

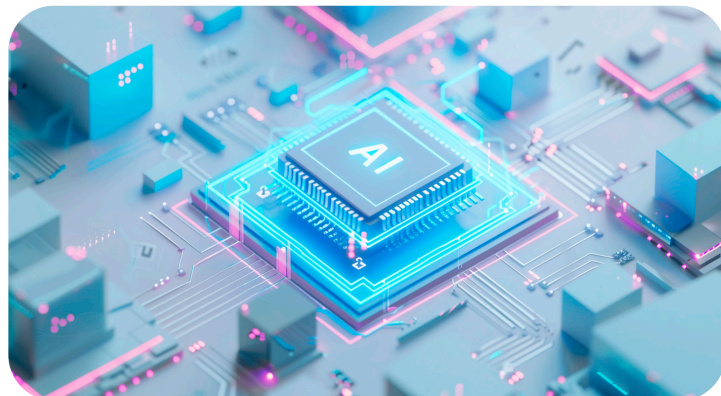
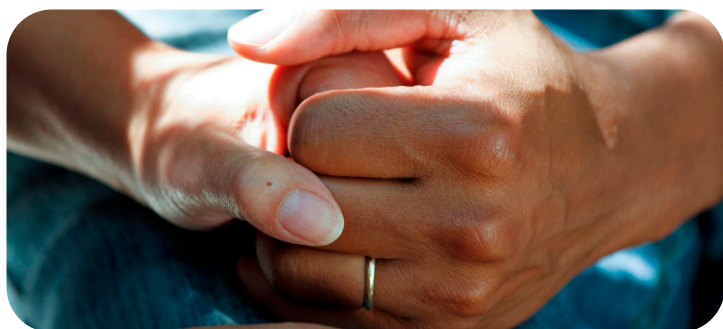


Project Information Leaflet  
for Data Providers

## What is our Vision

OPTIMA (Optimal Treatment for Patients with Solid Tumours in Europe Through Artificial intelligence) is a multi-stakeholder consortium with the vision that every oncology patient should have access to the most up-to-date individualised treatments and innovative therapies.

This collaborative endeavour is poised to revolutionise cancer care through advanced data-driven approaches and AI-augmented clinical decision support. By integrating real-world data, prioritising guideline adherence, and leveraging cutting-edge technologies, the project aims to significantly impact personalised cancer treatments and shared decision-making, ultimately leading to improved patient outcomes and well-being.



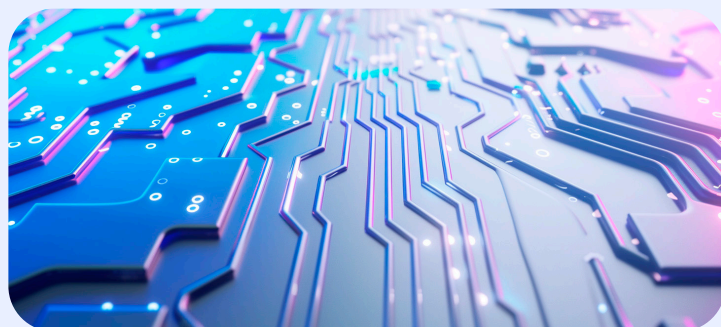
## Key facts about OPTIMA

OPTIMA - Private-Public Partnership under the umbrella of the Innovative Medicine Initiative (IMI)

-  Start date: October 2021
-  Duration: 5 years
-  38 partners across 14 countries in Europe in different fields
-  Project cost: 22,7 M Euro (EU contribution + EFPIA funding)
-  Project focus: lung, breast and prostate cancer

## What is our aim?

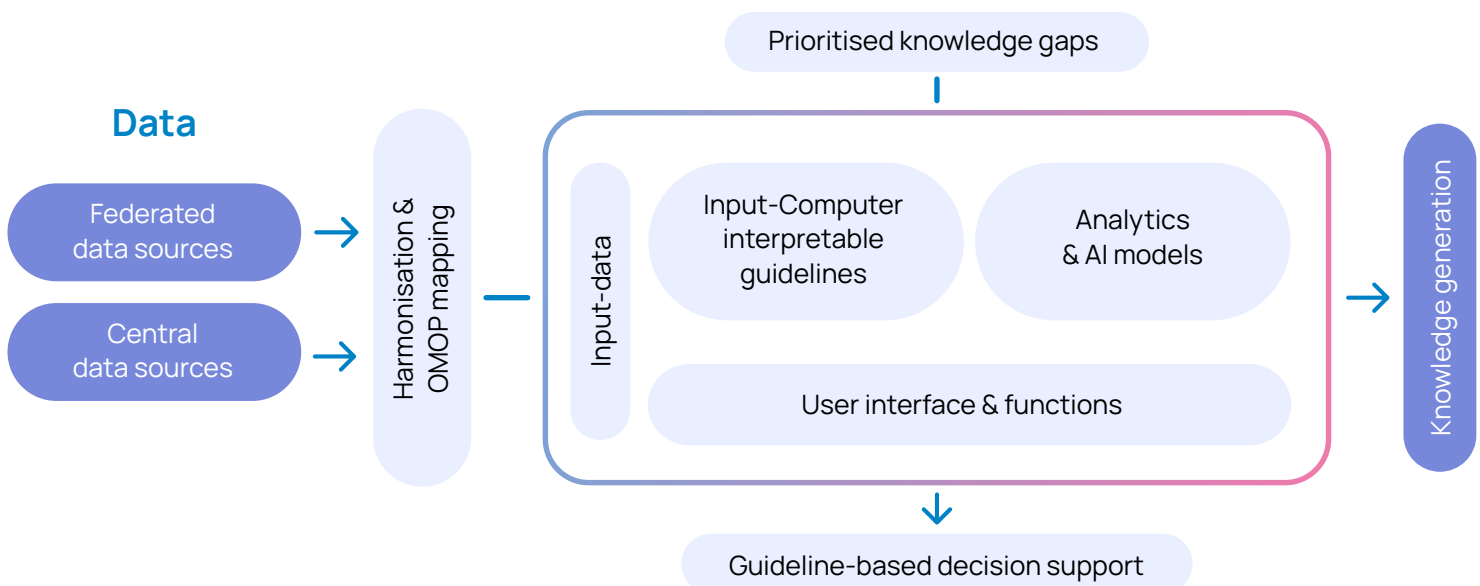
- ✓ Establishing a data catalogue by gathering and harmonising real-world datasets.
- ✓ Designing, developing and delivering the first interoperable and GDPR-compliant European real-world oncology data and evidence generation platform based on the needs of clinicians and patients, in an inclusive and sustainable way by developing guideline-based decision support tools and AI algorithms.
- ✓ Developing a scalable and regularly updated guideline decision-support toolset as part of the platform for the three prioritised indications: prostate, breast and lung cancer.
- ✓ Driving new knowledge generation through advanced analytics and AI-models.
- ✓ Ensuring the sustainability of OPTIMA's platform by developing and supporting business models based on consortium outcomes.



# What challenges does our project address – and which solutions do we offer?

Challenges	Solutions
Data not comparable and scattered over Europe	Harmonising and compiling relevant data using the European Common Data Model
No integrated platform available; privacy and data protection aspects preventing data processing	Designing and establishing the first GDPR compliant European platform
Scalability and transferability of solutions to other problems	Developing a platform that will allow the development of best practices on AI and federated AI solutions for specific problems and diverse large-scale data
Treatment decisions not tailored to the individual patient	Enabling personalised and patient-centered decisions for optimal treatment
Rapid progress in new clinical knowledge on treatment options	Providing clinicians with guidance on up-to-date treatment options for individual patients for better outcomes
Challenges related to data security and cyber threats	Implementing robust encryption methods and measures of access control
Balancing transparency with proprietary interests	Developing clear guidelines for handling data and intellectual property rights
Often limited timespan of existence of similar programs or initiatives	Securing long-term project funding and strong collaborations

# How is our platform structured?



# What progress have we made so far?

## Legal and ethical foundations

The legal and ethical framework of the project has been methodologically analysed and the requirements for data processing, such as the Art 26. and Art. 28 GDPR Agreements, are set in place for ensuring compliance and data security within a robust framework. A Collaboration Agreement will be provided for third parties contributing data sets to the project.

## Backend prototype

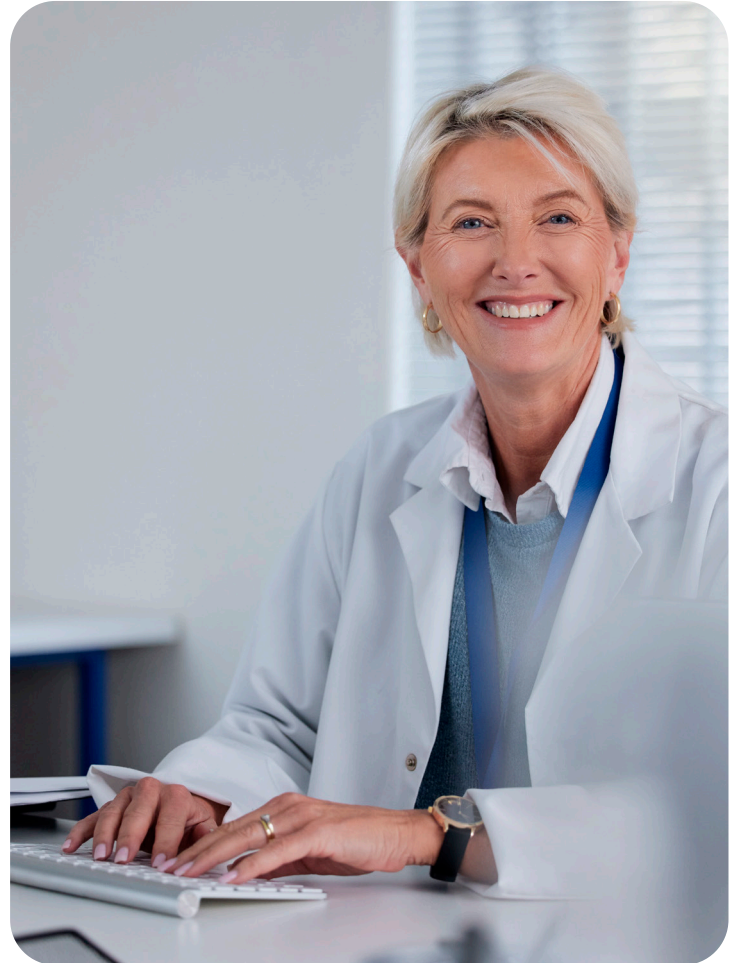
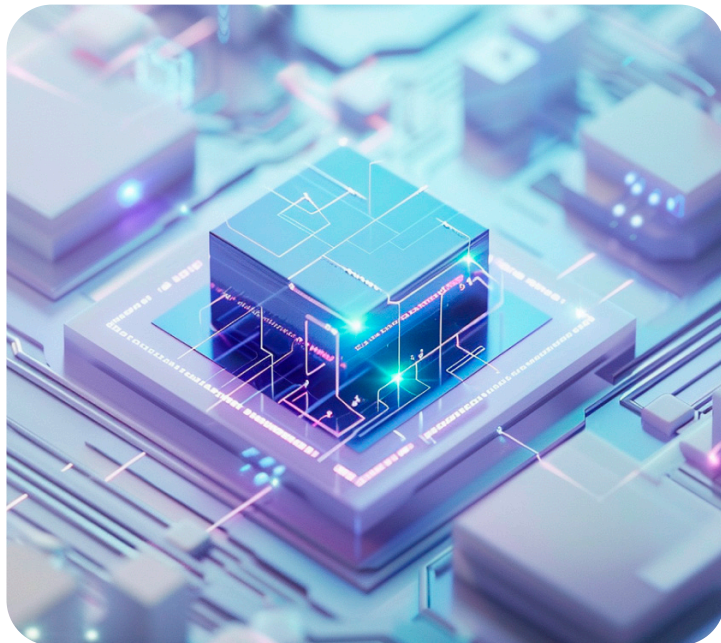
Our platform is already running with an advanced backend prototype, paving the way for seamless data integration and analysis.

## Implementation sites network

Our platform has already been successfully tested and installed in several sites in Germany, France, the Netherlands and Sweden, along with a simple procedure to add more sites.

## Data ingestion and analysis

We have successfully onboarded initial datasets, identified critical research questions and conducted preliminary analyses during our first prototyping workshop.



## Flexible access options

Our centralised and federated access approaches accommodate diverse data sources and enables providers to contribute in their preferred way.

## Advanced decision support

Based on pre-defined cancer care pathways, our guideline-based clinical decision support (CDS) tool is already in an advanced stage of development. We are currently testing and fine-tuning our CDS tool for prostate cancer cases.

## A systematic literature review

A literature review, to be published in a scientific journal on behalf of the consortium, examining the latest advancements in federated machine learning and its impact on breast, lung, and prostate cancer research.

# Why should you become part of OPTIMA?

## Become a member of the federated analytics and/or learning network

When contributing data, you can become part of the federated analytics or learning network, which enables you to join OPTIMA research questions teams; trigger analysis in the OPTIMA network of centres; train and validate models in the OPTIMA federated learning network, and be part of relevant publications.

## Benefit from data mapping

Assistance with mapping your data to the European Common Data Model OMOP-CDM.

## Become a platform implementation testing site

Benefit from the latest versions of our platform on your premises, have access to the network of data centres and to the guidelines-based clinical decision support tool, and help shape the next versions of the platform through feedback.

## Empower cancer patients

Contributing with data empowers patients by allowing them to contribute to scientific progress and medical innovation through a secure, standardised platform.

## Enhance clinical decision-making

Clinicians gain access to state-of-the-art CDS tools, enabling more informed decisions by physicians and patients.

## Enable cross-border insights

European collaboration provides a broad perspective on treatment outcomes across countries and helps to identify best practices and adapt strategies accordingly. This cross-border knowledge benefits patients and healthcare systems alike, while also offering learning and networking opportunities for your organisation.

## Advance medical research and innovation

By contributing with or giving access to your data, you become part of cutting-edge research, development of innovative treatments, understanding cancer mechanisms and finding new solutions.

## Gain early-stage access to project results

Be at the forefront of technical innovation and benefit from insights gained in early project phases.



## OPTIMA will

- ✓ Provide you with access to a federated analytics network
- ✓ Provide you with support with data mapping
- ✓ Update your database at an agreed timepoint or when relevant
- ✓ Provide you with a Collaboration Agreement to set out and agree on the terms of provision of your contribution

## How can data providers contribute to OPTIMA?

- ✓ Data contributors sharing to our central server are expected to adhere to the points below but have no further infrastructural burden.
- ✓ Data contributors wishing to keep their data in their premises are expected to adhere to the points below and provide the infrastructure to commit to either the federated analytics network requirements or the federated learning network requirements.
- ✓ Provide access to or a copy of their patient dataset (clinical, imaging, omics etc) to OPTIMA with support from OPTIMA data experts.
- ✓ Ensure harmonisation of their data to relevant standards with the support of OPTIMA whilst retaining the original mapped data free of rights.
- ✓ Regularly update the dataset available to OPTIMA (if relevant), when new patients are added or more data is available.

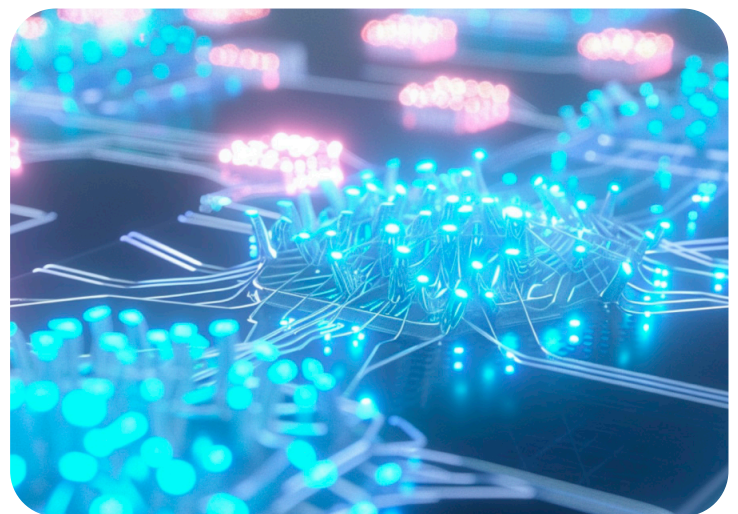
### Platform implementation test sites

- are expected to install the latest version of the platform's federated node components approximately every three months
- provide access to IT personnel for installation and maintenance
- provide infrastructure for a lightweight hardware footprint (docker image or similar system)
- agree to dedicate time from different in-house user personae (e.g. data scientist, clinicians, patients) to use the platform, test it and give feedback through OPTIMA feedback module

### Contributors to the federated analytics network

Data contributors choosing to keep their data in their premises:

- are responsible for installing the relevant software stack provided by OPTIMA
  - R, R studio, Python, JupyterNotebook as relevant
  - Federated analytics orchestrator (such as OHDSI Arachne)
  - Open a port to the outside world to your database mapped to OMOP-CDM standards
  - Commit to provide hardware sufficient to run the analyses (medium footprint, mostly CPU)
- dedicate time from data scientists, data controllers etc to allow analyses to run



### Contributors to the federated learning network

Data contributors choosing to keep their data in their premises, and wishing to be part of the AI models training and validation:

- are responsible for installing the relevant software stack provided by OPTIMA
  - Same as contributors to the federated analytics network
    - + ML/AI software and libraries
    - + federated learning orchestrator (NV Flare)
  - Provide the infrastructure for the AI models development (large footprint, CPU + GPU)
- dedicate time from data scientists, data controllers, ML or AI scientists to allow analyses to run

## Next steps

Do you have further questions about your potential role and would like to discuss with an expert? Reach out to us at [communication@optima-oncology.eu](mailto:communication@optima-oncology.eu)

Join us in OPTIMA to revolutionise cancer care by contributing your valuable datasets. Your contribution will help address gaps in existing clinical practice guidelines, leading to more effective and personalized cancer care. Additionally, your involvement will support the creation of AI-driven tools that refine treatment protocols through robust clinical validation.

Together, we can answer critical research questions and enhance clinical decision-making for patients with prostate, breast, and lung cancer. Be a part of this transformative mission to improve patient outcomes across Europe.



The logo for OPTIMA features a stylized white molecular structure on the left, composed of several circles of varying sizes connected by thin lines. To the right of this graphic, the word "OPTIMA" is written in a large, bold, white, sans-serif font.

# OPTIMA

Tackling Cancer through Real World Data and  
Artificial Intelligence.



OPTIMA is funded through the IMI2 Joint Undertaking and is listed under grant agreement No. 101034347. IMI2 receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations (EFPIA). IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.