DIGICORE is a new independent Public-Private Partnership in European Cancer Real World Evidence

Members

Industry

Academic cancer centres

IQVIA

illumina

unicancer

ALLIANCE AGAINST CANCER

OECI
Organisation of European Cancer Institutes

Other networks to be announced

DIGital Institute for Cancer Outcomes Research (DIGICORE)

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

"Network of networks" with >150 cancer centres, >300K new Dx per year inside an EEIG

Benefits and rationale

- For **Cancer Centres**, **pool cancer data across sites for improved translational research**
  - Improving patient outcomes #1
  - Academic research/ publication #2
  - More efficient trials
  - Trial and RWE research funding
- 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 Illumina,** **grow clinical evidence base for molecular diagnostic tests** in improving outcomes and **accelerate reimbursement** for all vendors

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

General Assembly
(Meets at least annually, 1 member 1 vote)

Appoints

President & Board
(Meets monthly)

Gennaro Ciliberto	Mario Campone	Xose Fernandez	Roberto Orecchia	Piers Mahon
Alleanza contro il cancro (ACC)	*Institut de Cancérologie de l'Ouest & Unicancer*	*Institut Curie*	*European Institute of Oncology*	*IQVIA*

- Academic Research Manager — *Serena di Cosimo, A.Albini-A.Traverso*
- Commercial Research Manager — *Piers Mahon*
- Working groups/ research committees

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

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

For DIGICORE to succeed, we need to create international digital interoperability in cancer data

- **Aligned Target Data Items** (what to capture to describe cancer)
- **Aligned Data Formats** (in what units, with what meta data, in what common data model)
- **Aligned Quality** (collected how frequently, in routine care alone or more ‘registry’ style)
- **Aligned Research Processes** (with what legal basis for research, with what privacy controls, with what access and authorisation processes for research)

Four study teams arose amongst the participants to develop proof-of-concept studies

Indication (team size)	Countries represented	# patients	Study title
Breast (8)	BE, IT, UK, FR, CZ, Poland, Portugal, Slovenia	780	The Causes and Consequences of Incomplete Paclitaxel Administration during the Neoadjuvant treatment of Early Triple negative and HER2 positive breast cancer (CIPNETH)
Colorectal (6)	CZ, IT, Croatia, Poland	980	CO(r)RECT Me- metastatic COloREctal Cancer Treatment Pathway
Head and neck (5)	Slovenia, Portugal, Norway, IT, Spain	530	Immunotherapy in recurrent/metastatic head and neck cancer: real-world data from six European countries (2017-2022)
Prostate (9)	NL, DK, Spain, FR, UK, IT	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

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COMPREHENSIVE CANCER INFRASTRUCTURES 4 EUROPE

The project's main objective is to improve or develop existing or future Comprehensive Cancer Infrastructures (CCIs).

Understanding | Prevention | Diagnostic and Treatment | Quality of Life | Equitable Access | Cross-Cutting Actions

13 Recommendations for bold actions

1. Launch **UNCAN.eu** – a European Initiative to Understand Cancer
2. Develop an EU-wide research programme to identify **(poly-) genic risk scores**
3. Support the development and implementation of **effective cancer prevention strategies** and policies within Member States and the EU
4. Optimise existing screening programmes and develop **novel approaches for screening and early detection**
5. Advance and implement **personalised medicine approaches** for all cancer patients in Europe
6. Develop an EU-wide research programme on **early diagnostic and minimally invasive treatment technologies**
7. Develop an EU-wide research programme and policy support to improve the **quality of life of cancer patients and survivors, family members and carers,** and all persons with an increased risk of cancer
8. Create a **European Cancer Patient Digital Centre** where cancer patients and survivors can deposit and share their data for personalised care
9. Achieve **Cancer Health Equity** in the EU across the continuum of the disease
10. Set up a network of **Comprehensive Cancer Infrastructures** within and across all EU Member States to increase quality of research and care

CCI4EU

11. **Childhood cancers** and cancers in adolescents and young adults: cure more and cure better
12. Accelerate innovation and implementation of new technologies and **create Oncology-focused Living Labs** to conquer cancer
13. **Transform cancer culture,** communication and capacity building

European Commission

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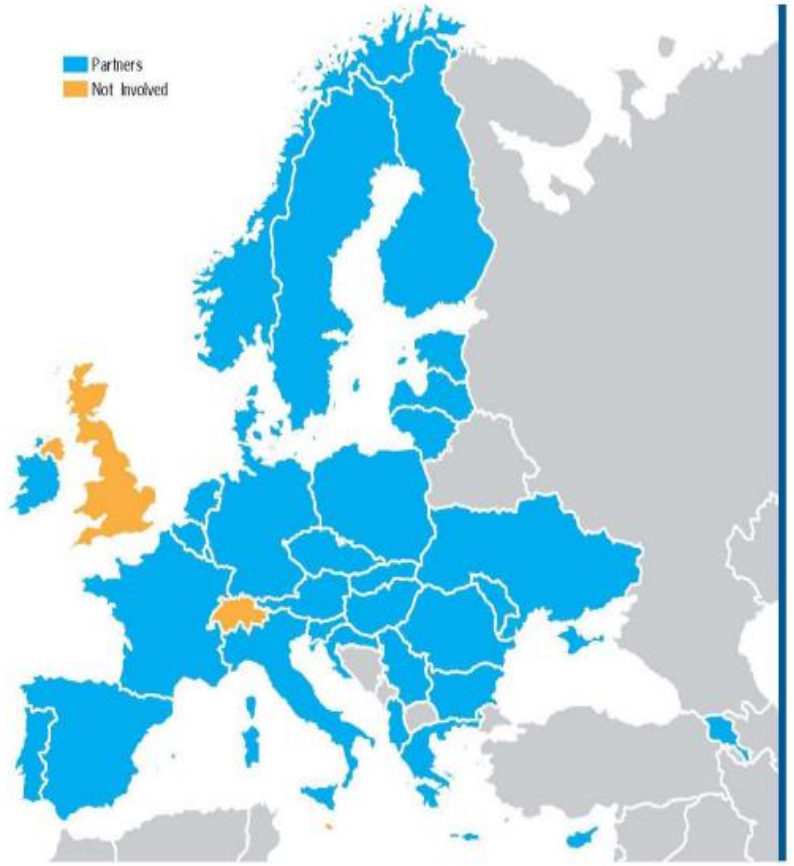
UPDATED MAP OF COUNTRIES PARTNERS



Partners

Albania
Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Georgia
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxemburg
Moldova
Norway
Poland
Portugal
Romania
Serbia
Slovakia
Slovenia
Spain
Sweden
The Netherlands
Ukraine

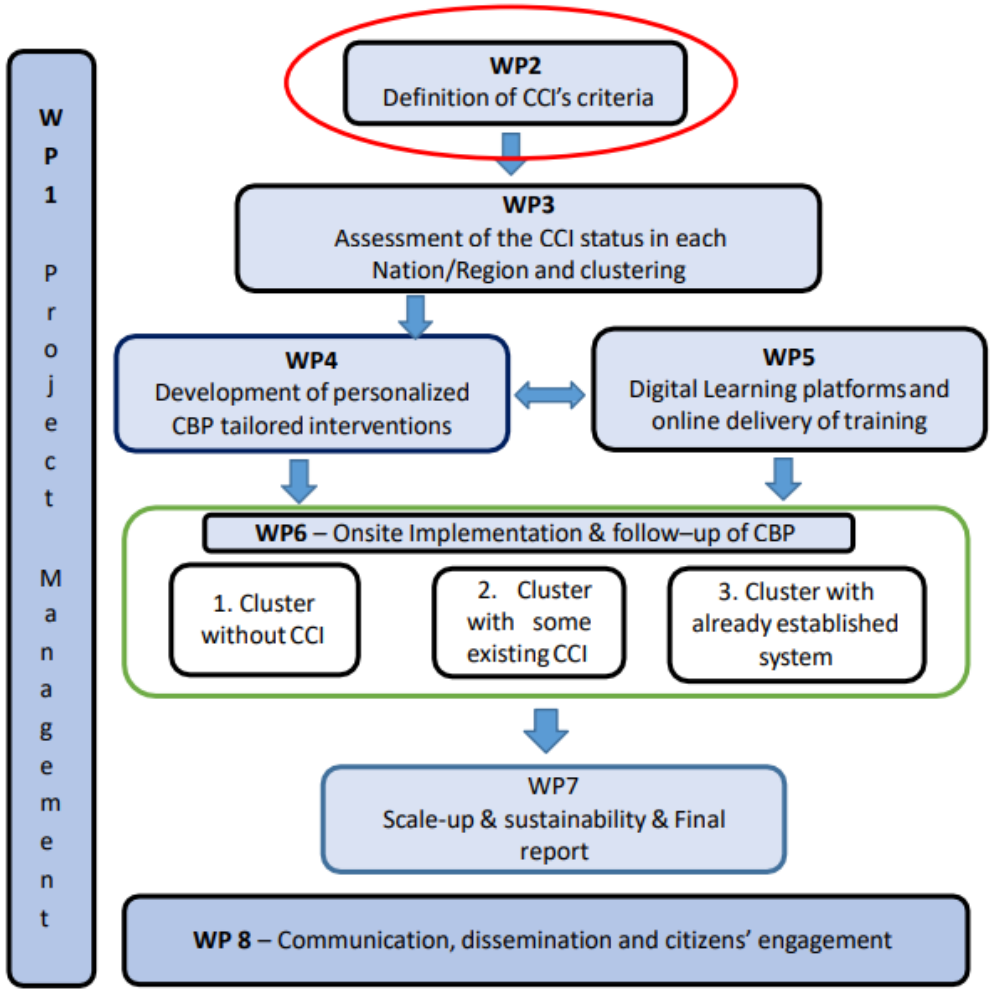
Not Involved

Malta
Switzerland
United Kingdom

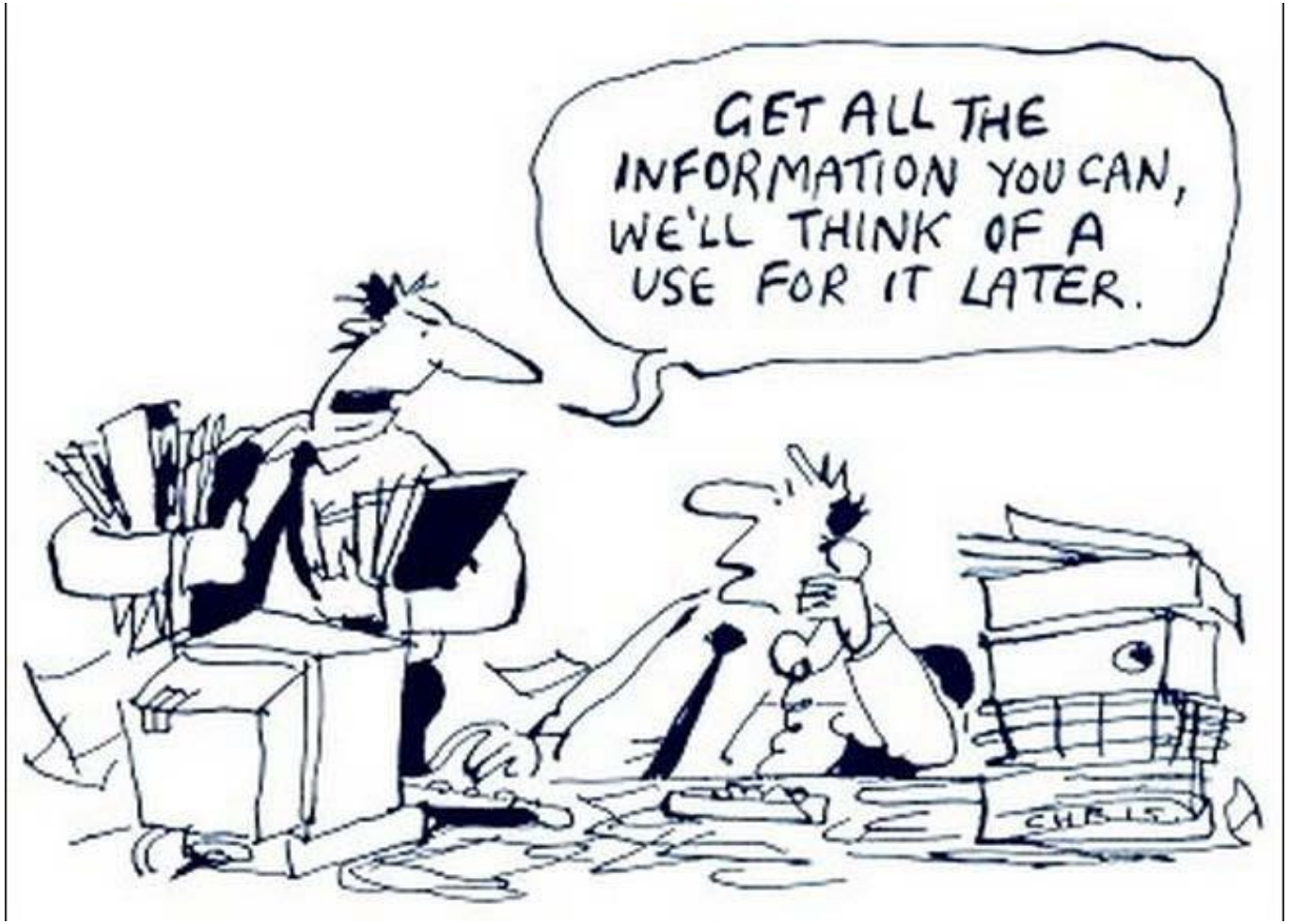
Consortium consolidated for 35 partners 30 affiliated entities.

IFO-IRE is affiliated entity of DIGICORE

Overview CCI4EU:



NATURE AND PURPOSE OF DATA COLLECTION IN CLINICAL RESEARCH



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Medical Statistics & BioInformatics

- *Medical Statistics*
  - Statistical consultation
    - Clinical trials
      - Design
      - Analysis
      - Data Safety and Monitoring Board
      - Medical Ethical Committee
  - Teaching
  - Research
- *Advanced Data Management*
  - Provide secure, advanced, cost-effective, web based data management infrastructures for clinical research
  - Make sure design facilitates the intended analyses as well as the intended users, maximizing privacy protection

Design of studies and type of privacy issues

- clinical trials
- cohort studies
- transition of data from Care to Research
- quality registers
- rare diseases
- mixtures: registries to support both qua
- ultra-sensitive registries

Protection by …

- Account (role) management
- encryption
- transparency => trust
- Principle of necessity, proportionality and subsidiarity

Some aspects of data collections

- Quality of data
- Missing data
- Follow-up
- Selection bias
  - Informed consent
  - Informed opt-out

Case law / jurisprudence?

"Before I write my name on the board, I'll need to know how you're planning to use that data."

Safeguarding privacy

- **The notion of "consent" (informed consent)**
- **Security**
- Intruder detection
- Encryption of identifiers
- Access limitation through roles
- No need to know the true identity of a subject or center! Such a need arises only during data management.
- **Certification Transparency**

  - **Data leak procedures**
  - **Privacy Impact Assessments**

HOW DO WE FIND A BALANCE …..

… between the need for scientific advance in research and care and the fundamental right of each individual to decide in an informed way on the way to live and the amount of privacy

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GPDP | GARANTE PER LA PROTEZIONE DEI DATI PERSONALI

Provvedimento del 29 ottobre 2020 [9517401]

VEDI ANCHE PROVVEDIMENTO DEL 25 MARZO 2021

[doc. web n. 9517401]

Provvedimento del 29 ottobre 2020

Registro dei provvedimenti
n. 202 del 29 ottobre 2020

IL GARANTE PER LA PROTEZIONE DEI DATI PERSONALI

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VISTO l'art. 110 del Codice che, in tema di trattamento di dati personali per ricerca medica, biomedica e epidemiologica, dispone che "il consenso non è inoltre necessario quando, a causa di particolari ragioni, informare gli interessati risulta impossibile o implica uno sforzo sproporzionato, oppure rischia di rendere impossibile o di pregiudicare gravemente il conseguimento delle finalità della ricerca. In tali casi, il titolare del trattamento adotta misure appropriate per tutelare i diritti, le libertà e i legittimi interessi dell'interessato, il programma di ricerca è oggetto di motivato parere favorevole del competente comitato etico a livello territoriale e deve essere sottoposto a preventiva consultazione del Garante ai sensi dell'articolo 36 del Regolamento";

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Reality of data in Europe today

The Tower of Babel

Pieter Bruegel the Elder

- ✕ We Speak Multiple Languages
- ✕ We Practice Medicine Differently
- ✕ We have different national care quality agendas
- ✕ We Have Bespoke IT systems and vendors
- ✕ We have Different clinical coding standards and claims systems
- ✕ We have different national (and local) interpretations of GDPR & privacy requirements