

Terms of Reference

External Independent Ethics Advisory Service

Funding Programme: Horizon Europe

Project title: IBeCHANGE - Addressing psychosocial and lifestyle risk factors to promote primary cancer prevention: an integrated platform to promote behavioural change

Project number: 101136840

Start date: 01/12/2023

End date: 30/11/2028

Coordinator: IEO Istituto Europeo di Oncologia, Italy

Beneficiaries:

EUT Fundació Eurecat, Spain

ICO Institut Català d'Oncologia, Spain

SD SporeData, Estonia

UNIPA Università degli Studi di Palermo, Italy

POLIMI Politecnico di Milano, Italy

i-HD The European Institute for Innovation through Health Data, Belgium

TU/e Technical University of Eindhoven, Netherlands

EAPM European Alliance for Personalised Medicine, Slovenia

SIMAVI Software Imagination & Vision, Romania

UMFCD University of Medicine and Pharmacy Carol, Davila Romania

Associated Partners:

ECANCER The eCancer Global Foundation, UK

A. Background

The service contract will be carried out under the iBeCHANGE project. The general aims of the action are defined below.

Project Summary

Europe's Beating Cancer Plan set has ambitious goals addressing key behavioural risk factors for cancer development, such as tobacco (target reduction of 30% by 2025), alcohol consumption (target reduction of 10% by 2025), unhealthy diets and physical inactivity (see also the HealthyLifestyle4All campaign). As "about 40% of cancer cases in the EU are preventable", health promotion and preventive measures for cancer can benefit from the implementation of behavioural change (BC) and emotional management (EM) in the general population. However, previous research and practice have generally failed to achieve sustainable BC due to two factors: 1) not taking into account recent BC concepts showing the need of personalizing interventions and techniques; 2) not considering psychosocial features and emotions (e.g. anxiety and depression),

which can interfere with effective BC and increase the risk of developing cancer. The main objective of this project is to design, develop, and test the iBeChange platform, a user-focused management system that empowers people to achieve healthy and sustainable behaviors and emotions. The iBeChange innovative system will be developed by experts from clinical and health psychology, oncology, epidemiology, ICT, data science, and the health policy. The iBeChange project will go beyond the state of the art of sustainable BC and EM by combining practice- and evidence-based knowledge coming from clinical psychology and BC theories with the potentialities of adaptive digital technologies and artificial intelligence. Thus, the iBeChange system will be able to dynamically observe, learn about user behaviours, and then deliver tailored and effective health interventions in a dynamic learning process. The final goal of the iBeChange project is to contribute to the goals of Europe's Beating Cancer Plan and European Code Against Cancer by improving long-term primary cancer prevention through informing, supporting, and empowering EU citizens.

B. Ethics management

The project entails the following ethics activities:

- In WP7 the consortium will ensure efficient management of ethics issues and monitor the correct implementation of the contractual provisions.
- In WP9 an External Independent Ethics Advisory Board (IEAB) shall be appointed to advise the consortium in relation to the activities described in point C below. IEO, as project coordinator, is in charge of the selection procedure of the IEAB.

C. Scope of the Work

The IBeCHANGE project will collect sensitive data of vulnerable individuals at scale (patients with cancer or at risk of cancer). This process could lead to risk of stigmatisation, discrimination and misuse and data monetisation. For these reasons, the consortium must appoint an External Independent Ethics Advisory Board (IEAB) to support the project team with skills (that are not their core competences) on cybersecurity, data protection, ethical and human-centred Artificial Intelligence. The IEAB will consist of three experts, working together as a panel in performing the tasks below in point D below. The appointed experts must be independent and external to the project and to the department(s) or group(s) conducting the research.

D. Activities to be carried out

The IEAB shall work in close collaboration with the consortium to perform the following activities:

- Advise on the primary ethical and potentially legal challenges and uncertainties that may arise when exploring the psychological and behavioural factors for designing the behaviour change platform.
- Help the project navigate the additional ethical challenges around bias, equity and self-determination that arise when applying novel technologies, including Artificial Intelligence using sensitive and personal health related and cancer management data.
- Provide an additional layer of support when addressing the above in the context of a deeply personal and distressing topic and working with potentially vulnerable participants.
- Ensure the project remains compliant in a complex and shifting regulatory framework, accounting for forthcoming regulations in the form of the AI Act and EHDS.

- Help considering emerging security challenges and appropriate configurations with novel technologies and reaching a level of assurance that is required for participants and the wider European citizenry.

E. Expected Deliverables/Outputs.

- Deliverable D9.2 - IEAB first report, due by 31/03/2025 and any updates thereof.
- Deliverable D9.3 - IEAB second report, due by 31/07/2026 and any updates thereof.
- Regular updates on the activities carried out by the IEAB according to the project reporting timeframe, as set out in the Grant Agreement:

Reporting Period No.	From Month	To Month	Duration	Start Date	End Date
1	1	18	18	01/12/2023	31/05/2025
2	19	36	18	01/06/2025	30/11/2026
3	37	48	12	01/12/2026	30/11/2027
4	49	60	12	01/12/2027	30/11/2028

- Any other documents as requested by the Granting Authority.

F. Duration of the Work

- The activities of the IEAB shall be carried out starting from the signature of the appointment letter until the end of reporting activity to the Granting Authority, which shall be concluded within 60 days after the end of the Project, namely by 30/01/2029. However, the IEAB shall carry out its activity also beyond the above-mentioned timeframe, in case the consortium asks for a formal extension of the project duration and/or in case the final reporting activities may require more than 60 days.
- In addition, also beyond the terms under point a), the IEAB shall promptly provide any document and information in any case of the audit, checks and reviews carried out by the bodies mentioned in Article 25 Grant Agreement.

G. Required expertise and qualifications

The Applicant is requested to have:

- Knowledge and a good understanding of the societal and ethical implications of AI and its use in health management and delivery for both point of care and citizen self-management and / or
- Awareness of forthcoming regulations across Europe around the governance of AI and health data, with a particular ability to understand existing data protection regulations and direct participant intervention and / or
- Understanding and knowledge of the Cybersecurity risks that exist in the existing and emerging paradigms of sensitive data handling using AI and machine learning practices.

In addition, the Applicant shall comply with the requirements set out in the document “*Ethics Advisors and Ethics Advisory Boards Roles and Function in EU-funded Projects*”¹ issued by the European Commission, especially under paragraph 2.2 (appropriate competencies) and 2.3 (independence and impartiality).

¹ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/roles-and-functions-of-ethics-advisory-ethics-advisory-boards-in-ec-funded-projects_he_en.pdf

H. Fee and Schedule of Payments

- Each Advisor will be remunerated with a maximum lump sum fee of EUR 15 000.00 inclusive of all expenses to be incurred for carrying out the activities, among which travel costs (although it is granted to the experts to possibility to work remotely). The amount includes VAT and any kind of taxes or social charges. Such an amount constitutes a basic tender price that can be reduced in the application form (see point I).
- The payments will be made in instalments based on the positive evaluation of the deliverables/outputs described in point E.
- The payment schedule will be agreed with the selected service provider.

I. Documents to be enclosed to the Application

Each applicant shall provide IEO with the following documents:

1. Application form, duly dated and signed, including the economic offer (specify any reduction to the proposed lump sum fee)
2. Recent CV, dated and signed, focusing on the experiences and achievements which are mostly relevant for the assignments.

J. How to submit the application and evaluation process

Applicants can submit the documentation by 9 February 2024 to unita.psiconcologia@ieo.it specifying in the subject line “iBeCHANGE - Ethics Advisor”.

The application documents, as well as all correspondence, shall be in English.

K. Selection procedure and criteria

The selection will be based on the criteria below. Applicants may be invited to an on-line interview. Lack of response by the Applicant will be considered a refusal to be appointed as Ethics Advisor.

Criteria	Weight (%)	Max. Point
Years of experience in dealing with ethics issues in EU funded projects, especially H2020 and Horizon	20	20
Demonstrated knowledge and skills in the fields of data protection, ethics, health data management, behaviour change, artificial intelligence and/or societal impacts.	50	50
Price reduction of the maximum lump sum of EUR 15.000,00	30	30
Total	100	100