

# INFO DAY – Digital Health Topics in Call 9



CNECT- Unit A6  
*AI in Health and Life Science*

**17 November 2025**

#DigitalEUProgramme

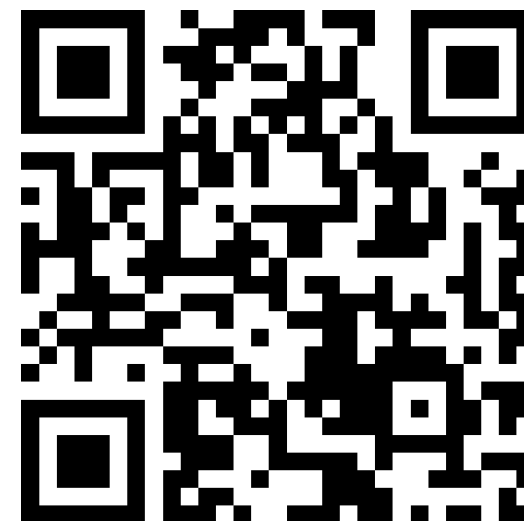


# DIGITAL EUROPE PROGRAMME

## INFO DAY – Digital Health topics in Call 9

### Webinar Rules

- The webinar is **recorded** - the recording will be available online in the Info Day webpage
- Microphones and cameras of participants will remain off
- You can post your questions in the Q&A window (bottom right corner)
- Pitching session – slides shared centrally; speakers will be unmuted; cameras remain off





# DIGITAL EUROPE PROGRAMME

## Digital Health topics in DIGITAL Europe Call 9

- DIGITAL-2026-AI-09-DS-HEALTH-TOOL – Health: Data ingestion capacities and data services for the European Genomic Data Infrastructure in the European Health Data Space: data tools
- DIGITAL-2026-AI-09-DS-HEALTH-STORAGE – Health: Data ingestion capacities and data services for the European Genomic Data Infrastructure in the European Health Data Space: data storage and processing capacity
- 2026-AI-09-SOLUTIONS-CANCER-STEP - Deployment of cutting-edge multi-modal AI-based solutions in medical imaging



# DIGITAL EUROPE PROGRAMME

## Call timeline

- Call deadline: 3 March 2026 – 17:00:00 CET (Brussels)
- Evaluation: March-April 2026
- Information on results: June 2026
- GA signature: September 2026

Topic conditions are detailed in the [call document](#)



# DIGITAL EUROPE PROGRAMME

## Eligibility criteria (section 6 of Call document)

### Eligible participants


- only entities from the following countries are eligible: **EU Member States, EEA countries and Switzerland.**
- Entities must not be directly or indirectly controlled from a country that is not an eligible country unless the granting authority agrees to allow for exceptional participation on the basis of a guarantee (**ownership control restriction**)
- Also eligible are: **International organisations of European Interest** within the meaning of Article 2 of the Digital Europe Regulation (i.e. international organisations the majority of whose members are Member States or whose headquarters are in a Member State).
- For other specific cases: see section 6 of [call document](#)



# DIGITAL EUROPE PROGRAMME

## INFO DAY – Digital Health topics in Call 9

### Agenda

Time	Topic	Presenter
10:00 – 10:05	<b>WELCOME AND INTRODUCTION</b>	<i>Szymon Bielecki – CNECT A6</i>
10:05 – 10:30	<b>GENOMIC TOPICS</b>	<i>Valentina Oberti – CNECT A6</i>
10:30 – 10:50	<b>RESTRICTED CALLS – AVAILABLE GUIDANCE AND MAIN ASPECTS</b>	<i>Mateja Pogacic – CNECT R5</i>
10:50 – 11:00	COFFEE BREAK 	
11:00 – 11:25	<b>AI SOLUTIONS IN MEDICAL IMAGING</b>	<i>Aleksandra Wesolowska – CNECT A6</i>
11:25 – 12:15	<b>PITCHING SESSION</b>	<i>Stakeholder presentations</i>



## INFO DAY – Digital Health Topics in Call 9

*Data ingestion capacities and data services for the European Genomic Data Infrastructure in the European Health Data Space*



**DIGITAL**  
EUROPE  
PROGRAMME

The illustration features a central purple circle with the text 'DIGITAL EUROPE PROGRAMME'. Surrounding this circle are four stylized human figures: a woman in a yellow shirt and black skirt holding a tablet, a man in a white lab coat holding a folder, a man in a white shirt and blue pants holding a smartphone, and a man in a yellow shirt and blue pants sitting on a stool using a laptop. Below the central text are six icons: a server rack, a heart with a pulse line, a factory with a smokestack, a shield with a padlock, a robot head, and a microchip. The background is dark purple with wavy lines and some abstract shapes.

CNECT- Unit A6  
*AI in Health and Life Science*

*Valentina.Oberti@ec.europa.eu*

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# DIGITAL EUROPE PROGRAMME

## DIGITAL-2026-AI-09-DS-HEALTH

**General information: 2 topics on genomics – total budget EUR 22.5M (5+17,5)**

- *Actions supporting the implementation of the [1+ Million Genomes Initiative](#) (1+MG).*
- *Ecosystem of ongoing implementing projects (DIGITAL funding): [Genomic Data Infrastructure](#), [Genome of Europe](#), [Beyond 1Million Genomes Plus](#).*
- *Consortium composition: minimum 5 independent applicants from 5 different eligible countries – RESTRICTED topic (Art. 12.6 Digital Europe Programme Regulation)*
- *Contribution to EU policies: AI - Data Spaces - [EHDS Regulation](#)*
- *Relevant projects to consider in the proposal: projects mentioned in the call text [QUANTUM](#), [Simple](#) platform, ongoing projects on genomics (GDI, GoE, B1MGplus) and projects collaborating with them ([EUCAIM](#), [ERDERA](#), [CANDLE](#), [UNCAN-Connect](#), [TEHDAS2](#), etc.).*







# DIGITAL EUROPE PROGRAMME

## DIGITAL-2026-AI-09-DS-HEALTH-TOOL:

*Data ingestion capacities and data services for the European Genomic Data Infrastructure in the European Health Data Space: data tools*





# DIGITAL EUROPE PROGRAMME

## DIGITAL-2026-AI-09-DS-HEALTH-TOOLS

**Indicative budget:** EUR 5 million (simple grant, 50% funding)

**Call identifier:** [DIGITAL-2026-AI-09-DS-HEALTH-TOOLS](#)

**Indicative duration of the action:** 48 months

### Objective

*to enhance the European genomic data infrastructure by supporting the deployment of advanced tools for data curation and use and its alignment with the European Health Data Space*



# DIGITAL EUROPE PROGRAMME

## DIGITAL-2026-AI-09-DS-HEALTH-TOOLS

### Activities

- develop, pilot and deploy tools, APIs and interfaces to **enable quality check at source, benchmarking, annotation and enhancement of data**. This includes data (and metadata) curation, inclusion, minimization, risk/security management.
- develop, pilot and deploy APIs and interfaces for **data discovery**, and **federated analysis and modelling** in a secure processing environment
- leverage **best practices and strategies for linking clinical and genomic data** at individual level, within the framework of EHDS (where appropriate)
- Implement **data de-identification/synthetisation methods** and support **multi-modal data discovery and analysis across the data infrastructures** (e.g. linking up with the Cancer Image Europe and HealthData@EU infrastructures)
- establish a **citizen portal for 1+MG** enabling citizens to exercise their **GDPR rights**:
  - obtaining information about data inclusion / processing and their legal basis
  - manage the consent
  - requesting data access, rectification or erasure



# DIGITAL EUROPE PROGRAMME

## DIGITAL-2026-AI-09-DS-HEALTH-TOOLS

### Outcomes & Deliverables

- *Tools to perform automated **data and metadata curation / inclusion / minimization** by data providers, foster **data quality assurance** and enable **compliance checks and risk/security management***
- ***Tools, APIs and interfaces developed, tested and deployed in the GDI**, covering needs of users from research, healthcare and public health policy*
- ***Citizens' portal**, allowing at least management of GDPR rights of citizens and citizens' engagement, to be established and operational at month 12 at the latest.*

### Targeted stakeholders

The consortium can include public and private entities such as (but not limited to):

- *Public administrations (national, regional and local level)*
- *Hospitals*
- *Research institutes, research agencies*
- *Research infrastructures*
- *Biobanks*
- *EDICs – European Digital Infrastructure Consortia*
- *HDABs – Health Data Access Bodies*



# DIGITAL EUROPE PROGRAMME

## DIGITAL-2026-AI-09-DS-HEALTH-STORAGE:

*Data ingestion capacities and data services for the European Genomic Data Infrastructure in the European Health Data Space: data storage and processing capacity*







# DIGITAL EUROPE PROGRAMME

## DIGITAL-2026-AI-09-DS-HEALTH-STORAGE

**Indicative budget:** EUR 17,5 million (grant for procurement, 50% funding)

**Call identifier:** [DIGITAL-2026-AI-09-DS-HEALTH-STORAGE](#)

**Indicative duration of the action:** 48 months

### Objective

*to boost the capacity of Member States to sequence human genomes through scaling up dedicated secure data storage and processing environments*



# DIGITAL EUROPE PROGRAMME

## DIGITAL-2026-AI-09-DS-HEALTH-TOOLS

### Activities

- *Development of a **data storage optimization strategy** for the 1+MG data infrastructure, including the most appropriate **data storage architecture, storage technology and legal aspects**. The strategy should ensure scalability and balance costs and data depth / breadth / versioning*
- ***Procurement and set-up of a secure federated data storage and processing capacity** for the 1+MG data infrastructure. It should include “**hot storage**” **working in synergy with secure processing environments aligned with the EHDS requirements**, such as compliance checks for secure processing environments and detached long-term storage for curated data made available to the 1+MG by the data providers, including the Genome of Europe dataset.*



# DIGITAL EUROPE PROGRAMME

## DIGITAL-2026-AI-09-DS-HEALTH-STORAGE

### Outcomes & Deliverables

- *1+MG data storage strategy*
- *Secure federated data **storage and processing capacity** for the 1+MG data infrastructure*

### Targeted stakeholders

The consortium can include public and private entities such as (but not limited to):

- *Public administrations (national, regional and local level)*
- *Hospitals*
- *Research institutes, research agencies*
- *Research infrastructures*
- *Biobanks*
- *EDICs – European Digital Infrastructure Consortia*




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 Passcode: **j4ga4c**





# *Restricted calls – available guidance and main aspects*



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# *Restricted calls (focus on DEP Article 12.6)*



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# Legal basis for restricted calls

## Legal basis: Digital Europe Programme Regulation, Art. 12(6):

- ✓ Procedures include an Ownership control assessment of participants followed by submission of guarantees, where envisaged

**Calls subject to such restrictions and the precise conditions for each call are set out, in the Work Programmes published on the Funding & Tenders Portal.**

### DEP Work Programme level

- ✓ Indicated in the topic description + justification
- ✓ *9.3 Appendix 3 – Implementation of Article 12(5) and 12(6)*

### DEP call documents

- ✓ Indicated in the specific topic conditions
- ✓ Indicated in *Section 6 Eligibility*
- ✓ *Annex 2 Eligibility restrictions under Articles 12(5) and (6) and 18(4) of the Digital Europe Regulation*



# Guidance documents restricted calls

## Funding and Tenders portal:



### EU Grants

Participation in Digital Europe Programme (DEP), Horizon Europe (HE) and European Defence Fund (EDF) restricted calls

Version 0.1 — DRAFT  
20 December 2021

■ *Participation in Digital Europe Programme (DEP), Horizon Europe (HE) and European Defence Fund (EDF) restricted calls – corporate guidance published on 22 December 2021 in the F&T Portal*

■ Corporate templates – Ownership control declaration and Guarantee template in the F&T Portal



# *High-risk suppliers*



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# High risks suppliers' restrictions in DEP

## **DEP WP 25-27 Appendix 4:** *Restrictions for the protection of European digital infrastructures, communication and information systems, and related supply chains*

- lays out the **applicable rules for the protection of strategic assets** and interests of the Union or its Member States, including the **EU Toolbox on 5G cybersecurity** in accordance with Article 136(2) of the Financial Regulation

Entities assessed as “high-risk suppliers”, are currently set out in:

- *Second report on Member States’ progress in implementing the EU toolbox on 5G cybersecurity of 2023;*
- *Related Commission Communication on the implementation of the 5G cybersecurity toolbox of 2023.*

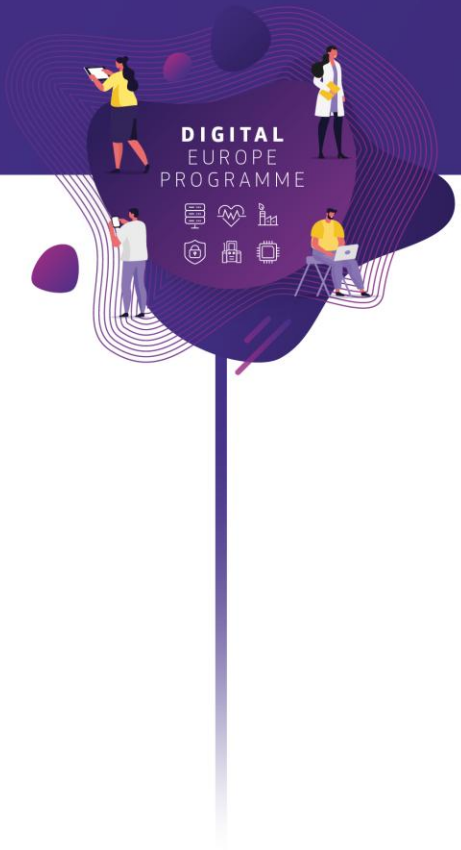


# High risks suppliers' restrictions in DEP

- Additional eligibility criteria apply under identified actions in the DEP WP 25-27 (all actions under DEP Article 12(6), all actions under Specific Objective 3 and additional actions listed in the Appendix 4):
  - Entities that are assessed as high-risk suppliers of mobile network communication equipment (and any entities they own or control) are not eligible to participate in any capacity (including e.g. subcontractors)
  - Introducing related cost/eligibility conditions regarding equipment and other goods, works and/or services (listed in the Appendix 4, such as cyber-security requirements)
- Practical implementation
  - Eligibility assessed at GAP
  - Risk-based approach



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**INFO DAY – Digital Health topics in Call 9**

**COFFEE BREAK**



## INFO DAY – Digital Health Topics in Call 9

*Deployment of cutting-edge multi-modal AI-based solutions in medical imaging*



CNECT- Unit A6  
*AI in Health and Life Science*

*Aleksandra.Wesolowska@ec.europa.eu*

**17 November 2025**

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# DIGITAL EUROPE PROGRAMME

## DIGITAL-2026-AI-09-AI-SOLUTIONS-CANCER-STEP Deployment of cutting-edge multi-modal AI-based solutions in medical imaging

**Maximum EU contribution:** EUR 14,4 million

**Type of action:** SME Support Action — 50% and 75% (for SMEs) funding rate

**Indicative duration of the action:** 48 months

**Restrictions:** Call restricted on the basis of Article 12(6) of the Regulation (EU) 2021/694

**Projects to be funded:** 1

**Consortium composition:** minimum 7 independent applicants (beneficiaries; not affiliated entities) from 7 different eligible countries

### Objective

*By building on, extending and leveraging the [Cancer Image Europe](#) platform, this action is expected to facilitate the uptake of EU AI-driven solutions in medical imaging (including Machine Learning and Generative AI), towards their deployment in clinical settings.*



## Objectives

- **Accelerate the uptake of EU AI-driven solutions** that are ready to be deployed in healthcare settings for patient care and for research purposes;
- Facilitate the **deployment of EU cutting-edge AI-driven solutions in medical imaging, combined with other health data**, for increased efficiency and better patient outcomes, **leveraging the Cancer Image Europe platform**;
- **Further develop the data, testing and validation services and user tools of Cancer Image Europe platform** in alignment with the legal and technical framework of the European Health Data Space, also towards supporting the development and uptake of EU cutting-edge multi-modal AI-based solutions in medical imaging for healthcare;
- Ensure **alignment and inter-operability of the Cancer Image Europe platform with the HealthData@EU infrastructure** of the EHDS;
- **Conduct multi-centre validation studies** of promising medical imaging-based and multi-modal AI solutions for screening, early detection, diagnosis and care, generating evidence for clinical utility and cost effectiveness of tested solutions.



## Scope – main elements

further development of **data, testing and validation services and user tools** of Cancer Image Europe

**interoperability of Cancer Image Europe with other health data infrastructures and with the HealthData@EU infrastructure** of the European Health Data Space (EHDS);

**multi-centre validation studies** of promising medical imaging-based and multi-modal AI solutions; **evidence generation**

appropriate involvement of and collaboration between **SMEs from the medtech sector and healthcare providing organisations**

### Outcomes & Deliverables

- **New data services and user tools for the Cancer Image Europe platform** covering data curation / inclusion by data providers, data quality assurance and compliance checks, and risk/security management in alignment with agreed standards, procedures and requirements, including the framework of the European Health Data Space.
- **Multi-centre validation of AI-driven solutions in the field of medical imaging**, including also evidence generation for clinical utility and cost efficiency.
- **Deployment of multi-modal, cutting-edge AI-driven solutions in the field of medical imaging in healthcare and research** settings, leveraging different types of data
- Training and upskilling of medical imaging personnel and/or healthcare professionals for the deployed technology and further use.



## KPIs

- Number of **tools, APIs and interfaces developed, tested and deployed** in the Cancer Image Europe platform, covering well documented needs of users from research, healthcare and Medtech companies and SMEs
- **Number of organisations which use the Cancer Image Europe platform** for working with imaging data: at least 60 organisations from at least 15 EU Member States
- **Number of Medtech companies and SMEs who have used the Cancer Image Europe platform** for developing, testing or validating AI solutions: at least 30 by project end
- **Number of multi-modal AI models deployed in research settings** for which clinical utility has been assessed in multi-centre studies
- **Number of software as medical device (SaMD) solutions** for which the **process of regulatory approval has been initiated** and where the Cancer Image Europe platform has supported the clinical validation/evidence generation
- **Number of AI solutions deployed/piloted in healthcare settings/healthcare organisations**

Additional KPIs should be proposed by applicants in the project proposal as appropriate.





## Targeted stakeholders

- Hospitals and outpatient clinics (both public and private),
- healthcare research institutions (e.g. university departments providing patient care and conducting clinical trials),
- relevant Member States authorities (e.g. ministries of health, regional health authorities, Health Data Access Bodies, ...),
- AI developers e.g. MedTech companies (especially SMEs) applying together with healthcare providers (hospitals/ outpatient clinics),
- European Digital Infrastructure Consortia (EDIC).



## Background documents:

- EUCAIM [public deliverables](#) and [platform documentation](#).

## Relevant EU policies:

- Europe's Beating Cancer Plan, in particular [European Cancer Imaging Initiative](#), [Apply AI strategy](#), data labs within the [AI Factories](#), [EU Life Sciences Strategy](#)
- Implementation of EU legislation: EHDS Regulation and AI Act

## Projects to consider / synergies:

- EUCAIM, GDI, UNCAN-CONNECT, CANDLE, TEF-Health and other projects mentioned in the call text or contributing to the European Cancer Imaging Initiative; encouraged also for the relevant projects beyond this list



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DIGITAL-2026-AI-09-AI-SOLUTIONS-CANCER-STEP

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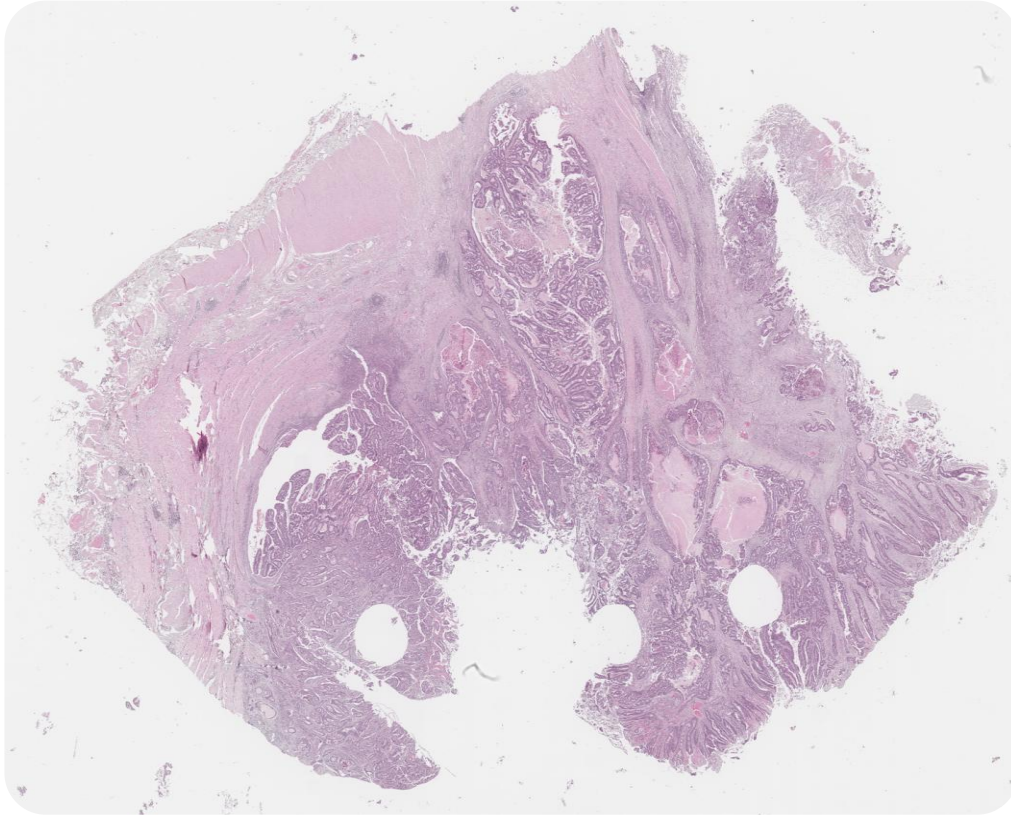
## INFO DAY – Digital Health topics in Call 9 Pitching session

Name	Organisation
Hanne Askautrud	Institute for Cancer Genetics and Informatics
Alfred Attipoe	Comunicare Solutions
Francesca Pia Caputo	University of Pisa
Francisco Javier Díez	Universidad Nacional de Educación a Distancia (UNED)
Lucas Antonio Díez Martínez	Avamed Synergy
María González-López	Virgen del Rocío University Hospital
Peter Gordebeke	European Institute for Biomedical Imaging Research
Yiannis Roussakis	German Medical Institute
Lorenzo Tumminello	Kode
Hannah van Kolfschooten	University of Basel



# DoMore-v1-CRC: a digital pathology marker for patient outcome prediction in high risk stage II and stage III colorectal cancer

Several factors determine a tumor's malignancy potential and patient drug benefit



Lancet. 2020 Feb 1;395(10221):350-360

- Genomic profile

*The focus until now*

- Epigenetics

*Deep tumor analysis with AI*

- Tissue patterns

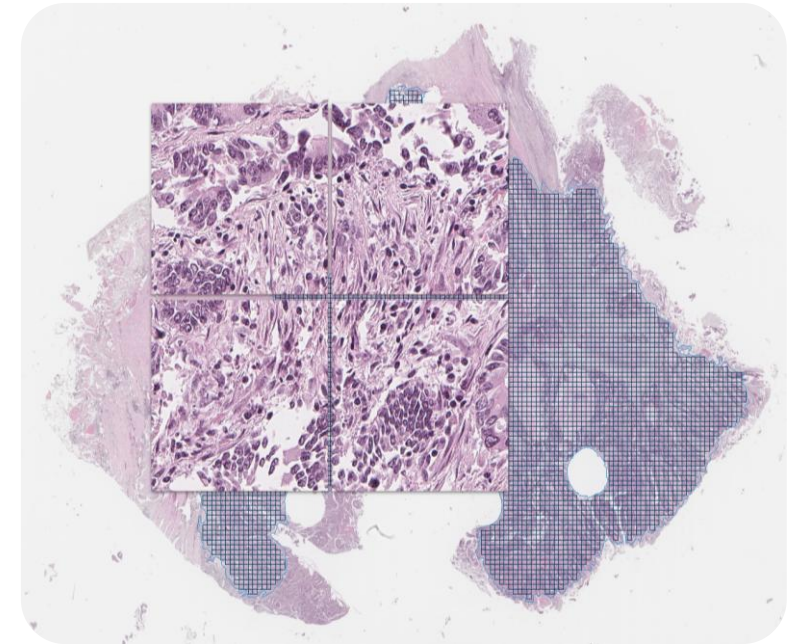
- Stroma

- Heterogeneity

- Microenvironment

- Tumor plasticity

- +++



Institute for  
Cancer Genetics and Informatics



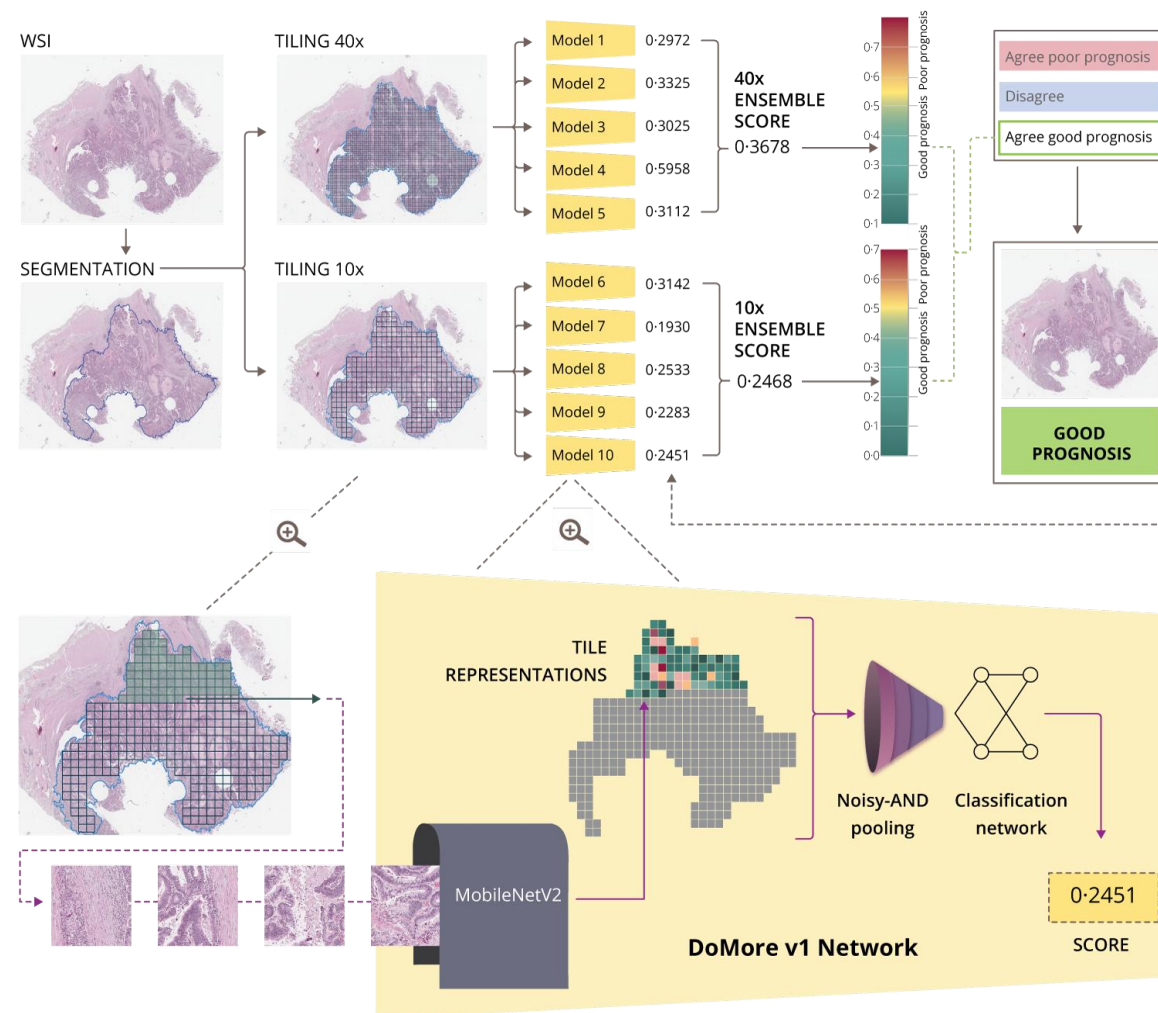
Contact: [hanne@icgi.no](mailto:hanne@icgi.no)



# DoMore-v1-CRC: a digital pathology marker for patient outcome prediction in high risk stage II and stage III colorectal cancer

## THE HISTOTYPE PX ALGORITHM

- Utilizes digital whole slide images (WSI)
- Automated segmentation of tumor area
- Analyzes tumor in 10x and 40x resolution
- Scoring the tumor: Ensemble of ten models
- Classification of prognosis



# DoMore-v1-CRC: a digital pathology marker for patient outcome prediction in high risk stage II and stage III colorectal cancer



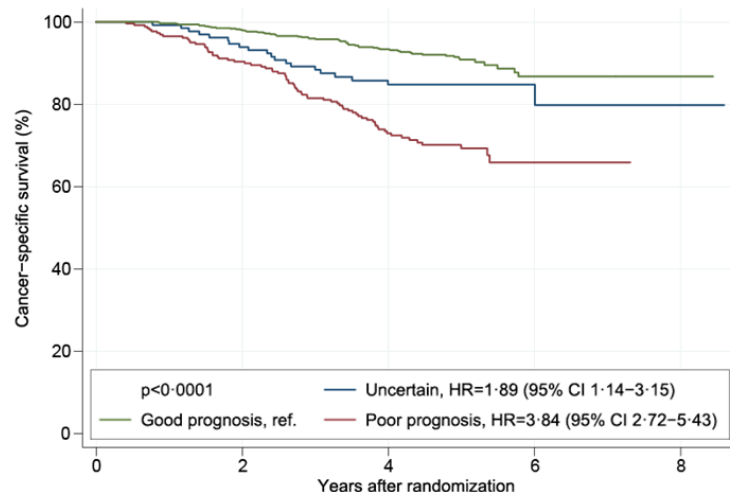
## Deep learning for prediction of colorectal cancer outcome: a discovery and validation study

Ole-Johan Skrede\*, Sepp De Raedt\*, Andreas Kleppe, Tarjei S Hveem, Knut Liestøl, John Maddison, Hanne A Askautrud, Manohar Pradhan, John Arne Nesheim, Fritz Albrechtsen, Inger Nina Farstad, Enric Domingo, David N Church, Arild Nesbakken, Neil A Shepherd, Ian Tomlinson, Rachel Kerr, Marco Novelli, David J Kerr, Håvard E Danielsen

### Summary

**Background** Improved markers of prognosis are needed to stratify patients with early-stage colorectal cancer to refine selection of adjuvant therapy. The aim of the present study was to develop a biomarker of patient outcome after primary colorectal cancer resection by directly analysing scanned conventional haematoxylin and eosin stained sections using deep learning.

Lancet 2020; 395: 350–60  
See Comment page 314  
\*Contributed equally  
Institute for Cancer Genetics and Informatics



Number at risk (number of events)

Good prognosis	704	(13)	659	(29)	492	(15)	71	(0)	1
Uncertain	136	(8)	121	(11)	87	(0)	17	(1)	1
Poor prognosis	270	(25)	228	(41)	151	(8)	26	(0)	0



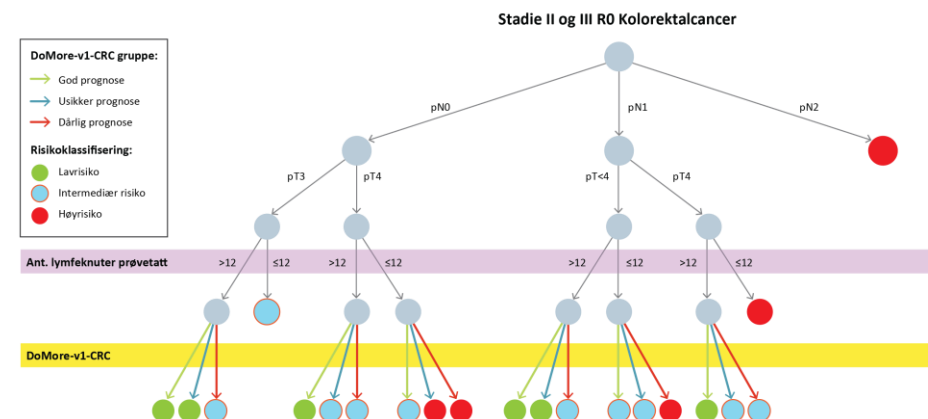
## A clinical decision support system optimising adjuvant chemotherapy for colorectal cancers by integrating deep learning and pathological staging markers: a development and validation study

Andreas Kleppe, Ole-Johan Skrede, Sepp De Raedt, Tarjei S Hveem, Hanne A Askautrud, Jørn E Jacobsen, David N Church, Arild Nesbakken, Neil A Shepherd, Marco Novelli, Rachel Kerr, Knut Liestøl, David J Kerr, Håvard E Danielsen

### Summary

**Background** The DoMore-v1-CRC marker was recently developed using deep learning and conventional haematoxylin and eosin-stained tissue sections, and was observed to outperform established molecular and morphological markers of patient outcome after primary colorectal cancer resection. The aim of the present study was to develop a clinical decision support system based on DoMore-v1-CRC and pathological staging markers to facilitate individualised selection of adjuvant treatment.

Lancet Oncol 2022  
Published Online  
August 11, 2022  
[https://doi.org/10.1016/S1473-2045\(22\)00391-6](https://doi.org/10.1016/S1473-2045(22)00391-6)  
Institute for Cancer Genetics and Informatics (A Kleppe PhD).





Alfred Attipoe  
CEO  
[a.attipoe@comunicare.be](mailto:a.attipoe@comunicare.be)

# Who are we?

Comunicare Solutions SA, public limited company incorporated in 2017, a **spin-off** of the **Université de Liège**, was born from the **experience of patients** and **informal care givers** in the context of **oncology**.

The company is supported by:

- Private and institutional investors (**ULiège**, **Noshaq**, **Leansquare**, **Benelux Health Ventures**)
- Grants from **Solidaris**, **Wallonia region**, **European Commission**
- The expertise of **Precision Medicine** specialists from the **University of Maastricht**
- A highly involved international **Scientific Advisory Board (SAB)**
- **A multidisciplinary staff** of 12 employees that includes Software Developers, Data Scientists and Healthcare Professionals

Our mission is to develop digital solutions for **patient empowerment**, **self-management**, and **shared decision making**



**Alfred Attipoe**  
**CEO**  
**Technology & Operations**



**Brice Van Eeckhout**  
**CEO**  
**Business Development**



**Bruno Le Marchand**  
**Advisor**



**Philippe de Broqueville**  
**Board member**  
ex Partner à Degroof  
Petercam



**Laurence Rosa**  
**Member of the board**  
Noshaq



**Etienne Defalque**  
**Chairman of the board**  
Ex SEMA., ACSE,  
Software AG



**Pr. Philippe Lambin**  
**Member of SAB**  
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(U Maastricht)

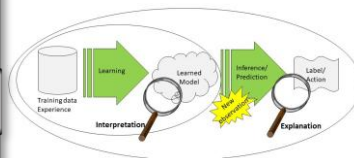
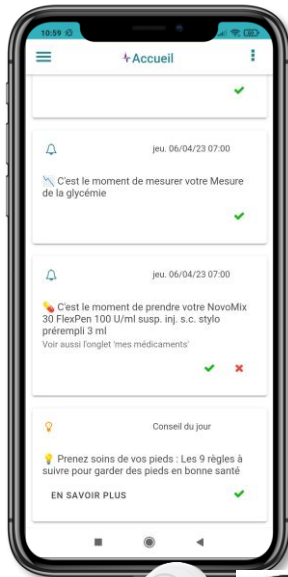
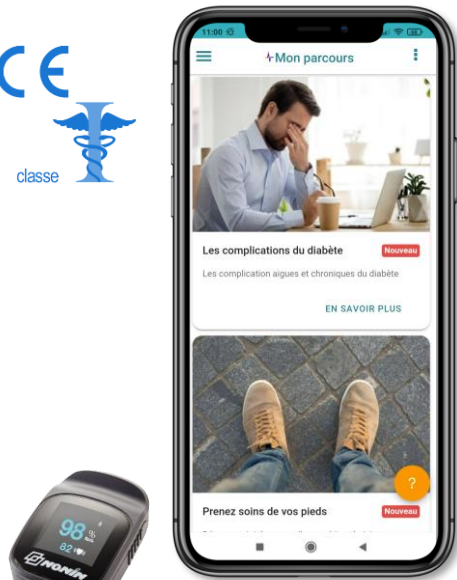


**Pr. Michel Dumontier**  
**Member of SAB**  
Professor of Data  
Sciences & co-founder of  
FAIR data principles

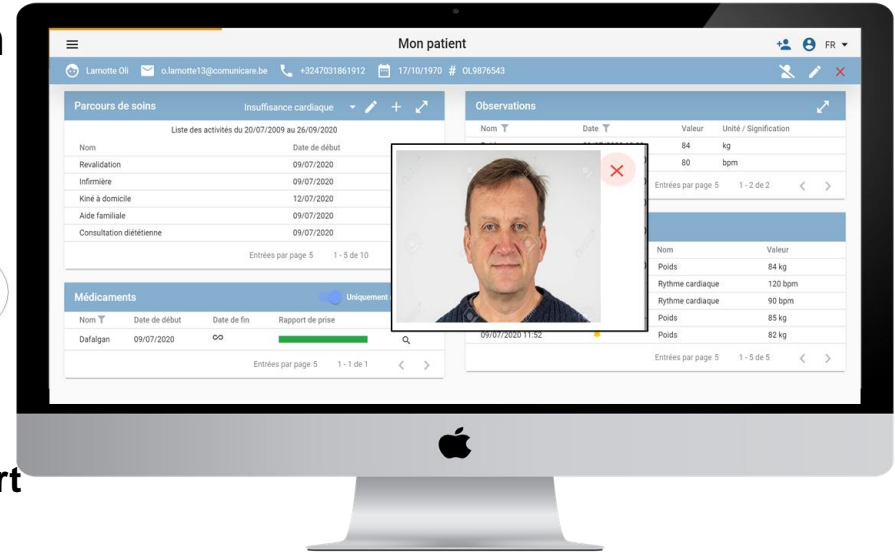


# Supporting Chronic Care and Home Care

A **mobile app** for the patient and his relatives: personalized education (therapy, side effects, recommendations), symptoms and QOL questionnaires, medication compliance, integrated with connected devices



AI-enabled  
&  
multi-omics support



A **platform** to collect and analyse the patient outcomes and a dashboard for the care givers: to enable preventing risk situations and provide means for measuring the quality of the therapy

COMUNICARE





# Collaborative R&D programs



Rapid and secure AI imaging based diagnosis, stratification, follow-up, and preparedness for coronavirus pandemics



Collaborative framework through which regulatory authorities, software developers, healthcare professionals and policy offers can jointly create and evaluate innovative AI-based medical device software



**BRAIN CARE**

Transforming patient care with BrainN20-PRO: a novel AI-powered device to transform the diagnosis, management and outcome of Subarachnoid Hemorrhage (SAH)



Building the EUropean Cancer Information Portals (EU-CiPs) which will provide reliable and easy-to-access cancer information for citizens in Europe.



First European platform to offer citizens a secure vault for DNA storage and risk profiling for complex common diseases and certain rare diseases.



Creating strategic biomarkers for the positioning of new drugs targeting RNA epitranscriptomics for cancer treatment





Università di Pisa

*Department Of Translational Research And Of New Surgical And Medical  
Technologies*

# IMAGING-LAB

Francesca Pia Caputo

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# OUR TEAM



Prof. Emanuele Neri

Chair of the Radiology Unit, S. Chiara



Prof.ssa Dania Cioni

Radiologist



Prof. Riccardo Lencioni

Radiologist



Dott. Francesca Pia Caputo

Medical Physicist



Prof. Lorenzo Faggioni

Radiologist



Prof. Giovanni Donato Aquaro

Radiologist



Dott. Giacomo Aringhieri

Radiologist



Dott. Chiara Romei

Radiologist



Dott. Salvatore Claudio Fanni

Radiologist



Dott. Gayane Aghakhanyan

Nuclear medicine doctor



Dott. Roberto Francischello

Physicist



Dott. Valentina Formica

Data Analyst

# OUR ACTIVITIES

## European Projects

We are part of AIH4 European Project Consortium (PRIMAGE, CHAIMELON, EuCanImage, Procancer-I) and EUCAIM.

Our main activities relies on:

- **Data Providers** for cancer cases;
- Technical activities for **AI Tools**;
- Project **Sustainability frameworks**
- lately coordination of the EUCAIM **legal and ethical training**

or users

- NICI project



## Italian National Projects

- **Leader** of the Tuscany Region project NAVIGATOR to create an Italian imaging repository for rectum, gastric and prostate cancer. Images have been collected together with clinical data to develop AI tool to promote cancer care and to help decision making processes.
- Involved in **national projects** such as HEALT ITALY-PE6 for colorectal cancer
- CALLIOPE project (heart disease)

## Local Research projects

- **Oncologic Imaging** (focus on colorectal cancer)
- **Muscular Sarcopenia**
- **Prostate** Imaging and disease detection
- **Natural Language Processing** for the automated conversion of free-form into structured reporting
- **Heart (CALLIOPE project)** and **Lung Project (ITALUNG project)**
- **Colorectal focus!**

*We are open to collaborations and networking!*



THANK YOU AND CONTACT US! E-mail: [francesca.caputo@med.unipi.it](mailto:francesca.caputo@med.unipi.it); [emanuele.neri@unipi.it](mailto:emanuele.neri@unipi.it)

# Cost-effective personalised breast cancer detection

**Francisco Javier Díez**

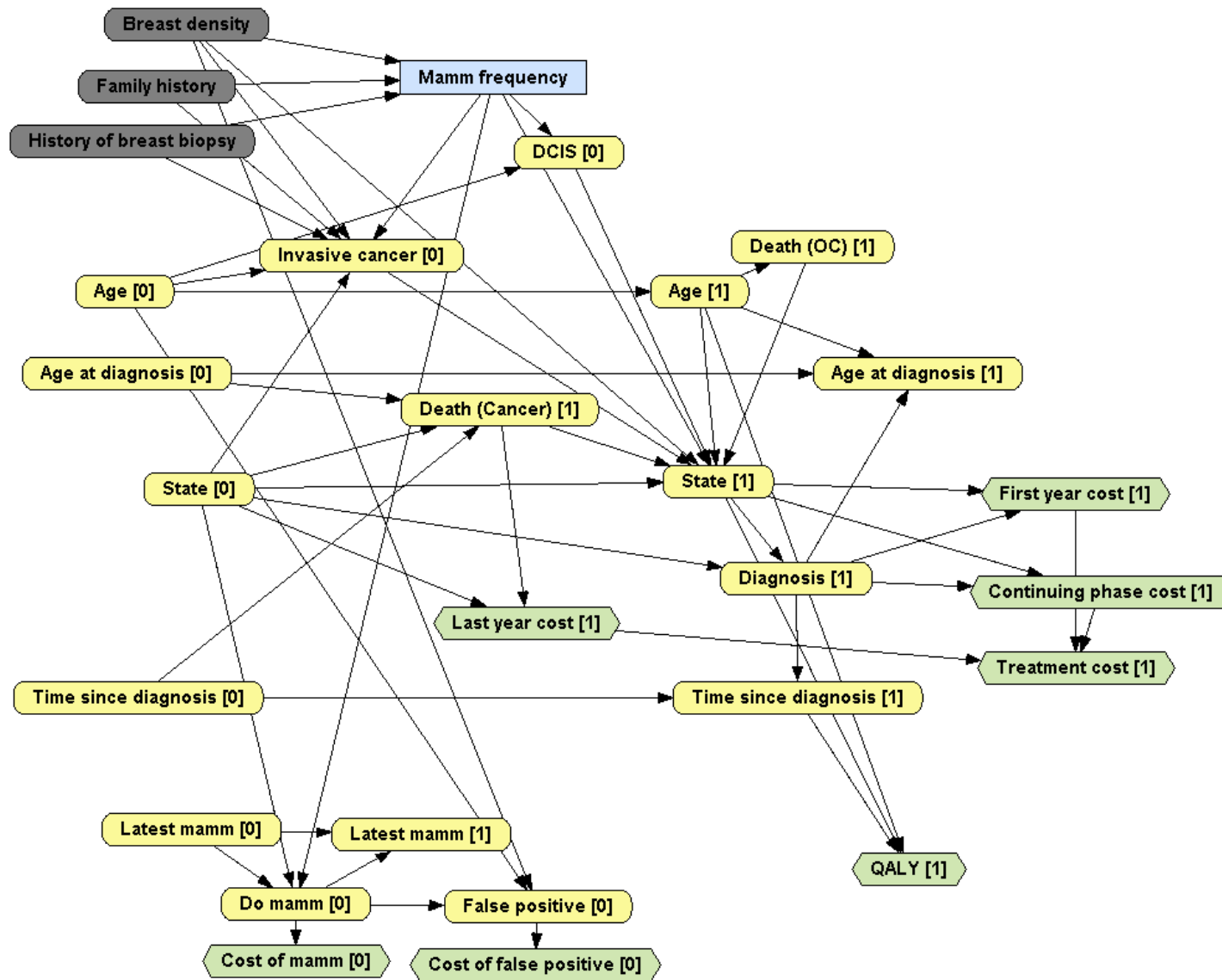
Dept. Artificial Intelligence, UNED, Madrid, Spain

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- Our goal
  - Screening:  
determining the optimal **interval** and the optimal imaging techniques
  - Diagnosis:  
deciding which **sequence of tests** to do in each case
  - **Personalised** for each woman, depending on:  
age, breast density, personal and familiar antecedents, genetic information...
  - Considering both **effectiveness** (duration and quality of life) and economic **cost**.



# A Markov influence diagram for breast cancer screening



- Built with OpenMarkov in Iñigo Bermejo's [PhD thesis](#)
  - Loosely based on ([Schousboe et al., 2011](#))
- We intend to extend it to more risk factors and more imaging techniques
- References about probabilistic graphical models for cost-effectiveness analysis:
  - [Markov influence diagrams](#)
  - [Decision analysis networks](#)
  - [CEA with unordered decisions](#)
  - [Discrete event simulation nets](#)
- Have a look at [our project](#).

# What makes us different from other research groups

- Expertise on both **cost-effectiveness analysis** with AI models and **breast cancer imaging** with deep learning
- Collaboration with low- and middle-income countries (**LMICs**)
- Our model intends to include **all imaging techniques**
  - ultrasound, mammography (DM, DBT, CEM...), MRI...

considering that

- some imaging techniques and treatments are not available in all settings
- sensitivity and specificity vary significantly  
(e.g., accuracy of mammography depends on breast density)
- economic costs must be explicitly taken into account
- willingness to pay (WTP) differs among countries and regions.

# Avamed Synergy: Approximation to the problem

In more than **30%** of treatments, the tumor **generates resistance** to it ...  
In **17%** of cases, the tumor **even grows**



## Consequences to patient

**1** 28% - 44% of diagnoses are usually late and **incorrect**, and even 1 in 4 patients receive initial treatment for another pathology



**2** In 72% of cases, **treatment** is not **optimized** for the patient. We cannot forget that **what kills** the cancer patient is the **resistance** of the cells to the treatment



**3** Excessive doses and prolonged treatments result in **chronic** diseases for 42% of patients



How and why do **neoplastic cells** change?



How do they get **rid of target drugs** and learn to survive?



**Resistance** is independent of the locations of the metastases.

**"Is more dependent on the characteristics of the tumor".**

**Cancer cells** are very different from one **tumor to another** and **different in each patient**.



Chief Executive Order

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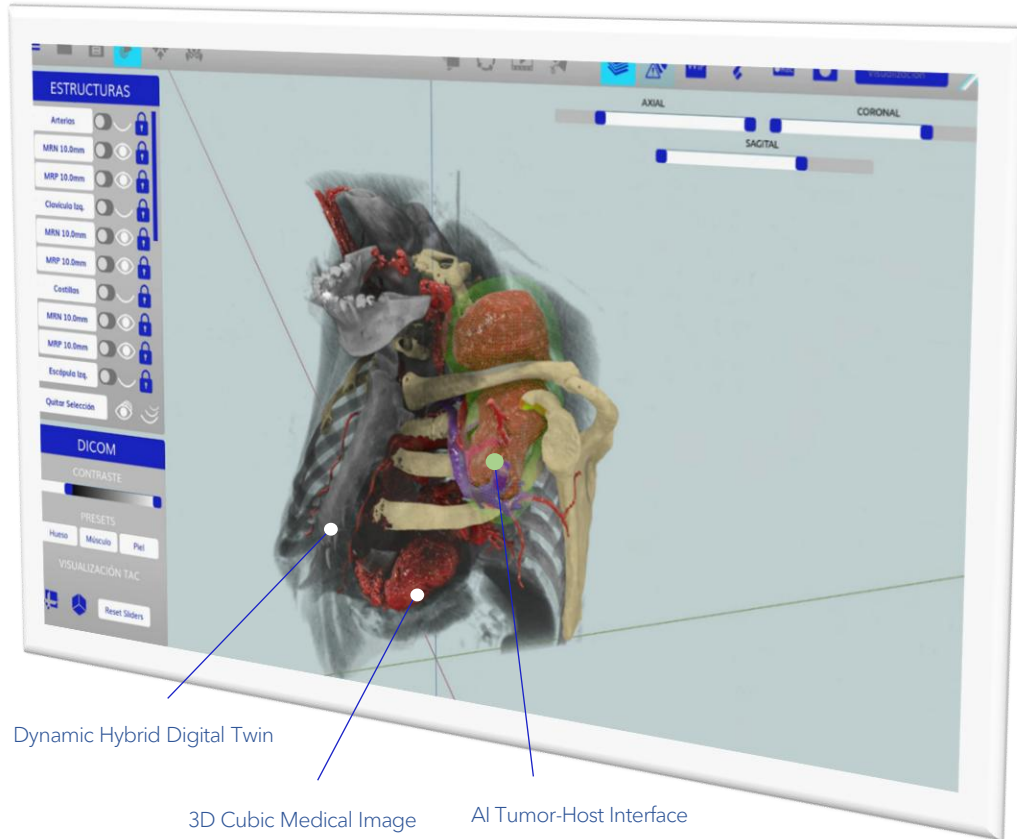
Cancer, the 1st cause of death in the world



Fluxus is a registered and protected brand by Avamed Synergy

# Solution

(USP) Unique AI tumor-host interface  
by Dynamic Hybrid Digital Twin



Advance the real from the digital

AI *fluxus* is the only clinical software that allows  
analyzing tumor growth and responses to treatments



## BENEFITS FOR ONCOLOGISTS

According to the results of our clinical trials (non-public medical study), Fluxus reduces false negatives by 95%, improves the effectiveness of the treatment strategy by 70% and helps avoid overdoses and excessive treatment times.



## BENEFITS FOR PATIENTS

Our studies estimate that in the next 10 to 15 years our technology will be able to reduce overdoses and excessive treatments by 80%, avoiding chronic diseases.



## BENEFITS FOR SOCIETY

Fluxus reduces surgical costs by 12% and overall costs by 29%, through more efficient and precise treatments. It also optimizes healthcare resources by allowing imaging equipment, such as MRI scanners, to be more available for other critical needs, improving the overall delivery of healthcare services.



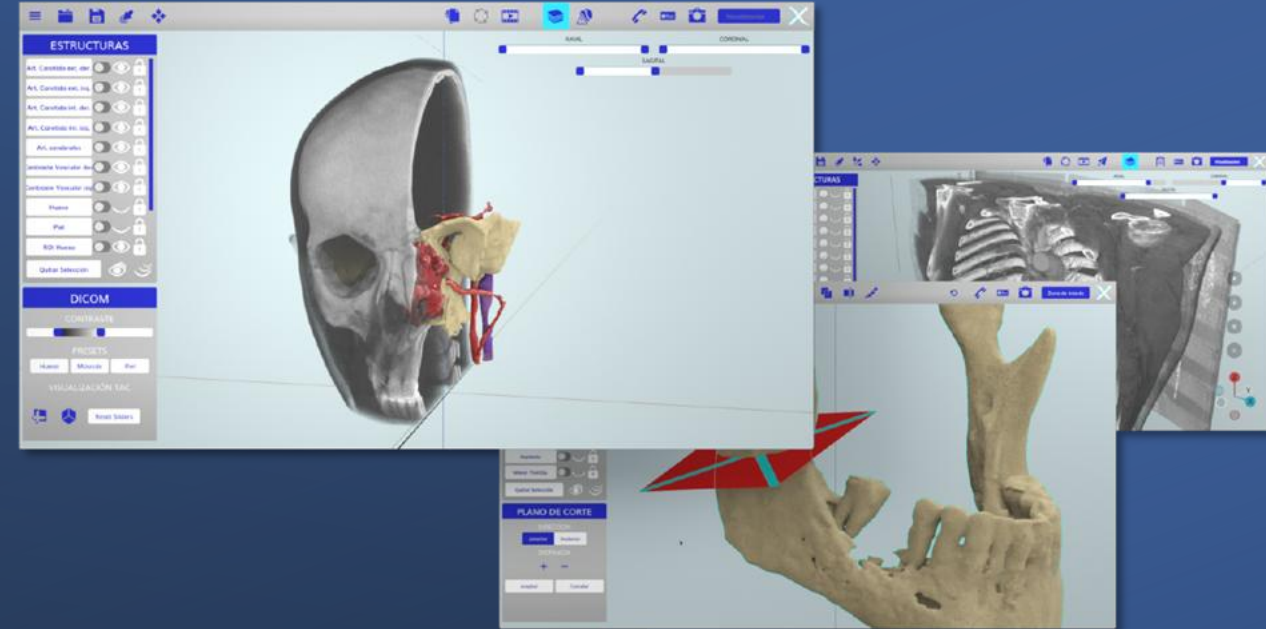
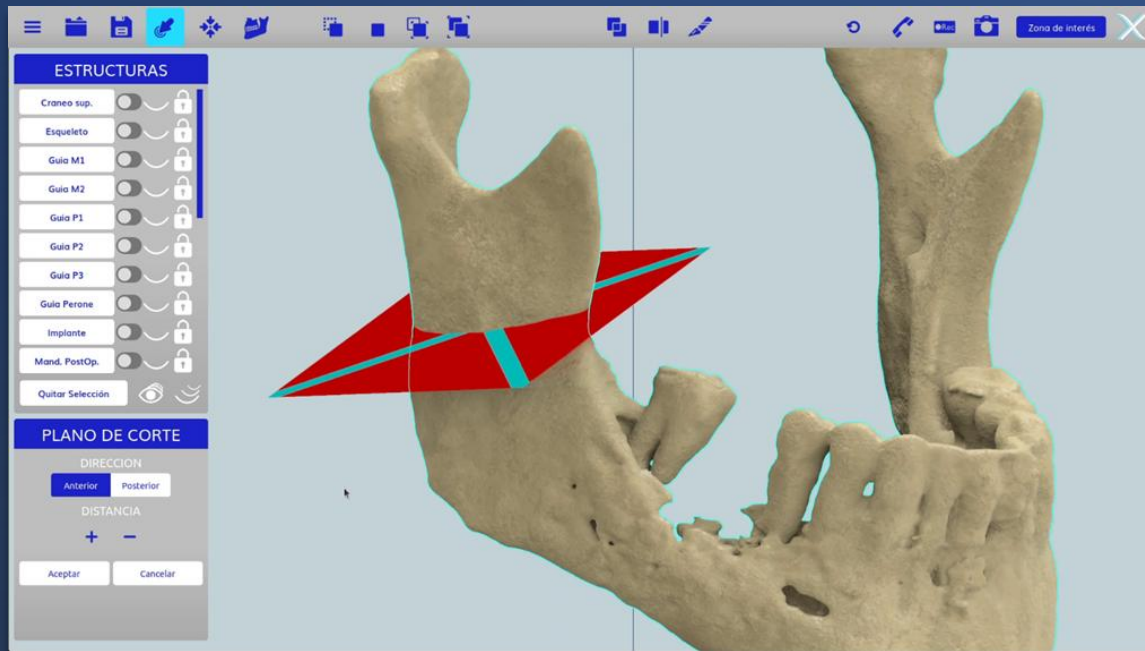
## BENEFITS FOR SURGEONS

Fluxus allows surgeons to rehearse complex surgeries, reducing surgical time by up to 30% and reducing non-tumor tissue resections by 15%. This leads to fewer postoperative complications and better outcomes for patients.



(USP) AI tumor-host interface  
by Dynamic Hybrid Digital Twin

Advance the real from the digital



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# Virgen del Rocío University Hospital



**Oncology Population → 800.000**

## Pathology

- New diagnosis 2024: 9.984
- NGS performed 2024: 1.120

## Radiology

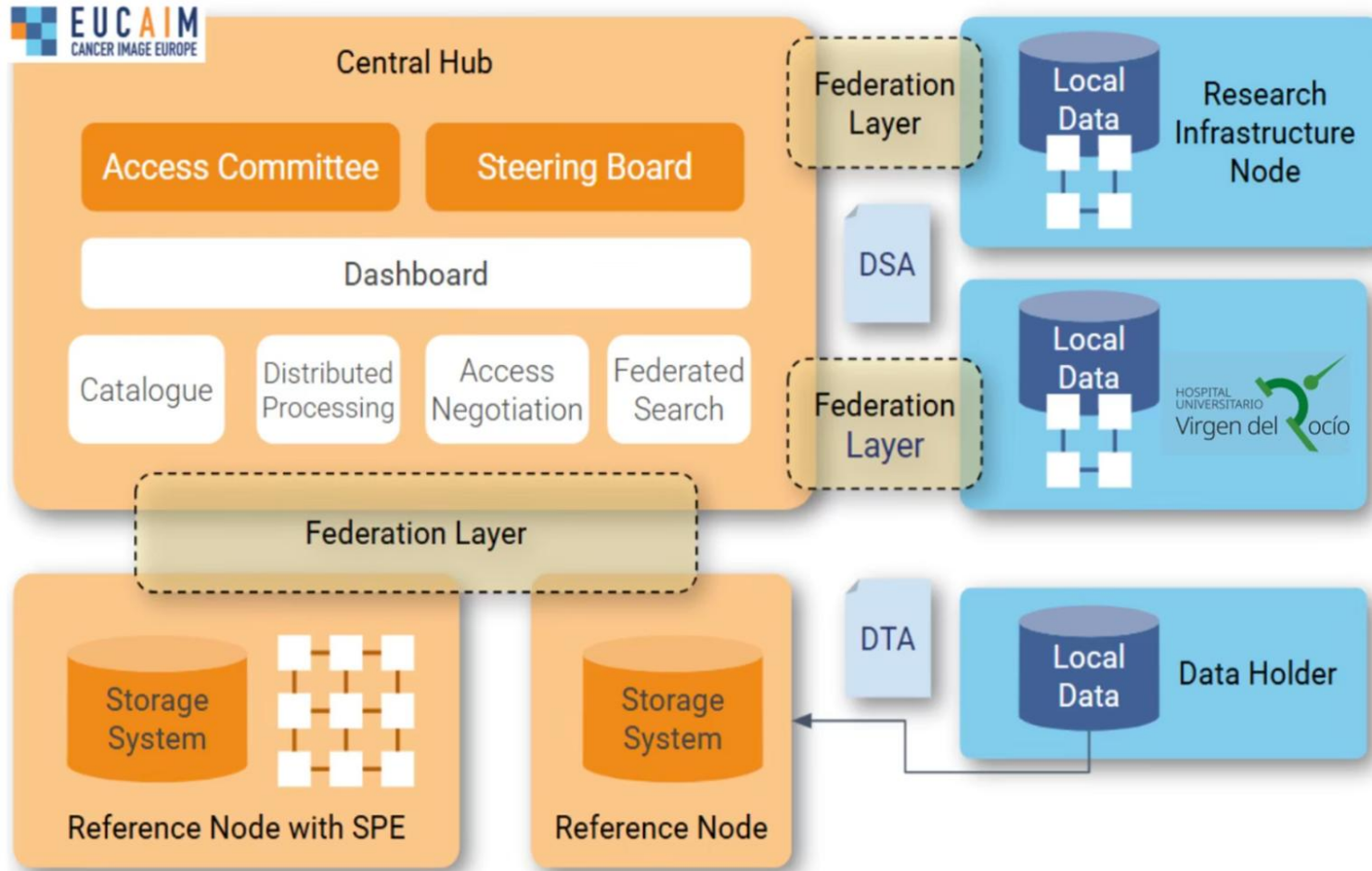
Interventional Procedures with US/MG/CT in 2024

- Core Needle Biopsy (CNB): 2.014
- Radiopaque Marker: 1.516
- Breat Hookwire Localization: 322

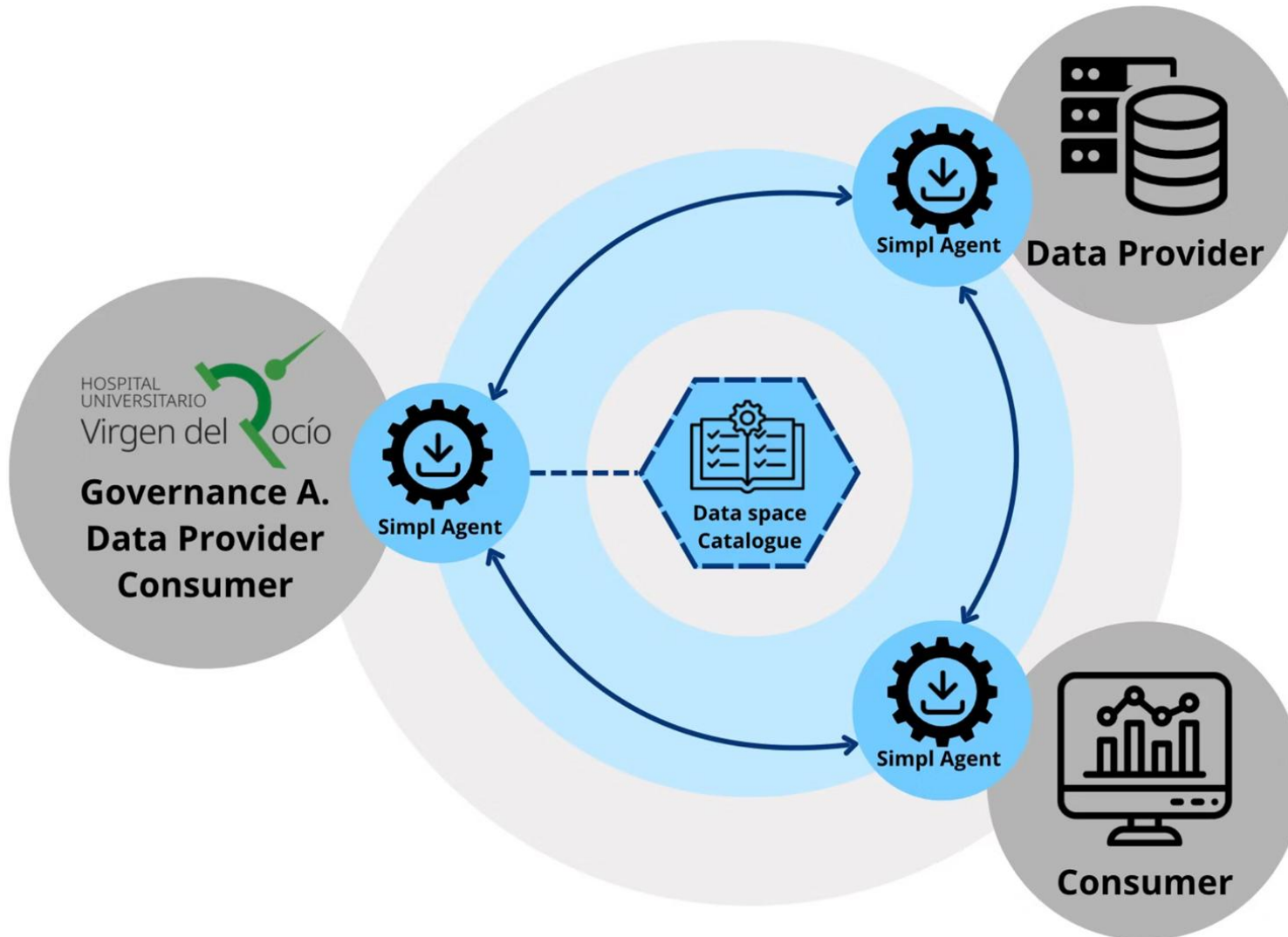
## Nuclear Medicines

- Nº non-PET Studies in 2024: 9.073
- Nº PET studies in 2024: 7.294
- Nº Cancer treatments: 316

# Data Holder EUCAIM



# SIMPL



Data Space using Simpl-Open



*PITCH FOR DIGITAL-2026-AI-09*

# ACCELERATING DEPLOYMENT OF AI IN CANCER IMAGING



## OUR GOAL

Validate European AI solutions in cancer imaging to high TRL for deployment in clinical settings

## FOUNDATION & ASSETS

The Cancer Image Europe platform (EUCAIM), evidence-based deployment guidelines (COMPASS-AI), foundation model from the Human Radiome Project

## THE ACTION

Bridging the gap from development to operational deployment and scaling

# OUR ACTION PLAN



## TRACK 1: AI Validation & Deployment

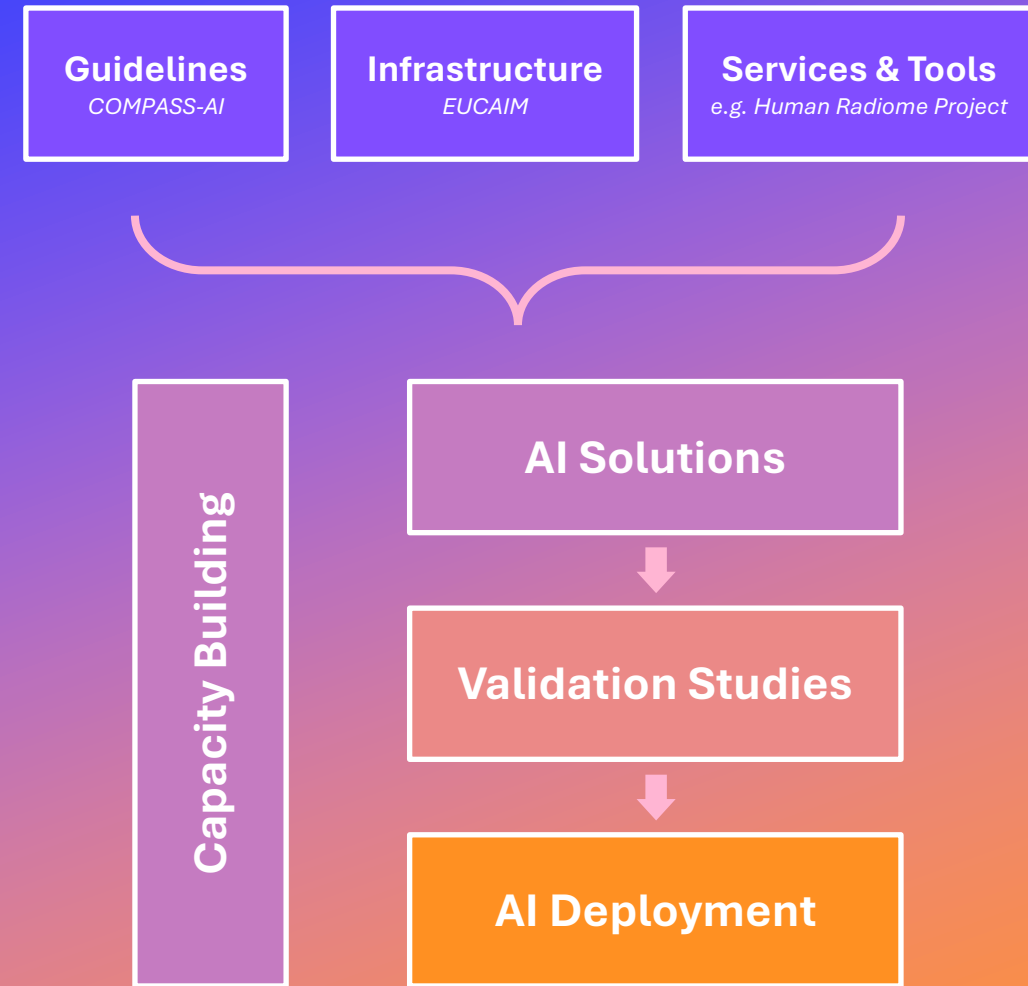
- Implement multi-centre validation studies for utility/effectiveness of developed EU AI solutions
  - Based on COMPASS-AI deployment guidelines
  - Using the Cancer Image Europe platform

## TRACK 2: Infrastructure & Sustainability

- Deploy new data services and tools for researchers and innovators on Cancer Image Europe (e.g. *Human Radiome Project*)

## TRACK 3: Capacity & Trust Building

- Scale up capacity building for end-users
- Extend policy and regulatory advocacy via deployment evidence and lessons learned





# OUR PLANNED OUTCOMES



1. Validated AI solutions initiating regulatory approval and improved healthcare decision for European patients
2. Increased capacity and trust in AI among EU healthcare professionals
3. Enhanced sustainability of Cancer Image Europe EDIC

We invite **SMEs & partnering clinical sites** to reach out to explore collaboration opportunities



# German Medical Institute (GMI)

## German Oncology Center (GOC)

Yiannis Roussakis, PhD

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[Yiannis.Roussakis@goc.com.cy](mailto:Yiannis.Roussakis@goc.com.cy)





# German Medical Institute – [gmi.com.cy](http://gmi.com.cy)

Departments include

Anesthesiology &  
Perioperative Medicine

Cardiac Surgery

Cardiology

General Internal Medicine

General Thoracic Surgery

Medical Oncology

Dermatology

Diagnostic &  
Interventional Radiology

Endocrinology

Medical Physics

Nephrology

Neurology

Gastroenterology

General Surgery

Gynaecology

Neurosurgery

Nuclear Medicine

Pain Clinic

Otorhinolaryngology

Oral, Maxillofacial and  
Head/Neck

Haematology and  
Transplantation

Plastic Surgery

Pulmonology

Radiation Oncology

Histopathology-Cytology

Infectious Diseases

Intensive Care Unit

Trauma & Orthopaedics

Urology

Vascular Surgery

# Interests

## Main Research interests

- Translation of new digital health technology in clinical practice
  - AI for cure and care applications
  - Wearables, medical devices, m-health, e-health, etc
- R&D of novel digital health technology
  - AI, GenAI, Federated learning
  - Digital Twins
  - Wearables, medical devices, m-health, e-health, etc
- Clinical trials
  - Utilising digital technology
  - Classic prospective clinical trials
- Health data
  - Ecosystems (EUCAIM, UNCAN.eu, etc)
  - Exchange (European EHR Exchange format, etc)

# Project Experience

## Selected funded projects we participate(d)

- EUCAIM (€36M) – [cancerimage.eu](https://cancerimage.eu)
- INCISIVE (€10M) – [incisive-project.eu](https://incisive-project.eu)
- DIOPTRA (€15M) – [dioptra-project.eu](https://dioptra-project.eu)
- Agora 3.0 (€2.5M) – [agora3.com.cy](https://agora3.com.cy)
- DTRIP4H (12M) – [dtrip4h.eu](https://dtrip4h.eu)
- SEARCH (15M) – [ihi-search.eu](https://ihi-search.eu)
- UNCAN-Connect (€30M) – [uncan.eu](https://uncan.eu) / [linkedin.com/company/uncan-connect/about/](https://linkedin.com/company/uncan-connect/about/)
- *And >20 more*



# Kode in a nutshell



Kode is part-owned by EBWorld, a company specialized in developing solutions and services that support Telcos, Utilities, Public Administrations, and businesses in managing the lifecycle of networks and assets. Through EBW, Kode also brings the added value of AI to the infrastructure level.

## Locations



## Seniority

**10** years  
of experience

## Conferences

**22** conferences  
as speakers /  
posters

## Team

**20** people with  
data passion

## Scientific Papers

**+30**

## Interdisciplinarity

**13** different  
University  
degree

## Clients

**+75**



# What we do



## Industry 4.0

Better control of processes enables to maximize yield, reduce waste and optimize energy consumption.

Predictive Maintenance   Anomaly Detection   Virtual Sensors  
Zero Defects   Energy Saving



## Sports Analytics

Sports data tools to get your sport performances to the next level.

Injury Prevention   Scouting   Performance Optimization



## Healthcare

Imaging, biosensors, omics sciences, wearable sensors: where AI can help caregivers make the best decisions.

Omics Science   Wearable Sensors   Imaging



## Computer Vision

We are able to derive meaningful information from digital images and videos and take action on that information.

Object Detection   Quality Inspection   Recognition



## Chemoinformatics

We develop solutions to manage chemical data, and ML/AI tools to predict chemical and toxicological properties for R&D and regulatory purposes.

Food & Agriculture   Biosensors  
Pharma & Ecotoxicology



## Geospatial & Mobility

We design solutions where space matters through maps, satellite imagery and state of the art algorithms for geocomputation.

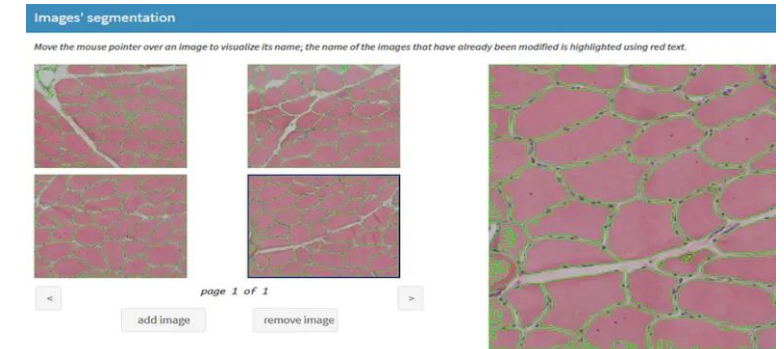
Environmental Analytics   Logistic & Mobility   Remote Sensing

# Portfolio Some Case Studies

## Stella Maris

### Muscular Biopsy Image Analysis

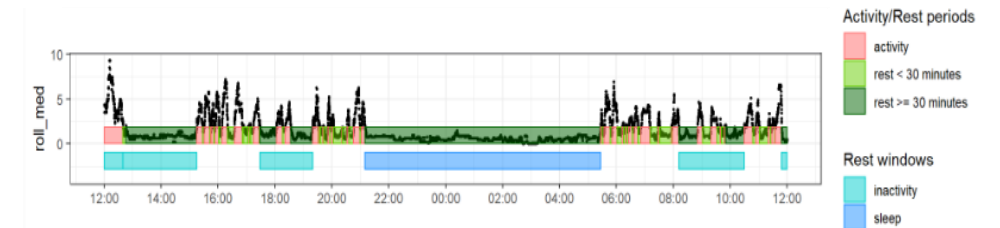
Development of an AI-powered software system to analyze **histological images** of skeletal muscle (stained with hematoxylin and eosin) and support physicians in detecting key disease patterns.



## SleepdetectoR

### Sleep detection from accelerometer data

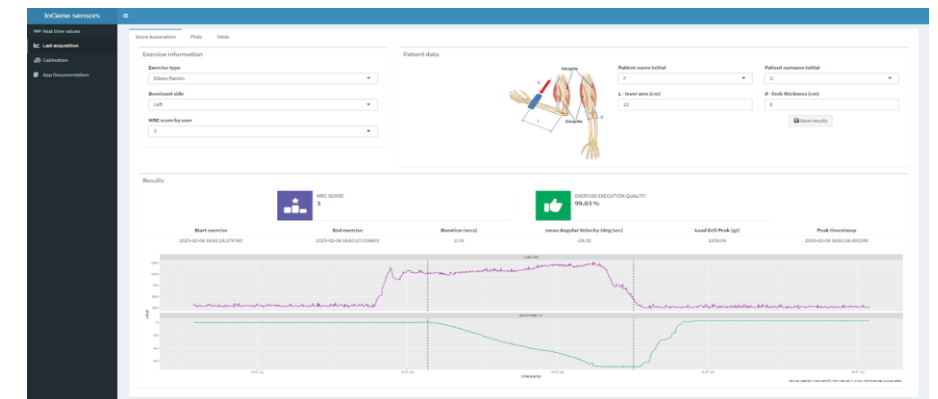
This project involved patients monitored for two weeks using sensors applied on the chest. Starting from raw accelerometer data, we reconstructed rest and activity periods during the whole day identifying the sleep period. As a result of this work an R package called **sleepdetectoR** was created and presented in a talk at e-Rum2020 conference.



## Ingene

### Objective movement evaluation

This project involved young patients with neuromuscular disease. The aim of the study was to objectify the assessment of muscle impairment carried out by the physiotherapist during the check-up visit.



*We are eager to connect and collaborate*



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Our Team	<i><a href="mailto:info@kode-solutions.net">info@kode-solutions.net</a></i>

# WP X: Legal, ethical & governance foundations for multi-modal AI in cancer imaging

Center for Life Sciences Law, University of Basel (CH)

## Why legal, ethical & policy expertise must be integrated early:

- Legal and ethical foundations build trust - and trust is essential for clinical uptake
- Unclear legal status under AI Act, MDR, EHDS, and GDPR
- Fragmented data governance and liability frameworks
- Limited clinician and patient trust

## Our aim:

Build the **legal, ethical, and governance backbone** that turns AI innovation into ethical, lawful, and safe medical technology.

# Our contribution to the consortium:

## Legal, ethical & governance foundations for AI

- **Legal and ethical analyses** of AI medical imaging systems within EU legal frameworks
- **Governance instruments** for human oversight, transparency, safety, and bias mitigation
- **Scholarly training modules** to build regulatory and ethical competence among researchers and clinicians

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Universität  
Basel

**ZLSR**

Centre for  
Life Sciences Law