

UNICA: Unified Network for International Cancer Advancement

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Abstract

The UNICA project will significantly expand the European Cancer Imaging Initiative (EUCAIM) by adding breast, lung, and prostate cancer screening imaging data to its federated infrastructure. By contributing data from different regions across Europe, including underrepresented areas, UNICA will ensure the availability of diverse and representative datasets for research and innovation. This project addresses the need for innovative approaches to cancer prevention, detection, and treatment, ensuring alignment with key EU initiatives. The objectives of the project include extending the geographical coverage of the initiative, standardizing the data in line with FAIR principles, EUCAIM requirements, and interoperability specifications, and supporting the European Health Data Space (EHDS) and the Enhanced Electronic Health Record framework (EEHRxF). In addition, UNICA aims to demonstrate the adoption and integration of AI-based technologies for cancer image analysis by piloting advanced AI models. At the same time, the project actively promotes patient data altruism through targeted communication strategies and dissemination efforts. These objectives will be achieved by facilitating the aggregation and secure sharing of de-identified cancer imaging and clinical data from screening programmes. The project involves 12 medical centres and aims to achieve the maximum EUCAIM integration (Tier 3), drawing on the project partners' expertise gained in EU-funded federated networks. The project is highly relevant to the work programme as it directly supports Europe's Beating Cancer Plan and EUCAIM. By increasing the availability of high-quality cancer imaging data and fostering the development of AI-based solutions, the project aims to improve cancer screening, early detection, and overall patient outcomes across Europe. This aligns with the EU's objectives to advance cancer treatment and care through digital technologies, supporting faster, more accurate clinical decision-making, diagnostics, and predictive medicine.

Keywords

European Cancer Imaging, EUCAIM, European Health Data Space, Cancer Imaging, Federated Network, Federated Learning, AI, Data Altruism,

1. Introduction

1.1. Context and Motivation

Cancer remains one of the leading causes of death globally, with a significant impact on the European Union. In 2022 alone, the EU saw 2.7 million new cancer diagnoses and over 1.3 million cancer-related deaths, with projections indicating a 32% increase in cancer deaths by 2040 [1, 2]. These statistics underscore the urgent need for innovative approaches to cancer prevention, detection, and treatment. The European Cancer Imaging Initiative, implementing Flagship 2 of Europe's Beating Cancer Plan aims to enhance cancer treatment and care through digital technologies, enabling faster and more accurate clinical decision-making, diagnostics, treatments, and predictive medicine. Under the EUCAIM [3]

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project, a pan-European federated infrastructure of de-identified cancer patient imaging data is being created. These data, sourced from EU medical centers, are intended to support clinicians, researchers, and innovators in developing AI-based solutions to improve cancer care. In this context, the UNICA project emerges in response to a pressing health challenge, recognizing the untapped potential of federated medical imaging data to revolutionise cancer care, starting with screening programs. Three key observations drive the project's rationale: (1) Vast repositories of cancer imaging data exist across European medical centres, but often remain siloed, limiting their potential impact on research and clinical practice. (2) Rapid advancements in artificial intelligence (AI) offer unprecedented opportunities to extract deeper insights from medical images, potentially transforming cancer screening and early detection. (3) In line with Europe's Beating Cancer Plan, these opportunities can be harnessed by enabling medical centres to become nodes in the European federated infrastructure provided by EUCAIM, contributing with cancer images and benefiting from AI-based tools that support cancer prevention and care. The project will focus on increasing the geographical reach of the EUCAIM by facilitating the federation and secure sharing of de-identified cancer imaging and clinical data, including, but not limited to, mammograms, X-rays, CT, and MRI scans, primarily from screening programmes and opportunistic screening for lung, breast, and prostate cancer. These data will include retrospective samples. By bringing together diverse stakeholders – from hospitals and research institutions to AI developers – UNICA aims to create an inclusive, sustainable, and innovative ecosystem for continuous improvement in cancer screening and early detection across Europe. UNICA seeks to catalyse a transformation in how Europe approaches cancer screening and early detection, leveraging the collective power of shared data and advanced analytics to improve outcomes for cancer patients across the continent. Crucially, UNICA aims to onboard 12 medical centres targeting EUCAIM Tier 3 integration, ensuring full compliance with the Cancer Image Europe data federation framework.

1.2. Overall project methodology

The proposed project builds on the experience gained by Datatrix Spa (Italy), Politecnico di Milano (POLIMI - Italy), Universitat Politècnica de València (UPV - Spain), in deploying security-by-design federated infrastructures in several real-world scenarios, enabling medical centres to share and analyse multi-sources health data via a federated learning paradigm in a GDPR compliant mechanism. The importance of this result is also highlighted in a recently published Nature article about the next generation of evidence-based medicine [4]. In this article, the authors present an iceberg where precision-medicine and evidence-based medicine represent only the tip of the iceberg, while the vast amount of different and heterogeneous data sources and processing tasks represent what lies underneath the water surface. The authors argue that *“a deep synthesis and amalgamation of all available data is needed to achieve next-generation, deep evidence-based medicine”*.

In line with the European Health Data Space (EHDS), and the Europe's Beating Cancer Plan [5] vision, UNICA aspires to enable multiple EU medical centres in joining the European Cancer Imaging Initiative by the EUCAIM project with the final aim of delivering better healthcare, advancing research, facilitating policy making and, enabling medical centres to make full use of the potential offered by a safe and secure exchange, use and reuse of health data. Clinical partners are responsible for deploying and operating local federated nodes, enabling secure data access and participation in distributed AI workflows while ensuring compliance with institutional and national regulations. Furthermore, two AI-powered tools will be piloted in order to demonstrate the potential of the federated network and the use of artificial intelligence in improving cancer screening. The first tool, based on the groundbreaking deep learning model developed at the MIT [6, 7], will provide a mammography-based risk assessment for breast cancer, demonstrating its potential to improve clinical workflows for risk prediction and early detection from cancer images. The second tool will target AI-assisted screening for lung cancer from CT scans and will build on another MIT study [8, 9]. This project follows an inclusive, rich inter- and trans-disciplinary methodology, not only across scientific disciplines but also facilitating and promoting knowledge sharing between universities, SMEs, and healthcare professionals. An Agile methodology is being adopted and a shared 'language' is being built to effectively close gaps between scientific

knowledge, clinical needs, policy changes and technological issues in a broader sense.

This project fosters brainstorming, collaborative design, and scientific collaboration across all use cases through the active participation (calls, meetings, workshops, events, etc.) of researchers, technology providers, healthcare professionals, and relevant stakeholders. This aims to ensure early validation and rapid development loops. The project follows a logical approach composed of 7 work packages: **(WP1)** planning and monitoring; **(WP2)** legal agreements and medical centres' onboarding; **(WP3)** regular collaboration and alignment with the EUCAIM project; **(WP4)** access to health datasets, FAIRification and preprocessing; **(WP5)** EUCAIM federated node activation and EHDS integration; **(WP6)** technological pilot of AI-based tools; and finally **(WP7)** communication and dissemination activities throughout the project. Among the proposed WPs, previous experience suggests that WP2 could be the most challenging in terms of timing, as legal agreements require multiple iterations among different committees. In addition, WP2 could limit WP3, 4, 5, and 6. For those reasons, DATRIX closely monitors WP2, seeking to onboard the large majority of medical centres in a timely fashion. The UNICA project's action plan includes the identification of potential risks during implementation, as well as a contingency plan to address them if necessary. Some of the identified risks are legal delays, data heterogeneity, low recruitment, and AI bias, which would be mitigated through parallel onboarding, harmonization pipelines, expanding sites, and cross-site validation, respectively.

1.3. Participants

The UNICA project consortium consists of four technology providers and twelve data providers, each selected for their specific expertise and ability to contribute to the project objectives. UNICA brings together experts from a wide range of disciplines, including clinical and medical sciences, computer science, AI, distributed analytics, biology, statistics, software engineering, law, communication and education. The combined expertise, as well as the strong territorial coverage that complements that of EUCAIM, ensures that the project will benefit from a multidisciplinary approach while providing representative data across diverse and often underrepresented European regions. UNICA is a EU4Health project with a duration of 42 months and the participation of 16 organizations from ten countries, including twelve clinical institutions and four technological centres:

- **Clinical Institutions:** Klinikum Der Universitaet Zu Koeln (UKK - Germany), Leipzig University (ULEI - Germany), Aristotelio Panepistimio Thessalonikis (PHAUT - Greece), University of Ioannina (UoI - Greece), The 3rd Regional Health Authority of Greece (3RHA - Greece), Hospital of Lithuanian University of Health Sciences Kauno klinikos (LSMU - Lithuania), Wojewódzki Szpital Specjalistyczny we Wrocławiu (WSSK - Poland), Grupo Lusiadas Saúde (LSA - Portugal), Hospital Divino Espirito Santo De Ponta Delgada (EPR - Portugal), Centro De Oncologia Dos Acores Prof Doutor Jose Conde (COA - Portugal), Univerzitetni Klinicni Center Maribor (SBM - Slovenia), and Central City Clinical Hospital of Ivano-Frankivsk City Council (UNE - Ukraine).
- **Technological Centers:** Datrrix Spa (Italy), Politecnico di Milano (POLIMI - Italy), Universitat Politècnica de València (UPV - Spain), and 81Watts OÜ (81W - Estonia).

1.4. Datasets: estimated size and coverage

The main aim of the UNICA project is to design, implement, populate, and continuously update a federated database of screening imaging data that will integrate the retrospective datasets collected by hospitals within the consortium. Data contributed by the clinical centres focus on imaging from screening programmes and opportunistic screening data for breast, lung, and prostate cancer, as well as patient medical records, annotations, segmentations and clinical data. Imaging modalities include X-ray, TC, MRI, and PET scans, ultrasound, and mammography. Imaging data is already stored in the standard DICOM format in the clinical centres' systems.

As part of the FAIRification and EUCAIM Tier 3 compliance efforts, UNICA adopts the technical and methodological choices defined by the EUCAIM consortium, including the data model and ontologies, metadata standards, and catalogue schema.

Cancer type	Imaging types	Screening age range	Prospective samples per year	Retrospective samples	Geographical coverage
Breast	X-rays, CT, MRI, PET, mammograms, US	45–74	78,500	78,000	
Lung	X-rays, CT, MRI, PET, US	35–74	31,000	31,000	
Prostate	X-rays, CT, MRI	45–80	28,500	29,000	

Figure 1: Datasets: estimated size and coverage

2. Objectives

- **Objective 1:** *Perform cancer data standardisation by applying FAIR principles in alignment with EUCAIM’s standards.*

Assist hospitals in the FAIRification of patient data by following a common schema to promote interoperability and the reuse of cancer images for research and innovation, driving new medical technologies such as AI models. This involves addressing all tasks necessary for data protection authorizations, implementing data warehouse architecture guidelines, cataloguing, and ontology mapping to integrate cancer data within the EUCAIM project. Additionally, data curation will follow EHDS interoperability specifications to support the emerging European Electronic Health Record exchange Format (EEHRxF). Legal and ethical considerations will be carefully addressed, and procedures for data access and reuse will be implemented. To mitigate the risk of personal data leaks, pseudonymization will be applied by default, followed by data quality and integrity assessments. The ultimate aim is to prepare high-quality lung, breast, and prostate cancer data (imaging and related clinical data) for federated analysis.

- **Objective 2:** *Expand the geographical coverage of the European Cancer Imaging Infrastructure (EUCAIM) by onboarding new imaging data repositories from underrepresented regions.*

Medical centres in Greece, Germany, Slovenia, Ukraine, Portugal, Lithuania, and Poland are guided and supported in activating an EUCAIM federated node, contributing cancer imaging data from screening programmes and opportunistic screening. Crucially, GDPR compliance and legal aspects related to joining a federated network are addressed, including (but not limited to) infrastructure usage agreements, data usage agreements, and joint controller agreements. This objective aims to enhance the availability of high-quality lung, breast, and prostate cancer data within EUCAIM for secondary use in research and innovation.

- **Objective 3:** *Demonstrate the adoption and integration of AI-based technologies for cancer imaging analysis by piloting advanced AI models.*

As an initial step, training will be provided to familiarise non-technical beneficiaries with distributed datasets and federated learning concepts. Later, by leveraging the EUCAIM federated infrastructure, innovative AI solutions to support cancer screening, detection, and treatment will be piloted. As a technological proof of concept and to promote adoption, this project aims to pilot AI-based models for breast cancer risk assessment and lung cancer detections from chest X-rays, showcasing the potential of federated learning approaches in improving early detection and personalised care strategies in a clinical setting. Throughout the development lifecycle, the European trustworthy AI guidelines [10] will be followed, with particular attention to the explainability of the developed tools.

- **Objective 4:** *Ensure comprehensive alignment with key EU initiatives.*

To avoid duplication of efforts and maximise impact, the project will maintain close coordination with the EUCAIM initiative throughout its duration. Additionally, it will seek alignment with other

relevant EU-funded initiatives, including but not limited to EHDS infrastructures (MyHealth@EU), Europe's Beating Cancer Plan, Cancer Mission, EU4Health-funded projects, XteHR (EEHRxF), and TEHDAS 2 joint actions, QUANTUM, and the HealthData@EU pilot project. Meetings, technical workshops, webinars, and collaborative events and publications will be organised to foster synergies and ensure alignment with these initiatives.

- **Objective 5:** *Promote patient empowerment through targeted communication strategies and dissemination.*

A key aspect of this project involves fostering patient data altruism, motivating and empowering patients to donate their health data. To better engage patients and address privacy concerns, methods to build trust, such as anonymisation technologies or clear opt-in/opt-out mechanisms, will be outlined. To enhance the project's impact, joint communication and dissemination activities will be organised in collaboration with data altruism organisations. Additionally, connections will be established with regional, national, and European initiatives focused on health data reuse. Furthermore, the project's results and best practices, along with scientific achievements and lessons learned, will be publicly shared. Importantly, communication and dissemination efforts will target a wide range of audiences, including but not limited to the general public, academics, patients, clinicians, and hospitals interested in joining the EUCAIM federated network. Those activities will also include capacity-building initiatives focused on health data analysis using AI, federated learning in healthcare, the EHDS, and other relevant topics.

3. Impact and Expected Outcomes

By leveraging cutting-edge technologies such as federated learning, AI, and the emerging EHDS, the project will push the boundaries of current practices in cancer screening and research. Below, we define the project's anticipated impacts, the target groups, and how it will trigger change and innovation.

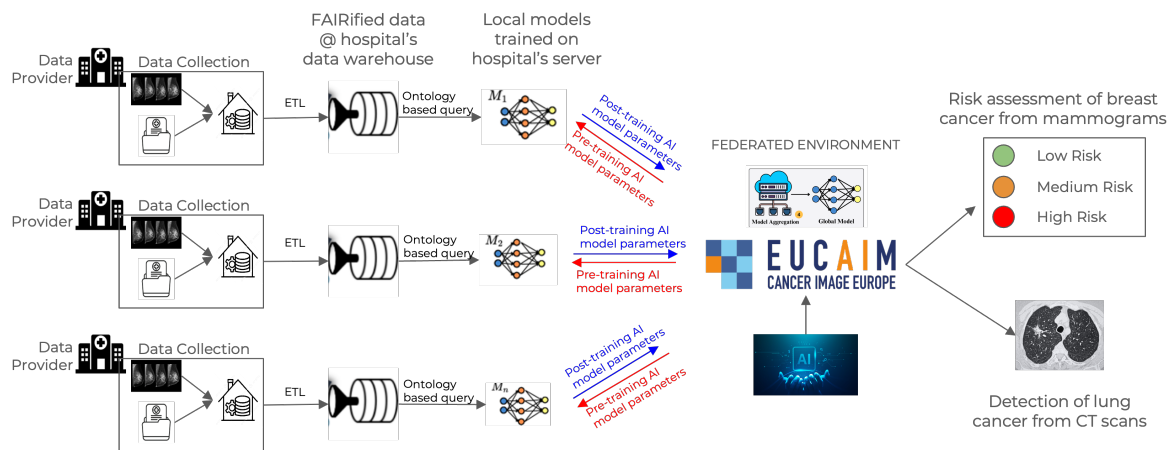


Figure 2: Final Output

- **Short-Term Effects (0-2 years):**

- **Target Groups** – Healthcare professionals, researchers, medical imaging centres.
- **Impact**

* *Improved Data Integration:* The project will rapidly integrate cancer imaging repositories into a federated, pan-European infrastructure. Medical imaging data (including X-rays, CT, MRI, PET scans, US, and mammograms), along with relevant clinical data (patient records, annotations, etc.), will be securely made available across borders in compliance with GDPR, improving the accessibility of high-quality cancer imaging datasets.

- * *Training and Capacity Building*: The project will provide extensive training to technical and clinical partners on federated learning infrastructure, FAIR principles, AI, and data analysis. This will increase the knowledge and skills of healthcare professionals and researchers in utilising AI for cancer screening.
 - **Progress Beyond State-of-the-Art**: The project will pioneer the integration of imaging data into a federated system, which contrasts with the traditional centralised data-sharing models, offering a scalable solution that respects data sovereignty and privacy regulations across Europe.
- **Medium-Term Effects (2-4 years):**
- **Target Groups** – Clinicians, healthcare providers, AI developers, policymakers.
 - **Impact**
 - * *AI-Driven Cancer Screening*: The project will leverage the newly integrated datasets to develop and validate innovative AI models for cancer screening and risk assessment. An AI-based breast cancer risk model will be piloted, enhancing early detection and personalised care strategies.
 - * *Clinical Integration*: The AI tools developed in the project will be evaluated and piloted in clinical settings to assess their potential for integration into daily practice. The adoption of these tools will be adapted on further validation, clinician feedback, and demonstrated improvements in cancer detection and diagnosis. If successful, these tools provide clinicians with valuable decision support, contributing to more informed and timely cancer care.
 - * *Contribution to Europe's Beating Cancer Plan*: By making the enriched datasets available for secondary uses, the project will support research on novel cancer diagnostics and treatments, in line with Europe's Beating Cancer Plan.
 - **Progress Beyond State-of-the-Art**: The project's focus on federated learning and AI for cancer screening represents a significant advancement over traditional methods, enabling the analysis of larger, more diverse datasets without compromising patient privacy. It will demonstrate the potential of federated learning in a real-world healthcare setting, offering a model for future AI-driven healthcare innovations.
- **Long-Term Effects (4+ years):**
- **Target Groups** – Patients, healthcare systems, and society at large.
 - **Impact**
 - * *Sustainable Ecosystem for Cancer Screening*: The project will create a sustainable ecosystem for continuous improvement in cancer screening and early detection across Europe. By establishing a network of imaging data repositories connected via a federated infrastructure, the project will enable ongoing research and innovation in cancer care.
 - * *Empowered Patients*: Patients will have new opportunities to contribute their health data for research through secure and ethical data donation pathways, fostering a culture of patient-driven research.
 - * *Improved Health Outcomes*: The project will lead to faster, more accurate cancer diagnosis, resulting in earlier interventions and improved survival rates. Long-term, this will contribute to more effective, efficient, and equitable cancer care across Europe.
 - **Progress Beyond State-of-the-Art**: The project's federated infrastructure will set a new standard for secure, cross-border data sharing in healthcare, aligning with the EHDS and influencing future health data policy. Additionally, the development of AI tools that operate across multiple data sources will push the boundaries of personalised medicine, improving both the quality of care and research productivity.

The project will result in the development of two deep learning-based models addressing key challenges in cancer detection and risk stratification:

- **Breast cancer risk assessment from mammographic images:** A predictive model capable of analyzing mammograms to estimate individual risk of developing breast cancer, supporting early identification of high-risk patients, and enabling more personalized screening strategies.
- **Lung cancer detection from CT scans:** An automated detection model designed to process thoracic CT images and identify suspicious pulmonary nodules, assisting clinicians in the early diagnosis of lung cancer and improving diagnostic efficiency.

4. Current Project Status and Future Work

During the current reporting period, significant progress has been made towards the integration of the UNICA project within the EUCAIM ecosystem. On the clinical side, the onboarding process with clinical partners has been successfully initiated, enabling the alignment of data, infrastructure, and operational requirements for participation in EUCAIM. This step represents a key milestone towards ensuring interoperability and readiness for federated data integration. In parallel, several coordination meetings with EUCAIM representatives have been held. These interactions have focused on identifying synergies, collaboration opportunities, and ensuring a smooth and compliant onboarding process, particularly in relation to technical and governance frameworks. The project is now transitioning towards the formalization of legal agreements, especially concerning data sharing and access policies. This stage is critical to ensure compliance with European regulations and to enable secure and ethical data exchange within the EUCAIM infrastructure. Additionally, ongoing efforts in dissemination and communication activities are being carried out to increase the visibility of the project, engage relevant stakeholders, and position UNICA within the broader European research and innovation landscape.

Looking ahead, the next steps will include the following: (1) *Finalizing legal and ethical frameworks for data sharing*, (2) *Advancing technical integration with EUCAIM services*, (3) *Expanding collaboration with additional clinical and research partners*, and (4) *Strengthening dissemination and stakeholder engagement activities*.

5. Relevance for CAiSE

The UNICA project is closely aligned with several research topics of relevance to the Information Systems Engineering (ISE) community. In particular, the project addresses key challenges including: (i) *the integration and management of distributed data through the use of a federated architecture*; (ii) *the application of ISE models, methods, and techniques to facilitate data understanding and exchange across institutions*; and (iii) *the adoption of innovative Artificial Intelligence (AI) techniques to extract deeper insights from medical imaging data, with the potential to transform cancer screening and early detection*. Overall, the project tackles a problem of significant societal impact by contributing substantial methodological and technological advances in the design and development of AI-enabled information systems that support cancer prevention and care.

6. Conclusions

The UNICA project aims to create an inclusive, sustainable, and innovative federated ecosystem for continuous improvement in cancer screening and early detection across Europe. It also seeks to catalyse a transformation in how Europe approaches cancer screening and early detection, leveraging the collective power of shared data and advanced analytics to improve outcomes for cancer patients across the continent. Crucially, UNICA aims to onboard 12 medical centres targeting EUCAIM Tier 3 integration, ensuring full compliance with the Cancer Image Europe data federation framework. This paper contributes to the field of ISE by federated data governance models, interoperability frameworks,

AI integration in distributed systems, and a methodology for onboarding clinical nodes. UNICA is a 42-month project, running from 09/01/2025 – 02/28/2029, financed by the European Union's EU4Health research and innovation program, with 16 participants from ten countries, including 12 clinical institutions and 4 technological centers. The overarching goal is to harness the full potential of multisource health data, enabling researchers, healthcare professionals, and innovators to conduct comprehensive analyses, integrate multimodal data types, and derive meaningful insights securely and cost-effectively.

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Declaration on Generative AI

The author(s) have not employed any Generative AI tools.

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