

DIGICORE's 2022 plan

*Outcome research programme and
funding opportunities*

15th March 2022



Introducing speakers



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Objectives for today



Introduce DIGICORE – The Digital Institute for Cancer Outcomes Research



Outline DIGICORE's 2022 activities and plans



Introduce two opportunities for cancer centres

- **The “Platinum fund”**: Up to €3M to get proof of concept for a federated cancer OMOP network
- **IDEAL4RWE**: An early career leadership development programme and pilot outcomes study fund



Next steps & Q+A

DIGICORE is a new collaboration that aims to transform and digitise cancer outcome research in Europe



Members

Academic cancer centres

unicancer

ALLIANCE AGAINST CANCER

Other networks to come

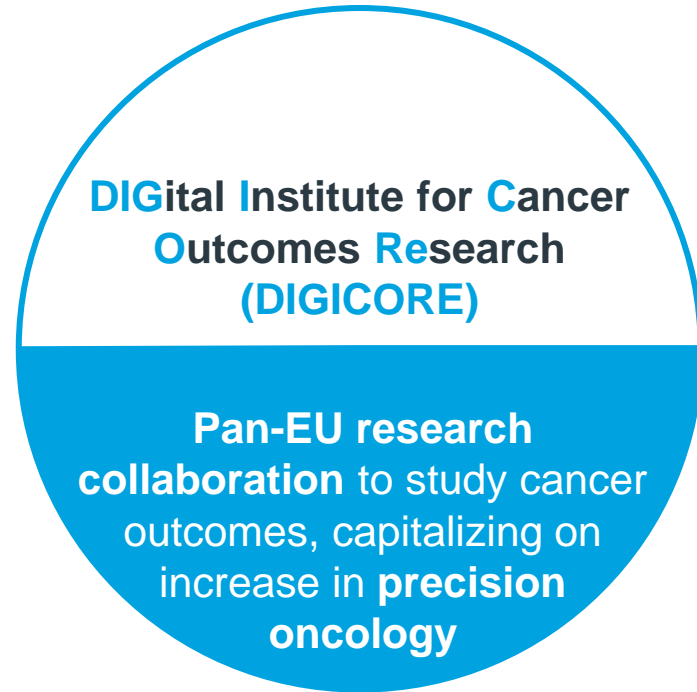
Industry

IQVIA

illumina®

Sister cancer network

OECI
ORGANISATION OF EUROPEAN CANCER INSTITUTES

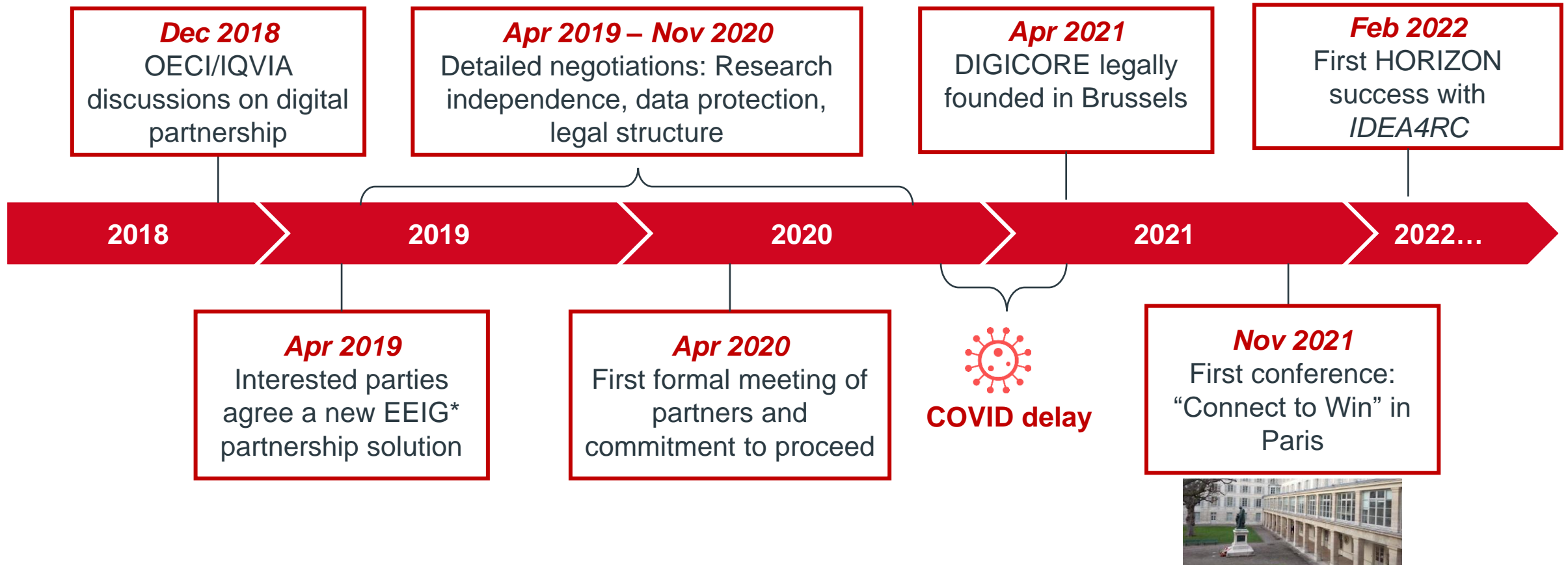


Independent European Economic Interest Group (like OEI) with 30 cancer centres today

Benefits and rationale

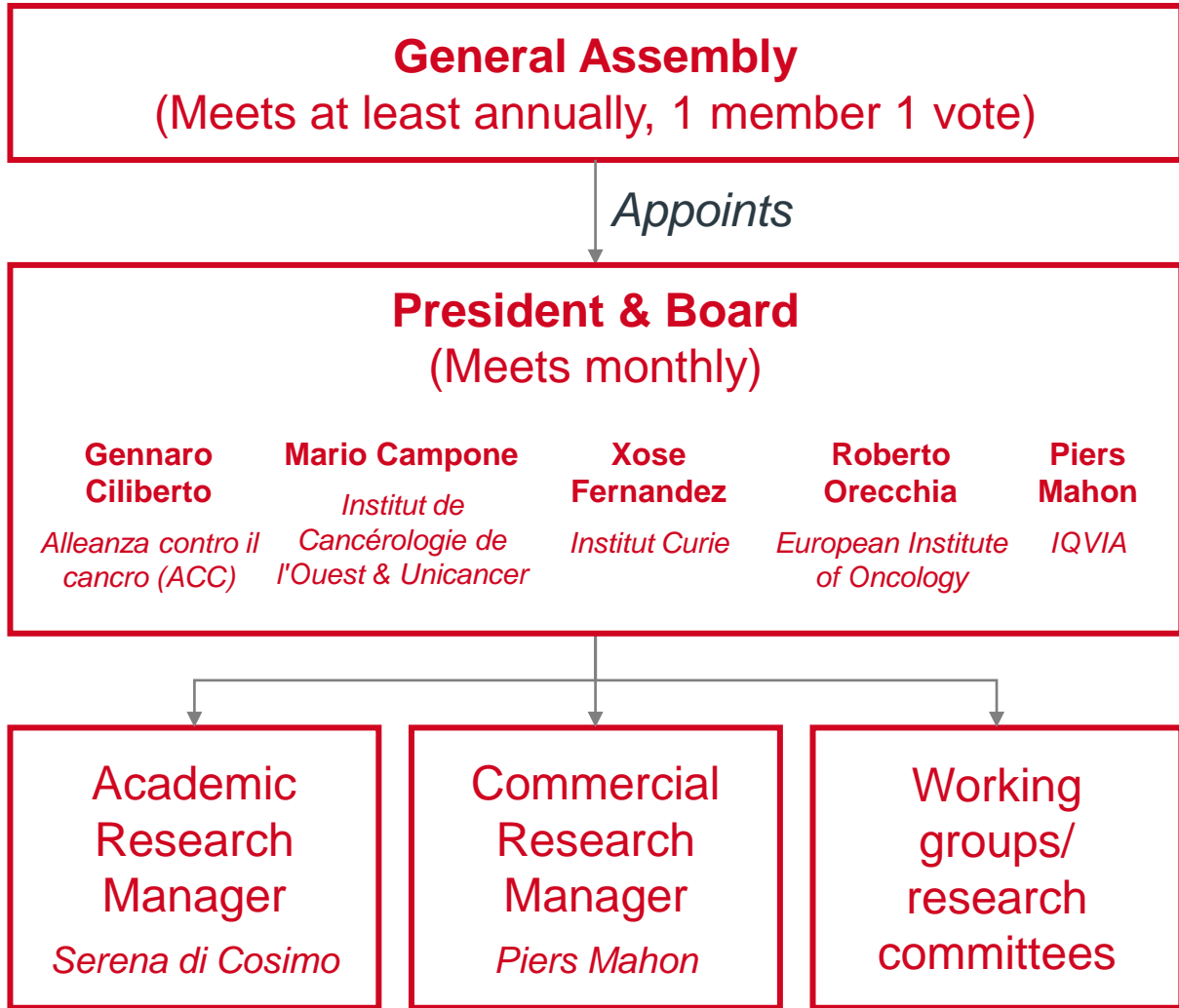
- For **Cancer Centres**, pool cancer data across sites for improved translational research
- For **Patients**, broader trial access and in future better outcomes
- For **IQVIA**, drive commercial multi- centre, international RWE projects in precision oncology and drive precision trial recruitment
-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

DIGICORE came about through 3 years of negotiations between the OECI, Unicancer, Alliance Against Cancer and IQVIA



* European Economic Interest Group, same legal structure as the OECI

Our foundational legal statutes built strong governance and protections for cancer centres

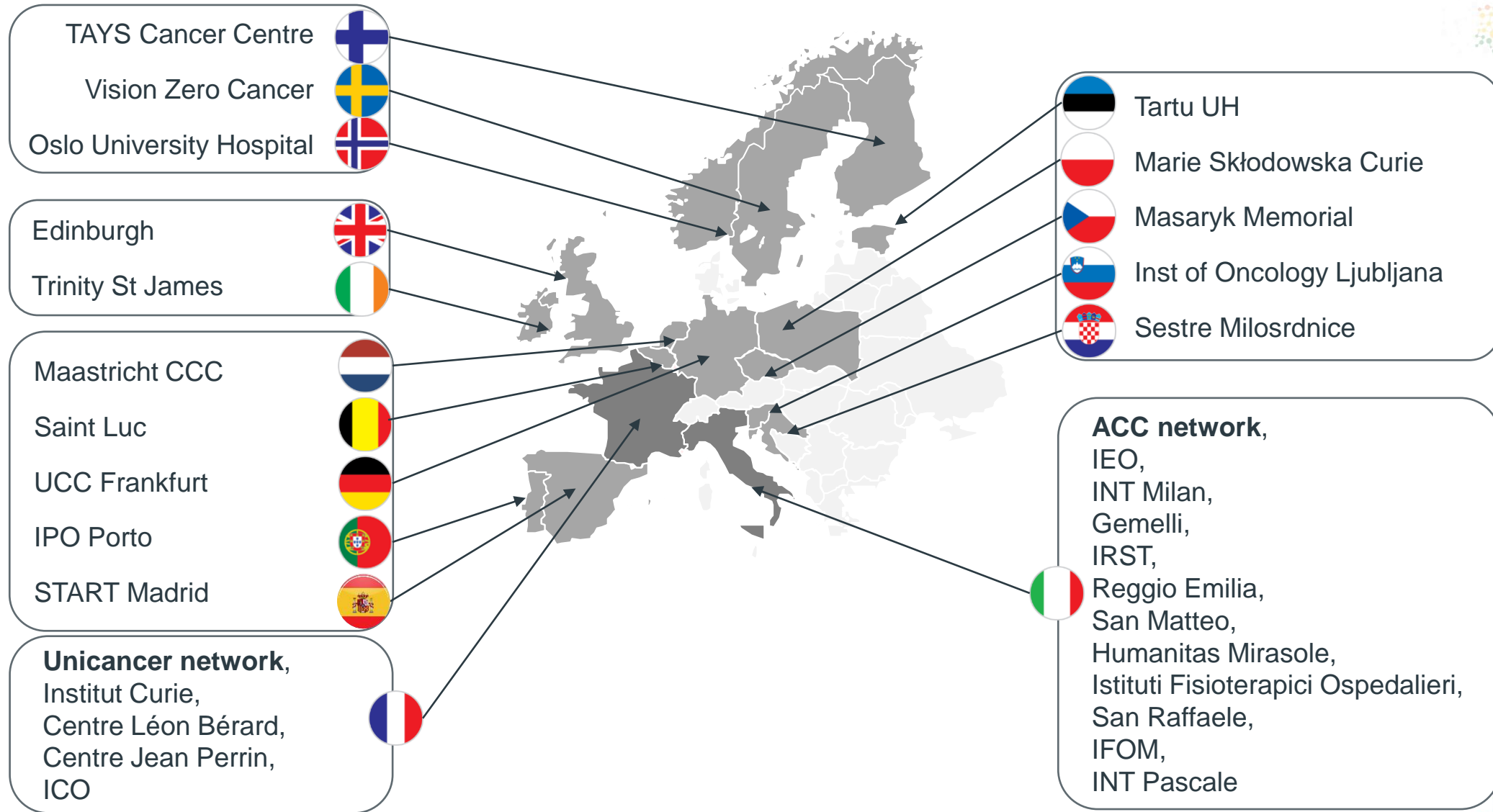


Key Principles*

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

* For more detail see: [OEI Magazine \(December 2020\)](#)

Current DIGICORE network of 30 centres and 2 national networks in 16 countries



How to join DIGICORE



Website instructions

Join Now

DIGICORE – EEIG Membership Application Instructions and Form

Each Institution that wishes to apply for Membership in DIGICORE-EEIG must fill-out the **DIGICORE Application Form**

Prior to filling in this form, the Applicant Institution shall verify that it meets the relevant requirements for membership set forth in the **DIGICORE-EEIG Statute**, and that it agrees to comply with the rules outlined in the DIGICORE-EEIG Statute.

Submitting procedure

1. Fill in the form (page 3-4 below) as clear and legible as possible. Once completed, please make a copy of the document and preserve it for your own records. The original signed form must be sent to:

Prof. **Claudio Lombardo**
c/o SOS Europe Srl
Via delle Campanule, 74
16148 Genova - Italy



2. Please send an electronic copy of the signed form to info@digicore-cancer.eu along with a copy of the Statute of the cancer centre/institute/organisation/company

Contact DIGICORE
(info@digicore-cancer.eu)
for application information
and introductory briefing (if
required)

Submit application
form
([https://digicore-
cancer.eu/Page.aspx
?name=JOIN](https://digicore-cancer.eu/Page.aspx?name=JOIN))

Full Membership: €10k per year
Associate Membership: €5k per year

Benefits to centres from participating in DIGICORE



Drive better research in Europe

- **Innovate collaboratively** to develop new methods and digital infrastructure
- Access **cutting edge methods**, IP and tools that increase your competitiveness
- **Statistical power for rare subgroup analysis** e.g., 1% mutations
- **Collaborate in precision oncology** and making large panels “the EU normal”

Access new funding streams

- Secure **EU collaborative grant income** – for digital infrastructure, digital tools, specific studies
- Drive **commercial research** via IQVIA – advanced RW studies, precision trials
- Access **global philanthropy investment** via IQVIA – e.g., paediatric oncology
- Propose **academic studies** to the grouping



Activities - Connect2Win: Our annual digital research planning conference launched in Paris in November 2021



Connect2Win, Paris 3-5 Nov 2021

Objectives

- Lay out the challenges of delivering digital precision medicine research at scale
- Grow the network, discuss collaborative research in EU Cancer Mission
- Propose a pathway to digital RWE readiness for diverse centres
- Encourage dialogue and collaboration on how to drive international cooperation on these issues



75 delegates

38 cancer centres

19 European countries

Major national centres represented, with 12 institutes joining network as a result

Plan for hosting in 2022 - Rome

Activities - DIGICORE's focus in 2022 is building capacity for digital international comparative cancer outcomes research



1. Mobilise our members for international cancer outcomes research

- Build out our **cancer specific outcome research committees** and support them to seek European and other funding
- NSCLC, NHL, Ovarian initial momentum (others welcome!)



2. Establish Pragmatic Technical Standards for Clinical Informatic Interoperability

- Mapping the digital maturity and systems of centres to develop a **common, practical approach to EHR research**
- Plan out how to make our data “mean the same thing” across Europe



3. Platinum Technology Fund

- Up to €3M available from IQIVA to establish proof of concept on **European federation of oncology EMR data** in OMOP
- Designed to help all DIGICORE members secure follow-on funds



4. IQVIA-DIGICORE Early Career Leadership programme for RWE (IDEAL4RWE)

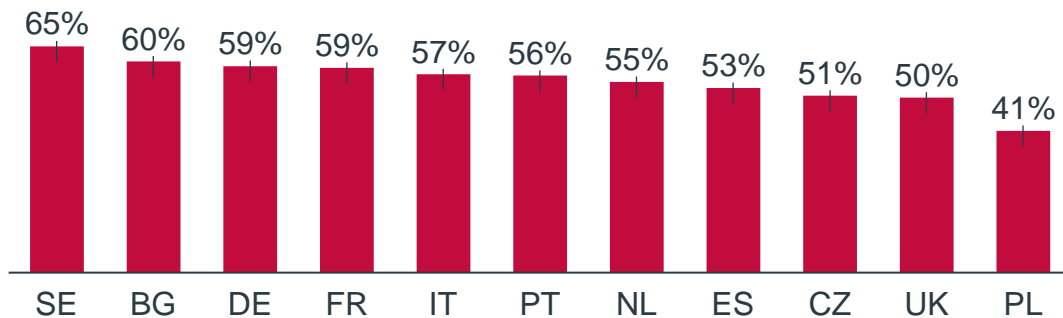
- **€500K of training in research leadership** & pilot study funding for teams of younger researchers in cancer outcomes research
- **Prepare the next generation for the digital revolution**

1. Mobilise our members for international cancer outcomes research to support national Beating Cancer Plans



Save tens of thousands of lives every year by closing the quality gap

Cancer 5 year survival (EU countries with over 10m population)



Source: Eurocare5, Cancer Research UK

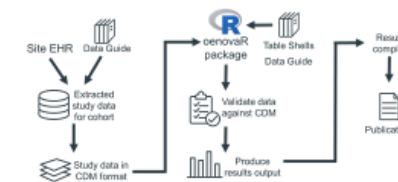
IQVIA seed funding and project management to support 3 PoC studies in other “hard to study” cancers beyond Ovarian

Problem: Ovarian is rare and has complex Tx patterns – can it even be studied in RWE from EMR?

Network of 7 HCPs

HCP	Ovarian 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

Changes the art of the possible under GDPR

- Proves RWE is possible in less common cancers via networked approaches without consent
 - First poster at ESGO 2020
 - Excellent protocol adherence
- “Oven ready” disease network for commercial or academic ovarian RWE e.g. on PARP inhibitors
- Repeatable model for other less common cancers

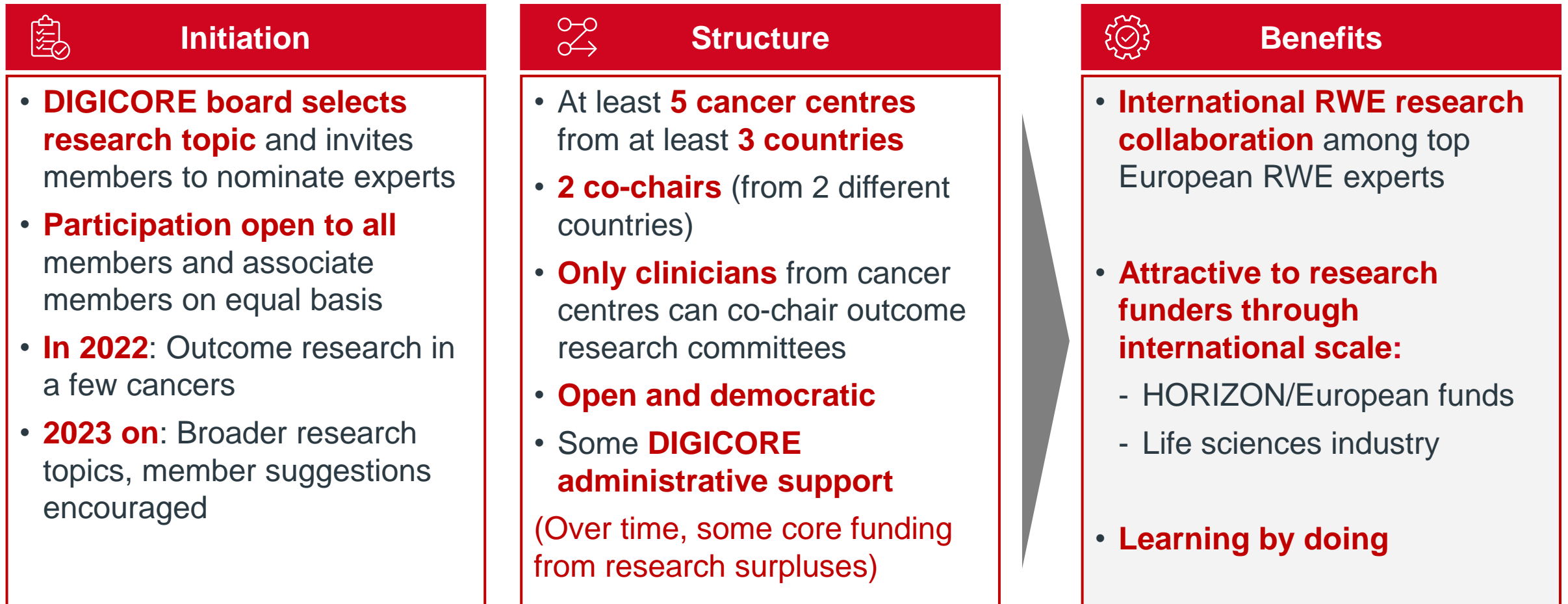
DigiCore

The Digital Institute for Cancer Outcomes Research

For more information see: [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(13\)70546-1/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(13)70546-1/fulltext),
https://ascopubs.org/doi/abs/10.1200/JCO.2021.39.15_suppl.5531

DigiCore

1. DIGICORE's research committee structure is designed to complement national outcome research programmes



Current involvement in EU research bid - won



HORIZON-HLTH-2021-TOOL-06-03

Project

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

Objectives

- Establish a 'Rare Cancer Data Ecosystem' to make possible the re-use of existing data (e.g. registries, biobanks, etc)
- Improve data system interoperability and leverage AI approaches to facilitate research in rare cancers and improve equality of care

DIGICORE role

- Engagement, definition of research and market needs and validation of approaches developed

Project coordinator:

Istituto Nazionale dei Tumori di Milano



Current involvement in EU research bid - submitted



HORIZON-MISS-2021-CANCER-02-02

Objective

- Develop and validate a set of quality of life and patient preference measures for cancer patients and survivors

Expected Outcomes

- New metrics based on self-reported evidence from cancer survivors
- Expanded high-quality data collection and analysis using appropriate digital tools.

DIGICORE role

- Lead organisation for WP5 – development of the ICT platform for data sharing; analysis of data on QoL indicators gathered during the Pilot survey

Project coordinator:

Istituto Nazionale dei Tumori di Milano

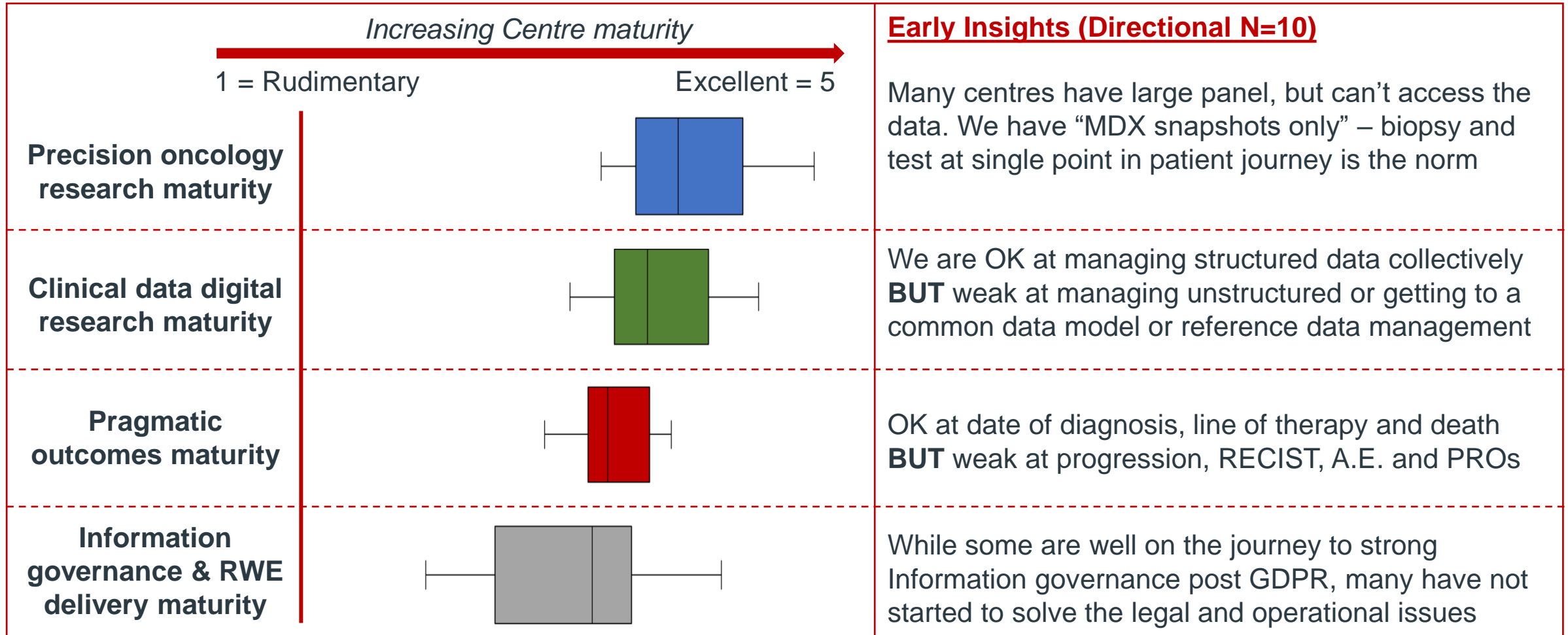


2. We have developed frameworks and self-assessment tools to help measure centre RWE readiness and plan improvements



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

2. We have started to map our members' digital readiness and will extend this in 2022



2. This year we aim to develop the fact base that allows members to co-create our technical solutions



Activities for clinical informatics interoperability Working Group:

Mapping the IT vendors and systems in DIGICORE members – e.g. who has what type of chemotherapy dosing software or EHR or access to NLP tools

Mapping individual centre readiness to use the data – what maturity of information governance, data teams, experience in direct for EHR research etc

Assess feasibility of internationalising OSIRIS: Convene a sub-group of international experts to review that minimal model, with extensions for haematological malignancies

in the second half of the year **use the working group to define common technical priorities**

Outputs expected in 2022:

Prepare a **briefing on our collective digital maturity and readiness** for September Board

Provide a simple benchmarking report back to centres that participate – score vs DIGICORE peers

Recommendation to the December board as to next steps

If N high enough, a **paper on comparative national “digital readiness”**

3. We believe significant funding for digital infrastructure investments is becoming available, but proof of concept needed



Potential source of funding next 5 years	Total funding (estimate)	Of which digital infrastructure (estimate)
Recovery and resilience facility	€100bn	€12bn*
Cancer mission	€2.6bn	€0.1 to 0.2bn**
IHI + life sciences industry	€500bn	€1.5 to 2bn***

*“What you have got to [in DIGICORE] is very impressive, you are very close to having what everyone needs and have de-risked the partnership side of these collaborations substantially. We realise we have to go external [innovation] now in cancer. **But you still have technology and study proof of concept to do, and it will be hard to convince my colleagues to invest without that”***

– Top 5 Pharma Global Head of Scientific Partnerships

* Digital transition in healthcare funding estimates

**5 to 10% total

*** IHI and in-house research programme funding vs. global R&D spend in Cancer

Source: European Commission Recovery and Resilience Scoreboard, Dec 2021

3. IQIVA will fund up to €3M for technology investment in proof of concepts – half cash, half in-kind








Objectives for the Platinum Fund



1. Create **digital interoperability** between 6 centres in 6 different countries; quickly to help secure follow-on funds
2. Agree a **common minimum dataset** that describes cancer; building from French OSIRIS
3. Build **GDPR-compliant research data repositories** (or “nodes”) in Platinum centres, using **Cancer-OMOP**
4. **Federate those nodes** to allow automated counts, trial planning and to answer simple research questions with appropriate controls

3. Platinum fund will support the development of a proof of concept network for advanced RWE research



 Who?	<ul style="list-style-type: none">Digitally-ambitious cancer centres needing investment
 What?	<ul style="list-style-type: none">An investment programme for advanced RWE technology – up to €3M€250K cash - €250K in-kind tech for 6 centres
 How?	<ul style="list-style-type: none">Individual cancer centres express interest, access funding details, training materials, get bid prep support and adviceSubmit bids outlining their plans for needed upgrade
 When?	<ul style="list-style-type: none">Expressions of interest early Jun 2022 (TBC)Deployment start in Oct 2022 (TBC)Concludes April 2023 (TBC)
 T&Cs?	<ul style="list-style-type: none">Any OECl or similar can apply, but to receive funding<ul style="list-style-type: none">Must become a member or associate of DIGICOREMust be willing to contract with IQVIA for commercial RWE

To Learn More

- Dedicated introductory seminar** date April tbc.
- Target Audience:** Heads of data, heads of IT, digitally interested heads of research or their deputies
- Outline content:** Overview of objectives, rules and process

4. We will need a new generation of outcome researchers to digitise cancer control



The Platinum fund will build “a better digital microscope” for cancer outcomes research..



..But to use it well will need new research skills and leadership inside cancer centres

Solution





IQVIA – DIGICORE Early Career Leadership Programme for Real World Evidence (IDEAL4RWE)

DigiCore

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4. IDEAL4RWE will address a skills gap and support proof of concept research involving emerging research leaders



 Who?	<ul style="list-style-type: none">• Under 45, clinicians, data scientists etc. Interested in outcome research and ambitious to lead digital revolution in RWE
 What?	<ul style="list-style-type: none">• Training on both technical and leadership skills for RWE• Based around an international proof-of-concept study
 How?	<ul style="list-style-type: none">• Mix of training styles: Face-to-face and virtual• Full programme involves “test” application – funding available
 When?	<ul style="list-style-type: none">• Starts in Q2 2022 - free “taster” programme• RWE studies start in Q4 2022/Q1 2023• Concludes H1 2023
 T&Cs?	<ul style="list-style-type: none">• Open to multi-centre teams of early career researchers• Must have support of their centre for some research time• Their centre must join DIGICORE• 80% study funds spent in centres contracted with IQVIA

To Learn More

- **Dedicated introductory seminar on 19th April**
- **Target Audience:** potential course participants (under-45, digitally-savvy, research-interested clinicians and others)
- **Outline content:** introduction to DIGICORE; introduction to RWE; overview of programme and benefits; next steps for participation
- **Register for introductory webinar at**
<https://tinyurl.com/IDEAL4RWE>



4. Part 1: basic training and team formation (to Q3 2022)

Basic training and team formation – light

Apr-May 2022

101 RWE basics

Basics of RWE and form teams

May-Jul 2022

102 Application training

Teams develop simple RWE study concepts

(From today) – course registration

Team formation starts

Study concept and submission (July)

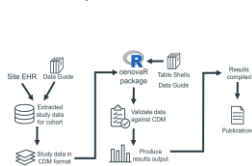
Training in outcomes study planning

Study overview

Patient cohort across 7 HCPs

HCP	Patent cohort
Site 1 - UK	515
Site 2 - France	698
Site 3 - Germany	139
Site 4 - France	466
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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

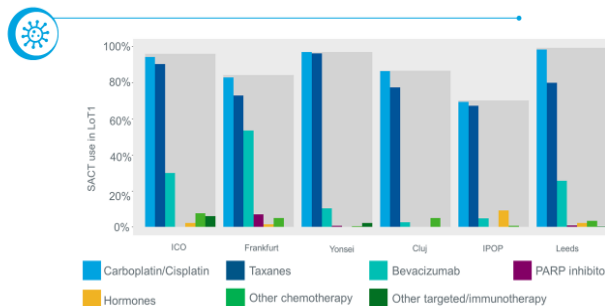
Study overview

- 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





4. Part 2: learning by doing (Q3 2022 to Q2 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

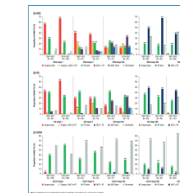
- Protocol
- Common data model
- Evidence of progress to date
- Up to €210k total for 3-4 studies
- Awarded by independent advisory board

3-4 teams get to output

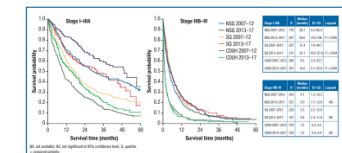
Key outputs



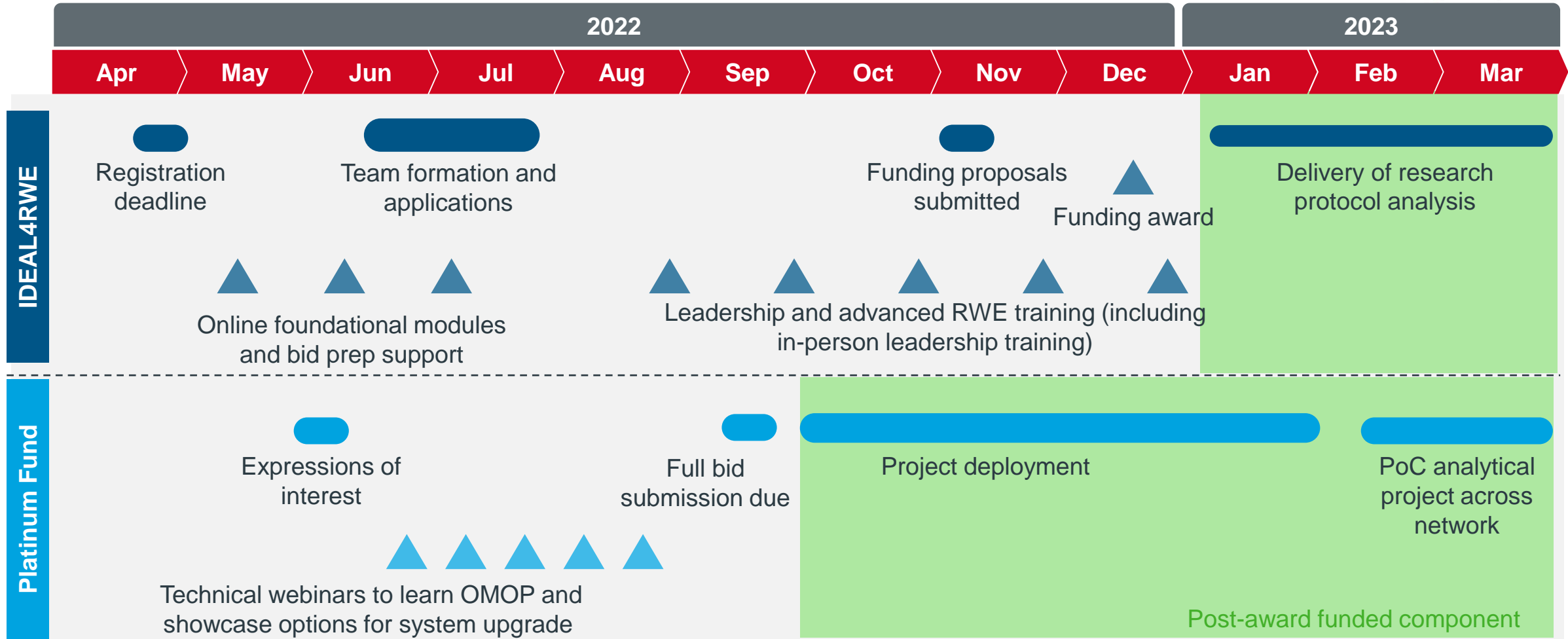
- Non-smal cell lung cancer
- Patient characteristics (e.g. histology, biomarkers, stage)
- Treatment patterns (lines of chemotherapy, and surgery)
- Outcomes from diagnosis, recurrence(s) to death



9th European Lung Cancer Congress (ELCC)



Activities timeline view



How to get involved and Q&A



If you are a cancer outcomes researcher under 45 years old or know of younger colleagues interested in outcomes research



Enrol for the introductory IDEAL4RWE webinar (19th April <https://tinyurl.com/IDEAL4RWE>) **and/or** circulate the webinar information to appropriate colleagues (brochure available from training@digicore-cancer.eu)



If you are interested in upgrading your cancer centre to a proof of concept federated OMOP network under GDPR (Platinum Fund)



Ensure appropriate colleagues enrol for the introductory Platinum Fund webinar (date/link tbc)



If you are interested in your cancer centre joining the DIGICORE network



Access the application form at <https://tinyurl.com/yus7kppv> or contact info@digicore-cancer.eu for more information



If you are interested in getting involved with the clinical informatics work



Identify an expert lead, and conduct self-assessment of informatics maturity. Contact info@digicore-cancer.eu for more information

Backup

A critical gap is the absence of appropriately trained “organising minds” for RWE research in the future

Likely requirements for clinical academics in RWE, from expert interviews



RWE technical/“hard” skills

- Understanding “the art of the possible”
 - Novel methodologies/designs/endpoints
 - Novel technologies (E.g., NLP, AI)
 - Basic programming and data science
- Understanding challenges and constraints
 - Types of RWD – strengths and weaknesses
 - Privacy/GDPR
 - Ethics
- Effective hypothesis generation and grant applications

“You need ‘**one brain**’ with sufficient clinical, data science and methodological understanding to understand what research is needed and what can be done with electronic medical data”

– Prof. Iain Buchan

“It is easier to **train clinicians to understand the data science** than to train data scientists to understand the clinical context”

- Prof. Janne Vehreschild

Leadership/“soft” skills

- Leading self, teams, and systems
 - Self-awareness: emotional intelligence (EQ)
 - Leading diverse teams
 - Working/“translating” across geographies/functions
 - Communications (written and verbal)
 - Building/navigating a career in RWE
 - Influencing health systems (bench to bedside)
- Project and time management

“**We are not taught how to be a leader**, how to build a team, how to get a diverse group of people to work together, and how to plan and manage a project”

– Prof. Iwona Lugowska

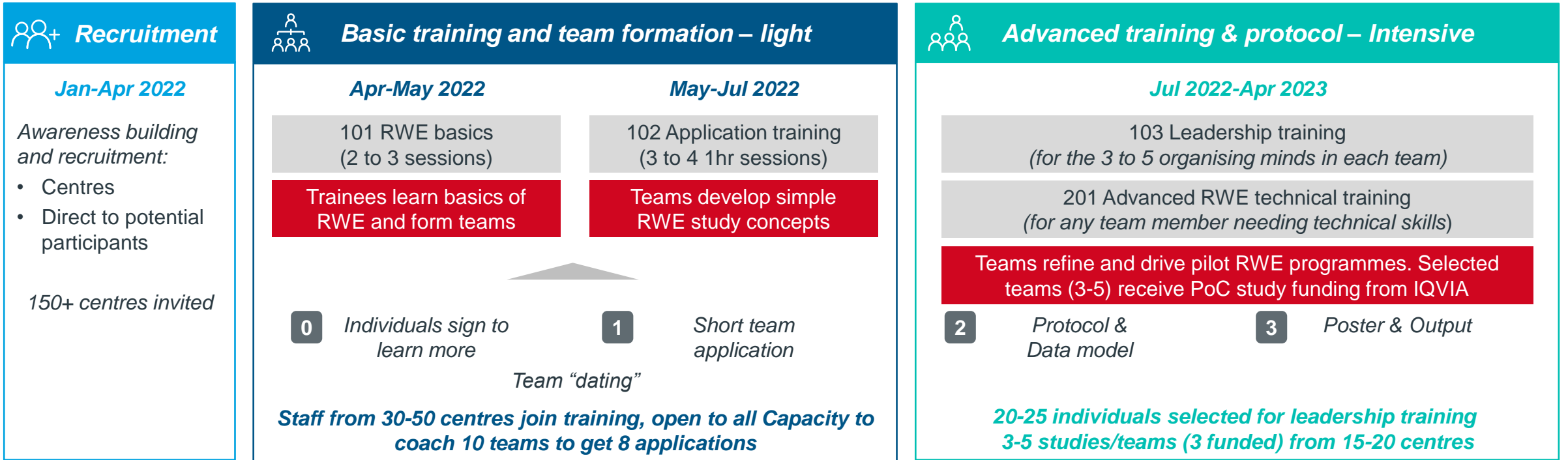
“Soft skills are an enormous gap – I spent 17 years training to be a consultant, but have never done any formal training on how to build and lead teams”

- Prof. Geoff Hall

Source: IQVIA interviews with clinical and RW leaders (n=12)



IDEAL4RWE aims to mobilise international teams in H1 2022 to get to PoC study output by Q1 2023



Mobilise “the digital native” generation of clinicians to DIGICORE

.. And get medical alignment on international definitions and proof of concept study output for follow-on funds (be that pharma or European)

IQVIA are committed to supporting and funding IDEAL4RWE

Options for scale/impact



1) Minimum viable product (IQVIA funded)

- Basics 101-102 open to all
- Light IQVIA project management support for **c. 8 applications**
- **20-25 participants** on F2F training (103 programme)
- **3 studies funded** at \$70k, v. limited IQVIA project management support (.2 FTE)
- Cost **c. €400k** + IQVIA in kind



For Discussion

1. Initial thoughts? Likely “elephant traps?”
2. Lessons learned from HDRUK/ others?
3. Possible HDRUK involvement?

Conditions for participation (sites)



Phase 2: Leadership training and proof of concept

1. Non-DIGICORE centres must join DIGICORE
2. Cancer centres provide time for research – 1 day a week to leadership trainees for 6 to 9 months
3. Leadership trainees will get both intensive offsite and virtual training
4. All selected teams get to protocol, common data model and a budget, some then selected to get funding to delivery. No manual retype studies.
5. 80% of the proof of concept cash funding is spent in centres that can do commercial research (given time in kind, many other centres could be in team)
6. We aim to deliver simple natural history and outcome studies by ~end 2022



A Leadership Advisory Board (LAB) will provide support and guidance throughout

