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

Project Number: 101136840

D1.2 – Scientific Assessment

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Authors	Gabriella Pravettoni, Marianna Masiero, Giorgia Miale, Elisa Tomezzoli, Patrizia Dorangricchia, Ottavia Battaglia Monica Casiraghi, Enrico Cassano, Elvio De Fiori, Filippo Pesapane, Anna Rotili (IEO)
Contributors	Nathan Lea (i-HD), Maria Serra Blasco, Anna García Serra (ICO), Laura Sistach Bosch (EUT)
Reviewers	iBeChange consortium

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Disclaimer

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List of Abbreviations

Abbreviation	Explanation
AI	Artificial Intelligence
BARD	Bayesian Adaptively Randomised Design
CT	Clinical trial
DMP	Data Management Plan
DPIA	Data Protection Impact Assessment
DRB	Deliverable review board
DSA	Data Sharing Agreement
DTA	Data Transfer Agreement
EAB	External Advisory Board
EC	Executive Committee
EHDS	European Health Data Space
EM	Ethics Manager
GDPR	General Data Protection Regulation
IEAB	Independent Ethical Advisory Board
PM	Project Manager
PS	Pilot study
PROMs	Patient-reported outcome measures
QM	Quality Manager
TMG	Trial Management Group
TSC	Trial Supervision Committee
WP	Work Package

Executive Summary

This report presents the scientific and clinical research quality assessment for the project iBeChange. The primary goal of this assessment is to ensure that the research adheres to high standards of reproducibility, transparency, and ethical compliance. Key outcomes include the successful implementation of a comprehensive monitoring framework, early identification of potential risks, and the improvement of research protocols.

1. Introduction

The primary goal of this deliverable (**D1.2**) is to ensure that the research conducted within the **iBeChange** project adheres to the highest standards of reproducibility, transparency, and ethical compliance. The outcomes of this deliverable include the successful implementation of a comprehensive monitoring framework, early identification of potential risks, and improvements to research protocols. In fact, ensuring the quality of scientific and clinical research is crucial for generating reliable, reproducible, and impactful results.

The **iBeChange** project aimed to improve cancer prevention through the development of an integrated platform that promotes behavioural change. The studies that will be performed under the iBeChange project entail the utilization of diverse types of human data, potentially eliciting a multitude of significant ethical and scientific considerations necessitating meticulous oversight by highly specialized professionals. Indeed, the iBeChange project will involve a series of retrospective and prospective studies, in which data regarding socio-demographic variables, behavioural habits, psychosocial and environmental risk factors and other physical and clinical information will be collected and analysed. Overall, these variables will be collected using retrospective data available in each clinical centre (ICO: COLSCREEN study for colorectal cancer screening; IEO: COSMOS study for lung cancer screening) (WP3), and prospectively via patient-reported outcome measures (PROMs), patient-reported experience measures (PREMs), and via smart and engaging interfaces to enable automatic monitoring (WP5). Furthermore, during the iBeChange project implementation we will make use of data retrieved by publicly available survey and self-reported data. All data collected will be analysed using different approaches, such as Reinforcement Learning and Virtual User Modelling. Additionally, literature reviews will be conducted during the project implementation, requiring careful scientific oversight.

The monitoring and evaluation procedures detailed in this document aim to guarantee that the research conducted meets the highest standards of scientific rigour, integrity, and ethical compliance, in alignment with global best practices and regulatory requirements. Consistently, the **D1.2** provides an in-depth overview of the quality assurance measures implemented and demonstrates their effectiveness in supporting the project’s research goals.

1.1 Assessment Framework

The assessment framework developed for this project is grounded in both qualitative and quantitative measures to ensure a holistic evaluation of research quality. This framework was designed to be flexible, allowing adjustments based on the specific needs of both the scientific and clinical arms of the project. Evaluation criteria include the robustness of data collection protocols, adherence to trial designs, and the extent to which research outputs contribute to the broader scientific community. Key pillars of the framework include data accuracy, methodological rigour, ethical compliance, and reproducibility. Specifically, this includes:

- **Data Accuracy**: Ensuring the reliability and validity of data collected from clinical and behavioural studies.
- **Methodological Rigour**: Ensuring that all research follows robust scientific methods, particularly in trial designs and data collection protocols.
- **Ethical Compliance**: Adhering to global ethical guidelines such as those outlined by the *World Health Organization*, ensuring patient safety and data privacy.
- **Reproducibility**: Ensuring that all research outputs can be replicated, thereby contributing to the broader scientific community.

2. Assessment Bodies

To ensure thorough and ongoing evaluation, the iBeChange project has established several monitoring bodies and procedures to oversee the quality and progress of research activities, from a scientific, clinical and ethical point of view. These include:

2.1 Independent Ethical Advisory Board

In connection with the verification of the Grant Agreement and the document REF.ARES (2023)5782926 - 24/08/2023, the European Commission has requested the establishment of the Independent Ethical Advisory Board (IEAB). On January 15th, 2024, a call for ethics experts was published on the IEO website, where candidates’ professional backgrounds and experience in addressing ethical challenges within EU projects were assessed. The three highest-ranking candidates were selected as IEAB members, and the board was formally constituted.

The IEAB, comprising experts in cybersecurity, data protection, and ethical, human-centred artificial intelligence, was appointed to work closely with the consortium to: a) provide advice on ethical and legal challenges associated with the deployment of a behaviour change platform; b) ensure compliance with the regulatory framework; and c) consider emerging security challenges posed by novel technologies.

The introductory meeting of the IEAB took place on June 26th, 2024, and the specific schedule and activities for this board were established based on the project’s unique requirements. To ensure meaningful input and effective oversight in the project’s development, the IEAB works in close collaboration with the Ethical Partner of the iBeChange consortium (i-HD, WP7). Furthermore, several deliverables and reports are anticipated in the Grant Agreement, aligning with the project’s critical milestones and schedule.

Details on the appointment, composition, roles and expected outcomes of the IEAB can be found in D9.1.

2.2 Executive Committee

The Executive Committee (EC) is composed of Work Package (WP) leaders and co-leaders from IEO, UNIPA, POLIMI, ICO, EUT, SD, i-HD, and EAPM teams. This committee is responsible for overseeing the coordination, planning, monitoring, and reporting of the project’s progress. The EC ensures that all tasks, milestones, and deliverables are completed on time and to the required standards. The EC convenes bi-monthly to assess project progress and address potential risks.

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

2.3 Quality and Ethics Manager

The project’s **Quality Manager** (QM), Monica Casiraghi, and **Ethics Manager** (EM), Nathan Lea, play pivotal roles in maintaining the integrity of the research outcomes. Their responsibilities include setting quality standards, ensuring compliance with ethical guidelines, conducting regular audits, and providing training to researchers on quality assurance protocols. Particularly they oversee all quality control processes, being responsible for defining criteria for research methodologies, ensuring ethical considerations are integrated, monitoring adherence to standards and identifying areas needing improvement.

Details on the roles of the QM and EM can be found in D1.4, par. 2.1.3.

2.4 Clinical manager and Innovation manager

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 (Laura Sistach Bosch), will lead the Clinical and Technical teams respectively.

Those figures play pivotal roles in ensuring coordination and quality management, continuously monitoring the achievement of task objectives and overseeing the work of the clinical and technical teams effectively. This coordination and monitoring include **organizing and leading meetings every two weeks** for each Body. These meetings review Clinical/Technical progress, present new advances, identify challenges, and align strategies between partners.

2.5 Trial Supervision Committee

The **Trial Supervision Committee** (TSC) plays a crucial role in overseeing the progress and ensuring the scientific and ethical integrity of the clinical studies within the iBeChange project. The appointment of the TSC is described in Task T5.2 – Studies management and supervision (lead: ICO; timeline: M16-24, M28-48). The TSC will be composed of representatives from each participating healthcare centre, the sponsor, and an independent chairperson for overseeing the multicentre clinical trial.
The TSC will oversee the reporting of trial progress, including regular updates on recruitment, data collection, and adherence to ethical guidelines. The committee will ensure that all data collected during the studies are aligned with the project's objectives and that any deviations from the protocol are promptly addressed. The TSC’s core responsibilities include reviewing safety and efficacy data, assessing participant recruitment and retention, and making recommendations to the trial management group regarding the continuation or modification of the study protocols.

Additionally, the TSC will oversee the implementation of tools enabling healthcare providers to assess psychosocial and behavioural risk factors in participants enrolled in the screening program. Particularly, the Point of Care tool (PoC) will be designed under T2.8, leveraging data from PROMs, self-reported measures, and findings from WP2 and WP3 and will consist in an advanced interface that will monitor users to deliver information in a timely manner to the relevant professionals involved, for them to identify high- risk users and facilitate online interactions and communication. This tool will enable monitoring the progress of the pilot and clinical study through the data collected from participant groups.
This continuous oversight guarantees that the trials maintain their scientific and ethical integrity, contributing to the overall success of the iBeChange project.

2.5.1 Clinical studies in the iBeChange project: quality and ethical assessment

The iBeChange project incorporates a series of clinical studies designed to evaluate the effectiveness and scalability of its digital platform, which aims to foster behavioural change to reduce cancer risk. The studies include the Pilot Study (iBC/PS) and the Clinical Trial (iBC/CT), and two Wearable sub-studies (iBC/WS1 and iBC/WS2), respectively embedded in the pilot and clinical trial. Each study has been developed using a hybrid Type II design, which allows for the simultaneous assessment of both intervention effectiveness and implementation strategies. This approach ensures that the platform is tested across different settings and populations, increasing the generalisability of the results.

The iBeChange studies are guided by the **RE-AIM framework** (Reach, Effectiveness, Adoption, Implementation, and Maintenance), which comprehensively evaluates an intervention’s impact across all key dimensions. This framework is crucial for understanding how well the platform performs in various real-world contexts, helping to identify factors that enhance or inhibit its effectiveness.

For the iBC/PS and iBC/CT studies, a **Bayesian Adaptively Randomised Design** (BARD) will be adopted. Compared to traditional frequentist trials, BARD allows for greater flexibility and efficiency. Interim analyses can be conducted throughout the study without statistical penalties, enabling real-time refinements to the study protocol, such as adjusting treatment allocation or stopping ineffective interventions early. This adaptive design leads to faster trial completion, reduced costs, and the ability to implement effective interventions in clinical practice more rapidly.

In parallel, the iBC/WS1 and iBC/WS2 wearable sub-studies will test the feasibility and added value of using wearable devices alongside the behavioural and psychosocial data collected via smartphone sensors. These studies aim to assess whether wearables provide a more nuanced detection of risk factors, particularly through the monitoring of physiological and behavioural metrics like heart rate, temperature, and blood pressure. Wearables will be used to enhance data reliability.

To ensure the rigour and quality of the research, the iBeChange studies will follow stringent methodological protocols based on literature reviews. The use of a Bayesian approach further strengthens the scientific validity of the findings, as it allows for continuous data assessment and dynamic trial adjustments. The project will fully comply with GDPR regulations to protect participant privacy and data integrity, with all data securely stored and managed throughout the trials.
Ethical considerations are central to the iBeChange clinical studies. All trials will undergo review and approval by the **Institutional Ethical Boards** of the participating clinical centres. Informed consent will be obtained from all participants before any procedures are implemented. The trials will use a simple randomisation method to allocate participants either to the intervention group, which will receive the iBeChange digital Health intervention, or to the control group, which will continue with the standard cancer screening and prevention care of their reference hospital. Randomisation will be computer-generated and concealed to ensure that neither the participants nor the research staff can influence the group assignments.

2.6 External Advisory Board

The External Advisory Board (EAB) in the iBeChange project functions as a key consultative body, offering scientific oversight and expert recommendations to ensure that the project meets its ambitious objectives in cancer prevention and behaviour modification. The board is composed of representatives from various organisations highly relevant to cancer prevention and patient advocacy, such as **Europa Donna**, **Lung Cancer Europe**, the **Director Plan of Oncology**, **Digestive Cancer Europe** and **members from the Prevention Unit of Regione Lombardia in Italy**. This diverse composition ensures a comprehensive approach to addressing cancer risk factors by integrating perspectives from advocacy, policy, and clinical practice.

Through regular meetings (scheduled to take place every 6 months), the EAB provides a consultative function to the consortium, contributing to the independent assessments of the project's scientific approach and monitoring its progress, contributing critical insights to enhance the quality and impact of project activities. Their input is pivotal in refining the strategies and interventions developed within iBeChange, particularly into the project’s prevention framework. This oversight fosters a scientifically rigorous approach, encouraging the application of innovative, evidence-based methods and digital tools that are tailored to address lifestyle and psychosocial risks in cancer prevention. By ensuring alignment with the latest research and public health policies, and the effective patient’s needs, the EAB’s contributions significantly strengthen the project's capacity to deliver effective and sustainable solutions for reducing cancer risk through behavioural change.

3. Monitoring and exploitation procedures

Several procedures have been established to continuously monitor the progress of the project and ensure that all activities align with the project's quality standards.

3.1 Deliverables and Milestones

Deliverables and milestones are a critical component of the quality management framework (refer to D1.1 – Project management plan for a complete overview of deliverables and milestones). Each deliverable undergoes a rigorous review process (see paragraph 3.1.1). Key deliverables are scheduled according to the Gantt Chart, allowing the project to stay on track with its goals and objectives. Deliverable acceptance involves thorough quality checks and adherence to predefined criteria for content relevance, clarity, and accuracy.

3.1.1 Deliverables review process

To ensure a streamlined, timely, and high-quality submission process for deliverables within the iBeChange project, a **Deliverable Review Board** (DRB) will be established. The goal is to leverage the expertise of each partner and ensure that the deliverables are reviewed rigorously before submission. By creating a rotating review system based on each partner's competencies, we aim to improve the review efficiency while ensuring compliance with project timelines. The DRB will consist of two representatives from each partner organisation within the iBeChange project. Each team will nominate two members based on their expertise in the relevant work packages or content areas. The composition of the review board will rotate, with different members selected for each deliverable, depending on the content and nature of the document being reviewed.

The Deliverable Review Procedure will consist of the following steps:

- **Initial Submission to Coordinator**: The partner responsible for a specific deliverable will send the draft document to the project coordinator (IEO) 20 days prior to the deliverable submission deadline.
- **Review Partner Selection**: Upon receipt of the draft, the project manager, in collaboration with the coordinator, will identify and select two reviewers most qualified to evaluate the deliverable. The selection will be based on expertise related to the specific deliverable's content (e.g., technical partners for technical deliverables, clinical partners for clinical deliverables, etc).
- **First Review**: The selected reviewers will review the deliverable. This first review phase will ensure that the document aligns with the project's technical, scientific, and reporting standards. Feedback will be provided to the responsible partner and the coordinator within 10 days.

- **Consortium-Wide Review**: Once the first review is complete, and feedback is incorporated, the revised deliverable will be circulated to the entire consortium 5 days prior to the submission deadline for final approval. The consortium members will have the opportunity to provide feedback or raise any concerns. Lack of response within the designated review period will be considered as implicit approval.
- **Final Submission**: After addressing any additional comments from the consortium-wide review, the deliverable will be finalised and submitted to the EU funding and tenders portal in accordance with the project deadlines.

This initiative will also allow partners to focus on their core activities while ensuring that deliverables meet the highest quality standards expected by the consortium.

3.2 Regular Meetings and Coordination

The PM schedules bi-weekly clinical and technical meetings, bi-monthly consortium meetings, by-monthly EC meetings and one annual in-person meetings among partners. These meetings provide a platform for interdisciplinary collaboration, facilitating the exchange of insights between clinical and technical teams. Particularly, the frequency and depth of bi-weekly clinical and technical meetings ensure the maintenance of an environment where technical and clinical perspectives are seamlessly integrated. Those meetings are led respectively by the clinical and technical leaders, who are responsible for the preparation of those sections, designing detailed agendas and preparing necessary materials to address the evolving needs of the project. Regular meeting minutes are distributed and uploaded to the shared Google Drive folder to ensure transparency, alignment, and an ongoing record of discussions and decisions across all partners.

3.3 Dissemination and scientific publications

The iBeChange project places a strong emphasis on the dissemination of its scientific findings to both the academic community and the general public. A detailed plan for scientific publications will be developed alongside the progress of the project. Based on the project findings, the various teams will have the opportunity to propose publications to ensure that the project's outcomes are shared broadly, facilitating the advancement of cancer prevention research and encouraging the adoption of effective behavioural change interventions.

Throughout the project's lifecycle, research findings will be disseminated in open science, high-impact and peer-reviewed journals, focusing on a range of topics such as cancer prevention, behavioural change, and digital health. The publications will aim to cover various aspects of the iBeChange platform's development, its clinical trials, and the outcomes of the studies related to the psychosocial and lifestyle risk factors for cancer.

In addition to traditional journal publications, the project will contribute to open-source databases by sharing anonymised research data, allowing for greater transparency and further validation of the project's methodology by other researchers. This open-access approach ensures that the iBeChange findings are widely accessible and can be utilised by clinicians, healthcare managers, and policymakers to enhance cancer prevention strategies.

The scientific publication plan is aligned with the project’s exploitation and communication strategies, ensuring that the findings not only contribute to scientific literature but also have a tangible impact on clinical practice and public health policies. By collaborating with relevant stakeholders and experts, the project aims to increase the visibility of its results, which will be crucial in promoting the integration of digital health tools like iBeChange into everyday healthcare practices.

Communication and dissemination activities include the development of a large variety of materials to transmit the goal of the project to various target audiences, including the broad European population. For this reason, the status and progress of iBeChange will be disclosed through blogs, a dedicated website, educational materials, campaigns, newsletters, press releases workshops and project presentations.

Further details on the exploitation efforts can be found in Deliverables D8.7 and D8.9.

4. Risk management and ethical compliance

4.1 Risk Management

The iBeChange project has developed a robust risk management framework that identifies, assesses, and mitigates potential risks. This includes strategies for addressing delays in clinical trial approvals, administrative bottlenecks, and recruitment challenges. The TSC, together with the IEAB, plays a critical role in monitoring and mitigating risks associated with clinical studies.

Refer to D1.4 – Quality and risk assessment.

4.2 Ethical and Legal Compliance

Ensuring compliance with ethical and legal frameworks is a cornerstone of the iBeChange project, especially considering its focus on innovative cancer prevention interventions, which include the use of artificial intelligence (AI)-driven platforms and clinical trials involving human participants.

In addition to complying with clinical and data regulations, the project adheres to ethical standards outlined in the Helsinki Declaration. All clinical trials are registered in public platforms (e.g., ISRCTN or ClinicalTrials.gov), ensuring transparency and accountability. Regular reporting to the IEAB and the European Commission is an integral part of the project’s ethical compliance strategy.

The project also closely monitors developments in the AI Act and the European Health Data Space (EHDS) initiative to ensure that the AI components of the platform align with emerging European regulations. This includes addressing concerns about the potential misuse of personal data, ensuring transparency in how AI analyses patient data, and integrating human oversight to avoid errors in AI-driven emotional or behavioural assessments.

4.2.1 Use of artificial intelligence, ethics and data protection

One of the principal objectives of the ethical and legal oversight is ensuring compliance with legal and regulatory requirements, particularly those related to clinical trials and the use of artificial intelligence. This includes ensuring transparency in AI-driven emotional and behavioural assessments, and the integration of human oversight to ensure the accuracy and fairness of the algorithms used within the platform. Additionally, the IEAB collaborates closely with the clinical and technical teams to ensure that the project meets both ethical and legal obligations, especially regarding data handling and patient privacy.

The management of data is subject to a series of existing regulatory requirements that are enshrined in Regulations such as the General Data Protection Regulation (GDPR), Data Governance Act and potentially the Medical Device Regulation at EU and European Economic Area (EEA) level, as well as existing national laws. A dditional Regulations

are being drafted at the EU/EEA level, including the European Health Data Space, Data Act and AI Regulation. The project will therefore work under the existing regulations and maintain a watching brief on the development of further regulations that may impact how data is managed. Since the project will share quality-controlled data and associated metadata, it will do so under the FAIR principles of Findability, Accessibility, Interoperability, and Reusability and, where possible, supporting open science. Personal data will be protected in accordance with EU and local laws, with a Data Management Plan (DMP) developed within the first six months of the project (refer to D7.1, Data Management Plan) and updated throughout its duration to address any issues that may arise. In parallel, a Data Protection by Design and Default approach, as proposed by GDPR, will be used to ensure that these requirements are addressed at the outset of the project. This will involve a Data Protection Impact Assessment (DPIA) for the project, which will inform the development of the DMP, Data Sharing Agreements, Codes of Conduct and Standard Operating Procedures for the management of the data. The DPIA will be continually updated and will be used to inform the development of software and wider interventions.

Additionally, data protection evaluations include the need to ethically and legally assess the development of the retrospective studies; each clinical centre has entered into a data access contract with technical partners to regulate the relationship between “processors” and “data controllers”. A Data transfer agreement (DTA) has been signed between ICO and SporeData and the approval of the same document for IEO and SporeData is ongoing. These DTAs will allow the data transfer of the two retrospective studies (COLSCREEN and COSMOS, respectively) from the two clinical centres to the technological partner that will use them.

5. Conclusions

This deliverable outlines the comprehensive measures implemented to safeguard the scientific quality and ethical integrity of the iBeChange project. Central to this process is a robust project management plan and a structured quality and risk assessment framework, supporting early identification and mitigation of challenges. These documents (Deliverables D1.1 and D1.4) provide a clear guide for the collaboration among key oversight bodies, ensuring that the research adheres to the highest standards of rigour, transparency, and ethical responsibility. In particular, the project has established several critical bodies—including the IEAB, EAB, Executive Committee, Quality Manager, and Ethics Manager—each tasked with a specific oversight role, scheduled meetings, and a precise remit to monitor progress. The clinical and technical leaders further support these structures, contributing expertise in specialised areas to ensure alignment with project milestones and European regulatory standards. Throughout the project’s duration, the project manager will coordinate and guide the contributions of these oversight bodies, adapting to the evolving needs of the scientific activities.

The project’s monitoring and development framework is fundamental for the early detection of potential challenges, which subsequently foster a continuous refinement of the research approach. This is fundamental considering that the iBeChange project is grounded in the research efforts, including the conduction of extensive literature reviews, retrospective studies, and clinical studies. The studies within iBeChange are designed to be both flexible and scientifically robust, increasing the generalisability of the findings across different populations and settings. Ethical considerations remain paramount, especially concerning AI and data protection, ensuring full alignment with European regulations.

The purpose of this scientific assessment document is twofold: to provide structured guidance for the ongoing development of scientific activities and to clearly delineate responsibilities across all project stages. This document is living, updated continuously in response to project developments and emerging needs, thus supporting accountability and efficient resource allocation. Through its commitment to interdisciplinary collaboration and rigorous quality standards, iBeChange is well-positioned to deliver tangible benefits for the population by promoting healthier behaviours and reducing cancer risks. To this end, the consortium is committed not only to producing high-quality results but also to disseminating them effectively, ensuring that project outcomes contribute to more effective public health policies. This dedication to both quality and outreach enhances the project’s impact on individual well-being and supports broader societal health initiatives, laying the foundation for lasting public health advancements.

Version history

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v1.0	First version	12\11\2024
v2.0	iBeChange Consortium revision	29\11\2024
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