OECI 2023 Oncology Days

DigiCore

DIGICORE an added value for European Outcomes research studies

Update on DIGICORE development

June 14, 2023

Prof. Gennaro Ciliberto
DIGICORE President
Scientific Director IRCCS National Cancer Center, Regina Elena, Rome, Italy

THE DIGITAL INSTITUTE FOR CANCER OUTCOMES RESEARCH

"make every willing cancer patient a research patient and so transform cancer care"

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

Members

Academic cancer centres

unicancer

ALLIANCE AGAINST CANCER

Individual cancer centers

Industry

IQVIA

illumina

DIGital Institute for Cancer Outcomes Research (DIGICORE)

Pan-EU research collaboration to study cancer outcomes, capitalizing on increase in **precision oncology**

Independent European Economic Interest Group (like OECI) with 38 cancer centres today

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

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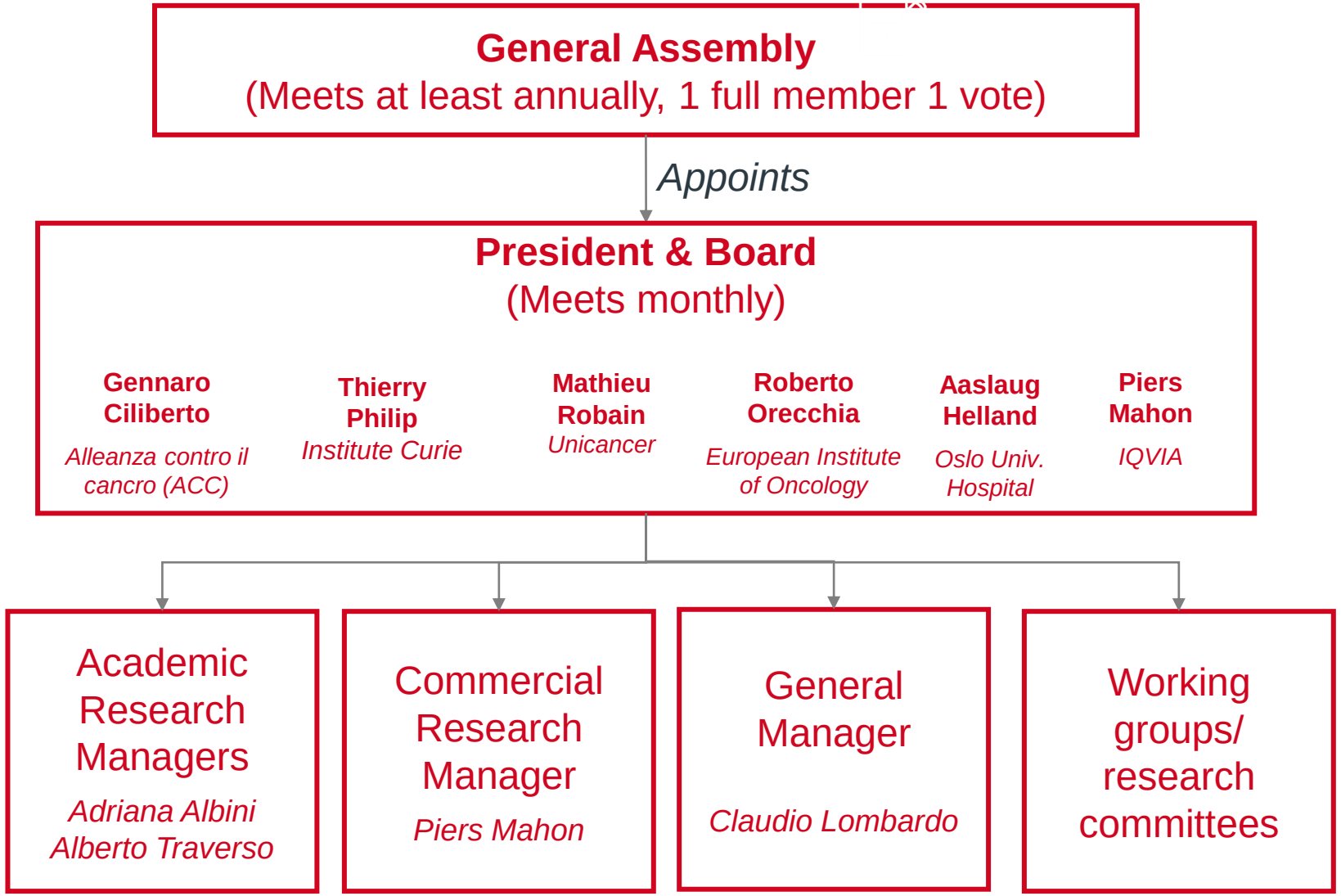
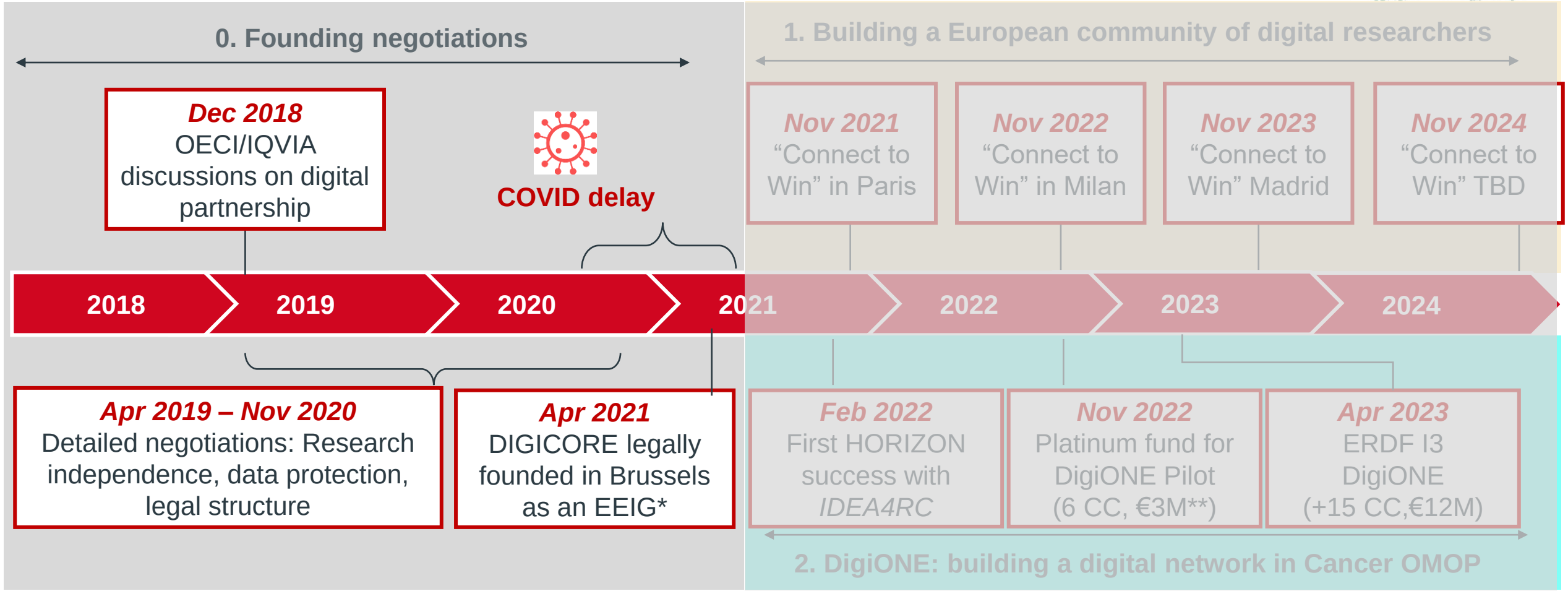
Our organization



Key Principles

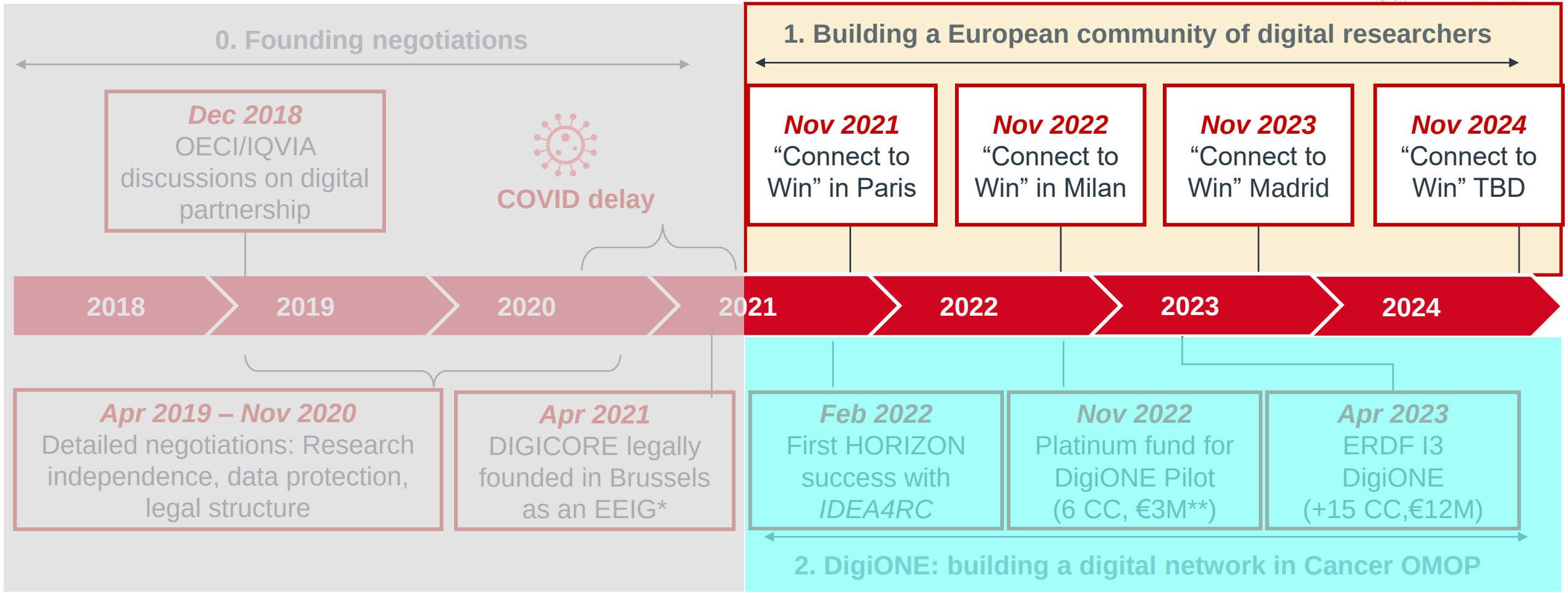
1. **Medical hypothesis neutrality** – no large pharma inside
2. Cancer centres retain **full data control** and autonomy over clinical decisions
3. Serve **both academic and commercial research**
4. **Institutional research autonomy** – right to refuse any study, or propose one
5. **Equality in research 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

Three chapters to DIGICORE's story so far



* European Economic Interest Grouping, same legal structure as OECI
** Funded by IQVIA and Illumina

How are we doing on building a European community of digital researchers?



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Connect To Win: Second annual digital research planning conference taking place in Milan November 2022

Connect2Win , Milan 7-9 Nov 2021

Objectives

- Assess progress over last year
- Further grow the network
- Better define of our common operational model and timeline for first deliverables!
- Discuss how to best position DIGICORE for success

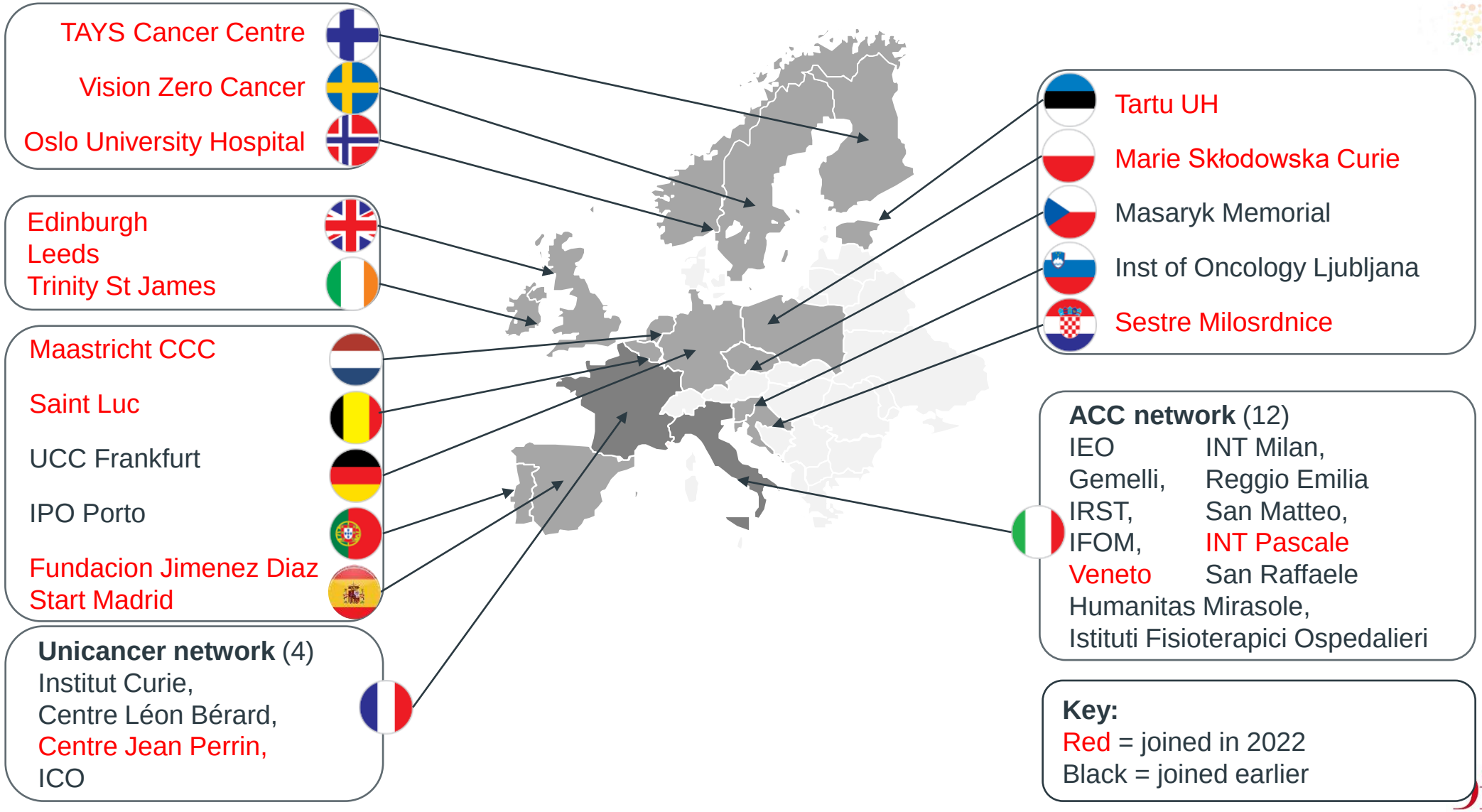
120 delegates

40 cancer centres

19 European countries + US + Companies

Major national centres represented

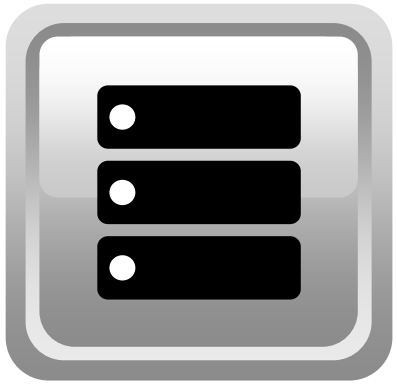
In 2022 DIGICORE grew from 22 to 38 cancer centres in 17 countries



Four elements to drive DIGICORE's future success and digitising the Beating Cancer Plans

1. Digitally skilled researchers

2. Common digital research infrastructure



3. Exciting scientific hypotheses

4. Funding

IDEAL4RWE training program and competition to address a skills gap and support proof of concept research involving emerging research leaders

Who?	• **Under 45,** clinicians, data scientists etc. Interested in **outcome research** and ambitious to lead digital revolution in RWE
What?	• Training on both **technical and leadership skills** for RWE • Based around an international **proof-of-concept** study
How?	• **Mix of training styles:** Face-to-face and virtual • Full programme **involves "test" application – funding available**
When?	• **Started** in Q2 2022 - free "taster" programme • **RWE studies started in Q4 2022/Q1 2023** • **Will Conclude** in year **2023**

DIGICORE's research committees' structure is designed to complement national outcome research programmes and will be scaled this year

Initiation

DIGICORE Board selected 3 research topic - Lung Cancer/ Breast Cancer/ Non-Hodgkin's Lymphoma - and invited members to nominate experts

- **Participation open to all** members and associate members on equal basis

Structure

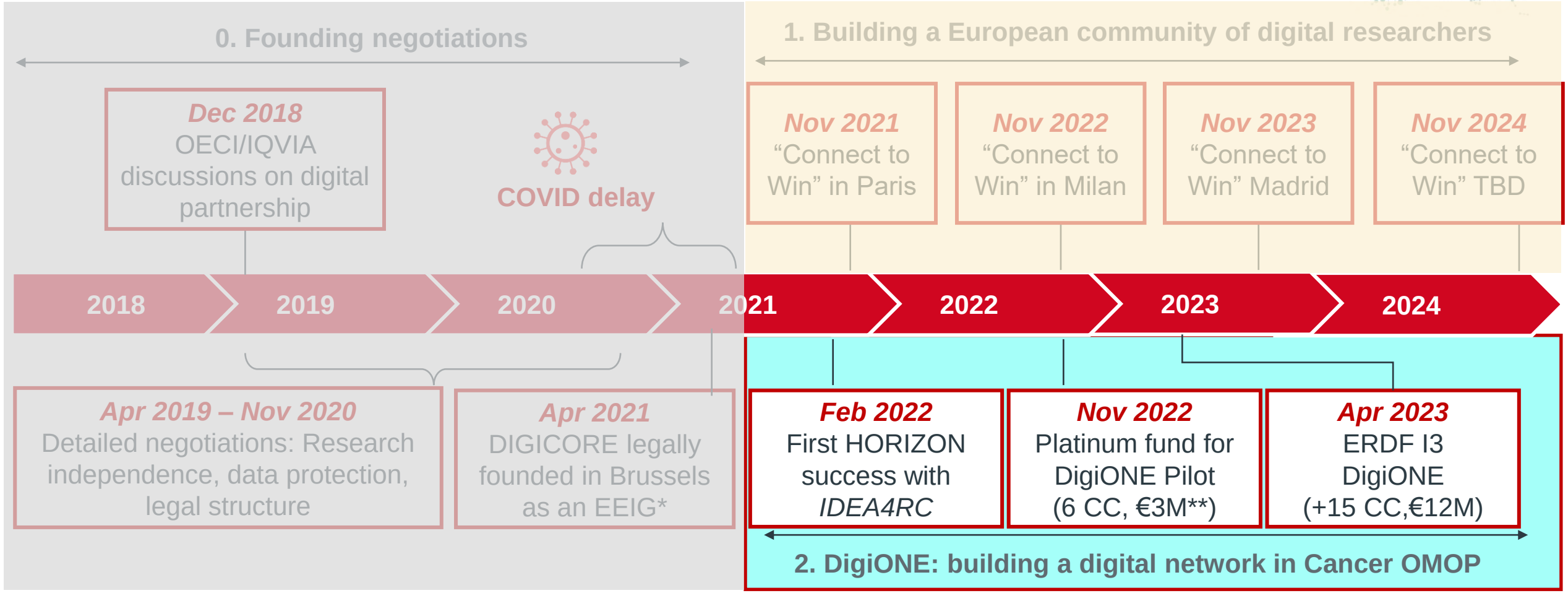
- At least **5 cancer centres** from at least **3 countries**
- **2 co-chairs** (from 2 different countries)
- **Only clinicians** from cancer centres can co-chair outcome research committees
- **Open and democratic**
- Some **DIGICORE administrative support**

(Over time, some core funding)

Benefits

- **International RWE research collaboration** among top European RWE experts
- **Attractive to research funders through international scale:**
  - HORIZON/European funds
  - Life sciences industry

How are we doing on building a common infrastructure?



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We are participating as a junior partner in 4 HORIZON bids to date

IDEA4RC

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

- Enlargement of

Project coordinator:
Istituto Nazionale dei Tumori di Milano

The Digital Institute

EUonQoL

HORIZON-MISS-2021-CANCER-02

Project

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

Objectives

- EUonQoL aims to develop, pilot and validate the EUonQoL-Kit, a patient-driven, unified system for the assessment of quality of life (QoL) based on evaluations and preferences of cancer patients and survivors. The EUonQoL-Kit will be developed from a patient perspective, administered digitally, available in the EU27 and Associated countries languages, and applicable in future, periodic surveys to contribute to the EU's mission on cancer.

Project coordinator:
Istituto Nazionale dei Tumori di Milano

CCI4EU

HORIZON-MISS-2022-CANCER-01-02

COMPREHENSIVE CANCER INFRASTRUCTURE IN EUROPE (CCI4EU)

Coordinator: **OECI**

- **DIGICORE Role**: **Partner**

Affiliated Entity: IFO
3° Parties: Vision Cancer Zero, IOV, Irst 'Dino Amadori', Institue de Cancérologie de l'Ouest

- **DIGICORE Activities** :
  - ✓ ***WP 2:*** Definition of criteria for Comprehensive Cancer Infrastructures (CCIs) using a Maturity Model
  - ✓ ***WP 3:*** Mapping of the current status and criteria of CCIs in EU MSs/regions and clustering

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The Digital Institute for Cancer Outcomes Research

CAN.HEAL

EU4H-2021-PJ2

Project

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

Objectives

- To develop an integrated approach to improve access of individuals and cancer patients to prevention, diagnosis and treatment of cancer through personalised medicine

DIGICORE' role

- Development of decision support tools
- Training and literacy initiatives addressed to patients and general public

Project coordinator:
Sciensano (Belgium)

DIGICORE Activities :

WP 10: ***Data integration and Dissemination***

WP 13: ***Educational activities***

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The Digital Institute for Cancer Outcomes Research

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Platinum fund competition to support the development of a proof of concept network for advanced RWE research

Who?	• Digitally-ambitious cancer centres needing investment
What?	• An investment programme for **advanced RWE technology** – **up to €3M** • **€250K cash - €250K in-kind** tech for 6 centres
How?	• **Individual cancer centres express interest**, access funding details, training materials, get bid prep support and advice • **Submit bids** outlining their plans for needed upgrade
When?	• **Expressions of interest** end of June 2022- Full appl Sep 2022 • **Awarded November** 2022 • **Started** March 2023 (kick off meeting in Frankfurt)
T&Cs?	• Any OECI or similar can apply, but **to receive funding** - Must become a member or associate of DIGICORE - Must be willing to contract for commercial RWE

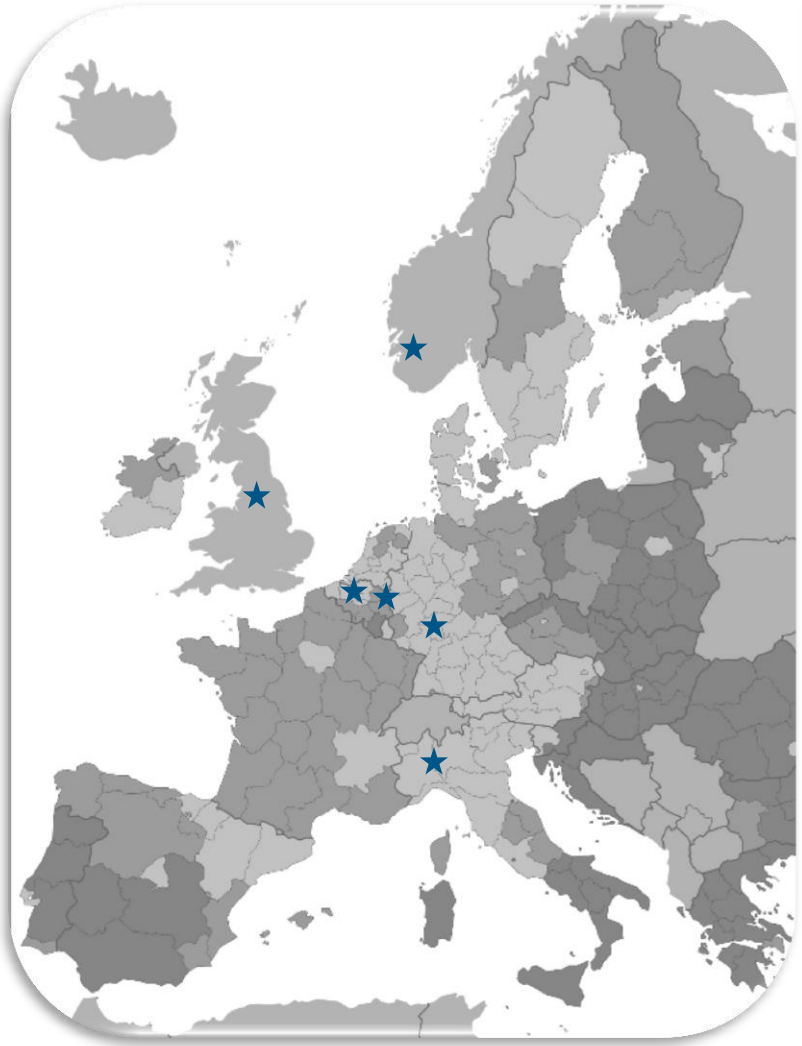
Platinum was anticipated by the establishment of frameworks and self-assessment tools to help measure centre RWE readiness and plan improvements

	Bronze Cancer Centres	Silver Cancer Centres	Gold Cancer Centres
1. Precision oncology research maturity	**MDX testing below NCCN guidelines** • Testing almost all “IHC + some Sanger” • Very limited local precision expertise • Don’t recruit to Biomarker driven trials	**Testing at / above NCCN guidelines** • Small panel the norm only in NSCLC • Some but limited precision expertise • Recruit rarely for SoC biomarker trials	**Large Panel MDX standard of care** • 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** • Siloed Clinical Systems, very partial data • Unstructured Data often paper based • No Data Standardisation • Traditional eCRF obs. studies only	**Basic clinically focused Data Warehouse** • 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** • 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) • Manual research processes established for date of death, but frequency of routine scans confounds RECIST	**Outcomes interested but gaps remain** • 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** • 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** • 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** • 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** • 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

DigiONE Pilot: €3M for technology investment in proof of concept to automate and federated cancer outcome research under GDPR

1. Define a **scalable common international minimum dataset for cancer (MEDOC)** 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

6 DigiONE Posters to be presented at OHDSI EU Symposium July 2023



Conceptual architecture for the Digital Oncology Network for Europe - an OMOP based European federated, automated cancer care quality ecosystem

Olivier Bouissou[1], Ismini Chatzitheofilou[2], Gennaro Ciliberto[3], Marco Denti[4], Xosé Fernández[5], Dennis Kadioglu[6], Stelios Theophanous[7], Joëlle Thonnard[8], Alberto Traverso[9], Piers Mahon[3,5]

Building a European cancer OMOP network in hospitals with limited OMOP experience using tiered and modular protocolised research

Atif Adam[1] and Piers Mahon[1,2]

[1]IQVIA Ltd. [2]Digital Institute for Cancer Outcomes Research (DIGICORE).

Data OMOPisation of cancer data at Cliniques universitaires Saint-Luc

Joëlle Thonnard[1], Frédéric Calay[1], Audrey Timmermans[1], Cédric Van Marcke[1],
[1] Clinique universitaires Saint-Luc, Brussels, Belgium

The DigiONE FORGE Approach to Providing OMOP Oncology Data for Federated Analyses

Daniel Maier[1,2], Fabienne A. U. Fox[1], Abishaa Vengadeswaran[3], Andrea Wolf[4], Christian Brandts[4], Daniel P. Brucker[4], Holger Storf[3], Jörg Janne Vehreschild[1,5,6], Timo Schneider[4], Dennis Kadioglu[3,7]

OMOP for oncology data: a single-centre and network perspective

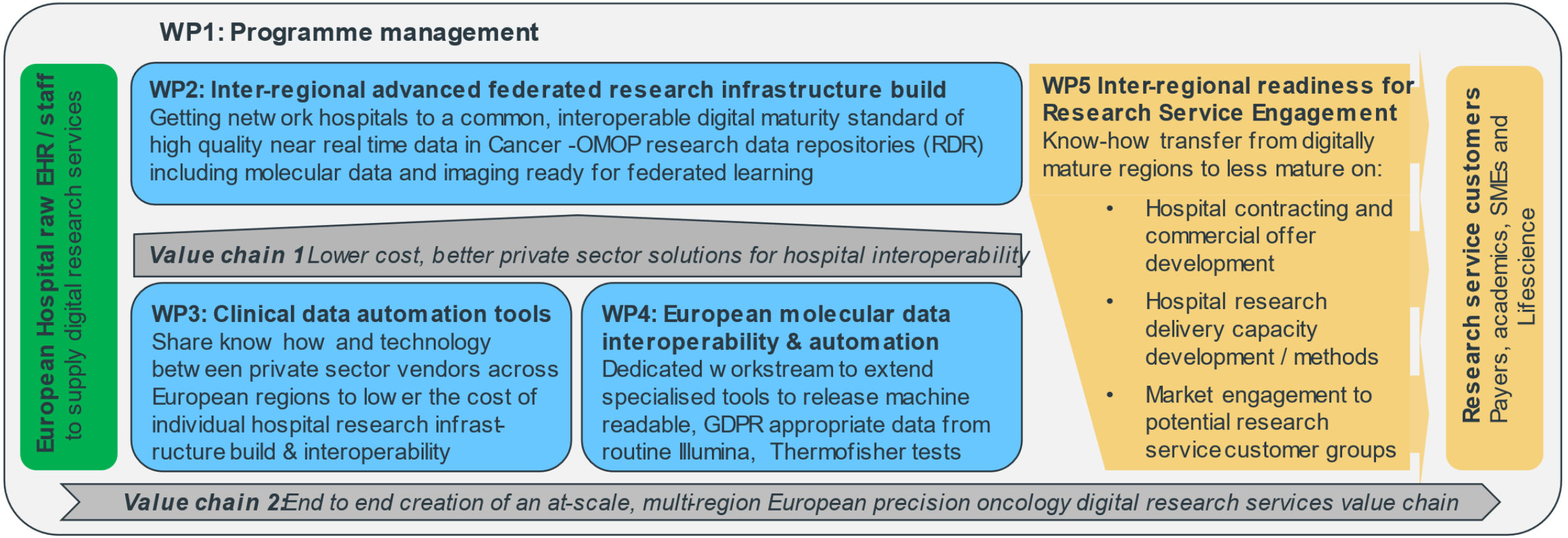
Stelios Theophanous[1], Kieran Zucker[2,3], Louise Hick[1], Edward Bolton[1], Majid Riaz[2,4], Hayley Fenton[2,4], John Corkett[1], Sue Cheeseman[1], Geoff Hall[2,3]

Oslo University Hospital Participation in a European Cancer OMOP Network

Olivier Bouissou[1], Ingrid K. S. Hanto[2], Elisabeth Ross[1]
[1] Division of Technology and Innovation, Oslo University Hospital
[2]Division of Cancer Medicine, Oslo University Hospital

DIGICORE coordinated and awarded (subject to contract) €12m bid to the ERDF I3 scheme to digitise another 15 hospitals to Cancer OMOP

DigiONE – I3: Digital Oncology Network for Europe



Summary

1. Growth higher than expected in little more than 2 years from foundation
2. Building a community of digital clinical young experts
3. Several RWE projects ongoing and more to come soon
4. Strong capability for fund raising
5. Building a large digital interoperable infrastructure for outcomes research

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**
- **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** – advanced RW studies, precision trials
- Propose **academic studies** to the grouping

How to join DIGICORE

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)

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

CONNECT TO WIN: November 13-15, 2023 Madrid-Spain

DigiCore

Don’t miss our next meeting in Madrid in November

CONNECT TO WIN

Thank you!