Introduction to the
INCISIVE project

Gianna Tsakou

Senior PM/Senior Analyst

INCISIVE Coordinator

Improving cancer diagnosis and prediction with AI and big data

About

A multimodal **AI-based toolbox** and an **interoperable health imaging repository** for the empowerment of imaging analysis related to the **diagnosis**, **prediction** and **follow-up** of **cancer.**

Duration: 42 months

From October 2020 to March 2024

Call: H2020-SC1-FA-DTS-2019

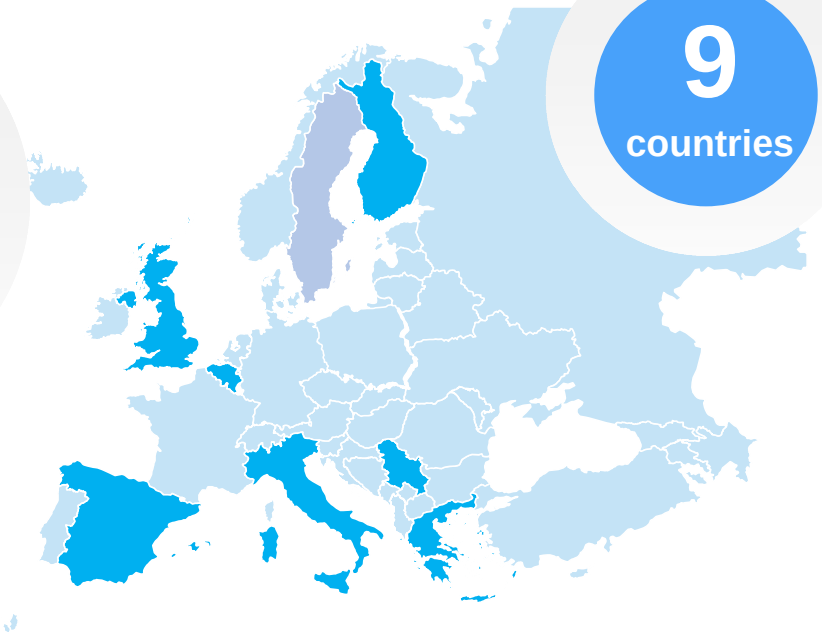
Topic: DT-TDS-05-2020 AI for Health Imaging

Funding: 9.995.727,50 €

This project has received funding from the European's Horizon 2020 research and innovation programme under Grant Agreement number: 952179

Our Consortium

26
partners



9
countries

- **9** Universities / Data providers
- **7** SMEs
- **6** Research / academic institutions
- **3** Large industries
- **2** Other

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Areas of expertise

AI for health imaging & data analytics

Security

High Performance Computing

Complex ICT systems/integration

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Areas of expertise

Cancer clinical research/practice & data sharing

German Oncology Center

Tor Vergata

IDIBAPS

ΕΛΛΗΝΙΚΗ ΑΝΤΙΚΑΡΚΙΝΙΚΗ ΕΤΑΙΡΕΙΑ
HELLENIC CANCER SOCIETY

VISARIS

Patient representation & evaluation

Cyprus University of Technology

PASYKAF

Kingston University London

Legal and ethical issues

TIMELEX

Innovation and business planning

WHITE RESEARCH

Medtronic
Further,Together

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Main objectives

AI-based toolbox that enhances the accuracy, specificity, sensitivity, interpretability and cost-effectiveness of existing cancer imaging methods

Interoperable pan-European **federated health data repository** (medical images & clinical data) that enables secure data sharing in compliance with ethical, legal and privacy requirements

TARGETED IMPACT ON:

- Healthcare professionals involved in cancer care
- AI developers
  AI experts
- Researchers

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Clinical & Tech pillars

4 cycles

Data collection

Retrospective/prospective data

- for AI training

Prospective data

- for AI training
- AI validation
- AI testing

AI Development

AI models' development in three iterations

AI toobox prototypes

First M18

M26

second M30

final M42

Infrastructure

Supports development and delivery of all services

Temporary infrastructure

- central data storage

Federated space

- distributed data storage

Hybrid infrastructure

- both central and distributed data nodes

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Obj. 1: AI toolbox

Development of AI services to meet clinical needs

	Necessary Features of the AI Toolbox	Nice to have Features of the AI toolbox
1.	Classifying abnormalities as malignant/benign	Modelling/mapping the potential changes of the tumor in time
2.	Calcification detection in mammographies	Prediction of metastasis risk
3.	Determine the extense of the disease (multifocal vs multicentric)	Accurate discretization between healthy and pathologic tissue
4.	Accurate identification of metastasis	Assessing tumor heterogeneity through medical imaging
5.	Grade of malignancy prediction	Prediction of molecular subtype of cancer through medical imaging
6.	Extraction of novel biomarkers	Prediction of medication/intervention effect based on imaging/histopathology/lab results
7.	Cancer staging using different types of data	Association of genetic features with imaging
8.		Optimization of decision making

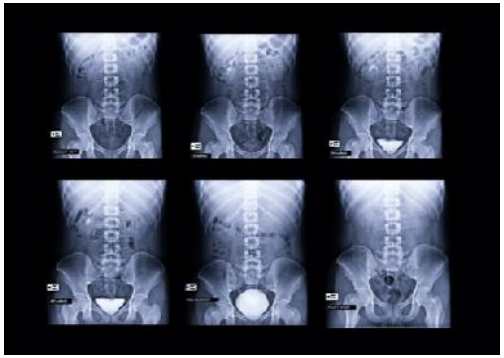
- Segmentation of medical images
- Combination of multiple modalities and types of data (imaging + clinical)
- Decision support to HCPs
- Explainability of AI
- Intuitive UI:
  - Medical images → medical reports
  - AR enhanced visualization
- Model-as-a-Service and Federated Learning

n's Horizon 2020 research
ment number: 952179

Pilot studies

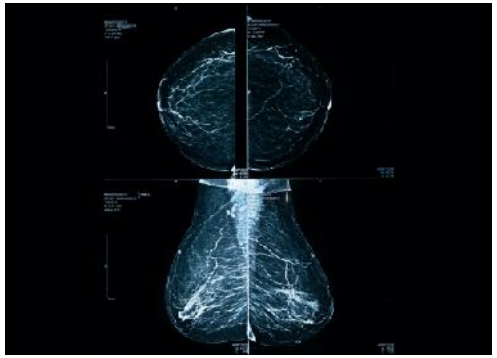
LUNG CANCER

(Cyprus, Greece, Italy)



PROSTATE CANCER

(Cyprus, Greece, Spain)



BREAST CANCER

(Cyprus, Greece, Italy, Serbia)

COLORECTAL CANCER

(Cyprus, Greece, Italy)

2,000 patients will participate in 8 pilot studies in 5 countries for a period of 18-months.

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Obj. 2: Data collection

Steps followed

ETHICAL APPROVAL ACTIONS
- From M3-M12

PATIENT SELECTION
- Within hospital data collection
- Complete cases – Incomplete cases (less time points available)

IMAGE DE-IDENTIFICATION
- CTP DICOM de-identification tool → INCISIVE-specific de-identification tool

CLINICAL DATA EXTRACTION
- Extraction of clinical data from HIS into predefined data templates

DATA QUALITY CHECK
- checks the agreement between data templates and images to be uploaded

IMAGE ANNOTATION
- Annotation guidelines
- ITK SNAP tool → INCISIVE-specific annotation tool

DATA UPLOAD to INCISIVE REPOSITORY
- Prepare and monitor data upload

9 data providers from 4 countries

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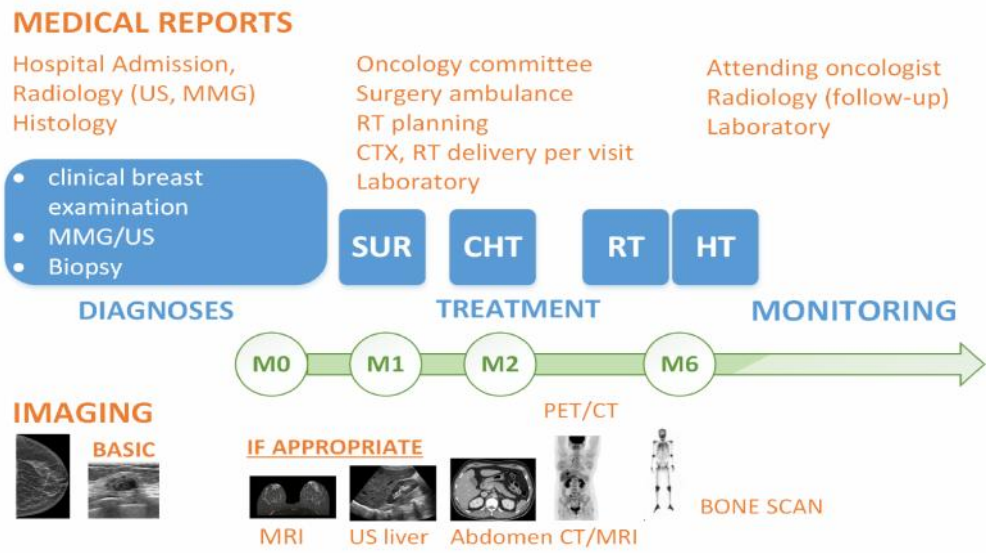
Obj. 2: Data collection

Steps followed

- **Challenging data integration** - combining multi-source data in a single view. Two categories of data:
  - clinical and biological data
  - imaging data

- **INCISIVE solution** - Data collection guidelines
  - Defined clinical representation for each cancer type (data templates)
  - Medical image type and quality specifications
  - Defined data structure & naming conventions



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WHY Data Sharing?

- **Citizens' health data**: first and most important link in the data sharing chain

Data Donation	Processing	Results & Sharing
o **Key Stakeholders**: - Citizens/patients - Healthcare providers/Care centers	o Safe storage & analysis o Data interoperability o Data curation o Anonymisation o Annotation	o Secure & transparent sharing o Sustainability

- Right to determine if and for which purposes health data may be shared
- Compliance with **legal/ethical requirements** is indispensable
- **Secure & transparent** sharing of healthcare data according to **FAIR** principles (**F**indability**, A**ccessibility**, I**nteroperability and **R**eusability]
- Major form of **participation** and **contribution** to the research process
- Empowering **better healthcare services** through deidentified data sharing

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Benefits of data sharing*

Transparency	Maximising the utility and impact of the data collected	Making collaboration easier	Research acceleration
Reproducibility	Data citation & credit	Long-term data preservation	Meeting requirements of funding and publications

*based on ODAP The Open Data Assistance Program at Harvard (https://projects.iq.harvard.edu/odap/benefits-sharing-data), https://www.ccdc.cam.ac.uk/Community/depositastructure/cif-deposition-guidelines/benefits-of-data-sharing/

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Barriers of data sharing*

Technical	Motivational	Economic	Political	Legal and ethical
inadequate data collection; lack of standardization and of common; varying data quality; incompatibility between databases; language barriers	lack of incentives to share data	lack the financial resources for disease surveillance, skilled human resources, limited training capacity, difficulties in retaining staff	restrictive data access policies; bureaucratic hurdles, lack of guidelines; and lack of trust	ambiguous and complex legal framework

*based on Sane, J. and Edelstein, M. (2015). Overcoming Barriers to Data Sharing in Public Health: A Global Perspective.

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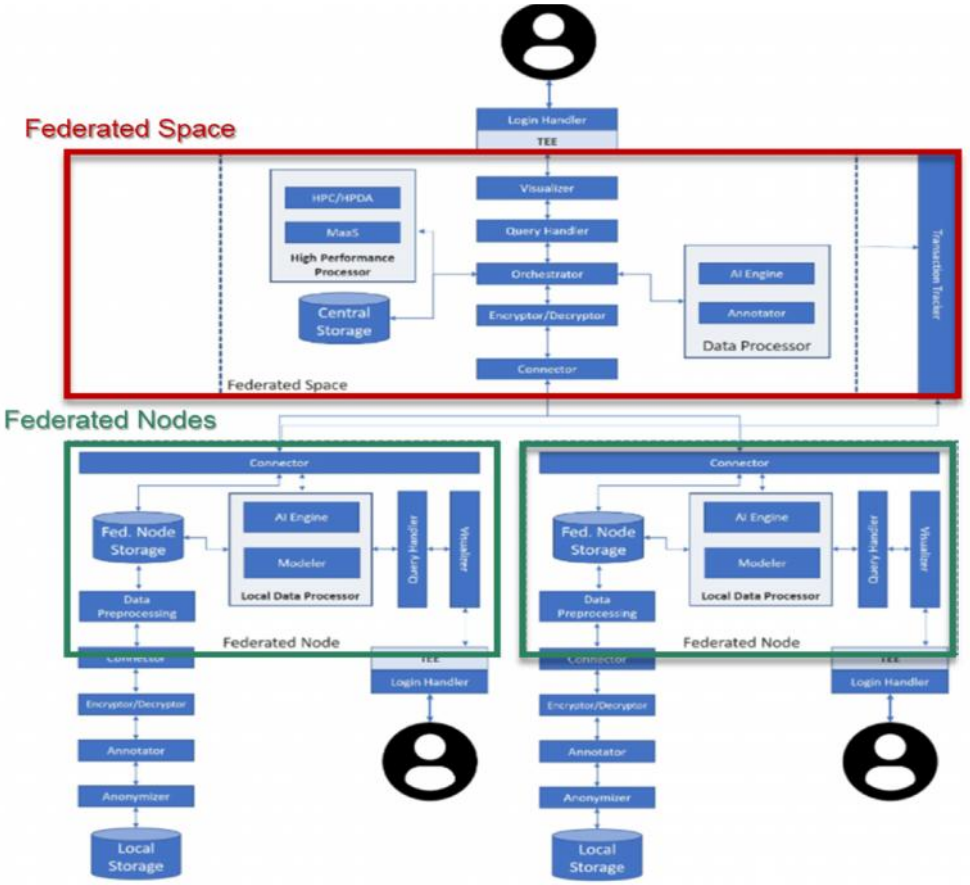
Federated data sharing



"The main benefit of a federated approach is that the data stays with the data provider and does not have to leave the premises where it normally resides"

Data federation facilitates:

- aggregation of data from multiple sources
- ethical, legal and privacy compliance
- transparency and traceability all along the data sharing process → strengthens trust
- Hybrid (central/distributed) storage: selection based on data provider's needs

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INCISIVE model for data sharing & access

„Controlled access +"

SHARING by Data Providers

- Data providers (DP) contact the INCISIVE platform to contribute data
- When sharing data, DP have to accept T&C and provide description of the data

ACCESS by Users (AI Providers)

- Information about data sets and terms of use available on an open site
- Researchers have to apply to be admitted to INCISIVE secure platform environment => present research proposal and accept T&C
- User acceptance process with advisory role of a Data Access Committee
- If AI developer is accepted, he/she can use the data in the repository available for training

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Data Sharing Framework

INCISIVE data infrastructure

meets

LEGAL/ETHICAL REQUIREMENTS

- Data governance and access management framework
- GDRP compliance
- Support for de-identification & annotation of health images, quality check of clinical data – tools and guidance

RESEARCHERS NEEDS

- Making the data available for re-use by researchers, incl. AI developers
- Multi-centre, multi-country data sources
- Standardised, interoperable, quality-checked data

facilitates

data holders to share medical images & health data with minimum effort

OPEN INVITATION to interested Data Providers!

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Main achievements
(so far...)

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Achievements

4 types of cancer

FIRST PROTOTYPE

2.9M cancer images

7.4k de-identified patients

9+ data providers

4/9 data providers integrated / federated repository

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Achievements

- 98% of retrospective data available / shared
- Data management plan & ethical approvals in place
- JCA signed & DPIA in place
- AI services defined
- Data preparation flows fully operational
- Central repository for data sharing fully operational
- Federated data storage/sharing/search proof-of-concept operational
- Federated Learning proof-of-concept operational
- User requirements defined & system functionalities prioritised
- Architecture design completed
- All main technical components operational (v1 → v2)
- Initial AI models implemented & integrated in INCISIVE platform

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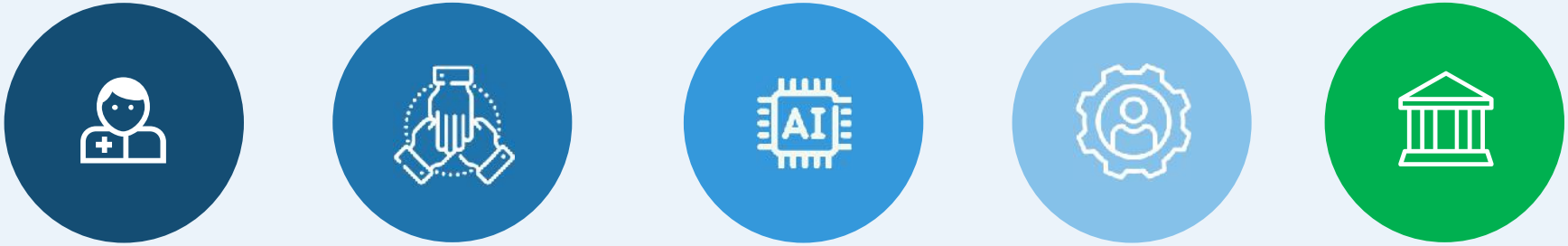
Open for opinion of end-users

CONSULTATION ACTIVITIES WITH END-USERS → UX WORKSHOPS, SURVEYS, INTERVIEWS, LITERATURE REVIEW, ETC.



Healthcare professionals

Patients' associations

AI researchers

Technology developers

Legal and ethics experts

We would love to hear your feedback!

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THANKS FOR YOUR ATTENTION

AINCISIVE

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