's Tasks

The DoA (annex 1 – part A) describes the list of iBeChange's tasks, task leaders and starting/ending month, as indicated in the table below.

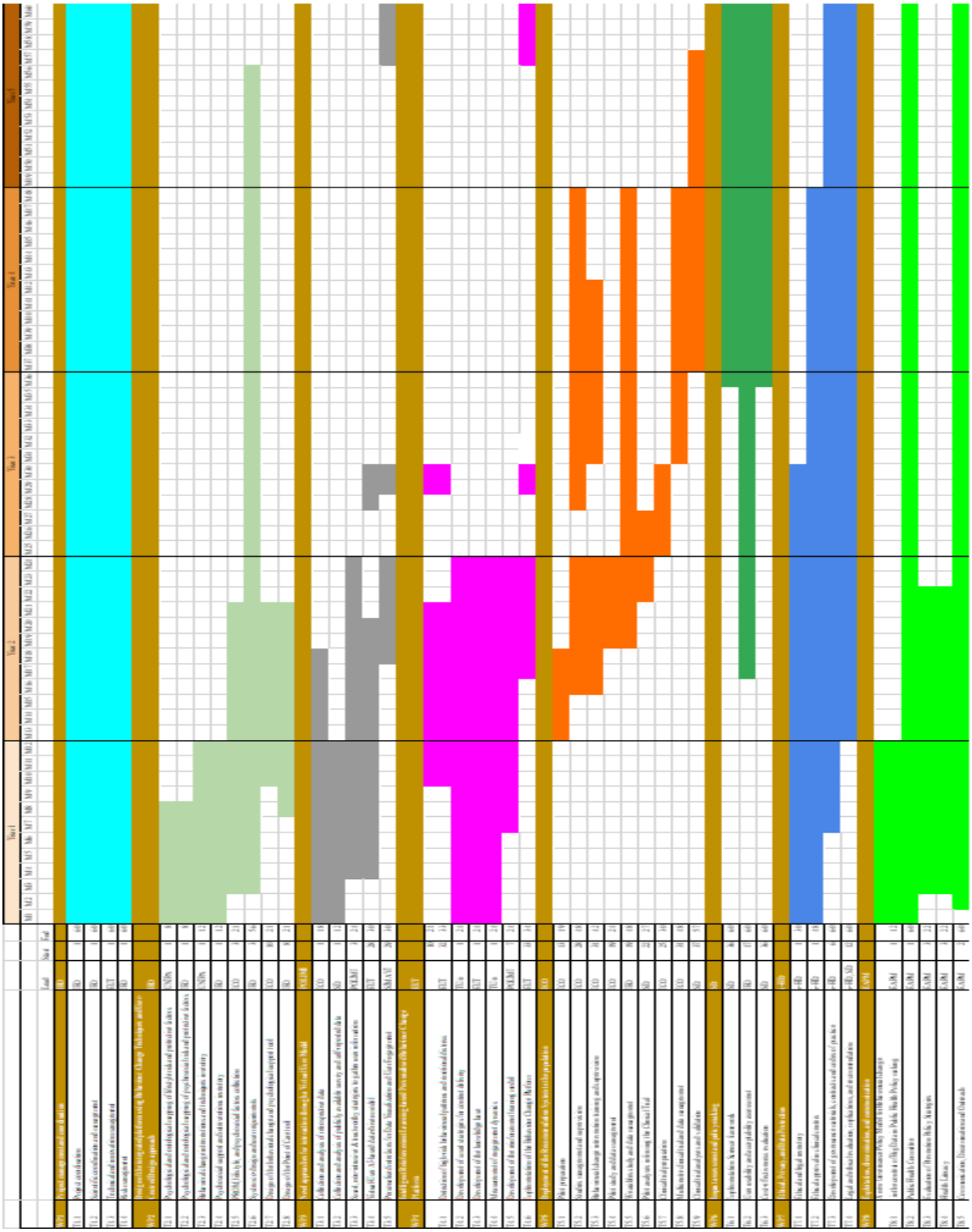
Table 4. iBeChange WPs' tasks.

Task	Title	Leader	Collaborating partner	Start month	End month
T1.1	Project management and coordination	IEO	ALL	1	60
T1.2	Scientific coordination and management	IEO	ALL	1	60
T1.3	Technical and innovation management	EUT	ALL	1	60
T1.4	Risk management	IEO	ALL	1	60
T2.1	Psychological and ontological mapping of lifestyle risk and protective factors	UNIPA	IEO, EUT, ICO, SD, POLIMI, i~HD	1	8
T2.2	Psychological and ontological mapping of psychosocial risk and protective factors	IEO	UNIPA, ICO, POLIMI, EUT, SD, i~HD	1	8
T2.3	Behavioural change interventions and techniques inventory	UNIPA	IEO, EUT, ICO, SD, UMFCD	1	12
T2.4	Psychosocial support and interventions inventory	IEO	UNIPA, ICO	1	12
T2.5	PROM, lifestyle, and psychosocial factors collection	ICO	IEO, SD, UNIPA, POLIMI, UMFCD	3	21
T2.6	System co-design and user requirements	IEO	ICO, UNIPA, TU/e, SIMAVI, UMFCD	3	56
T2.7	Design of the behavioural change and psychological support tool	ICO	IEO, EUT, UNIPA	10	21
T2.8	Design of the Point of Care tool	IEO	EUT, ICO, UNIPA, POLIMI, SIMAVI, UMFCD	8	21
T3.1	Collection and analysis of retrospective data	ICO	IEO, SD, SIMAVI, UMFCD	1	18
T3.2	Collection and analysis of publicly available survey and self-reported data	SD	IEO, UNIPA	1	12
T3.3	Smart, non-intrusive & trustworthy strategies to gather user information	POLIMI	IEO, EUT, SD, UNIPA, SIMAVI	3	24
T3.4	Virtual-User AI-based data-driven model	EUT	IEO, SD, UNIPA, POLIMI, TU/e	4 28	20 30
T3.5	Personalised interfaces for Data Visualization and User Engagement	SIMAVI	IEO, EUT, UNIPA, POLIMI, TU/e	18 29 57	24 30 60
T4.1	Detection of high-risk behavioural patterns and emotional distress	EUT	IEO, ICO, UNIPA, POLIMI, TU/e, SIMAVI	10 32	21 33
T4.2	Development of smart strategies for content delivery	TU/e;	IEO, EUT, SD, UNIPA, POLIMI	1	24
T4.3	Development of the content knowledge base	EUT	IEO, ICO, UNIPA, POLIMI, SIMAVI)	1	24
T4.4	Development of the reinforcement learning model	POLIMI	EUT, UNIPA, TU/e)	7	24
T4.6	Implementation of the Behaviour Change Platform	EUT	IEO, UNIPA, POLIMI, TU/e, SIMAVI	17 33 57	24 34 60
T5.1	Pilot preparation	ICO, EURECAT	IEO, EUT, UMFCD, POLIMI	3	19
T5.2	Studies management and supervision	ICO	IEO, UMFCD, UNIPA	16 28	24 48
T5.3	Behavioural change intervention training and supervision	ICO	IEO, UNIPA, UMFCD	16 31	24 42
T5.4	Pilot study and data management	ICO, EURECAT, i~HD	IEO, UMFCD, SD	19	24
T5.5	Wearables study and data management	IEO	UNIPA, ICO, POLIMI, UMFCD, SD	19	48

T5.6	Pilot analyses informing the clinical trial	SD	ICO; IEO, UMFCD	22	27
T5.7	Clinical trial preparation	ICO	IEO, UMFCD	25	30
T5.8	Multicentre clinical trial and data management	ICO	EO, UMFCD, i~HD, POLIMI, SD	31	48
T5.9	Clinical trial analyses and validation	SD	ICO; IEO, UMFCD, POLIMI	37	57
T6.1	Implementation Science framework	SD	IEO, ICO, UMFCD, UNIPA	36	60
T6.2	User usability and acceptability assessment	IEO	SD, UNIPA	17	60
T6.3	Cost-effectiveness evaluation	SD	IEO, ICO, UMFCD, UNIPA	36	60
T7.1	Ethical and legal inventory	i~HD	IEO, EUT, SD	1	30
T7.2	Ethical approval in clinical centres	i~HD	IEO, EUT, ICO, SD, POLIMI	1	48
T7.3	Development of governance materials, contracts and codes of practice	i~HD	IEO, EUT, ICO, SD, POLIMI	6	60
T7.4	Legal and ethical evaluation, implications, and recommendation	I~HD	SD, EAPM	12	60
T8.1	A new Governance Policy Model for behav-ioural change in the context of Big Data in Public Health Policy making	EAPM	UNIPA	1	12
T8.2	Public Health Committee (PAC) & Exploitation	EAPM	IEO, UNIPA	1	60
T8.3	T8.3 Evaluation of Prevention Policy Strategies	EAPM	IEO, UNIPA, eCancer	3	22
T8.4	Health Literacy	EAPM	IEO, UNIPA, eCancer	3	22
T8.5	Communication, Dissemination and Outreach	EAPM	IEO, ICO, SD, UNIPA, POLIMI, i~HD, eCan-cer, EUT	2	60

3.4 Gantt chart of the workplan

Figure 2. iBeChange Gantt chart.



3.5 Deliverables

Each project deliverable is linked to a specific task within a work package. The Coordinator Centre IEO is in charge of the responsibility to coordinate the deliverable submission procedure. Additionally, IEO PM oversees the review phase in collaboration with the involved partners and ensures the quality of submitted documents. Additionally, a deliverable template has been developed and shared among the consortium members (further details on this topic can be found in section 5.2). The table below provides a list of Deliverables along with their respective deadlines.

Table 5. iBeChange deliverables.

Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D1.1	Project management plan	WP1	1 - IEO	R — Document report	PU - Public	6
D1.2	Scientific assessment	WP1	1 - IEO	R — Document report	PU - Public	12
D1.3	Technical assessment	WP1	2 - EUT	R — Document, report	PU - Public	20
D1.4	Quality and risk assessment	WP1	1 - IEO	R — Document, report	PU - Public	8
D1.5	Scientific work plan of the Prevention Cluster	WP1	1 - IEO	R — Document, report	PU - Public	3
D1.6	Report of the annual meeting of the Prevention Cluster (1)	WP1	1 - IEO	R — Document, report	PU - Public	12
D1.7	Report of the annual meeting of the Prevention Cluster (2)	WP1	1 - IEO	R — Document, report	PU- Public	24
D1.8	Report of the annual meeting of the Prevention Cluster (3)	WP1	1 - IEO	R — Document, report	PU - Public	36
D1.9	Report of the annual meeting of the Prevention Cluster (4)	WP1	1 - IEO	R — Document, report	PU - Public	4
D1.10	Report of the annual meeting of the Prevention Cluster (5)	WP1	1 - IEO	R — Document, report	PU - Public	60
D2.1	Mapping of behavioural and psychosocial protective and risk factors	WP2	1 - IEO	R — Document, report	PU - Public	8
D2.2	Psychosocial support and behavioural change interventions and techniques to be included in the iBeChange system	WP2	6 - UNIPA	R — Document, report	PU - Public	12
D2.3	PROM, lifestyle, and psychosocial factors measures to include in the iBeChange system	WP2	3 - ICO	R — Document, report	PU - Public	21
D2.4	Report about system co-design and user	WP2	1 - IEO	R — Document, report	PU - Public	21

	requirements (1)					
D2.5	Updated report about system co-design and user requirements (2)	WP2	1 - IEO	R — Document, report	PU - Public	56
D2.6	Contents, interventions, procedures, and strategies to promote healthy habits and psychosocial adjustment and PoC	WP2	1 - IEO	R — Document, report	PU - Public	21
D3.1	Retrospective data analysis	WP3	3 - ICO	R — Document, report	PU - Public	18
D3.2	Analysis of publicly available data	WP3	5 - SD	R — Document, report	PU - Public	12
D3.3	Strategies to gather user information	WP3	4 - POLIMI	R — Document, report	PU - Public	24
D3.4	Virtual User Model (1)	WP3	2 - EUT	OTHER	SEN - Sensitive	20
D3.5	Virtual User Model (2)	WP3	2 - EUT	OTHER	SEN - Sensitive	30
D3.6	User interfaces (1)	WP3	10 - SIMAVI	DEM — Demonstrator, pilot, prototype	PU - Public	24
D3.7	Update on the user interfaces (2)	WP3	10 - SIMAVI	DEM — Demonstrator, pilot, prototype	PU - Public	60
D4.1	High-risk behavioural Pattern and emotional distress Detection Module	WP4	2 - EUT	OTHER	SEN - Sensitive	21
D4.2	Smart Content Delivery Module	WP4	8 - TU/e	OTHER	SEN - Sensitive	24
D4.3	Knowledge Base for Recommendations	WP4	2 - EUT	DATA — data sets, microdata, etc	SEN - Sensitive	24
D4.4	Engagement Dynamics Module	WP4	8 - TU/e	OTHER	SEN - Sensitive	24
D4.5	Reinforcement Learning Model	WP4	4 - POLIMI	R — Document, report	PU - Public	30
D4.6	Reinforcement Learning Approach	WP4	4 - POLIMI	OTHER	PU - Public	30
D4.7	Infrastructure for deploying the Behaviour Change Platform	WP4	2 - EUT	OTHER	SEN - Sensitive	21
D4.8	Behaviour Change Platform (1)	WP4	2 - EUT	OTHER	SEN - Sensitive	21
D4.9	Update on the Behaviour Change Platform (2)	WP4	2 - EUT	OTHER	SEN - Sensitive	30
D4.10	Behaviour Change Platform specifications	WP4	2 - EUT	R — Document, report	PU - Public	60
D5.1	iBC/PS protocol approval and registration	WP5	3 - ICO	R — Document, report	PU - Public	16
D5.2	iBC/WS protocol approval and registration	WP5	1 - IEO	R — Document, report	PU - Public	16
D5.3	Results of iBC/PS and recommendations to optimise intervention and the iBC/CT	WP5	5 - SD	R — Document, report	SEN - Sensitive	27

D5.4	Results of the iBC/WS	WP5	5 - SD	R — Document, report	SEN - Sensitive	27
D5.5	Study initiation package for iBC/CT	WP5	3 - ICO	R — Document, report	PU - Public	30
D5.6	Mid-term iBC/CT recruitment report	WP5	3 - ICO	R — Document, report	PU - Public	37
D5.7	iBC/CT baseline results	WP5	5 - SD	R — Document, report	SEN - Sensitive	45
D5.8	Report on the status of posting results of the iBC/CT	WP5	5 - SD	R — Document, report	SEN - Sensitive	57
D6.1	Report on Implementation Science	WP6	5 - SD	R — Document, report	SEN - Sensitive	60
D6.2	Report on user acceptability and usability	WP6	5 - SD	R — Document, report	SEN - Sensitive	60
D6.3	Report on cost-effectiveness analysis	WP6	5 - SD	R — Document, report	SEN - Sensitive	60
D7.1	Data Management Plan (DMP)	WP7	7 - I-HD	R — Document, report	PU - Public	6
D7.2	iBeChange Platform Design Regulatory Requirements	WP7	7 - I-HD	R — Document, report	PU - Public	12
D7.3	First Report of the EAB	WP7	7 - I-HD	R — Document, report	SEN - Sensitive	18
D7.4	Information Governance Framework for iBeChange	WP7	7 - I-HD	R — Document, report	SEN - Sensitive	18
D7.5	iBeChange Platform Implementation Compliance Review	WP7	7 - I-HD	R — Document, report	SEN - Sensitive	30
D7.6	Second Report of the EAB	WP7	7 - I-HD	R — Document, report	SEN - Sensitive	30
D7.7	Update to the Data Management Plan (DMP)	WP7	7 - I-HD	R — Document, report	PU - Public	36
D7.8	Final Report of the EAB	WP7	7 - I-HD	R — Document, report	PU - Public	48
D8.1	White Paper	WP8	9 - EAPM	R — Document, report	PU - Public	12
D8.2	Public Health Policy Advisory Committee (PAC)	WP8	9 - EAPM	R — Document, report	PU - Public	5
D8.3	Policy Report on Prevention Strategies,	WP8	9 - EAPM	R — Document report	PU - Public	12
D8.4	White paper on "Health Literacy supporting Public Health policies and Big data"	WP8	9 - EAPM	R — Document, report	PU - Public	22
D8.5	Policy Round Table	WP8	9 - EAPM	R — Document, report	PU - Public	22
D8.6	Sustainable policy strategy	WP8	9 - EAPM	R — Document, report	PU - Public	36
D8.7	Online communication platforms & Intranet	WP8	12 - ECANCER	R — Document, report	PU - Public	5
D8.8	External Communication Engagement	WP8	12 - ECANCER	R — Document, report	PU - Public	3
D8.9	Dissemination and exploitation Plan	WP8	12 - ECANCER	R — Document, report	PU - Public	6
D8.10	Communication and dissemination of the	WP8	1 - IEO	R — Document, report	PU - Public	12

	Prevention Cluster					
D8.11	Annual policy recommendations of the Prevention Cluster (1)	WP8	9 - EAPM	R — Document, report	PU - Public	12
D8.12	Annual policy recommendations of the Prevention Cluster (2)	WP8	9 - EAPM	R — Document, report	PU- Public	24
D8.13	Annual policy recommendations of the Prevention Cluster (3)	WP8	9 - EAPM	R — Document, report	PU - Public	36
D8.14	Annual policy recommendations of the Prevention Cluster (4)	WP8	9 - EAPM	R — Document, report	PU - Public	48
D8.15	Citizen engagement summary report	WP8	9 - EAPM	R — Document, report	PU - Public	56
D8.16	Addressing inequalities recommendations	WP8	1 - IEO	R — Document, report	PU - Public	56
D8.17	Annual policy recommendations of the Prevention Cluster (5)	WP8	9 - EAPM	R — Document, report	PU - Public	60
D9.1	POPD - OEI - AI - Requirement No. 1	WP9	1 - IEO	ETHICS	SEN - Sensitive	1
D9.2	POPD - OEI - AI - Requirement No. 2	WP9	1 - IEO	ETHICS	SEN - Sensitive	16
D9.3	POPD - OEI - AI - Requirement No. 3	WP9	1 - IEO	ETHICS	SEN - Sensitive	32

3.6 Milestones

The table below shows the list of Milestones and the related deadlines.

Table 6. iBeChange milestones.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
1	Kick-off meeting	WP1	1-IEO	Minutes of meeting	6
2	Quality and risk management	WP1	1-IEO	Report published	20
3	Description of the iBeChange integrated platform and PoC	WP2	6-UNIPA	Report published	21
4	Selection of wearables sensors	WP3	4-POLIMI	report published	6
5	Deployment of interfaces for data collection, data visualisation and user engagement	WP3	2-EUT	Software Release	24
6	Deployment of the iBeChange platform	WP4	2-EUT	Software Release	24

7	Trial Supervision Committee appointed and co-supervision meetings scheduled	WP5	3-ICO	First meeting minutes	16
8	Start of the iBC/PS and iBC/WS	WP5	3-ICO	First participant recruited in each study	19
9	Start of the iBC/CT	WP5	3-ICO	First participant recruited	31
10	Completion of iBC platform access to control participants	WP5	3-ICO	Three months after the access of the last control participant	51
11	Development of cost-effectiveness analysis model	WP6	5-SD	Cost effectiveness analysis protocol	54
12	Data Management Plan completed	WP7	7-I-HD	Report Published	6
13	Regulatory Requirements provided for Platform Design	WP7	7-I-HD	Requirements for contribution to WP2 and T2.2 and T2.3	10
14	First Meeting of the Ethics Advisory Board	WP7	7-I-HD	Meeting held	15
15	Platform Compliance Review Completed	WP7	7-I-HD	Review Completed and ready for Publication	28
16	Second Meeting of EAB held	WP7	7-I-HD	Meeting held	33
17	DMP Updated	WP7	7-I-HD	Report Published	36
18	Final meeting held for EAB	WP7	7- I-HD	Meeting held	45
19	White Paper Developed	WP8	9-EAPM	White paper finalised	14
20	Public Advisory Group	WP8	9-EAPM	Group Established	5
21	Policy Prevention report	WP8	9-EAPM	Report launched	12
22	Health Literacy Report	WP8	9-EAPM	Report launched	24
23	Policy Roundtable	WP8	9-EAPM	Event taking place	22
24	Sustainable Policy Strategy	WP8	9-EAPM	Policy Strategy developed	36
25	Website and logo developed	WP8	12-ECANCER	Website/logo developed	3
26	Intranet	WP8	12-ECANCER	Intranet developed	6
27	Monthly Videos	WP8	12-ECANCER	Videos developed	60
28	Quarterly newsletter	WP8	12-ECANCER	Newsletter developed	60
29	External Communication Strategy & Twitter	WP8	12-ECANCER	External Communication document	60

3.7 Project Timeline and Request for Modifications

The information presented in Paragraph 3 (Project Workplan) refers to the organisational structure of the iBeChange project, based on the details provided in the research proposal and in the Grant Agreement; it will serve as a guide for the project management. However, with the official launch of the project and following several discussions among all partners, the need to request modifications to the timeline has arisen. Below, we will present the changes requested to the Project Officer (PO) regarding to the timeline of certain tasks (see subparagraph 3.6.1). The proposed amendments have been officially approved by the PO; consequently, the tables and the Gantt chart presented in this document will be updated accordingly and will be considered for monitoring all project activities.

3.7.1 Request for changes to the project timeline

The iBeChange consortium has identified the need for reorganisation for some tasks within WP3 and WP4 and has therefore sent a *Justification Letter* to the PO.
The requested modifications will be budget-neutral and are aimed at optimising our project's workflow. We believe these adjustments are crucial to ensure optimal achievement of our set objectives, and we are committed to ensuring the project's success.
Regarding WP3 and WP4, we proposed extending specific tasks (refer to Tab. 7) to allow our technical partners to continue working on the iBeChange platform after the conclusion of the Pilot Study (M24) and until the beginning of the RCT (M31). This change will facilitate further refinement of modules, ensuring a stronger performance for the version of the platform that will be used for the RCT. Additionally, in order to allocate more time for platform development prior to the Pilot Study, we also proposed advancing tasks 3.5 and 4.6 (see Tab. 7). As a consequence, we suggested modifying the due dates for the associated deliverables (Tab. 8) and milestones (Tab. 9) within WP3 and WP4. This adjustment ensures that the deliverables align consistently with the following three key time points: the delivery of the initial version of the platform (M17), the delivery of the version of the platform that will be used for the RCT (M30), and the delivery of the final version of the platform (M60).

Table 7. Modification requested for tasks within WP3, WP4.

		Lead	Start	End	Request		Change description
WP3	**Novel approaches for interaction through a Virtual User Model**	**POLIMI**			**Start**	**End**	
T3.3	Smart, non-intrusive & trustworthy strategies to gather user information	POLIMI	3	24	3	30	6-month extension to fine tune the platform after the end of the pilot study (M24) and until the beginning of the RCT (M31)
T3.4	Virtual-User AI-based data-driven model	EUT	4 28	20 30	4	30	No interruption between M20-28 to keep fine tuning the platform until the beginning of the RCT (M31)

T3.5	Personalised interfaces for Data Visualization and User Engagement	SIMAVI	18* 29 57*	24* 30 60*	4 57	30 60	Anticipation of the task from M18 to M4 to have more time to consider the potential platform interfaces and no interruption between M24-M29 to keep fine tuning the platform after the end of the pilot study (M24) and until the beginning of the RCT (M31)
WP4	**Intelligent Reinforcement Learning-based Personalised Behaviour Change Platform**	**EUT**					
T4.1	Detection of high-risk behavioural patterns and emotional distress	EUT	10*	21*	10	30	9-month extension to fine tune the platform after the end of the pilot study (M24) and until the beginning of the RCT (M31)
T4.2	Development of smart strategies for content delivery	TU/e	1	24	1	30	6-month extension to fine tune the platform after the end of the pilot study (M24) and until the beginning of the RCT (M31)
T4.3	Development of the content knowledge base	EUT	1	24	1	30	
T4.4	Measurement of engagement dynamics	TU/e	1	24	1	30	
T4.5	Development of the reinforcement learning model	POLIMI	7	24	7	30	
T4.6	Implementation of the Behaviour Change Platform	EUT	17* 33 57*	24* 34 60*	13 57	30 60	4-month anticipation of the task to run with no interruptions until M30 to have more time to test, improve and fine tune the platform until the beginning of the RCT (M31)

* Months included in the proposal and in the text of the Grant Agreement, but not represented in the Gantt Chart of the Grant Agreement.

Table 8. Modification requested for deliverables within tasks WP3, WP4.

		Lead	Due Month	Request
WP3	**Novel approaches for interaction through a Virtual User Model**	**POLIMI**		
D3.3	Strategies to gather user information	POLIMI	24	27
D3.6	User interfaces (1)	SIMAVI	24	27
WP4	**Intelligent Reinforcement Learning-based Personalised Behaviour Change Platform**	**EUT**		
D4.1	High-risk behavioural Pattern and emotional distress Detection Module	EUT	21	27
D4.2	Smart Content Delivery Module	TU/e	24	27
D4.3	Knowledge Base for Recommendations	EUT	24	27
D4.4	Engagement Dynamics Module	TU/e	24	27

Table 9. Modification requested for milestones within WP3, WP4.

		Lead	Due Month	Request
WP3	**Novel approaches for interaction through a Virtual User Model**	**POLIMI**		
5	Deployment of interfaces for data collection, data visualisation and user engagement	EUT	24	30
WP4	**Intelligent Reinforcement Learning-based Personalised Behaviour Change Platform**	**EUT**		
6	Deployment of the iBeChange platform	EUT	24	30

3.7.2 Management strategy for delays in deliverables submission

Despite our continued commitment to ensuring timely presentation of results, delays may occur. Delays in the submission of deliverables may be caused by unforeseen events or may be foreseeable, based on the understanding that in the life of the project some activities may take longer than expected.

By understanding these reasons and implementing effective strategies, the consortium can better manage deliverables submission times and minimize delays. An effective delays management strategy begins with the attempt to prevent them through clear communication and includes prioritization and time management using tools such as calendars, that also allow tracking progress. A clear planning is another important strategy: building buffer time into schedules can accommodate unexpected delays. If, on the other hand, delays are foreseen and unavoidable, depending on the delay in completing some tasks, measures are taken to inform the consortium, due adapting the timetable of eventual connected activities and deliverables accordingly. As well as within the consortium, it is essential to communicate delays in the submission of documents to the PO. The PO is informed

through the "*EU funding and tenders portal*", the communications area among the partners and the European Commission. When the delay is recognized, IEO team reports it to the PO; in the case of short delays, reasons are explained in detail when the product is presented. In the case of a more significant delay, it is necessary to ask the PO to postpone the expiring date of the deliverable in object, justifying such request with all the available information and with the forecast of the time-line within which the document can be submitted. In the submission phase, a comment is drafted and uploaded through the aforementioned portal to keep track of the delay.

4. Communication within the Consortium

The internal communication strategy is designed to keep partners fully informed about project status, planning, and other pertinent issues to maximize transparency and cooperation. Interactive management meetings play a crucial role in this strategy. A robust internal communication system also facilitates project monitoring and control processes, which are essential for planning, monitoring work progress, and addressing any events that may impact ongoing activities.
The main occasions for project control are meetings, which provide the entire consortium with opportunities for detailed project planning and the assessment of work progress. All regular meetings among the Consortium and its constituent bodies are scheduled in proper advance to facilitate the attendance for each member, accordingly with an appropriate agenda distributed to all members before the meeting. These meetings are conducted face-to-face to foster personal relationships and provide an optimal environment for discussing problems.

4.1 In-person meetings

4.1.2 Kick-off meeting

A comprehensive **Kick-off meeting (KoM)** was convened in Milan at European Institute of Oncology (IEO) on **January 22nd-23rd, 2024**, marking the official inauguration of the iBeChange project. This meeting provided a crucial platform for presenting the project's guidelines to all partners. Discussions primarily focused on outlining the planned activities for the project's first year, as well as defining standard operating procedures and protocols. Moreover, the meeting facilitated initial contact and collaboration discussions between iBeChange and the other project winners of the Prevention Cluster, MELIORA and SUNRISE projects. This engagement allowed for the exchange of information and the outlining of preliminary collaborative strategies, enhancing synergies, and fostering cooperation between the projects.
On this occasion, a session was dedicated to the presentation and approval of two organs that will provide external support, offering their expertise across various project areas: the aforementioned EC and the **External Advisory Board**. This board is designed to serve a consultative function, is constituted of notable organizations members including Europa Donna, Lung Cancer Europe (LuCe), the Director Plan of Oncology and UO Prevention Members for Regione Lombardia. This board will convene every six months, fostering a regular exchange of insights and recommendations to enhance the project's strategic direction.
The organization and management of this event included the production of materials that have been archived for partner consultation along with other project-related materials. Specifically, the meeting minutes (revised by all partners), the meeting agendas, an official sign-in sheet to record attendance, and the power point presentations produced.

4.1.3 Annual meeting

An annual meeting among consortium members will function as a checkpoint to evaluate the project's progress, exchange data and results, and address any encountered obstacles.
The iBeChange in-person consortium meetings occur annually and are organized on a rotational basis among the consortium partners. The hosting centre is responsible for covering organizational

expenses, including conference room, coffee break, etc. Conversely, each partner of the Consortium is responsible for their own travel expenses (e.g., accommodation, travel, etc.).
Looking ahead, the second **iBeChange annual meeting is scheduled for September 2024** and will be held in Barcelona. This decision stemmed from the consideration that all involved partners, including consortium partners and colleagues from other cluster projects, might have an interest in attending the **ESMO** (European Society for Medical Oncology) congress in Barcelona (that will be held from September 13th to 17th, 2024). Indeed, holding the iBeChange annual meeting in Barcelona on the dates of ESMO congress and hosting the Cluster meeting (see paragraph 6.2) could be an opportunity to optimize resources. The ICO and IEO teams started the organisation of the event, taking in charge of the responsibility to decide the logistics and the meeting agenda, accordingly to the project needs.

4.1.4 Meetings and final major symposium

During these occasions, the results of the project will be presented, and conclusions drawn from the project's findings will be incorporated into the completion report. Additionally, an event will be organized to promote and disseminate the benefits of the iBeChange initiative, providing stakeholders with an opportunity to recognize its impact.

4.2 Online meetings

4.2.1 Bi-weekly clinical and technical partners meetings

To enhance collaborative work methodology and streamline the division of responsibilities and tasks, consortium members have been categorized into two macro-teams based on their contributions to the project: clinical partners and technical partners. These two groups work synchronously on their respective tasks, fostering collaboration both within their own group and with colleagues from the other group. To facilitate communication, leaders have been designated for each team: **ICO leads the clinical partners**, while **EUT leads the technical partners**. **Bi-weekly meetings** have been scheduled for both clinical and technical partners, with IEO, as the coordinator centre, responsible for scheduling the agenda of the meetings year by year. ICO and EUT are responsible for drafting the agenda of each clinical and technical meeting and also for redacting and sharing to all the Consortium members the meeting minutes. The **day before each scheduled meeting, the agenda is shared among participants** by the respective team leader. Additionally, during clinical meetings, designated members of the technical team participate to relay any emerging needs and requests back to their colleagues. Similarly, during technical meetings, designated members of the clinical team participate collecting technical requests and communicating needs favouring communication between teams.

4.2.2 Bi-monthly Consortium Meetings

To facilitate interoperability among consortium members, **Bi-monthly Consortium meetings have been scheduled**. These meetings serve as valuable opportunities for exchanging information and keeping all partners updated on actions implemented and those planned within the project. The meeting agenda for the first year of the project has been prepared by the IEO PM and shared among

the partners, along with the link (Microsoft Teams) to access the meetings. The agenda of the meeting is shared well in advance and is updated accordingly with proposals from partners.

4.2.3 Bi-monthly Executive Committee meetings

Bi-monthly EC meetings are convened to address fundamental topics related to project execution and to resolve any issues that may arise during its course. As with the consortium meetings, the agenda for these EC meetings has been prepared by the IEO PM for the first year of the project and shared among the partners, along with the access link. The agenda of the meeting is shared in advance and updated as needed based on inputs from members.

4.3. Repository of project-related documents

In order to streamline internal communication and facilitate the exchange of project-related documents among partners, a **cloud storage solution** will be implemented. This platform will feature a dedicated shared folder specifically for the iBeChange project. Within this shared folder, each participating institute will have a designated responsible person granted access, ensuring that all project-related documents and materials are readily accessible to all involved partners.
The shared materials housed within this platform will encompass a variety of resources essential for project management and collaboration. These include templates, Gantt charts outlining timelines, deadlines for deliverables and milestones, presentation slides used during meetings and events, work package documents, official versions of deliverables, meeting minutes, contact details of consortium partners, and agendas.
As the coordinating center, IEO is tasked with the creation of this platform. However, due to limitations in its internal infrastructure and privacy concerns, IEO has opted to procure the repository externally. To this end, technical specifications were defined in collaboration with technical partners, and three quotes were obtained from different providers. In adherence to the commitment to secure the best value for money while upholding principles of cost-effectiveness, IEO engaged with its Grant Office to conduct a comparative evaluation of the quotes before finalising the procurement process. Meanwhile, we are also considering the possibility of using the extranet that will be implemented in the iBeChange website that eCancer is developing as a repository.
To compensate the delay in the implementation of the sharepoint, a **Slack channel** has been established by EUT, acting as the leader of the technical partners, to facilitate smooth and immediate communication among partners involved in executing tasks that require close collaboration and frequent exchange of ideas and materials. This tool, functioning as a platform to share communications and project-related materials cannot be intended as a data repository.

4.4 Contact list

A centralised contact list is maintained by the Project Coordinator and periodically updated based on input from partners. The contact list is organised according to the work plan structure (e.g., Tasks, Work Packages, etc.) and is accessible in the workspace for collaboration among partners.

5. Monitoring activities and Risk Mitigation strategies

As a guiding principle, the approach to project management in the iBeChange project prioritises consensus building and promotion to foster maximum cooperation within the consortium. The structure of iBeChange Consortium, as established in the DoA, enables a bottom-up approach to conflict resolution: if conflicts arise during project activities, the WP leaders will assist resolving the conflict at a WP level, notifying the Principal Investigator the eventually unsolved conflict, who will work towards an objective resolution. The PI, in collaboration with the PM, holds the responsibility of defining and implementing risk mitigation strategies. Additionally, the Quality and the Ethics Managers support the project PI in monitoring the quality and risks associated with the execution of clinical studies, while the Innovation Manager oversees quality and monitors risks related to technical tasks.

Key monitoring activities include:

- Templates
- Meetings
- Project progress monitoring
- Quality Assessment strategies

5.1 Continuous monitoring

The PM will monitor project progress through updates requested during bi-weekly meetings with the responsible partners for ongoing tasks at that time. Additionally, to oversee the progress of each WP, the PM has devised a **Project Progress Table**, which is distributed to the WP Leaders comprising the EC. The WP Leaders are tasked with completing the table every two months, outlining and presenting during EC meeting the activities undertaken in the preceding two months and those planned for the following two months. The purpose of the Project Progress Table is to aid WP Leaders in project management and to foster collaboration among WPs on specific tasks and subtasks. The table includes the explanation of the ongoing, concluded and starting tasks along with a timeline for key actions requested for its completion.

5.2 Shared templates

Templates provided by the Project Coordinator will be utilized and completed by Work Package Leaders, with input from Task Leaders and contributors to WP activities. These templates can be updated as needed throughout the project and will be accessible to partners in the common online workspace dedicated to the project. Specifically, a template for deliverables and PowerPoint presentations was shared by the IEO team during the second month of the project, and updated accordingly with the iBeChange logo developed by the responsible partners.

5.3 Organizing meetings (agenda, chair and minutes)

The PM serves as the chairperson for project meetings. Calendar invitations with Microsoft Teams meeting links have been created for each clinical, technical, and EC meeting in the first year of the project and sent to all involved partners. An agenda for each meeting is circulated via email the day before to outline discussion items, which may be updated based on participant requests. During meetings, the PM and, in the case of clinical and technical meetings, team leaders redact minutes and highlight important action points or decisions for follow-up.
After the completion of every meeting, the meeting minutes are sent by the PM or by the Team Leaders to the partners involved for review. Once reviewed, the minutes are shared among the consortium in their final version. Subsequently, the meeting minutes will be archived in the dedicated file folder within the repository as soon as it will be available, due being accessible to all partners for consultation.

5.4 Quality Assessment and risk mitigation strategies

Quality assessment strategies are implemented to establish criteria for monitoring the quality of data collection, analysis, and the execution of tasks and deliverables within each WP. These strategies ensure adherence to project standards and facilitate effective feedback channels. The primary objectives of the quality assessment include: **a.** providing guidance on the scientific aspects of project work; **b.** supervising activities across different WP to ensure consistency and scientific quality; **c.** ensuring the effectiveness of project meetings; **d.** evaluating and reviewing project outcomes and deliverables before final submission to the European Commission. These objectives are achieved through various mechanisms:

- **Quality of Coordination**: The Project Coordinator and PM are responsible for assessing the quality of coordination. This involves tasks such as sending deadline reminders, reporting progress, addressing delays and issues, and facilitating collaboration among partners.
- **Quality of Tasks and WPs**: Task and WP quality is monitored at multiple levels: by the WP leader, the PM, and ultimately by the European Commission through project reviews after delivery.
- **Quality of Deliverables**: Each WP Leader and the PM are accountable for ensuring the quality of deliverables. This entails drafting and reviewing deliverables according to specific guidelines, respecting timelines, and meeting quality requirements such as punctuality, template/structure adherence, and content relevance, completeness, clarity, and accuracy.
- **Quality of Milestones**: WP Leaders and the PM oversee the quality of achieved milestones.
- **Quality of Meeting Minutes**: The PM monitors the quality of meeting minutes.
- **Quality of Communication and Dissemination Activities**: This encompasses the project website, social media accounts, and all public materials (e.g., brochures, videos, newsletters, conference presentations, papers, publications).

- **Quality of Research Studies**: WP Leaders, along with the Quality Manager, ensure the quality of research studies by monitoring factors such as ethics compliance, timing, procedures, statistical analysis, and the relevance of scientific publications.

The completion of the aforementioned activities will inform and support the application of the risk mitigation strategies. Risk mitigation strategies include conducting a risk assessment, adhering to regulatory requirements, prioritizing patient safety, safeguarding data security, and implementing contingency plans, researchers can minimize potential risks and maximize the impact of their research findings. Those objectives will be achieved through the support of the responsible team members, boards, and responsible execution bodies. Particularly, i-HD is in charge of the drafting of DPIA and DMP.

6. Prevention and Early Detection Cluster

The **Prevention & Early Detection (Behavioural Change) Cluster** includes the iBeChange, **MELIORA**, and **SUNRISE** Projects, focusing on prevention and early detection.
The effectiveness of clusters relies on enhancing research and innovation synergies and exploring collaborative opportunities across sectors: common efforts will be addressed in facing current challenges and adopting impact assessment methodologies to promote excellence among partners while adhering to ethical standards, thereby enhancing research and innovation in Europe and safeguarding citizens' well-being.

6.1 Cluster activities

Within the context of cluster activities, six key areas of collaboration within the Prevention & Early Detection (Behavioural Change) Cluster have been identified: Research and innovation; Communication and dissemination; Data management; Addressing inequalities; Citizen engagement; Organization of Annual cluster meetings. The iBeChange project, as decided in the initial cluster kick-off meeting, is primarily positioned in the **areas of communication**, **dissemination**, and **data management**, with the collaboration of EAPM and i-HD, the consortium partners responsible for communication and ethics activities respectively. Taking the lead in these areas, iBeChange will engage in collaborative activities alongside MELIORA and SUNRISE. For example, proposed activities include cross-promotion on social media, joint outreach campaigns targeting specific audiences, and a podcast series featuring stakeholders discussing various aspects of cancer research and treatment.

6.2 Cluster annual meetings

Projects within the cluster are called to meet annually in an annual meeting aimed at better organising their collaborative activities. Cluster annual meetings among the projects within the prevention and early detection cluster are scheduled on a rotational basis, with each project coordinator (MELIORA, SUNRISE, iBeChange) taking turns to host.

The **initial Cluster meeting** held on **March 6th** was organized by the European Commission and aimed to coordinate the initial steps of collaborative work. Various strands of the projects were presented, and each project was asked to decide which strand to lead. During this meeting, the IEO team explored the possibility of integrating the Cluster annual meeting with the iBeChange Annual Consortium meeting. This proposal aimed to optimize resource utilization and timing by aligning the schedules of both events. This proposal was shared with the consortium partners and with ICO, which will be responsible for organising the **iBeChange Annual Meeting 2024,** together with IEO as responsible for the Cluster meeting. The proposal was also well-received by the various projects, who confirmed their willingness to participate in the meeting. The meeting agenda, drafted by IEO and ICO will be finalised in accordance with the iBeChange Consortium and the cluster colleagues.

7. Conclusions

The current deliverable aimed to synthetise procedures, strategies and tasks that have been and will be implemented by the Project Coordination Team and the iBeChange PMto coordinate the iBeChange project in its ongoing. Specifically, this **Project Management Plan** outlines the project's objectives, scope, timeline, quality standards, risk management strategies, communication plan, and stakeholder engagement approach. By adhering to the guidelines and methodologies detailed in this document, we aim to ensure that the project meets its goals and delivers value to all stakeholders.

The key to our project's success will be the diligent application of the project management principles, continuous monitoring and control, and proactive communication among all team members and stakeholders. The risk management plan and mitigation strategies will help us anticipate and address potential challenges, ensuring that we remain on track and within budget. Furthermore, our commitment to quality will be strengthened by the oversight of the designated execution bodies, guiding us towards achieving the highest standards of performance.

As the project progresses, this plan will serve as a living and dynamic document, to be updated and refined based on feedback and changing circumstances through the project lifetime. Regular reviews and updates will ensure that the project remains aligned with its objectives and stakeholder expectations.

The current Project Management plan is be completed and accompanied by a Data Management Plan (**DMP**), which has been submitted through Deliverable D7.1 (may 2024), and a Data Protection Impact Assessment (**DPIA**). Both of these documents, drafted by i-HD are aimed at ensuring compliance with data protection regulations and effective data management practices.

Looking ahead, our immediate focus will be on finalising the creation of the SharePoint site, which will facilitate collaboration and streamline document sharing among team members. We will also be addressing the management of the schedule and tackling any delays in the delivery of specific deliverables to keep the project on track. Organizing the upcoming meetings will be crucial to maintain continuous coordination and communication within the team. Additionally, we will ensure effective management of financial resources to adhere to the budget constraints. Continuous support and supervision will be provided to our partners to maintain alignment and ensure the successful execution of the project.

Version history

Version	Description	Date completed
v1.0	First draft	04/06/2024
v2.0	Consortium revision	13/06/2024