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

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D8.1 – White paper on Governance Model for Big Data and Behavioral Change in EU health policy making

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List of Abbreviations

Abbreviation	Explanation
AI	Artificial Intelligence
BCI	Behaviour Change Interventions
EU	European Union
EHDS	European Health Data Space
GDPR	General Data Protection Regulation
HER	Electronic Health Records
HCP	Healthcare Professionals
NGS	Next-Generation Sequencing
RWE	Real -World Evidence
WHO	World Health Organization
OECD	Organisation for Economic Co-operation and Development

Executive Summary

The iBeChange project, funded under the Horizon Europe research and innovation program, seeks to revolutionise cancer prevention by addressing psychosocial and lifestyle risk factors. Through innovative behaviour change interventions (BCIs) supported by advanced digital tools, artificial intelligence (AI), and evidence-based psychology, the project empowers individuals and healthcare systems to foster sustainable habits and reduce cancer incidence.

This deliverable, **D8.1 – White Paper on Governance Model for Big Data and BC in EU Health Policy Making**, outlines a strategic framework for integrating BCIs into European Union (EU) health policies. It emphasises the critical role of health literacy in building public trust, promoting stakeholder collaboration, and ensuring the effective implementation of prevention strategies. By leveraging the European Health Data Space (EHDS), the project addresses systemic challenges, including fragmented data sharing, legal and ethical disparities, and limited stakeholder engagement.

Key recommendations include:

- Strengthening health literacy to empower citizens and healthcare professionals.
- Fostering collaboration among policymakers, practitioners, and the public.
- Enhancing data interoperability across EU member states to support BCIs.
- Leveraging digital innovations for personalised, scalable, and impactful interventions.

To advance these recommendations, the white paper will be disseminated through peer-reviewed publications, policy forums, and digital channels. Engagement with stakeholders will be prioritised through conferences and advocacy partnerships. Pilot initiatives and collaborative projects will operationalise the proposed governance model, refining its application to real-world scenarios.

iBeChange demonstrates how integrating BCIs, health literacy, and big data into a unified policy framework can redefine cancer prevention and public health outcomes. This approach aligns with EU ambitions for equitable and sustainable healthcare, creating a roadmap for transformative change.

1. Introduction

Nearly half of all cancers may indeed be preventable, as health authorities routinely – and correctly - proclaim, but prevention depends largely on the behaviour of citizens[1]. For prevention to really mean what it says, public healthcare systems must reach citizens as well as patients – and before citizens become patients[2]. But despite the advent of a wealth of new tools that can revolutionise understanding of cancer, this huge opportunity has proved difficult to turn into reality[3].

1.1 Until now

iBeChange is developing a novel combination of tools and technologies that actively promote the prevention of cancer. The project addresses psychosocial and lifestyle risk factors to provide more effective encouragement of behaviours that reduce avoidable risks. Until now, attempts to win great attention to the risks of cancer have neglected the importance of personalised interventions and ignored the disruptive impact of emotions such as anxiety and depression – factors that themselves increase the risk of developing cancer. iBeChange is changing all that by creating a user-focused management system to empower people to achieve healthy and sustainable behaviours and emotions. It aims to trigger sustainable behaviour change towards habits that have been shown to reduce the risk of developing cancer[4].

The approach is intensely innovative. iBeChange is designing, developing and testing an integrated platform that influences behaviour change in individuals to achieve healthy and sustainable behaviours and emotions. It draws on evidence-based knowledge from clinical psychology and behaviour change theories and combines this with the capabilities of adaptive digital technologies and AI. It also emphasises developing trust as a necessary component for a policy relating so directly to individual citizens and the population at large[5].

2. The possibilities and the problem

The possibilities of tackling cancer continue to grow rapidly. The ever-deepening understanding of the underlying mechanisms is combined with new tools for diagnosis and treatment while understanding also widens the powerful societal and personal factors influencing cancer incidence and treatment[6].

Effective cancer diagnosis, treatment and control depend on interactions among numerous distinct factors, from technology to data to skills to sociology. Unprecedented options for improvements in health and advances in science and healthcare delivery are now possible through deploying the increasing wealth of data – as long as the data can be shared. A further central influence is the extent to which health systems take account of the distinct perspectives of the many different groups of interdependent stakeholders concerned with cancer, including patients, practitioners and planners. The growing consensus is that cancer is best tackled not as a series of isolated actions but at a strategic level that actively involves all stakeholders— health care professionals (HCP), of course, and patients (as the emerging scope of personalised medicine permits and demands), but equally researchers, drug developers, civil society organisations and regulatory authorities, as well as policy circles and political decision makers[7].

Findings from earlier studies by the World Health Organization, European Public Health Alliance, Organization for Economic Co-operation and Development, and other relevant data indexes underscore the importance of a multifaceted approach to integrating behavioural and cultural insights into healthcare systems. Building understanding and support for behavioural change interventions (BCIs), fostering stakeholder networks, investing in research, conducting impact evaluations, allocating resources, and developing dedicated strategies are all critical components of successful implementation. Specifically for cancer care, there is a pressing need for more focused research and strategy development to better address the unique needs of cancer patients. Studies show an inverse correlation between BCIs and cancer incidence, highlighting the potential for behavioural sciences to significantly reduce cancer rates and enhance overall public health. By prioritising these efforts, healthcare systems can leverage the power of BCIs to promote healthier behaviors, improve preventive measures, and ultimately reduce the burden of cancer and other diseases[8].

2.1 Data deficiencies, over-simplification, and collaboration gaps

Key elements that have also been absent in promoting effective cancer prevention include uniform, timely and user-friendly data sharing, which has been sub-optimal in Europe. At the same time, fragmented systems of health informatics prevent comprehensive analysis of the real-world impact of new treatments or precise estimates of the impact of new cancer technologies on health systems. These handicaps are compounded by the many distinct approaches taken in regional prioritizations in cancer treatment[9].

Crucially, there has also been insufficient collaboration. Even where Europe has paid lip service to the concept of collaboration and has made halting steps towards it in some areas, its health systems and healthcare players are not accustomed to collaboration in practice. Instead, they have tended to persist with comfortably familiar and firmly-rooted habits and long-established practices in everything from budgeting to local guidelines. This has bred an innate resistance to the acceptance – and much more to the take-up and implementation – of novel approaches that could bring benefits[10].

One of the significant obstacles lies in the fragmented landscape of data collection and sharing across Europe. Despite the EU's efforts to create frameworks like the General Data Protection Regulation (GDPR) to standardise data practices, considerable discrepancies remain in how data is collected, categorised, and utilised in different member states. Variations in national policies and legal requirements often limit the cross-border exchange of healthcare data, preventing a unified approach to addressing cancer prevention and care. For example, some countries prioritise demographic data, while others focus on epidemiological or clinical data, resulting in gaps that hinder the ability to conduct comprehensive analyses or compare outcomes across regions[11].

The heterogeneity in data collection methodologies further complicates efforts to harmonise datasets. National healthcare systems often use diverse protocols for gathering patient data influenced by local priorities, available resources, and technological infrastructure. These inconsistencies create challenges in aggregating data at the EU level for large-scale studies or initiatives such as the European Health Data Space (EHDS). For instance, while some countries rely on electronic health records (EHRs) with robust interoperability standards, others continue to depend on paper-based or legacy systems that are incompatible with modern data-sharing platforms[12].

Additionally, the diversity in target populations and sampling methods further exacerbates the problem. Health systems in Northern and Western Europe may focus on different demographic groups compared to those in Southern or Eastern Europe, leading to skewed datasets that fail to reflect the true diversity of Europe's population. This imbalance makes it difficult to identify trends or develop interventions that are equitable and effective across the EU[13].

Efforts to streamline data sharing are also hindered by limited trust among stakeholders, including healthcare providers, policymakers, and patients. Concerns about data privacy and the potential misuse of sensitive health information remain significant barriers to adopting unified systems. Moreover, the lack of robust governance structures to oversee cross-border data initiatives has left many stakeholders uncertain about their roles and responsibilities in collaborative efforts[14].

These challenges underscore the need for a more integrated approach to health informatics in Europe. Addressing these deficiencies requires not only harmonised policies but also substantial investments in interoperable technologies, standardised data collection protocols, and education campaigns to build trust among stakeholders. Initiatives such as the EHDS and the Cancer Mission under Horizon Europe offer promising frameworks, but their success will depend on sustained political will and cross-sector collaboration at all levels of the EU[15].

3. The solutions

To overcome these challenges and foster a holistic and equitable provision of cancer care in Europe, iBeChange brings a wider vision and a new precision. It identifies disparities in age-specific approaches to cancer prevention, emphasising the necessity for tailored strategies to address unique age group perspectives. It considers regional variations when shaping future cancer care strategies. It also promotes collaborative data sharing supported by technological innovation. This personalized and adaptive platform will leverage AI techniques and tailor interventions for each user based on assessing individuals’ risk factors, motivation, and readiness for change. It will provide customised messages and recommendations that align with users' levels of understanding, complexity, and receptivity, including gamification elements, focusing on creating a user-centric, adaptive, and effective platform[16].

In particular, iBeChange takes advantage of the growing engagement of and with patients and citizens, which is shifting much of the traditional thinking about tackling cancer. It builds upon previous research that has emphasised the importance of robust data infrastructure, age-specific approaches in cancer prevention, variations in perceptions and priorities of cancer prevention and treatment, and the need for improved data sharing and interpretation practices in genomics. It factors into its approach the differences in perception of cancer care among different stakeholders: healthcare professionals, researchers, policymakers or patients. Behaviour change models include a wide collection of key components for explaining, predicting, and promoting sustainable healthy behaviours. Health behaviour interventions using digital technologies have the advantages of being cost-effective and having greater reach than traditional health services[17].

Areas with well-established BCI systems tend to have fewer cancer cases per 100,000 individuals, suggesting strongly that effective BCI may contribute to reducing the prevalence of cancer by promoting healthier behaviours and improving preventive measures. Behavioural sciences can play a critical role in reducing cancer rates and enhancing overall public health. Behavioural change interventions such as smoking cessation programs, dietary modifications, and increased physical activity have well-documented benefits in reducing cancer risk. By effectively implementing these interventions, healthcare systems can significantly lower cancer rates and improve overall public health[18].

iBeChange also exercises a new degree of refinement in its appreciation of the distinct priorities, concerns and attitudes among different patients. Demand for information related to their disease and treatment is higher among younger patients, female patients, patients recently diagnosed and those in poor health or exhibiting symptoms of anxiety or depression. Demand is lower in patients who show higher satisfaction with their physician and trust for nurses or receive more care. It matches the 13 recommendations of the Board for the Mission on Cancer and explores, as never before, how understanding the multiple correlations and factors in cancer can guide the development of targeted interventions, tailored educational campaigns and improved utilisation of genomic data for personalised medicine and cancer care.

Based on identified preventable cancer risk factors, iBeChange will combine machine learning models with health psychology theories and clinical guidelines to identify effective behaviour change therapies and psychological interventions[19].

The iBeChange platform will allow the unobtrusive monitoring of behavioural and psychological risk factors for developing cancer and support users with personalised effective behaviour change therapies and psychological support interventions. It will develop a reinforcement learning-based recommender system that suggests personalized preventive measures based on an individual's health status and risk factors. It will collect patient-reported outcome measures, patient-reported experience measures, and other self-reported information regarding behavioural habits and psychosocial and environmental risk factors via smart and engaging interfaces to enable long-term monitoring. It will also develop an interface for medical personnel to assess the psychosocial and behavioural risk factors of individuals in screening programs, monitor their progress in behaviour change, and receive personalised alerts for those with high psychosocial and behavioural risk. Moreover, it will define recommendations and guidelines for policymakers to support systemic transformations towards healthy environments that promote primary cancer prevention[20].

4. Necessary Conditions

Effective use of innovative approaches to BCI depends on putting certain conditions in place. Robust support and understanding of BCIs are crucial for their successful implementation and adequate resource allocation. These initiatives ensure that BCIs are effectively integrated into health strategies, thereby enhancing their impact on public health. Ensuring that BCIs are well-resourced and strategically integrated can significantly enhance their impact on public health outcomes. A dedicated strategy will help, but alone is not sufficient; comprehensive support, resources, and integration are also essential for the success of BCIs. Research plays a critical role in advancing BCI efforts, ensuring that interventions are evidence-based and effectively address public health challenges. There is a need for continuous evaluation and refinement of BCIs to ensure their effectiveness. And they must be effectively integrated into broader health strategies[21].

This integration can be achieved by aligning BCIs with existing public health frameworks, ensuring they complement and enhance current policies rather than function in isolation. For instance, BCIs can be embedded into national cancer plans, with clear objectives and measurable outcomes that are regularly monitored and reported. Coordination between different levels of healthcare delivery—local, regional, and national—should be fostered to ensure consistent implementation and avoid duplication of efforts[22].

Collaboration among key stakeholders is equally important. Policymakers, healthcare providers, researchers, and community organisations must work together to design interventions that are not only evidence-based but also culturally sensitive and tailored to specific populations. This can be facilitated by creating multi-stakeholder advisory groups to guide the development and rollout of BCIs, ensuring diverse perspectives are represented, and the interventions are accessible to all[23].

Additionally, leveraging digital health tools and technologies can enhance integration by providing platforms for data sharing, patient engagement, and monitoring of BCI outcomes. For example, mobile health applications and wearable devices can be used to track behaviour changes in real time, while AI-driven analytics can help identify patterns and refine interventions based on individual needs. These technologies can also bridge gaps between primary care providers and patients, promoting continuous engagement and adherence to BCI goals[24].

Lastly, sustained funding and political commitment are necessary to support long-term integration. Governments and public health authorities must allocate dedicated budgets to BCIs and incentivise their adoption within healthcare systems. This includes investing in capacity-building initiatives to train healthcare professionals in the effective use of BCIs and ensuring that their benefits are communicated clearly to the public to build trust and acceptance[25].

By embedding BCIs into the fabric of public health strategies, supported by collaboration, technology, and adequate resources, their potential to improve health outcomes and reduce disease burden can be fully realised.

5. Promoting real sharing

iBeChange is predicated on sharing essential information for cancer control and ensuring the advancement of precision oncology that can play a central role in it. This means making use of data from population-based cancer registries - key sources of information on cancer incidence and survival – or responses to targeted drugs of patients with rare mutations or complex mutational patterns. It means a digital health agenda that is genuinely able to deploy data to underpin cancer research and its real-world translation for the benefit of human health and well-being. This, in turn, cannot emerge without the relevant bioinformatic, statistical and advanced data analytics skills and frameworks[26].

Accordingly, the development of a knowledge-based database is essential, where real-world clinical and molecular data are collected and periodically reviewed by expert pathologists and that supports healthcare personnel in the clinical administration of cancer patients. Success depends on overcoming the challenges of uneven and inconsistent performance in access across member states and the diversity of permission procedures and rights. It depends on the EU connecting national data-sharing networks so that data remains stored locally but is accessible across Europe, addressing concerns related to the movement of data[27].

Studies provide evidence that a stronger data infrastructure is associated with a heightened emphasis on research, showing a direct relationship with a focus on cancer prevention and data sharing and an emphasis on understanding treatment sensitivity and resistance. Overall, the data underscores the significant role of data infrastructure in shaping and driving the cancer research agenda, aiding tailored strategies for more effective cancer care and research[28].

6. Collaboration

A seamless and equitable provision of cancer care across Europe will depend on a combination of conducive factors through collaboration across a range of stakeholders and within individual stakeholder groups, particularly on data sharing. It will need support for translational research, greater clarity over acceptability (and reimbursement) of NGS and liquid biopsy testing, continued investment in data infrastructure, closer standardisation of data technology practices, greater regulatory readiness to accept RWE, and skill development among practitioners and regulators. There will have to be action to sustain innovation in research institutes and big and small industries, as well as resolution of legal and ethical questions over safeguarding patients and their rights. It will also need recognition of the variation among patients/citizens in different countries and regions and different age groups in their attitudes to cancer prevention and treatment. However, these challenges are not insuperable if collaborative data sharing is supported by technological innovation[29].

Personalised medicine requires engaged, informed and empowered patients who contribute not only to their health but also to knowledge creation and, potentially, its governance. Engagement is defined as the "process by which people are enabled to become actively and genuinely involved in defining the issues of concern to them, in making decisions about factors that affect their lives, in formulating and implementing policies, in planning, developing, and delivering services, and in taking action to active change" (WHO, 1992). This can be only based on adequate understanding. Earning and retaining the trust of a broad range of stakeholders will be essential for effective data sharing in health. This can be achieved but will require robust frameworks and broad participation of different stakeholders from distinct national contexts and with diverse cultural backgrounds in the development of these policies. It will require attention to patient organisations and citizens[30].

In all of this, health literacy is essential. It is vital to ensure that trust is established through communication and information to help alleviate concerns and build trust in data sharing. Health literacy has a potential role in improving community empowerment – although that will require capacity building among citizens and attention to the quality of information provided. The destination is to ensure that all citizens and patients have the appropriate best quality of care. In building towards that tomorrow, it will be vital to make sure that all stakeholders, top-down and bottom-up, know what is recommended and why. The requirements will range from investment in human and technical infrastructure capacity to collaboration among all stakeholders to creating an adequate framework[31].

The recently agreed regulation creating a European Health Data Space (EHDS) suggested an increasing – if still incomplete - recognition of the need for collaboration, although many implementation questions remain to be answered, including imprecision and ambiguity. The challenge of EHDS is not untypical of the EU's performance in health legislation, which has repeatedly generated over-ambitious frameworks that proved inadequate or ill-considered once put into law - on medical devices and in vitro diagnostics, on clinical trials, on health technology assessment, and on data protection[32].

Against this background, it is possible to conceive frameworks that can bring new precision to care, with benefits for patients and society as a whole. Fostering the quality of individuals' lives through improving physical health and psychological well-being will also reduce the societal cost of poor health and make it possible to formulate health policies that integrate digital health interventions into the delivery and reimbursement of healthcare services and the education of providers, citizens, and payers. A successful framework must, however, meet certain conditions for realising its potential. For Europe to fulfil the conditions for success, a new spirit of cooperation will have to overcome the handicaps of the continent’s fragmented technical and legal landscape. While health policy is encouraging and promoting (and indeed very largely depending on) science to solve challenges in cancer, it also has to acknowledge the importance of bringing society along with developments, to foster understanding and to counter scepticism, suspicion, doubt and even hostility. Public understanding is vital in itself to gain trust in this data acquisition – but it is also an indispensable condition for obtaining the policy support that novel cancer prevention methods are dependent on[33].

7. Recommendations

To ensure the success and sustainability of behavior change interventions (BCIs) in cancer prevention and care, it is essential to address the challenges identified throughout this report with clear, actionable strategies. The recommendations below outline the critical steps necessary to foster collaboration, build infrastructure, and enhance the effectiveness of BCIs in promoting healthier behaviours and reducing cancer incidence. These measures aim to align stakeholders, strengthen support systems, and leverage technological innovations to drive meaningful and lasting change in public health outcomes.

- Strengthening understanding and support for BCIs through education and training
- Enhancing stakeholder engagement through networks and community involvement
- Investing in research and impact through funding and frameworks for evaluation
- Allocating adequate resources, including for infrastructure development
- Integrating BCIs into health plans, strategically and with policy support
- Delivering dedicated BCI strategies through planning, integration and monitoring
- Focusing on cancer-specific interventions, with targeted BCIs and collaborative efforts

8. Next steps

To ensure the proposed recommendations translate into actionable outcomes, the next steps will focus on effective dissemination and engagement strategies. Publishing this white paper through recognised platforms such as peer-reviewed journals, professional health organisations, and policy forums will maximise its visibility and credibility. Additionally, presenting its findings at relevant conferences and workshops can foster dialogue among stakeholders. To enhance outreach, leveraging digital channels, including social media campaigns, webinars, and partnerships with patient advocacy groups, will help amplify the key messages and engage a broader audience. Establishing follow-up initiatives, such as pilot projects or collaborative task forces, can also drive the practical implementation of these recommendations and ensure their impact on cancer prevention and care.

9. Conclusions

The iBeChange project aligns closely with its grant agreement objectives, emphasising the importance of tailored behaviour change interventions (BCIs) to address the unique challenges of cancer prevention and care. These interventions include educational programs on cancer risk factors, initiatives for screening and early detection, and support for sustainable lifestyle changes that reduce cancer risk.

While the European Union has shown some ambition in prevention, clearer strategic vision and firmer implementation plans are needed. iBeChange is well-positioned to advance this agenda by leveraging innovative digital tools, personalised strategies, and collaborative frameworks to ensure prevention becomes central to healthcare strategies.

The insights from organisational change research, such as the study by Nilsen et al. (2020), underscore that successful change depends on three interdependent factors: the opportunity for stakeholders to influence change, sufficient preparation for its implementation, and the recognition of its value[34]. These elements resonate strongly with the iBeChange approach. By involving healthcare professionals, policymakers, and patients early in the process, the project fosters a shared sense of ownership and legitimacy for its initiatives. Clear communication and preparation will further enhance the likelihood of successful adoption while emphasising the patient-centred benefits of the project, ensuring its alignment with the values of healthcare professionals and citizens alike.

Moreover, a health-in-all-policies approach, as emphasised in the grant agreement, is essential for addressing the systemic nature of health determinants. This approach must tackle challenges such as achieving data interoperability across member states and creating a unified European Health Data Space (EHDS). iBeChange actively contributes to this goal by demonstrating how advanced data-sharing practices and behavioural insights can support effective cancer prevention and public health outcomes.

The findings of iBeChange provide a foundation for drafting a new governance policy model that integrates adaptive digital tools, personalised BCIs, and strengthened stakeholder collaboration. By focusing on creating a supportive institutional climate, this project lays the groundwork for empowering healthcare organisations and professionals to meet evolving community expectations and align with the EU’s broader vision for sustainable healthcare.

Incorporating these insights ensures that iBeChange not only addresses the challenges of today but also paves the way for a robust framework that empowers stakeholders and fosters sustainable change. The time to act is now. Delaying these critical steps will leave many preventable cancers unaddressed, unnecessarily transforming citizens into patients. By prioritising these elements, iBeChange exemplifies a thoughtful and strategic approach to reducing the burden of cancer and enhancing public health outcomes.

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Version history

Version	Description	Date completed
v1.0	First version	24\11\2024
v2.0	Final version (consortium revision)	06\12\2024