

**DIGICORE – a community to  
transform cancer outcomes  
research across Europe**

*Prof. Ciliberto*  
*DIGICORE President*

CONNECT TO WIN 2023 Meeting  
Madrid 13.-14 Nov 2023



## What I will cover today



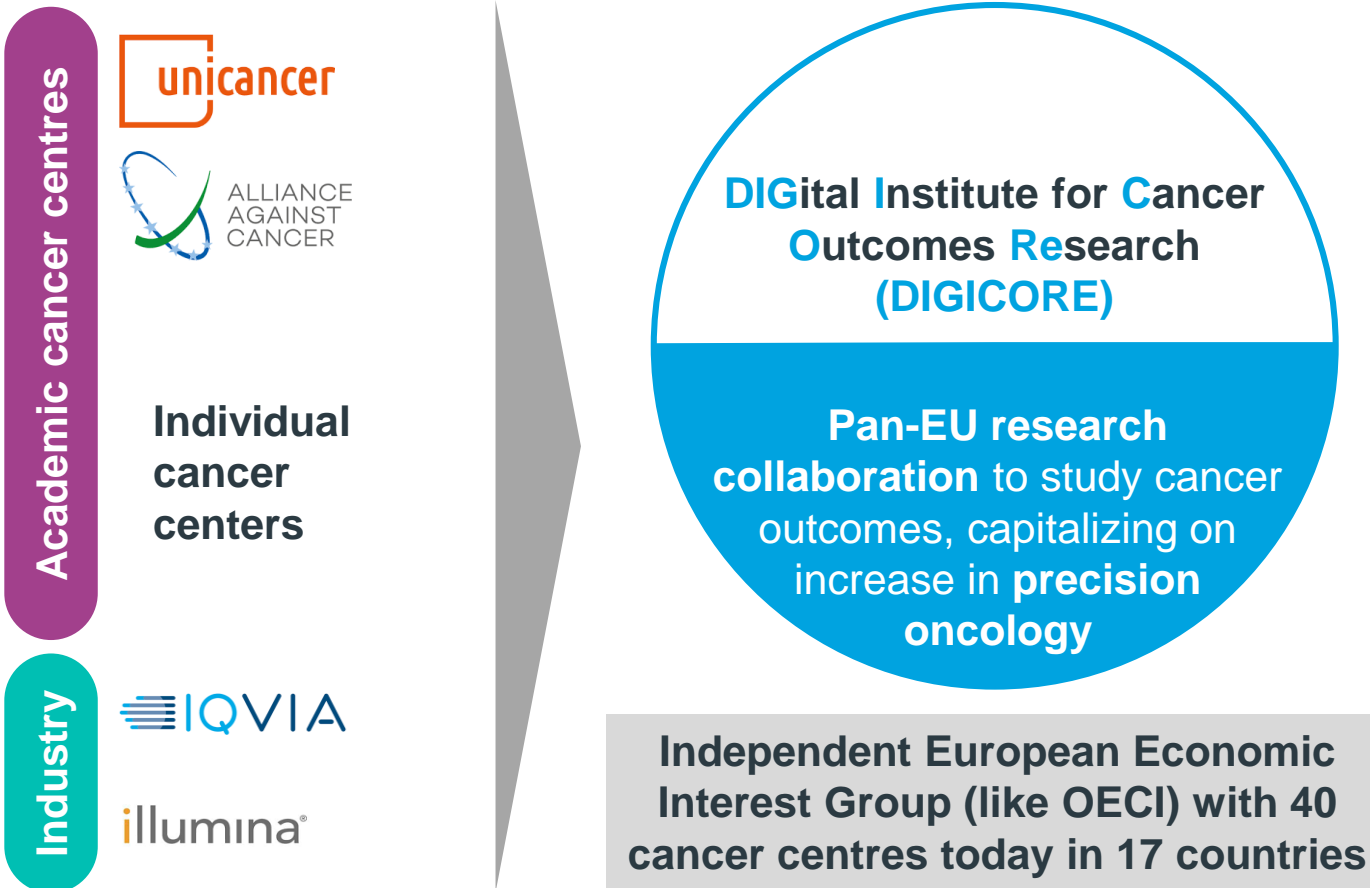
- Extend you all a warm welcome
- Provide an introduction to DIGICORE for those new to our community
- Share what DIGICORE has achieved in 2023
- Share some thoughts on what to look forwards to in 2024-2025

# DIGICORE is an international consortium that aims to transform and digitise cancer outcomes research in Europe



## Members

## Benefits and rationale

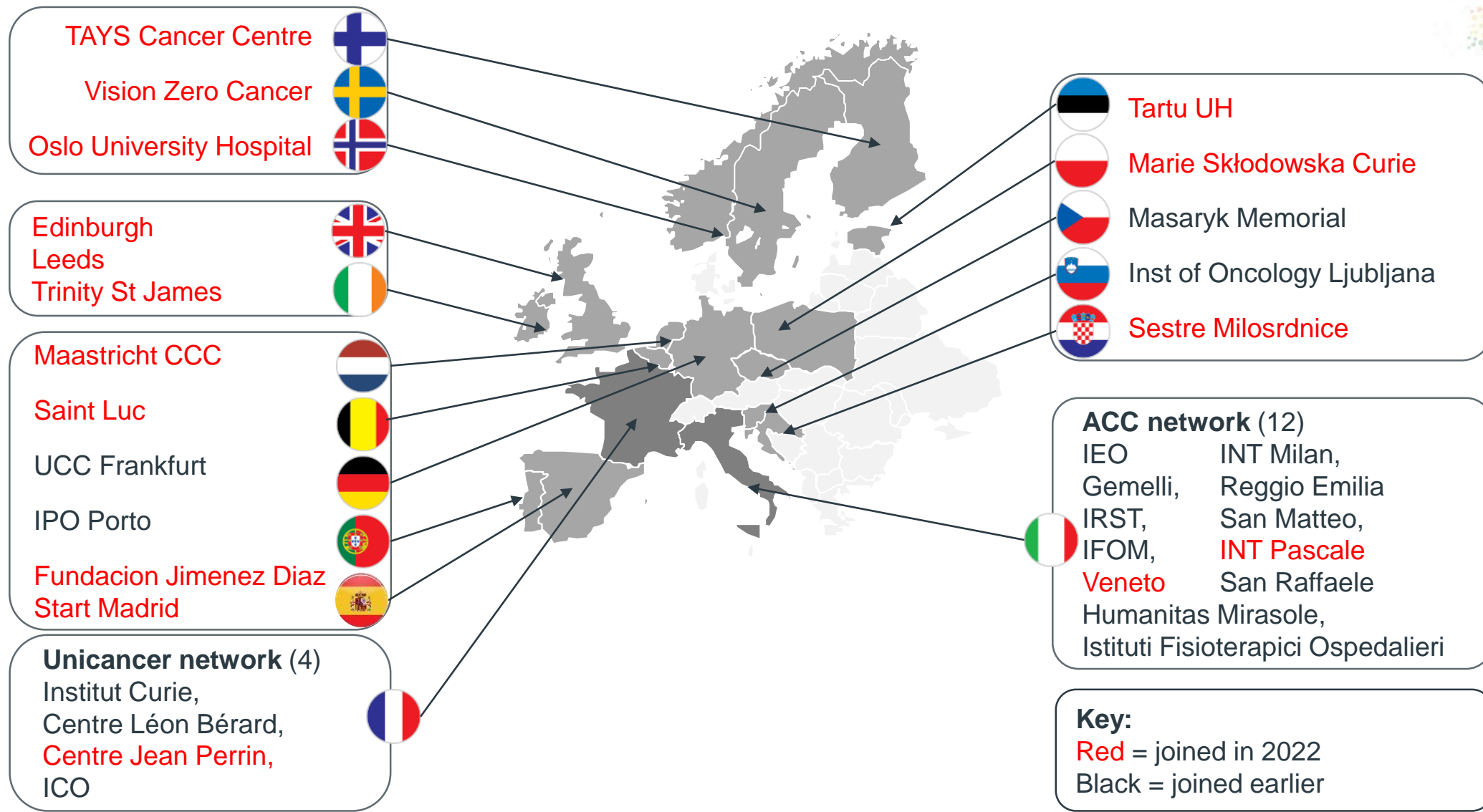


- For **Cancer Centres**, interoperability of cancer data across sites for improved translational research
- For **Patients**, broader trial access and in future better outcomes
- For **Industrial Partners**: drive commercial multi- centre, international RWE projects in precision oncology and drive precision trial recruitment
- Grow clinical evidence base for molecular diagnostic tests in improving outcomes and accelerate reimbursement for all vendors

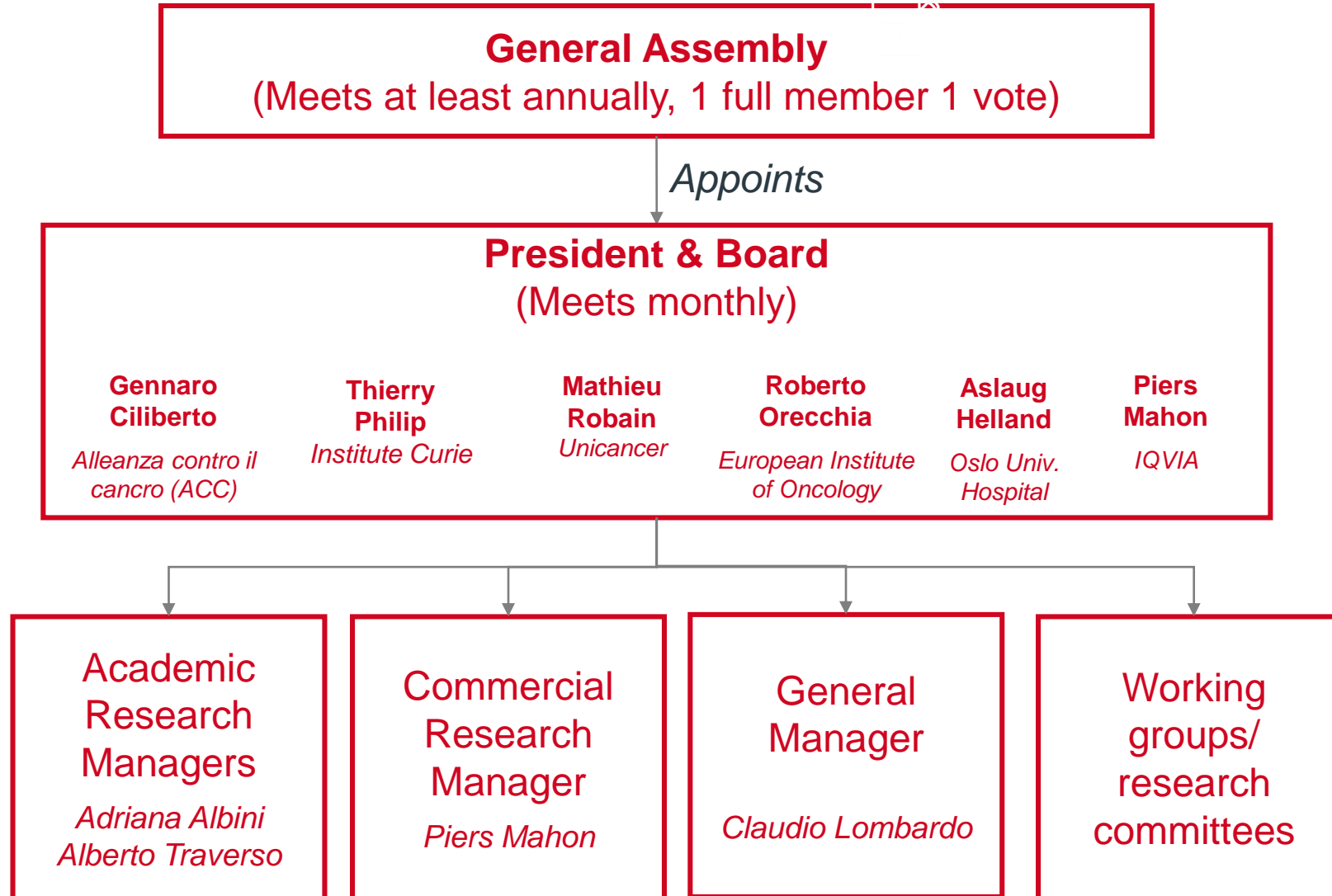
## Key Principles Built Into DIGICORE's Legal Constitution

1. **Medical hypothesis neutrality** – no large pharma inside
2. Cancer centres retain **full data control** and autonomy over clinical decisions
3. Serve **both academic and commercial research**
4. **Institutional research autonomy** – right to refuse any study, or propose one
5. **Equality in research activity** of Associate members and Full Members
6. Technical solutions will be **federated**, include a **common data model** but do not have to be implemented until / unless funded

# DIGICORE now includes 40 cancer centres in 17 countries – everyone welcome to join!

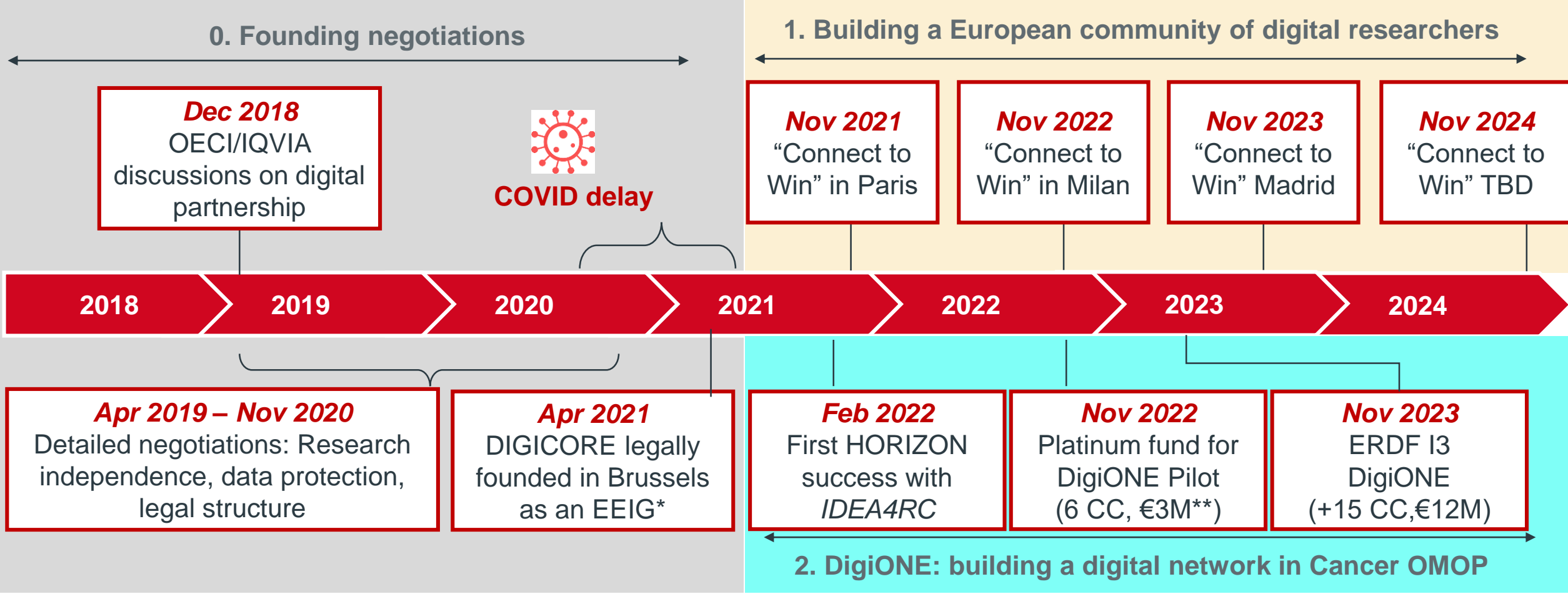


# We are organised legally as a European Economic Interest Grouping





# Three chapters to DIGICORE's story so far



\* European Economic Interest Grouping, same legal structure as OECI

\*\* Funded by IQVIA and Illumina

# We are participating to 4 HORIZON projects and have started a major internal project (DigiONE) directed to build a Digital infrastructure involving our centers



**DigiCore**  
**IDEA4RC**  
Intelligent Ecosystem to improve the governance, the sharing and the re-use of health Data for Rare Cancers

**DigiCore**  
**CAN.HEAL**  
Building the EU Cancer and Health Genomics platform

**DigiCore**  
**EUonQoL**  
Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe

**DigiCore**  
**DigiONE**  
DIGItal Infrastructure for ONcology in Europe  
Building a European federated digital research network

**DigiCore**  
**CCI4EU**  
Comprehensive Cancer Infrastructures for Europe



# In 2023 we completed our first a multi-centre study methods training program for early career researchers – IDEAL4RWE



## The story in numbers

- **47 participants** signed up for phase 1
- **4 seminars** delivered on RWE technical content
- **4 teams** self-organised and working on studies
- **3 teams** awarded funding by IQVIA (LAB decision)
- **2 “leadership retreats”** in Paris (Sept '22) and Frankfurt (March '23)
- **2** conference abstracts submitted
- Overall **feedback** received
  - “How likely to recommend?” **8.8/10**
  - “Net promoter score” **62%**



*...a real opportunity to foster skills we are not used to using in daily practice*

**Clinician**



*I'm very impressed with the programme... I have learned a lot about myself and how I relate to others in meetings and my work environment*

**Data Scientist**











*the topics [covered]...made it possible to think critically through our own project/process*

**Clinician**

# You will hear later from some of the participants and studies that program created over the last 2 years and see their early results



Indication (team size)	Countries represented	# patients	Study title
 <b>Breast (8)</b>		780	The Causes and Consequences of Incomplete Paclitaxel Administration during the Neoadjuvant treatment of Early Triple negative and HER2 positive breast cancer (CIPNETH)
 <b>Colorectal (6)</b>		980	CO(r)RECT Me- metastatic COloRECTal Cancer Treatment Pathway
 <b>Head and neck (5)</b>		530	Immunotherapy in recurrent/metastatic head and neck cancer: real-world data from six European countries (2017-2022)
 <b>Prostate (9)</b>		1,010	Treatment patterns and survival outcomes for metastatic castration sensitive prostate cancer: real world evidence from five different European countries.

## Supported by

Leadership retreats

Peer learning sets

1:1 coaching

Technical seminars

# We are 60% through the DigiONE Pilot: €3M for technology proof of concept to automate and federated cancer outcome research under GDPR



## Objectives for DigiONE – Funded jointly by IQVIA and Illumina



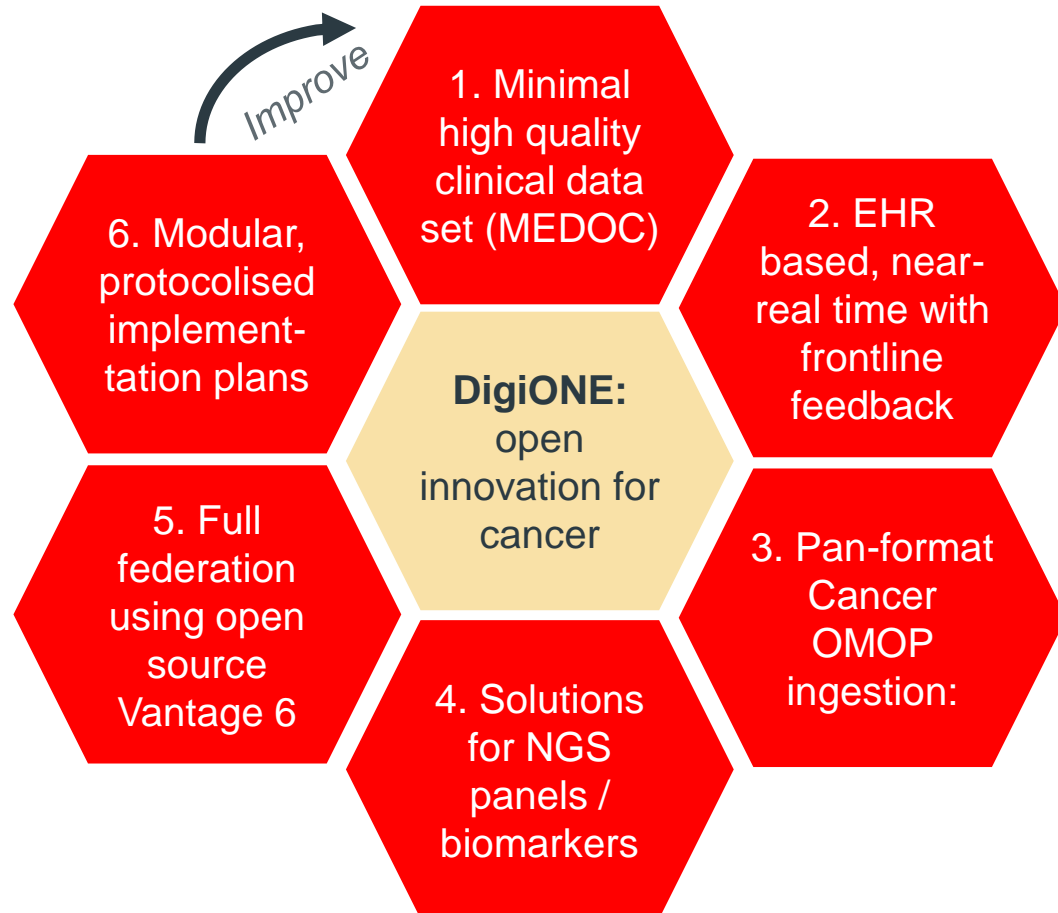
1. Define a **scalable common international minimum dataset for cancer**, building from French OSIRIS
2. **Achieve interoperability and high data quality** on that dataset between 6 centres across Europe under GDPR
3. **Federate those centres** to allow aggregated statistics like counts and to answer simple research questions, with appropriate information governance and contracting
4. **Link routine molecular and clinical data** (despite the format challenges on molecular PDFs)
5. Work out how to **scale up digitally less mature hospitals** with a **variety of technologies and vendors** in DIGICORE's learning – by- doing community

# Developed frameworks and self-assessment tools to help measure centre RWE readiness and plan improvements



	Bronze Cancer Centres	Silver Cancer Centres	Gold Cancer Centres
<b>1. Precision oncology research maturity</b>	<b>MDX testing below NCCN guidelines</b> <ul style="list-style-type: none"> <li>• Testing almost all “IHC + some Sanger”</li> <li>• Very limited local precision expertise</li> <li>• Don’t recruit to Biomarker driven trials</li> </ul>	<b>Testing at / above NCCN guidelines</b> <ul style="list-style-type: none"> <li>• Small panel the norm only in NSCLC</li> <li>• Some but limited precision expertise</li> <li>• Recruit rarely for SoC biomarker trials</li> </ul>	<b>Large Panel MDX standard of care</b> <ul style="list-style-type: none"> <li>• Molecular tumour board pilots</li> <li>• Lots of precision trials underway, especially in “new biomarkers”</li> </ul>
<b>2. Routine clinical data digital research maturity</b>	<b>No Data Warehouse, but core EMR exists</b> <ul style="list-style-type: none"> <li>• Siloed Clinical Systems, very partial data</li> <li>• Unstructured Data often paper based</li> <li>• No Data Standardisation</li> <li>• Traditional eCRF obs. studies only</li> </ul>	<b>Basic clinically focused Data Warehouse</b> <ul style="list-style-type: none"> <li>• Core Clinical Systems integrated</li> <li>• Identifiable Data, some standardisation</li> <li>• Unstructured Data is digital, un-mapped</li> <li>• Taking first steps in Database Research</li> </ul>	<b>A research ready local Data Warehouse</b> <ul style="list-style-type: none"> <li>• All cancer data in (chemo, radio, path), with strong master data management</li> <li>• Strong privacy norms (pseudo etc)</li> <li>• Multi-site database research routine</li> </ul>
<b>3. Pragmatic outcomes maturity</b>	<b>Minimal routine outcomes in EMR</b> (death in hospital, ER admissions only) <ul style="list-style-type: none"> <li>• Manual research processes established for date of death, but frequency of routine scans confounds RECIST</li> </ul>	<b>Outcomes interested but gaps remain</b> <ul style="list-style-type: none"> <li>• Some communities of care track key outcomes, often outside of EMR</li> <li>• Progression only well tracked where easy to measure (e.g. CA125 in ovarian)</li> </ul>	<b>Preparing for outcomes research at scale</b> <ul style="list-style-type: none"> <li>• EMR captures progression and death</li> <li>• Experimenting with routine digital outcomes – PROs tools, AI on scans etc</li> <li>• Maybe pilots in liquid biopsy for relapse</li> </ul>
<b>4. Information Governance &amp; Delivery Maturity</b>	<b>Not systematic on GDPR research reuse</b> <ul style="list-style-type: none"> <li>• Very basic patient notifications on data, often limited to clinical use</li> <li>• eCRF processes use traditional pathways of study specific consent</li> <li>• Very limited capacity to support planning or commercial projects</li> </ul>	<b>GDPR foundations based on notification</b> <ul style="list-style-type: none"> <li>• High Quality Patient Notification and Opt-out process cover research</li> <li>• Aggregated data released without consent, consent needed for patient level</li> <li>• Some spare capacity, but tends to be cancer specific and easily saturated</li> </ul>	<b>Strong secondary use consents the norm</b> <ul style="list-style-type: none"> <li>• Secondary consents routine, and provide a broad basis for processing</li> <li>• Strong processes for privacy management on patient level releases</li> <li>• Large central data science teams with spare capacity for commercial studies</li> </ul>

# The main focus in 2023 has been to get to a technical design for our network for high quality Cancer OMOP studies with 6 local builds underway



## Digital Oncology Network for Europe (DIGIONE) (6 abstracts at OHDSI Europe – posters outside)

- 1: **Minimal Essential Description Of Cancer (MEDOC)**
- 2: **Near-real time frontline feedback loops** to improve data
- 3: **Pan-format Cancer data ingestion.** Not just ETL also NLP, OCR
- 4: **GDPR recital 34 privacy conserving solutions for NGS**
- 5: **Full federation with open source Vantage6** to allow statistical analysis equivalent to centralised data, but without data pooling
- 6: **Modular, protocolized implementation plans** to solve for limited data normalisation skills in most hospitals
7. **All in open standards and vendor agnostic**

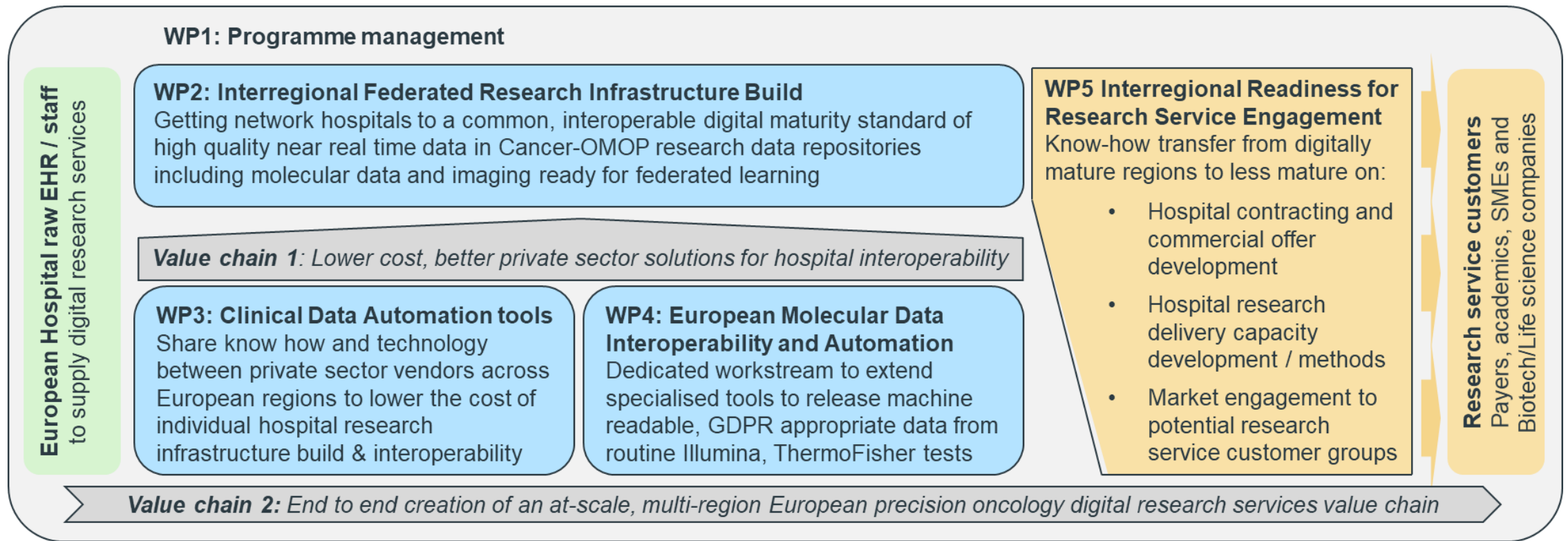
## 4 multi-centre cancer OMOP studies are underway to test that technology, and we would welcome other centres to join them



	Pan cancer / C19	mNSCLC	Breast Cancer	Ovarian cancer
<b>PI</b>	<b>Elin Hallan Naderi</b> , Oslo University Hospital, Norway	<b>Åslaug Helland</b> , Oslo University Hospital, Norway	<b>Cédric van Marcke</b> , Cliniques Universitaires Saint-Luc, Belgium	<b>Geoff Hall</b> , Leeds Teaching Hospital NHS Trust, UK
<b>Title</b>	Impact of COVID-19 on cancer care in European centres based on number of new diagnoses and 12-month survival	A disease natural history and outcomes study with care quality assessment (DINASTY) in patients with metastatic NSCLC	DINASTY in patients with HR positive HER2 negative metastatic breast cancer	DINASTY in patients with epithelial ovarian cancer (EOC)
<b># centres committed</b>	5 <i>(X with data @ 10 Nov)</i>	5	4	4
<b>Estimated cohort size</b>	124,000	9,500	3,000	1,500
<b># Ethics approvals</b>	5	2	<i>Not yet submitted</i>	<i>Not yet submitted</i>
<b>Contact point</b>	Project Manager: Rosie McDonald, IQVIA, <a href="mailto:rosie.mcdonald@iqvia.com">rosie.mcdonald@iqvia.com</a>			

# We have secured ERDF funding to scale up the network with an additional 15 host via the €12.5M DigiONE I3 project - with 15 hospitals, 12 other partners

Welcome colleagues from ESMIEA (Michael)





## What should we look forwards to in 2024-2025

- Welcoming many more new members – including many here!
- Build deeper relationships with national outcomes / digital initiatives
- First major research outputs published
- DigiONE I3 programme starts expanding the working network
- Academic working groups set up to coordinate our outcome research
- Additional collaborative grants sought for technology and science
- DIGICORE positioned well to help transform Cancer Outcomes



# ESMO Real World Data and Digital Oncology



Call for Papers: New Journal

## Introducing the first papers published in ESMO Real World Data and Digital Oncology

Some highlights from first articles:

1. [Exploring the Utility and Limitations of ChatGPT in Scientific Literature Searches](#)
2. [ESMO Real-World Data and Digital Oncology: a journal to understand how health systems can help provide better cancer care](#)
3. [ESMO Guidance for Reporting Oncology real-World evidence \(GROW\)](#)



# European Initiative to UNderstand CANcer (UNCAN.eu)

*Towards the creation of unique digital platform where researchers from all over the world share and have access to high-quality research data*



This project has received funding from the European Union's Horizon Europe Coordination and Support Actions programme under grant agreement No 101069496

**DigiCore**

# AMBITION

September 1, 2022

November 30, 2023

**4.UNCAN.eu**

**UNCAN.eu**

**A Coordination and  
Support Action**

**Blueprint  
(sustainability, governance)**

1

2

3

4

**European  
Federated  
Cancer Research  
Data hub.**

**Use cases**

**Address inequalities**

**Patients,  
Patient advocates  
Citizens**



2025 2026 2027 2028 2029 2030 2031 2032 2033 2034

Funded by the European Union

USE CASES

USE CASES

USE CASES

USE CASES

National Nodes  
UNCAN.eu



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2025 2026 2027 2028 2029 2030 2031 2032 2033 2034

Funded by  
the European Union

USE CASES

USE CASES

USE CASES

Serial calls:

- at least 3 every year
- at least 3 teams per use case
- up to 20-25 M€ / 5-years / use case
- 2 steps: LOI/Full project
- 2 parts: Science /Data

ional Nodes  
NCAN.eu



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# Data collected will be shared for secondary use



## Funds for a use case may be divided into 2 parts:

- the **scientific challenge** to be addressed : a unique scientific question so far unanswered that requires sharing datasets
- the **sharing of data sets** (collection, harmonization etc...) which is needed to address the challenge

**Data sets** = existing and/or newly generated research and/or real-world data.

## Leveraging on existing

- European health research infrastructures -> scientific challenges
- European initiatives and infrastructures -> data management

**Thank you for your attention and  
enjoy next two days!**

