

IDEAL4OMOP

Introduction and outline

February 2024



Introducing speakers



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Development
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**Prof Iwona
Lugowska**

*Oncology institute,
Poland*



Cédric van Marcke

*Professor
Cliniques
Universitaire,
St Luc*

Please take a moment to introduce yourselves in the chat: your name, role, where you work, cancer specialism

The IQVIA-DIGICORE Early Career Leadership programme for OMOP*

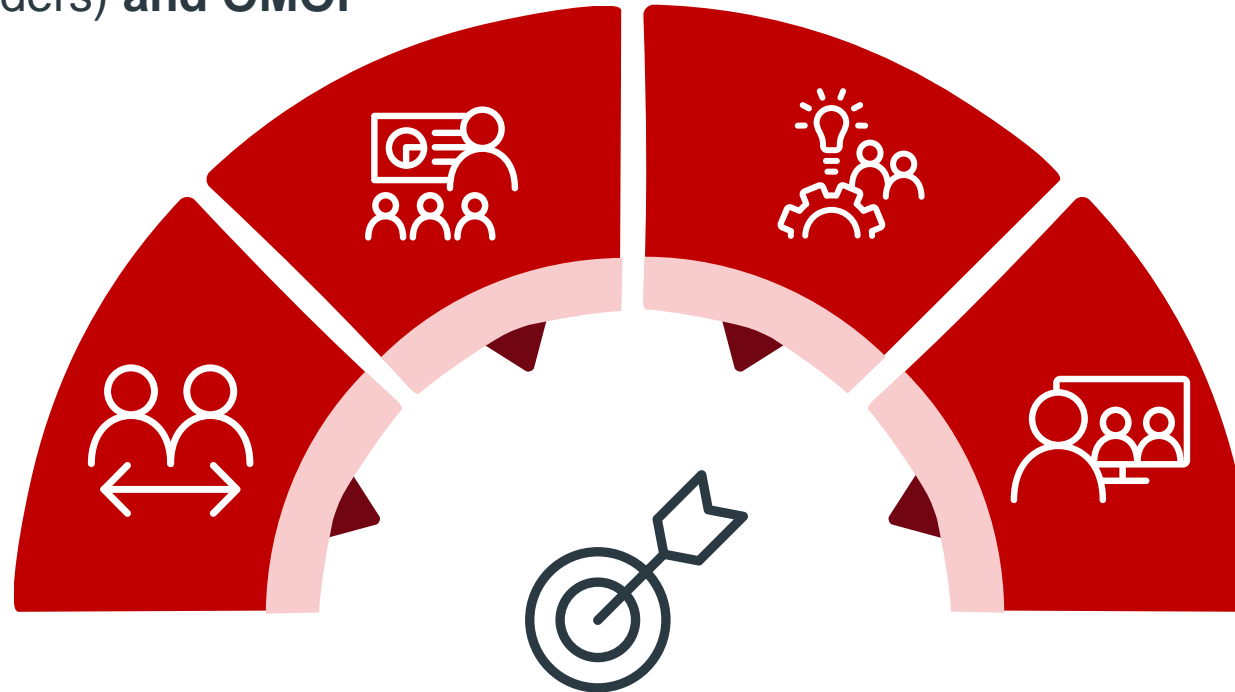
Objectives for today



Tell you about **DIGICORE**,
DigiONE-I3 (programme
fundes) and **OMOP**

Introduce the **IDEAL4OMOP**
training programme

Introduce you to us
and to each other



Discuss next steps to
**enrol in the
programme**

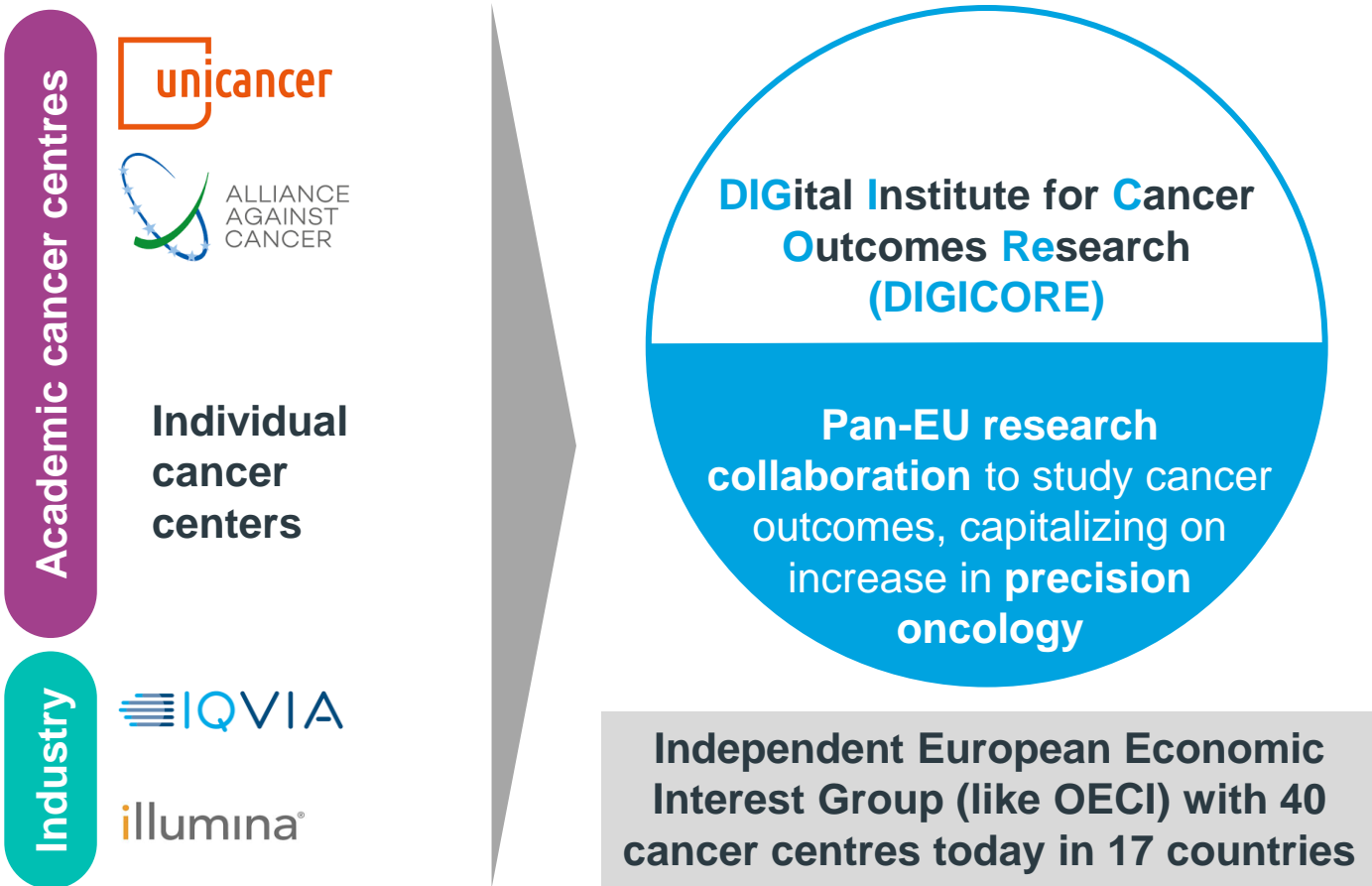
* Observational Medical Outcomes Partnership



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

Members

Benefits and rationale

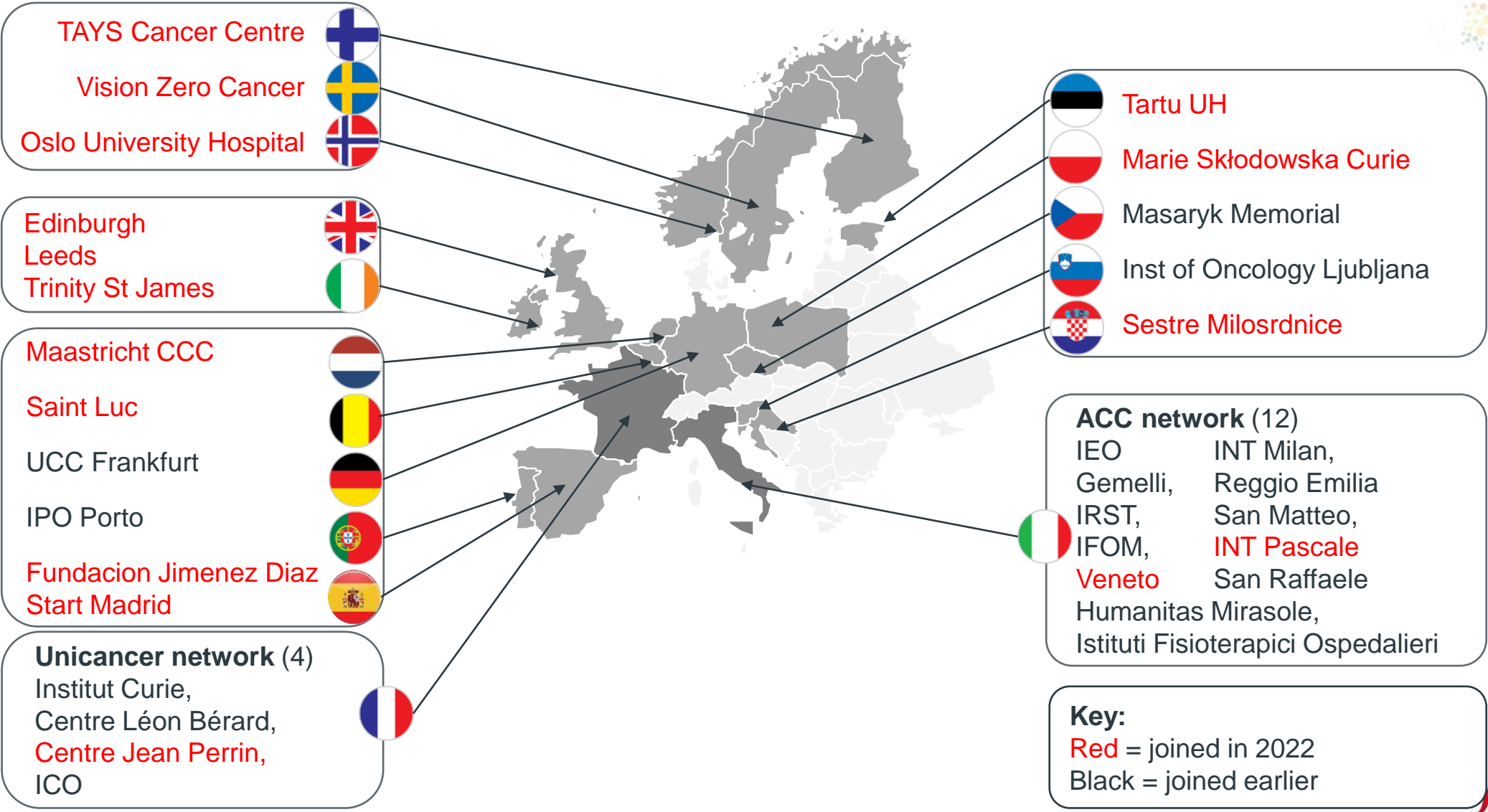


- For **Cancer Centres**, interoperability of cancer data across sites for improved translational research
- For **Patients**, broader trial access and in future better outcomes
- For **Industrial Partners**: drive commercial multi- centre, international RWE projects in precision oncology and drive precision 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
7. **Non-exclusivity** - hospitals can do commercial research with any party

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



DigiONE I3 Consortium: €12.4m to upgrade 15 new sites to cancer OMOP

Country	Hospital
Belgium	Grand Hôpital de Charleroi Saint Luc
Czechia	Masaryk Memorial Cancer Institute
Estonia	Tartu University Hospital
Germany	Charité Medical University Berlin Hospital
	Greifswald University Hospital
	Frankfurt University Hospital
	University Hospital Carl Gustav Carus Dresden
Ireland	Trinity St. James's Cancer Institute
Italy	Istituto Nazionale Tumori Regina Elena
	San Raffaele Hospital
Lithuania	Vilnius University Hospital Santaros Klinikos
Netherlands	Maastricht University Medical Centre
	Maastricht Clinic
	University Medical Center Groningen
Norway	Oslo university hospital
Poland	(+1 to be confirmed)
	Maria Skłodowska-Curie Institute of Oncology
UK	Leeds Teaching Hospital NHS Trust

Coordinator (EEIG)



Oncology Research Partner



IQVIA Cancer Research BV

Q-Helix Partner



Private Sector IT Partners










Create a federated, privacy-managed, high quality, digital research network built on open standards that links routine clinical data with routine molecular data at leading cancer centres across Europe

- Launched Nov 2023
- Partners invest 30% of project budget
- Pre-financing (70% of I3 funds) disbursed to partners on achieving project milestones; remainder after final report

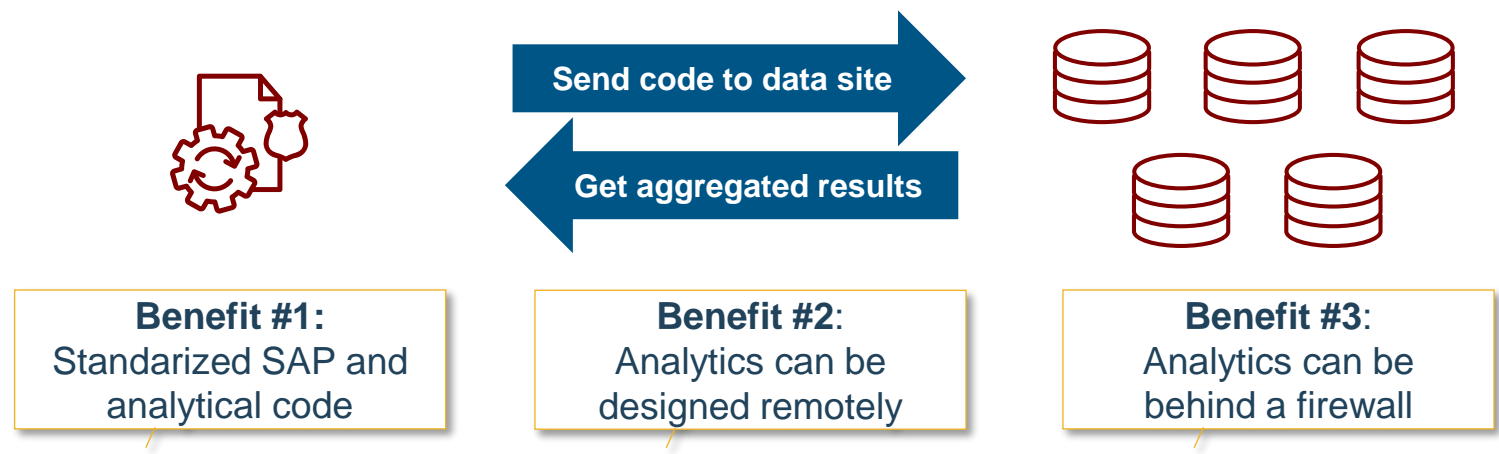


Data standardization enables reliable, reproducible and faster network studies

Classic network study:

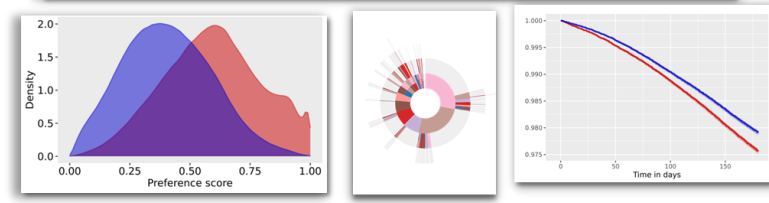
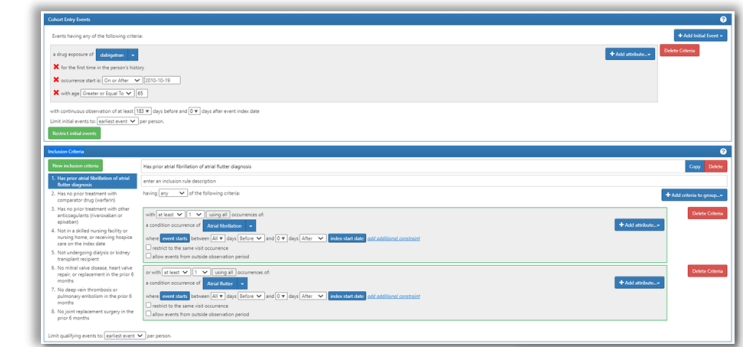
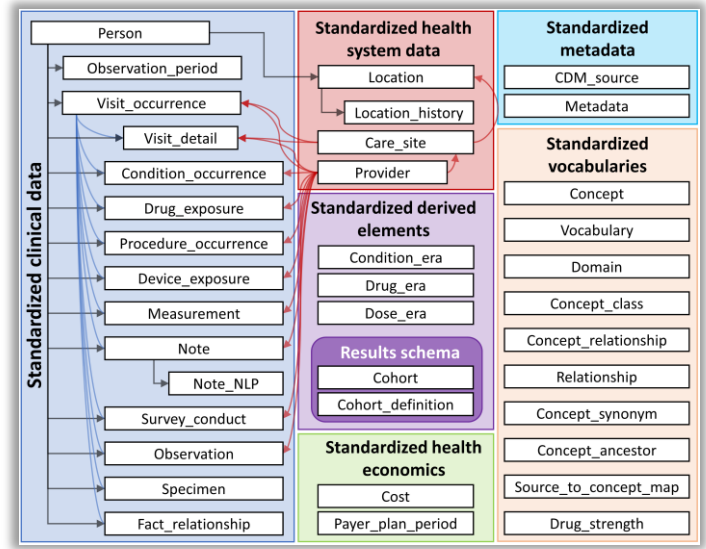
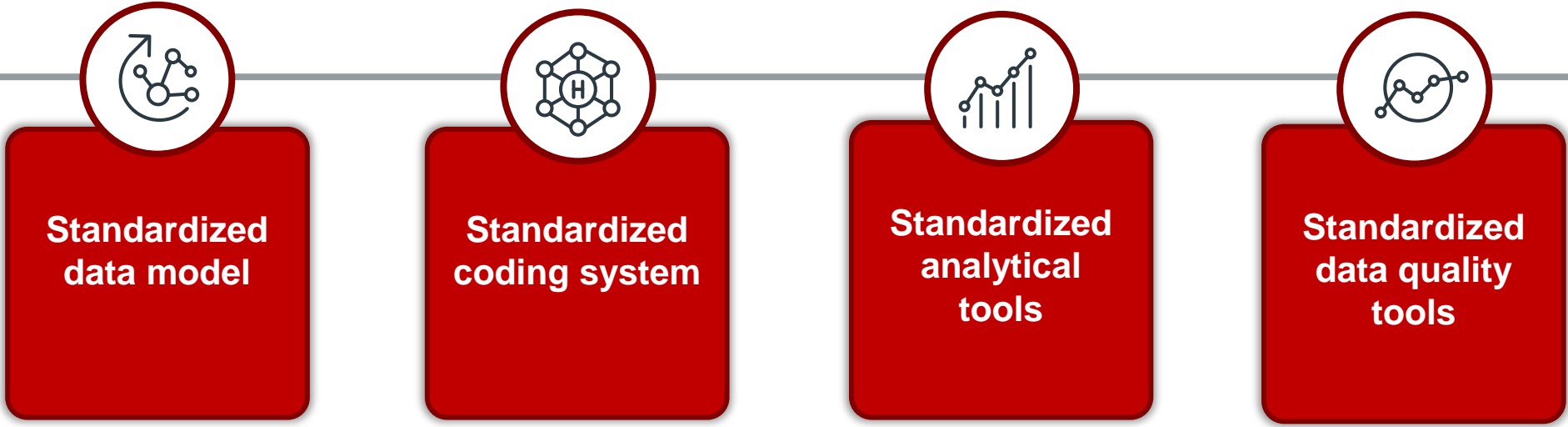


Data standardized network study:






OMOP means standardization





OMOP team publications


>40 Publications Since 2018


17 Infectious Disease publications 

9 Cardiovascular publications 

5 Oncology publications 

19 Methods publications 

4 Mental Health publications 

3 Musculoskeletal publications 

Frontiers **Dove Press** **PDS** **Pediatrics**
JCO Clinical Cancer Informatics **Clinical Pharmacology Therapies** **British Medical Journal**
Science Reports **Pharmacoepidemiology and Drug Safety**
Translational Psychiatry **JAMA**
International Journal of Obesity **The Lancet** **The Lancet Rheumatology** **Frontiers in Pharmacology**
Journal Of Biomedical Informatics **Annals of Internal Medicine** **Science Direct** **PLoS One**
Rheumatology **Blood Advances** **Hypertension**

Academic Partners



Publications by Category

- Disease & Treatment Patterns
- Patient-level Clinical Evidence
- Healthcare Costs
- Policy Levers

Research Areas

- Drug safety
- Drug efficacy
- Descriptive statistics
- Cohort characterization
- Risk analysis
- Comparative studies
- Method development and validation
- Combination therapy
- Vaccines



DigiONE I3 will not succeed without the right skills and experience



The people with the skills needed to conduct international digital research in OMOP **do not currently exist** in sufficient numbers

We need not only the skills, but **evidence of application of these skills, in proof-of-concept studies**, to persuade grant-makers and commercial partners

A cadre of OMOP-proficient leaders will **underpin future success for all partners**, academic and commercial



IDEAL4OMOP is a critical part of this skills building

Training programmes to support i3

1

MEDOC/ ETL training

To upskill hospital IT staff and data scientists to extract and configure data to MEDOC OMOP standard for cancer studies



2

IDEAL4OMOP






To give early career researchers (clinical and non-clinical) the skills they need to design and run cancer OMOP studies



Funding from i3 award budget, with additional contributions from IQVIA

IDEAL4OMOP is aimed at early career researchers, developing technical and leadership skills, with study funding available



 Who?	<ul style="list-style-type: none"> • Under 45yr clinicians, data scientists etc. • Working in European health systems/ academia • Want to lead or support OMOP enabled oncology research
 What?	<ul style="list-style-type: none"> • Training on both technical and leadership skills • Development of an OMOP protocol ready for ethics • Delivery of an international proof-of-concept OMOP study
 How?	<ul style="list-style-type: none"> • Mix of training styles: seminars, practical work • Funding available (can cover backfill) • Advisory board oversight <u>and allocation of funding</u>
 When?	<ul style="list-style-type: none"> • Recruitment and free introductory programme in Q2 2024 • Study selection / funding Q4 2024 off draft protocols • OMOP studies start in Q4 2024, conclude 2025
 T&Cs?	<ul style="list-style-type: none"> • Cancer OMOP instance preferred (or planned with funding) • For backfill study funding: centre must be DIGICORE member. Others can participate – but no funding • Balance of different tumour types (solid/ haem/ rare)

Aims
<p>By Q4 2025</p> <ul style="list-style-type: none"> • A cohort of 30 future research leaders skilled in OMOP research • c. 3 proof of concept studies delivering analytic outputs (IQVIA provides study fund of €300k) • Increased awareness of DIGICORE

IDEAL4OMOP builds in stages towards the development of a funded proof-of-concept study

Training
Team activity

Recruitment

Jan-Apr 2024

Awareness building and recruitment:

- Centres
- Networks
- Direct to potential participants

Basic training, team formation and scientific concept Open to all

Apr-Oct 2024

101 RWE/ OMOP basics 102 Application training

Teams form **Teams develop OMOP study concepts**

1 Individuals sign to learn more 2 Short team Application (commitment to OMOP required)

Team "dating"

c.50 applicants from 30 centres join training

Advanced: protocol development and execution Successful teams

Nov 2024-Q4 2025

103 Leadership training (tbc)

201 Advanced OMOP training and support

Teams refine and drive pilot OMOP programmes with PoC study funding from IQVIA

2 Protocol & data plans 3 Poster & Output

3-5 studies funded (tbc), 25-40 participants

Funding/ selection announced at CtW 2024

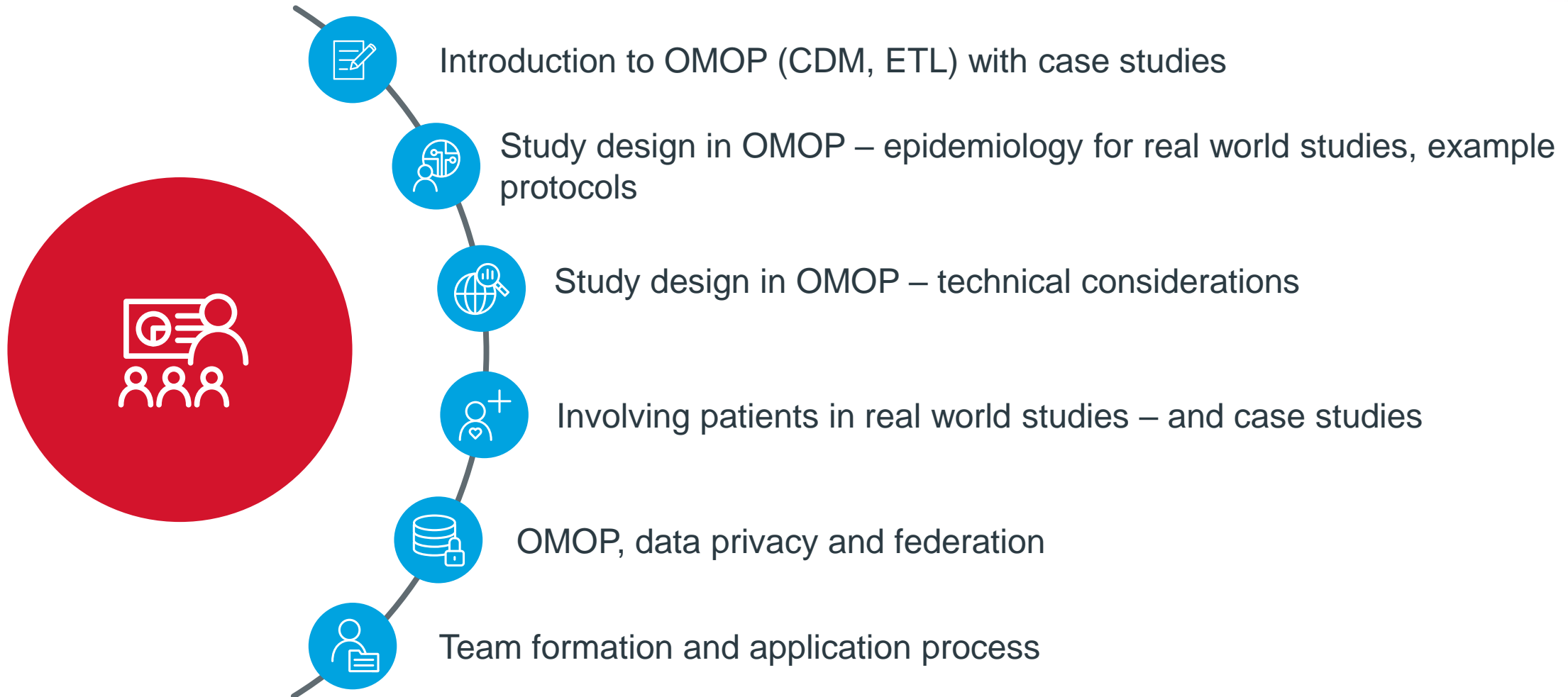
Mobilisation

Proof of concept study output for follow-on funds

Additional cancer OMOP nodes coming online over 2024



101: RWE/ OMOP basics: example training topics (exact details tbc)



An example international Cancer-OMOP protocol from hospital EHR: Disease Natural hiSTory and care quality assessment in mNSCLC (DINASTY NSCLC)



COHORTS

Patients diagnosed with mNSCLC between 1st November 2018 – 30th November 2023

- Subgroups by stage at diagnosis of NSCLC
 - De novo metastases
 - Initially diagnosed with NSCLC at earlier stage
- Subgroups with metastases at index date in:
 - Each of these single sites: brain, liver, adrenal gland, bone, other lung, other single sites
 - Multiple sites: including brain, excluding brain
- Subgroup prescribed immunotherapies as 1st LoT for mNSCLC

RESEARCH OBJECTIVES SUMMARISED

1. Describe demographic and clinical characteristics, **genetic phenotype, re-biopsy rates**, and Tx received for NSCLC prior to index
2. Describe **SACT patterns by 1st and 2nd LoT, radiotherapy and surgery** for mNSCLC
3. Assess **OS and TtNT by 1st and 2nd LoT** incl. adjustment for prognostic characteristics
4. Describe duration of Tx, starting dose, and dose intensity by age and gender in patients prescribed **1st LoT immunotherapies** for mNSCLC
5. Benchmark **care quality** between the centres vs. ESMO guidelines

Ethics approved: 5 centres
Interested to join: another 4

IDEAL4OMOP builds on the success of the previous IDEAL4RWE programme

IDEAL4RWE overview

The story in numbers

- **Ran from 2022-2023**
- **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 **€210k 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



An expert Leadership Advisory Board (LAB) will guide the programme and oversee funding awards



Role of Leadership Advisory Board

- Help shape the programme
- Promote and disseminate opportunities for participation
- Advise study proposals
- Award funding
- Mentoring/ training/ inspiration (time permitting)

Leadership advisory board: Members

IDEAL4OMOP Leadership Advisory Board



Prof David Cameron
(Edinburgh University) – Co chair



Prof Iwona Lugowska
(Oncology Institute, Poland) – Co-chair



Prof Massimo di Maio
(Oncology Department, Turin)



Prof Mieke Van Hemelrijck
(King's College London)



Dr Sue Cheeseman
(Leeds Teaching Hospital)



Rachel Giles
(International Kidney Cancer Coalition)



Asieh Golozar
(OHDSI)



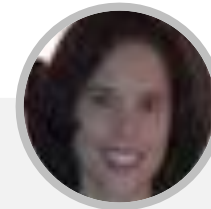
Andre Dekker
(Maastricht Comprehensive Cancer Centre)



Will Sopwith
(IQVIA)



James Brash
(IQVIA)



Barbara Bressolles
(IQVIA Senior Director, Privacy)



James Anderson
(DIGICORE)







Setting you up for future success in real world research

Be at the cutting edge of the digital revolution

What you get

New skills


-  **6-8 virtual seminars** from leading researchers
-  **Face-to-face** training (tbc)
-  **Peer learning**
-  **Coaching**



Potential **funding** for an outcome study (up to **€300k** for **3+** studies)





Network of like-minded collaborators and mentorship from **leading international** researchers




A **proof-of-concept OMOP study** to support future funding applications


What you need to commit

Time

-  **2-3** total days to November
-  **IF SELECTED**, then **1 day/week** to study conclusion (likely in 2025)



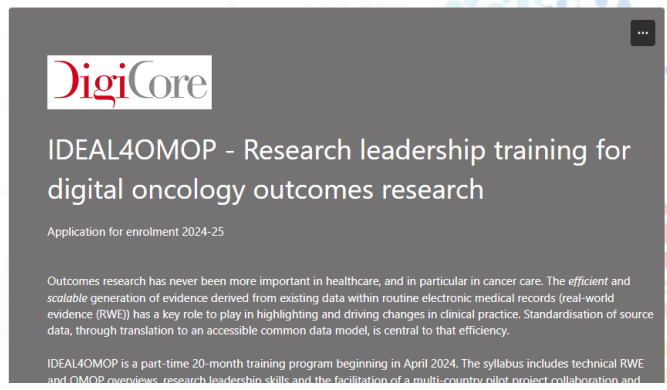
Enthusiasm for working with peers on an international outcomes study



The backing of **your employer** and supporting resource if needed (e.g., data scientists)

Next steps to register, and what to expect

- Slides and a recording of this introductory session will be made available to you in the coming days – **please tell others who may be interested**
- If you would be interested to apply for the program, please use the link to the right to access a short application form – **you will need agreement from your employer to give the necessary time**
- Registration deadline is **31st March 2024**
- Program will begin for successful applicants in **April 2024**



<https://forms.office.com/r/cmEzdh1ksD>

Backup

Target audience for IDEAL4OMOP, and what's in it for them?

Target clinician (statistician/ epi) is research interested (but not research obsessed)

What is in it for them?

% clinicians in Cancer centre X



- Seed funding & training for pilot studies
- International peers in their disease (= HORIZON team ready)
- Deep methods expertise from partners
- Dedicated secretarial / coordination support



A unique opportunity to create large scale, fundable outcomes research consortia



Part 1: Basic training and team formation (to July 2022)

Basic training and team formation

Apr-May 2022

101 RWE basics (2 seminars)

Basics of RWE and form teams

(From today) –
course registration

Team formation
starts

May-Jul 2022

102 Application training (2 seminars)

Teams develop simple
RWE study concepts

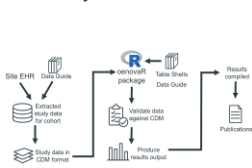
Study concept and
submission (July)

Training in outcomes study planning

Study overview

HCP	Patent cohort
Site 1 - UK	515
Site 2 - France	698
Site 3 - Germany	139
Site 4 - France	466
Site 5 - Iberia	300
Site 6 – E. Europe	446
Site 7 - Asia	957
Total	3,055

Harmonized data analysis by local teams



Analysis performed in
less than 4 weeks

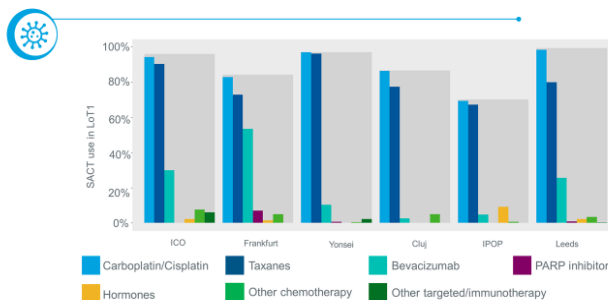
Study overview

- Epithelial ovarian cancer
 - Patient characteristics (e.g. histology, biomarkers, stage, breast cancer)
 - Genetic and molecular phenotype (germline, somatic BRCA, HRD)
 - Treatment patterns (surgery, lines of chemotherapy)
 - Outcomes from diagnosis & recurrence(s) to death



Training on relevant outcome case studies

Multi-centre study – Ovarian cancer – ORWIC – First-line therapy



Building a team to plan an outcomes study

- **TA:** p53 wild-type NSCLC
- **Objectives:** Natural history, treatment patterns and outcomes (2015-2020)
- **Patient cohort:** 1800 from 4 countries
- **Project milestones:** LPI, data curation, analysis, output





Part 2: Learning by doing (July 2022 to April 2023)

Advanced team-based training & protocol – Intensive

Jul 2022-Apr 2023

103 Leadership training/201 Advanced RWE technical training

Teams refine and drive pilot RWE programmes.
Selected teams (3-5) receive PoC study funding from IQVIA

Teams apply for funding

6-8 teams get intensive training

F2F Leadership Training

Peer Learning Sets

Optional 1:1 Coaching

Advanced Technical Training

Outcome study funding application

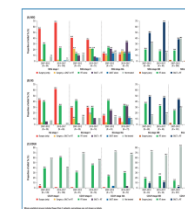
- Protocol
- Common data model
- Evidence of progress to date
- Up to €210k total for 3-4 studies
- Awarded by independent advisory board

3-4 teams get to output

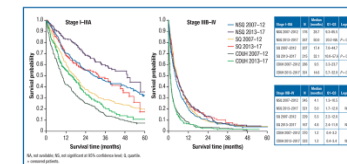
Key outputs



- Non-small cell lung cancer
 - Patient characteristics (e.g. histology, biomarkers, stage)
 - Treatment patterns (lines of chemotherapy, and surgery)
 - Outcomes from diagnosis, recurrence(s) to death



9th European Lung Cancer Congress (ELCC)





IDEAL4RWE – the participants



I think it fills a void in our education: we are expected to lead, but there is very little focus on leadership development in research and speciality training



Willingness to recommend: 8.9/10

101: RWE/ OMOP basics: example training topics (exact details tbc)



Introduction to OMOP with case studies



Study design in OMOP – technical considerations



Study design in OMOP – epidemiology for real world studies



Involving patients in real world studies



OMOP, data privacy and federation



Team formation and application process