CONNECT TO WIN: November 7-9, 2022 Milan- Italy

Sistema Socio Sanitario

Fondazione IRCCS Istituto Nazionale dei Tumori

Regione Lombardia

in collaboration with

DigiCore

IRE Regina Elena

CONNECT TO WIN

INTRODUCTION TO DIGICORE

November 8, 2022

Prof. Gennaro Ciliberto

Scientific Director

IRCCS National Cancer Institute Regina Elena, Rome

DIGICORE President

THE DIGITAL INSTITUTE FOR CANCER OUTCOMES RESEARCH

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

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

2018

Dec 2018
OECI/IQVIA discussions on digital partnership

2019

Apr 2019
Interested parties agree a new EEIG* partnership solution

Apr 2019 – Nov 2020
Detailed negotiations: Research independence, data protection, legal structure

2020

Apr 2020
First formal meeting of partners and commitment to proceed

COVID delay

2021

Apr 2021
DIGICORE legally founded in Brussels

Nov 2021
First conference: “Connect to Win” in Paris

2022…

Feb 2022
First HORIZON success with *IDEA4RC*

* European Economic Interest Grouping, same legal structure as OECI

Connect To Win: Our first 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

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

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 33 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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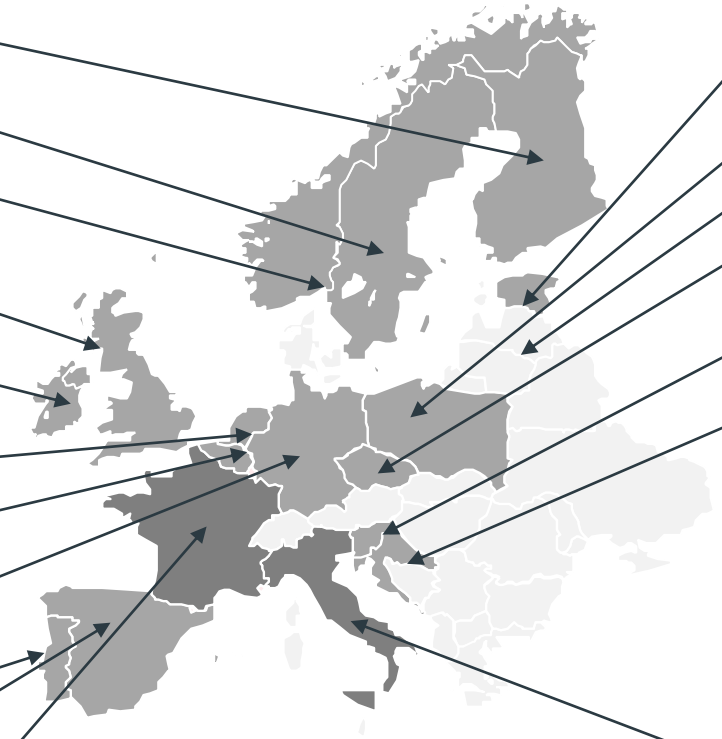
Current DIGICORE network of 33 centres, 2 national networks and 2 commercial partners in 16 countries

TAYS Cancer Centre
Vision Zero Cancer
Oslo University Hospital

Edinburgh
Leeds Teaching Hospital
Trinity St James

Maastricht CCC
Illumina Netherlands
Saint Luc
IQVIA Belgium
UCC Frankfurt
IPO Porto
START Madrid
Fundacion Jemènez Diaz
Madrid

Unicancer network
Institut Curie
Centre Léon Bérard
Centre Jean Perrin
ICO



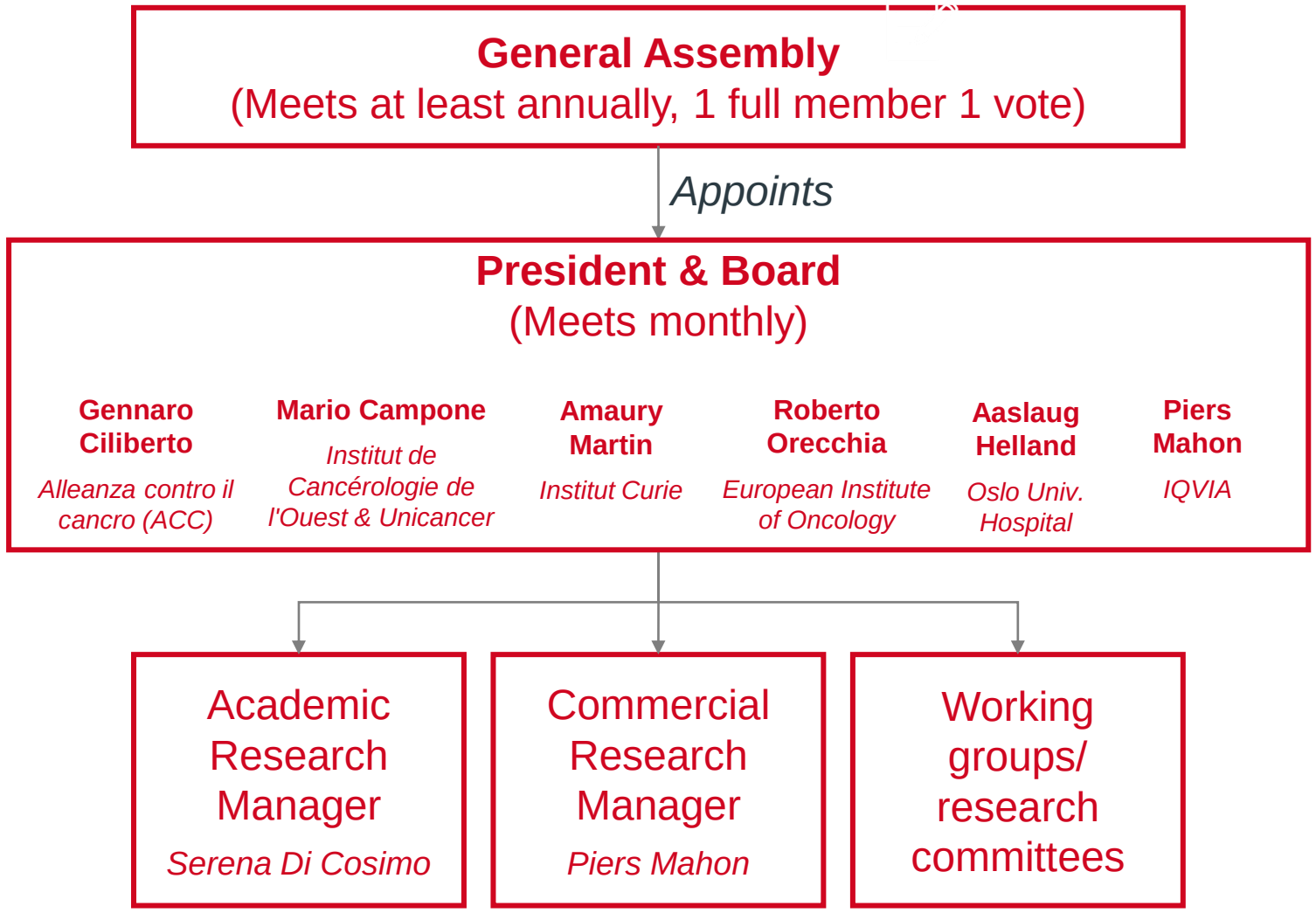
Tartu UN. Hospital
Marie Skłodowska Curie
Natl. Cancer Inst. Vilnius
Masaryk Memorial
Inst of Oncology Ljubljana
Sestre Milosrdnice

ACC network
IEO
INT Milan
Gemelli
IRST
Reggio Emilia
San Matteo
Humanitas Mirasole
Istituti Fisioterapici Ospedalieri
San Raffaele
IFOM
INT Pascale
IOV Padua

DIGICORE's keywords

- Digital Revolution
- Electronic Medical Records
- Molecular Diagnostics
- Trial Automation
- Outcomes research
- Quality Management

Our organization



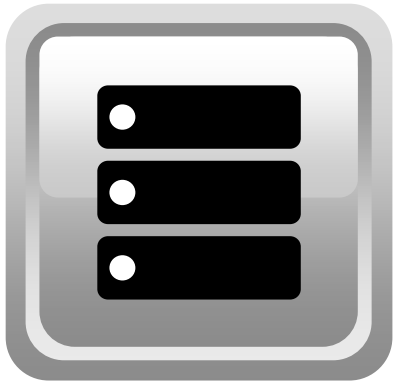
Key Principles*

1. **Medical hypothesis neutrality** – no large pharma inside
2. Cancer centres retain **full data control** and autonomy over clinical decision making
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 implemented until / unless funded

Four elements to drive DIGICORE's future success

1. Digitally skilled researchers

2. Common digital research infrastructure



3. Exciting scientific hypotheses

4. Funding

DIGICORE's focus in 2022-2023 is building capacity for digital international comparative cancer outcomes research

1. 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

2. 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

3. 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**

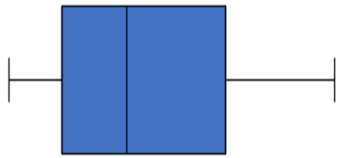
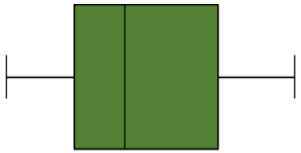
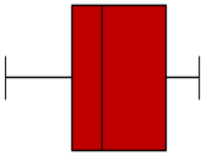
4. Mobilise our members for international cancer outcomes research

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

1. Set up a Clinical Informatics Interoperability WG to map our members' digital readiness

Increasing Centre maturity

1 = Rudimentary — Excellent = 5

Precision oncology research maturity		Many centres have large panel, but can't access the data. We have "MDX snapshots only" – biopsy and test at single point in patient journey is the norm
Clinical data digital research maturity		We are OK at managing structured data collectively **BUT** weak at managing unstructured or getting to a **common data model** or reference data management
Pragmatic outcomes maturity		OK at date of diagnosis, line of therapy and death **BUT** weak at progression, RECIST, A.E. and PROs
Information governance & RWE delivery maturity		While some are well on the journey to strong Information governance post GDPR, many have not started to solve the legal and operational issues

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Technology solutions need to recognise that health data today is "messy"

1. MOST EHRS TODAY ARE REALLY "PAPER IN DISGUISE"

2. AS A RESULT WE WILL NEED SOLUTIONS FOR UNSTRUCTURED TEXT & PDF

Typical EHR *(some are much more structured)*

i) **Structured or semi-structured** data

ii) **Electronic free text** (most medical notes and observations in core EHR)

iii) **Image or PDF based information**

- PDF text, e.g. scanned referral letters, laboratory test reports, molecular diagnostic test results
- Images e.g. radiology, digital pathology

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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** • 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

2. DIGICORE will fund up to €3M for technology investment in proof of concepts – half cash, half in-kind via the Platinum Technology Fund

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

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2. 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 • **Deployment start in** December 2022 • **Concludes** November 2023
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

3. 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

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

3. 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 start in Q4 2022/Q1 2023** • **Concludes** H1 2023
T&Cs?	• 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

4. DIGICORE's research committees' structure is designed to complement national outcome research programmes

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

DIGICORE Activities:

- Fund Raising

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

- Enlargement of the Rare Cancer Data ecosystem

Project coordinator:
Istituto Nazionale dei Tumori di Milano

Current involvement in EU research bid - won

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***

Current involvement in EU research bid - won

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.

DIGICORE role

- **Leader WP5** - ICT Platform and Data Analysis, SW development, digital toolkit

Project coordinator:
Istituto Nazionale dei Tumori di Milano

Current involvement in EU research bid - submitted

HORIZON-MISS-2022-CANCER-01-02

COMPREHENSIVE CANCER INFRASTRUCTURE IN EUROPE (CCI4EU)

Coordinator: **OECI**

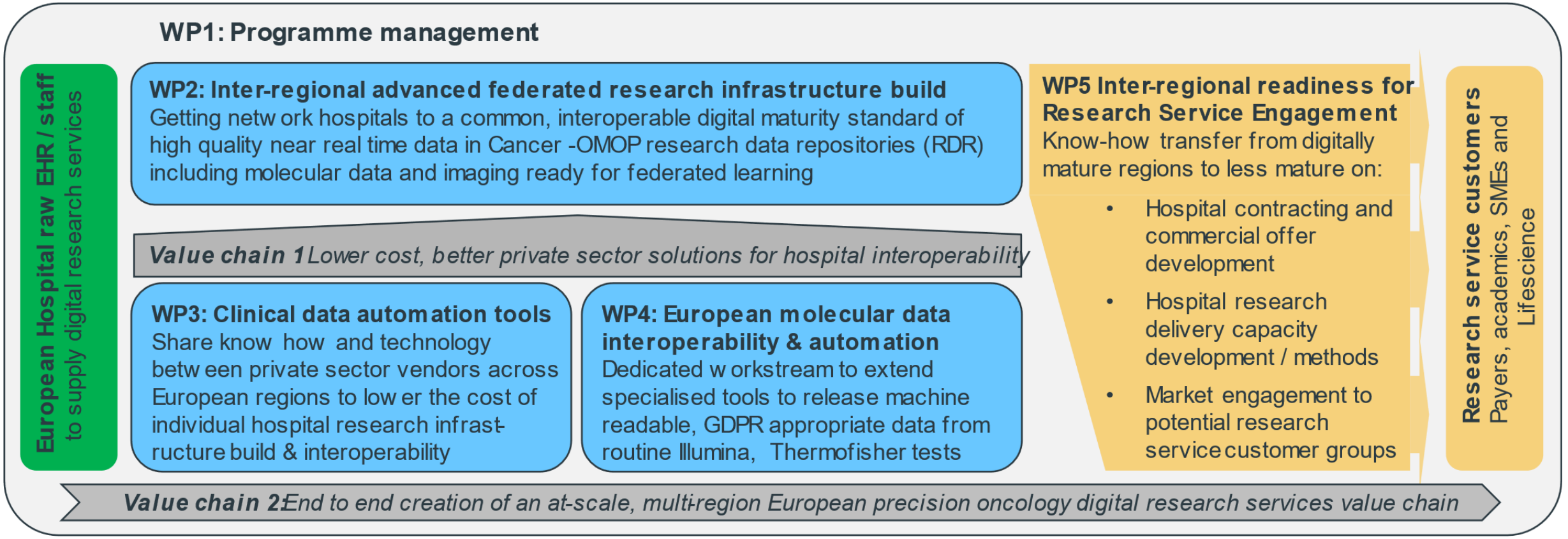
- **DIGICORE Role**: **Partner**

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

DIGICORE submitted a €12m bid to the ERDF I3 scheme to digitise 15 hospitals to a common standard - DigiONE

Digital Oncology Network for Europe



Over the next 2 days we will touch on progress on each element

1. Digitally skilled researchers

- **IDEAL4RWE training programme**
- Clinical ambassador scheme

2. Common digital research infrastructure

- **Clinical informatics** working group
- **Platinum funding** scheme for DIGI-ONE prototype
- Advances in clinical informatics methods

3. Exciting scientific hypotheses

- **3 new outcome research working groups** in Breast, NSCLC, NHL
- Industry speakers on their needs
- **Pragmatic trials discussion on 9th**
- Informal peer to peer discussions

4. Funding

- **Review of our EU participations in 2022**
- Discussion on **novel EU funding schemes**

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** via IQVIA – advanced RW studies, precision trials
- Access **global philanthropy investment** via IQVIA – e.g., paediatric oncology
- 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

Thank you!