CR-g-24-37 Call for proposals to support integration of cancer images into the federated pan-European infrastructure to foster screening programmes

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#EUCancerPlan #CancerImaging #EHDS

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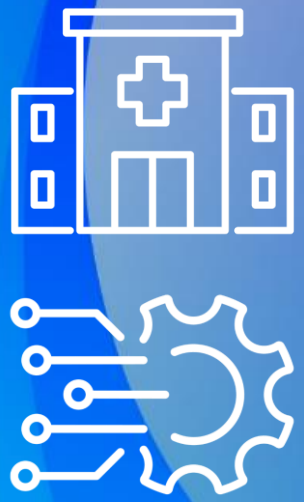
Flagship 2. “European Cancer Imaging Initiative”



Aim: foster innovation and deployment of digital technologies in cancer treatment and care, to achieve more precise and faster clinical decision-making, diagnostics, treatments, and predictive medicine for cancer patients

Launched by the EC in December 2022:
https://digital-strategy.ec.europa.eu/en/policies/cancer-imaging

Main implementing action: EUCAIM project funded under the 2021 DIGITAL Europe Work Programme deploying a pan-European federated infrastructure of de-identified, real-world imaging data of cancer patients

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Cancer Image Europe

EUCAIM CANCER IMAGE EUROPE

www.cancerimage.eu

- Pan-European digital infrastructure for cancer images and related clinical data for AI development and testing
  - deployed by **EUCAIM project** (January 2023 – December 2026) under DIGITAL Europe programme (budget 36 MEUR)
  - radiological and nuclear medicine images (MRI, CT, mammography, PET…) and related clinical information
  - standardised and harmonised, ready to be used to develop Artificial Intelligence (AI) tools for Precision Medicine
  - Users: **researchers**, **innovators** and **clinicians**

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Cancer Image Europe – status of deployment

- interim version of the infrastructure available → final release is expected by the end of 2025
- rules for participation as data holder defined: https://dashboard.eucaim.cancerimage.eu/become-a-data-holder
- three levels of compliance with EUCAIM's data model defined
- data (pre-processing) tools and services for data holders and research communities
- ongoing work on establishing a European Digital Infrastructure Consortium (EDIC) to operate Cancer Image Europe beyond 2026
- special focus on engaging cancer screening programmes - https://dashboard.eucaim.cancerimage.eu/become-a-member

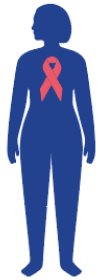
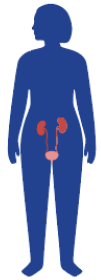
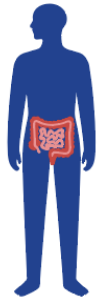
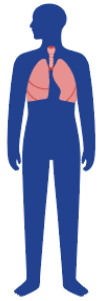
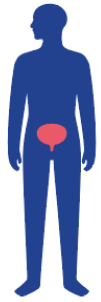
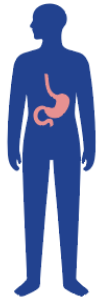
Cancer Image Europe – benefits for healthcare

EUCAIM
CANCER IMAGE EUROPE

- **capacity building/improved processes for handling imaging data**, in particular in view of ensuring interoperability and preparation for immediate secondary use – tools and services for data holders
- **access to advanced data processing and analysis tools**, for example in the context of cancer screening programmes
- **evidence-based healthcare**: Cancer Image Europe supports **evidence generation for changed clinical pathways**
- **involvement of clinicians in research**, e.g. on novel biomarkers that could be identified and validated that result in changed clinical pathways, or new/alternative diagnostic tools can be developed/validated, impacting clinical pathways; faster and more efficient conduct of observational studies
- **support for Regulatory Bodies:** reference or certified datasets and tools for regulatory bodies

Flagship “EU Cancer Screening Scheme”

Council Recommendation of 9 December 2022 on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC
(https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2022.473.01.0001.01.ENG)

 BREAST CANCER suggesting a lower age limit of 45 and a higher age limit of 74 (standard 50 – 69), plus MRI scans when medically appropriate	 HPV testing for women aged 30 to 65, every 5 years or more, to detect CERVICAL CANCER, taking account of HPV vaccination status	 Triage testing for COLORECTAL CANCER in people aged 50 – 74 through faecal immunochemical testing (FIT) to determine follow-up via endoscopy/colonoscopy
 LUNG CANCER testing for individuals at high risk (i.e. smokers), incl. prevention approaches	 Prostate specific antigen testing for PROSTATE CANCER in men, plus MRI scans for follow-up	 In places with high GASTRIC CANCER incidence and death rates, screening for Helicobacter pylori and surveillance of precancerous stomach lesions

Imaging techniques in EU cancer screening recommendations

- LUNG: screening with use of low-dose computed tomography
- BREAST: either digital breast tomosynthesis or digital mammography; magnetic resonance imaging (MRI) when medically appropriate
- PROSTATE: prostate-specific antigen (PSA) testing in combination with magnetic resonance imaging (MRI) as a follow-up test

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A new EU Cancer Screening Scheme

- the Council asks Member States to "*collect, manage and evaluate the data, and to consider, where appropriate,* ***making the data available for*** *cancer research, including implementation research and for* ***the development of improved technological possibilities for early cancer diagnosis and prevention****, in full compliance with applicable data protection legislation"*

European guidelines for cancer screening

- EU recommendations based on the latest technology, scientific developments and evidence
- **European guidelines for screening:** https://cancer-screening-and-care.jrc.ec.europa.eu/en

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AI and cancer screening

- AI potential in cancer screening: improved workflows, decreased time and cost; e.g. low-dose CT with AI reconstruction in lung screening; MR with AI reconstruction; identification of lesions that are relevant and clinically significant in prostate screening…
- Image analysis and interpretation support can reduce false-positive findings and potentially shorten the time between screening and diagnosis
- European guidelines on breast cancer screening includes conditional recommendation on double-reading with AI support

Relevant EU funded actions - examples

- Joint Action EUCanScreen, SOLACE, PRAISE-U

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Rationale of this call

- AI-based technological solutions for imaging data can support Member States in the implementation of screening programmes
- imaging data representative of the European population is necessary to develop transferable AI-based solutions that can cover different European regions and benefit the European population

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European Health Data Space (EHDS) Regulation

Aim: facilitating the findability, accessibility and reuse of health data for healthcare provision, research, innovation, policy-making and regulatory activities in a secure way

health data access bodies (HDABs) will facilitate the secondary use of health data, i.e. reuse of health data for a different purpose than the one they were collected for

A number of preparatory actions ongoing, e.g.: Joint Actions TEHDAS 2 and Xt-EHR, direct grants to Member States to establish HDABs, HDABs community of practice, QUANTUM CSA, capacity building projects on primary and secondary use…

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Objectives of this call

- provide **enabling support for cancer imaging data providers**, to **contribute to and benefit from the European Cancer Imaging Initiative**
- improve readiness of national, regional or local imaging data repositories:
  - ✓ to **connect and make available their data via the Cancer Image Europe infrastructure**
  - ✓ to **use this infrastructure for data enrichment and insights by accessing the nodes, tools and methodologies** offered by EUCAIM
- **seek alignment** and, where applicable, link cancer imaging databases **with the relevant bodies and infrastructures in the proposed EHDS**, particularly health data access bodies and HealthData@EU
- **leverage on the EHDS interoperability specifications for the European Electronic Health Record exchange Format**, including relevant eHealth Network guidelines, as well as minimum specifications for datasets to be used for research and innovation

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Activities

- all tasks necessary for federating data into the Cancer Image Europe platform, including creating the data warehouses and establishing processes necessary for making the imaging data and related clinical data available for secondary use

- networking, communication, coordination, planning, training, reporting, and dissemination activities

Activities - data

a) increase the geographical coverage of the European Cancer Imaging Initiative;

b) increase the availability of cancer imaging data representative of the European population for the development of trustworthy and scalable AI-based solutions for cancer screening and care in the area of breast, lung and prostate cancers in the context of the European Cancer Imaging Initiative;

c) increase the availability of cancer imaging data made available for research and innovation in the context of the proposed European Health Data Space;

d) contribute to the alignment with the relevant bodies and infrastructures of the proposed European Health Data Space, particularly health data access bodies, HealthData@EU and MyHealth@EU;

Activities – support and training in relation to data

e) provide targeted and onsite support in adopting the guidelines on the best data warehouse architectures, creating the data warehouses necessary for making the data available for secondary use, establishing internal processes, training and addressing the legal issues in alignment and complementarity with the activities under the EUCAIM project and in alignment with the proposed European Health Data Space rules and infrastructures;

f) provide support measures for quality-control, annotation and extraction of the data from the Electronic Health Records (EHRs) to the data warehouse, supporting the uptake of the European Electronic Health Record exchange Format;

g) use and contribute to applicable minimum specifications for datasets related to cancer imaging, including data elements, controlled vocabularies, quality requirements, in alignment with the proposed European Health Data Space Regulation;

h) increase the awareness, in cancer-related use cases, of medical images and reports specifications of the European Electronic Health Record exchange Format;

Activities towards AI uptake

i) provide activities to facilitate the adoption of AI-based technologies based on imaging data in the daily practice of clinical centres to support cancer screening, detection and treatment;

j) increase access to and uptake of innovative AI-based solutions based on imaging data for cancer detection and treatment;

l) increase resource efficiency of national healthcare providers through the deployment of AI-based technological solutions;

Other activities

k) empower patients to donate their health data through data altruism, including incentives, methods and tools for data altruism targeted at empowering patients in relation to donating their health data, in particular imaging data;

m) contribute to other relevant actions under the Europe's Beating Cancer Plan and Cancer Mission, involving patient organisations and establishing links with data altruism organisations and regional, national or European initiatives on health data reuse for research and innovation.

Mandatory deliverables and milestones

In the proposal, describe:

- cancer image datasets, their expected size and level of standardisation and harmonisation with the EUCAIM agreed data requirements
- the processes and tools for harmonisation and quality evaluation that will be applied
- *compliance or work/timeline towards meeting* the minimum technical requirements elaborated in the context of the European Cancer Imaging Initiative by the EUCAIM project

During project implementation:

- coordination with Cancer Image Europe activities → specific work package
- mandatory report every 6 months to HaDEA on progress, challenges and alignment with Cancer Image Europe + sustainability report
- compliance with the EHDS metadata standard - Health DCAT-AP
- visual identity and communication materials aligned with Cancer Image Europe

Impact

Short-term: strengthening the collaboration between national and regional screening programmes for breast, lung and prostate cancers, with the European Cancer Imaging Infrastructure (Cancer Image Europe)

Medium-term: increased geographical reach of the European Cancer Imaging Initiative and alignment of the European Cancer Imaging Infrastructure with the proposed EHDS infrastructures and processes

Key Performance Indicators

- A number of indicators that the applicants should consider next to other suitable indicators which may be defined in the proposals
- KPIs may be subject to adjustment during GAP
- KPIs relating to:

- number of providers who adopted guidelines/best practices and those who federated data into Cancer Image Europe
- number of datasets listed in the metadata catalogue of Cancer Image Europe and compliant with EHDS metadata standard
- dataset sizes made available in Cancer Image Europe and their coverage
- number of active users of Cancer Image Europe platform
- number of training activities, onsite visits and activities to support uptake of AI
- number of AI-based solutions implemented or piloted

Other topic requirements and conditions

- TOPIC BUDGET: 8 MEUR
- INDICATIVE PROJECT SIZE: 4 MEUR
- Applicants: Academia and education establishments, research institutes, hospitals, expert networks including ERNs, civil cociety organisations: associations, foundations, NGOs and similar entities, private entities (for profit/not for profit), Member States' authorities
- Consortium composition: a consortium composed of at least 7 applicant organisations established in at least 7 different eligible countries
- Expected project duration: 36 to 48 months
- Special requirements: Purchase of medical radiology equipment is not eligible

Thank you

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