Impact on cancer

How IHI and IMI projects are tackling cancer

19 May 2025

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Use the Q&A box

Ask questions and interact with the speakers *(bottom of your screen)*

The session is being **recorded.**
The recording will be posted on IHI's website and Youtube channel.

COCIR efpia EuropaBio MedTech Europe from diagnosis to cure Vaccines Europe Co-funded by the European Union

Cancer Epidemiology

IHI Cancer Portfolio

Focus on Specific Projects:

PIONEER

OPTIMA

GUIDE MRD

IMAGIO

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Cancer Epidemiology

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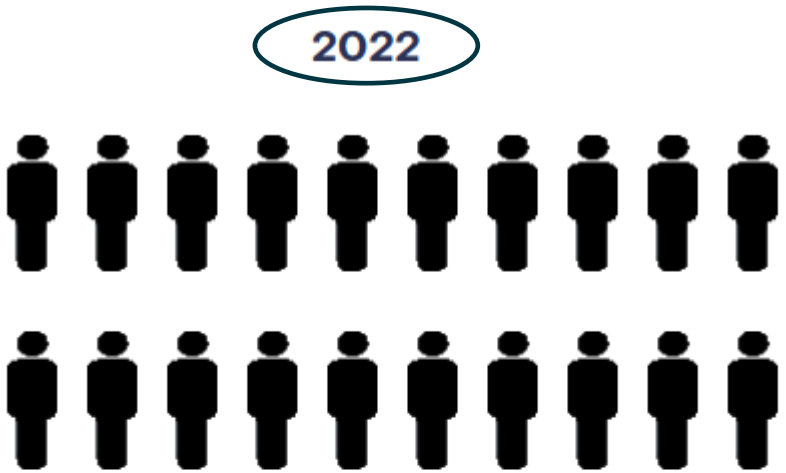
Cancer Today



20 Million

New cases in a year

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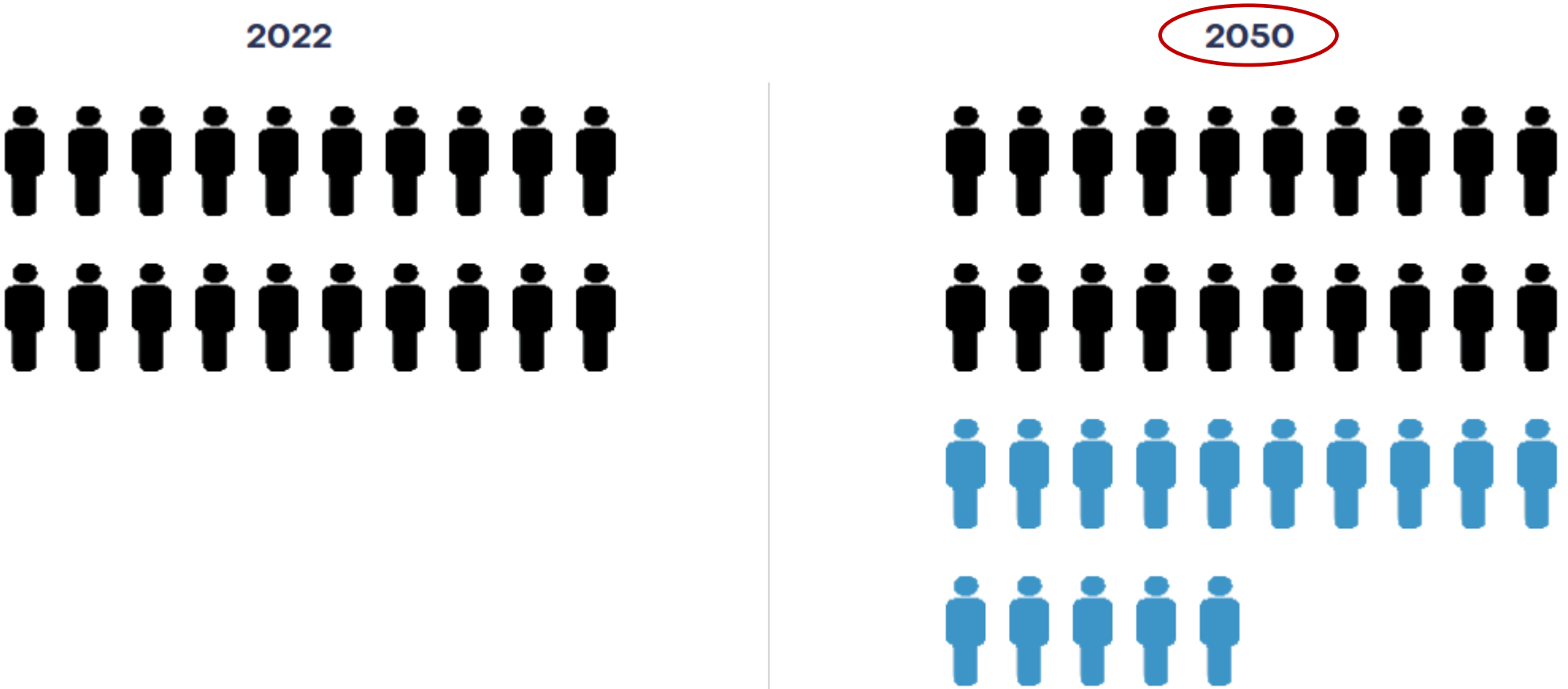
https://gco.iarc.fr/en

Cancer Tomorrow



20 Million
New cases in a year

+ 77%

35,3 Million
New cases in a year

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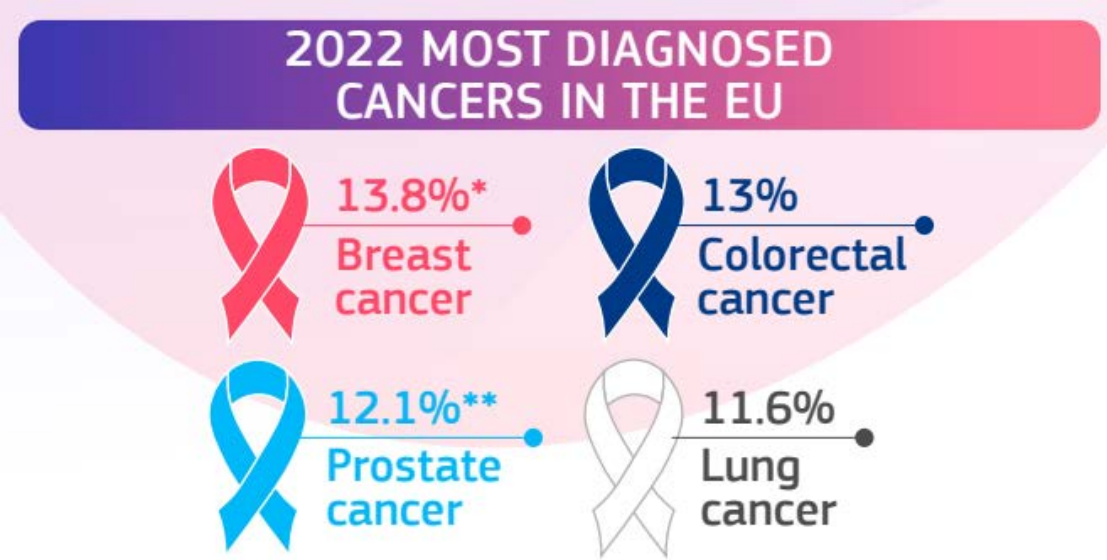
Cancer in the European Union

2,7 Million new cases / year

Cancer in the European Union

2,7 Million new cases / year



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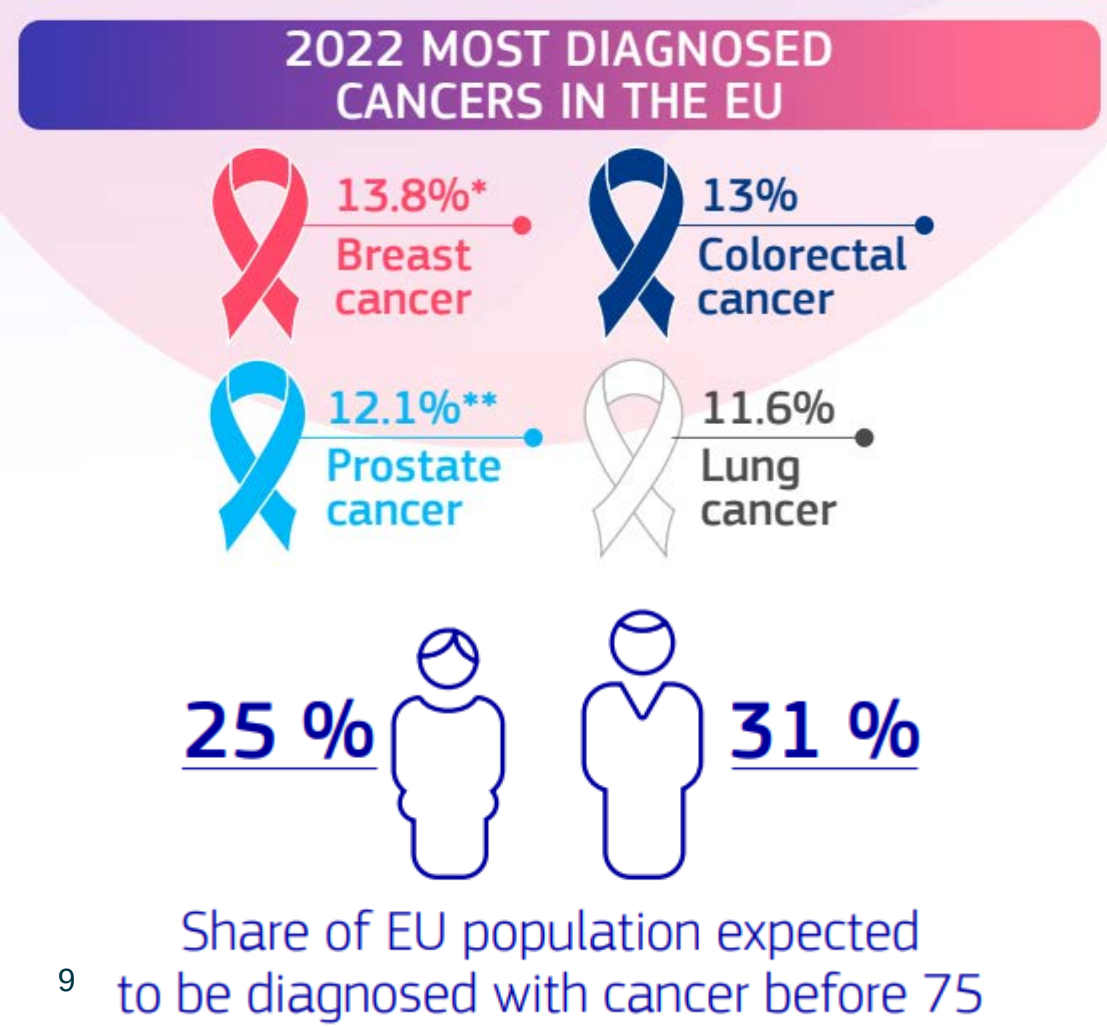
Cancer in the European Union

2,7 Million new cases / year



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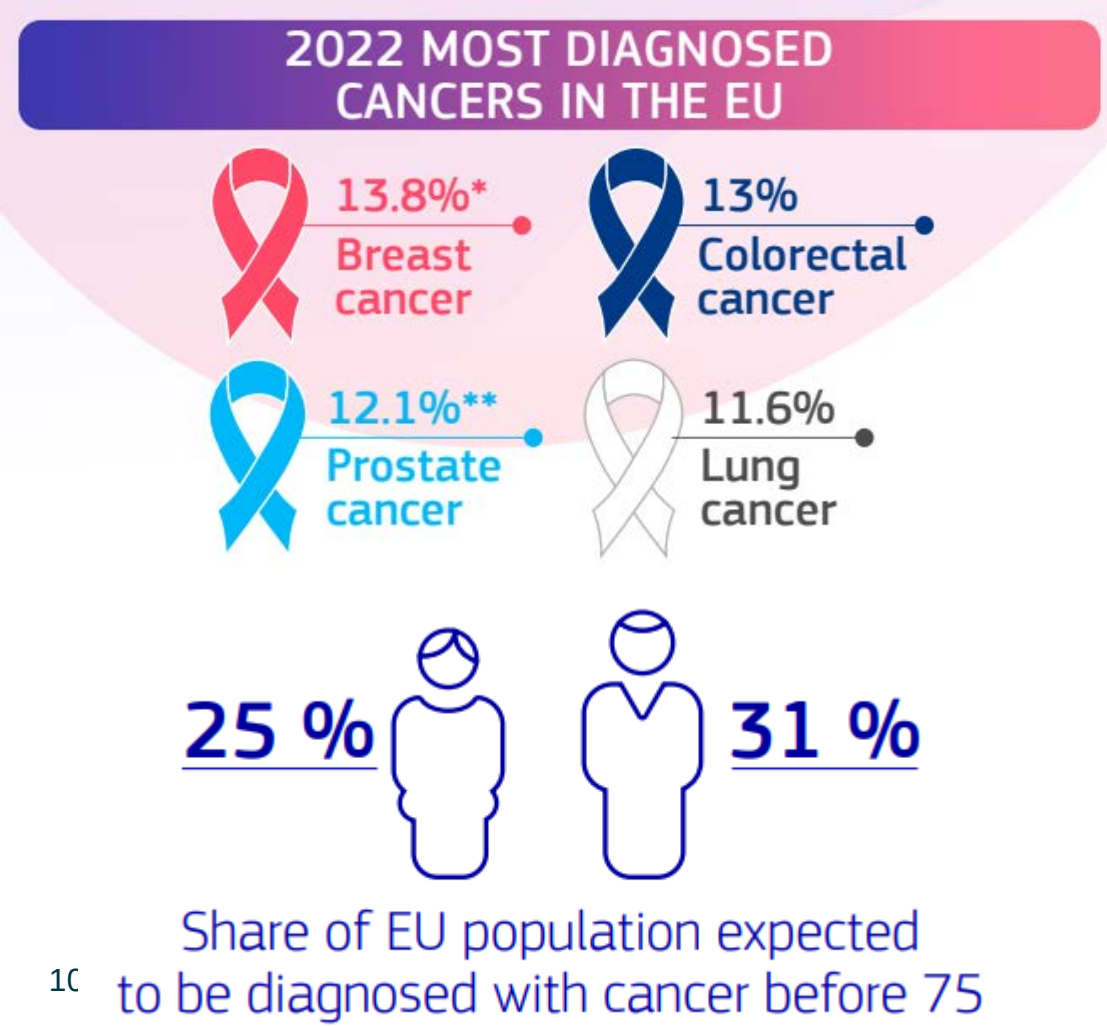
Cancer in the European Union

2,7 Million new cases / year

1,3 Million death / year



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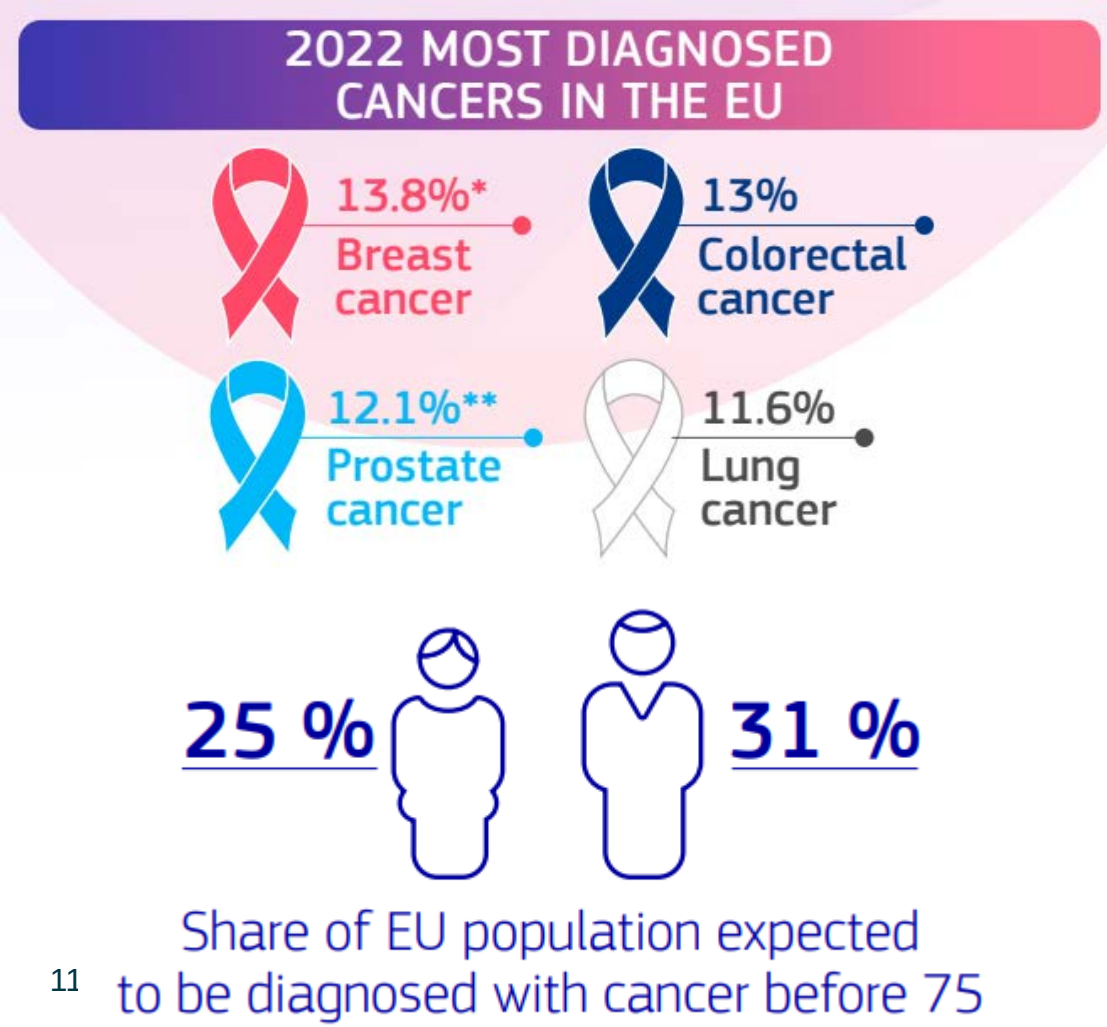
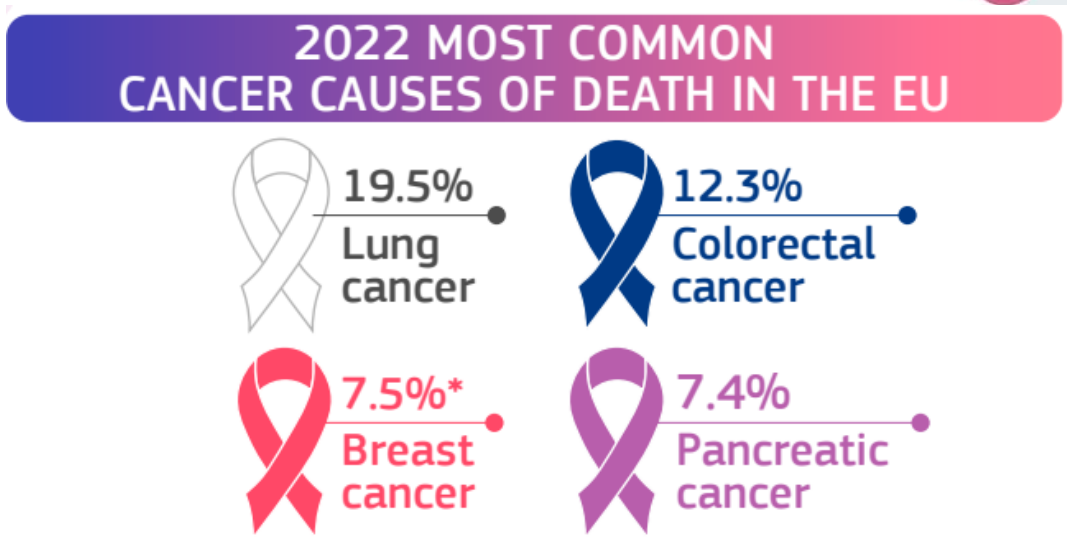
Cancer in the European Union

2,7 Million new cases / year



1,3 Million death / year



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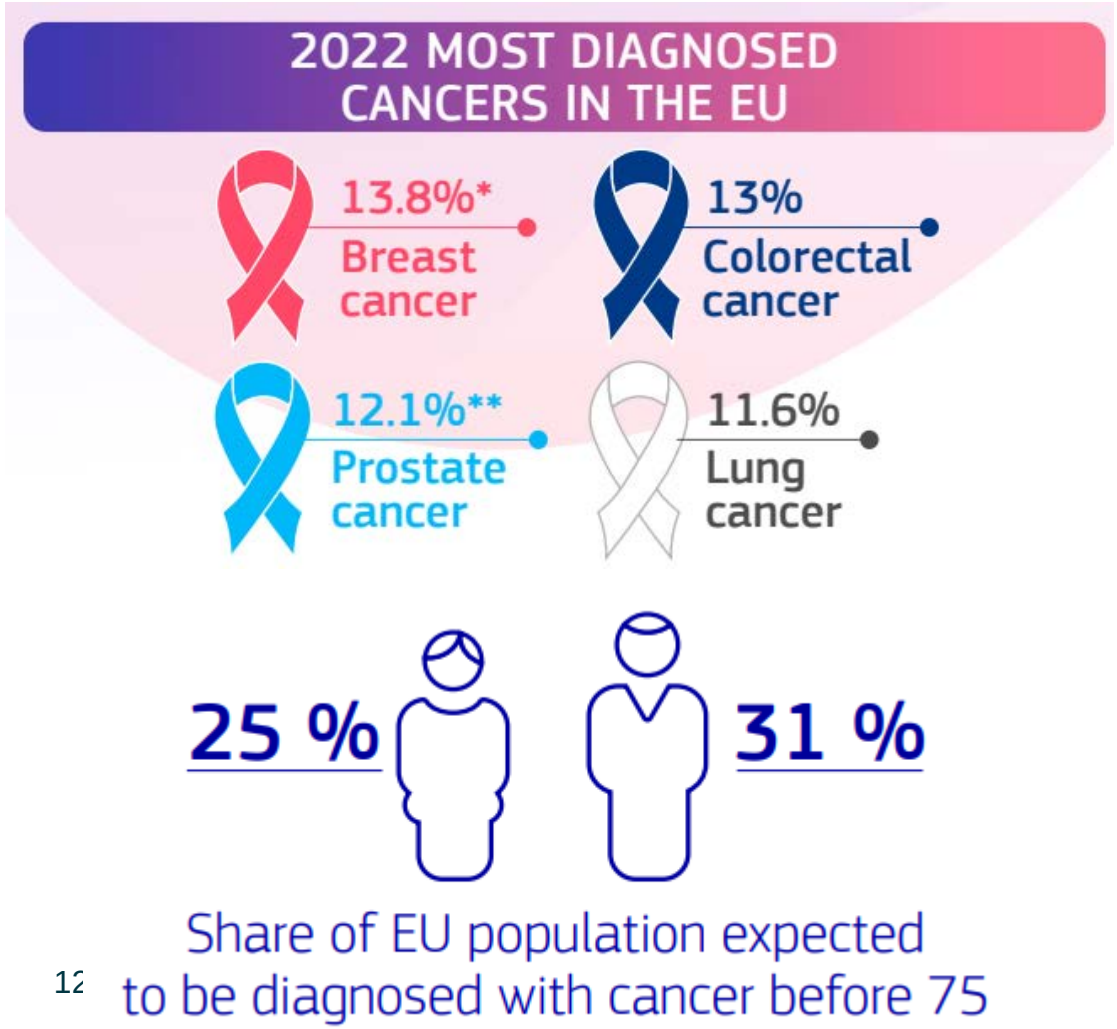
Cancer in the European Union

2,7 Million new cases / year



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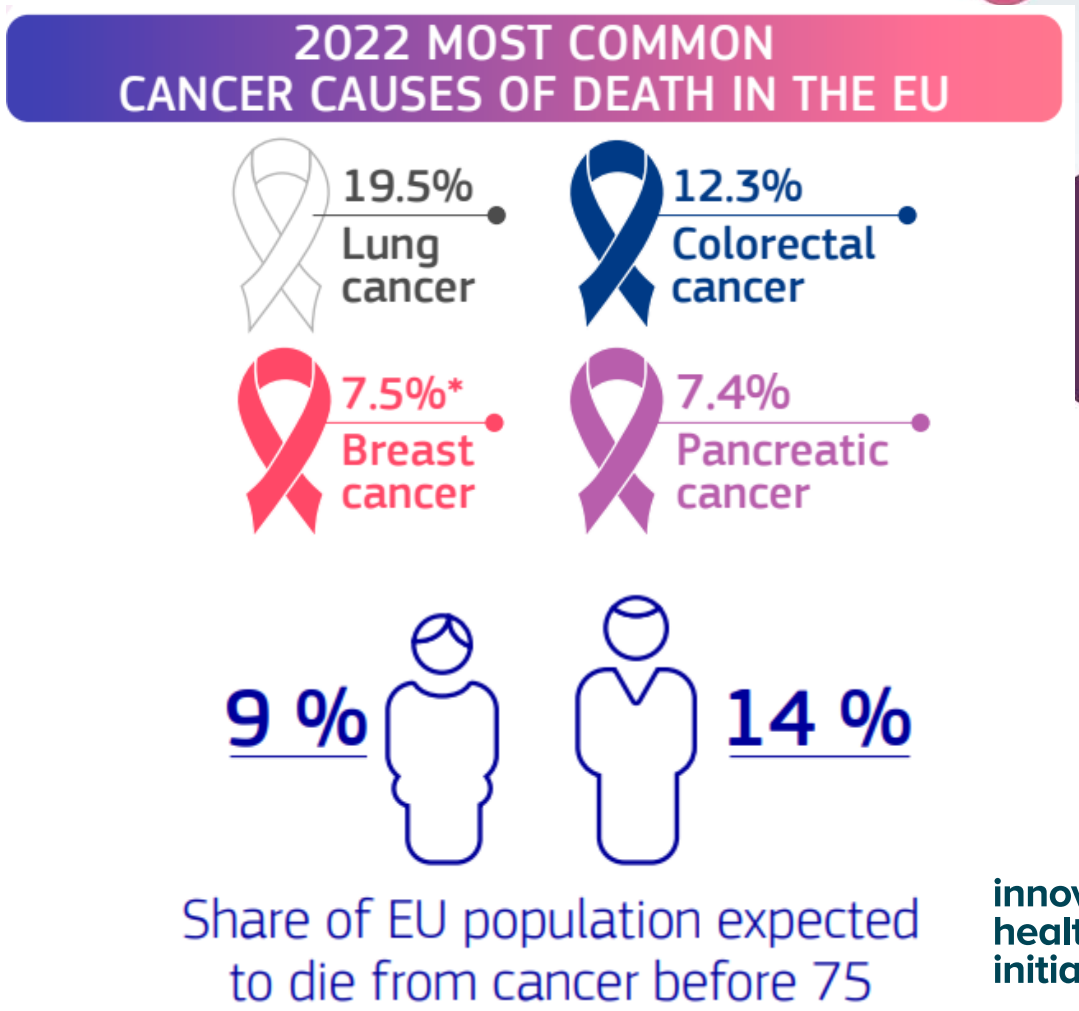

https://ecis.jrc.ec.europa.eu/

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Cancer Epidemiology

IHI Cancer Portfolio

Focus on Specific Projects:

PIONEER

OPTIMA

GUIDE MRD

IMAGIO

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IHI Cancer portfolio per Indication

Lung

- IMMUCAN
- PERSIST SEQ
- OPTIMA
- IMAGIO
- IDHERA
- GUIDE MRD

Cancer Incidence (World)

Lung

IHI Cancer portfolio per Indication

Lung
- IMMUCAN
- PERSIST SEQ
- OPTIMA
- IMAGIO
- IDHERA
- GUIDE MRD

Breast
- **IMMUCAN**
- **PERSIST SEQ**
- **OPTIMA**
- **ACCELERATE EU**

Cancer Incidence (World)

Lung **Breast**

IHI Cancer portfolio per Indication

Lung
- IMMUCAN
- PERSIST SEQ
- OPTIMA
- IMAGIO
- IDHERA
- GUIDE MRD

Breast
- IMMUCAN
- PERSIST SEQ
- OPTIMA
- ACCELERATE EU

Colorectal
- **IMMUCAN**
- **PERSIST SEQ**
- **GUIDE MRD**

Cancer Incidence (World)

Lung Breast **Colorectal**

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IHI Cancer portfolio per Indication

Lung
- IMMUCAN
- PERSIST SEQ
- OPTIMA
- IMAGIO
- IDHERA
- GUIDE MRD

Breast
- IMMUCAN
- PERSIST SEQ
- OPTIMA
- ACCELERATE EU

Prostate
- **PIONEER**
- **OPTIMA**
- **ILLUMINATE**
- **THERA4CARE**
- **BRECISE**

Colorectal
- IMMUCAN
- PERSIST SEQ
- GUIDE MRD

Cancer Incidence (World)

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IHI Cancer portfolio per Indication

14 Cancer Indications

Lung
- IMMUCAN
- PERSIST SEQ
- OPTIMA
- IMAGIO
- IDHERA
- GUIDE MRD

Colorectal
- IMMUCAN
- PERSIST SEQ
- GUIDE MRD

Liver
- IMAGIO

Pancreatic
- GUIDE MRD
- ACCELERATE EU

Breast
- IMMUCAN
- PERSIST SEQ
- OPTIMA
- ACCELERATE EU

Prostate
- PIONEER
- OPTIMA
- ILLUMINATE
- THERA4CARE
- BRECISE

Head & neck
- IMMUCAN

Oesophagus
- PROTECT TRIAL

Blood
- HARMONY
- HARMONY PLUS
- T2EVOLVE
- ITCCP4

Sarcoma
- IMAGIO
- THERA4CARE
- ITCCP4

Brain
- ACCELERATE EU
- ITCCP4

Ovarian
- THERA4CARE

Kidney
- IMMUCAN

Bladder
- BRECISE

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Focus of Today's Webinar

4 Projects

PIONEER

OPTIMA

GUIDEMRD

IMAGIO

7 Cancer Indications

Lung

Prostate

Breast

Sarcoma

Colorectal
Liver
Pancreatic

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Cancer Epidemiology

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PIONEER

The European Network of Excellence for Big Data in Prostate Cancer

PIONEER – Our Consortium Journey

Susan Evans Axelsson, PhD

General Manager EAU UroEvidenceHub

*PIONEER Project Industry Lead, Bayer AG

www.prostate-pioneer.eu

@ProstatePioneer

@Pioneer-big-data-in-prostate-cancer

IMI project in Prostate Cancer: **PIONEER**

- **PIONEER** is an IMI2 funded pan-European public private partnership consisting of 36 stakeholders from across 9 countries

- Launched in May 2018 PIONEER brings together all relevant stakeholders in the field of **prostate cancer research** as well as clinical and social care

- Five year (2018-2023) 12 Million € program

- **PIONEER aims** to transform the field of prostate cancer care with particular focus on:
  - improving prostate-cancer related outcomes
  - health system efficiency
  - the quality of health and social care across Europe

Prostate Cancer: a major health issue

- 2021: the European Commission set overall economic impact of cancer to exceed €100 billion annually[3]

Prostate Cancer: a major health issue

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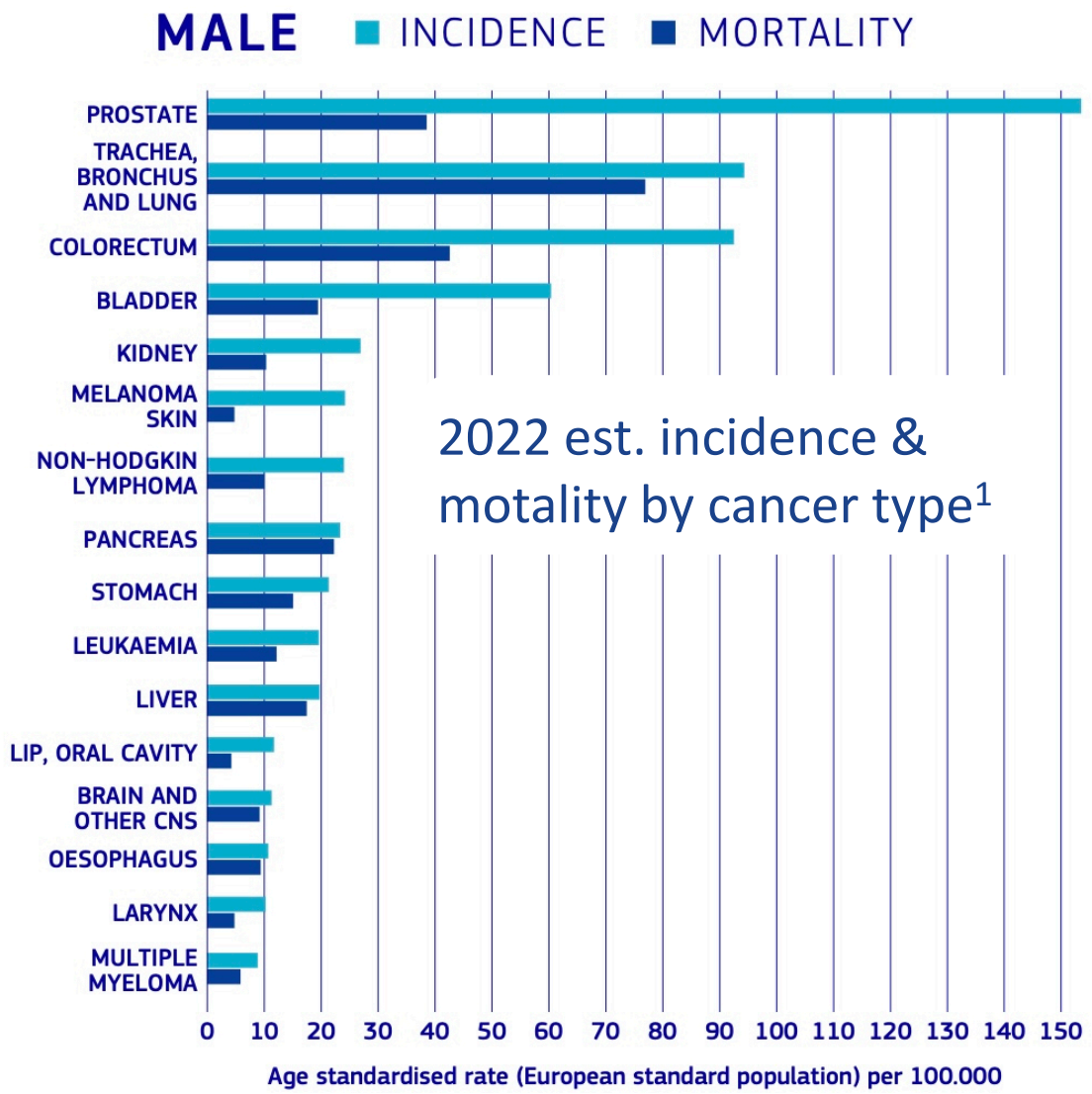
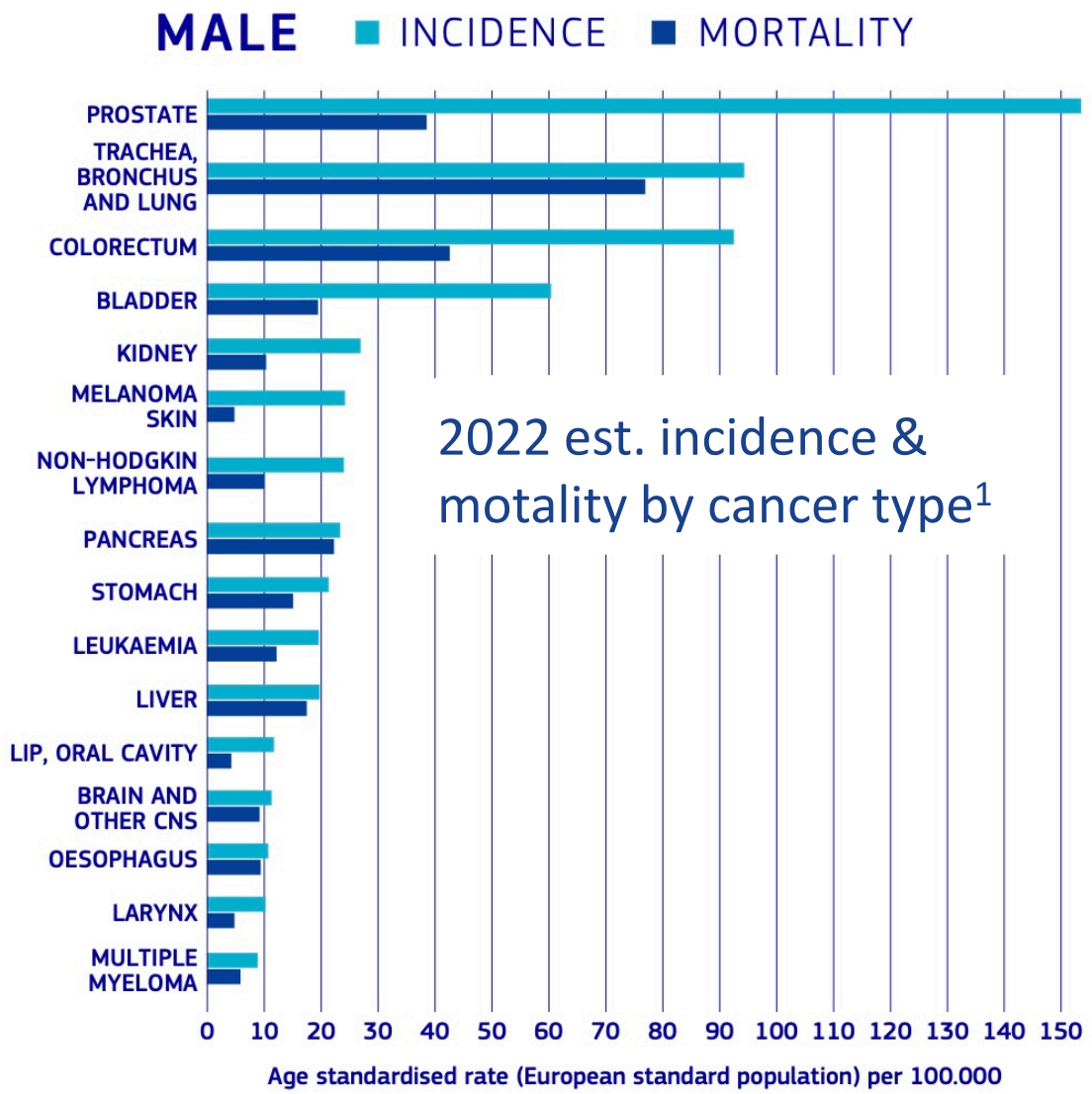
- Worldwide: **second** most commonly diagnosed cancer and the **fifth** leading cause of cancer death[2]



2022 est. incidence & motality by cancer type[1]

Prostate Cancer: a major health issue

- 2021: the European Commission set overall economic impact of cancer to exceed €100 billion annually[3]
- Worldwide: **second** most commonly diagnosed cancer and the **fifth** leading cause of cancer death[2]
- EU: **most** common cancers in men and the **third** leading cause of death in men[1]



2022 est. incidence & motality by cancer type[1]

Challenges of Prostate Cancer screening, diagnosis & treatment

- Insufficient knowledge on **risk factors** and **patient characteristics**
- Need for **integration of real-world clinical data** into disease classification and care pathways
- Lack of standardisation of **definitions** and Prostate Cancer-related **outcomes**
  - Lack of appropriate **patient stratification**
    - separating patients based on established criteria e.g. gender, ethnicity, risk, disease state, socio-economic condition, etc
  - Insufficient meaningful **engagement of stakeholders,** including patients
  - **Suboptimal care** for prostate cancer patients

Prostate Cancer Treatment: Goals

- Long-term oncologic control (**improve survival!**)
- Minimize treatment-related side effects
- Maintain Quality of Life
- Identify patients who should receive treatment

IMI project in Prostate Cancer: **PIONEER**

Data Sources:

3,5 millions prostate cancer patients

IMI project in Prostate Cancer: **PIONEER**

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3,5 millions prostate cancer patients

→ Real-World Data (RWD) →

Big Data Analytics

Data relating to patient health status and/or delivery of health care **routinely collected** from a different sources and **not collected within a controlled clinical trial.**

IMI project in Prostate Cancer: **PIONEER**

Data Sources:
3,5 millions prostate cancer patients

→ **Real-World Data (RWD)**

Data relating to patient health status and/or delivery of health care **routinely collected** from a different sources and **not collected within a controlled clinical trial.**

→ Big Data Analytics →

Real-World Evidence (RWE)

Analysis of RWD leads to generation of **Real-World Evidence (RWE)** which ultimately improves the process of developing **medicines, treatments and research**.

IMI project in Prostate Cancer: **PIONEER achievements**

- **56 research questions identified**
- **14 active research question teams**
- **3 International large-scale Studyathons**

A **study-a-thon** is a focused multi-day meeting to generate medical evidence on a specific topic across different countries and health care systems achieved through the joint work of a multidisciplinary team, including **clinicians, researcher, data scientists, patients, etc.**

1

5 days virtual
245 participants
20 countries
*published European Urology

2

5 days hybrid
35 participants
10 countries

3

5 days hybrid
53 participants
9 countries

IMI project in Prostate Cancer: **PIONEER achievements**

Research Questions Results: Study-a-thon 1

Publication on **conservative management**: **delaying or even avoiding curative therapy** of prostate cancer patients

Prostate Cancer: When to recommend 'Conservative Management'

- While Prostate Cancer is the second leading cause of male cancer deaths, for many patients, curative-intentioned treatment is **not always the best option**.
- Up to now, **it is not clear** when to recommend a 'conservative management' approach and when to recommend treatment.
- PIONEER analysed **over 500,000 prostate cancer patients** to identify the most important factors for choosing between these two treatment options: **Age, hypertension, obesity and type 2 diabetes.**

IMI project in Prostate Cancer: **PIONEER achievements**

Research Questions Results Study-a-thon 2

- Which patient will **benefit the most according** to the different treatment schemes in metastatic hormone-sensitive prostate cancer (Protocol publication)

Paper 1: Baseline characteristics of metastatic Prostate Cancer patients

- Describe **demographics and clinical characteristics** of patients with Metastatic Prostate Cancer across a distributed network of observational databases.

Paper 2: Treatment patterns in metastatic Prostate Cancer patients

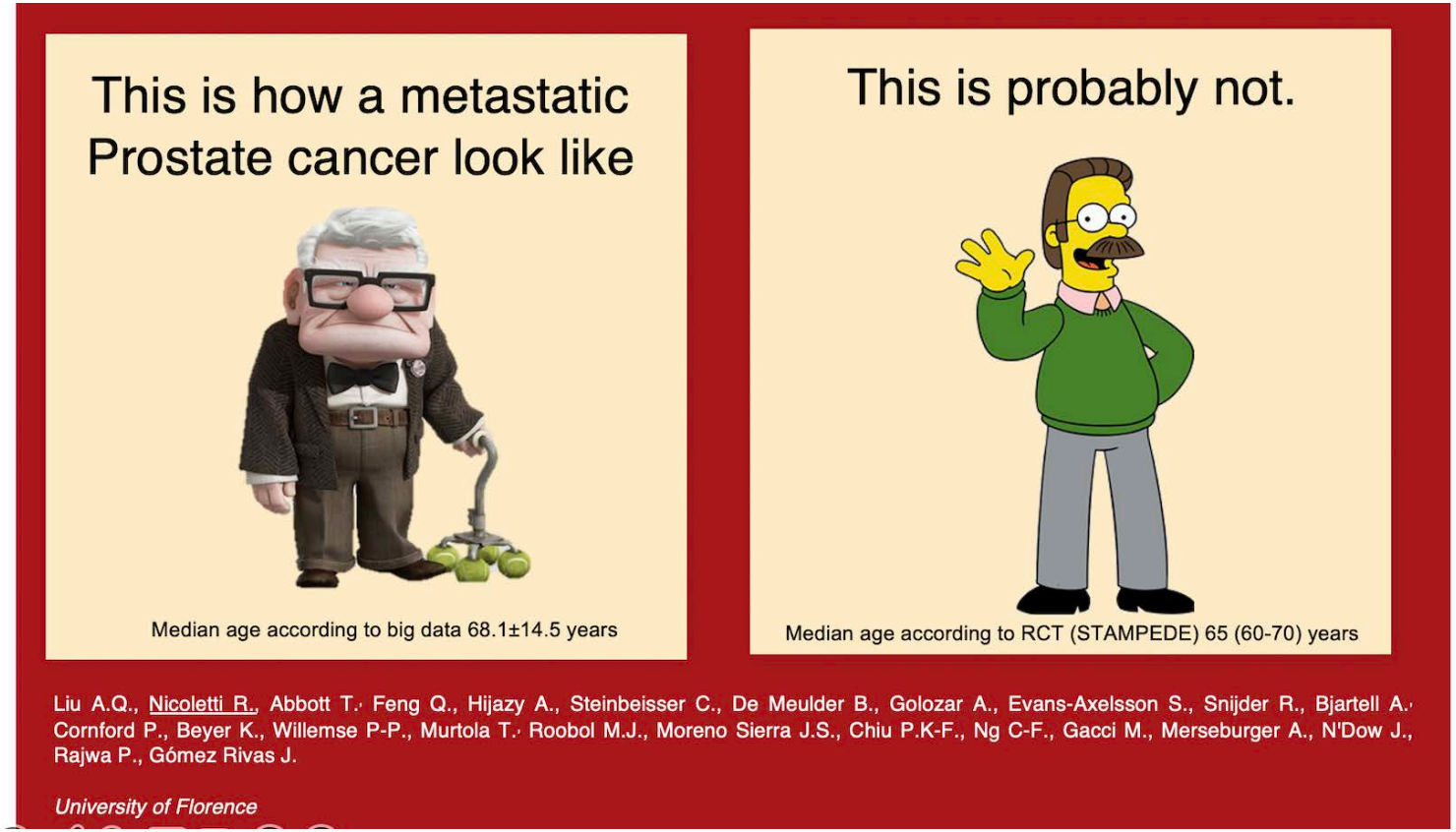
- **Describe** what **treatments** patients with Metastatic Prostate Cancer were exposed to and in which **sequence** across a distributed network of observational databases.
- **Characterize** the **clinical outcomes** of patients with Metastatic Prostate Cancer at 1,3 and 5 years: overall survival, cancer-specific survival, time to symptomatic progression, time to develop resistance, time to the next treatment (treatment switch)

IMI project in Prostate Cancer: PIONEER achievements

Baseline characteristics of metastatic Prostate Cancer patients

Result :

Evidence from real-world data indicates that men diagnosed with metastatic prostate cancer tend to be **older** and have **more comorbidities** compared to those observed in Randomized Controlled Trials.



IMI project in Prostate Cancer: **PIONEER achievements**

Research Questions Results Study-a-thon 3

- Observational Health Data Analysis on the **Cardiovascular Adverse Events of Systemic Treatment** in Patients with Metastatic Hormone-Sensitive Prostate Cancer: Big Data Analytics (Protocol publication)

Results:

- This is the **first** large-scale Big Data observational study analyzing cardiovascular toxicities of systemic therapies in metastatic Prostate Cancer, with data from over 100,000 treated patients.
- Real-world patients have a **higher comorbidity burden at treatment initiation** compared to those in clinical trials.
- **Cardiovascular Adverse Events are common** in real-world settings and should not be overlooked
- **Substantial heterogeneity** exists across databases, emphasizing the need to consider data sources when interpreting findings

IMI project in Prostate Cancer: PIONEER achievements

Research Questions Results Randomized Clinical Trials vs Real World Evidence

- The **generalizability** of randomized controlled trials focusing on newly diagnosed metastatic prostate cancer using real-world data (**Protocol publication**)

Conclusion: Randomized Clinical Trials generalizability is limited by their strict exclusion criteria, resulting in findings based on a limited and highly selected cohort of patients with newly diagnosed metastatic Prostate Cancer

- This **limitation should be considered when prescribing treatments** recommended based on Randomized Clinical Trial findings
- Future Randomized Clinical Trials should **adopt less restrictive criteria** and enroll a more heterogeneous and representative cohort of patients

IMI project in Prostate Cancer: PIONEER achievements

Core Outcomes Set: Patient **outcomes** after treatment for prostate cancer are difficult to **compare** because of **variability**. PIONEER has standardized and recommended **outcomes** (and their definitions) that should be **collected** as a **minimum** in all future **studies**.

Core Outcome Sets: What they are and why they are important

Why are they important?

- When 2 studies are finished, we cannot compare or combine their results if they have used different outcomes.
- Like comparing apples to oranges:
  - it makes it nearly impossible to give a conclusive recommendation about the effectiveness of the intervention or treatment, since the evidence can't be properly combined.

PIONEER Core Outcome Sets

Play a vital role in clinical research and patient care:

- They ensure we're comparing apples to apples in research.
- They guide healthcare professionals to adopt the most effective, patient-relevant treatments quickly.
- They help safeguard patients against bias in reporting outcomes.

Localised prostate cancer

Clinician-reported outcomes
Overall survival
Prostate cancer specific survival
Biochemical recurrence
Local disease recurrence
Distant disease recurrence/metastases
Need for curative R
Treatment failure in ablative procedures
Positive surgical margins
Major surgical complications
Radiation toxicity/Major radiation complication

Patient-reported outcomes
Bowel dysfunction/incontinence
Urinary dysfunction/incontinence
Sexual dysfunction
Side effects of hormone therapy
Overall Quality of Life

Metastatic prostate cancer

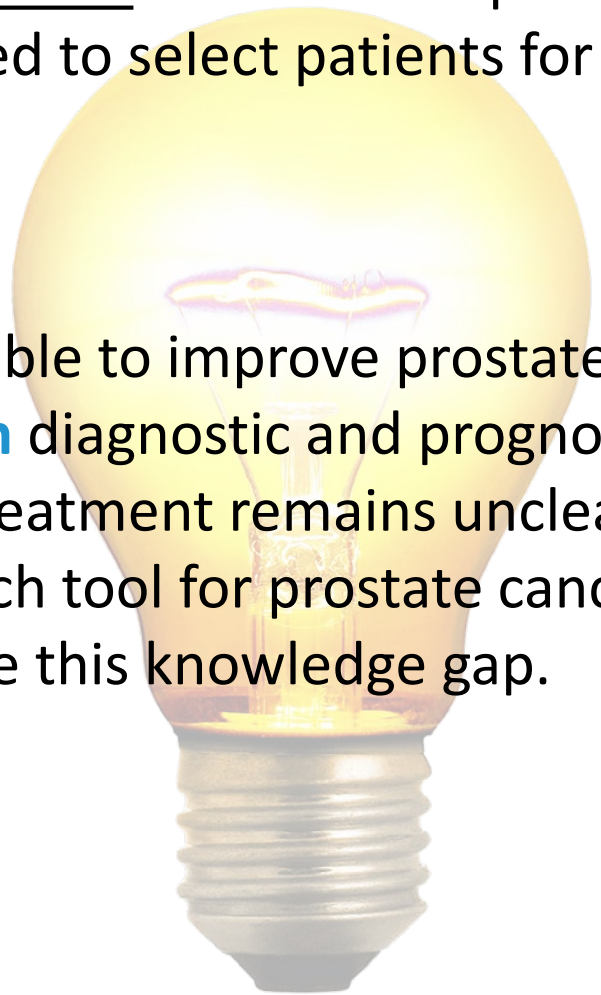
Clinician-reported outcomes
Overall survival
Prostate cancer specific survival
Development of castration-resistant disease in HSPC
Biochemical progression-free survival (bPFS)
Radiographic progression-free survival (rPFS)
Clinician-reported
PSA response
Procedures needed for local progression
Symptomatic skeletal event

Patient-reported outcomes
Bowel dysfunction
Urinary dysfunction
Sexual dysfunction
Side effects of systemic therapy
Emotional dysfunction
Physical dysfunction
Pain
Fatigue
Performance status

IMI project in Prostate Cancer: **PIONEER achievements**

Diagnostic and prognostic search tool: Tool that helps determine which diagnostic and prognostic biomarkers can be used to select patients for a specific treatment

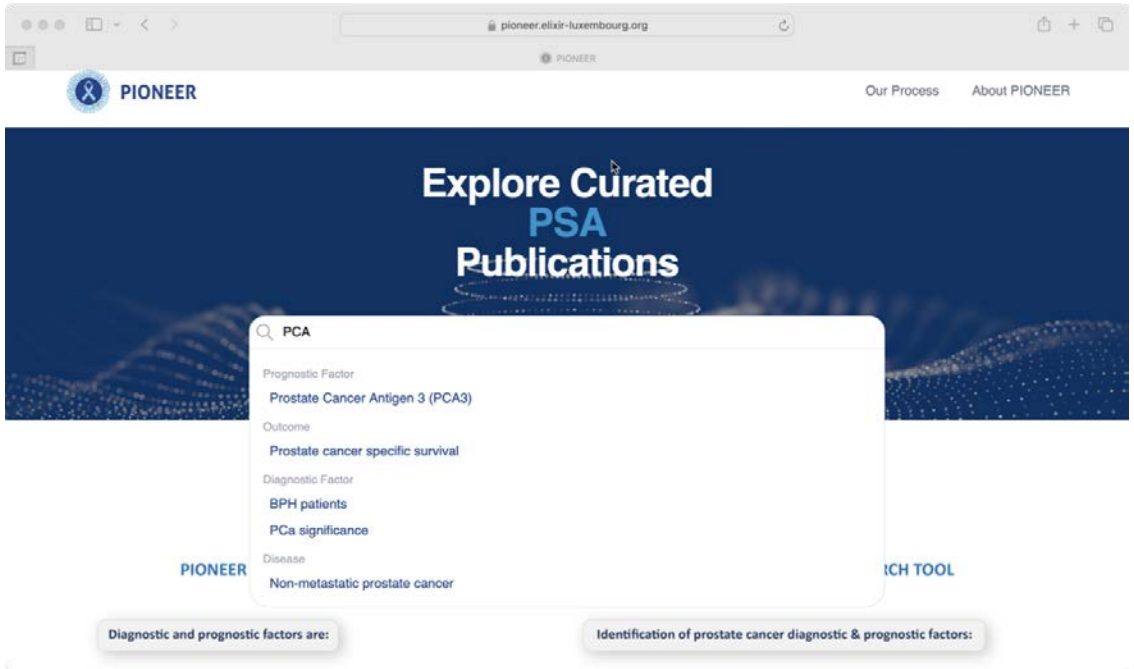
The online search tool

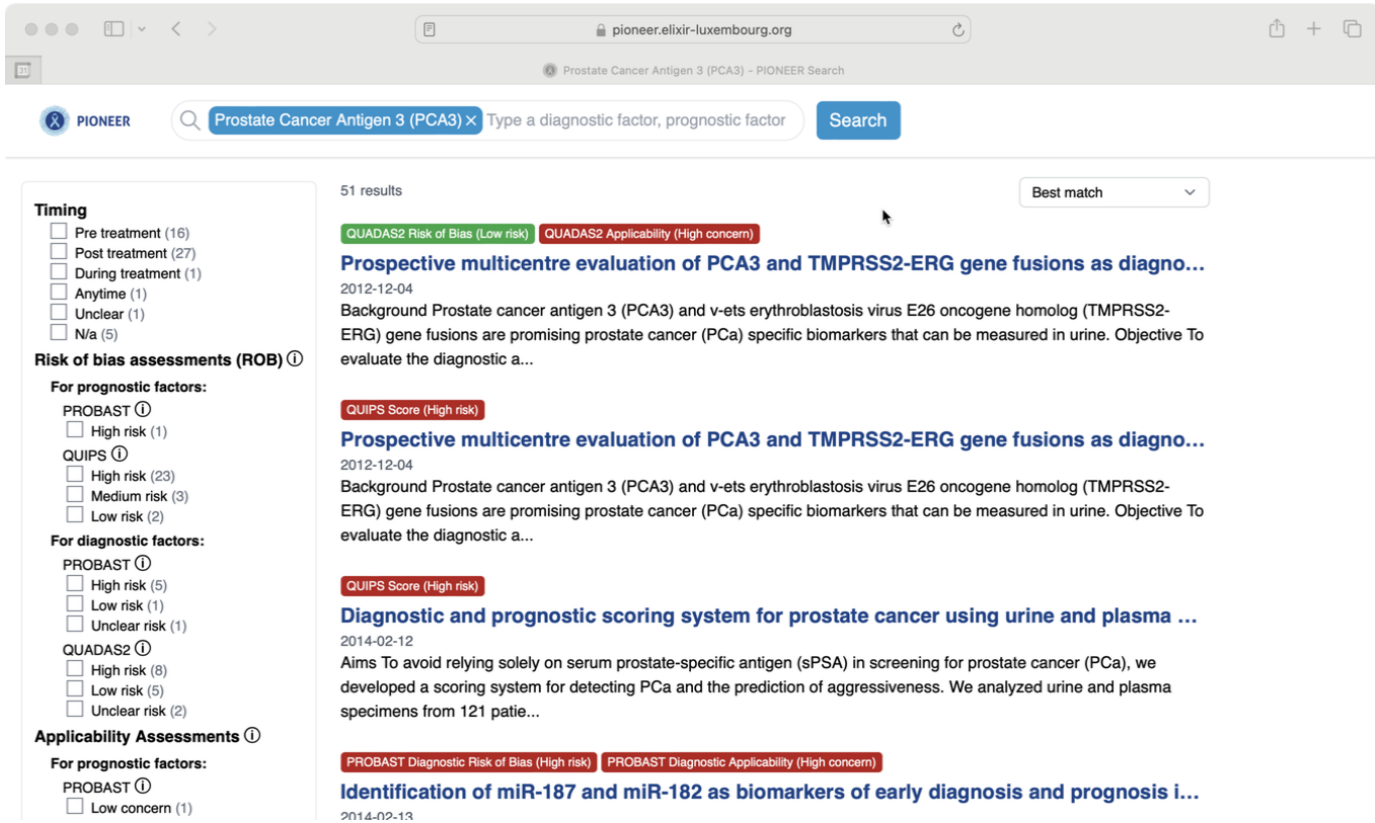


Why is this important?

- Multiple biomarkers are available to improve prostate cancer **diagnosis** and **prognosis**.
- However, knowledge on **which** diagnostic and prognostic biomarkers can be used to select patients for a specific treatment remains unclear.
    - The PIONEER online search tool for prostate cancer diagnostic and prognostic biomarkers aims to bridge this knowledge gap.

PIONEER Diagnostic & prognostic factors search tool





IMI project in Prostate Cancer: **PIONEER achievements**

- Research Questions Results:
  Under analysis

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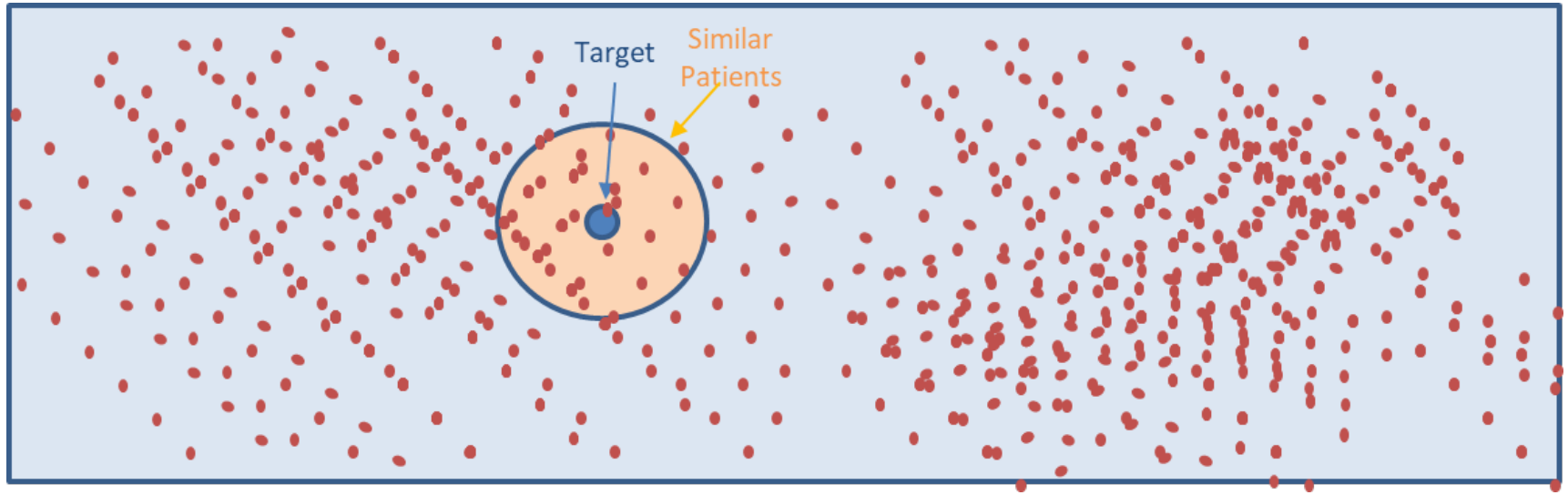
  The guide to use the online tool

- **Clinical decision support tool pilot:** Conceptual development of a tool with the aim at serving as a **clinician decision support tool.** Extracting **optimal treatment** pathways from collective data to **provide clinicians** with an **overview of treatment and outcomes** of similar patients. Continued development in UroEvidenceHub

Patient Experience Engine

Empirical Clinical decision support (eCDS) tool pilot

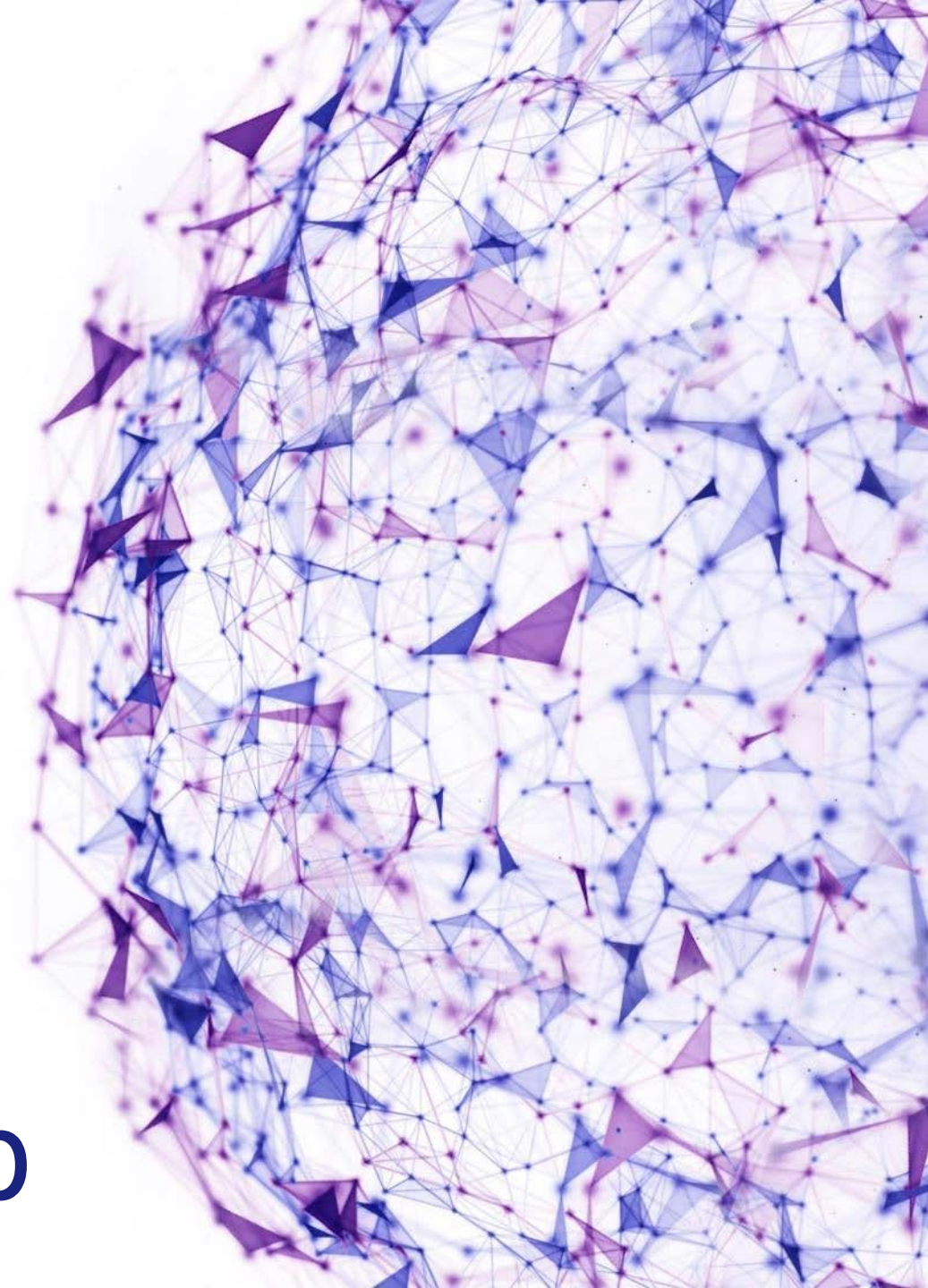
- **Under development** to enhance **decision making** (development continued in EAU UroEvidenceHub)
- Utilizing **key patient features**, comparing to comprehensive database to find **similar patients**
- Extracting **optimal treatment** pathways from collective data
- Will **provide clinicians** with an **overview of treatment and outcomes** of similar patients
- Aim at serving as a **clinician decision support tool**



PIONEER

PIONEER+

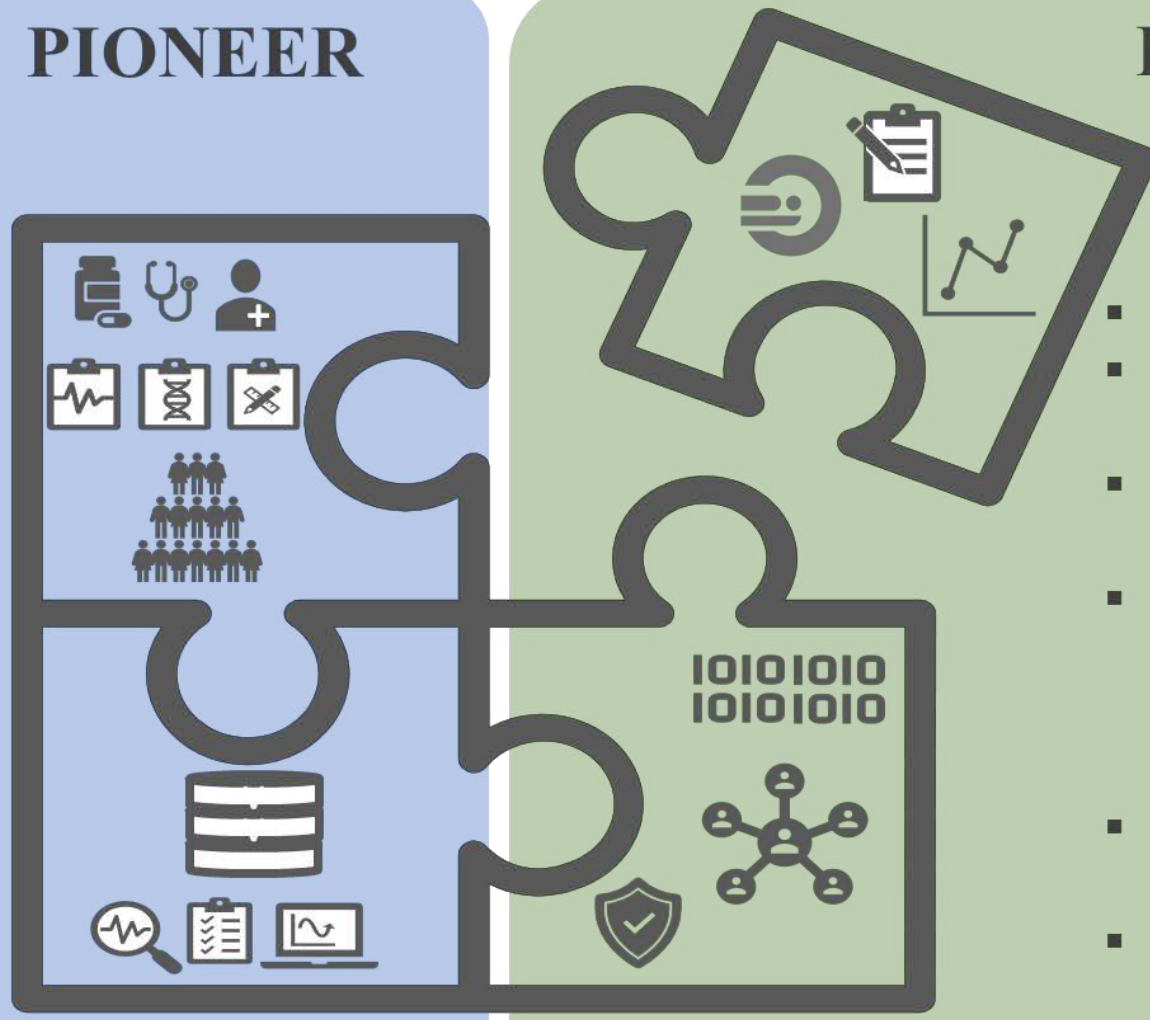
EAU UroEvidenceHub



PIONEER

PIONEER

- Identify critical evidence gaps
- Clinical, OMICS, study design, and demographics data
- Data sources
- Structured data
- Single data platform
- Identify, broaden, and standardize PCa-related diagnosis and treatment



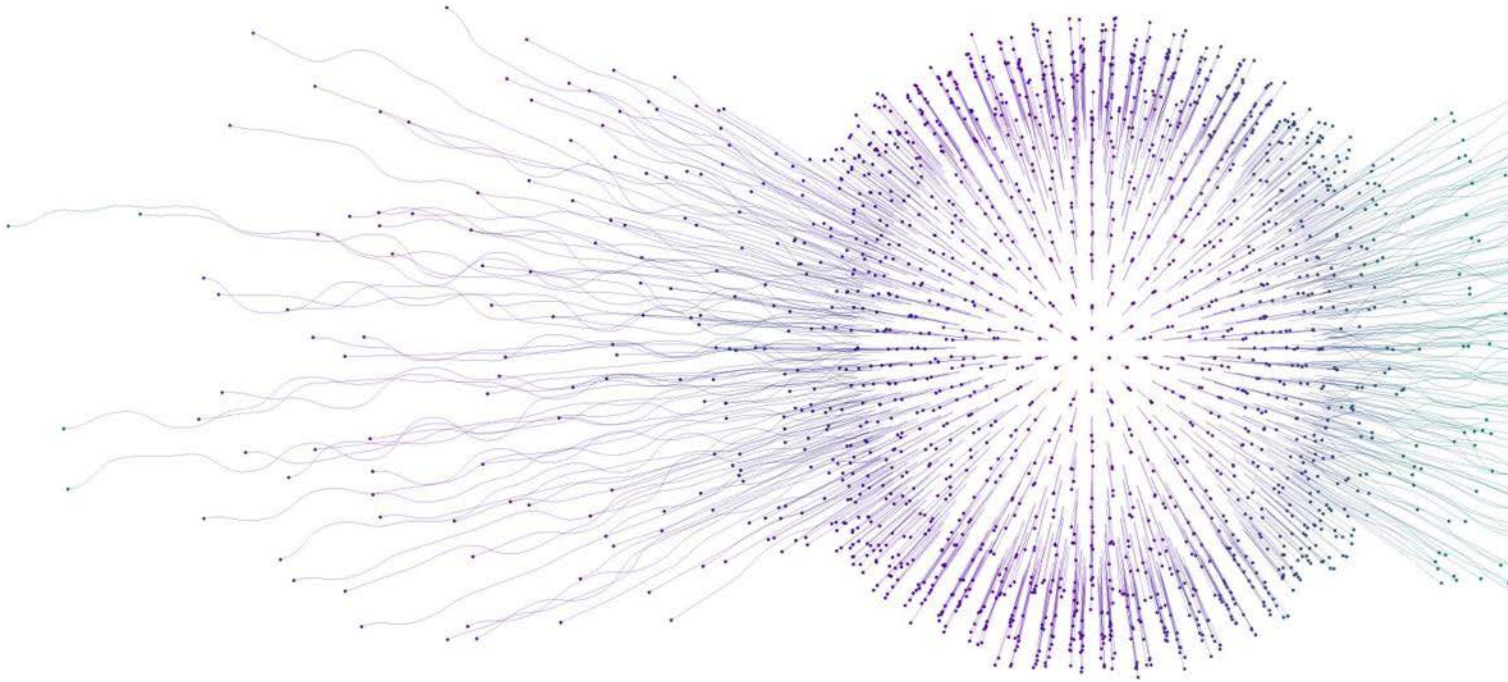
PIONEER-Plus

- MRI imaging/EHR
- Unstructured (semi-)live EHR and MRI data
- AI-based risk classification module
- Specialised computation for AI and analytics, storage for medical images
- Federated learning approach
- Data anonymization

Clinical needs definition, Data collection, standardization, harmonization of PCa patients

Decision support in diagnosis and stratification of prostate cancer patients in clinical practice

eau uro evidence hub



Open for experts in urology, RWE generation, artificial intelligence in healthcare, epidemiology, data science & statistics, patient engagement and guideline development

Let's build an ecosystem of excellence together!

Building on the sound foundation and experience of:

PIONEER

OPTIMA

HZDR
HELMHOLTZ ZENTRUM DRESDEN ROSSENDORF

PIONEER

Prostate cancer diagnosis and treatment enhancement through the power of big data in Europe

Research-based platform built to use RWD to answer evidence gaps identified as most importatant by clinicians and patients.

OPTIMA

Optimal treatment for patients with solid tumours in Europe through artificial intelligence

Further development the work from **PIONEER**, with the specific goal of enabling the use of artificial intelligence (AI) to improve care for patients with **prostate, breast and lung cancer**.

Cancer Epidemiology

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OPTIMA

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UNIVERSITY OF ABERDEEN

OPTIMA

European Association of Urology

Prof. Dr. James N'Dow, Urological Surgeon

EAU Adjunct Secretary General, University of Aberdeen

OPTIMA Academic Coordinator

Funded by

imi efpia

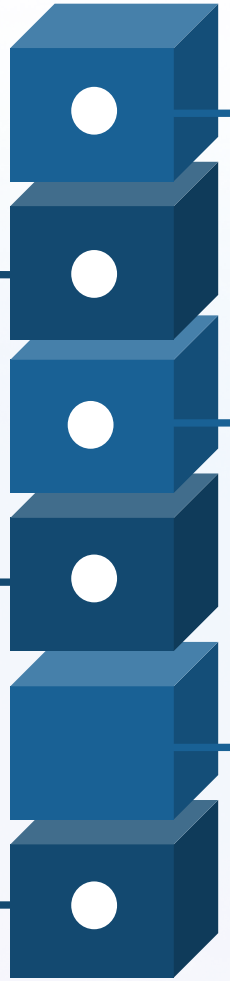
No financial conflicts of interest to disclose

Challenges of cancer patient care needing global solutions

- A staggering 90% of the content found in scientific publications is deemed unreliable and inappropriate for instigating alterations in Clinical Practice Guideline Recommendations.

- In several EU member countries, approximately 4 out of 5 patients **DO NOT GET** access to evidence-based treatment for specific urological cancers.
  - This situation increases the likelihood of adverse outcomes.
  - It leads to unnecessary complications.
  - It incurs additional costs.
  - There is a risk of providing potentially harmful care (25%).

EXPANDING Real-World Evidence has high potential to boost urology research and address current cancer treatment challenges Globally



Current published outcomes from centers of excellence are not representative of general urological practice everywhere.

Evidence gaps are not filled fast enough with high-quality Clinical Trials.

Information about long-term adverse effects and safety is missing.

Key subgroups are often not represented (elderly, multiple comorbidities, obesity, ethnic minorities, polypharmacy, LMICs).

Clinical trials are conducted on a small scale, with highly controlled not generalisable populations

Many recommendations cannot be underpinned with high-quality trials.

Data and real-world evidence are the GAME CHANGERS!

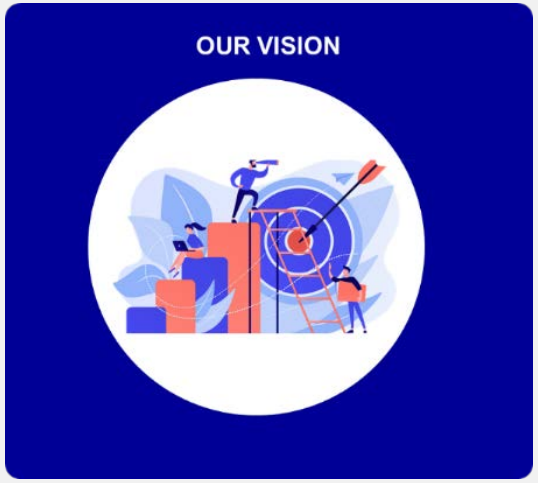
Living Guidelines incorporating Real World Evidence

Next generation “living” guidelines and a new way of interaction between **clinicians**, **patients** and **care-givers**.

- improved quality of care
- strengthening the role of shared treatment decisions
- empower individualised treatment recommendations and care plans that consider physical, emotional and psychological patient needs preferences.
- Context-sensitive (eg. high-income versus low-income countries)

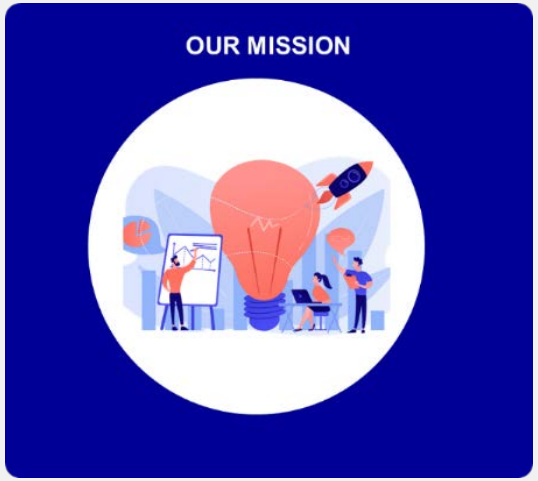
€21.3M EU IMI funding launched in October 2021

Three Forms of Cancer: Prostate Cancer, Breast Cancer, Lung Cancer



That every patient should have access to
the most up-to-date individualised treatments and to innovative therapies.

By strengthening shared decision-making based on **dynamic computer-interpretable guidelines**, innovative broad **data access** and **AI-driven technology and tools**, we envision revolutionizing oncology care in Europe.



To **design**, **develop** and **deliver** an interoperable and GDPR-compliant European real-world oncology data and evidence generation platform from the onset **based on the needs of the clinicians and patients**, in an inclusive and sustainable way

eau Guidelines eau European Association of Urology

A strong alliance of public & private partners

38 Partners across 13 countries in the following fields:

- IMI experienced researchers / SMEs
- Professional medical societies
- Cancer key opinion leaders
- Leading guideline developers
- Patient organisations
- Committed industry partners
- EMA steering group members
- AI in healthcare experts
- Implementation scientists

What can patients expect from OPTIMA

1. **Improved treatment decisions:** AI-driven decision-support tools will help clinicians and patients make more informed choices about prostate, breast, and lung cancer treatments.
2. **Access to Cutting-Edge Research:** Patients will benefit from new knowledge generated through advanced analytics and AI models, leading to better treatment recommendations.
3. **Personalized Care:** The platform will integrate real-world data from electronic health records (EHRs) and other sources, allowing for more individualized treatment plans.

Access to the right data

OPTIMA has secured access to data covering >200 million people

- Electronic Health Record data of **>138 million** people in Europe and **>56 million** people in the US
- Biobanks, cancer registries and cohort data of **>7 million** patients in Europe
- Trial or prospective cohort data of **>6,000** participants

From generic guideline recommendations to truly individualising patient care driven by data

Prostate Cancer

Breast Cancer

Lung Cancer

- Prioritisation of Research Questions (Knowledge gaps) with all stakeholders.
- Assessments of the quality of existing Prostate Cancer, Breast Cancer and Lung Cancer Clinical Practice Guidelines.
- Care pathways most commonly used by clinicians.

Objective: Answering relevant research questions for OPTIMA

Examples topics of research questions

Prostate cancer

- Questions like “What is the pathogenesis in patients undergoing active surveillance, and what are the effects of comorbidities and life expectancy?”
- or questions such as “What are the molecular mechanisms behind resistance and reasons for treatment failure?”

Breast cancer

- Questions like “What is the best clinical outcome for each treatment sequence for metastatic breast cancer? Which therapy is most effective after CDK4/6i endocrine combination therapy”
- or questions such as “What is the BRCA mutation rate in metastatic breast cancer patients in real life? And what is the best course of treatment for these patients?”

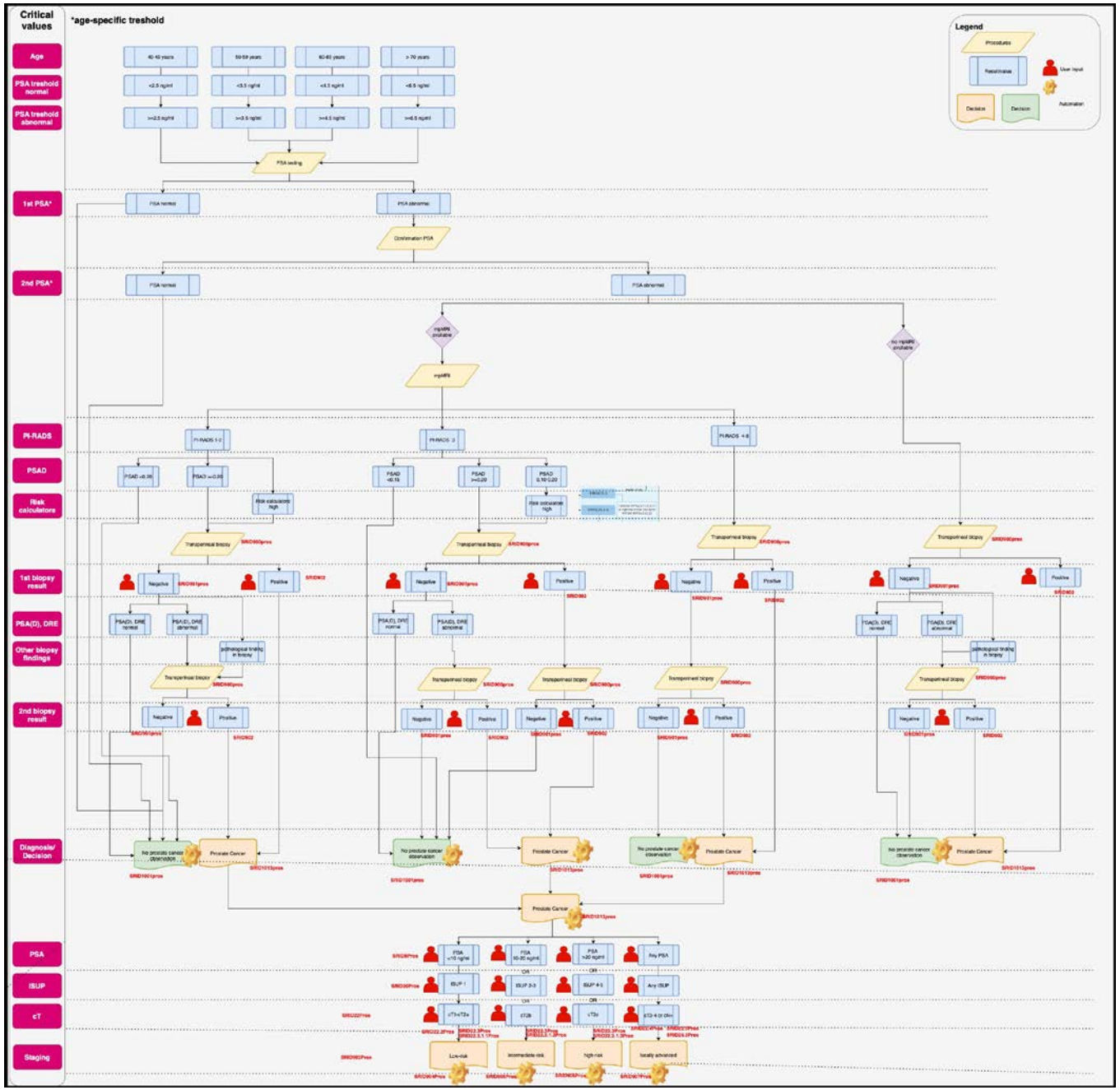
Lung cancer

- Questions like “What is the optimal treatment for patients who have a disease progression during or after cellular immunotherapy?”
- or questions such as “Can AI help to detect treatment-related adverse events at an early stage and thus support therapy management?"

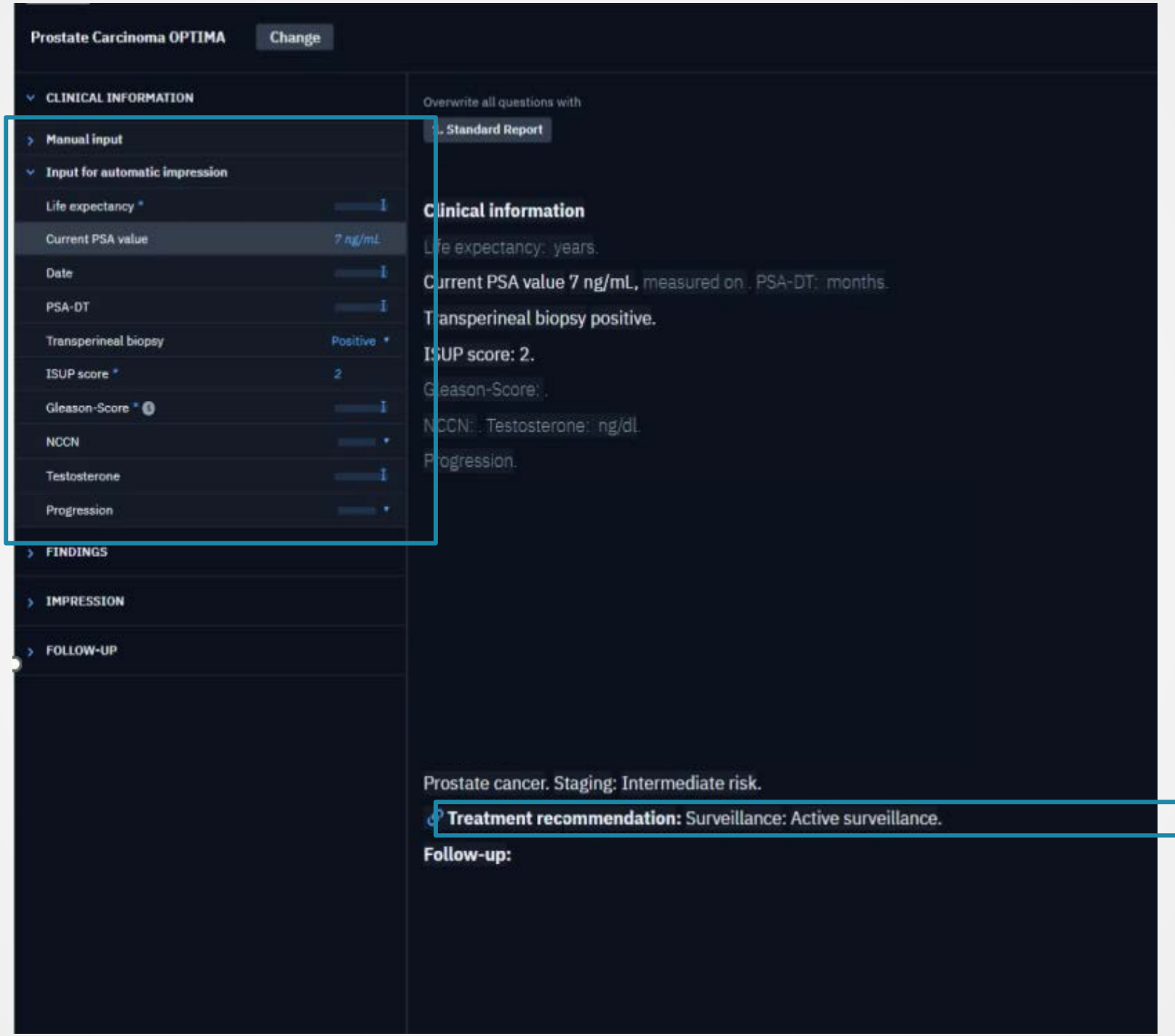
Map for diagnosis and staging

- From diagnosing cancers to deciding the right treatment is very complex.
- There are many details to track, including imaging results, lab tests, and patient factors.
- In OPTIMA, we create detailed treatment pathways to support clinical decisions.

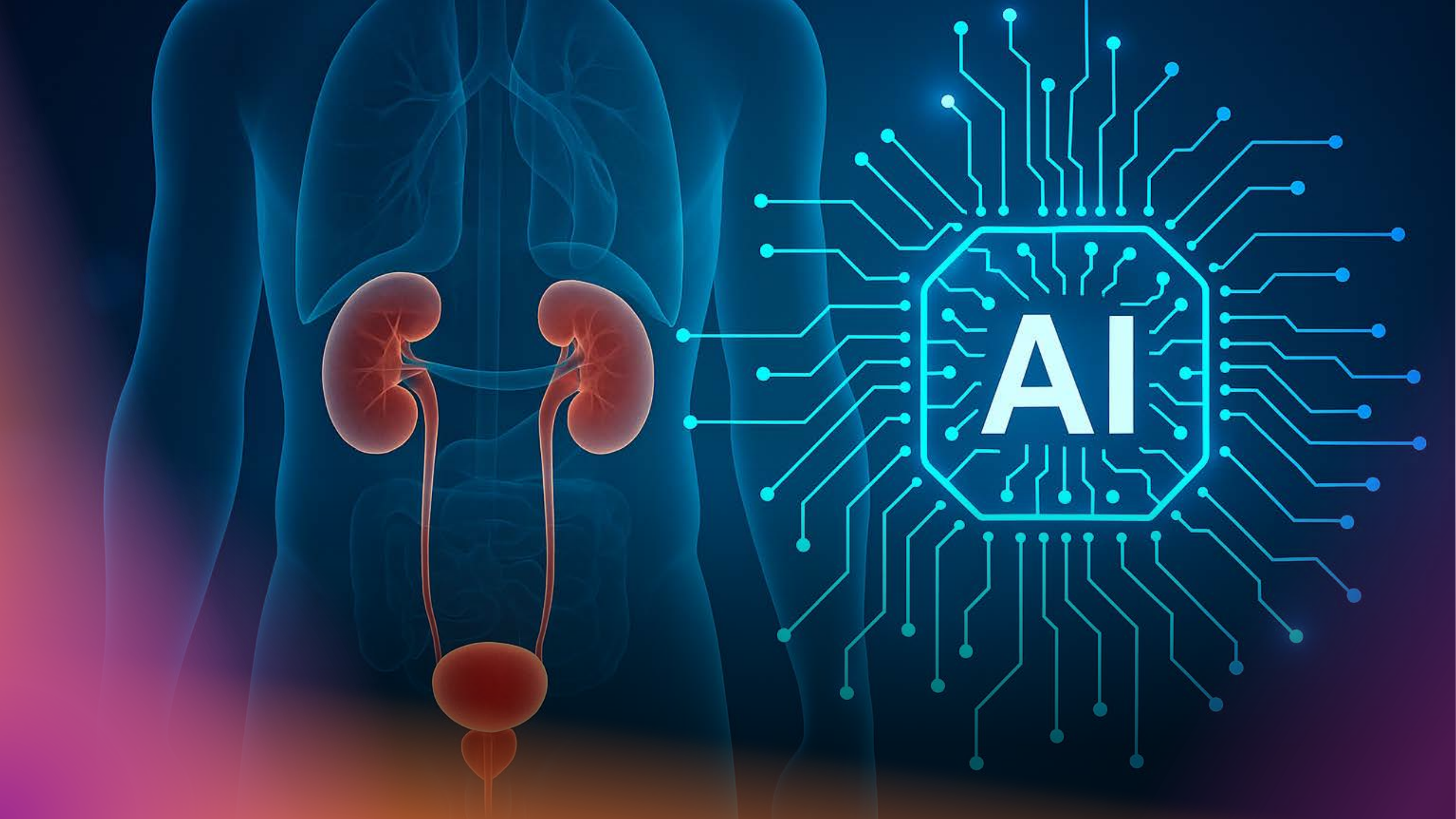
Our **clinical decision support tools** will help simplify this complexity so that healthcare providers can **choose the best treatment options with confidence**



1. User enters clinical information



2. Treatment recommendation is calculated automatically


AI

Impact of AI in cancer
Current Applications in Prostate cancer

- **Detecting Cancerous Growths:**
  AI systems can accurately tell the difference between harmless lumps and those that might be cancerous.
- **Better Than the Human Eye:**
  Advanced computer programs that analyze medical images (like X-rays or MRIs) can sometimes catch early signs of cancer more reliably than radiologists because they are fine-tuned to pick up subtle details.
- **Smarter Slide Analysis:**
  When doctors look at tissue samples under a microscope, AI tools help interpret these slides more accurately. This means relying less on extra, complex lab tests and still getting a clear diagnosis.

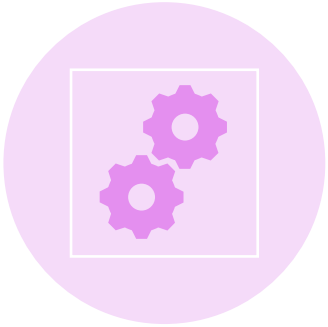
Future Directions and Potential

Personalised Oncology: AI will enable multi-omic integration (genomics, imaging, pathology) to tailor treatment pathways with increased precision.

Ensures you receive the right treatment at the right time

Predictive Modelling: Real-time analytics may inform prognosis and therapeutic response, guiding dynamic adjustments in treatment plans.

Empowers healthcare providers to quickly fine-tune treatments as patient conditions change



Workflow Automation: AI will streamline clinical workflows by automating image segmentation, report generation, and prioritisation of high-risk cases.

Frees up healthcare professionals to focus on patient care by reducing repetitive tasks

Decentralised Diagnostics: AI-driven mobile and telehealth platforms could improve early cancer detection in low-resource settings or underserved populations.

Makes cutting-edge diagnostic services accessible to communities where traditional healthcare facilities are limited.

OPTIMA

OPTIMA will revolutionize oncology in Europe:

- Ensure every cancer patient **accesses** the latest individualized treatments through **shared decision-making** powered by dynamic, computer-interpretable guidelines, diverse real-world data, and AI tools.

OPTIMA will personalize treatment via Clinical Decision Support:

- **Leverage the synergy** of real-world evidence and traditional clinical trials to deliver personalized care, with special focus on underserved populations.

Transformative Insights with Explainable AI:

- Harness explainable AI to uncover novel insights for the early diagnosis and treatment of **prostate**, **breast**, and **lung cancers**.

Thank you for your attention!

www.optima-oncology.eu
Twitter: @OPTIMA_oncology
Email: communication@optima-oncology.eu

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.

Cancer Epidemiology

IHI Cancer Portfolio

Focus on Specific Projects:

PIONEER

OPTIMA

GUIDE MRD

IMAGIO

GUIDEMRD

innovative health initiative

Liquid biopsy: From discovery to clinical implementation

Klaus Pantel

Director, Institute for Tumor Biology, UKE, University Cancer Center Hamburg (UCCH)

Founder & President of the European Liquid Biopsy Society (ELBS)

Academic coordinator of the GUIDE MRD project

This project is supported by the Innovative Health Initiative Joint Undertaking (JU) under grant agreement No 101112066. The JU receives support from the European Union's Horizon Europe research and innovation programme and EFPIA (including Vaccines Europe), MedTech Europe and LGC Clinical Diagnostics INC. Funded by the European Union, the private members, and those contributing partners of the IHI JU. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the aforementioned parties. Neither of the aforementioned parties can be held responsible for them.

Liquid Biopsy: The Concept

Definition: Liquid Biopsy* - Analysis of tumor cells (CTCs) or their products (e.g., DNA, miRNA, extracellular vesicles) and host cells (e.g., immune cells, endothelial cells) in blood (or other body fluids)

Rationale: Tissue biopsies are invasive and some locations are difficult to access (e.g., lung or brain)

In contrast, drawing blood from a peripheral vein is only minimally invasive

Moreover, blood is a pool of tumor cells (and their products) released from primary and metastatic lesions including all locations in a cancer patients

Sequential blood analyses in individual patients allow real-time monitoring of tumor evolution & therapy response

Vision: Comprehensive and real-time tumor information by the analyses of blood (or other body fluids)

CANCER ID

GUIDEMRD

innovative health initiative

Co-funded by the European Union

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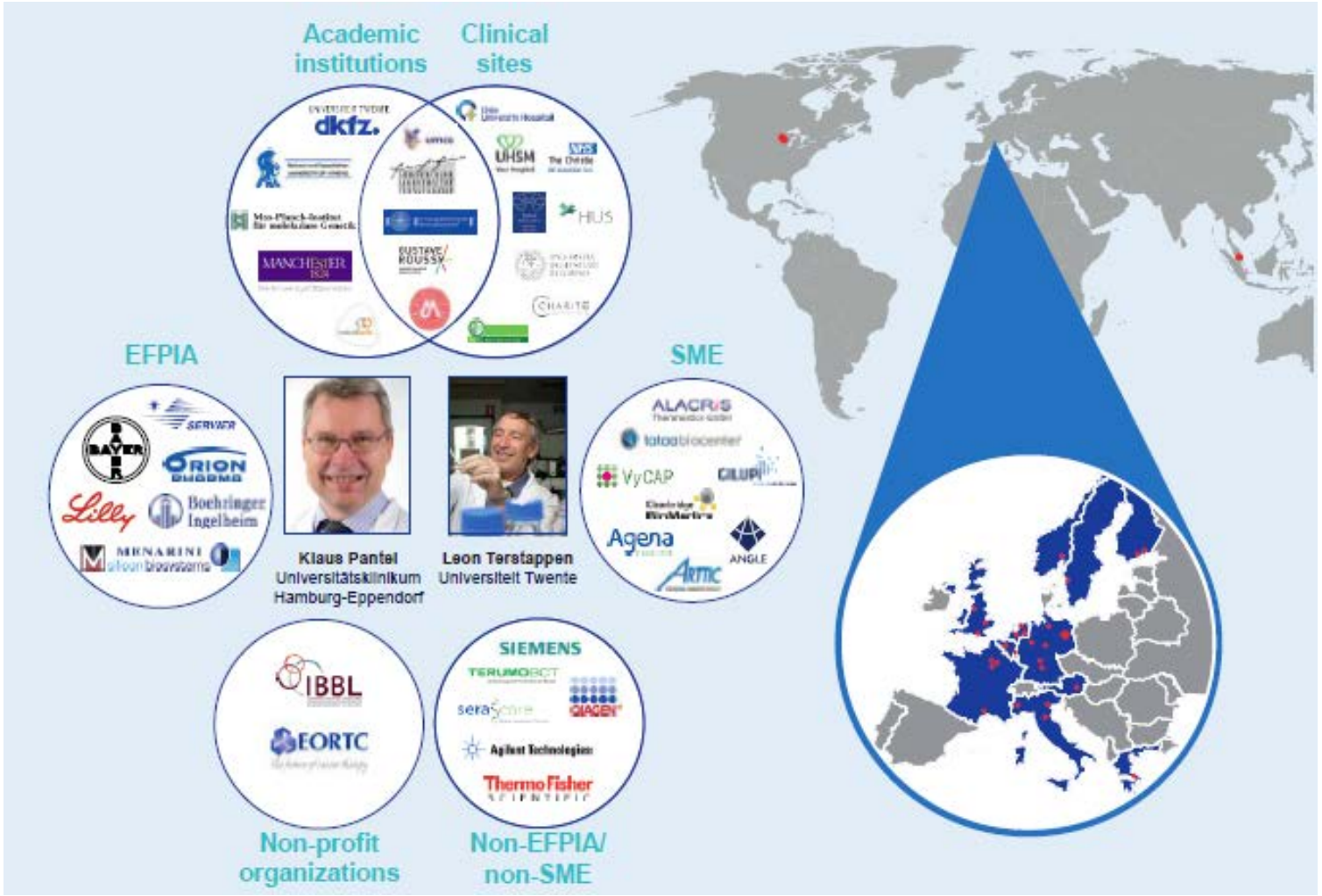
CANCER-ID: the Origin of ELBS

Evaluation of technologies for tumor liquid biopsy in Lung Cancer and metastatic Breast Cancer.
(e.g. CTCs, ctDNA and cfmiRNAs)

- 40 partners from academia and industry
- 5-year project (2015-2019)
- Combined budget of 18 Million €
- ✓ > 50 scientific publications, more added each year



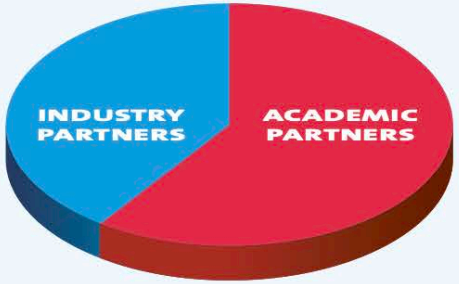
Consortium of 93 Institutions from academia and industry: Clinical implementation of Liquid biopsy

(ELBS – “Legacy” (EU/IMI Factsheet 05/2022)

ELBS

EUROPEAN LIQUID BIOPSY SOCIETY

CURRENT MEMBERS



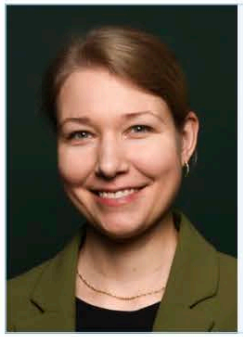
ORGANIZATION TEAM

CHAIRMAN | ELBS

Prof. Dr. med. Klaus Pantel
Director of the institute

Center for Experimental Medicine
Institute of Tumor Biology

pantel@uke.de
+49 (0) 40 7410 – 53503



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WORKING GROUPS

ELBS Outputs and achievements of CANCER-ID/ELBS

Scientific Publications	"ELBS-approved" technologies and assays	Data for ISO certification of labs
White Papers	Best Practices (SOPs)	Research Collaborations & Projects
Clinical Study Guidelines	Research Grants	Healthcare Coverage and Reimbursement

innovative health initiative

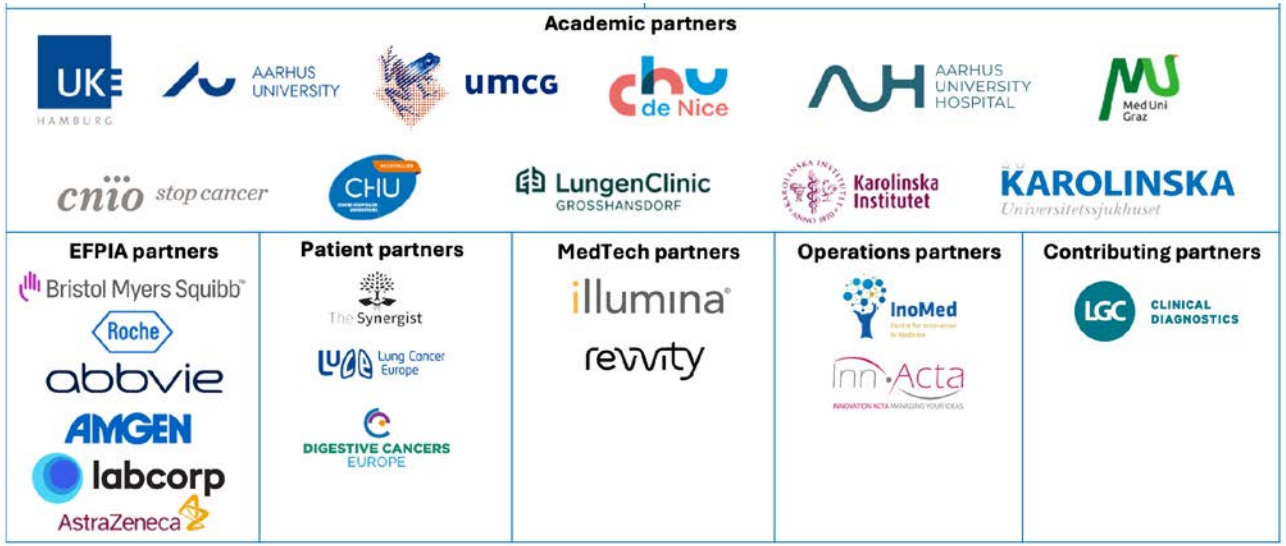
GUIDE.MRD

GUIding multi-moDal thErapies against MRD by liquid biopsies

GUIDE.MRD Objectives
Create reference standards & benchmark liquid biopsy assays (ctDNA)
Robust clinical validation of Liquid biopsy in colorectal, pancreatic and lung cancer
Integration of Minimal Residual Disease as a decision tool to guide treatment selection

Project duration: 5 years 2023-2028

Total cost: 35 Million € (EU contribution: 17,6 Million €)



efpia MedTech Europe from diagnosis to cure COCIR Advancing Healthcare EuropaBio Vaccines Europe

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Funded by the European Union

Early Detection of Minimal Residual Disease (MRD)

Minimal **R**esidual **D**isease: the small number of cancer cells in the body after cancer treatment

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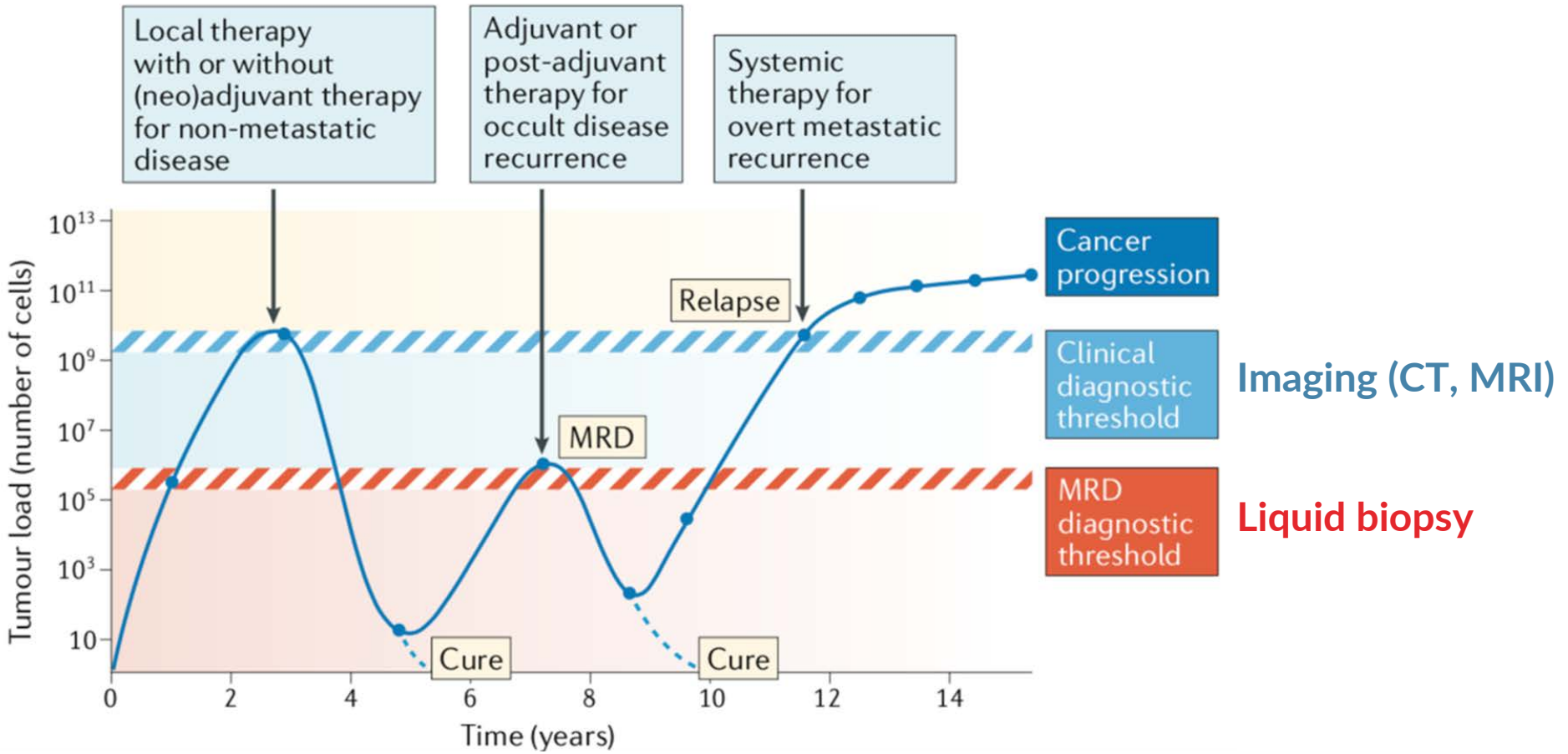
Early Detection of Minimal Residual Disease (MRD)

Minimal **R**esidual **D**isease: the small number of cancer cells in the body after cancer treatment



Pantel and Alix-Panabières, *Nature Rev. Clin. Oncol.* 2019

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Circulating cell-free DNA in the blood

ctDNA tests:

1st method : To use tumor tissue - Sequencing -> Patient-specific probes for liquid biopsy with Ultra high sensitivity

2nd method: No tumor tissue required but lower sensitivity

ctDNA challenges:

- FALSE POSITIVE: Normal cells such as breast or bladder epithelium
- FALSE NEGATIVE: Tumor lesions that are non-shedders
- LOW concentrations in early-stage disease/MRD

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GUIDE.MRD: Overall aims and Objectives

Objective 1

To **benchmark available circulating tumor DNA (ctDNA) assays** for sensitivity, specificity, and predictive value in the adjuvant setting, where minimal residual disease (MRD) is indicative of disease progression

Objective 2

To **clinically validate the top ranking ctDNA assays** prospectively in patients diagnosed with **Lung, colorectal and pancreatic cancer** and produce a patient-centric **roadmap for the clinical implementation** of ctDNA diagnostics

Objective 3

To determine the **utility of ctDNA assays as prospective decision tools** of clinical response and **choice of multi-modal therapy** including novel combination therapies

Objective 4

To reach consensus with the **key stakeholders** - health authorities, payers and patient groups - towards **implementation of ctDNA into clinical practice**

GUIDEMRD innovative health initiative Co-funded by the European Union

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Clinical Studies in GUIDE.MRD

GUIDE.MRD-01-Colorectal Cancer

(prospective observational clinical trial)

GUIDE.MRD-02-Pancreatic Cancer

(prospective observational clinical trial)

GUIDE.MRD-03-Lung cancer

(prospective observational clinical trial)

GUIDE.MRD-04-COMPARATIVE

(retrospective clinical trial)

Non-inferiority of the top-performing ctDNA diagnostic (existing trials + GUIDE.MRD results)

GUIDE.MRD-05-RANDOM

(prospective randomized interventional clinical trial)

Post adjuvant therapy in ctDNA+ patients with recurrence from GUIDE.MRD trials (n = 56)

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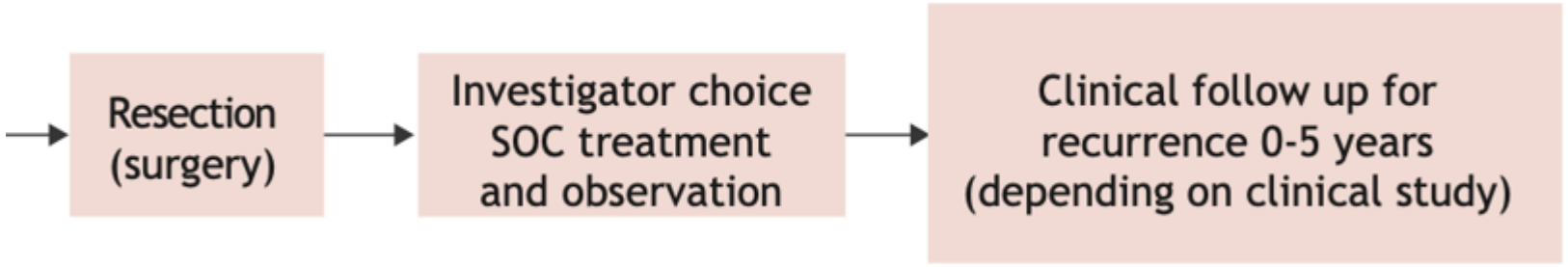
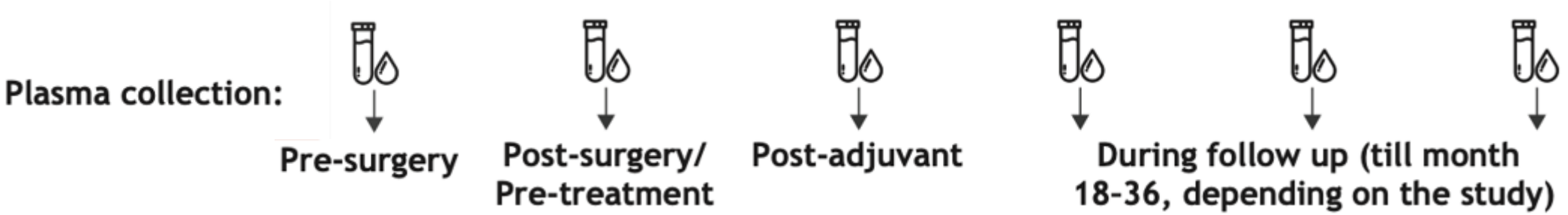
GUIDE.MRD through 3 observational clinical studies

Total: 960 patients

Colorectal Cancer
590 patients
Pancreatic Cancer
184 patients
Lung Cancer
186 patients





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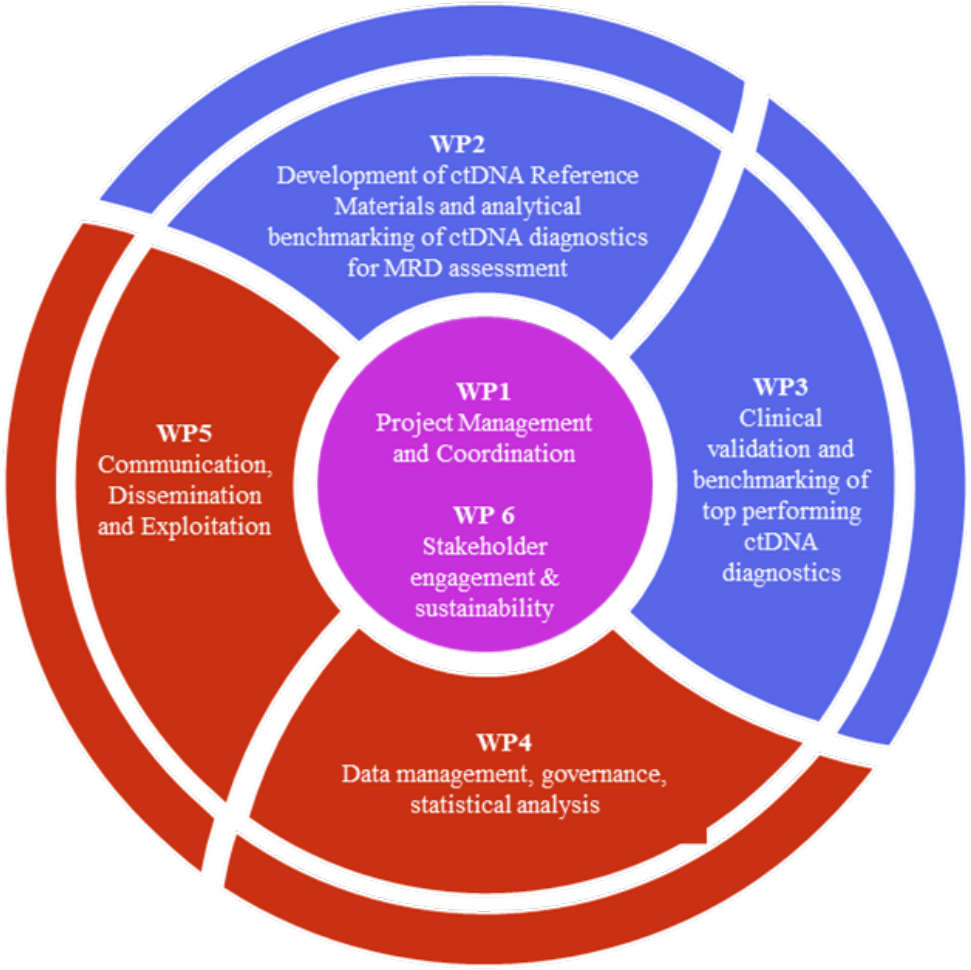
Strong collaboration within the project

- **Strong connections** between each of the work packages to achieve the objectives of GUIDE.MRD
- **World leading academics** & **industry partners** working together in the GUIDE.MRD project
- Academia lead and industry **co-leads** ensure an efficient environment bringing knowledge together
- Inclusion of two major **patient organizations** (DICE and LuCE) as well as planned inclusion of **patient advisors**
- Strong **multi-stakeholder engagement** (The Synergist)



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Summary

Early detection of Minimal Residual Disease /relapse requires ultrasensitive assays

Tumor burden and molecular characterization of ctDNA are relevant for therapy decisions

Molecular tumor composition can shift during surveillance period – discordance between primary and (micro)metastatic lesions/Minimal Residual Disease

Assays need to be validated and harmonized – ELBS

Interventional studies are important to demonstrate that early Minimal Residual Disease detection leads to improved clinical outcome

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Clinical Utility of Liquid Biopsy

Cancer screening, detection, and early diagnosis

Pre- or postoperative risk assessment and prognosis

Minimal Residual Disease detection and prediction of recurrence

Treatment selection

Identification of therapeutic targets & resistance mechanisms

Treatment response assessment

Alix-Panabieres & Pantel, Cancer Discovery, 2021; Hofbauer, Pantel et al., Nature Rev. Clin. Oncol. 2022; Lawrence, Pantel et al, Nature Rev. Clin. Oncol. 2023; Pantel & Alix-Panabieres, Nature Rev. Clin. Oncol. 2025

CANCER ID

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Thank you for your attention

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Cancer Epidemiology

IHI Cancer Portfolio

Focus on Specific Projects:

PIONEER

OPTIMA

GUIDE MRD

IMAGIO

IMAGIO

innovative health initiative

Robert Hofsink
(Philips Image Guided Therapy)

Coosje Verhagen
(Leiden University Medical Center)

A new pillar in cancer treatment

What is Interventional Oncology?

- Minimally invasive
- Image guided
- Treatment through the skin or the blood vessels
- Tumor destroying techniques:
  1. Local application of chemotherapy
  2. Radioactive particles
  3. Heating or freezing

Benefits of Interventional Oncology

Smaller incision: fewer complications & less pain

Alternative to open surgery: when this is not possible or when patients are too weak

Can be used in combination with other techniques → increase treatment efficacy

Faster recovery → Shorter hospitalization → lower healthcare costs

Overall project Objectives

IMAGIO will leverage **Interventional Oncology** in the clinical setting to improve the cancer survival outcomes, through minimally invasive, efficient, and affordable care pathways for three disease states:

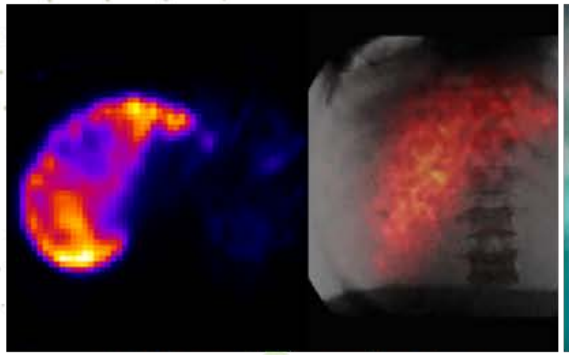
Liver cancer

Lung cancer

Sarcoma

In IMAGIO, **top innovators** in MedTech and Pharma and expert academic clinical centers will mature the **next-generation Interventional Oncology**

Overall project Objectives

Objective 1	Objective 2	Objective 3	Objective 4
			
Multimodal imaging for radioembolization therapy for liver cancer	Multimodal ablation therapy for liver cancer	Multimodal diagnosis and therapy for lung cancer	Multimodal MR-HIFU-enabled therapy for sarcoma

Clinical validation studies

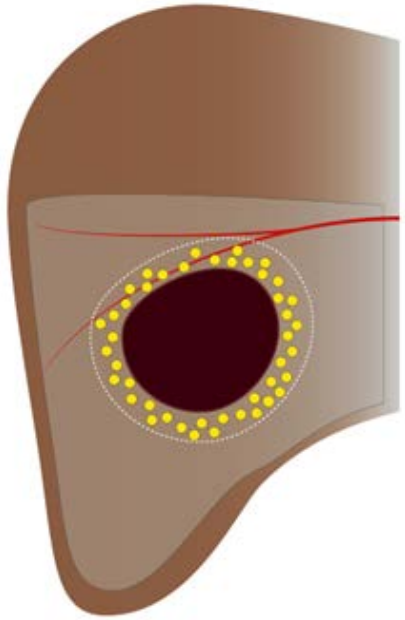
Image-based guidance during treatment

AI-based image processing for diagnosis and treatment planning

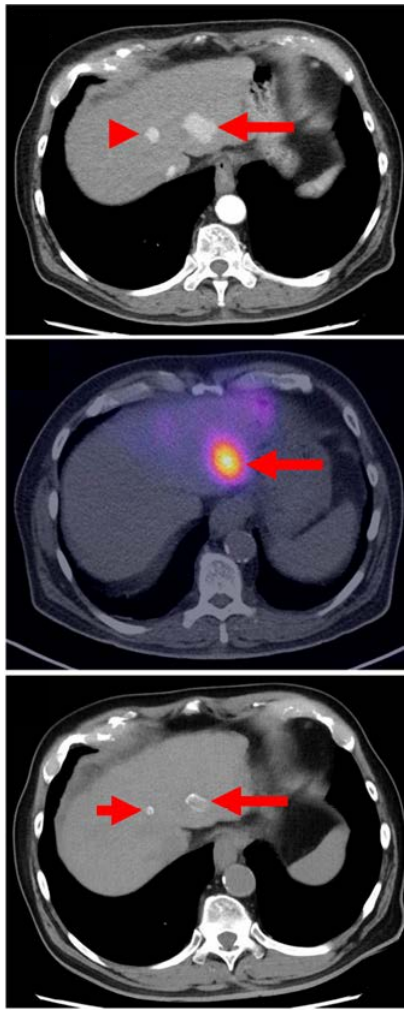
Advanced multi-modal imaging technologies

Objective 1

What is radioembolization in liver cancer?



- Administration of radio-active beads through the blood vessels
- Accumulation in, and in proximity to, the tumor
- The beads deliver high doses of radiation to the tumor, killing it over time

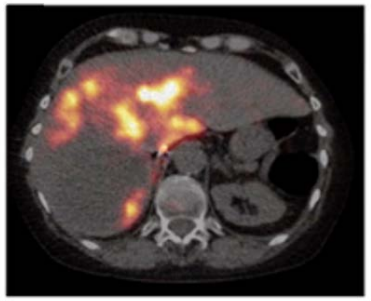


[1] Drescher R. et al.. (2023) doi:10.3390/biomedicines11071831

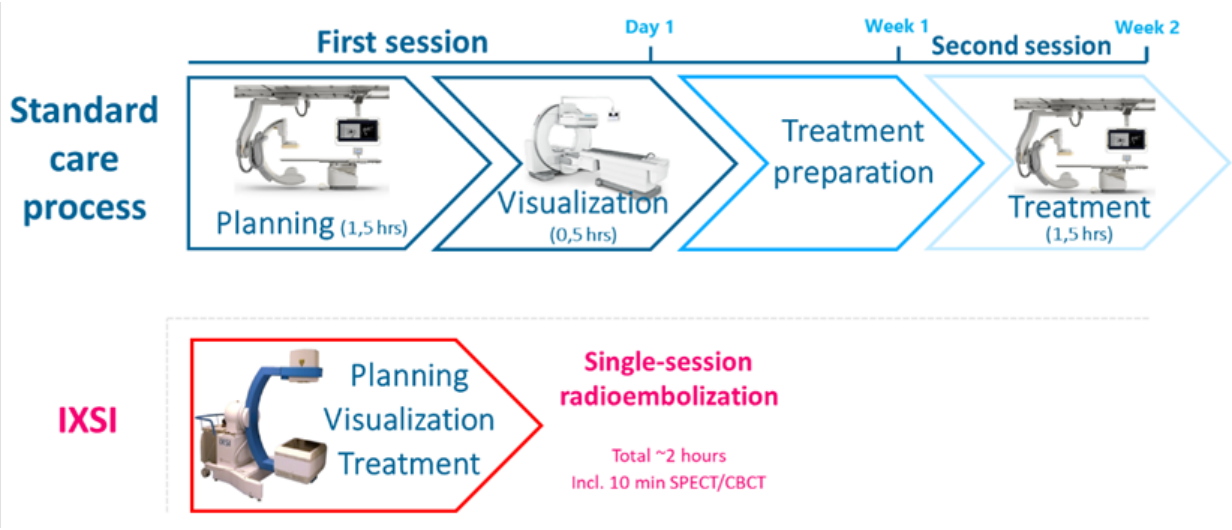
Objective 1

Multimodal imaging for fast radioembolization therapy of liver cancer

- Integration of combined imaging techniques to get the procedure shorter and more precise for patients → Single session for radioembolization

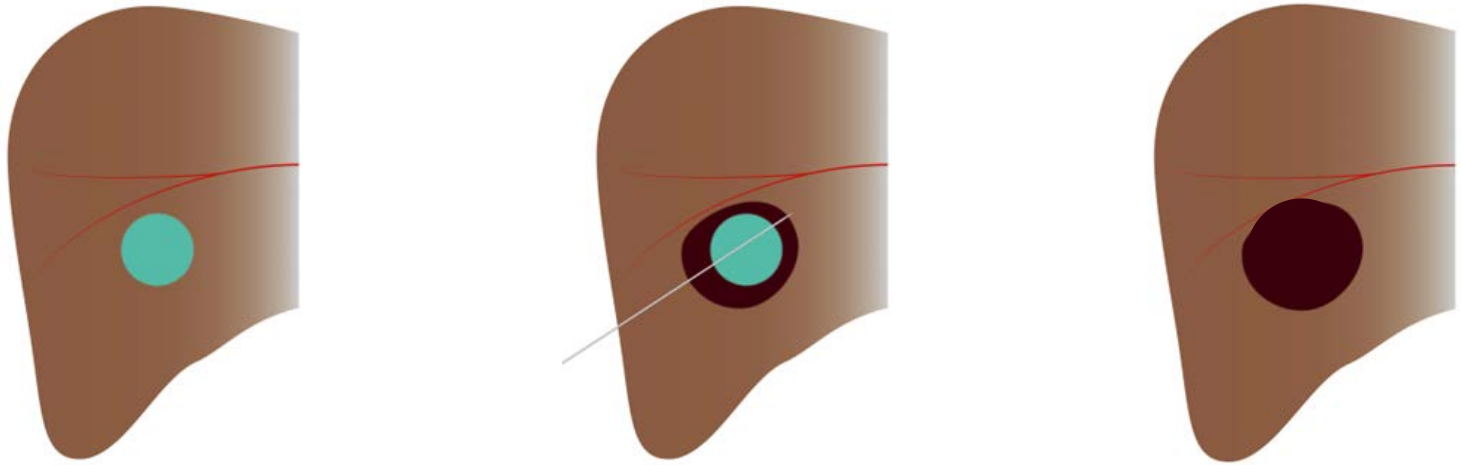


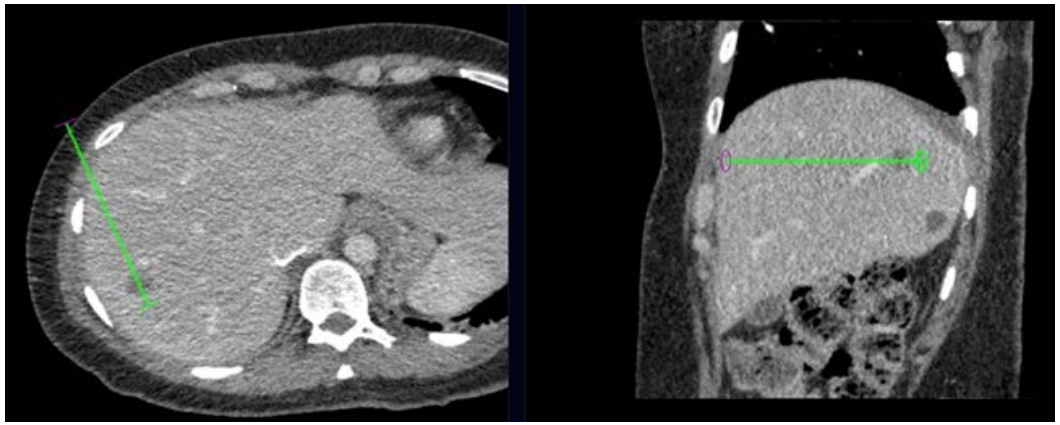
SPECT for liver and tumor dose

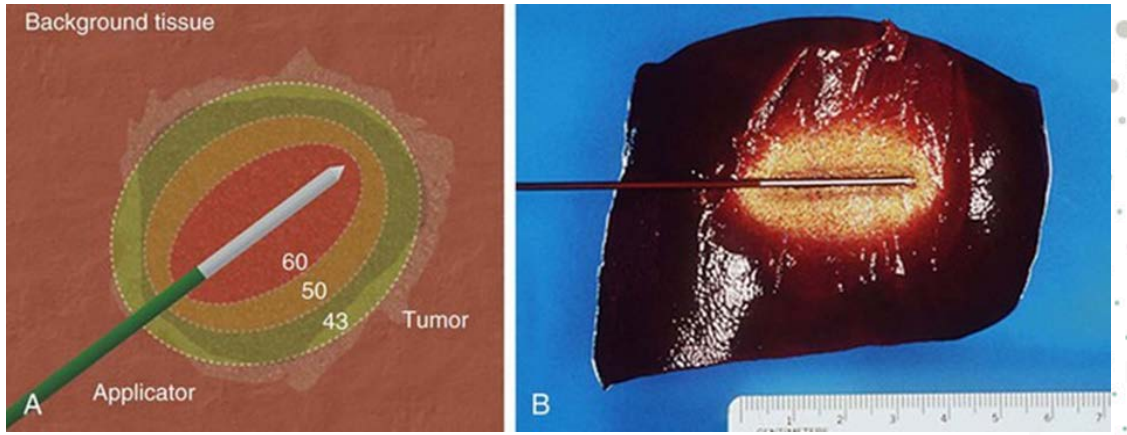


Objective 2

What is thermal ablation?





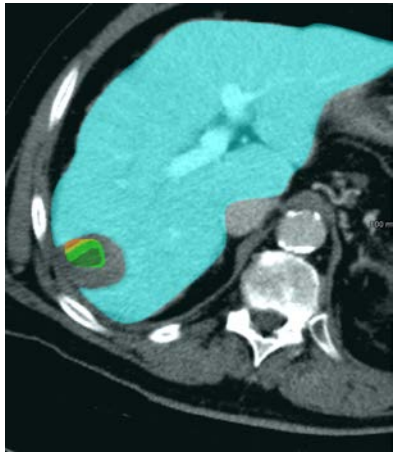


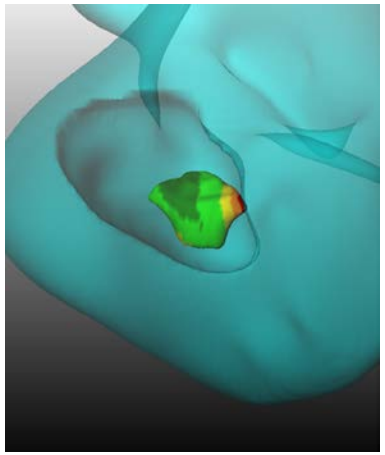
- A thin needle is inserted through the skin, guided by imaging to reach the liver tumor.
- Heat is applied through the needle to destroy the tumor

Objective 2

Multimodal thermal ablation therapy for liver cancer

- Artificial Intelligence-based segmentation algorithms for the liver, tumor and ablation zone integrated in deLIVERed software, providing real time feedback on treatment efficacy.
- Develop Artificial Intelligence tools to predict post-treatment recurrence and guide personalized follow-up strategies

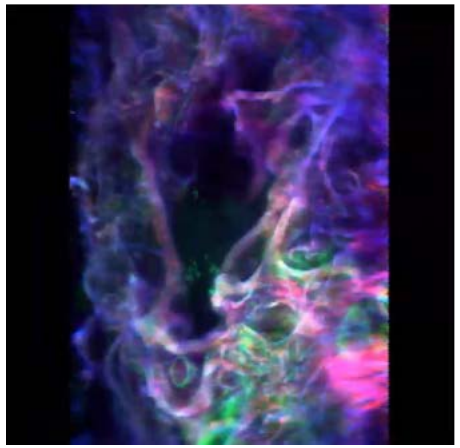


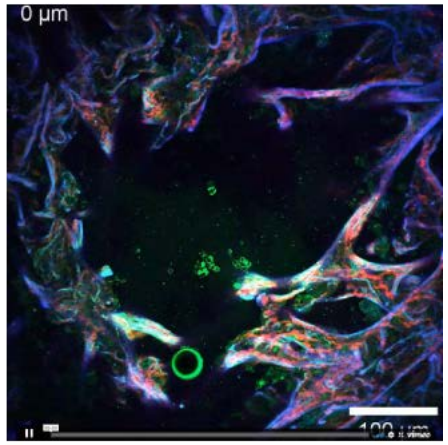


Objective 3

Multimodal diagnosis and therapy for early-stage lung cancer

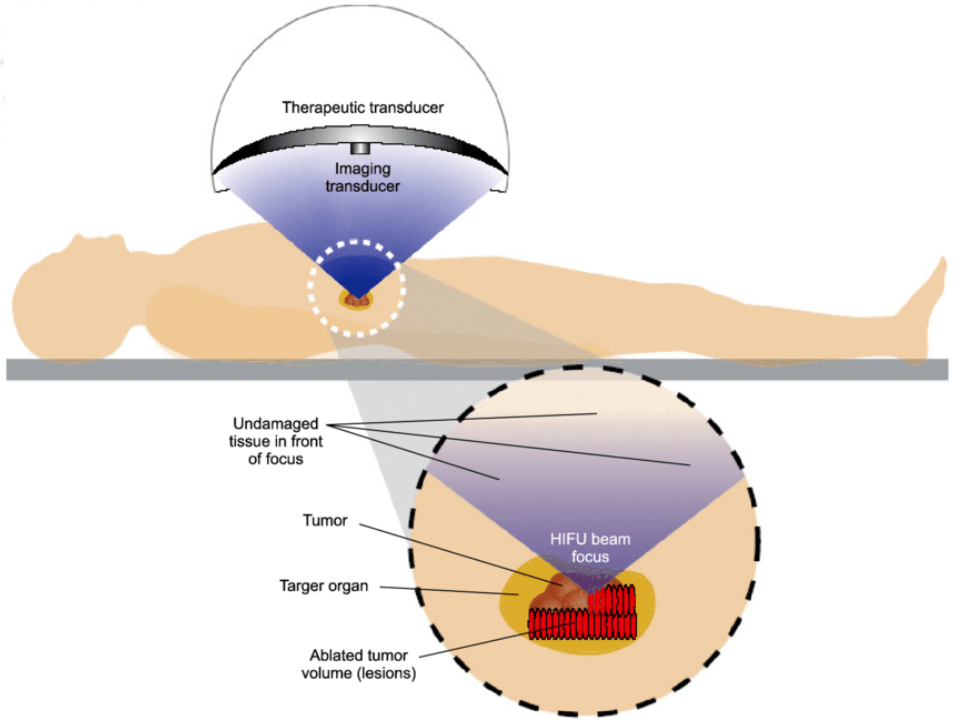
- Imaging and patient data collected for Artificial Intelligence-supported decision model to predict treatment outcome and cost effectiveness
- Novel microscope prototype has been completed. Benefit: much faster workflow, time for pathology biopsy sample analysis shortened from days to minutes

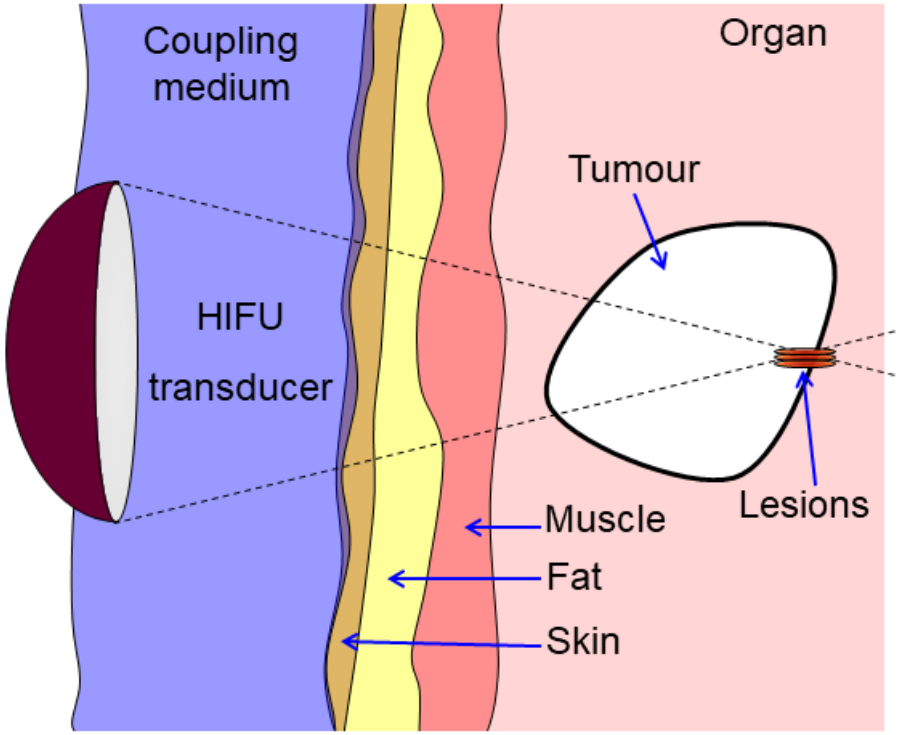




Objective 4

What is MR-HIFU: Magnetic Resonance-guided High-Intensity Focused Ultrasound?

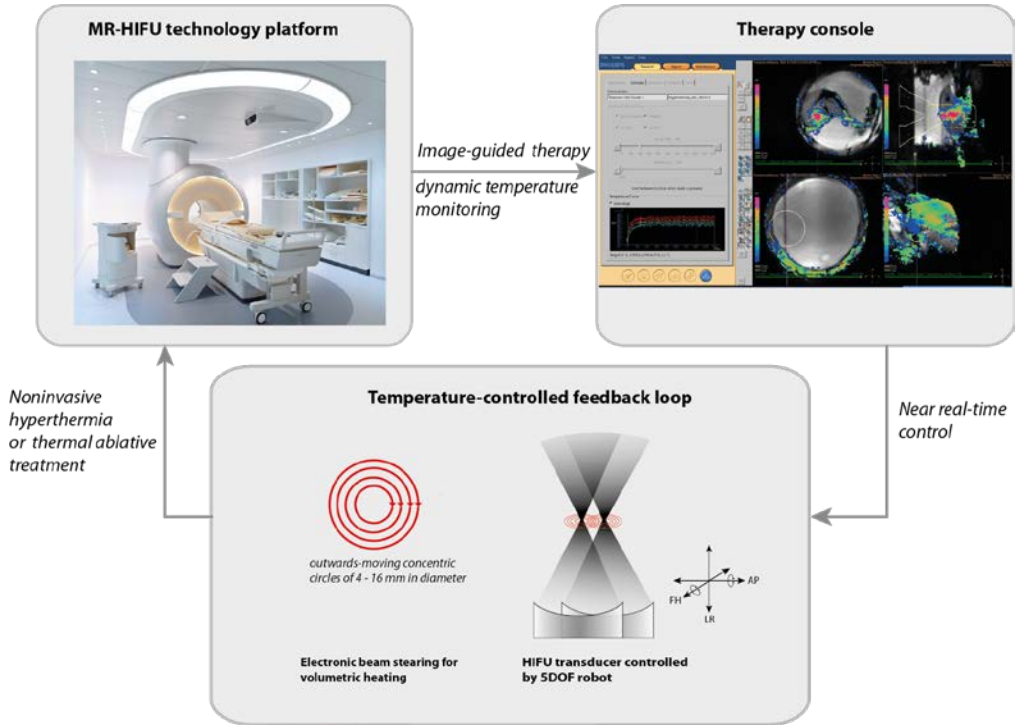




Objective 4

Multimodal MR-HIFU-enabled therapy for sarcoma

- Integration of High Intensity Focused Ultrasound (HIFU) and MRI guidance
- Artificial Intelligence-based algorithms for the automation of personalized treatment planning, leads to easier workflow for physicians and better treatment reproducibility.



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Spotlight on Liver Ablation

Multimodal ablation therapy as treatment for liver cancer

Leiden University Medical Center

Maastricht UMC+

PHILIPS

innovative health initiative

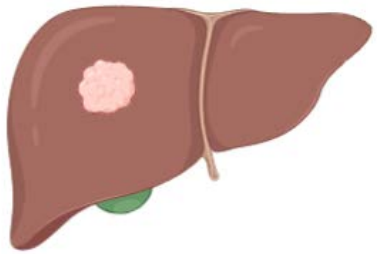
European Commission

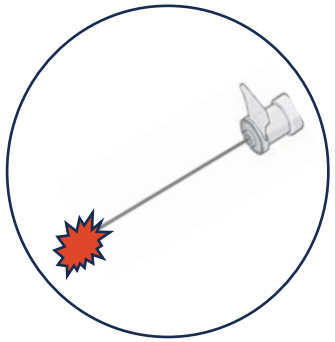
Global burden of liver cancer

Projected to become the **3rd leading cause** of c**ancer-related death** by 2030

Projected to increase to **800-900 thousand new cases per year by 2040**, with a **5-year survival rate of 40-50%**

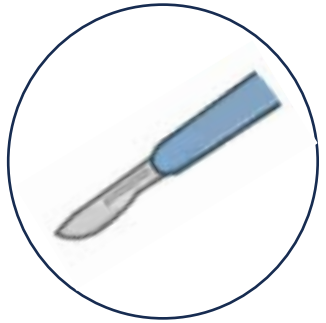
Treatment of (early staged) liver tumors





Thermal ablation

- ↓ Associated complications & death rates
- ↑ Cost effective
- ↑ Little contra-indications
- ↓ Short hospital admissions (1-2 days)
- Maximal tumor diameter ≈ 5cm



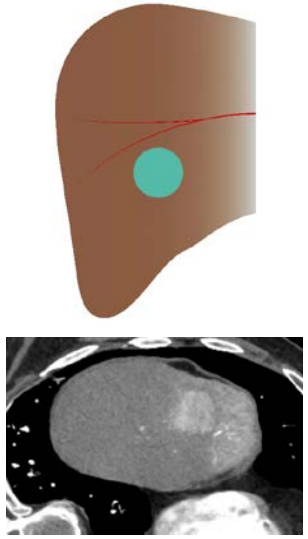
Surgical resection

- ↑ Death and complication rates
- ↑ Patient related contra-indactions
- ↑ longer hospital admissions (≈ 5-10 days)
- ↑ Suitable for small and large tumors

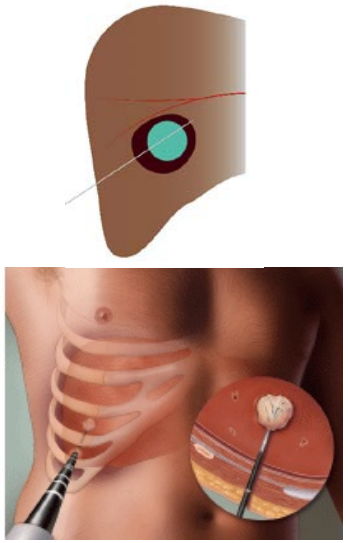
Liver tumor(s) treated with thermal ablation

1. Bring the patient to the intervention room

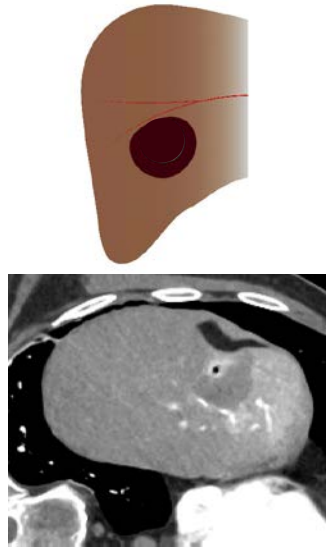
2. General anesthesia or sedation



3. Find the tumor and plan the needle trajectory



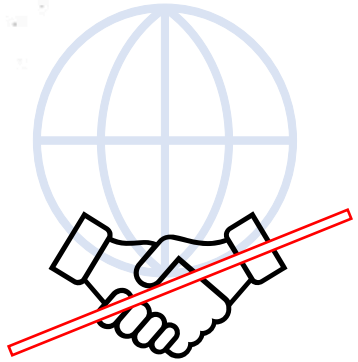
4. Insert the needle into the tumor and ablate



5. Check if the entire tumor is treated

6. Hospital discharge, ≈1day after procedure

Kick off IMAGIO : Focus group discussion with European experts



Thermal ablation often not the treatment of choice for patients with a liver tumor(s) due to **diversity in outcomes across different centers/countries**

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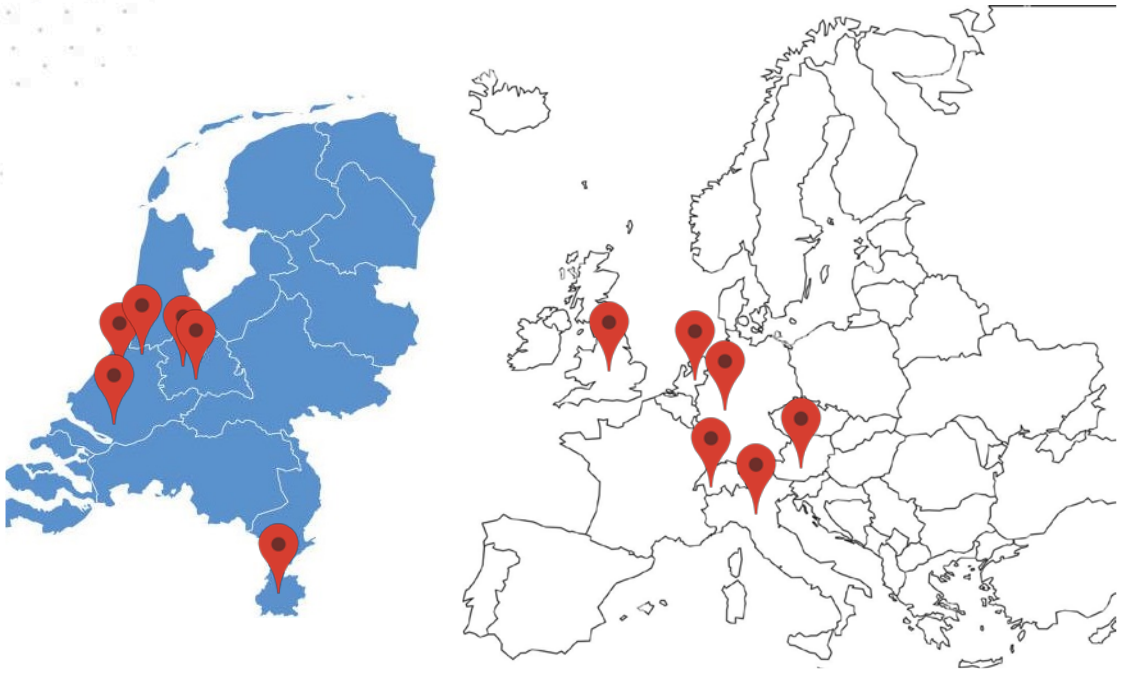
Clinical study on ablation within IMAGIO project (A-IMAGIO)

Obtain and analyze large-scaled international data on thermal liver ablation



Maastricht UMC+

Leids Universitair Medisch Centrum

Radboudumc

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een santeon ziekenhuis

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MEDIZINISCHE UNIVERSITÄT INNSBRUCK

NHS
The Newcastle upon Tyne Hospitals
NHS Foundation Trust

Fondazione IRCCS
Istituto Nazionale dei Tumori

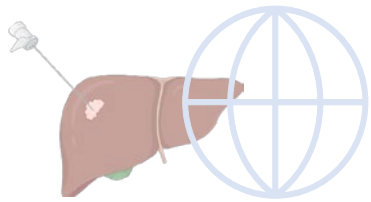
1. Identify ‘best practices’
2. Evaluate efficacy and safety of thermal ablation

Expected impact for thermal ablation

- ✓ Guidance in decision making for personalized treatment
- ✓ AI-based algorithms that allow optimized procedures
- ✓ AI-based algorithms that allow automated treatment evaluation
- ✓ Computational model to identify patients at risk of recurrence

More **standardized**, partly AI driven, approach for thermal ablation of malignant liver tumors.

Comparable outcomes worldwide



Thermal ablation as the treatment of choice for the majority of liver tumors

Conclusions and outlook

- Interventional Oncology uses image guidance for the minimally invasive treatment of cancer patients
- Benefits: fewer complications, faster recovery, shorter hospitalization, cost effective
- The IMAGIO project will deliver impactful results in the areas of imaging and AI-supported treatment delivery to advance the field of Interventional Oncology
- The A-IMAGIO clinical study will accelerate the adoption of multimodal ablation therapy as the first-line treatment for liver tumors


IMAGIO
IMAGING AND ADVANCED GUIDANCE FOR WORKFLOW
OPTIMIZATION IN INTERVENTIONAL ONCOLOGY

Q&A time

Use the **chat** below to ask questions to the speakers

innovative health initiative

innovative health initiative

Thank you for your attention

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