DIGI-ONE: going digital and federated, to impact cancer care

Dr. Alberto Traverso
Faculty of Medicine, University Salute Vita San Raffaele
Academy manager DIGICORE

traverso.alberto@unisr.it

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

Sister cancer network

OECI
Organisation of European Cancer Institutes

DIGital Institute for Cancer Outcomes Research (DIGICORE)

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

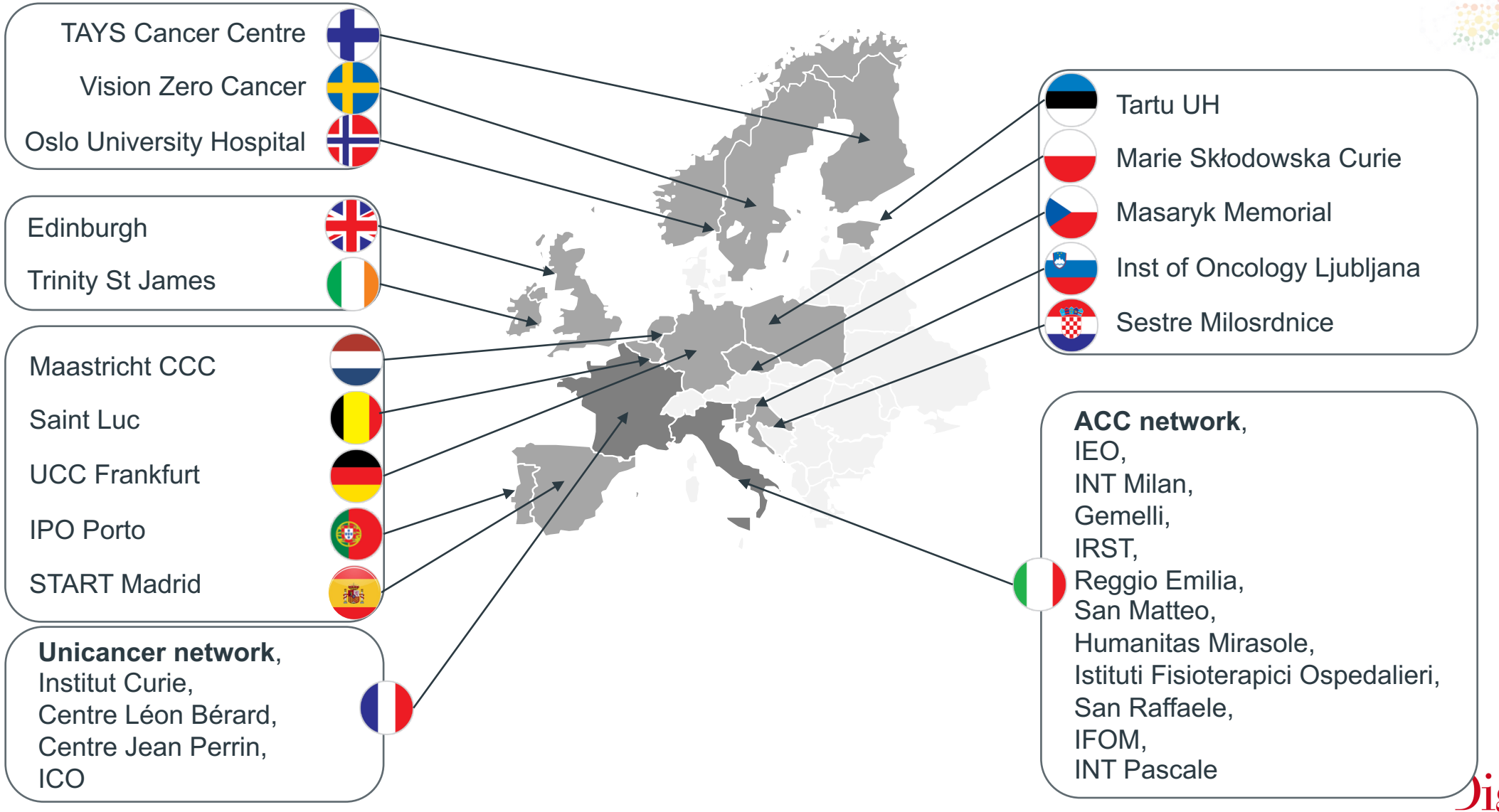
Independent European Economic Interest Group (like OECI) with 30 cancer centres today

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

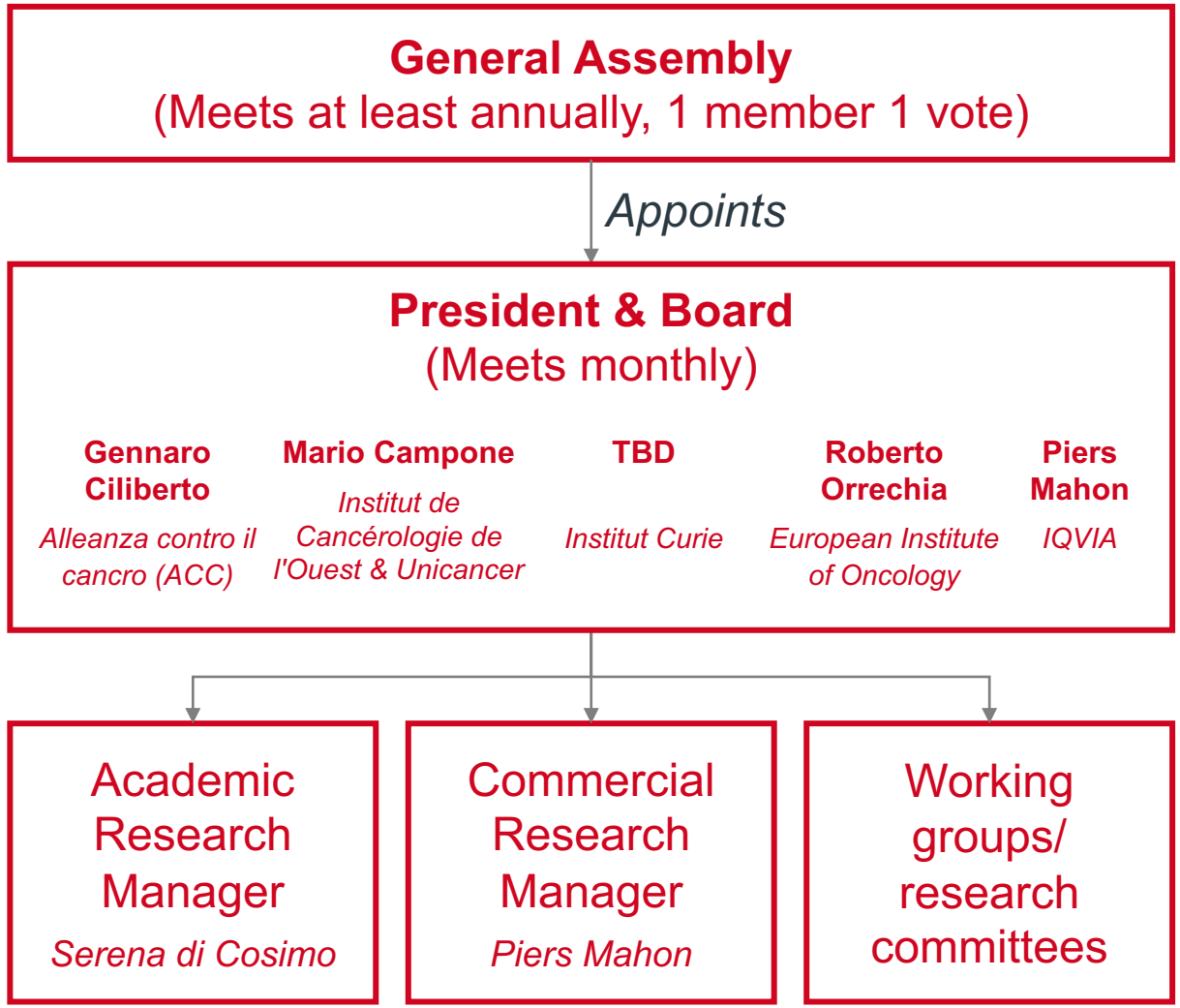
DigiCore

Current DIGICORE network of 34 centres and 2 national networks in 16 countries. More welcome to join



* https://www.digicore-cancer.eu/Page.aspx?name=CONN_WIN_22

DIGIOCRE foundational legal statutes built strong governance and protections for cancer centres (= air traffic control)



Key Principles*

1. **Medical hypothesis neutrality** – no large pharma inside, Surgery & Radio matter
2. **Cancer centres retain full data control** and autonomy over clinical decisions
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: OECI Magazine (December 2020)

DIGICORE is building a federated ecosystem for Precision Oncology Real World Evidence

Objectives

1. Define a **scalable common international minimum dataset for cancer**, 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. **Demonstrate commercial real world evidence possible** in a broader range of European countries than today
6. Work out how to **scale up digitally less mature hospitals** with a **variety of technologies and vendors** in DIGICORE's learning – by- doing community

**half cash, half in-kind labour*

Data sharing : a necessity inherent to cancer disease

"The molecular uniqueness of each cancer and the number of genetic variants present in an individual's genome makes precision oncology not only challenging from a clinical and biological perspective but also from a computational perspective".

NhanDo et al. Seminars in Oncology 2019

« The real value of genomic data will be realized only when they are linked to high-quality, longitudinal, computationally amenable clinical information, allowing researchers to identify precise genotype phenotype associations.

If we don't concentrate our efforts (and dedicate substantial resources) to robustly improve data sharing, we risk undermining precision oncology's capacity to deliver substantive advances for people with cancer ». *NEJM*, May 2017

OSIRIS overview

- **First stable release - version 1.1 (6 septembre 2018)**
  - 67 clinical items (13 objects)
  - 62 omics items (10 objects)
  - Over 40 value sets

- **Mapping with international standards**
  - FHIR
  - UMLS
  - LOINC
  - ICD-10
  - ICD-O-3 (Topo/Morpho)
  - ATC
  - MedDRA/CTCAE
  - TNM
  - RECIST
  - HGVS
  - …

OSIRIS : why we need common data models?

- To accelerate data sharing between health institutes
- To allow translational studies on large datasets
- To support clinical studies as well as real world data studies
- To provide qualitative datasets for Open Data and AI approaches

Current selection for essential/important data items for the pilot

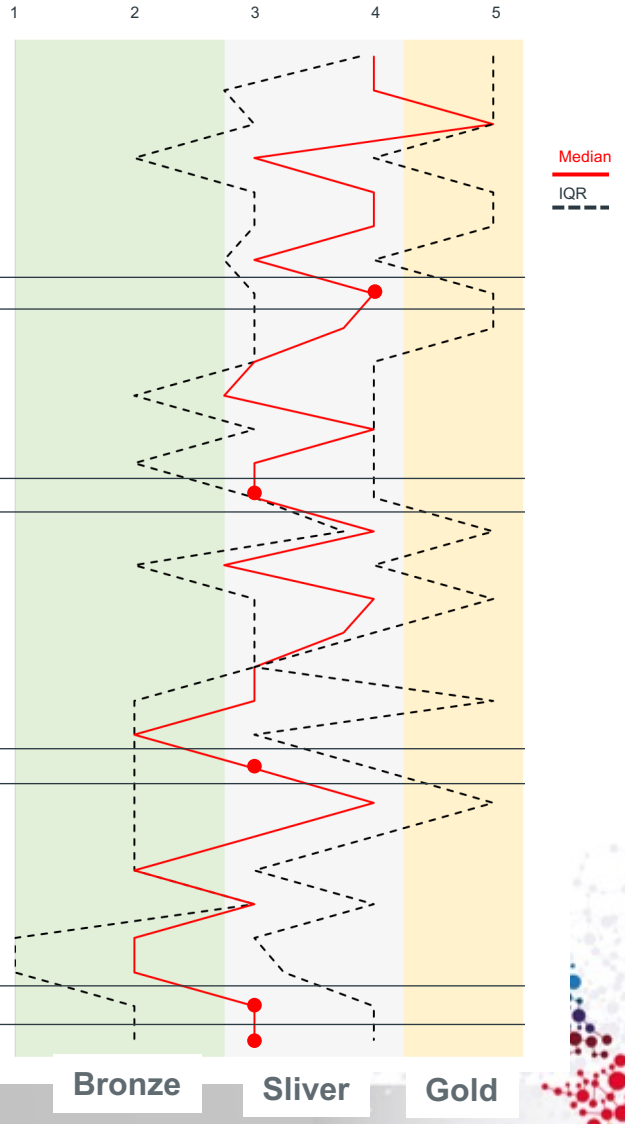
Patient Registration & Consent	Clinical Diagnosis & Clinical Phenotype	Biomarkers & sample source	Omics Items (Entire data set, LIMS)	Treatment	Outcomes & Side effects
Birth date (data item 3.1)	*TBD: Confirmation of diagnosis type / method) (data items 10.1)*	Biomarker type name (code), (data items 13.1, 13.2)	Alteration in Sample; Variant	Treatment type (data item 11.1)	Date of death & cause (data item 4.3 & 4.4)
Gender (data item 3.2)	Date of diagnosis (data item 10.2)	Biomarker measure (data items 13.3)		Treatment start & end dates (data item 11.5, 11.6)	Date of last follow-up (data item 4.2)
Local Patient ID (data item 2.1)	ECOG/Karnofsky / G8 /OMS performance status (data items 9.1, 9.2, 9.3)	Biological sample identifier and date (data items 14.1, 14.3)		Clinical trial (y/n) (data item 11.7)	Presence / absence of metastasis (data item 7.3)
Healthcare centre identifier (data item 2.2)	Comorbidity (date item 5.1)			Name of clinical trial (data item 11.8)	Disease progression (data items 8.1, 8.2, 8.3)
Consent date & auth. for genetic analysis (item 1.1 & 1.2)	TNM type, stage, version (data items 7.4, 7.5, 7.6)			Name & ATC code of administered molecule (data item 11.2, 11.3)	
Add: Weight & Height/dates	Histological / morphological type, stage & grade) (data items 7.7, 7.8, 9.9)	*Add: Lab measures in std biochem.on organ fitness (23 already included)*			*TBD: Vital status (data item 4.1)*

Red: To be Discussed/Surveyed

DigiCore

Range of digital maturities in our community

Precision Oncology	1.1	Availability and access of patient's biopsies throughout the patient's cancer pathway
	1.2	Systematic collection of sample from consented cancer patients for research
	1.3	Maturity and strength of Molecular Diagnostics testing focused on somatic biomarker mutations
	1.4	Breath and depth of the centre's molecular data availability to research from routine testing in appropriate machine readable formats
	1.5	Maturity and strength of advice/decision support to treating oncologists and patients for precision medicine
	1.6	Policy and approach of interventional clinical trials play in cancer patient management in your centre
	1.7	Maturity of clinical trials into routine care (expresses as percentage)
	Overall	**Precision Oncology**
Clinical Data	2.1	Digital maturity of clinical cancer systems at your centre based on the HIMMS EMRAM
	2.2	Availability of digitally structured cancer data as common types of research information
	2.3	Sophistication and maturity at the centre for accessing unstructured cancer data for research on large cohorts
	2.4	Level of adoption of (inter)national standards for reference data and health terminology on cancer data
	2.5	Level of sophistication possible at your centre with regard to routine retrospective observational medical research
	Overall	**Routine Clinical Data/Digital Research**
Pragmatic Outcome	3.1	Level of sophistication and maturity of the digital date of diagnosis in your routine records is for cancer patients
	3.2	Availability of date of progression data for cancer patients at your centre
	3.3	Level of maturity and strength of your centre's access to date of death for research purposes
	3.4	Maturity and availability to call line of therapy locally, and get a date of next therapy start
	3.5	Maturity and availability to access RECIST information locally for retrospective research
	3.6	Level of maturity and sophistication of your medical records as a source for adverse events for retrospective research
	3.7	Level of sophistication of Quality of Life (QoL) indicators or patient reported symptoms captured at your centre
	Overall	**Pragmatic Outcomes**
Information Governance & Research Operations	4.1	Strength and sophistication of the main legal basis for research processing for real world evidence at your institute
	4.2	Strength and sophistication of access of patient level data for the purpose of research without study specific consent
	4.3	Level of sophistication of the commercial study preparation lead times at your centre, including ethics, contracting, privacy review etc.
	4.4	Maturity and ability to support commercial research once approved
	4.5	Indicate how many commercial "direct from EMR" multi-centre real world evidence studies participated in over last 3 years
	4.6	Indicate how many academic "direct from EMR" multi-centre real world evidence studies your centre has participated in over last 3 years registries
	Overall	**Information Governance & Research Operations**
	Overall	



Decision 2: How do we “walk before we run” and build up our skill?

Observations

We need to “walk before we can run” so need a **simple study first.**

A good simple first study would have these features:

- **Get proof of output via federation**,
- Uses structured data that is easy to harmonise in OMOP format,
- **All 6 centres willing to run** it and easy for others to join

The more interesting studies like disease natural history will need more technology such as NLP (and manual quality control), but there is more risk and complexity

For discussion

- *Which is the best place to start: Dx volumes in Covid19 or benchmarking access to innovation?*

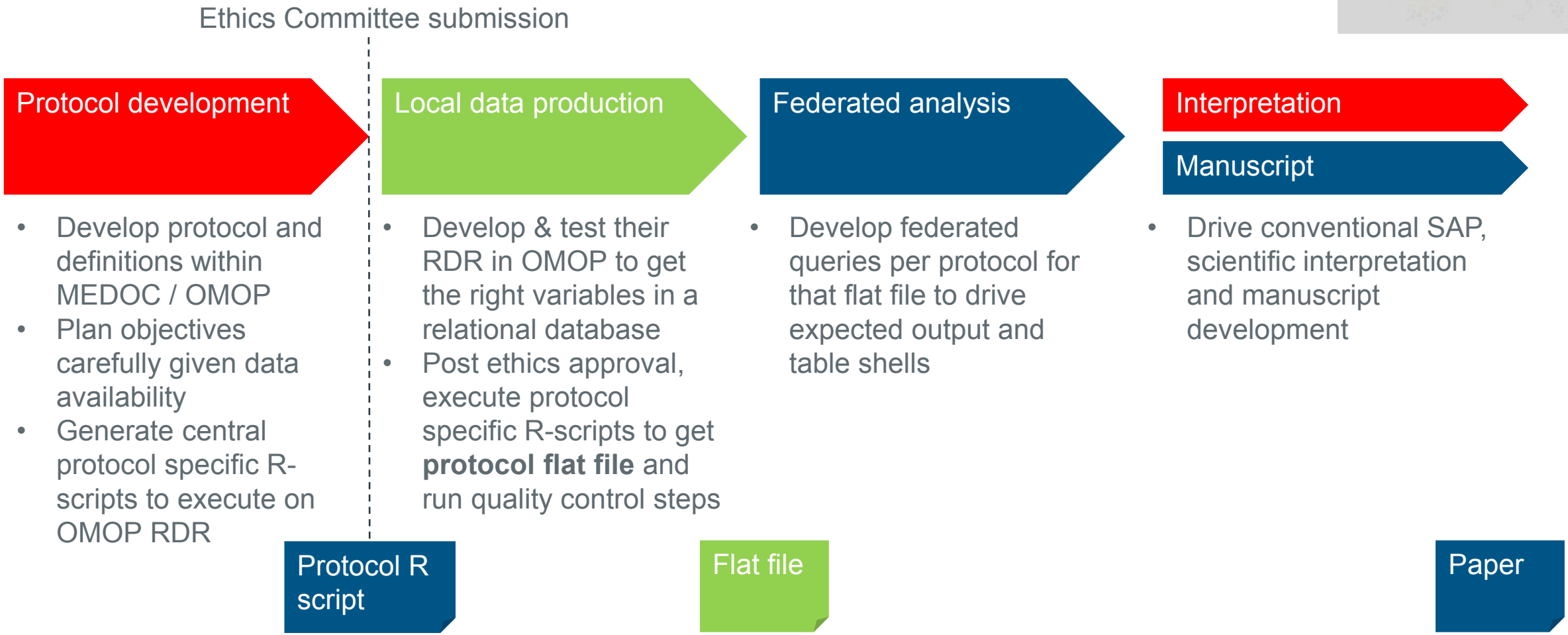
- *Is there a way to make a **repeatable model** to build a Cancer OMOP solution in a given cancer?*
  - *Simple study*
  - *Medium study*
  - *Disease natural history*
- *We then use that model in every cancer*

Decision 2: Is there a better step-wise sequence than this to manage risk?

The model for a cancer e.g. NSCLC

	Covid19 Impact	**Benchmarking Access To INnovation**	**Federated Advanced Prognostics**	**Disease Natural history with care quality assessment**
Acronym	C19	BATIN	FEDAPT	DINASTY
Description	Examine changes in diagnostic patterns and time to treatment during C19	Examine whether access to new drugs, tests or procedures varies by ECOG, sex or age	Large scale federated learning to predict 2-year survival	Natural history and treatment outcomes studies with care quality assessment
Data concepts covered	• 5 to 10 • Demographics, ICD10, stage and time to Tx	• 15 • Treatments, procedures	• 15 to 20 • Clinical phenotype	• All of MEDOC, including biomarkers
Coverage	Solid cancer diagnosis (excl. haem and skin)	NSCLC, HER2- Breast, EOC		
Complexity	Very simple	Simple	Moderate	Hard

These three types of contributors will be involved in the process in this way



Work plan

Provide a brief description of the overall structure of the work plan (list of work packages or graphical presentation (Pert chart or similar)).