Stakeholder engagement and societal impact of AI-enabled CRC screening tools within the ONCOSCREEN project

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Abstract
The adoption of AI-enabled healthcare technologies depends not only on technical performance, but also on stakeholder engagement, user acceptance, communication strategies, and measurable societal impact. The Horizon Europe ONCOSCREEN project addresses these challenges through an integrated ecosystem for colorectal cancer (CRC) screening and prevention, combining AI-assisted risk stratification, mobile health applications, wearable technologies, clinical decision-support systems, and evidence-based analytics for policy makers. Within this framework, particular emphasis is placed on the engagement of diverse stakeholder groups, including citizens, patients, clinicians, healthcare authorities, researchers, and policy makers. The project incorporates targeted dissemination campaigns, citizen-awareness activities, training sessions, workshops, and participatory co-design approaches in order to increase trust, accessibility, and acceptance of digital health solutions. The project also supports the deployment and operational integration of digital tools within clinical environments, including wearable-supported behavioural analytics, mobile application services for self-assessment and monitoring, and support activities related to multicentric clinical trials. These activities contribute to the broader objective of enabling personalized prevention pathways and improving citizen participation in CRC screening programmes. The paper analyses how stakeholder-oriented communication and engagement strategies can facilitate the adoption of trustworthy AI systems in healthcare and strengthen the societal impact of smart medical technologies. Particular attention is given to the role of collaborative ecosystems, real-world user feedback, and awareness campaigns in supporting resilient, citizen-centric healthcare services within future smart cities. The presented approach demonstrates that sustainable innovation in digital healthcare requires the integration of technological excellence with continuous stakeholder involvement, transparent communication, and evidence-based public health strategies.

Keywords: Digital Health, Smart Healthcare, Patient Empowerment, Trustworthy AI

1. Introduction
The development of smart cities is increasingly connected to the capacity of public institutions, healthcare systems, research organisations and technology providers to use digital tools for improving quality of life, resilience and access to essential services. Recent research in the Smart Cities and Regional Development field emphasises that smart-city initiatives should not be understood only as technology-driven interventions, but as multi-stakeholder ecosystems in which social impact, citizen orientation, trust and inclusion are central conditions for sustainable adoption [1]. In healthcare, this perspective is particularly relevant because digital transformation affects not only institutional efficiency, but also prevention, early diagnosis, patient empowerment and the relationship between citizens and public health services. Studies on ICT-enabled hospital and smart-city infrastructures

show that digital technologies can support better coordination between actors, improve operational efficiency and strengthen the resilience of healthcare systems when they are implemented through appropriate policies and stakeholder engagement [2].

Colorectal cancer (CRC) screening represents a highly relevant case for analysing the societal value of AI-enabled health technologies in smart and resilient urban ecosystems. CRC remains one of the most significant public health challenges worldwide, with more than 1.9 million new cases and approximately 904,000 deaths estimated in 2022 [4]. At the same time, CRC is one of the cancers for which organized screening can have a strong preventive and early-detection role, as screening can identify cancer at earlier stages and can also detect precancerous lesions before disease progression [5]. However, the effectiveness of CRC screening programmes depends not only on the existence of medical tests, but also on participation, accessibility, user acceptance, follow-up capacity, and the ability of healthcare systems to reach different population groups.

Within this context, AI-enabled tools, mobile health applications, risk stratification engines, clinical decision-support systems and policy dashboards can support a transition from reactive healthcare to more proactive, preventive and personalized public health models. Nevertheless, their real-world impact depends on how these tools are introduced, explained, governed and used by citizens, clinicians, healthcare professionals and public authorities. Therefore, this paper focuses on stakeholder engagement and societal impact as enabling dimensions for the adoption of AI-supported CRC screening tools within the ONCOSCREEN project.

1.1 Background: colorectal cancer screening and the need for early, accessible, and personalized prevention

CRC screening is widely recognized as an essential public health intervention because it can reduce the burden of disease through early detection and prevention. Current screening strategies include stool-based tests, such as the faecal immunochemical test (FIT), and endoscopic procedures, such as colonoscopy, each with specific advantages, limitations and implementation requirements [5]. FIT is frequently used in population-based screening because it is non-invasive, relatively low-cost and suitable for organized outreach programmes, while colonoscopy remains a key diagnostic and therapeutic procedure, particularly after a positive screening result [5,6]. Evidence from recent studies supports the association between completed FIT screening and reduced CRC mortality, highlighting the importance of systematic and accessible screening pathways [6].

Despite this evidence, screening participation remains a major challenge. Non-participation is rarely caused by a single factor. Instead, it can result from lack of knowledge, low perceived personal relevance, fear, discomfort, aversion to the screening procedure, practical constraints, or insufficient support from healthcare professionals [7]. These barriers are especially important in the European context, where participation in CRC screening programmes differs substantially between countries and regions, and where organized screening infrastructure is not uniformly implemented [8]. Such variation shows that technological availability alone is not enough; screening programmes must also be understandable, trustworthy, inclusive and easy to access.

The need for personalized prevention is also increasing because CRC risk is influenced by multiple factors, including age, sex, family history, body mass index, lifestyle, behavioural patterns, genetic predisposition, socio-economic status and environmental exposures. Traditional age-based screening remains important, but risk-stratified approaches may help healthcare systems identify individuals or groups who could benefit from earlier, more frequent or more targeted screening interventions [9]. Recent evidence suggests that risk-stratified screening can optimize the benefits of screening by directing attention and resources toward higher-risk groups, while integrated risk models combining demographic, clinical and genetic information may further support early diagnosis and decision-making [9,10].

However, personalized prevention also introduces new implementation challenges. Risk-based recommendations must be clearly communicated, clinically justified and accepted by both citizens and healthcare professionals. A recent systematic review on personalized risk-based cancer screening found that such approaches are generally viewed as acceptable, but their implementation depends on trust in risk calculations, transparency, communication, resources and organizational readiness [11]. In this regard, stakeholder engagement becomes a core requirement for digital health adoption. Citizens need understandable information and reassurance; clinicians need training, explainability and workflow integration; and policy makers need reliable evidence to support decisions at population level.

From a smart-city perspective, AI-enabled CRC screening tools can contribute to resilient healthcare ecosystems by linking prevention, clinical practice, citizen engagement and evidence-based public health planning. At the same time, digital health interventions must avoid creating new inequalities. Research on digital inclusion in smart-city contexts shows that older citizens and digitally vulnerable groups may face barriers when public services become increasingly digital [3]. Therefore, early, accessible and personalized CRC prevention should combine technological innovation with inclusive communication, patient education, human support and responsible data governance.

1.2 The role of AI-enabled tools in smart healthcare ecosystems

Smart healthcare ecosystems are emerging as a core component of smart and resilient cities, linking clinical services, citizens, digital infrastructures, public institutions and data-driven decision-making. In this context, healthcare innovation is no longer limited to the digitalization of isolated medical processes, but increasingly involves interconnected platforms capable of collecting, processing and transforming health-related data into actionable information for prevention, diagnosis, monitoring and policy planning. Previous work on smart healthcare for smart cities has highlighted the potential of sensors, cloud-based data processing and machine-learning systems to support continuous health monitoring and more responsive public health services [12]. Similarly, research on ICT in smart-city hospital environments shows that digital technologies can improve coordination, operational efficiency and service delivery when they are adapted to local institutional needs and integrated into broader urban and healthcare strategies [2].

AI-enabled tools can contribute to this transformation at several levels. First, they can support the analysis of heterogeneous data sources, including clinical records, diagnostic outputs, lifestyle information, imaging data, patient-reported outcomes and environmental or socio-economic indicators. Second, they can assist clinicians through decision-support systems that aggregate information, identify relevant patterns and provide recommendations for diagnosis or follow-up. Third, they can support citizens through mobile applications, personalized educational content and self-monitoring functions. Finally, they can assist public authorities by transforming aggregated and privacy-preserving information into dashboards, indicators and predictive insights for evidence-based health policy. This multi-layered role is particularly relevant for CRC screening, where effective prevention depends on the combination of medical accuracy, population outreach, user participation and timely follow-up.

The literature on AI in healthcare shows that machine-learning and deep-learning models have been applied across multiple clinical domains, including imaging, risk prediction, diagnosis, patient monitoring and clinical decision support [13]. In CRC, AI applications have been particularly visible in colonoscopy support, polyp detection, pathology image analysis and risk prediction. Recent studies indicate that AI-assisted colonoscopy can improve the detection of colorectal lesions, while risk-stratification models may help identify individuals who could benefit from earlier or more targeted screening strategies [14,15]. However, these tools should be understood as decision-support mechanisms rather than replacements for medical expertise. Their value depends on the quality of data, clinical validation, transparency, workflow integration and the capacity of professionals to interpret and use AI-generated outputs responsibly.

Explainability and trust are therefore central to the adoption of AI-enabled healthcare tools. In medical contexts, opaque algorithmic outputs may create uncertainty among clinicians and patients, especially when decisions affect diagnosis, screening intervals or follow-up recommendations. Reviews on explainable artificial intelligence in healthcare emphasize that interpretability is essential in safety-critical environments because it can support accountability, clinical understanding and informed decision-making [16]. At the same time, trust in AI-based clinical decision-support systems is influenced by perceived usefulness, transparency, reliability, professional training, organizational readiness and governance mechanisms [17]. These findings are particularly important for smart healthcare ecosystems, where technical performance must be accompanied by ethical, legal and social acceptability.

The ONCOSCREEN project follows this ecosystem logic by combining multiple digital and clinical components for CRC screening and prevention. Its architecture includes tools for citizen engagement and self-monitoring, clinical decision support, risk stratification, diagnostic innovation, training and evidence-based analytics for policy makers. The mobile application supports self-assessment, monitoring and awareness activities, while the clinical decision-support component is designed to aggregate patient-related information and support medical decision-making through both machine-learning and rule-based mechanisms. In parallel, evidence-based analytics can support policy makers by providing secure, aggregated and standards-aligned information for planning and monitoring public

health interventions. Through this combination, AI-enabled tools become part of a broader stakeholder-centred ecosystem in which citizens, clinicians, researchers and public authorities interact around a shared objective: improving early CRC detection and personalized prevention while maintaining trust, privacy and responsible data governance.

1.3 Aim and contribution of the paper

The aim of this paper is to analyse how stakeholder engagement can support the adoption and societal impact of AI-enabled CRC screening tools within the ONCOSCREEN project. Rather than focusing only on the technical performance of individual tools, the paper examines the broader conditions required for these tools to become useful, trusted and sustainable in real healthcare environments. Particular attention is given to the interaction between digital health technologies, citizens, patients, clinicians, healthcare professionals and policy makers, as well as to the role of communication, training, awareness and feedback mechanisms in increasing acceptance and long-term impact.

The paper uses ONCOSCREEN as a case study of an integrated smart healthcare ecosystem that combines diagnostic innovation, risk stratification, mobile health, clinical decision support, training tools and evidence-based policy analytics. From this perspective, the contribution of the paper is threefold. First, it frames AI-enabled CRC screening as a stakeholder-centred process, showing that technological innovation must be accompanied by user engagement, education and trust-building activities. Second, it discusses the potential societal impact of such tools in terms of early detection, personalized prevention, improved screening participation and better support for public health decision-making. Third, it connects the ONCOSCREEN approach to the wider agenda of smart, resilient and citizen-centric healthcare systems, where digital tools must be secure, explainable, inclusive and aligned with ethical and data protection requirements.

By focusing on stakeholder engagement and societal value, the paper contributes to the discussion on how AI-enabled healthcare solutions can move from research and development toward practical adoption. The analysis is relevant for researchers, technology developers, healthcare practitioners and public authorities interested in the implementation of trustworthy digital health tools in smart city contexts.

2. The ONCOSCREEN Digital Health Ecosystem

The ONCOSCREEN project can be understood as a digital health ecosystem designed to support colorectal cancer (CRC) screening and prevention through the integration of clinical knowledge, diagnostic innovation, AI-enabled analysis, citizen engagement and evidence-based decision-making. Instead of developing a single isolated tool, the project proposes a connected set of components addressed to multiple stakeholder groups, including citizens, patients, clinicians, nurses, researchers, healthcare authorities and policy makers. This ecosystem perspective is essential because CRC screening involves several interdependent processes: risk identification, screening participation, diagnostic confirmation, clinical interpretation, patient communication, data protection and public health planning.

The ONCOSCREEN ecosystem includes both clinical and digital components. On the clinical side, it integrates novel diagnostic approaches and biomarker-related knowledge intended to support earlier and more precise CRC detection. On the digital side, it includes tools for self-assessment and monitoring, risk stratification, clinical decision support, training, data management and policy analytics. These tools are not designed to replace medical expertise, but to support different actors in the screening pathway by providing structured information, personalized recommendations, improved communication and evidence-based insights.

A central characteristic of the ecosystem is its co-designed architecture. The ONCOSCREEN technical framework has been developed through an iterative process involving end-user and technical requirements, partner feedback, laboratory integration testing and continuous refinement of tool prototypes. This approach is relevant for stakeholder engagement because the adoption of AI-enabled healthcare technologies depends not only on algorithmic performance, but also on usability, workflow compatibility, trust, explainability and organizational readiness. Therefore, ONCOSCREEN positions digital health innovation as a collaborative process that connects technological development with clinical practice and public health needs.

2.1 Overview of the integrated ONCOSCREEN approach

The integrated ONCOSCREEN approach is structured around five main pillars: data, analysis, diagnosis, stratification and evidence-based decisions. These pillars define the logic through which information is collected, transformed and used across the ecosystem. The data pillar includes clinical knowledge, retrospective information, registries, scientific literature and relevant medical and non-medical factors. The analysis pillar supports the interpretation of heterogeneous data sources, including clinical, behavioural, socio-economic and environmental indicators. The diagnosis pillar includes novel CRC screening and diagnostic tools. The stratification pillar focuses on personalized risk assessment, while the evidence-based decision pillar supports recommendations for citizens, clinicians and public authorities.

At the foundation of the approach is the Clinical Knowledge Database, which provides scientific and clinical background for the development of ONCOSCREEN tools. It includes CRC prevalence factors, target groups, biomarkers, retrospective data analysis and evidence that can support risk-based stratification and recommendations. This knowledge base is important because it links the technological components of the project to clinical relevance and scientific evidence. In this way, the system is not based only on technical data processing, but also on curated knowledge, expert input and evidence-based rules.

For citizens and patients, the integrated approach is represented mainly through digital engagement and self-monitoring functionalities. The mobile application supports self-assessment, longitudinal monitoring, awareness activities and two-way communication, allowing users to receive information and contribute relevant data to the screening pathway. This component is particularly important for prevention because citizen participation is a key condition for effective CRC screening. By connecting self-assessment, wearable-

supported monitoring and educational interactions, the system aims to make prevention more personalized and understandable.

For clinicians, the approach is supported by clinical decision-support and diagnostic components. The ONCOSCREEN architecture includes tools able to aggregate patient-related information, visualize relevant data and support recommendations for screening or diagnostic follow-up. The clinical decision-support component is particularly important because it combines data-driven and rule-based mechanisms, allowing AI-supported outputs to remain connected to medical expertise and institutional practice. In addition, training-oriented tools support the improvement of professional skills and user familiarity with AI-assisted screening technologies.

For policy makers and healthcare authorities, the ONCOSCREEN ecosystem includes evidence-based analytics intended to support strategic decision-making. Aggregated and privacy-preserving information can help authorities understand screening trends, population-level risks, inequalities and possible intervention needs. This function connects the project to the broader smart-city agenda, where healthcare systems are expected to become more preventive, data-driven and responsive to population needs. As a result, ONCOSCREEN does not address CRC screening only as a clinical process, but as a public health challenge requiring coordination between technology providers, medical professionals, citizens and decision makers.

Overall, the integrated ONCOSCREEN approach demonstrates how AI-enabled health tools can be embedded into a wider ecosystem for prevention and early detection. Its value lies not only in the individual performance of diagnostic or analytical tools, but also in the way these tools are connected through data flows, stakeholder interactions, feedback mechanisms, clinical validation and evidence-based governance. This integration provides the basis for analysing stakeholder engagement and societal impact in the following sections.

2.2 Main categories of tools: diagnostic, risk stratification, mobile health, clinical decision support, and policy analytics

The ONCOSCREEN ecosystem is composed of several categories of tools that address different stages of the CRC screening and prevention pathway. These categories include diagnostic tools, risk stratification mechanisms, mobile health services, clinical decision-support components and policy analytics. Together, they create a multi-actor environment in which citizens, patients, clinicians and healthcare authorities can interact with different levels of information according to their roles and needs.

The first category is represented by diagnostic tools designed to support earlier and more precise CRC detection. The ONCOSCREEN toolkit includes several diagnostic approaches, such as ONCO-VOC, ONCO-CTC, ONCO-CRISPR and ONCO-NMR. These tools are associated with different types of biological or chemical indicators, including volatile organic compounds, circulating tumour cells, molecular biomarkers and metabolomic profiles. Their purpose within the ecosystem is not only to generate diagnostic outputs, but also to contribute data that can be further interpreted by other components of

the platform, especially the risk stratification and clinical decision-support layers. In this way, diagnostic innovation becomes part of a wider data-driven screening workflow rather than a stand-alone testing activity.

The second category is represented by the risk stratification component, ONCO-RISTE. This tool is intended to support personalized CRC risk assessment by combining different types of information, including clinical knowledge, prevalence factors, behavioural indicators, socio-economic aspects and outputs from diagnostic tools. The role of risk stratification is particularly important for personalized prevention because it can support the identification of individuals or groups requiring more targeted screening recommendations. In a public health context, this can contribute to a more efficient allocation of screening resources and to the design of more adaptive prevention strategies.

The third category is mobile health, represented by ONCO-CAWA, the companion mobile application of the ONCOSCREEN ecosystem. This component acts as a citizen-facing interface for self-assessment, monitoring and awareness. Through questionnaires, data visualization, educational content and interaction with other tools, the mobile application can support patient engagement and continuous participation in the screening pathway. From a stakeholder engagement perspective, this tool is essential because citizens and patients are not passive recipients of medical decisions, but active participants who provide information, receive feedback and interact with prevention-oriented recommendations.

The fourth category is clinical decision support, represented by ONCO-CLIDE. This component is designed to support clinicians by aggregating patient-related information and assisting decision-making during the CRC screening and diagnostic process. Its value lies in the integration of structured data, diagnostic outputs, medical knowledge and recommendation mechanisms into a clinical workflow. In such systems, AI-assisted outputs should remain interpretable and connected to professional judgement. Therefore, clinical decision support should be seen as a tool for enhancing medical work, not replacing it.

The fifth category is policy analytics, represented by ONCO-EVIDA. This tool is intended to support healthcare authorities and policy makers through aggregated and evidence-based insights. At this level, the focus shifts from individual recommendations to population-level understanding. Policy analytics can help identify screening trends, possible inequalities, regional differences, risk patterns and areas where public health interventions may be needed. This category is particularly relevant for smart healthcare ecosystems, where data-driven governance can support more responsive and preventive health policies.

Across these categories, the ONCOSCREEN approach illustrates how digital health tools can be connected into an integrated ecosystem. Diagnostic tools generate relevant biomedical information; risk stratification translates heterogeneous data into personalized prevention logic; mobile health tools support citizen engagement; clinical decision-support systems assist healthcare professionals; and policy analytics provide evidence for strategic decision-making. The societal impact of the ecosystem depends on the ability of these tools to operate together in a secure, understandable and stakeholder-oriented manner.

2.3 Stakeholder groups addressed by the ecosystem: citizens, patients, clinicians, nurses, researchers, healthcare authorities, and policy makers

The ONCOSCREEN ecosystem addresses a broad range of stakeholders because CRC screening and prevention require coordinated action between individuals, healthcare professionals, research actors and public institutions. In line with smart-city and smart-healthcare principles, the value of the ecosystem depends not only on the availability of advanced technologies, but also on the extent to which different user groups understand, trust and adopt them [1]. The co-design process of ONCOSCREEN reflects this multi-stakeholder orientation by involving technical partners, clinical end-users, policy-making end-users and patient end-users in the development and refinement of system requirements.

Citizens represent one of the primary stakeholder groups because screening effectiveness depends on awareness, participation and preventive behaviour. For this group, the ecosystem provides digital engagement mechanisms such as self-assessment, monitoring and educational support through the mobile health component. The objective is to make CRC prevention more accessible and understandable, while encouraging individuals to become active participants in their own health journey. In this sense, citizens are not only potential users of digital tools, but also beneficiaries of awareness activities, personalized recommendations and improved access to preventive healthcare pathways.

Patients represent a more specific group within the citizen population, particularly those enrolled in screening pathways or clinical validation activities. Their needs are connected to transparency, informed consent, privacy, communication with healthcare professionals and trust in the screening process. Patient-oriented functionalities can support longitudinal monitoring, feedback, risk communication and education regarding available screening options. This is important because patient engagement can influence both adherence to screening recommendations and the quality of information available for personalized prevention.

Clinicians are another central stakeholder group because they interpret clinical information, validate recommendations and make final medical decisions. In ONCOSCREEN, AI-enabled tools and clinical decision-support components are intended to assist clinicians by organizing heterogeneous information, supporting diagnosis and improving access to relevant evidence. However, the clinical usefulness of such tools depends on their integration into real workflows, their explainability and the ability of clinicians to evaluate AI-supported outputs critically. Therefore, clinicians are both users and evaluators of the ecosystem.

Nurses and other healthcare professionals play an essential operational and communicational role in the screening pathway. They often support patient onboarding, explain procedures, assist with sample-related workflows, ensure documentation quality and contribute to patient education. Training materials developed within the project recognize nurses as a distinct user group, with responsibilities related to patient support, documentation and interaction with several ONCOSCREEN tools. Their involvement is

important because they frequently act as intermediaries between digital tools, clinical teams and patients.

Researchers and technical partners contribute to the development, validation and improvement of the ecosystem. Their role includes the design of AI models, data management components, interoperability mechanisms, diagnostic tools and knowledge-based resources. The Clinical Knowledge Database, for example, connects scientific literature, clinical expertise, biomarkers, prevalence factors and retrospective data analysis in order to support evidence-based tool development. Researchers therefore ensure that the system remains scientifically grounded, while technical partners translate these requirements into functional digital components.

Healthcare authorities and policy makers form another key stakeholder group because CRC screening is also a public health and governance challenge. Through evidence-based analytics, the ecosystem can provide aggregated insights related to screening uptake, risk factors, inequalities and regional trends. Such information can support public health planning, targeted awareness campaigns and more efficient allocation of resources. In this way, the ONCOSCREEN ecosystem connects individual-level prevention with population-level decision-making.

Overall, the stakeholder groups addressed by ONCOSCREEN reflect the complexity of implementing AI-enabled health technologies in practice. Citizens and patients need accessible information, trust and empowerment; clinicians and nurses need usable tools, training and workflow integration; researchers need structured knowledge and data-driven validation; and healthcare authorities need reliable evidence for policy decisions. The interaction between these groups is essential for transforming AI-enabled CRC screening from a technological innovation into a sustainable and socially meaningful healthcare intervention.

3. Stakeholder Engagement Approach

Stakeholder engagement is a central element in the development and adoption of AI-enabled healthcare technologies. In digital health, technical performance alone does not guarantee real-world implementation, especially when tools are expected to support prevention, diagnosis, patient communication, clinical decision-making and public health planning. The involvement of stakeholders from early design stages can help ensure that tools are relevant, usable, ethically acceptable and aligned with the needs of different user groups. In healthcare, co-design is commonly understood as a collaborative process in which stakeholders actively contribute to the definition of problems, requirements and possible solutions [18]. Such approaches are particularly important for AI-enabled systems because their adoption depends on trust, transparency, workflow compatibility and the perceived value of the technology for end users.

The ONCOSCREEN stakeholder engagement approach follows this logic by treating the development of digital health tools as an iterative and collaborative process. The ecosystem involves several stakeholder categories, including technical partners, clinical end-users, policy-making end-users and patient end-users. This structure allows the project to address

different expectations at the same time: citizens and patients need accessible information and trustworthy engagement tools; clinicians and nurses need support for practical workflows and decision-making; researchers and technical partners need structured requirements and validation feedback; and public authorities need aggregated insights for evidence-based policy decisions. Therefore, stakeholder engagement is not an additional communication activity, but a functional part of the system development process.

From the perspective of societal impact, stakeholder engagement also contributes to adoption and sustainability. Digital tools designed without sufficient user involvement may face resistance, low usability, poor integration into workflows or limited public trust. By contrast, participatory approaches can help identify barriers early, adapt functionalities to real contexts and create a shared understanding between developers and users [19]. In ONCOSCREEN, this is particularly relevant because the project combines different categories of tools, including diagnostic technologies, mobile health services, risk stratification, clinical decision support and policy analytics. Each of these components has different end users, different operational conditions and different adoption challenges.

3.1 Co-design and end-user requirements collection

The co-design process in ONCOSCREEN was used to collect, refine and prioritize end-user and technical requirements for the project's tools. This process was designed as a continuous and iterative activity, allowing user perspectives to be integrated throughout the design and implementation phases. The project involved four main stakeholder groups in the requirements process: technical partners responsible for developing the tools; clinical end-users, including healthcare professionals, healthcare facilities and academic institutions; policy-making end-users, including ministries of health, consultancy organisations and think-tanks; and patient end-users represented through patient organisations.

The first stage of requirements collection started during the project kick-off meeting, where the initial co-design workshops took place and partners agreed on a common co-creation methodology. After this stage, technical partners prepared descriptions of the ONCOSCREEN tools, while end-users reviewed the descriptions, provided clarifications and expressed their interest in contributing to requirements beyond their initially assigned tools. This was followed by a series of virtual meetings between technical partners and end-users, during which feedback was collected and documented in structured formats. The process also included requirement prioritisation, allowing end-users to rank proposed functionalities according to perceived importance.

A key strength of this approach is the translation of end-user expectations into technical requirements. After end-users provided and ranked their needs, technical partners analysed the feasibility of these requests and proposed corresponding technical requirements. Alignment meetings were then used to clarify priorities, discuss development timelines and ensure that user needs were interpreted correctly by the technical teams. This step is important because stakeholder engagement in digital health should not remain at a purely consultative level. Instead, feedback must be transformed into concrete design choices, system functionalities and implementation decisions.

The co-design process also continued through laboratory integration tests and prototype feedback rounds. During these activities, technical partners demonstrated the development progress of ONCOSCREEN tools, while end-users provided feedback and suggested additional requirements. This created a feedback loop between prototype development and stakeholder evaluation. Such iterative cycles are consistent with good practices in participatory digital health design, where users should be involved not only at the beginning of a project, but also during testing, refinement and implementation [19,20].

An important aspect of the ONCOSCREEN co-creation process is that it was designed not to require the collection of personal data. This is relevant from an ethical and data protection perspective because the project operates in a sensitive healthcare domain. By separating requirements collection from personal health data processing, the project could involve stakeholders in tool development while reducing privacy risks during the design phase. This approach supports responsible innovation and shows that stakeholder engagement can be organized in a way that respects privacy-by-design principles.

Overall, the ONCOSCREEN co-design and end-user requirements process illustrates how complex AI-enabled healthcare ecosystems can be shaped through structured collaboration. The process helped connect technological development with the practical needs of clinicians, patients, healthcare organisations and policy actors. It also provided a mechanism for improving usability, trust and adoption potential before large-scale deployment. In this sense, co-design becomes an adoption enabler, linking the technical architecture of the project with its expected societal impact.

3.2 Training and support activities for clinical and healthcare stakeholders

Training and support activities are essential for the adoption of AI-enabled healthcare tools because clinical users must understand not only how to operate digital systems, but also how to interpret their outputs, limitations and relevance for patient care. Previous studies on AI and clinical decision-support systems show that healthcare professionals may hesitate to use such tools when they do not understand how outputs are generated, when the added value is unclear, or when new systems increase workload and disrupt established workflows [21,22]. Therefore, training should be understood as an implementation mechanism that connects technological innovation with clinical practice, user confidence and responsible adoption.

Within the ONCOSCREEN ecosystem, training activities address several categories of healthcare stakeholders, including clinicians, diagnosticians, nurses, junior gastroenterologists, nurse practitioners and trainers. The Integrated Clinical Tools Training Manual structures training around the main tools and user groups, including modules for medical professionals, nurses and patient education. This structure reflects the fact that different stakeholders interact with the ecosystem in different ways. Clinicians need to understand how diagnostic and risk-stratification tools support personalized CRC assessment; nurses need practical knowledge for patient interaction, workflow coordination and documentation; and patients need clear explanations that support participation, consent and trust.

For medical professionals, the training approach focuses on understanding the clinical utility of the ONCOSCREEN tools and their integration into personalized CRC risk assessment and decision support. The training materials present the role of tools such as ONCO-CTC, ONCO-CRISPR, ONCO-NMR, ONCO-VOC and ONCO-CAWA in relation to early detection, non-invasive testing, metabolic or behavioural monitoring and patient-reported information. The purpose is not to create autonomous technological decision-making, but to support clinicians in using multiple sources of information more effectively. This is important because AI-enabled systems should complement professional expertise and help clinicians interpret complex information without replacing clinical responsibility.

For nurses and other healthcare professionals, training is especially relevant because they often act as a bridge between patients, clinicians and digital tools. Their role may include patient intake, explanation of digital components, support for tool navigation, documentation, follow-up coordination and communication of practical information to patients. In this sense, nurses contribute directly to stakeholder engagement. If they understand the tools and can communicate their purpose clearly, they can reduce patient uncertainty and increase confidence in the screening pathway. Training for nurses therefore supports both operational implementation and patient-centred care.

A specific training-oriented component of the ONCOSCREEN ecosystem is ONCO-AICO, a web platform intended to assist and train junior gastroenterologists and nurse practitioners in the interpretation of colonoscopy videos with support from AI algorithms. The tool allows trainees to select areas of interest in videos, receive performance scores and interact with explainable AI elements such as LIME and SHAP-based visual hints. Trainers can review exercises, assess ambiguous annotations and provide feedback. This creates a structured learning loop in which trainees can compare their annotations with AI-supported outputs and expert feedback. Such functionality is relevant not only for technical skill development, but also for building familiarity with AI-assisted reasoning in a controlled training environment.

The ONCO-AICO training workflow also illustrates the importance of feedback and explainability in clinical education. By combining trainee exercises, automated scoring, trainer review and explainable AI visualizations, the platform supports gradual learning and reflection. This approach is consistent with the broader literature on AI adoption in healthcare, which emphasizes that clinicians need education, transparency and practical experience in order to develop confidence in AI-based tools [21]. Training environments can therefore reduce uncertainty by allowing users to explore how AI outputs are generated, when they are useful, and how they should be interpreted in relation to professional judgement.

Support activities are also needed beyond initial training. AI-enabled health tools evolve during implementation, and users may require continuous assistance, updated guidance and opportunities to provide feedback. The ONCOSCREEN approach includes feedback mechanisms that allow trainees and trainers to contribute to platform improvement while maintaining privacy and data security. This is important because successful implementation

depends on the continuous alignment between tools, workflows and user expectations. Support activities can help identify usability problems, clarify misunderstandings and ensure that digital tools remain acceptable and useful in clinical environments.

Overall, training and support activities represent a key link between stakeholder engagement and societal impact. They help healthcare professionals understand the ONCOSCREEN tools, integrate them into clinical routines, communicate them to patients and use AI-supported outputs responsibly. By strengthening user competence, trust and workflow integration, training contributes to the broader objective of making AI-enabled CRC screening tools more adoptable, transparent and sustainable in real healthcare settings.

3.3 Citizen awareness, patient education, and digital engagement

Citizen awareness and patient education are essential components of effective CRC screening because participation depends not only on the availability of screening tools, but also on the ability of individuals to understand the value, purpose and implications of screening. Previous research shows that non-participation in CRC screening can be influenced by limited knowledge, fear, embarrassment, low perceived risk, lack of trust, practical constraints and insufficient communication with healthcare providers [7]. Therefore, awareness activities should not be treated as secondary dissemination actions, but as central mechanisms for improving screening acceptance and supporting preventive behaviour.

Digital engagement can contribute to this objective by creating continuous communication channels between citizens, patients and healthcare ecosystems. Digital health interventions, including mobile applications, web-based tools, electronic reminders and patient portals, are increasingly used to support CRC screening participation and follow-up [23]. However, their effectiveness depends on how well they are adapted to user needs, health literacy levels, local contexts and existing healthcare workflows. In smart healthcare ecosystems, digital engagement should therefore combine technological accessibility with understandable information, human support and trust-building communication.

Within ONCOSCREEN, citizen engagement is supported mainly through ONCO-CAWA, the companion mobile application designed for self-assessment, monitoring and awareness. The tool supports daily and periodic health questionnaires, integration with wearable sensors, visualization of personal information, educational dialogues and feedback mechanisms. Through these functionalities, citizens and patients can be involved more actively in the prevention pathway. Instead of receiving information only during occasional clinical encounters, users can interact with digital content, provide patient-reported information and follow their own health-related indicators over time.

Patient education is particularly important when new AI-enabled and diagnostic tools are introduced into screening pathways. Citizens may not immediately understand how non-invasive tests, risk stratification, mobile monitoring or AI-supported recommendations fit into clinical care. The ONCOSCREEN patient education approach emphasizes that the tools are designed to support early detection, reduce burden where possible, and assist clinical decision-making, while the physician remains responsible for medical care. This

message is important for maintaining trust and avoiding unrealistic expectations regarding automation. Patient education should clearly explain what the tools do, what they do not do, how personal data are protected, and how results should be interpreted within a clinical pathway.

Digital engagement also supports behavioural awareness. CRC risk is associated with multiple behavioural and lifestyle factors, including diet, physical activity, alcohol consumption, smoking and body weight. By enabling self-reporting, wearable-supported monitoring and feedback, mobile health tools can help citizens reflect on preventive behaviours and understand how lifestyle-related information may contribute to personalized risk assessment. This does not mean that digital tools should place responsibility only on individuals. Rather, they can support shared prevention by connecting individual awareness with clinical guidance and public health strategies.

Another relevant dimension is patient navigation and support. Evidence from cancer screening research indicates that navigation services can improve screening participation, particularly for populations facing practical, informational or socio-economic barriers [24]. In the ONCOSCREEN context, digital engagement can complement such support by helping patients understand the screening pathway, follow recommendations, receive reminders and ask questions. However, digital tools should not replace human interaction. Nurses, clinicians and support staff remain essential for explaining procedures, addressing concerns, and helping users who may have low digital literacy or limited confidence in health technologies.

Inclusiveness is therefore a critical condition for digital engagement. Smart healthcare systems may unintentionally widen inequalities if they are accessible only to digitally confident users. This is especially relevant for older adults, vulnerable groups and populations with limited access to digital infrastructure or lower health literacy [3]. For this reason, citizen awareness and patient education should be designed in a simple, transparent and culturally sensitive manner. The use of mobile applications, educational dialogues and digital monitoring should be accompanied by clear consent processes, privacy explanations and non-digital support alternatives when needed.

Overall, citizen awareness, patient education and digital engagement act as adoption enablers for AI-enabled CRC screening tools. They help transform complex technologies into understandable and usable services, increase trust in the screening pathway, and support continuous participation. In the ONCOSCREEN ecosystem, these activities connect citizens and patients with clinicians, digital tools and public health objectives, contributing to a more preventive, participatory and resilient model of smart healthcare.

3.4 Feedback loops for improving usability, trust, and adoption

Feedback loops are essential in the development of AI-enabled healthcare tools because they allow the system to evolve according to real user needs, practical constraints and emerging implementation challenges. In digital health, usability problems, lack of workflow fit, insufficient transparency and low user confidence can limit adoption even when a technology is technically advanced [25]. For this reason, feedback should not be

limited to final-stage evaluation, but should be integrated throughout design, testing, training and deployment. In the case of AI-supported clinical tools, continuous feedback is also important for trust, because users need opportunities to understand how the system behaves, question its outputs, and see their concerns reflected in system improvements [26].

Within ONCOSCREEN, feedback loops are embedded in the co-design and validation process. The project's end-user requirements were not treated as static specifications, but as evolving inputs collected through workshops, virtual meetings, prioritisation exercises, alignment teleconferences and Laboratory Integration Tests. This iterative process allowed technical partners to present tool progress, while clinical users, patient representatives and other stakeholders provided feedback, requested clarifications and suggested additional requirements. As a result, feedback became a mechanism for translating stakeholder needs into functional and non-functional technical requirements.

The Laboratory Integration Test activities illustrate how feedback was used to improve usability and implementation readiness. During the first testing rounds, technical partners demonstrated the initial development of the tools and end-users provided additional comments and requirements. Later iterations focused on more mature prototypes and enabled closer interaction between technical and clinical partners. In particular, the third Laboratory Integration Test emphasized near-real testing conditions, user experience, functional validation, interoperability and readiness for the next clinical phase, while the fourth iteration enabled end-users to interact directly with mature prototypes and validate requirements derived from their own needs. This progression shows that feedback loops supported both technical refinement and stakeholder confidence.

Feedback loops are also relevant at the level of clinical training. Training-oriented tools, such as ONCO-AICO, create structured interaction between trainees, trainers and AI-supported outputs. Trainees complete exercises, receive performance scores and can compare their annotations with AI-generated support, while trainers review exercises and provide further assessment. This creates a learning cycle in which users do not passively receive AI results, but engage with them, evaluate them and receive human feedback. Such interaction is important for adoption because it supports gradual familiarisation with AI-assisted reasoning and reinforces the idea that AI should support, rather than replace, professional judgement.

For citizens and patients, feedback mechanisms support engagement and trust in the screening pathway. ONCO-CAWA, the mobile health component, is designed to facilitate longitudinal self-assessment, monitoring, educational dialogues and two-way communication. These functions can help users understand their role in prevention, provide patient-reported information and receive feedback related to awareness and risk reduction. Patient feedback sessions and educational interactions can also help address fear, uncertainty or misunderstanding regarding screening tools. In this sense, feedback is not only a technical development mechanism, but also a communication process that supports patient empowerment.

Trust is strengthened when feedback loops are connected to transparency, privacy and responsiveness. Healthcare stakeholders are more likely to adopt digital and AI-enabled tools when they understand how the tools are used, how data are protected, and how their feedback influences future development [26]. In ONCOSCREEN, feedback collection is linked to the broader co-design approach and to horizontal requirements such as security, compliance and reliability. These requirements are particularly important in a healthcare project because sensitive data, clinical responsibility and patient confidence are central to adoption. Therefore, usability and trust must be developed together.

Overall, feedback loops act as a bridge between technology development and real-world adoption. They help identify usability barriers, clarify stakeholder expectations, improve workflow integration, refine tool functionalities and build confidence among users. In the ONCOSCREEN ecosystem, continuous feedback from clinicians, patients, researchers and policy-oriented stakeholders contributes to making AI-enabled CRC screening tools more understandable, acceptable and practically relevant. This supports the broader objective of transforming digital health innovation into sustainable societal impact.

4. Societal Impact of AI-Enabled CRC Screening Tools

The societal impact of AI-enabled CRC screening tools should be evaluated not only through technical performance, but also through their capacity to improve prevention, participation, accessibility, clinical coordination and public health decision-making. CRC screening has a strong public health relevance because it can support both early diagnosis and prevention by identifying precancerous lesions before disease progression [5]. However, the impact of screening programmes depends on multiple social and organizational factors, including citizen awareness, accessibility of screening pathways, adherence to recommendations, trust in healthcare services, and the ability of clinical teams to manage follow-up efficiently.

AI-enabled tools can contribute to this impact by supporting more personalized and data-driven screening pathways. Instead of relying exclusively on uniform age-based approaches, digital health ecosystems can integrate clinical, behavioural, demographic, genetic, socio-economic and environmental information to support more targeted prevention strategies [9]. This is particularly relevant in smart healthcare environments, where prevention is increasingly connected to data integration, citizen engagement and evidence-based governance. In this context, the expected societal value of ONCOSCREEN lies in its capacity to connect diagnostic innovation, risk stratification, mobile health, clinical decision support and policy analytics within a common ecosystem.

The ONCOSCREEN approach also reflects a shift from isolated medical interventions to collaborative healthcare ecosystems. Citizens and patients are engaged through mobile self-assessment and awareness tools; clinicians are supported through decision-support and diagnostic components; researchers contribute clinical knowledge and data models; and policy makers can benefit from aggregated insights for population-level planning. Therefore, societal impact is generated through the interaction between technological tools and stakeholder engagement processes. This interaction is particularly important for AI-

enabled healthcare, where adoption depends on usability, trust, transparency, training and responsible data governance.

4.1 Supporting early detection and personalized prevention pathways

Early detection is one of the most important objectives of CRC screening. When CRC or precancerous lesions are detected earlier, the chances of effective treatment and prevention of disease progression increase substantially [5]. Evidence from population-based screening studies shows that completed FIT screening is associated with a lower risk of CRC death, supporting the role of organized and accessible screening programmes [6]. At the same time, endoscopic screening methods can contribute to both detection and prevention because they allow the identification and removal of premalignant lesions [5]. These findings demonstrate why early detection remains a key public health priority.

Nevertheless, traditional screening pathways face several limitations. Age-based screening programmes are necessary and widely used, but they may not fully capture individual differences in CRC risk. Some individuals may present increased risk due to family history, lifestyle, body mass index, behavioural factors, co-morbidities, socio-economic vulnerability or environmental exposures, while others may have lower risk profiles [9]. A personalized prevention pathway aims to address this variability by adapting screening recommendations and prevention messages according to a more complete understanding of individual and group-level risk.

Risk-stratified screening has been proposed as a way to improve the efficiency and relevance of CRC prevention. Recent evidence suggests that risk stratification may help identify groups that benefit more strongly from screening, supporting the development of targeted screening strategies [9]. In this context, AI-enabled risk assessment can support the integration of heterogeneous information into more actionable prevention pathways. However, such systems must remain clinically interpretable and should support, rather than replace, professional judgement. Their value depends on the quality of input data, validation, explainability and integration into clinical workflows.

Within ONCOSCREEN, personalized prevention is supported through the combination of the Clinical Knowledge Database, the ONCO-RISTE risk stratification engine, the ONCO-CAWA mobile application and clinical decision-support components. The Clinical Knowledge Database provides evidence on CRC prevalence factors, biomarkers, target groups and relevant scientific resources. This knowledge supports the development of risk-based logic and recommendations. ONCO-RISTE uses heterogeneous information to classify individuals into risk groups, while ONCO-CAWA enables self-assessment, monitoring, education and feedback for citizens and patients. In this way, the project links clinical evidence, user-reported information and digital engagement.

The potential impact of this approach is twofold. First, it can support earlier identification of individuals or groups who may require closer attention, earlier screening or more targeted preventive communication. Second, it can make prevention more understandable for citizens by connecting risk information with personalized recommendations and educational content. This is important because personalized prevention is not only a

technical process of calculating risk; it is also a communication process that must help users understand why screening matters, what actions are recommended, and how they can participate responsibly in their own care.

The ONCOSCREEN ecosystem also supports personalized prevention by integrating behavioural and lifestyle-related information. Factors such as physical activity, smoking, alcohol consumption, nutrition and other behavioural indicators are relevant for CRC risk and prevention. Through mobile self-assessment and wearable-supported monitoring, such information can contribute to a more dynamic understanding of risk. This may help clinicians and healthcare teams provide more tailored recommendations, while also supporting citizens in reflecting on preventive behaviours. However, these tools should be implemented carefully, avoiding excessive individual responsibility and ensuring that recommendations are clinically justified, transparent and inclusive.

Overall, AI-enabled CRC screening tools can support early detection and personalized prevention by connecting scientific evidence, diagnostic innovation, risk assessment and citizen engagement. In ONCOSCREEN, this integration is designed to strengthen the screening pathway from both individual and public health perspectives. Its societal impact will depend on the extent to which these tools are validated, trusted, adopted by healthcare professionals, understood by citizens and integrated into existing screening programmes.

4.2 Improving citizen participation in CRC screening programmes

Improving citizen participation is one of the most important conditions for increasing the societal impact of CRC screening programmes. Even when effective screening methods are available, their public health value depends on whether eligible individuals understand the purpose of screening, accept the invitation, complete the test, and follow the recommended pathway after receiving results. Non-participation in CRC screening is a complex phenomenon influenced by emotional, informational, cultural, practical and organizational factors. Previous research shows that individuals may avoid screening because of fear, embarrassment, low perceived personal risk, lack of knowledge, distrust, inconvenience, or insufficient support from healthcare professionals [7]. Therefore, increasing participation requires more than providing access to screening tests; it also requires communication, education, trust-building and practical support.

Digital health tools can contribute to participation by making screening-related information more accessible and by creating additional points of contact between citizens and healthcare services. Mobile applications, reminders, patient portals, educational materials and web-based interventions have been used to support CRC screening uptake and follow-up [23]. These tools can help citizens understand why screening is important, when they should participate, what steps are involved, and how results are used. However, digital engagement should be designed carefully, because the same tools that improve access for some users may create barriers for others, especially older adults, digitally vulnerable groups or individuals with limited health literacy [3]. For this reason, digital participation strategies should be simple, inclusive and supported by human interaction when needed.

Within the ONCOSCREEN ecosystem, citizen participation is supported mainly through awareness, self-assessment and monitoring functions included in the mobile health component. ONCO-CAWA is designed to provide questionnaires, educational content, feedback mechanisms and self-monitoring functionalities that can increase user involvement in the prevention process. By enabling citizens and patients to contribute relevant information and receive personalized educational support, the tool can make the screening pathway more interactive and understandable. This is important because participation is more likely when individuals perceive screening as relevant to their own health status and when they understand the reasons behind recommendations.

Patient education also plays a central role in participation. CRC screening can involve unfamiliar technologies, medical terminology and decision points that may generate uncertainty. Educational materials should therefore explain the purpose of early detection, the role of different screening and diagnostic tools, the meaning of risk assessment, and the limits of AI-enabled recommendations. In ONCOSCREEN, patient-oriented training and education emphasize that digital tools are designed to support prevention and clinical decision-making, while medical professionals remain responsible for diagnosis and care. This distinction is important for trust, because citizens should understand that AI-enabled tools support, but do not replace, professional medical judgement.

Participation can also be improved through patient navigation and support mechanisms. Evidence from cancer screening research shows that navigation services can increase screening participation, particularly among populations affected by health disparities [24]. In practice, navigation may include reminders, explanations, help with appointments, clarification of results and support for follow-up procedures. In an AI-enabled digital health ecosystem, navigation can be complemented by mobile communication and educational feedback, but it should not be fully automated. Human support remains important for addressing fears, answering questions and helping users who may face practical or digital barriers.

The improvement of citizen participation is also connected to equity. European data show that CRC screening participation varies across countries and population groups, reflecting differences in screening organization, access, awareness and broader socio-economic conditions [8]. AI-enabled tools and mobile applications should therefore be implemented in ways that reduce, rather than amplify, inequalities. This means that digital engagement should be accompanied by accessible language, transparent consent processes, privacy explanations, and alternative support channels for users who cannot or do not want to rely exclusively on digital tools.

Overall, ONCOSCREEN can support citizen participation by combining technological tools with awareness, education and stakeholder engagement. The mobile application, patient education materials, feedback mechanisms and clinical support activities can help transform screening from a one-time medical invitation into a continuous prevention-oriented interaction between citizens and healthcare systems. In this way, improving participation becomes not only a matter of digital access, but also a matter of trust, inclusion and shared responsibility in public health.

4.3 Enhancing clinical workflows and multidisciplinary collaboration

AI-enabled CRC screening tools can enhance clinical workflows by supporting the organization, interpretation and exchange of information across the screening and diagnostic pathway. In many healthcare environments, clinicians must work with heterogeneous data sources, including patient history, laboratory results, imaging, diagnostic reports, risk indicators and follow-up recommendations. When these data are fragmented across systems or formats, clinical interpretation may become slower and more difficult. Clinical decision-support systems can help address this challenge by aggregating relevant information, supporting structured decision-making and improving access to patient-related evidence at the point of care [22,27].

Within the ONCOSCREEN ecosystem, this role is mainly represented by ONCO-CLIDE, the clinical decision-support component. The system is designed as an integrated hub for the CRC screening and diagnostic pathway, providing functionalities for patient management, data aggregation, visualization and decision support. Its multi-user structure reflects the fact that clinical workflows involve different professionals with different responsibilities. Doctors, laboratory personnel, administrative users and system maintainers interact with the platform according to role-based permissions, supporting both collaboration and data protection. This is important because effective clinical workflow support must provide access to relevant information while respecting professional roles and privacy requirements.

A significant contribution of ONCO-CLIDE is its dual decision-support logic. The platform combines an adaptive machine-learning component with a rule-based component that allows clinical expertise and institutional guidelines to be represented in a transparent way. This hybrid approach is relevant for adoption because clinicians are more likely to trust systems that provide explainable and clinically meaningful outputs. Rather than replacing professional judgement, AI-supported recommendations can support clinicians by presenting structured suggestions for next-step screening or diagnostic actions. This aligns with the broader literature on CDSS adoption, which shows that usefulness, workflow fit, transparency and limited additional workload are important conditions for implementation [22,27].

Multidisciplinary collaboration is also a central element of CRC care. Screening, diagnosis and follow-up may involve gastroenterologists, oncologists, pathologists, radiologists, laboratory specialists, nurses and other healthcare professionals. In complex cases, collaboration across disciplines is necessary for interpreting results and deciding appropriate next steps. ONCO-CLIDE supports this need through collaborative workflow tools, including a Virtual Tumour Board and a staging component. Virtual tumour boards are increasingly recognized as mechanisms that can facilitate multidisciplinary discussion, improve access to expertise and support more consistent oncology decision-making across healthcare settings [28].

From an impact perspective, workflow enhancement is not only a matter of efficiency. It can also improve communication between professionals, reduce information fragmentation

and support more consistent clinical reasoning. When diagnostic results, patient profiles and risk indicators are available in a structured environment, clinicians can spend less effort searching for information and more effort interpreting it. Moreover, multidisciplinary features can help document discussions, clarify responsibilities and support continuity across the screening and diagnostic process.

However, the successful integration of AI-enabled tools into clinical workflows requires careful implementation. If digital tools are perceived as complex, time-consuming or poorly aligned with existing routines, they may increase workload rather than reduce it. Therefore, training, feedback loops and end-user involvement are essential for ensuring that clinical tools remain usable and relevant. In ONCOSCREEN, the co-design and testing process helps address this challenge by involving clinical stakeholders in requirements collection, prototype evaluation and validation activities. This stakeholder-oriented approach supports the transformation of AI-enabled tools from technical prototypes into practical components of clinical care.

Overall, AI-enabled tools can enhance clinical workflows and multidisciplinary collaboration by improving data aggregation, supporting transparent decision-making and enabling structured communication between healthcare professionals. In ONCOSCREEN, these functions contribute to the broader societal objective of creating more coordinated, evidence-based and patient-centred CRC screening pathways.

4.4. Supporting evidence-based decision-making for healthcare authorities and policy makers

The societal impact of AI-enabled CRC screening tools extends beyond individual clinical decisions. CRC screening is also a public health challenge that requires planning, resource allocation, communication strategies and continuous monitoring at local, regional and national levels. Healthcare authorities and policy makers need reliable evidence to understand screening participation, population risk, inequalities, environmental factors and the possible effects of alternative screening strategies. In this context, data analytics and dashboards can support evidence-based decision-making by transforming complex datasets into accessible visual indicators and policy-relevant insights [29].

Within ONCOSCREEN, this function is represented by ONCO-EVIDA, the evidence-based decision analytics dashboard. The tool is designed to support policy makers in healthcare, public health and environmental health by integrating multiple data sources, including CRC screening data, retrospective data, open databases, socio-economic information and air-quality data. By combining these sources, the dashboard can help users identify trends, stratify information and explore potential relationships between screening uptake, CRC-related indicators and contextual risk factors. This is particularly relevant because CRC screening participation and outcomes may vary across regions and population groups [8].

A key contribution of policy analytics is the ability to connect screening data with geographic and socio-economic information. ONCO-EVIDA is designed to provide local and regional visualizations that can help policy makers identify areas where screening

promotion may be needed. Such functionality can support more targeted interventions, including awareness campaigns, resource planning and outreach activities for vulnerable groups. In this way, policy analytics can help move from general public health recommendations toward more adaptive and evidence-informed strategies.

The dashboard approach is also relevant for monitoring inequalities. European data show that CRC screening participation differs across countries and socio-demographic groups, indicating the need for better evidence on barriers, access and participation patterns [8]. By enabling data filtering, stratification and visualization, analytics tools can support decision makers in identifying underserved populations and monitoring whether interventions are reaching the intended groups. This is important because smart healthcare systems should not only become more technologically advanced, but also more inclusive and responsive to social disparities.

Evidence-based decision-making also depends on usability and trust. Dashboards can support policy decisions only if they present information clearly, allow users to explore data meaningfully and provide transparent assumptions behind indicators and recommendations [29]. ONCO-EVIDA addresses this need through interactive visualizations, customizable dashboards, filtering options, data export and access control mechanisms. These functionalities support both practical use and responsible governance, because policy users must be able to interpret results while ensuring that data remain secure and appropriately managed.

Another important dimension is the connection between individual-level prevention and population-level planning. Information generated through diagnostic tools, risk stratification, mobile engagement and clinical workflows can contribute to broader knowledge about screening needs and intervention priorities when aggregated and governed responsibly. This does not mean that individual patient data should be exposed to policy users. Rather, the value of the ecosystem lies in transforming privacy-preserving and aggregated information into insights that can support public health decisions. This is essential for maintaining trust and complying with ethical and data protection requirements.

Overall, ONCO-EVIDA illustrates how AI-enabled screening ecosystems can support healthcare authorities and policy makers by providing integrated, visual and evidence-based information. Its potential societal impact lies in helping decision makers understand CRC screening trends, identify inequalities, target interventions and evaluate policy options. In smart healthcare ecosystems, such tools can strengthen the connection between clinical innovation and public health governance, supporting more preventive, inclusive and data-driven healthcare strategies.

5. Trust, Ethics, Data Protection, and Security as Adoption Enablers

Trust, ethics, data protection and security are fundamental adoption enablers for AI-enabled healthcare ecosystems. In CRC screening, digital tools may process or support decisions based on highly sensitive information, including clinical data, behavioural indicators, diagnostic outputs and risk-related variables. For this reason, stakeholders must be confident that the system protects privacy, supports medical responsibility, provides

understandable information and follows ethical principles. If these conditions are not met, even technically advanced tools may face resistance from clinicians, patients, healthcare institutions or public authorities.

In the European context, the responsible implementation of digital health technologies is closely connected to the General Data Protection Regulation (GDPR), the Medical Device Regulation, and the EU Artificial Intelligence Act. GDPR establishes strong protections for health-related data, while Article 25 requires data protection by design and by default [30,31]. The EU AI Act further strengthens the governance of AI systems, especially in sectors such as healthcare, where AI-based software intended for medical purposes may fall under high-risk obligations related to risk management, data quality, transparency, human oversight and cybersecurity [32,33]. These regulatory frameworks are not only compliance requirements, but also mechanisms for building trust in AI-enabled healthcare.

Within ONCOSCREEN, trust is approached as a system-level requirement. The project integrates security, privacy, interoperability, clinical validation, explainability and user training into the design of its tools. This is important because trust cannot be created only through communication campaigns. It must be embedded into the technical architecture, data governance, user interfaces, consent processes and stakeholder engagement activities.

5.1. Privacy-by-design and responsible handling of sensitive health data

Privacy-by-design is essential in AI-enabled healthcare because health data are among the most sensitive categories of personal data. GDPR treats data concerning health, genetic data and biometric data as special categories of personal data, requiring enhanced protection and appropriate legal grounds for processing [30]. In this context, digital health tools must limit data collection to what is necessary, protect data during transfer and storage, restrict access to authorized users, and ensure that processing is aligned with clearly defined purposes.

The ONCOSCREEN architecture reflects these principles through several privacy-preserving mechanisms. First, the project follows a federated data strategy, where data can remain under the control of the original institution instead of being systematically centralized. This approach can reduce exposure risks and support institutional data autonomy, which is particularly important when multiple hospitals, research partners and technical components are involved. Second, the system relies on access controls, metadata-based permissions, encryption mechanisms and audit-related information to support secure and accountable data handling.

A specific privacy-preserving component is the KGen anonymization tool, which is designed to operate within the hospital environment so that non-anonymized data do not leave the clinical institution. The tool applies k-anonymity principles and allows users to define which attributes should be anonymized, while maintaining a balance between data utility and privacy protection. This local processing model is particularly relevant for clinical research and AI development because it supports the use of medical data while reducing the risk of exposing identifiable information.

Responsible handling of sensitive health data also requires pseudonymisation and clear data governance. In the ONCOSCREEN integration with ONCO-RISTE, patient identifiers are pseudonymized as UUIDs, and prediction outputs are logged together with the relevant input information for audit and analysis purposes. This supports accountability while reducing the risk of improper exposure of direct identifiers. Moreover, the use of standardized data formats, semantic alignment and interoperability mechanisms can help ensure that data are exchanged in a controlled and meaningful way.

Privacy-by-design therefore contributes directly to stakeholder trust. Patients are more likely to accept digital health tools when they know that their data are protected, that only necessary information is used, and that participation is based on informed consent. Clinicians and healthcare institutions are more likely to adopt tools that respect confidentiality, legal obligations and professional responsibility. For policy makers, privacy-preserving analytics can provide population-level insights without exposing individual-level patient information.

5.2. Transparency, explainability, and user confidence in AI-assisted healthcare tools

Transparency and explainability are essential for user confidence in AI-assisted healthcare tools. In clinical contexts, users need to understand what a tool does, what data it uses, what type of recommendation it produces, and what limitations should be considered. Explainable artificial intelligence (XAI) is particularly important in safety-critical domains such as healthcare, where unclear or opaque outputs can reduce trust and create uncertainty for clinicians and patients [16]. Reviews of AI-based clinical decision-support systems show that transparency, perceived usefulness, workflow fit and trust are important factors influencing adoption among healthcare professionals [26].

In ONCOSCREEN, explainability is relevant at multiple levels. The clinical decision-support component combines machine-learning and rule-based mechanisms, allowing AI-supported outputs to remain connected to clinical knowledge and professional judgement. This hybrid approach is important because rule-based elements can make recommendations more interpretable, while machine-learning components can support pattern recognition and data-driven insights. For clinicians, this can help transform AI outputs from abstract predictions into more understandable decision-support information.

Training-oriented tools also contribute to explainability and trust. ONCO-AICO, for example, enables users to interact with AI-supported analysis and request visual hints based on explainability methods such as LIME and SHAP. Such features can help trainees and trainers understand which visual regions or patterns influence AI-supported outputs. In this way, explainability becomes part of the learning process, not only a technical feature. It supports gradual familiarisation with AI-assisted reasoning while preserving the role of expert review and human judgement.

For citizens and patients, transparency must be expressed in simple and accessible language. Patient education materials should clarify that AI-enabled tools are support systems, not replacements for doctors, and that medical professionals remain responsible for care decisions. This distinction is essential for avoiding both excessive fear and

unrealistic expectations. Patients should also understand how their data may be used, what rights they have, whether they can opt out of digital tools, and how privacy is protected.

Transparency is also relevant for policy analytics. Dashboards and aggregated insights can influence strategic healthcare decisions, awareness campaigns and resource allocation. Therefore, policy users need to understand the data sources, assumptions, limitations and aggregation methods behind visual indicators. Without such transparency, dashboards may create an impression of objectivity while hiding uncertainty, bias or incomplete data. Responsible analytics should therefore combine visualization with clear explanations, access control and appropriate interpretation guidance.

Overall, transparency and explainability support trust by making AI-enabled tools more understandable, accountable and usable. In healthcare, this does not mean that every technical detail must be exposed to every user. Rather, each stakeholder group should receive explanations appropriate to its role: clinicians need clinical interpretability and workflow relevance; patients need clear information and reassurance; trainers need educational feedback; and policy makers need meaningful indicators and limitations.

5.3. Ethical considerations in stakeholder engagement and digital health adoption

Ethical digital health adoption requires more than legal compliance. It also requires respect for autonomy, fairness, inclusiveness, accountability and human oversight. The World Health Organization identifies key ethical principles for AI in health, including protecting human autonomy, promoting well-being and safety, ensuring transparency and explainability, fostering responsibility, ensuring inclusiveness and promoting responsive and sustainable AI [34]. These principles are highly relevant for CRC screening because digital tools may influence prevention behaviour, risk perception, clinical communication and public health decisions.

Informed consent is a central ethical requirement. Patients and citizens should understand what participation involves, what data may be collected, how the data will be protected, and whether they can decline or withdraw from digital components without negative effects on their care. ONCOSCREEN patient education materials explicitly emphasize consent, transparency, data privacy and the possibility of opting out of digital tools without affecting care quality. This approach supports autonomy and reduces the risk that citizens perceive digital health participation as mandatory or unclear.

Fairness and inclusiveness are also essential. AI-enabled screening tools must avoid reinforcing existing inequalities in healthcare access, digital literacy or screening participation. Older adults, vulnerable populations and people with limited digital skills may face barriers when healthcare services become increasingly digital [3]. Therefore, stakeholder engagement should include accessible communication, human support, patient education and alternative pathways for individuals who cannot rely only on mobile or digital tools. Digital engagement should support inclusion rather than become a new source of exclusion.

Ethical stakeholder engagement also requires clear allocation of responsibility. AI-enabled tools may support recommendations, risk assessment or clinical interpretation, but accountability must remain with qualified professionals and responsible institutions. This is particularly important in clinical decision-support systems, where recommendations should be interpreted as assistance rather than autonomous medical decisions. Human oversight is therefore not only a regulatory requirement, but also an ethical condition for maintaining professional responsibility and patient trust.

Bias and data quality represent additional ethical concerns. AI systems trained or validated on incomplete, unrepresentative or poorly governed datasets may produce outputs that are less reliable for certain groups. In CRC screening, this issue is relevant because risk factors, screening participation and healthcare access can differ across gender, age, socio-economic status, region and other population characteristics. Responsible implementation should therefore include careful data governance, validation, monitoring and feedback from diverse stakeholders.

Finally, ethical digital health adoption requires continuous dialogue. Stakeholder engagement should not end once tools are deployed. Patients, clinicians, nurses, researchers and policy makers should be able to provide feedback, report usability issues, question outputs and contribute to improvement. In this sense, ethics is not only a checklist applied at the beginning of a project; it is an ongoing practice of accountability, transparency and responsiveness.

Overall, trust, ethics, data protection and security are not external constraints on innovation. They are conditions that make innovation adoptable. In the ONCOSCREEN ecosystem, privacy-preserving architecture, explainable AI, informed consent, role-based access, clinical oversight and stakeholder engagement support the responsible implementation of AI-enabled CRC screening tools. These elements strengthen the connection between technological development and societal impact, making digital health innovation more suitable for smart, resilient and citizen-centric healthcare ecosystems.

6. Discussion: Lessons for Smart Healthcare and Cyber-Resilient Intelligent Cities

The ONCOSCREEN case illustrates that AI-enabled healthcare innovation should be understood as a socio-technical process rather than only a technological one. The project combines diagnostic innovation, risk stratification, mobile engagement, clinical decision support, training tools and policy analytics, but its potential impact depends on how these components are adopted by different stakeholders. In this sense, the project is relevant for the broader debate on smart healthcare and cyber-resilient intelligent cities, where digital transformation must support not only efficiency, but also trust, inclusion, security and public value [1,2,12].

From a smart-city perspective, healthcare systems are becoming increasingly data-driven and interconnected. This creates new opportunities for prevention, personalized care and evidence-based governance, but it also introduces new risks related to data protection, cybersecurity, digital exclusion, algorithmic opacity and institutional readiness. The ONCOSCREEN ecosystem addresses these challenges through a multi-stakeholder and

privacy-aware approach, integrating co-design, end-user feedback, clinical validation, training, security requirements and responsible data governance. Therefore, the main lesson is that sustainable digital health ecosystems require alignment between technological capabilities, user needs, institutional workflows and ethical safeguards.

6.1. From technological innovation to sustainable adoption

The first lesson concerns the transition from technological innovation to sustainable adoption. AI-enabled tools can offer significant value for CRC screening and prevention, but their implementation cannot rely only on technical performance. In healthcare, adoption is influenced by trust, usability, workflow integration, explainability, training, institutional support and compliance with ethical and legal requirements [22,26]. If clinicians do not understand how a tool supports their work, if patients do not trust how their data are handled, or if healthcare institutions cannot integrate the system into existing workflows, the innovation may remain limited to a research prototype.

ONCOSCREEN addresses this challenge by designing its tools as part of an integrated ecosystem rather than as isolated solutions. Diagnostic outputs, risk stratification, mobile self-assessment, clinical decision support and policy analytics are connected through shared objectives and stakeholder-oriented functionalities. This integrated approach can support continuity between prevention, diagnosis, clinical interpretation and public health planning. However, sustainable adoption also requires continuous training and support. Training activities for clinicians, nurses and other healthcare professionals help translate technical functionalities into practical use, while patient education supports understanding, participation and informed engagement.

Another condition for sustainable adoption is security and compliance by design. In AI-enabled healthcare ecosystems, trust depends on whether users and institutions believe that sensitive data are handled responsibly. The use of role-based access control, encrypted communication, auditability, privacy-preserving data flows and standards-based interoperability can reduce risks and support institutional confidence. These elements show that cybersecurity and data protection should not be treated as separate technical layers added at the end of development, but as adoption requirements embedded from the beginning.

6.2. Stakeholder engagement as a condition for societal impact

The second lesson is that stakeholder engagement is a condition for societal impact. AI-enabled CRC screening tools can support early detection, personalized prevention and better decision-making, but these benefits can only be achieved if citizens, patients, clinicians, nurses, researchers and policy makers are actively involved. Stakeholder engagement helps identify real needs, clarify expectations, reduce resistance and improve tool usability. It also supports trust because users are more likely to accept technologies that reflect their concerns and practical contexts.

In ONCOSCREEN, stakeholder engagement is operationalized through co-design, end-user requirements collection, iterative testing, feedback loops, training and patient education. These activities connect the technical development process with the lived

realities of clinical work and citizen participation. For clinicians, engagement helps ensure that tools are compatible with professional judgement and workflow needs. For patients and citizens, engagement supports understandable communication, awareness and confidence in digital health services. For policy makers, engagement helps ensure that analytics tools provide relevant and interpretable evidence for public health action.

This stakeholder-oriented approach is also important for equity. Smart healthcare ecosystems may unintentionally exclude people with lower digital literacy, limited access to digital services or low trust in institutions [3]. Therefore, digital engagement must be accompanied by accessible information, human support, clear consent processes and inclusive communication. In this sense, stakeholder engagement is not only a method for improving usability; it is also a mechanism for preventing digital health inequalities and ensuring that innovation contributes to broader societal value.

6.3. Transferability of the ONCOSCREEN approach to smart city healthcare contexts

The third lesson concerns transferability. The ONCOSCREEN approach is relevant beyond the specific case of CRC screening because it proposes a model for integrating AI-enabled tools into smart healthcare ecosystems. Its modular structure, based on data, analysis, diagnosis, stratification and evidence-based decisions, can be adapted to other prevention-oriented healthcare domains where early detection, citizen participation and coordinated decision-making are essential. The same logic could be applied to other chronic diseases or screening programmes that require risk assessment, patient engagement, clinical interpretation and population-level monitoring.

Transferability also depends on interoperability and governance. Smart city healthcare contexts are characterized by multiple institutions, heterogeneous data sources, different professional roles and varying levels of digital maturity. For this reason, AI-enabled tools must be designed to communicate securely with other systems, follow recognized standards, respect data protection rules and provide clear responsibilities for data access and decision-making [30,32]. The ONCOSCREEN model shows that technical integration must be accompanied by governance mechanisms such as role-based access, auditability, privacy-preserving processing and stakeholder-defined requirements.

At the same time, transferability should not be interpreted as simple replication. Each healthcare system has different legal, organizational, cultural and infrastructural conditions. Therefore, the ONCOSCREEN approach is most transferable as a framework rather than as a fixed technological package. Its broader lesson is that smart healthcare solutions should combine modular digital tools, clinical evidence, co-design, training, privacy-by-design, explainable AI and evidence-based policy analytics. When these elements are aligned, AI-enabled healthcare ecosystems can contribute to cyber-resilient intelligent cities by strengthening prevention, public trust, institutional coordination and responsible data-driven governance.

Overall, the ONCOSCREEN experience suggests that the future of smart healthcare depends on the capacity to connect innovation with adoption, security with usability, and data-driven intelligence with human-centred care. AI-enabled CRC screening tools can

support more personalized and preventive health pathways, but their long-term societal impact depends on trust, stakeholder engagement and responsible implementation.

7. Conclusions

This paper analysed the role of stakeholder engagement and societal impact in the adoption of AI-enabled CRC screening tools within the ONCOSCREEN project. The discussion showed that the value of such tools does not depend only on diagnostic or algorithmic performance, but also on their capacity to be understood, trusted and adopted by the different actors involved in screening and prevention. CRC screening is a public health challenge that requires the participation of citizens and patients, the involvement of clinicians and nurses, the contribution of researchers and technology developers, and the support of healthcare authorities and policy makers.

The ONCOSCREEN ecosystem illustrates how AI-enabled healthcare tools can be integrated into a broader smart healthcare model. Its components include diagnostic tools, risk stratification, mobile self-assessment, clinical decision support, training tools and evidence-based policy analytics. Together, these elements support a more connected approach to CRC prevention, where clinical evidence, digital engagement, stakeholder feedback and responsible data governance are combined. The paper also highlighted that trust, ethics, data protection and security are not secondary requirements, but central adoption enablers for AI-supported healthcare.

7.1. Summary of key findings

The first key finding is that AI-enabled CRC screening tools can support early detection and personalized prevention pathways by integrating heterogeneous sources of information, including clinical knowledge, behavioural indicators, diagnostic outputs and risk factors. This can help move CRC screening from a uniform approach toward more targeted and adaptive prevention strategies.

The second finding is that stakeholder engagement is essential for adoption. Co-design, end-user requirements collection, training, patient education and feedback loops help ensure that digital tools are aligned with real needs, clinical workflows and user expectations. Without these processes, even technically advanced tools may face low acceptance or limited practical impact.

The third finding is that citizen participation must be supported through awareness, education and accessible digital engagement. Mobile health tools and patient-facing interfaces can improve understanding and involvement, but they must be designed inclusively and supported by human interaction when needed.

The fourth finding is that clinical decision support and policy analytics can strengthen both individual and population-level healthcare decisions. Clinical tools can assist professionals by organizing information and supporting multidisciplinary collaboration, while policy dashboards can help authorities monitor trends, identify inequalities and plan targeted interventions.

Finally, the paper showed that privacy-by-design, explainability, role-based access, informed consent and cybersecurity are necessary conditions for trustworthy digital health ecosystems. In sensitive domains such as cancer screening, responsible governance is inseparable from technological innovation.

7.2. Implications for future AI-enabled public health initiatives

Future AI-enabled public health initiatives should be designed as socio-technical ecosystems rather than isolated digital tools. This means that technological development should be accompanied by stakeholder engagement, training, ethical assessment, privacy-preserving architecture and continuous feedback. Public health technologies should not only generate predictions or recommendations, but also support communication, trust and coordinated action between citizens, healthcare professionals and institutions.

For healthcare practitioners, the ONCOSCREEN approach suggests that AI tools should be introduced as support mechanisms that enhance, rather than replace, professional judgement. For policy makers, the project highlights the importance of evidence-based dashboards and aggregated analytics for planning preventive interventions and addressing inequalities. For researchers and developers, the main implication is that usability, explainability, interoperability and security must be considered from the early design stages.

In the context of smart and cyber-resilient cities, AI-enabled healthcare tools can contribute to more preventive, inclusive and responsive public health systems. However, their long-term societal impact depends on whether they are implemented responsibly, transparently and in collaboration with the stakeholders who will use and be affected by them. The ONCOSCREEN case therefore demonstrates that sustainable digital health innovation requires the integration of technological excellence with human-centred design, ethical governance and public trust.

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