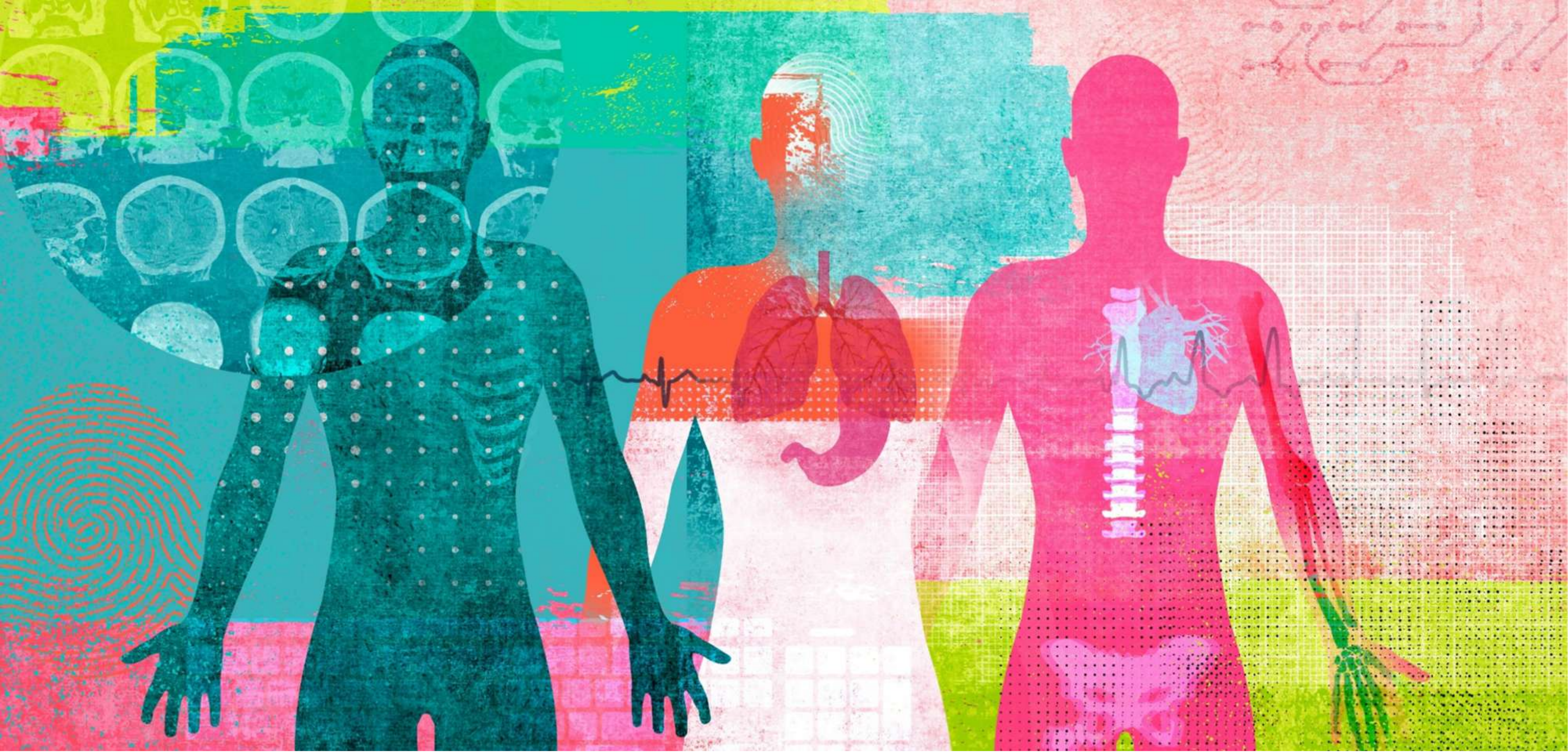
efpia

ONCOLOGY
DATA SUMMIT

Unleashing the potential of data to improve cancer care

18/06/19
Brussels

#OncologyDataSummit



SETTING THE SCENE

#OncologyDataSummit

WELCOME

Alexander Roediger

Chair of the EFPIA Oncology Steering Committee

Tamsin Rose

Senior Fellow, Friends of Europe

ONCOLOGY DATA LANDSCAPE REPORT

Calypso Montouchet

Manager, AT Kearney

James Anderson

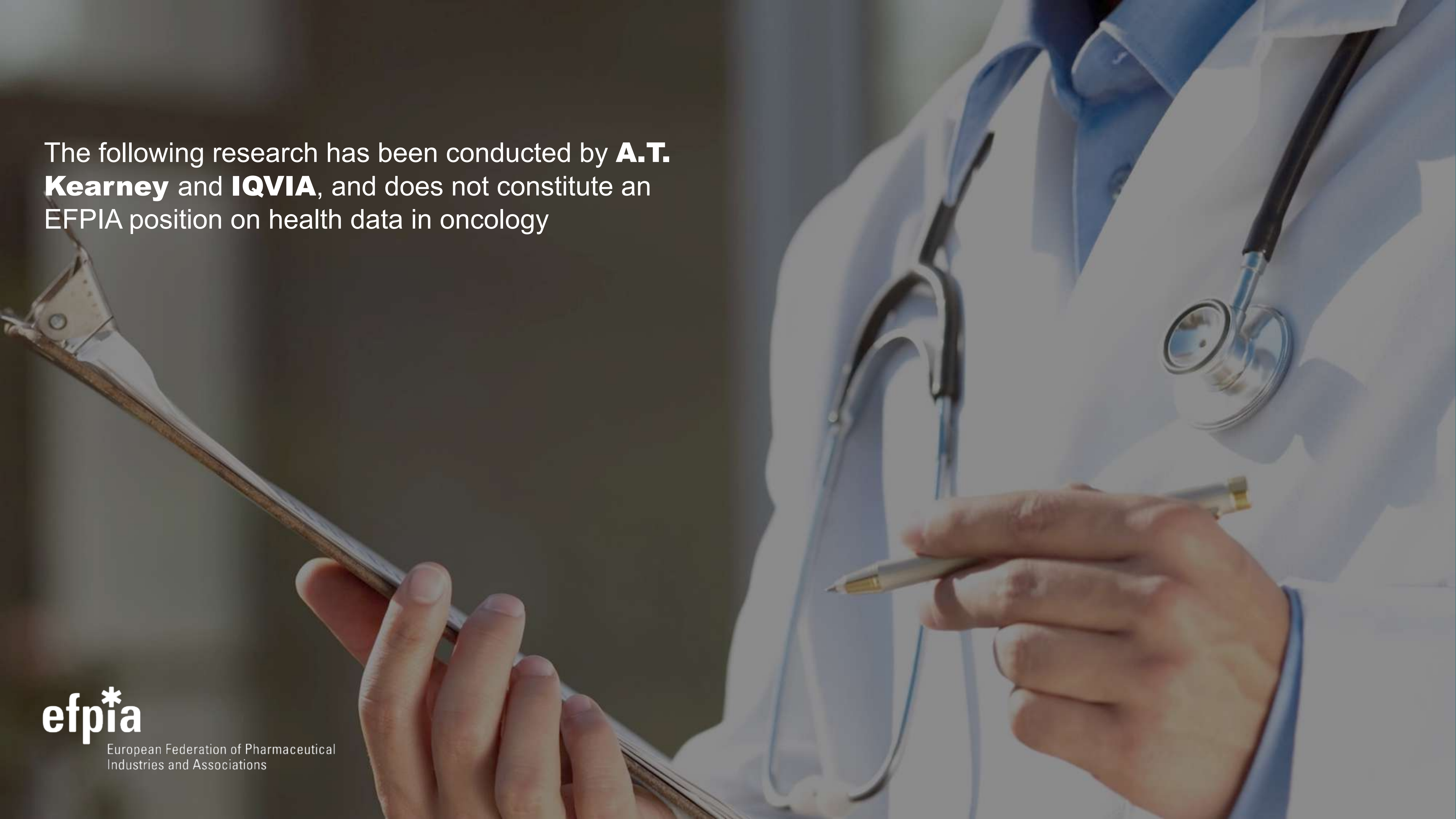
Principal in Real-World & Analytics Solution, IQVIA

Mapping Oncology Health Data in Europe

efpia

European Federation of Pharmaceutical Industries and Associations

18 June 2019

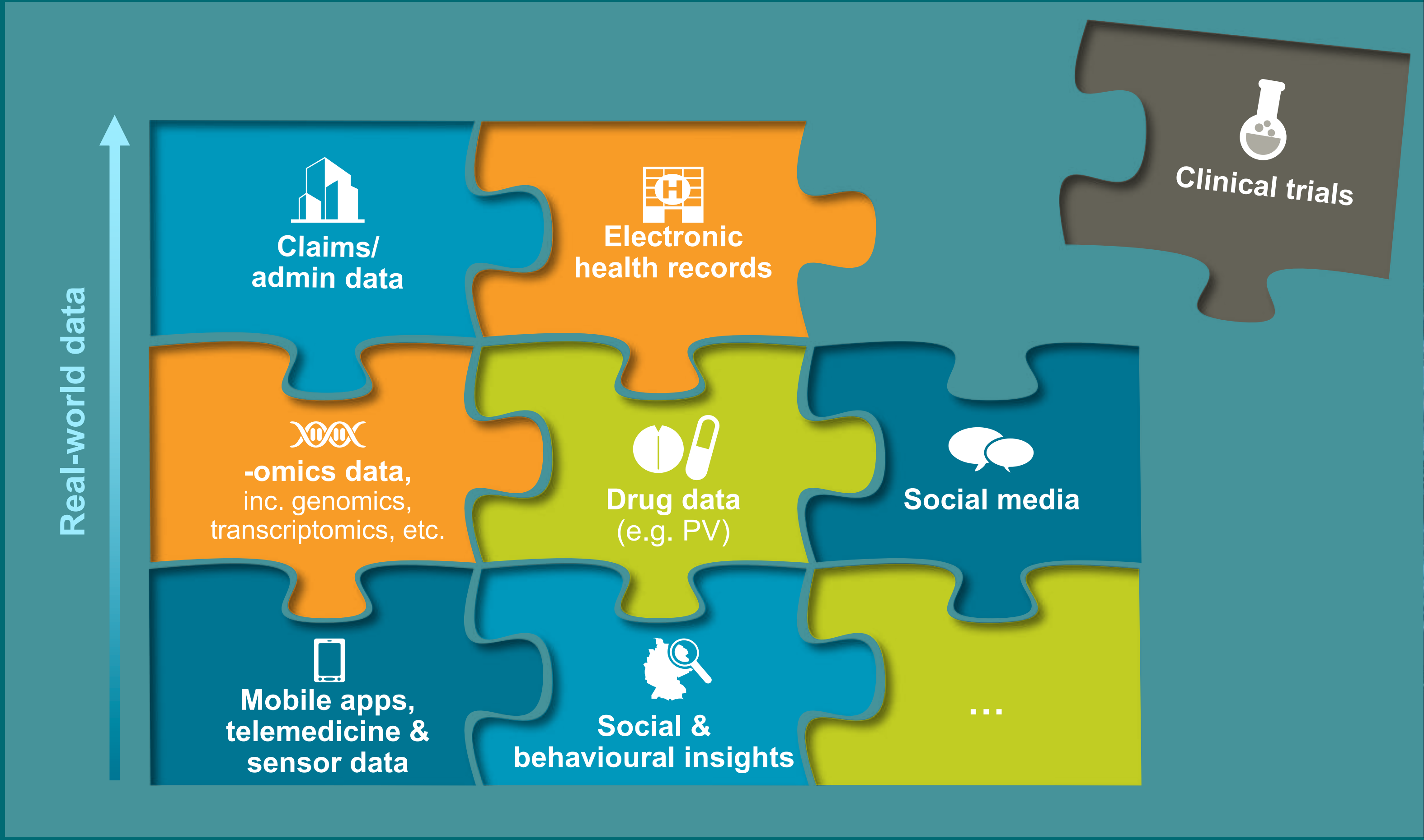


The following research has been conducted by **A.T. Kearney** and **IQVIA**, and does not constitute an EFPIA position on health data in oncology

efpia
European Federation of Pharmaceutical
Industries and Associations

New sources of real world health data in oncology are becoming increasingly important…

About health data in oncology



Real-world data

Claims/ admin data

Electronic health records

Clinical trials

-omics data, inc. genomics, transcriptomics, etc.

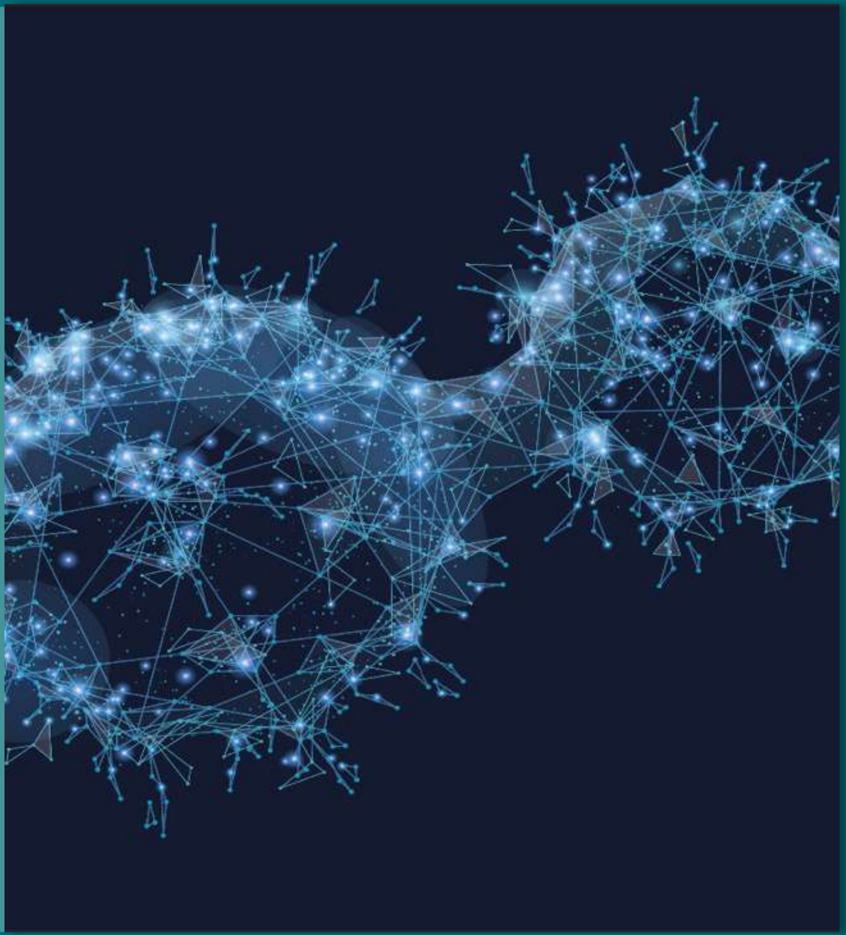
Drug data (e.g. PV)

Social media

Mobile apps, telemedicine & sensor data

Social & behavioural insights

…



PV = pharmacovigilance
Source: RAND. 'Understanding value in health data ecosystems' (2017)

… and have multiple potential use cases

Applications of health data

R&D enablement
Supporting identification, investigation & smarter clinical trials

Healthcare context
Understanding the context of the disease & patient populations

Treatment patterns
Understanding real-world usage of treatments

Real-world clinical value
Measuring the delivery of cancer interventions' clinical promises

Socio-econ value
Capturing the value of interventions beyond patients & health systems

Pricing enablement
Providing a mechanism for pricing based on use, indication and/ or outcomes

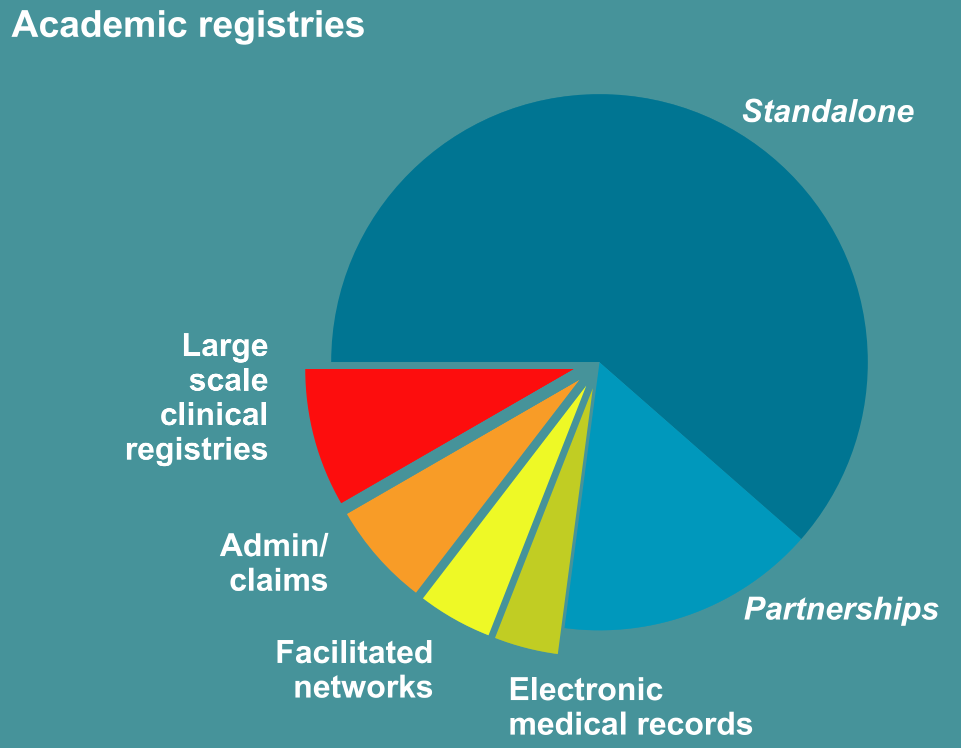
Patient perspective
Offering insight into QoL beyond clinical outcomes

QoL = quality of life
Source: EFPIA

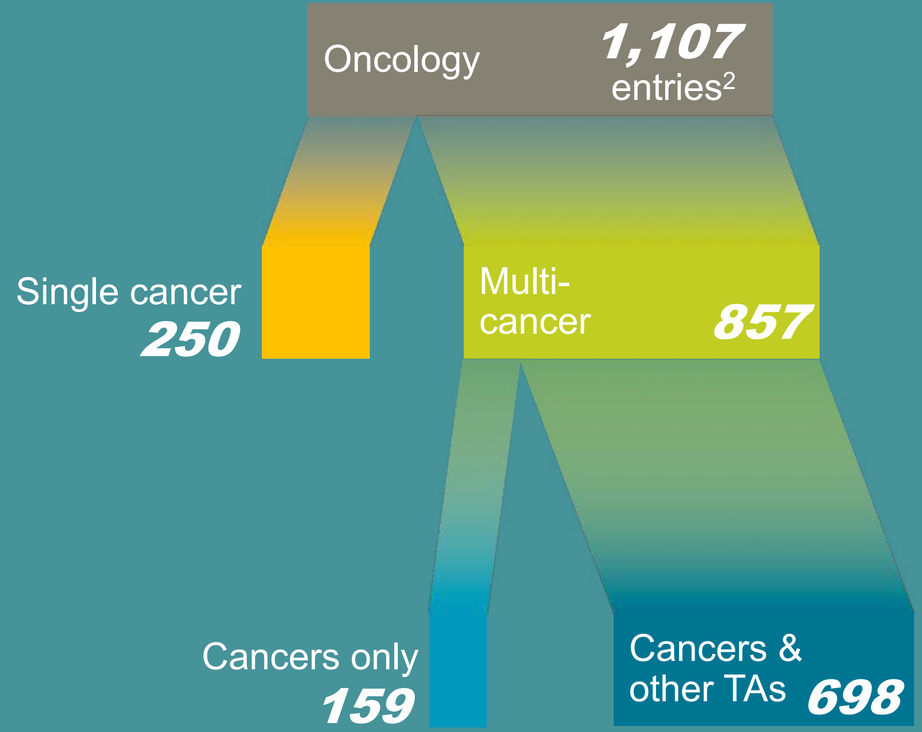
There are many oncology health data sources in Europe, but these are fragmented...

Overview of oncology data sources in Europe

Types of sources



Focus of sources, by therapy area



1. Data sources used in analysis are those captured within the IQVIA RWD catalogue (>1100); does not account for size of database nor country population; 2. Entries reflect sources listed in the IQVIA RWD catalogue; EHR = electronic health record

Source: IQVIA RWD Catalogue & IQVIA research

… and generally lack scale and robustness to support decisions

Strength of oncology data sources

	Research database standalone	**Research database** partnerships	**Facilitated networks**	**EMR** linked source	**Admin/ claims**	**Large clinical registries**
R&D enablement	Poor	Poor	Poor	Variable	Poor	Poor
Healthcare context	Variable	Variable	Variable	Variable	Variable	Variable
Treatment patterns	Variable	Variable	**Good**	Variable	**Good**	Variable
Real-world clinical value	Variable	Variable	Variable	Variable	Poor	Variable
Socio-econ. Value	Poor	Poor	Poor	Poor	Poor	Poor
Pricing enablement	Poor	Poor	Variable	Variable	Variable	Poor
Patient perspective	Poor	Poor	Poor	Poor	Poor	Poor

Source: IQVIA RWD Catalogue & IQVIA research

Several challenges affect health data collection and use

Challenges to health data

Data

- Data not captured (ECOG, PFS, endpoints)
- Unstructured data
- Variable coding standards
- Variable quality/ quality control

Structure

- No national/regional consistency
- Limited linkage
- Short-term, fragmented funding
- Complex access to funding

Process

- Complex data access processes
- Governance
- Complex patient consent
- Data protection requirements

Technology

- Poor interoperability
- Manual processing
- Outdated technology

People

- Data science skills
- Divergent interests
- Data privacy concerns

ECOG = Eastern Cooperative Oncology Group; PFS = progression-free survival
Source: EFPIA

Emerging initiatives aim to tackle some of the key barriers head on

Data initiatives in Europe[1]

Improve access

Aims to improve access to existing datasets or allow their interrogation

- Big Data for Better Outcomes (BD4BO)
- Collaboration for Oncology Data in Europe (CODE)
- Innovative Medicines Initiative (IMI)
- INSITE

Improve collation

Aims to incorporate existing datasets into a central repository

- European Commission Initiative on Breast Cancer (ECIBC)
- I-O Optimise
- European Network of Cancer Registries (ENCR)

Standardise data

Aims to standardise how data is collected so that datasets are comparable

- European Health Data Network (EHDN)
- International Consortium for Health Outcomes Measurement (ICHOM)
- Observational Medical Outcomes Partnership (OMOP) Oncology

Collect new data types

Aims to collect data that does not yet exist, often via novel approaches

- EUROSTAT
- IRONMAN
- OWise
- SCAN-B
- WEB-RADR

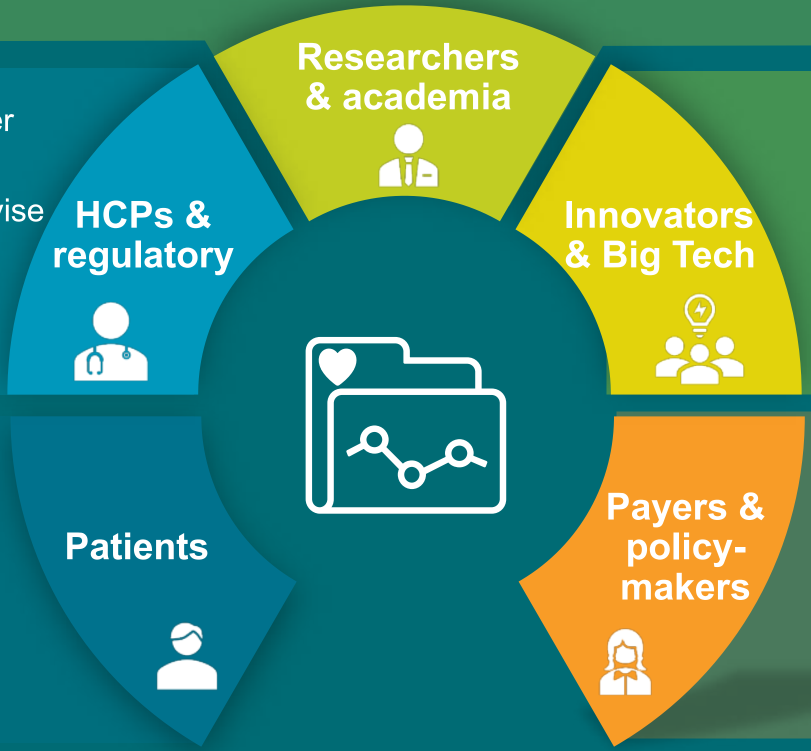
---

1. Not exhaustive

Source: IQVIA RWD Catalogue & IQVIA research

A concerted set of actions could overcome these barriers and help make the most of oncology health data

Actions for health data stakeholders



Researchers & academia

1. Collaborate to convey the importance of linkage & define standards
2. Develop & share best-practice privacy protocols
3. Build a platform that collects & enables the sharing of raw, anonymised data

HCPs & regulatory

1. Foster the continuous collaboration of cancer experts, researchers & data experts
2. Advocate the need for & methods to incentivise high-quality data capture
3. Create an independent body to support regulatory-compliant data

Innovators & Big Tech

1. Improve understanding & use of technology
2. Build awareness of data science as a core R&D & health skill

Patients

1. Develop a patient data donation platform
2. Inform reflection on patient consent processes & forms

Payers & policy-makers

1. Address GDPR locally to ensure use of health data
2. Create an environment that fosters scalability & long-term funding
3. Develop alignment on EU & national grants for health data

Source: EFPIA

KEYNOTE SPECCH

Roberto Viola

Director General, DG CONNECT, European Commission

Unleashing the potential of data to improve cancer care

EFPIA Oncology Data Summit
Brussels, 18 June 2019

Roberto Viola
Director General, Communications Networks, Content and Technology
European Commission

HORIZON 2020

Data-driven Health Care innovation and the Digital Single Market

European
Commission

Digital Transformation of Health and Care


High-performance computing


Artificial Intelligence

Internet of Things (IoT)


Cloud computing

Use **digital** services for citizen empowerment and person-centred care

Give citizens **better access** to their **health data**, everywhere in the EU

Connect and share health data for research, faster diagnosis and better health outcomes


mHealth


Wearables


Telehealth

4G/5G


The Economist

Theresa May: dead woman standing still

Ponzi schemes in China

Higher education, lower returns

Pity the pangolin

Doctor You

How data will transform health care


The Economist

Crunch time in France

Ten years on: banking after the crisis

South Korea's unfinished revolution

Biology, but without the cells

The world's most valuable resource

Data and the new rules of competition

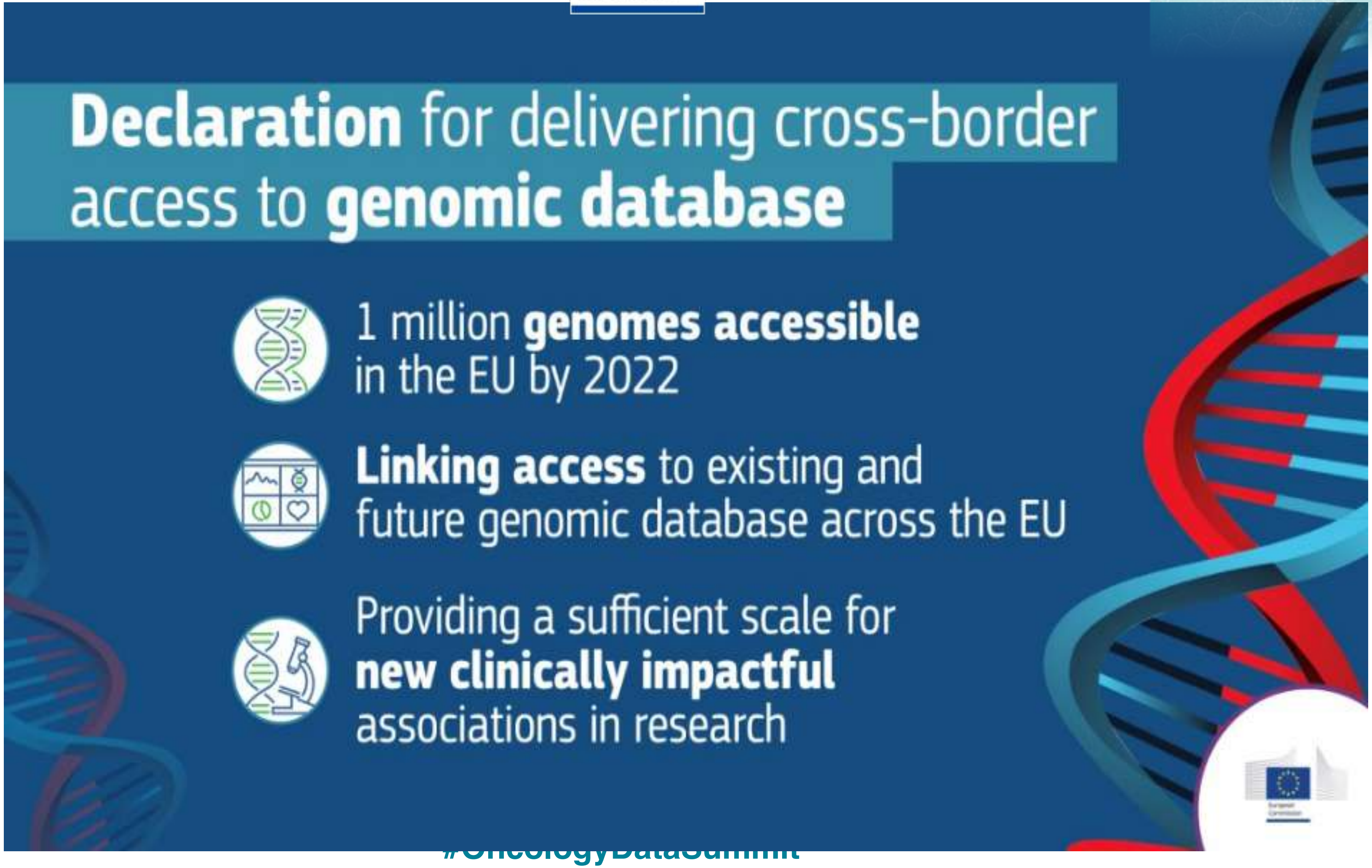

MIT Technology Review

BUSINESS REPORT

Data-Driven Health Care

Can Technology Fix Medicine?

#Oncol



Declaration for delivering cross-border access to **genomic database**

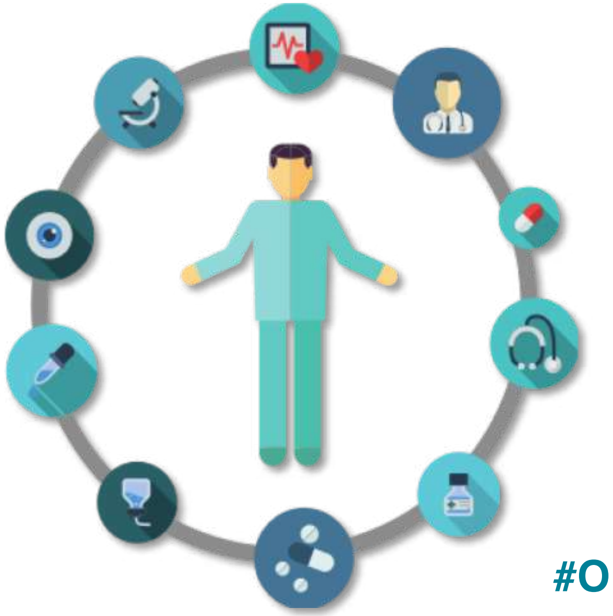
- 1 million **genomes accessible** in the EU by 2022
- **Linking access** to existing and future genomic database across the EU
- Providing a sufficient scale for **new clinically impactful** associations in research

AI for Health Imaging

- A “federated” database of digital images
- Open to innovators wishing to develop AI
- Able to receive data donations
- Horizon2020 work programme to be adopted in July

EUROPEAN EHR exchange format

Commission Recommendation to encourage and support MS to develop **interoperable and citizen centric** electronic health records systems



European Commission

Examples of projects

MY HEALTH MY DATA

Project developing a blockchain-based health data platform enabling privacy-preserving consented data sharing and big data analytics.http://www.myhealthmydata.eu/

PRIMAGE

Medical imaging
Artificial intelligence
Childhood cancer research

PRIMAGE is one of the largest and more ambitious European research projects in medical imaging, artificial intelligence and childhood cancer.

https://www.primageproject.eu/

Funding opportunities for eHealth 2021-27

Digital Europe Programme and Connecting Europe Facility

Horizon Europe

European Social Fund + and European Globalisation Adjustment Fund

European Regional Development Fund

InvestEU Programme

Investing in the future:

Digital Europe Programme

€ 9.2 billion in total

Digital transformation & Interoperability
1.3 € billion

Advanced digital skills
0.7 € billion

High performance computing
2.7 € billion

Cybersecurity & trust
2 € billion

Artificial intelligence
2.5 € billion

#EUBudget
#DigitalEurope

European Commission

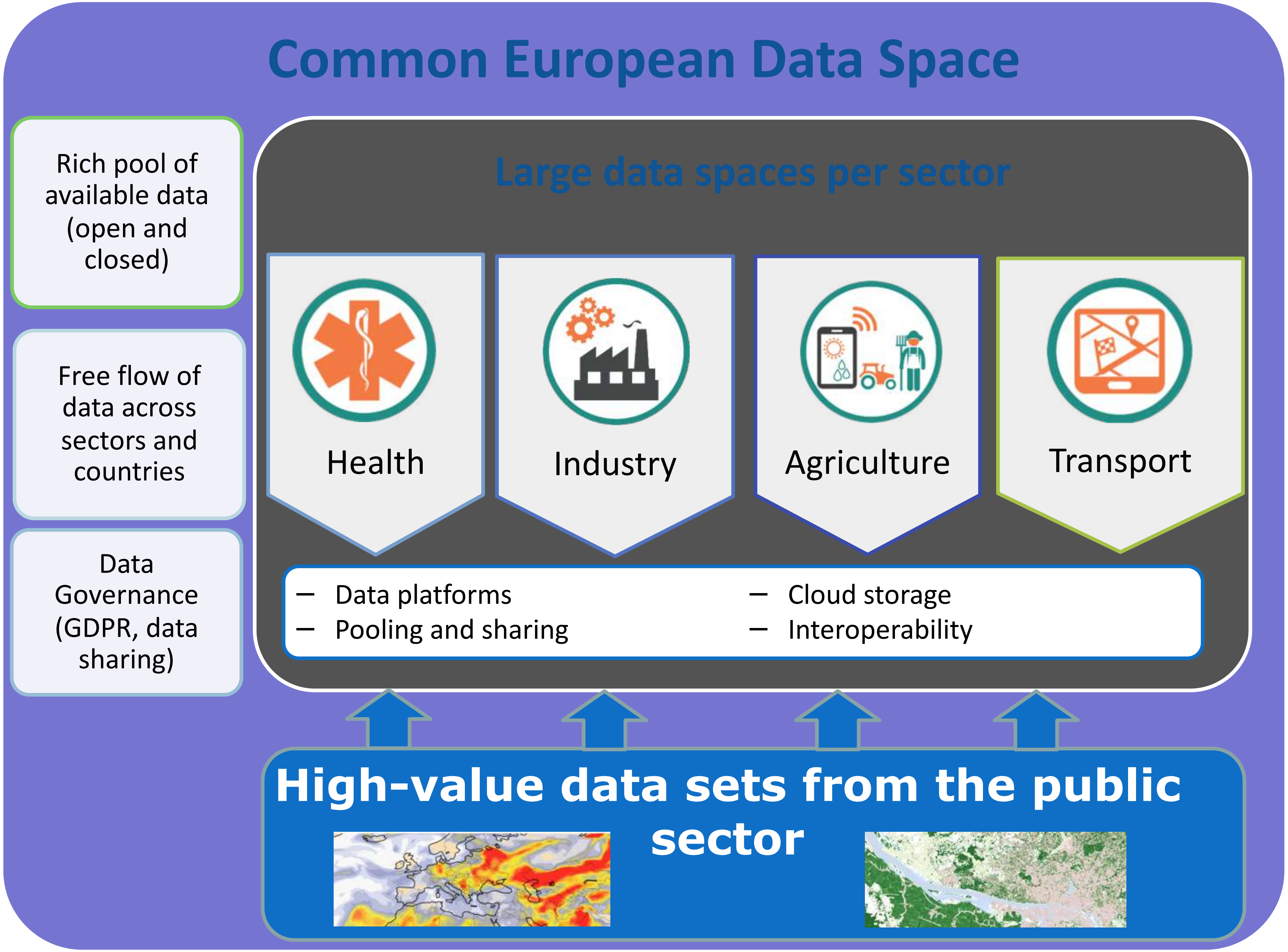
Supporting activities

Digital Europe Programme (DEP): Specific Objective 2 'Data for Artificial Intelligence (AI)' will strengthen core AI capacities in Europe, including data resources.

It will notably include the:

"Creation of **Common European Data spaces** that aggregate public information across Europe and become a data input source for AI solutions. The spaces would also be open to public and private sector. For increased usage, data within a space should be made interoperable as much as possible, both in the interactions between public and private sectors, within sectors and across sectors (semantic interoperability)."

Common European Data Space



Rich pool of available data (open and closed)

Free flow of data across sectors and countries

Data Governance (GDPR, data sharing)

Large data spaces per sector

Health

Industry

Agriculture

Transport

- Data platforms
- Pooling and sharing
- Cloud storage
- Interoperability

High-value data sets from the public sector

European Commission

THANK YOU!

bit.ly/EUdigitalhealthcare

Twitter: @eHealth_EU

Facebook: EU.ehealth

Subscribe to our newsletter 'eHealth, Wellbeing & Ageing' via *bit.ly/eHealthinFocus*

DATA SAVES LIVES PROJECT

Nicola Bedlington

Former Secretary General, European Patient's Forum

Dipak Kalra

European Institute for Innovation through Health Data

Data Saves Lives

www.datasaveslives.eu
@LivesData

What is the DataSavesLives initiative striving to achieve?

- a **web portal** where neutral information on key issues related to health data is made available to patients and the health interested public
- a **trusted environment** for multi-stakeholder dialogue about the uses of health data across Europe

Vision and Mission

➢Vision:

“A Europe where informed data sharing **supports health** and **scientific research** to meet the needs of patients and address the challenges faced by our healthcare systems”

➢Mission:

“To create a **European Health Data Portal** that will build awareness and understanding on:

- ✓why data is important;
- ✓how it is used, and
- ✓provide a trusted environment for dialogue about the use of health data in Europe”

Objectives

- **Raise awareness** about the value of health data in supporting health research and improving healthcare
- **Increase understanding** in how data is used and encourage discussion about responsible use
- **Empower patients and healthcare professionals** to realize the potential of new sources of data and digital technologies
- **Create resources** adaptable to use at national/local level
- **Show real-life examples** on how data is used for the benefit of patients

Principles

- Integrity
- Transparency
- Neutrality
- Evidence-based

Governance

Core Group

Chair elected for 2 years

Decisions by consensus

12 representatives:

- Patient groups
- Public Sector
- Researchers
- Health Data Networks
- Health knowledge and Innovation Communities
- Health Industry representatives

Advisory Group

Comments on the overall strategy

Membership from:

- European Institutions
- Ethics experts
- Senior figures from the research and data community

Editorial Group

Meets 3 times a year

Independent body that ensures the highest quality and ethical standards

Reviews all resources developed by the web portal

Transparent about who they are, their employers, positions and any relevant interests

6 representatives:

- Patient representatives
- Health data experts
- Health writers
- Ethicists
- Experts in plain language

Planning 2019

June

- “**Soft launch**” of the website
- Initial content development
- **Upload** of the **materials** and **user testing**
- Agenda and invitations **Health Community Meeting**

July

- Continuous **content** and **visual material** development
- Initial **social media & outreach strategy**

August

- Planning and material development for the **official launch event** (17 September 2019)
- **Agenda** Health Community Meeting
- **Campaign concept** and launch materials

September

- **Official launch** of the website with basic content
- **Health Community Meeting**
- **Guiding Principles** on Health Data Use
- **Communications** tools for outreach

October-December

- Detailed **social media & outreach strategy**
- Continuous **content** and **visual material** development

The value offered by the trustworthy reuse of health data for research

- ***Explain and educate***
  - *enable people to make better informed decisions*
  - *not to persuade or to assure*

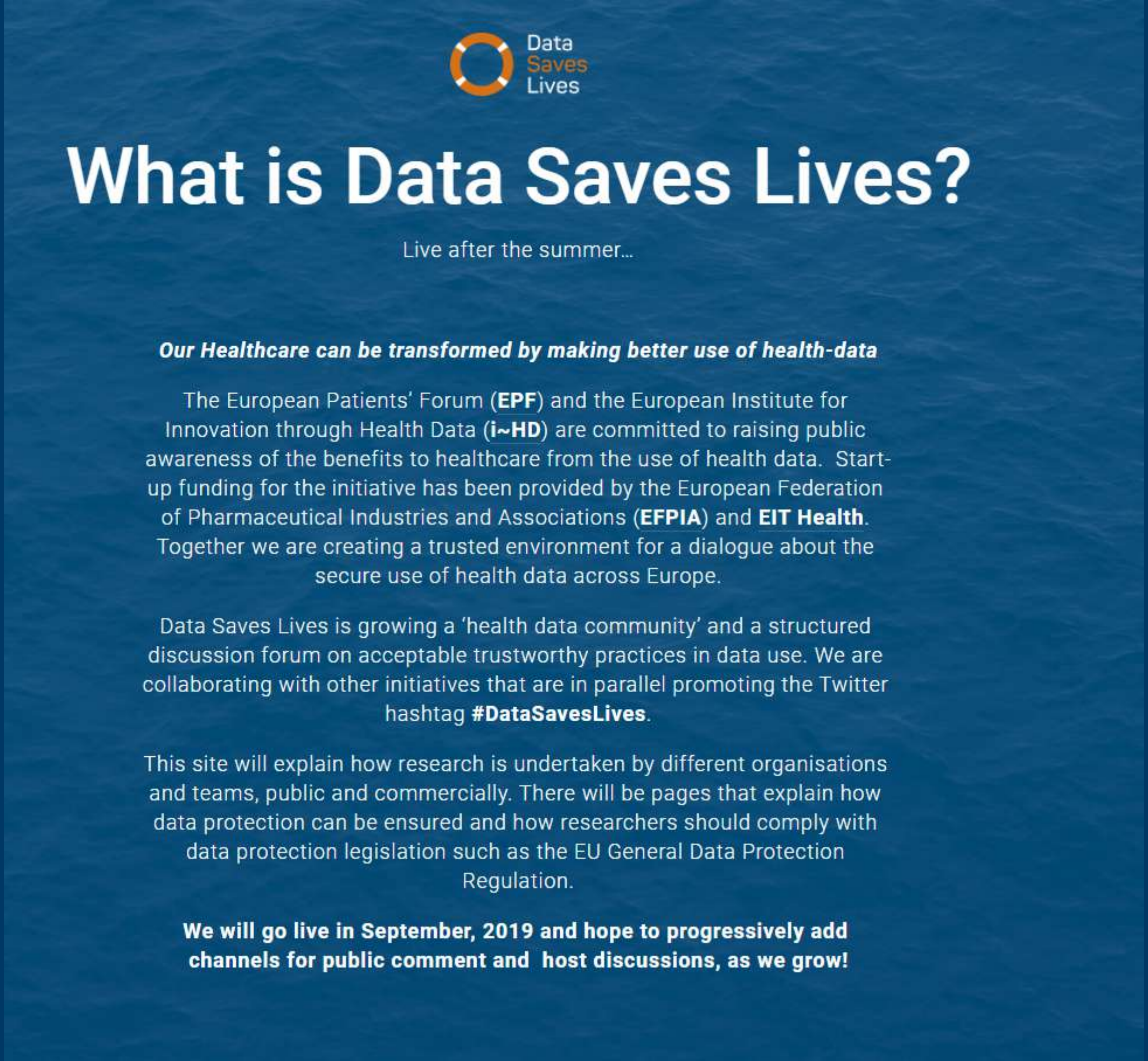
- ***Key messages***
  - *The importance of data for **meaningful health-related research***
    - *more rapid and accurate diagnosis*
    - *innovative treatments*
    - *care pathway improvements*
    - *better tools to support care and decisions*
    - *prevention measures*
    - *personalization of care and, more…*

  - *Research is undertaken by **different actors, public and private**, who can equally operate in trustworthy ways and contribute societal value.*

  - *High standards of research conduct can ensure **privacy protection***

Main topics we wish to cover

- *Why health data are useful for research and quality improvement*
- *The kinds of health data that are useful*
- *The actors and organisations who need to use health data*
- *How research uses health data*
- *What data protection is and why is it important, including the GDPR*
- *How data can be protected, including de-identification and security*
- *What studies tell us about patient attitudes on data use*
- *How patients/citizens can become better data users*



What is Data Saves Lives?

Live after the summer…

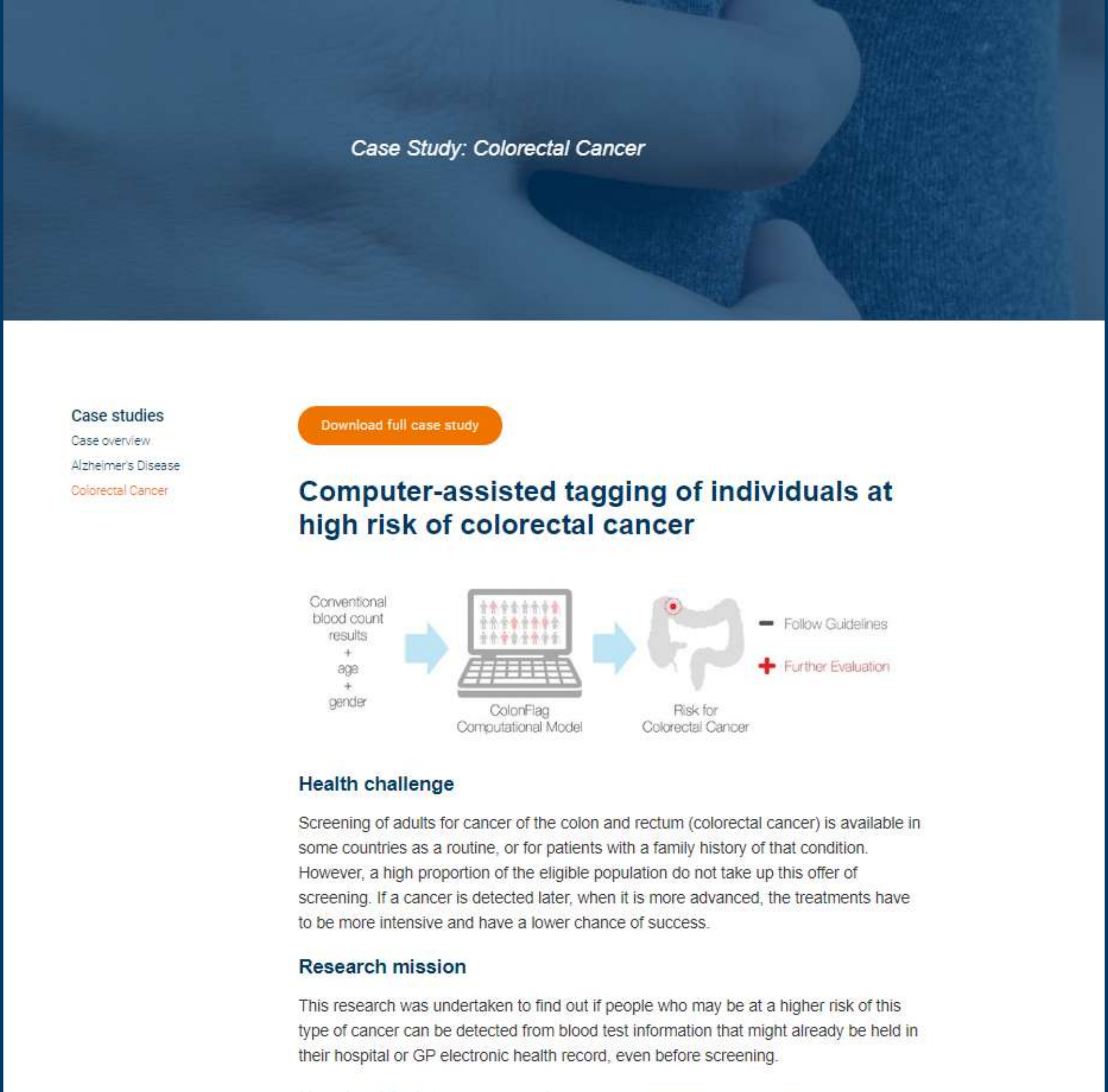
Our Healthcare can be transformed by making better use of health-data

The European Patients' Forum (**EPF**) and the European Institute for Innovation through Health Data (**i~HD**) are committed to raising public awareness of the benefits to healthcare from the use of health data. Start-up funding for the initiative has been provided by the European Federation of Pharmaceutical Industries and Associations (**EFPIA**) and **EIT Health**. Together we are creating a trusted environment for a dialogue about the secure use of health data across Europe.

Data Saves Lives is growing a 'health data community' and a structured discussion forum on acceptable trustworthy practices in data use. We are collaborating with other initiatives that are in parallel promoting the Twitter hashtag **#DataSavesLives**.

This site will explain how research is undertaken by different organisations and teams, public and commercially. There will be pages that explain how data protection can be ensured and how researchers should comply with data protection legislation such as the EU General Data Protection Regulation.

We will go live in September, 2019 and hope to progressively add channels for public comment and host discussions, as we grow!



Case Study: Colorectal Cancer

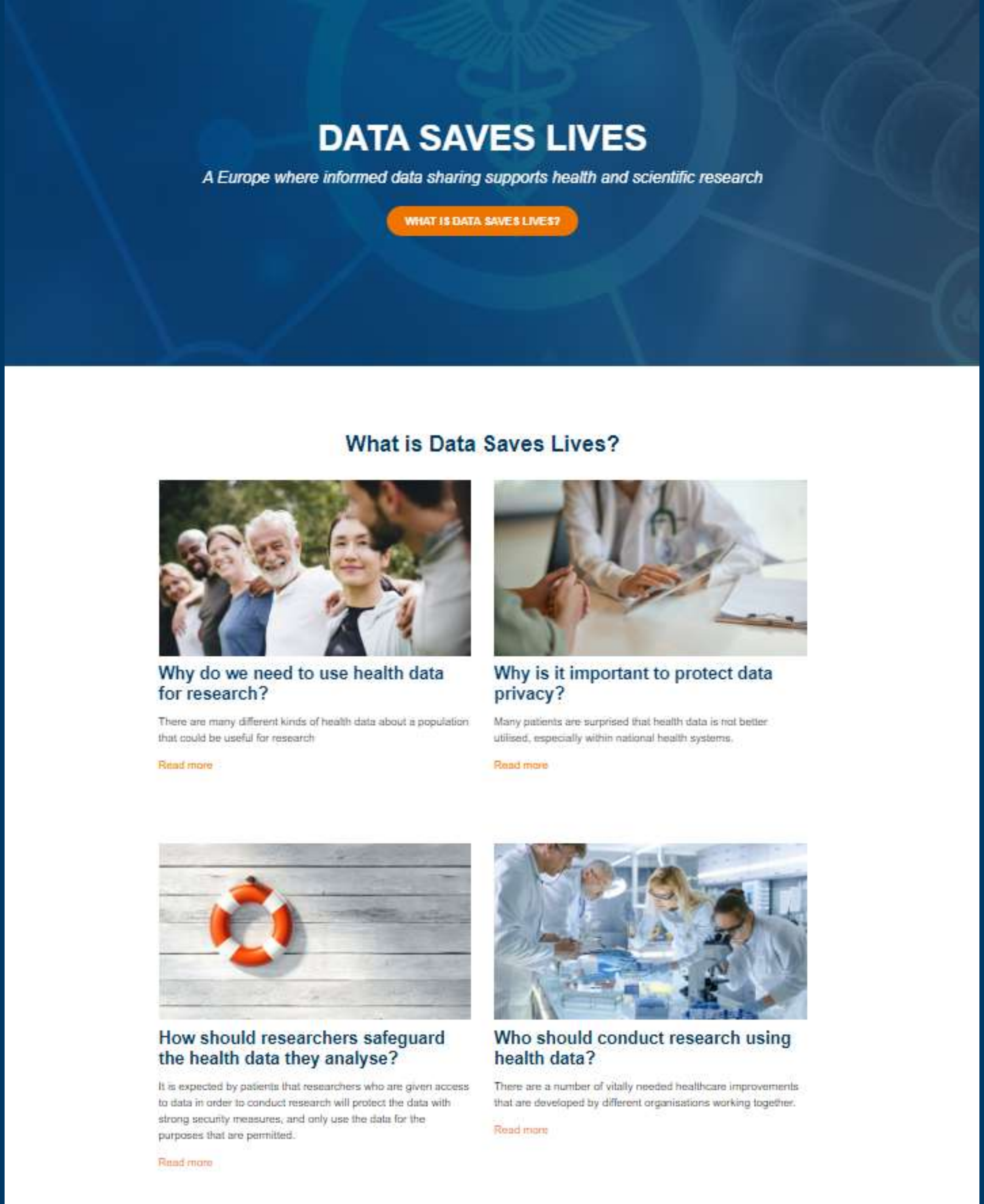
Computer-assisted tagging of individuals at high risk of colorectal cancer

Health challenge

Screening of adults for cancer of the colon and rectum (colorectal cancer) is available in some countries as a routine, or for patients with a family history of that condition. However, a high proportion of the eligible population do not take up this offer of screening. If a cancer is detected later, when it is more advanced, the treatments have to be more intensive and have a lower chance of success.

Research mission

This research was undertaken to find out if people who may be at a higher risk of this type of cancer can be detected from blood test information that might already be held in their hospital or GP electronic health record, even before screening.



DATA SAVES LIVES

A Europe where informed data sharing supports health and scientific research

What is Data Saves Lives?

Why do we need to use health data for research?

There are many different kinds of health data about a population that could be useful for research

Why is it important to protect data privacy?

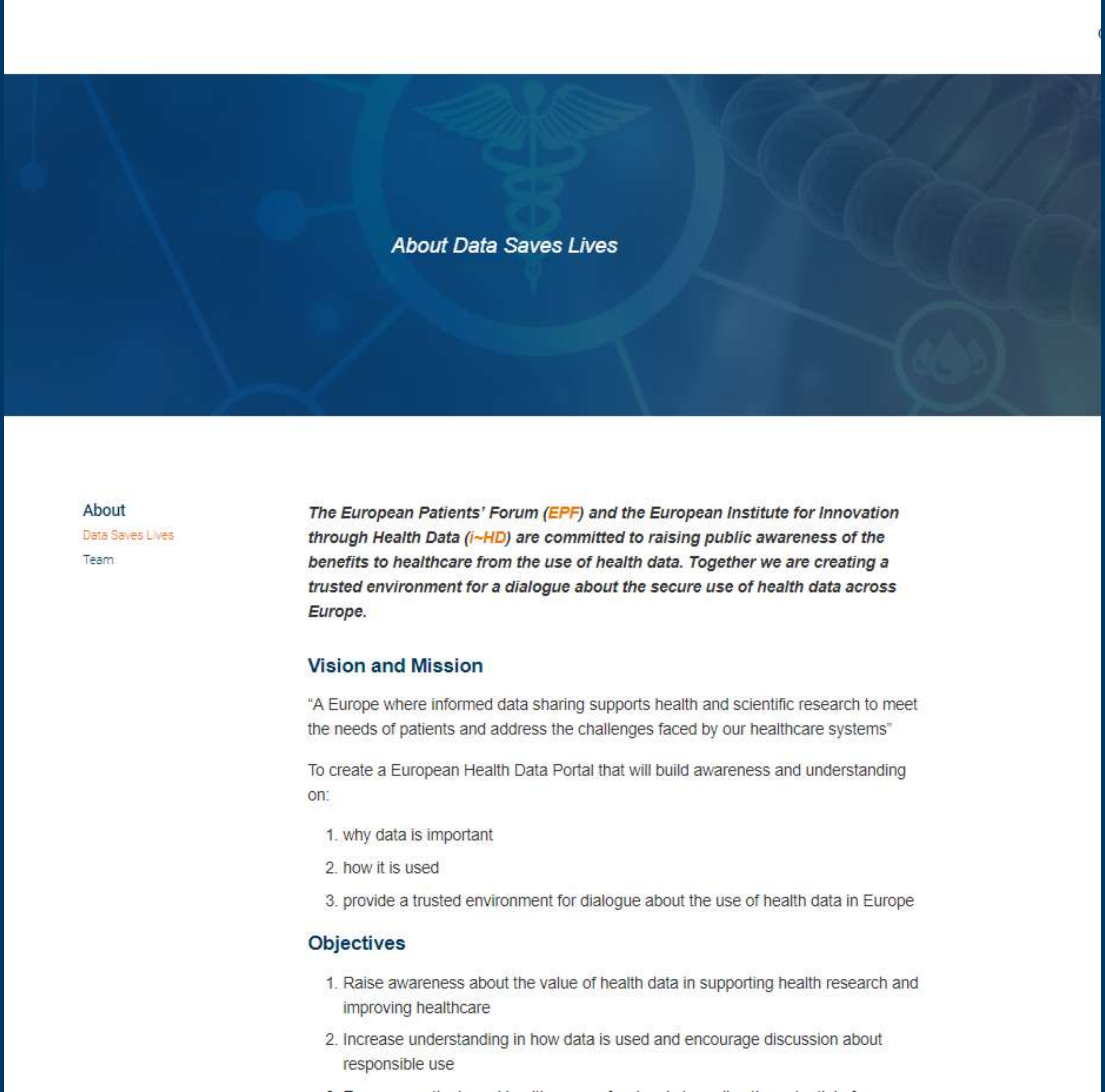
Many patients are surprised that health data is not better utilised, especially within national health systems.

How should researchers safeguard the health data they analyse?

It is expected by patients that researchers who are given access to data in order to conduct research will protect the data with strong security measures, and only use the data for the purposes that are permitted.

Who should conduct research using health data?

There are a number of vitally needed healthcare improvements that are developed by different organisations working together.



About Data Saves Lives

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Vision and Mission

"A Europe where informed data sharing supports health and scientific research to meet the needs of patients and address the challenges faced by our healthcare systems"

To create a European Health Data Portal that will build awareness and understanding on:

1. why data is important
2. how it is used
3. provide a trusted environment for dialogue about the use of health data in Europe

Objectives

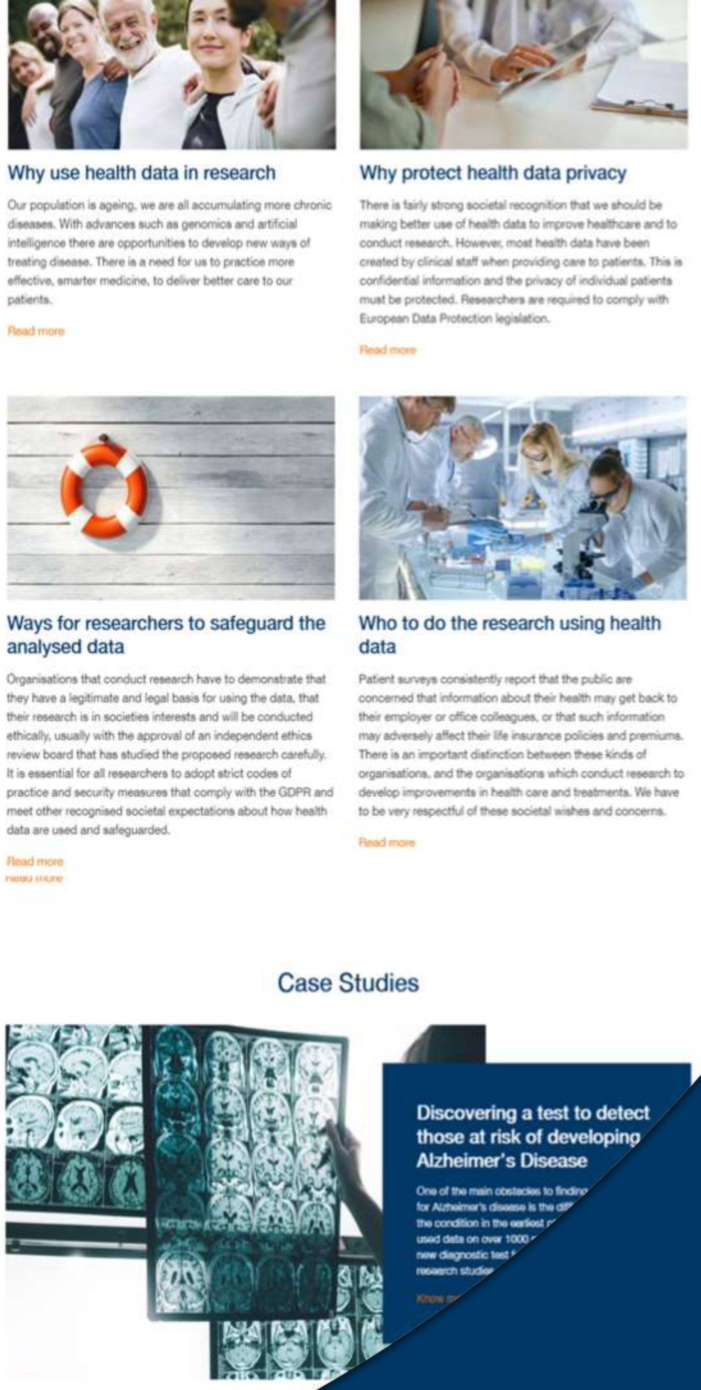
1. Raise awareness about the value of health data in supporting health research and improving healthcare
2. Increase understanding in how data is used and encourage discussion about responsible use

Editorial Principals

- *A **balanced** multi-stakeholder editorial board*
- *High **ethical** and **moral** standards of editorial conduct*
- ***Transparent** about:*
  - *Who we are*
  - *Our purpose*
  - *What our purpose is **not***
  - *Our principals*
  - *Our Editorial Board and its decisions*
- ***Publish factual** materials and resources*
- ***A balanced spectrum of** case study examples*
- *News items to **raise awareness***
- *Enable **informed** debate and decision making by all*

Sharing the resources

- ***Collaborate with patient organisations across Europe***
  - *contribute resources that we can host*
  - *download, translate, customise and freely use resources for their communities*
  - *participate in our community*
- ***As resources permit, aim to make the materials***
  - *more lay friendly, graphical*
  - *more suitable for diverse levels of data literacy*
  - *more suitable for people with different health issues and disabilities*



Why use health data in research

Our population is ageing, we are all accumulating more chronic diseases. With advances such as genomics and artificial intelligence there are opportunities to develop new ways of treating disease. There is a need for us to practice more effective, smarter medicine, to deliver better care to our patients.

Read more

Why protect health data privacy

There is fairly strong societal recognition that we should be making better use of health data to improve healthcare and to conduct research. However, most health data have been created by clinical staff when providing care to patients. This is confidential information and the privacy of individual patients must be protected. Researchers are required to comply with European Data Protection legislation.

Read more

Ways for researchers to safeguard the analysed data

Organisations that conduct research have to demonstrate that they have a legitimate and legal basis for using the data, that their research is in societies interests and will be conducted ethically, usually with the approval of an independent ethics review board that has studied the proposed research carefully. It is essential for all researchers to adopt strict codes of practice and security measures that comply with the GDPR and meet other recognised societal expectations about how health data are used and safeguarded.

Read more

Read more

Who to do the research using health data

Patient surveys consistently report that the public are concerned that information about their health may get back to their employer or office colleagues, or that such information may adversely affect their life insurance policies and premiums. There is an important distinction between these kinds of organisations, and the organisations which conduct research to develop improvements in health care and treatments. We have to be very respectful of these societal wishes and concerns.

Read more

Case Studies

Discovering a test to detect those at risk of developing Alzheimer's Disease

One of the main obstacles to findin
for Alzheimer's disease is the di
the condition in the earliest
used data on over 1000
new diagnostic test
research studie

Know m

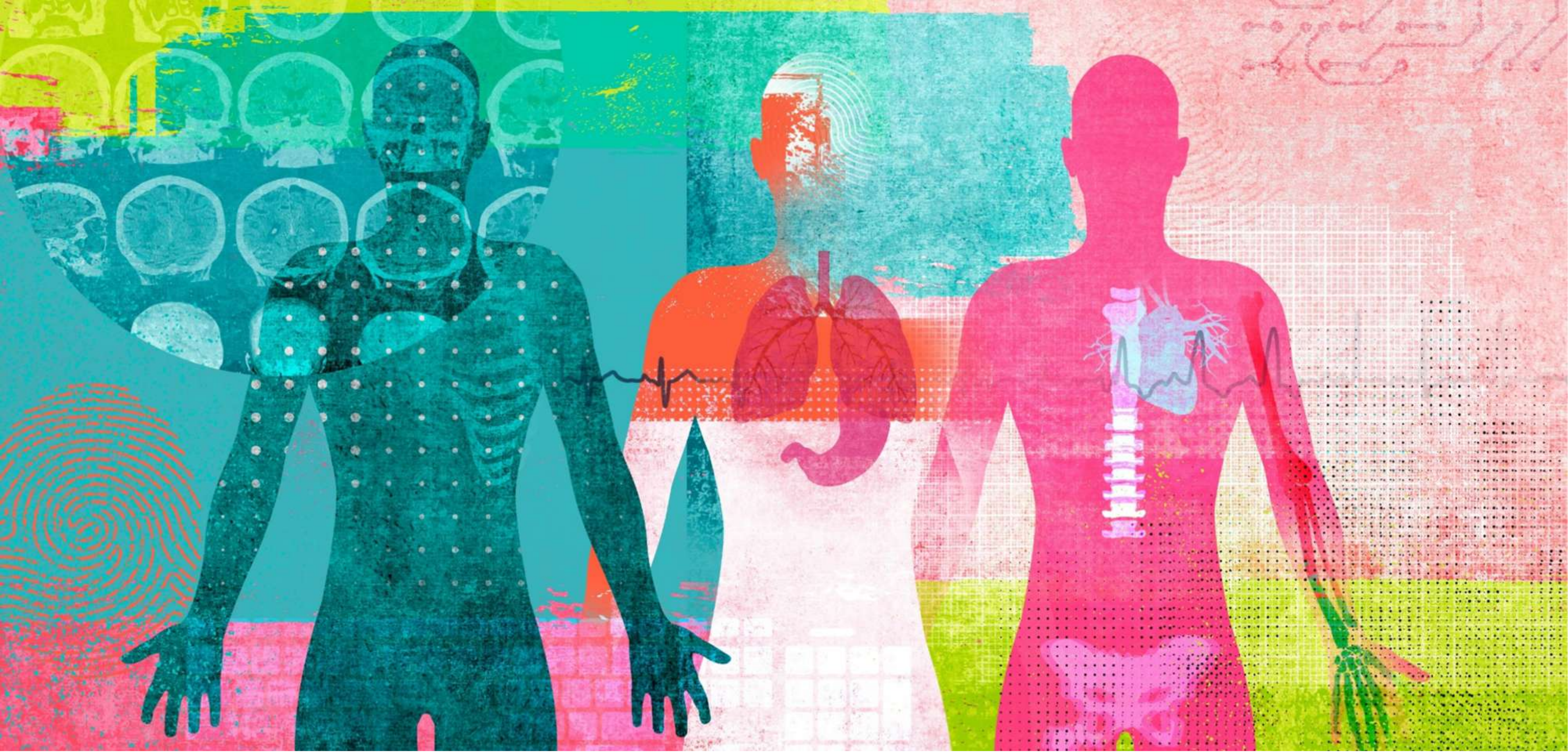
You can **join us co-create and roll-out DataSavesLives** helping **patients** and **health-interested public** in your local community get a better understanding of the use of health data

For further information please contact:
gozde.susuzlu@eu-patient.eu

CONCLUSION

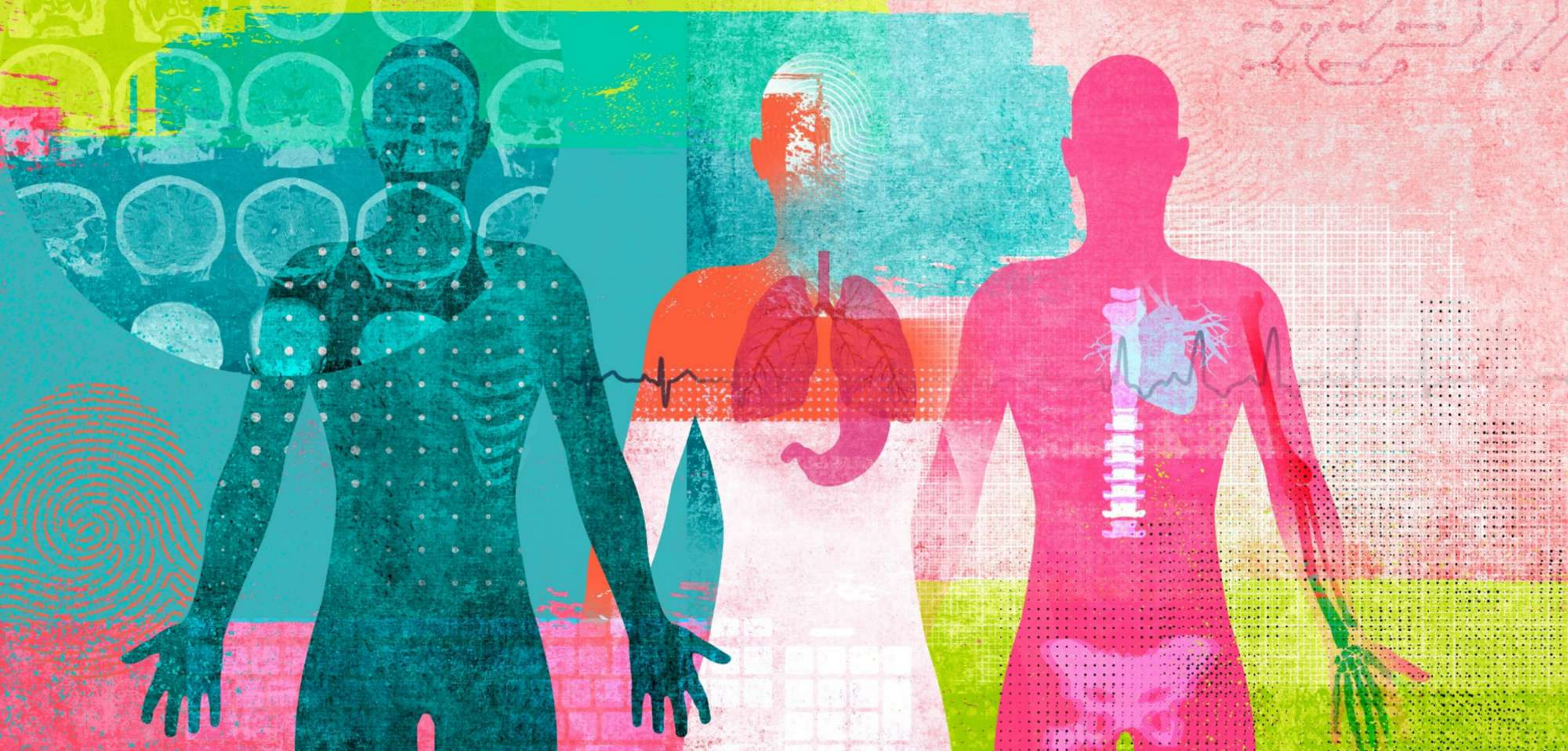
Nathalie Moll

Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA)



NETWORKING COFFEE BREAK & POSTERS

#OncologyDataSummit



VALUE OF HEALTH DATA FOR CANCER CARE

#OncologyDataSummit

CASE STUDIES

Maurits-Jan Prinz

Personalised Healthcare Policy Strategy Leader, Roche

Loubna Bouarfa

CEO and Founder, OKRA Technologies

Piers Mahon

Senior Principal, European Data and Evidence Networks, IQVIA

Francesco Florindi

Strategy & Partnership Manager at BBMRI-ERIC

Deep and broad data from multiple sources

Genomics

EHR / RWD

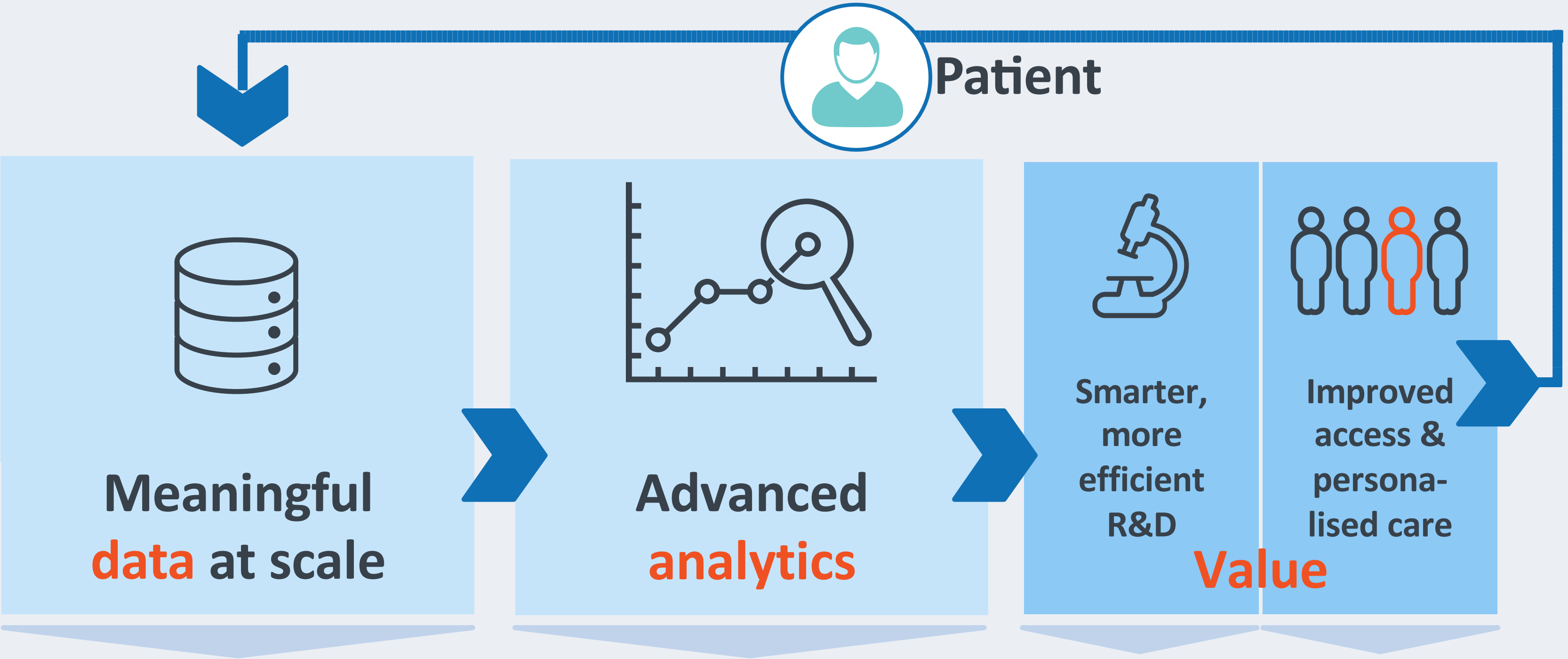
Digital Health tools

Advanced imaging

Digital pathology

High resolution view of each patient and their disease

A Data-Driven Personalised Healthcare Ecosystem



Patient

Meaningful data at scale

Advanced analytics

Smarter, more efficient R&D

Improved access & persona-lised care

Value

Deeper scientific insights

Faster, more efficient trials

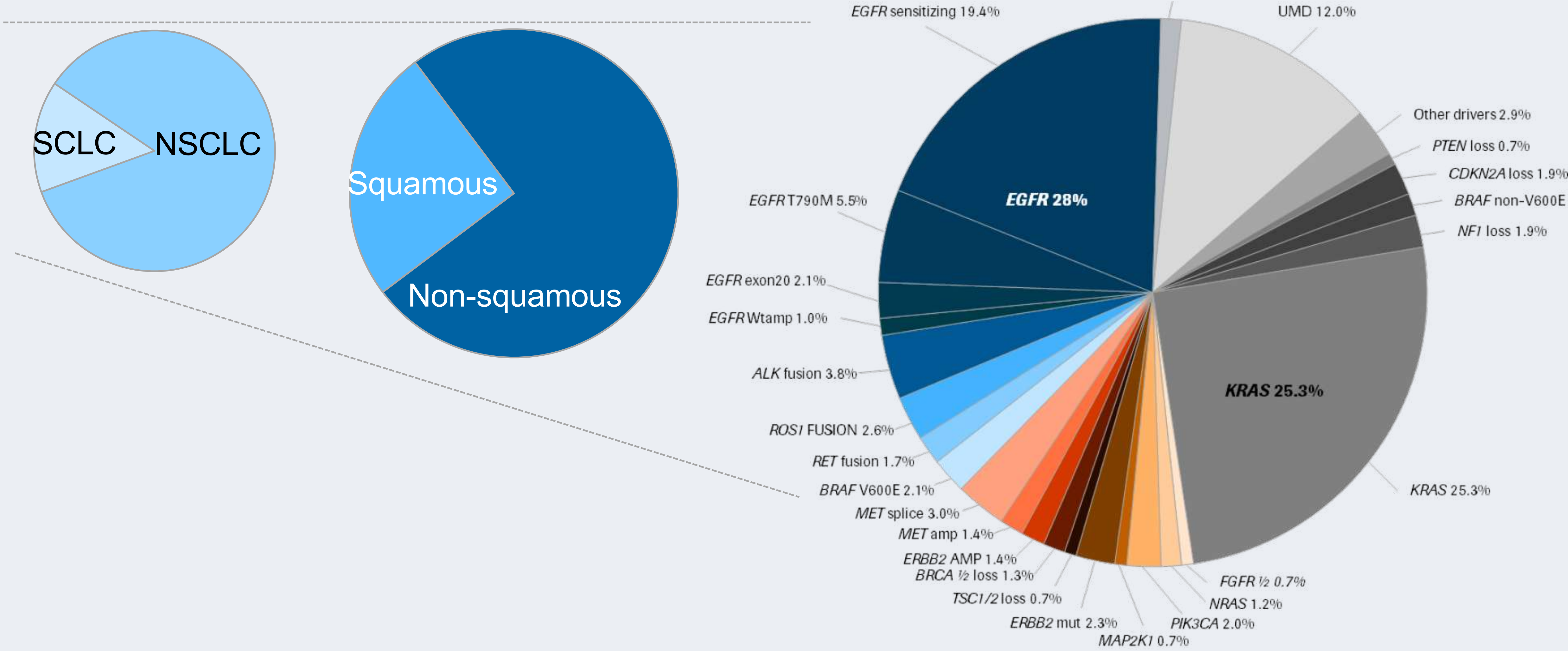
Enhanced patient-therapy matching

Value-based healthcare

Care optimisation & clinical decision support

Cancer as a genomic disease:

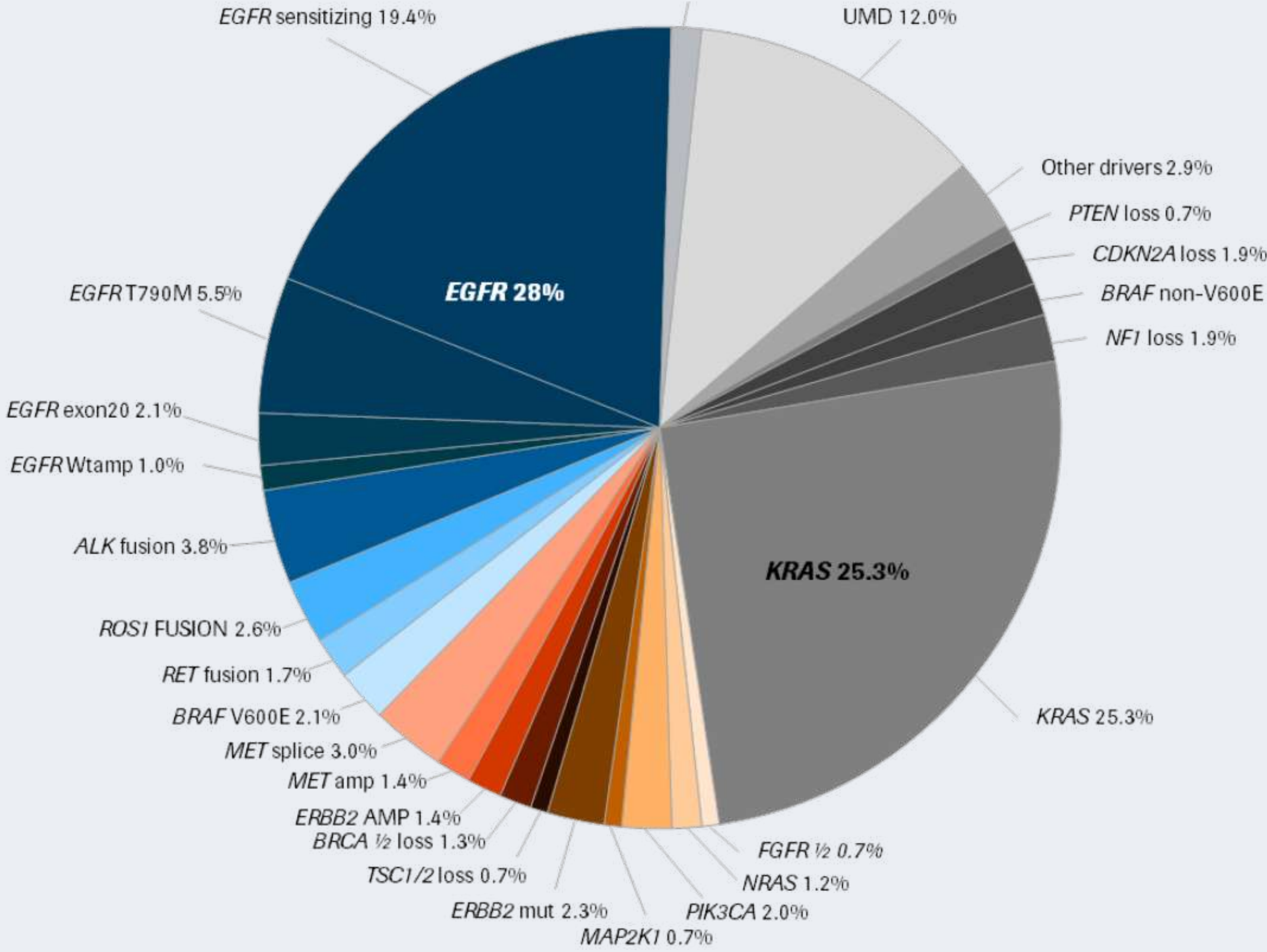
The importance of new sources of data



Jordan EJ *et al.* (2017) *Cancer Discov.* 2017; 7: 596-609

Cancer as a genomic disease:
The importance of new sources of data

- The **rarer** the disease,
- the **more targeted** the treatment,
- the **more challenging** it is to find the right patients,
- the **more difficult** it is to generate large sets of clinical trial data,
- the **more important** it is to collect data from other sources



Jordan EJ *et al.* (2017) *Cancer Discov.* 2017; 7: 596-609

Doing now what patients need next

CASE STUDIES

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Strategy & Partnership Manager at BBMRI-ERIC

Connecting the European cancer community with data in new and powerful ways

EFPIA Oncology Data Summit

June 2019

Dr Piers Mahon, Senior Principal, European Data and Evidence Networks, IQVIA

oncology data network

code

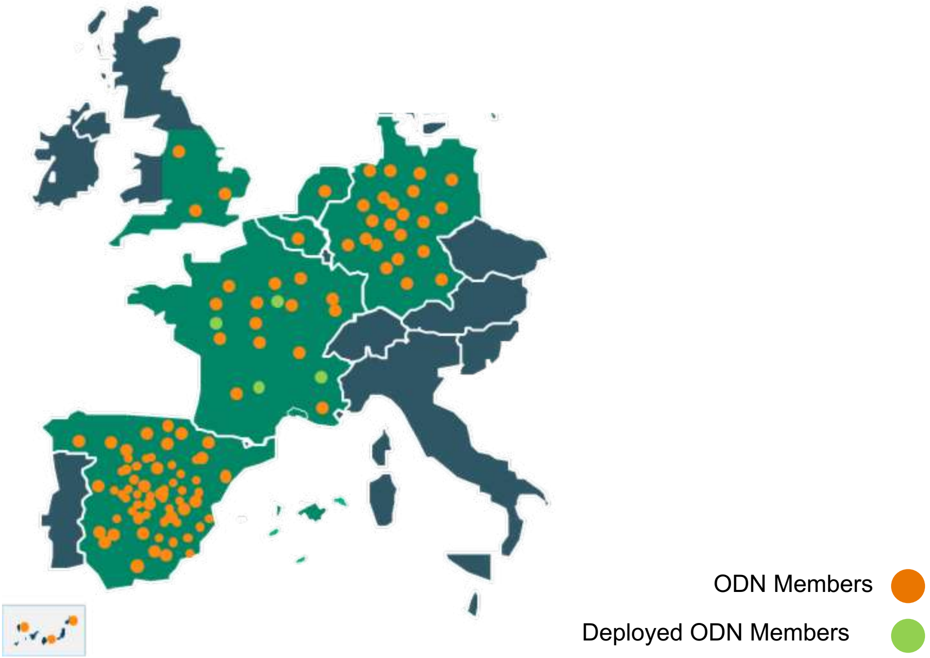
collaboration for oncology data in europe

The Oncology Data Network (ODN) aims to support the oncology community's work to address the complex challenges it is facing

CHALLENGES	THE ODN
Improving Quality Cancer Care	*elps* ***inform effective*** *and* ***efficient cancer care*** *delivered by your clinicians*
Accelerating Clinical Research	*elps clinicians* ***identify new areas for research*** *and* ***expedite patient recruitment*** *for clinical trials and studies*
Ensuring financial sustainability & access	*nables* ***novel payment agreements*** *that can help address the challenge of financial sustainability*

oncology data network

Since we launched at ESMO in 2017, our international footprint has already grown to 113 member hospitals



One up-to-date, tech-enabled, accessible and internationally comparable dataset

6+

Countries in scope

113

ODN Member hospitals*

1,500

Distinct Anti-Cancer Regimens

77,000+

Est. Annual Patients on Anti-Cancer Therapy

30

Leading Clinicians
Current members of the European CASC and Country CAGs (Clinical Advisory Group)

50

Technology Partners
Contracted with IQVIA for the ODN Build

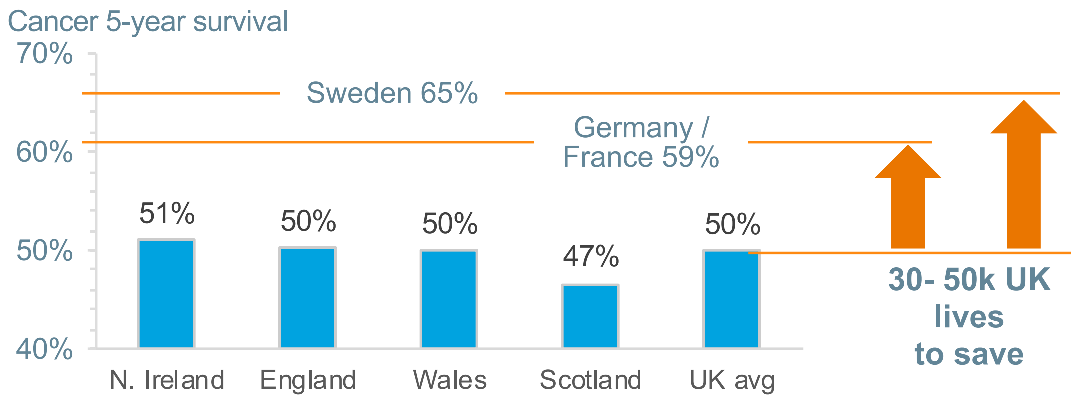
100

Organisations Engaged
Including a Major Partnership with ECCO

**As of May 2019*

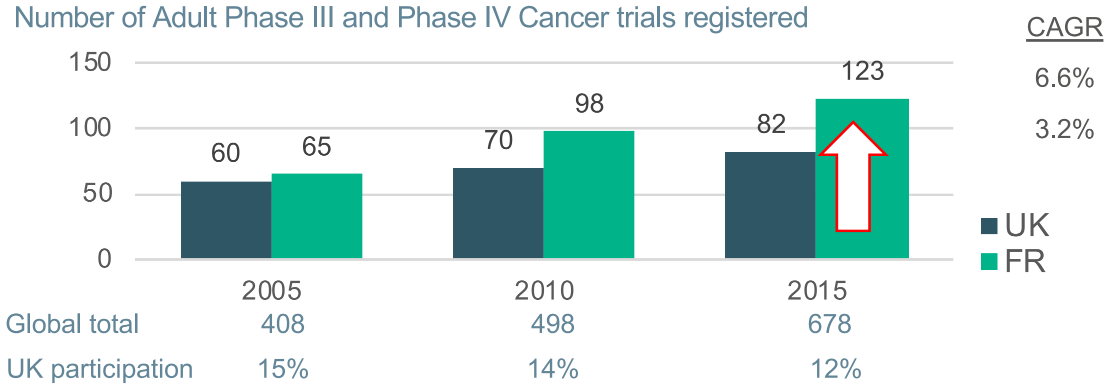
The public and patient benefit from real world data

Save 100,000 lives a year by improving care quality



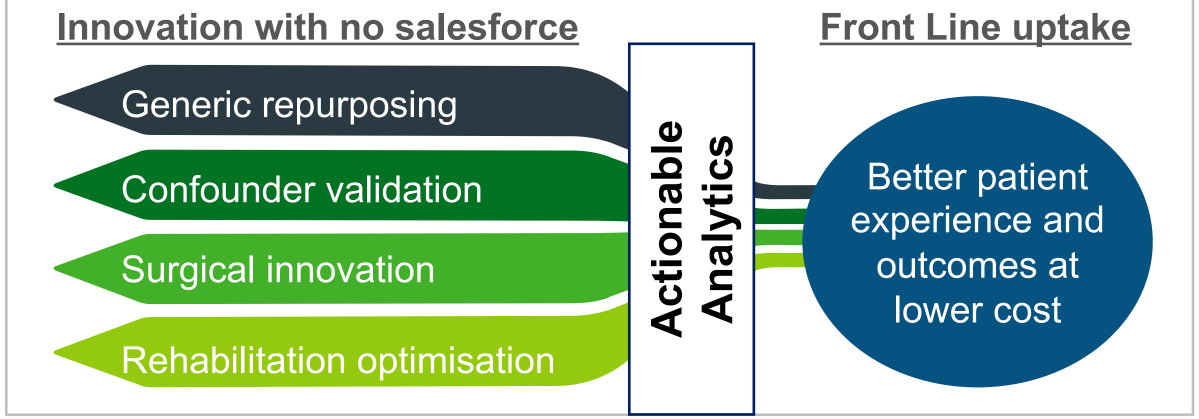
Source: Eurocare5, Cancer Research UK

Increase patients in innovative medicine trials by 50%



Source: US National Library of Medicine (clinicaltrials.gov)

Create a path for non-commercial innovation uptake



Create financial oxygen for innovation by switching off legacy care pathways

INSTITUT NATIONAL DU CANCER

National confounder testing programme

Gefitinib, KRAS lung cancer
- Testing: €1.7M p.a.
- Drug costs saved: €69M
- **Net saving: €67M**

Source: Prof. Fabien Calvo, personal communication

oncology data network

CASE STUDIES

Maurits-Jan Prinz

Personalised Healthcare Policy Strategy Leader, Roche

Loubna Bouarfa

CEO and Founder, OKRA Technologies

Piers Mahon

Senior Principal, European Data and Evidence Networks, IQVIA

Francesco Florindi

Strategy & Partnership Manager at BBMRI-ERIC

BBMRI-ERIC®

THE WORLD‘S BIGGEST
BIOBANK DIRECTORY

WHAT WE
OFFER

SUPPORT
WITH ETHICAL, LEGAL AND SOCIETAL ISSUES

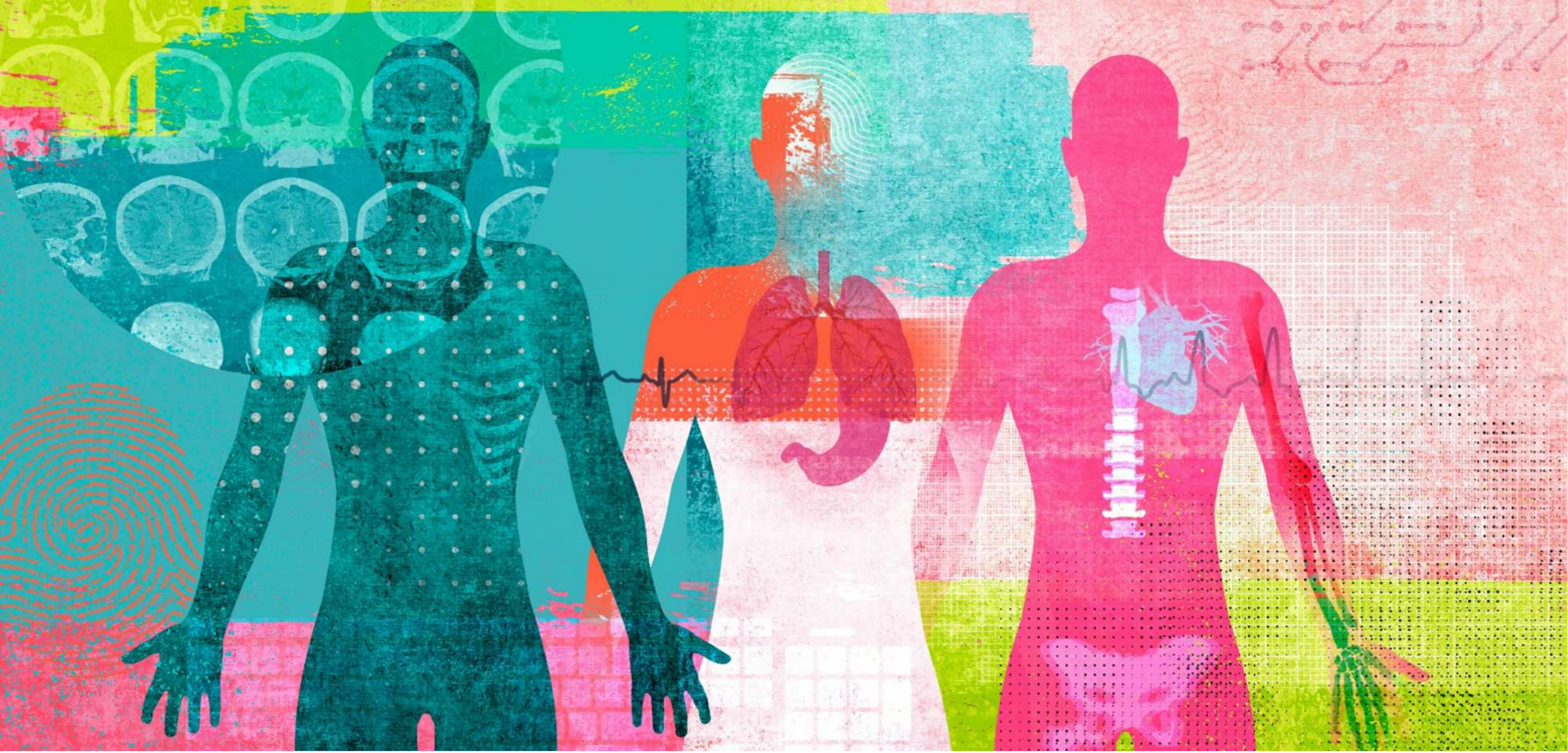
IT TOOLS
AND EXPERTISE

QUALITY
MANAGEMENT SERVICES

Largest real-world colorectal cancer collection

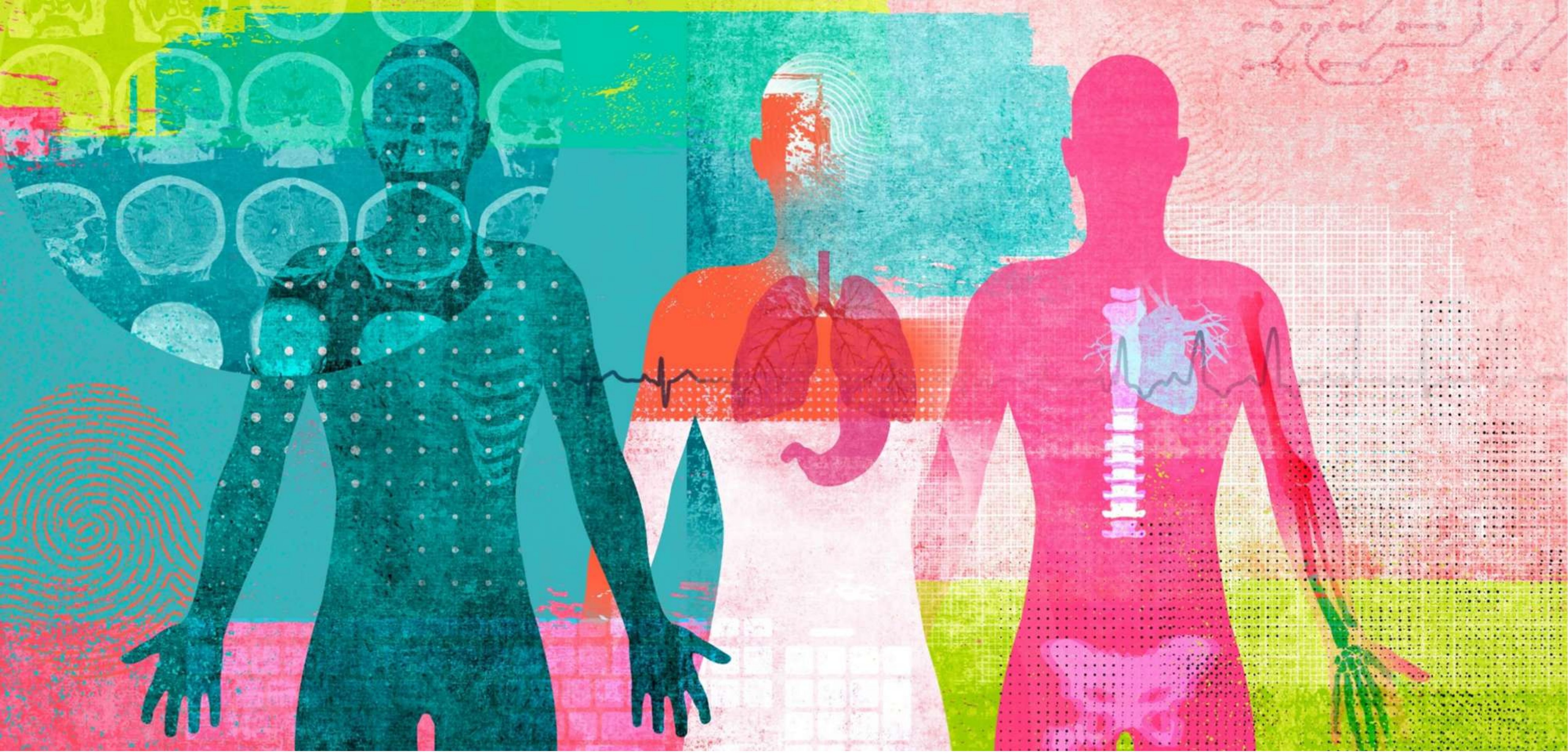
(>10.000 patients) with rich clinical data

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 676550.



NETWORKING LUNCH & POSTERS

#OncologyDataSummit



SPOTLIGHT ON ACCESS TO DATA

#OncologyDataSummit

PANEL: DATA GOVERNANCE, PROTECTION & PRIVACY

Šarūnas Narbutas

Co-founder and Chairman, Youth Cancer Europe

Martijn ten Bloemendaal

European Regional Privacy Counsel, AbbVie

Tapani Piha

Special Adviser, Fipra International & Former Head of Unit, Cross-border Healthcare & eHealth, European Commission

John Butler

VP External Innovation & Alliances at Bayer Pharmaceuticals Division, Responsible for the IMI Harmony project at External Innovation & Alliances, Bayer

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Is it possible to increase the secondary use of health data?

Tapani Piha
Special Adviser, Fipra International
2012-2018 Head of Unit for Cross-border Healthcare & eHealth, European Commission

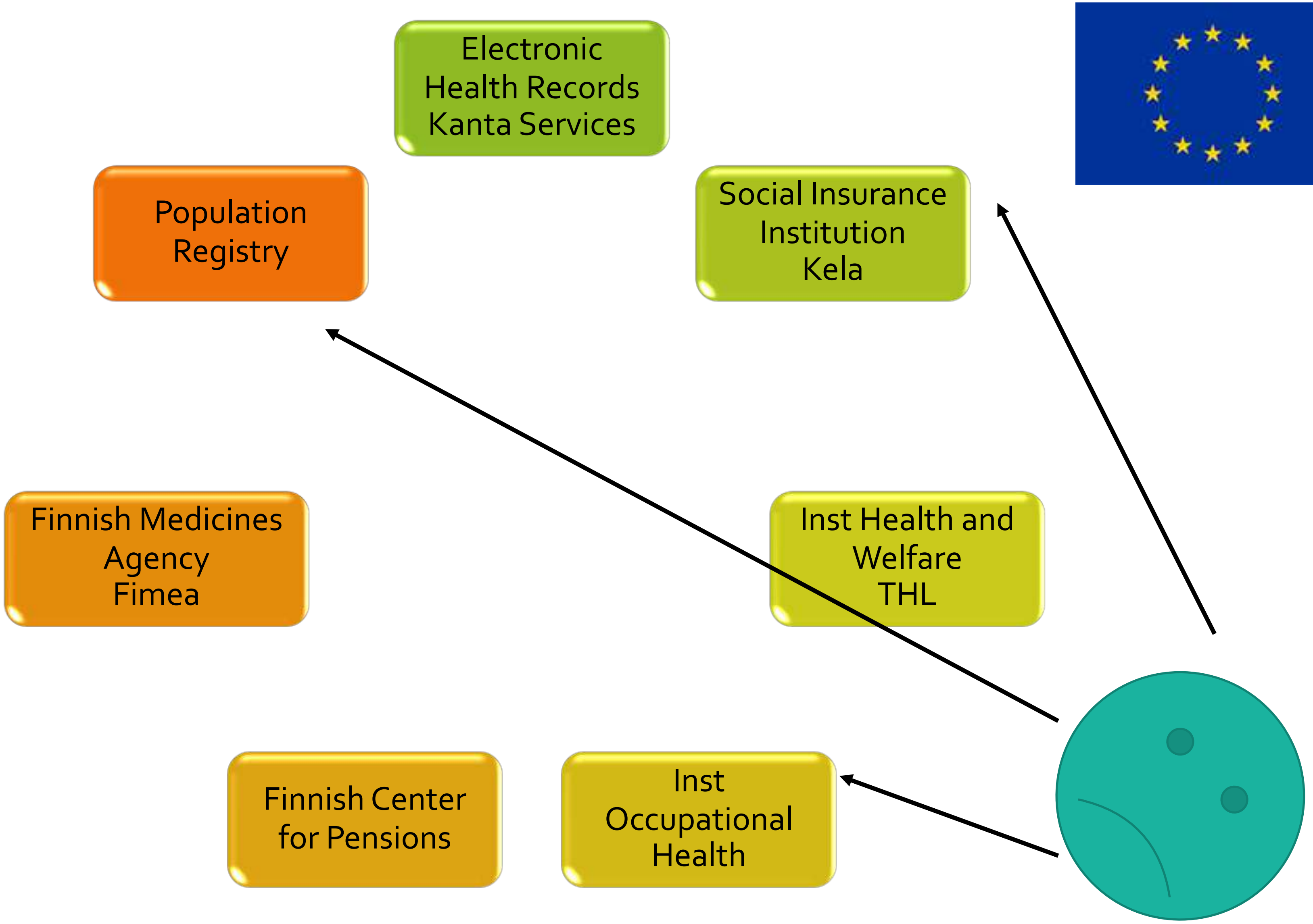
@tapani_piha
working with
@fipra_network
@eu2019fi

#OncologyDataSummit
#ImprovingCancerCare
#datasaveslives

#FinData #SecondaryUse
#healthdata

#EconomyofWellbeing

Data exists but it is hard to use for research



Electronic
Health Records
Kanta Services

Population
Registry

Social Insurance
Institution
Kela

Finnish Medicines
Agency
Fimea

Inst Health and
Welfare
THL

Finnish Center
for Pensions

Inst
Occupational
Health

Finland

Act on Secondary Use of Health and Social Data

- Enacted in April 2019
- Purpose is to enable the effective and secure processing of personal data stored in connection with healthcare and social welfare activities.
- Enabling legislation
- Establishes the Data Permit Authority, **Findata,** and its processes

FINDATA

Slides adapted from the MInistry of Social Affairs and Health, Sitra

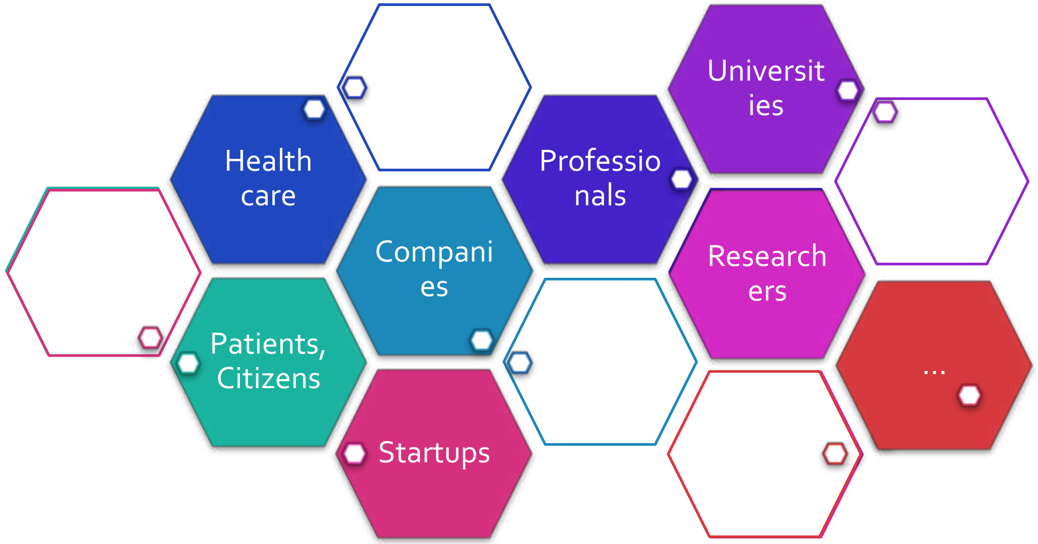
Finland

Act on Secondary Use of Health and Social Data

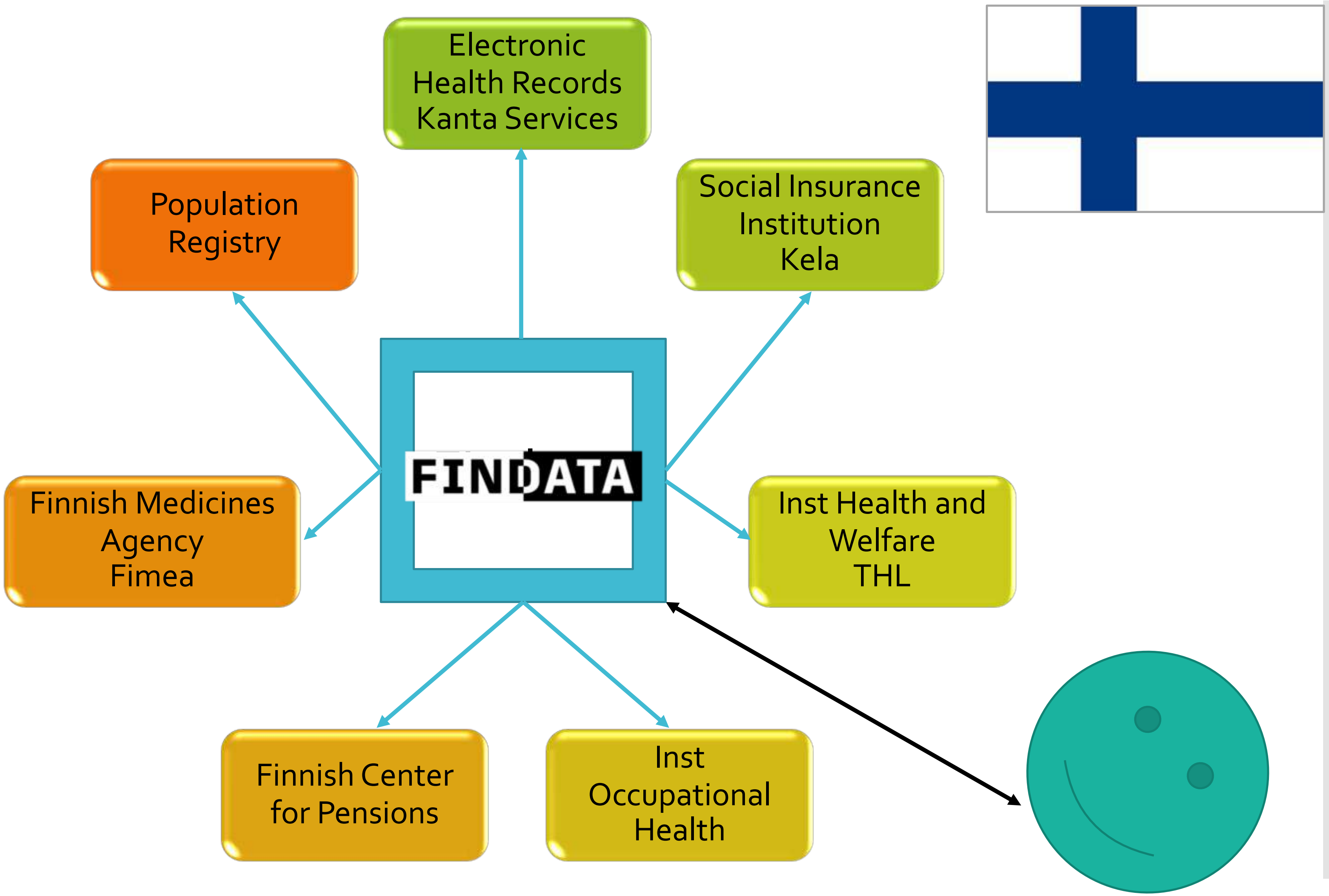
Solid GDPR-compliant legal basis for secondary use

Benefits of the New Act on Secondary Use of Social and Health Data

- More uses possible of social and health data
  - Research
  - Evidence-based decision making
- Faster and improved access to data
  - Combining data from different sources gets easier
- Data protection taken care of centrally
- Secure information management environment

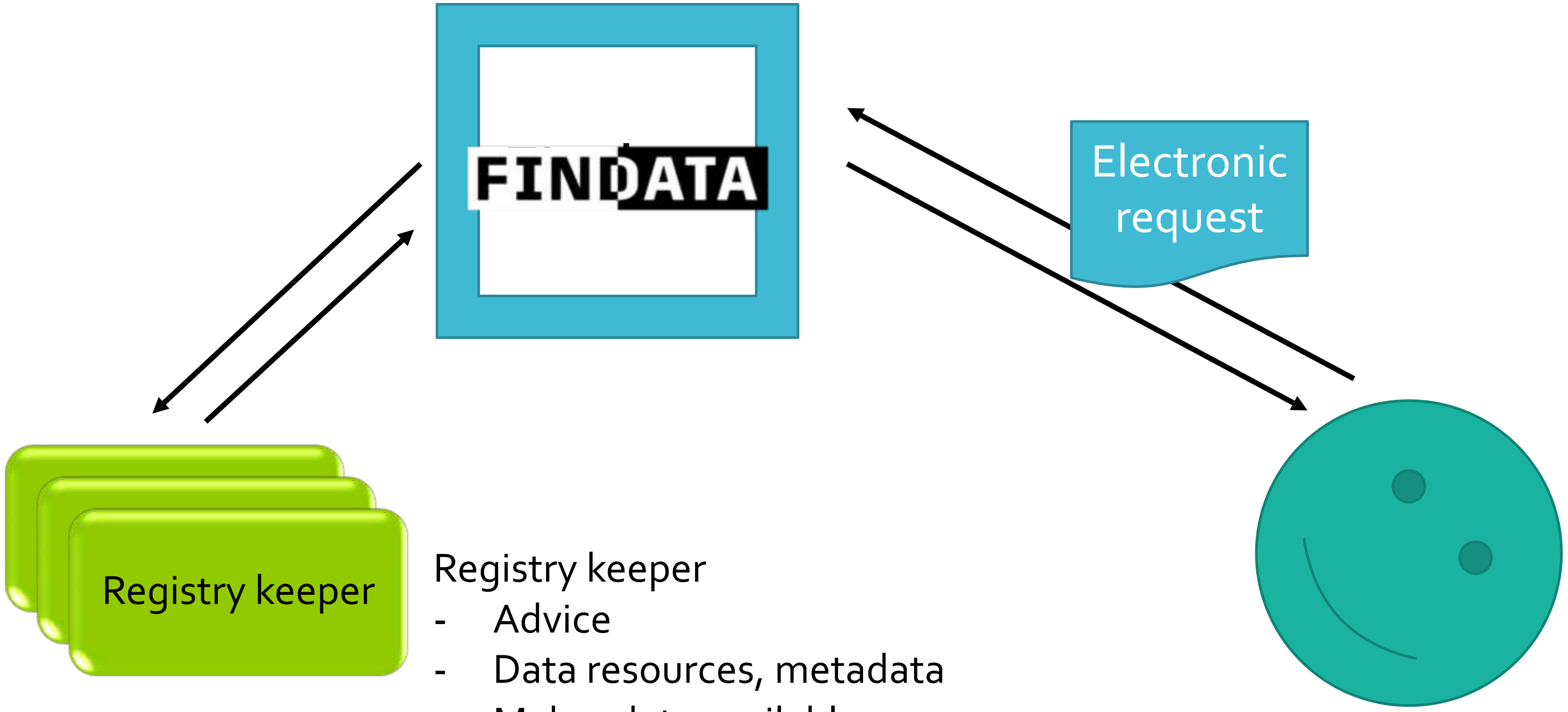


Findata authority creates a one-stop shop to all data providers



The one-stop shop process

Data Permit Authority
- Grants the data permit or accepts the data request – with a deadline
- Collects the data, combines, anonymises
- Releases data in a secure environment
- Gives advice and guidance



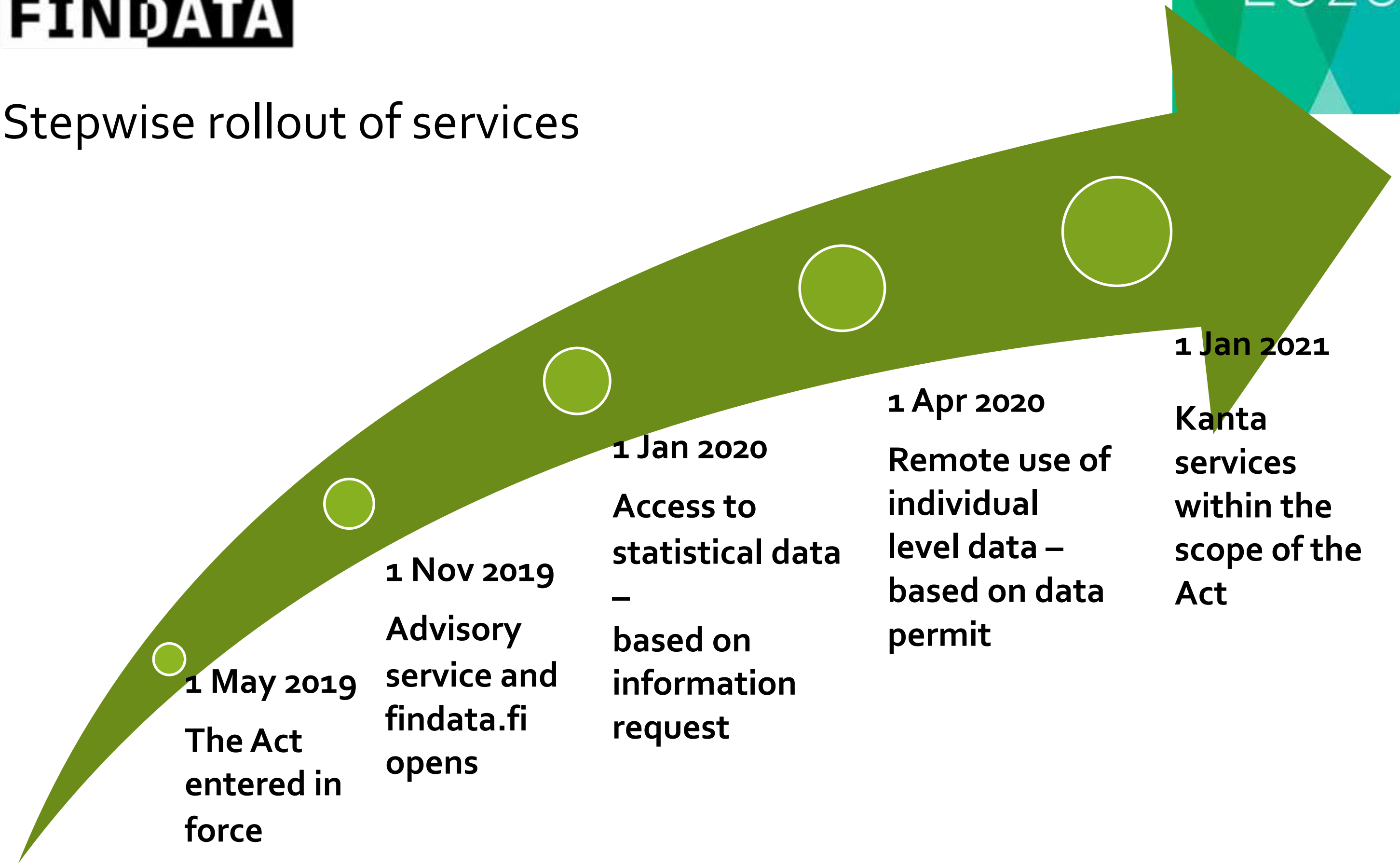
Registry keeper
- Advice
- Data resources, metadata
- Makes data available

Let the efficient and secure secondary is of data begin!

FINDATA

EU2019.FI

Stepwise rollout of services



1 May 2019
The Act entered in force

1 Nov 2019
Advisory service and findata.fi opens

1 Jan 2020
Access to statistical data –
based on information request

1 Apr 2020
Remote use of individual level data – based on data permit

1 Jan 2021
Kanta services within the scope of the Act

Presidencies **Finland** ➡ Croatia ➡ Germany

Further information

- The Ministry’s web pages on the new law.
  https://stm.fi/en/secondary-use-of-health-and-social-data
- Seminar on 11 June 2019 in Helsinki, linked to HIMSS2019, web streaming
  https://webcast.sst.fi/cast/himss-side-event-secondary-use-of-health-data/public
- Sitra’s book about the new law
  https://www.sitra.fi/en/publications/a-finnish-model-for-the-secure-and-effective-use-of-data/

Thank you!

Tapani Piha

@tapani_piha

Helsinki, Finland

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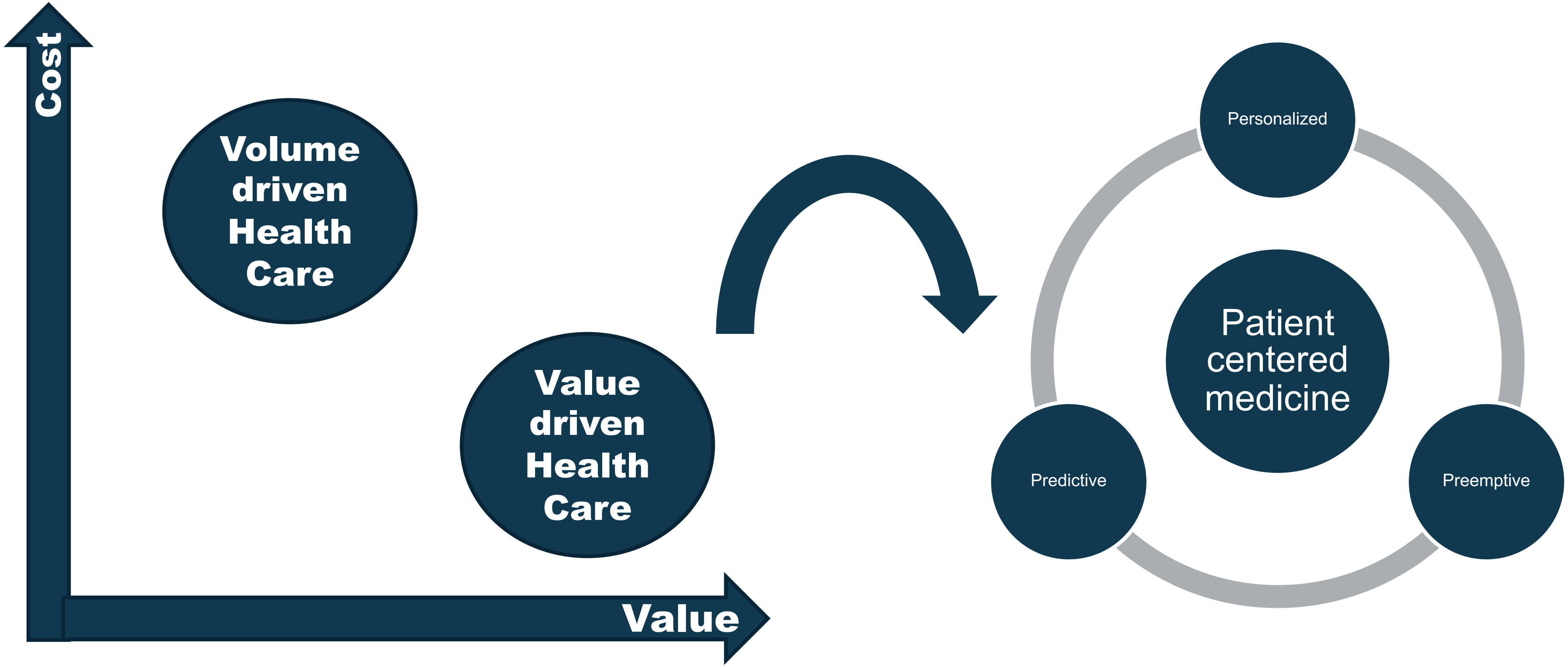
Data Privacy and Big Data Analysis in HARMONY

EFPIA Oncology Data Summit,
Brussels 18/06/2019

Dr. John Butler
Bayer AG
Pharmaceutical Division

Our health care payment and delivery systems are shifting from volume-based to value-based care



Cost

Volume driven Health Care

Value driven Health Care

Value

Personalized

Patient centered medicine

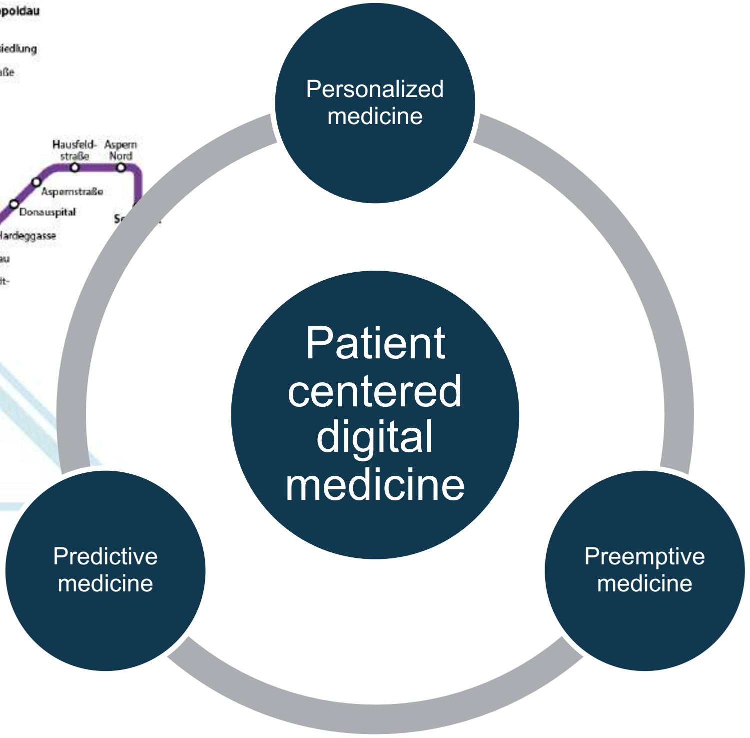
Predictive

Preemptive

How do we get from here to there?

By building the health information backbone necessary to deliver on the promise of Digital Medicine

One-size-fits-all


Personalized medicine

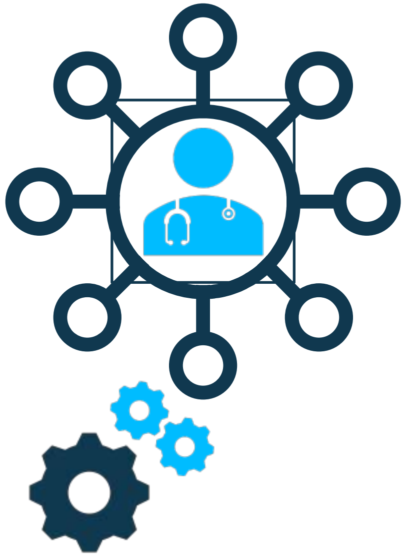
Patient centered digital medicine

Predictive medicine

Preemptive medicine

protocol and patient-specific outcomes data are prerequisite to predictive analytics

HARMONY: applying Big Data to improve outcomes for patients with hematological malignancies



- longitudinal diagnosis / treatment information continuously added
- from multiple sources (within and outside the consortium)
- combined and harmonized on a common data model
- accessible for research by partners and third parties
- compliant with all relevant national and European law
- Enabling individually tailored, informed therapeutic decisions

Why Big Data for Outcomes Research?

- Providers have large amounts of **patient's data on diagnosis, treatment choice and outcomes**.
- Payers (Insurance) have large amounts of patients data on prescription costs and care measures.
- Some countries and regions have large data sources pertaining social consequences of disease.

Combining this data should:

1. Improve diagnosis and **patient stratification**,
2. Optimize **therapeutic choices**,
3. Provide robust data on **therapeutic value**

Data Privacy is the biggest hurdle.
Changing regulations and legal environment have generated two phenomena:

- Naïve ignorance of the current legal framework
- Paralysis by analysis: uncertainty leading to fear and inaction.

Anonymization is key to HARMONY‘s success

Personal data ➔ data privacy requirements

- Requires informed consent
- Use for defined purposes
- restricted transfer to other legal entities / countries
- Individual’s rights must be fulfilled

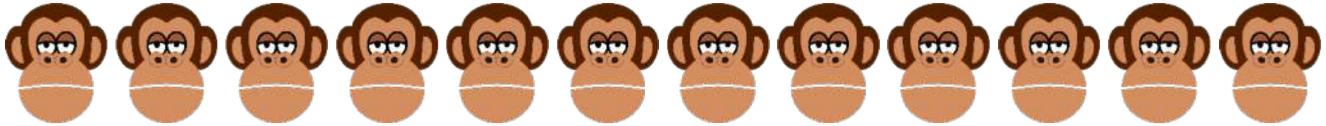
Anonymous data ➔ no privacy restrictions

- Obtain data from third-parties, e.g. real world data from clinical sites
- Provide data to third parties, e.g. HARMONY consortium
- In-house secondary use of data (i.e. for different than original purposes)

Can data be anonymized without rendering it useless for research?

Absolute anonymization is impossible

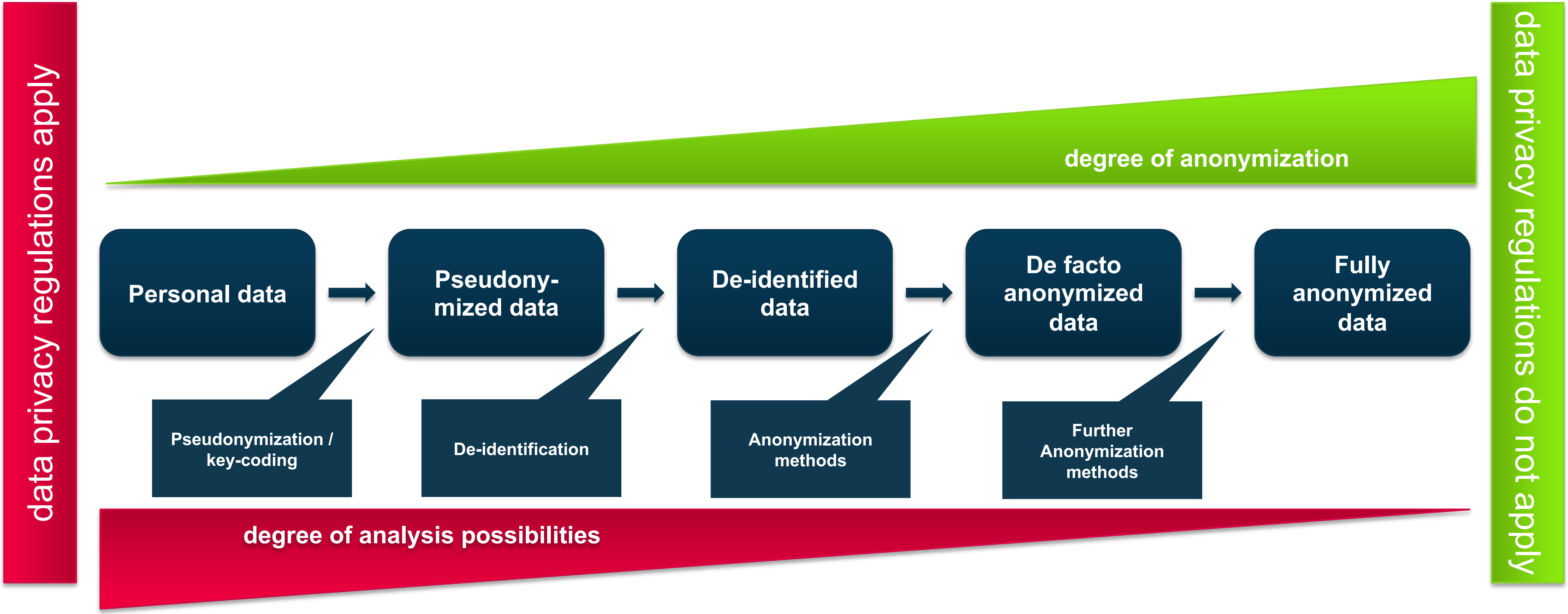
The *infinite monkey theorem*



a monkey hitting keys at random on a typewriter keyboard for an infinite amount of time will almost surely type any given text, such as the complete works of Shakespeare.

If this holds true, high performance computing can eventually break any code and identify individuals based on unique data sets.

Anonymization is not black & white


data privacy regulations apply

degree of anonymization

Personal data → Pseudonymized data → De-identified data → De facto anonymized data → Fully anonymized data

Pseudonymization / key-coding

De-identification

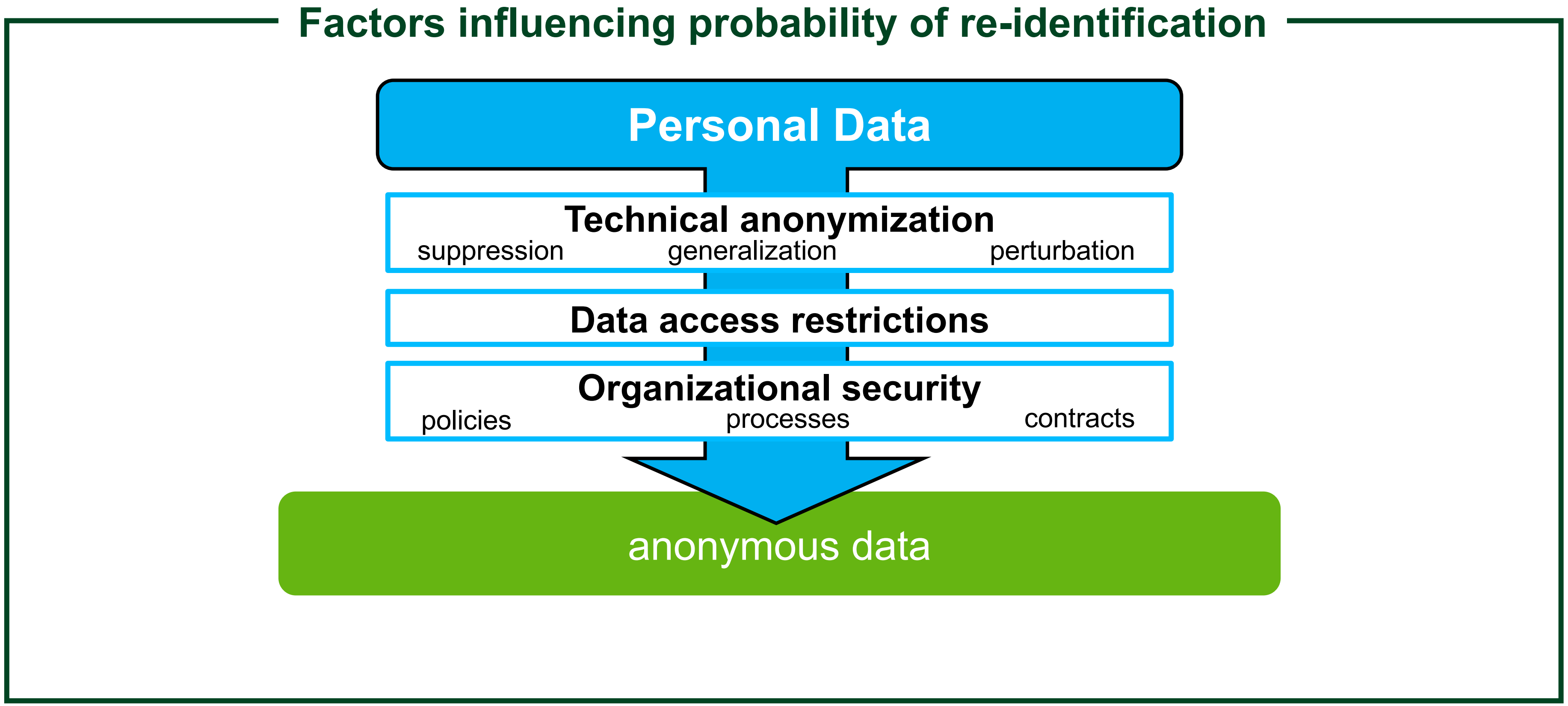
Anonymization methods

Further Anonymization methods

degree of analysis possibilities

data privacy regulations do not apply

Assessment anonymization in HARMONY



Factors influencing probability of re-identification

Personal Data

Technical anonymization

suppression generalization perturbation

Data access restrictions

Organizational security

policies processes contracts

anonymous data

HARMONY’s “AML Proof-of-concept Study”

L Bullinger *et al. EHA Meeting Amsterdam 2019*

The picture can't be displayed.

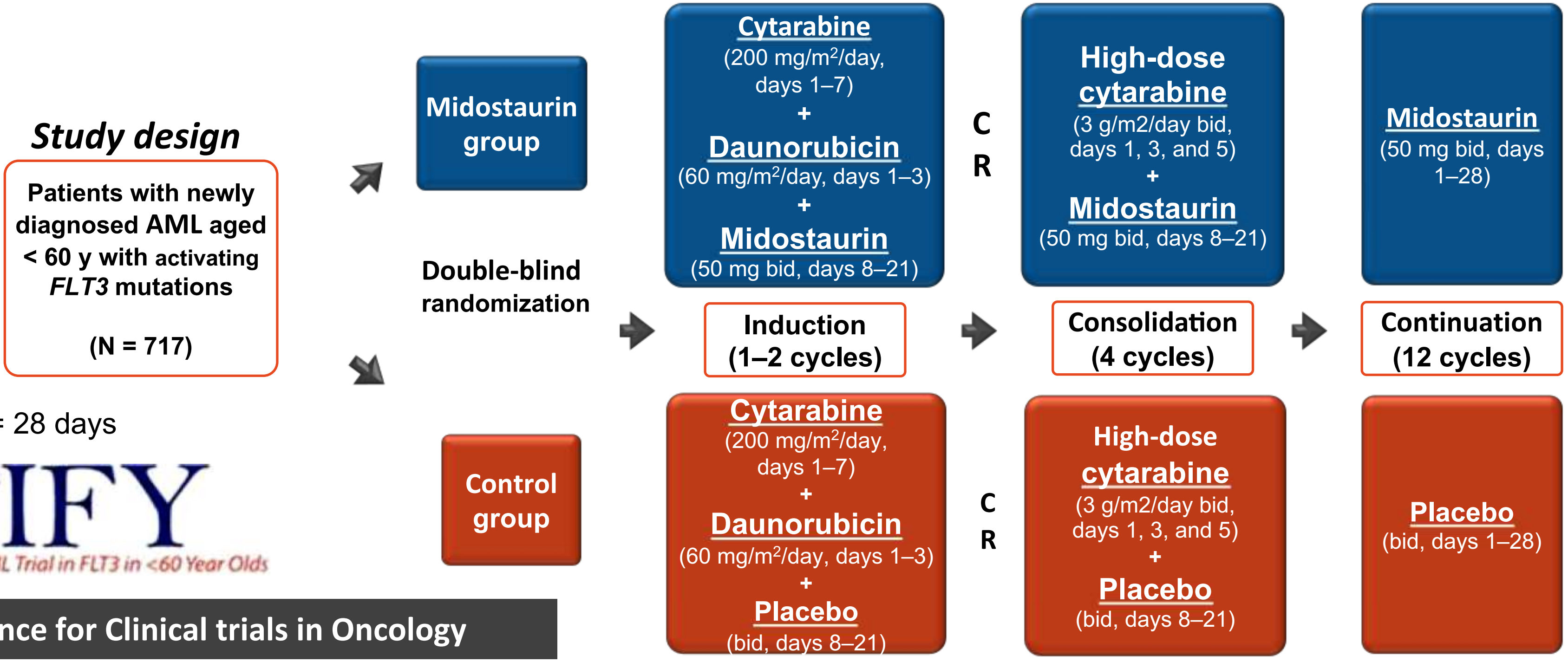
To establish the legal and ethical framework

To evaluate gene–gene interactions in patients with AML, which may influence treatment outcomes.

Project Partnership

- **VU University Medical Center Amsterdam**
- **University of Ulm**
- **Novartis**
- **Klinikum der Universität München**

Novartis Oncology - first industry partner to transfer study data to HARMONY



Study design

Patients with newly diagnosed AML aged < 60 y with activating *FLT3* mutations

(N = 717)

Double-blind randomization

Midostaurin group

Cytarabine (200 mg/m²/day, days 1–7) + **Daunorubicin** (60 mg/m²/day, days 1–3) + **Midostaurin** (50 mg bid, days 8–21)

CR

High-dose cytarabine (3 g/m2/day bid, days 1, 3, and 5) + **Midostaurin** (50 mg bid, days 8–21)

Midostaurin (50 mg bid, days 1–28)

Induction (1–2 cycles)

Consolidation (4 cycles)

Continuation (12 cycles)

Control group

Cytarabine (200 mg/m²/day, days 1–7) + **Daunorubicin** (60 mg/m²/day, days 1–3) + **Placebo** (bid, days 8–21)

CR

High-dose cytarabine (3 g/m2/day bid, days 1, 3, and 5) + **Placebo** (bid, days 8–21)

Placebo (bid, days 1–28)

1 cycle = 28 days

RATIFY
Randomized AML Trial in FLT3 in <60 Year Olds

with the Alliance for Clinical trials in Oncology

RATIFY: Midostaurin in Newly Diagnosed Patients With AML Activating FLT3 Mutations

- **177 centers in EU, US & AUS**
- **>700 patients**

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Select: Search...

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☐ ASXL1+STAG2
☐ BCOR
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☐ BRAF
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☐ CEBPA
☐ CREBBP
☐ CSF3R
☐ CUX1
☐ DNMT3A
☐ DNMT3A+BCOR
☐ DNMT3A+FLT3
☐ DNMT3A+IDH1
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☐ DNMT3A+NPM1
☐ DNMT3A+NRAS

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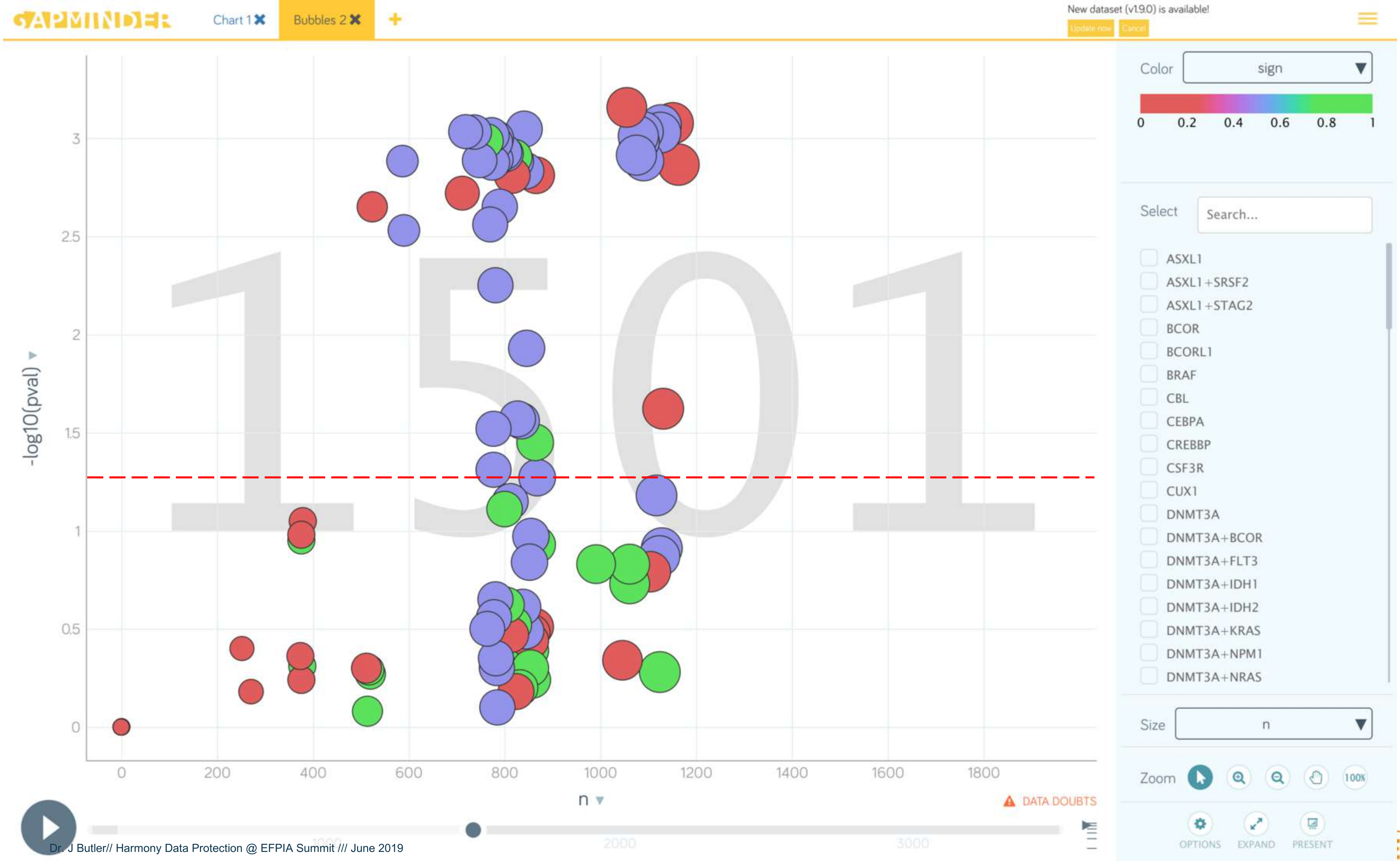
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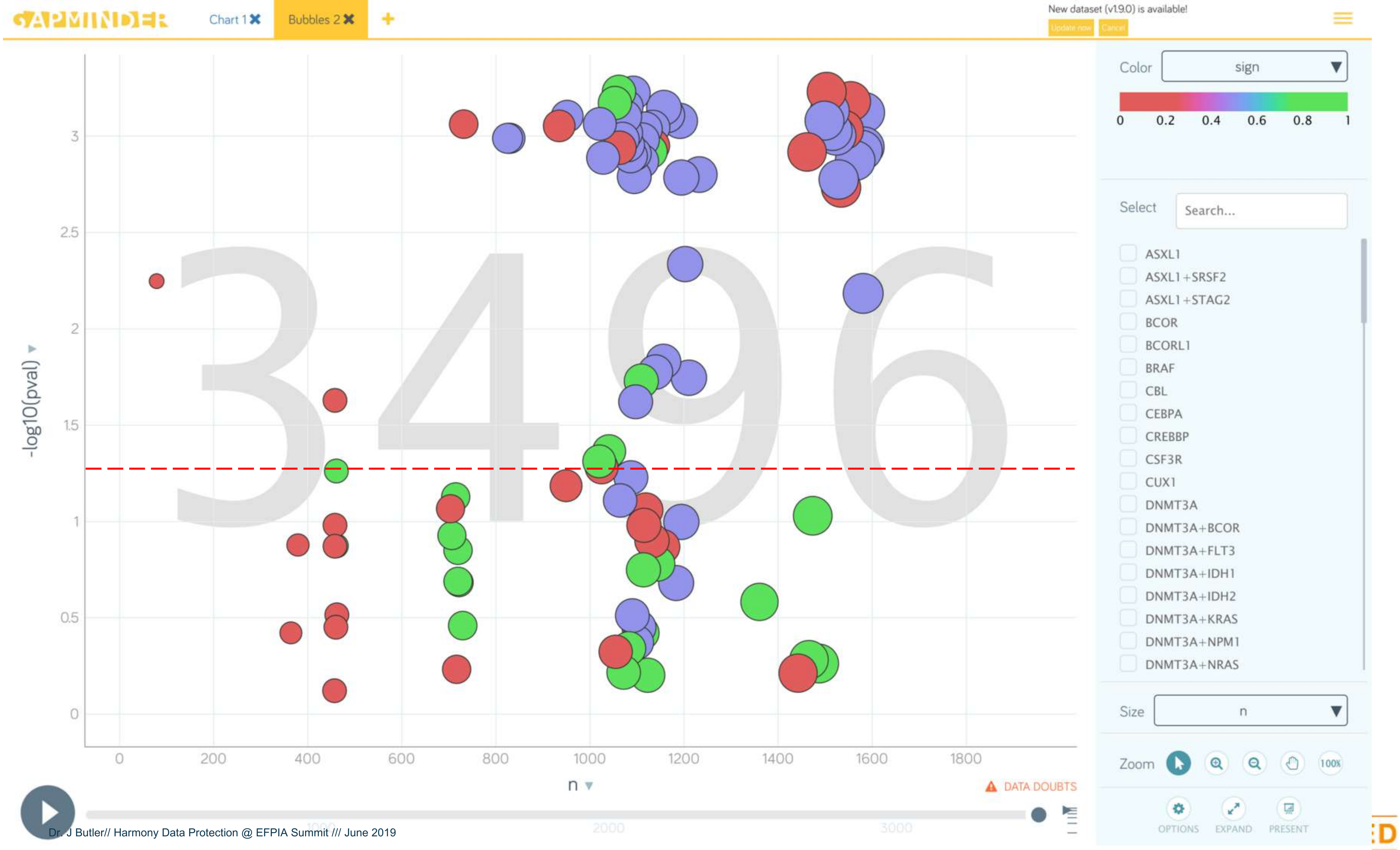
GAPMINDER
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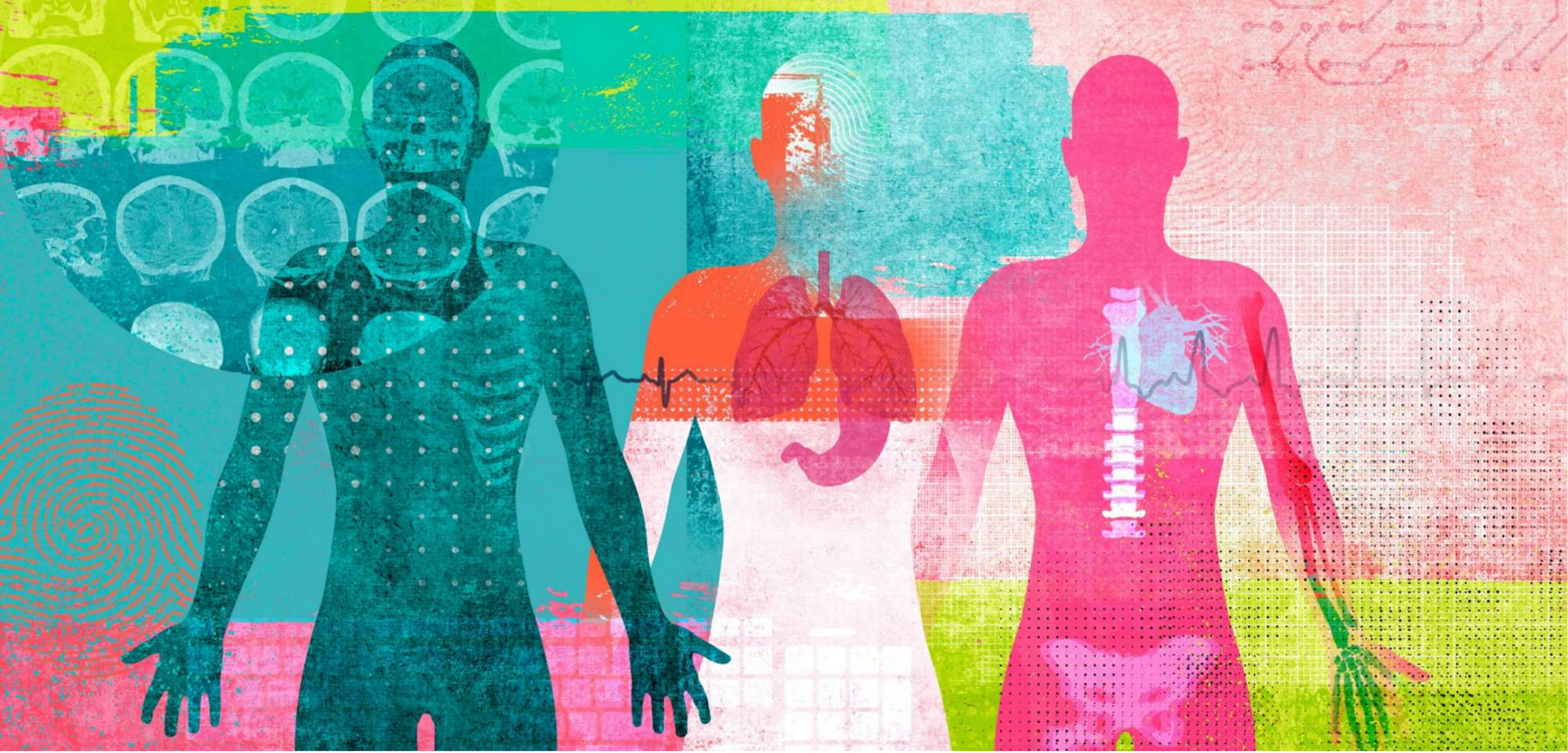
Summary:

- **HARMONY data sets qualify as anonymous and <u>not</u> personal data**
- **Sufficient anonymity is reached if identification would require an unreasonable effort.**
- **HARMONY anonymization protocol is sufficient to exclude qualification as “personal data”**
- **“The HARMONY Anonymization Concept takes into account all necessary factors” ensuring that “no means required by applicable data protection law is ignored”.**

“the HARMONY Anonymization Concept can ensure that the intended import of data into the HARMONY Platform and their subsequent uses as envisaged within the HARMONY Project complies with applicable data protection laws on EU level including the General Data Protection Regulation (GDPR)”

.

- *Osborne Clarke “Legal Assessment of the Anonymization Concept for the HARMONY Project” V 29.01.18*



QUESTIONS & ANSWERS

#OncologyDataSummit

PANEL: STANDARDS AND INFRASTRUCTURE

Otto Visser

Director, Netherlands Cancer Registry & Chair, European Network of Cancer Registries (ENCR)

Melinda J. Daumont

Director, Worldwide Health Economics and Outcomes Research, Oncology, Bristol-Myers Squibb

Fabien Calvo

Chief Scientific Officer, Cancer Core Europe

Nigel Hughes

European Health Data & Evidence Network (EHDEN Initiative)

ENCR - the European Network of Cancer Registries

Collecting, monitoring and improving cancer data

Otto Visser, MD PhD

ONCOLOGY DATA SUMMIT, Centre Nobel, Brussels 18-02-2019

European Commission

The Network and its structure

- Active since 1990
- Established within the framework of the "*Europe Against Cancer " programme of the **European Commission*** on the initiative of IARC, ANCR, IACR and GRELL
- Governed by a **Steering Committee** (currently 11 people) with 3-years term
- **Secretariat** hosted at the EC **Joint Research Centre** since 2012 (previously at IARC)
- The JRC also supporting the ENCR in its activities aimed at harmonisation and improvement of cancer registration in Europe

The EC Joint Research Centre

EC Initiative requested by the Council of the EU, endorsed by the European Parliament and coordinated by the European Commission aimed to

PROVIDE TIMELY COMPARABLE DATA ON CANCER BURDEN

- evidence for development and monitoring of policies to prevent and treat cancer
- resource for epidemiological research
- promotion of citizens empowerment

ENCR Objectives

- **Quality**, **comparability** and **availability** of cancer incidence data
- **Monitoring** cancer incidence and mortality
- Providing **information** on the burden of cancer
- Promoting the use of **cancer registries**

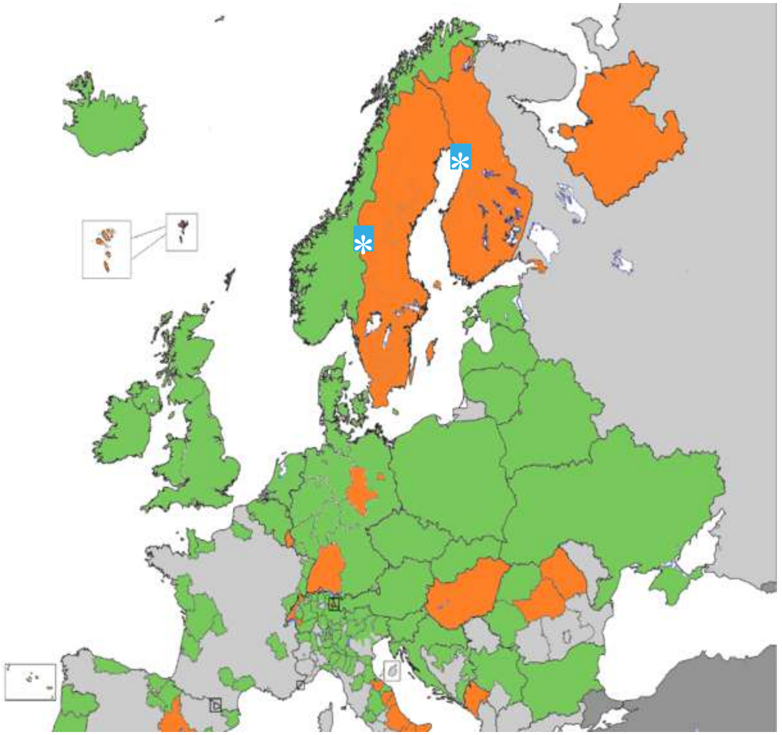
Active members / Participation in latest call for data (2015)

132 population-based registries

33,000,000 records

30 countries

60% of the EU/EFTA population



🟩 **Data submitted**

🟧 **Data not submitted**

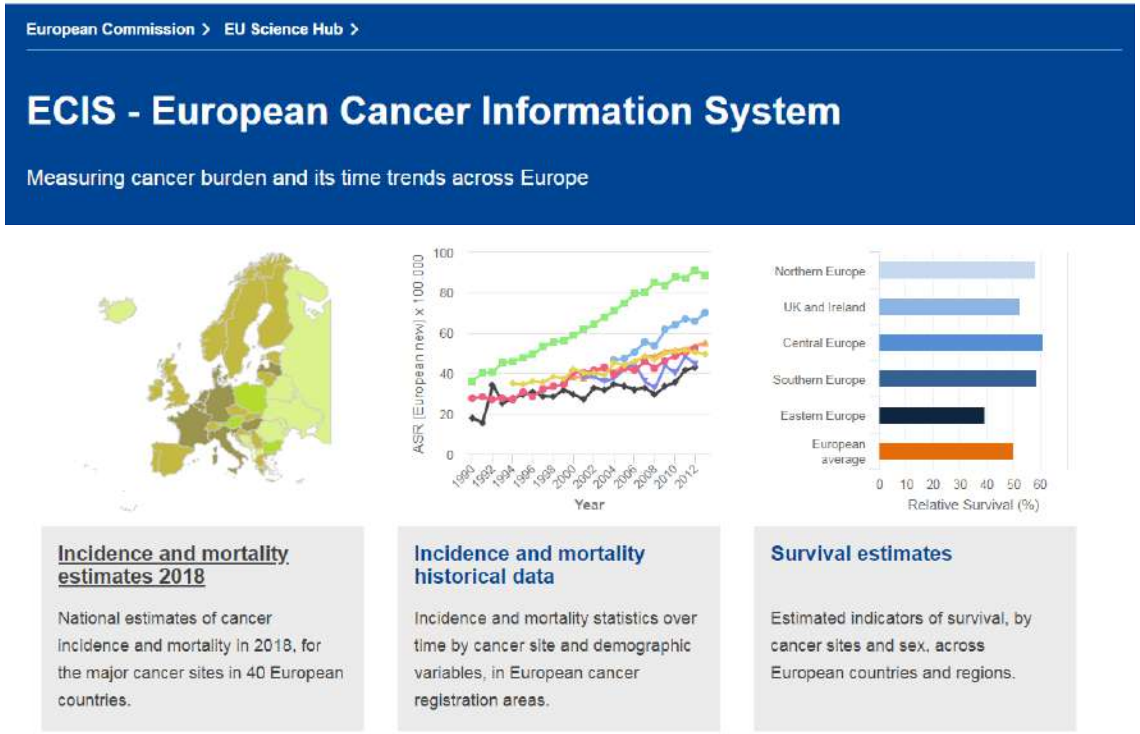
✱ **Data with privacy issues**

⬜ **Data not available**

Main activities of the ENCR

- Standardization & data quality
  - Recommendations & guidelines on coding
  - Promote the use of international classifications, such as from UICC (TNM) , WHO (ICD-O), etc.
  - Trainings
  - Quality check program
- Increase the use of data
  - Bi-annual conference to exchange knowledge
  - ECIS-database
  - Develop cancer-specific factsheets
- Support registries, for example how to implement GDPR

The European Cancer Information System (ECIS)



European Commission > EU Science Hub >

ECIS - European Cancer Information System

Measuring cancer burden and its time trends across Europe

Incidence and mortality estimates 2018

National estimates of cancer incidence and mortality in 2018, for the major cancer sites in 40 European countries.

Incidence and mortality historical data

Incidence and mortality statistics over time by cancer site and demographic variables, in European cancer registration areas.

Survival estimates

Estimated indicators of survival, by cancer sites and sex, across European countries and regions.

www.encr.eu

PANEL: STANDARDS AND INFRASTRUCTURE

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ONCOLOGY DATA SUMMIT – UNLEASHING THE POTENTIAL OF DATA TO IMPROVE CANCER CARE

Panel discussion on standards and infrastructure

Dr. Melinda J Daumont, PhD Director WW HEOR, Oncology, I-Optimise by BMS

RWE, A “MUST-HAVE” IN THE NEW ERA OF DECISION MAKING

	Pre-launch	Post-launch	Indication expansion
	Increasing use of RWE	**Traditional use case** Post-market safety	*Increasing use of RWE*
Regulator	Natural history of disease studies	Evidence to support conditional approval requirements	Prove effectiveness in un-mandated patient groups to support indication expansion
HTA/Payer	Unmet need studies Budget impact and cost effectiveness modelling	Demonstrate RW benefit vs. local comparators Support design and use of novel value based payment mechanisms Determine optimal market access	Evidence to support broader access
HCP & Patients	Identify undiagnosed patients Identify where the product fits within the current SoC	Inform clinical guidelines Identify the use of the right medicine at the right time	Reassure patients and HCPs in using products in new patient populations

Adapted from: M. Gores *et al.* RWE: FROM “NICE TO HAVE” TO “MUST HAVE”, IQVIA whitepaper

I-O OPTIMISE DELIVERS MULTI-STAKEHOLDER INSIGHTS VIA SUSTAINABLE EVIDENCE GENERATION IN LUNG CANCER

International & varied data portfolio

- **Data assets from EU and Canada** enabling cross-country comparisons
- **A fit for purpose approach to data sourcing** with a data portfolio consisting of broad national registries to clinically rich research databases

Multi-stakeholder collaborations

- Multi-stakeholder engagement through the setting up of an external scientific committee, patient voice forum, policy forum and data source owners forum

Powerful research aiming to enable access to the right medicine for the right patient

- **Standardised research protocols** allow cross-evaluation of insights
- Changes in practice over time captured

Sustainable use of RWD

- Upfront investment and resource support to **existing data infrastructure** to improve data quality, operational capabilities and enable better research efficiency for future initiatives.

BETTER ACCESS UNLOCKS UNTAPPED POTENTIAL

Barriers

Immature infrastructure

Fragmentation of data

Lack of trust & poor information governance

Required change

- **Long-term trusted partnerships** with healthcare, to generate evidence to support mutually beneficial objectives
- **Provide upfront investment and resource support** to existing data assets enabling improvement in data quality and operational capabilities

- Improvement of **interoperability of data** sources within EU
- Development of **linkage standards across data sources** within countries and across the EU

- Creation of **consistent methods to analyse heterogeneous data** sources and **ensure patient data privacy**
- Development of **methods to validate data extraction**
- **Multi-stakeholder collaborations** to accelerate the curation of data standards

Untapped potential

Revolutionise how we understand clinical practice

Move from overall survival to overall quality of life through the use of PROs and QoL data

Power the shift towards precision medicine using genomic data

PANEL: STANDARDS AND INFRASTRUCTURE

Otto Visser

Director, Netherlands Cancer Registry & Chair, European Network of Cancer Registries (ENCR)

Melinda J. Daumont

Director, Worldwide Health Economics and Outcomes Research, Oncology, Bristol-Myers Squibb

Fabien Calvo

Chief Scientific Officer, Cancer Core Europe

Nigel Hughes

European Health Data & Evidence Network (EHDEN Initiative)

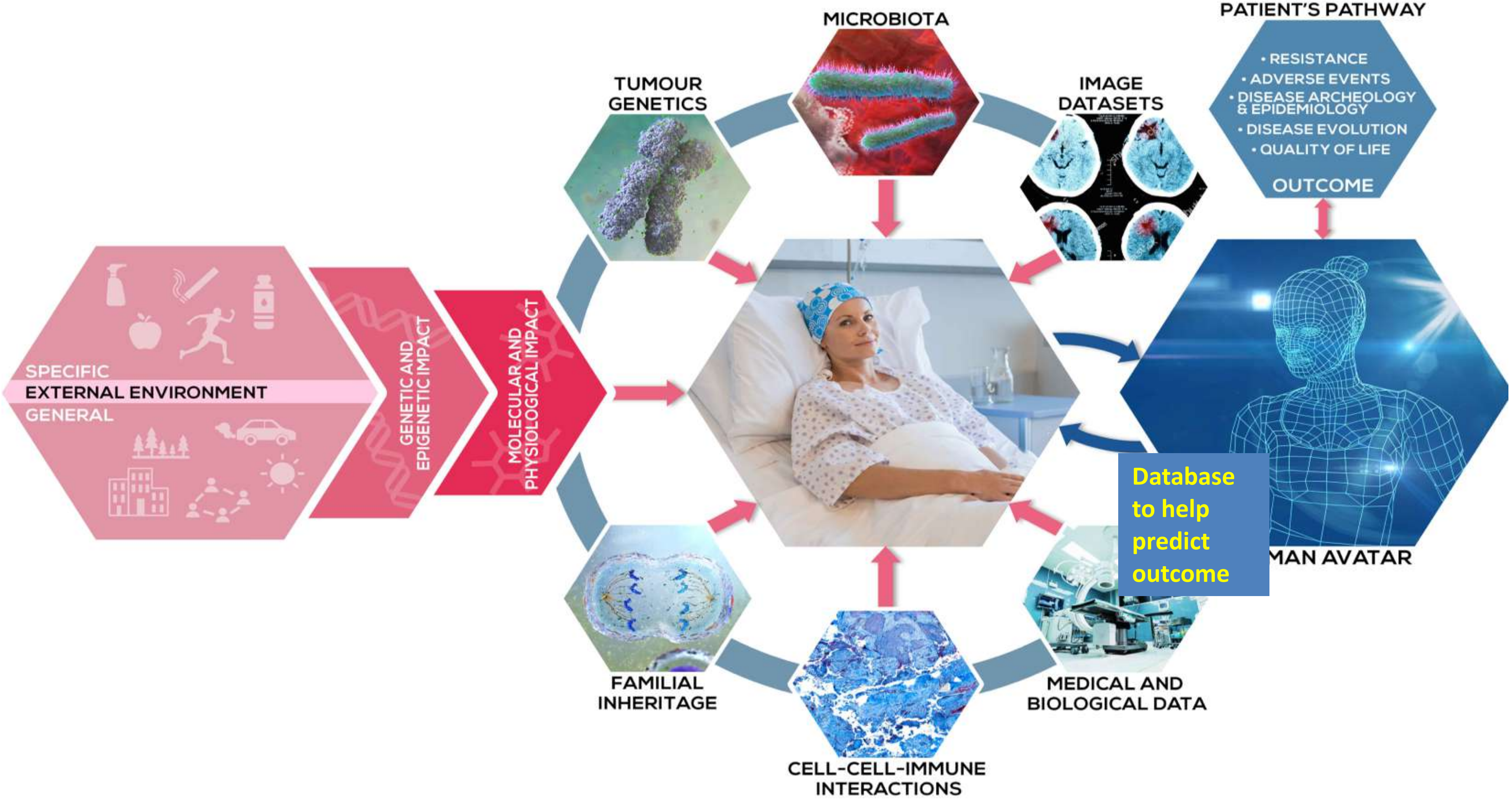
Research Database to Improve Cancer Care

Pr Fabien Calvo,

CSO, Cancer Core Europe

Co founder of ICGC and ICGCmed

Cancer Complexity in the 21st Century needs databases … and good data (+/- completeness but quality +++ !



SPECIFIC

EXTERNAL ENVIRONMENT

GENERAL

GENETIC AND EPIGENETIC IMPACT

MOLECULAR AND PHYSIOLOGICAL IMPACT

TUMOUR GENETICS

MICROBIOTA

IMAGE DATASETS

PATIENT'S PATHWAY

- RESISTANCE
- ADVERSE EVENTS
- DISEASE ARCHEOLOGY & EPIDEMIOLOGY
- DISEASE EVOLUTION
- QUALITY OF LIFE

OUTCOME

MAN AVATAR

FAMILIAL INHERITAGE

CELL-CELL-IMMUNE INTERACTIONS

MEDICAL AND BIOLOGICAL DATA

Database to help predict outcome

ICGC med

A collaborative international (17 countries) project to explore genomic data (25,000 patients, >2,700 with extensive data)

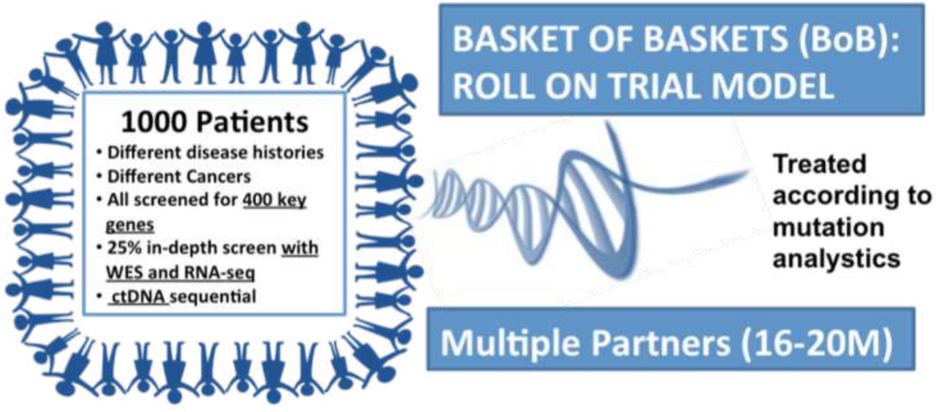
Data Release 28
March 27th, 2019
Cancer projects
86
Cancer primary sites
22
Donor with molecular data in DCC
22,330
Total Donors
24,289
Simple somatic mutations
81,782,588

Data Type	# Donors	# Files	Format	Size
SGV	2,715	8,505	VCF	517.27 GB
StGV	2,715	5,668	VCF	7.29 GB
Aligned Reads	2,793	12,169	BAM	794.42 TB
Simple Somatic Mutations	2,715	25,501	VCF	189.99 GB
Copy Number Somatic Mutations	2,715	5,671	VCF	132.62 MB
Structural Somatic Mutations	2,715	14,195	VCF	1.61 GB

The Data Access Compliance Office accepts applications from researchers for access to Controlled Data: 1- Register 2- Fill an application 3- submit to DACO – Next step is ICGC ARGO

Cancer Core Europe

Clinical trial quality controlled: History- evolution- Genomics- immunobiology-mes



BASKET OF BASKETS (BoB): ROLL ON TRIAL MODEL

1000 Patients
- Different disease histories
- Different Cancers
- All screened for 400 key genes
- 25% in-depth screen with WES and RNA-seq
- ctDNA sequential

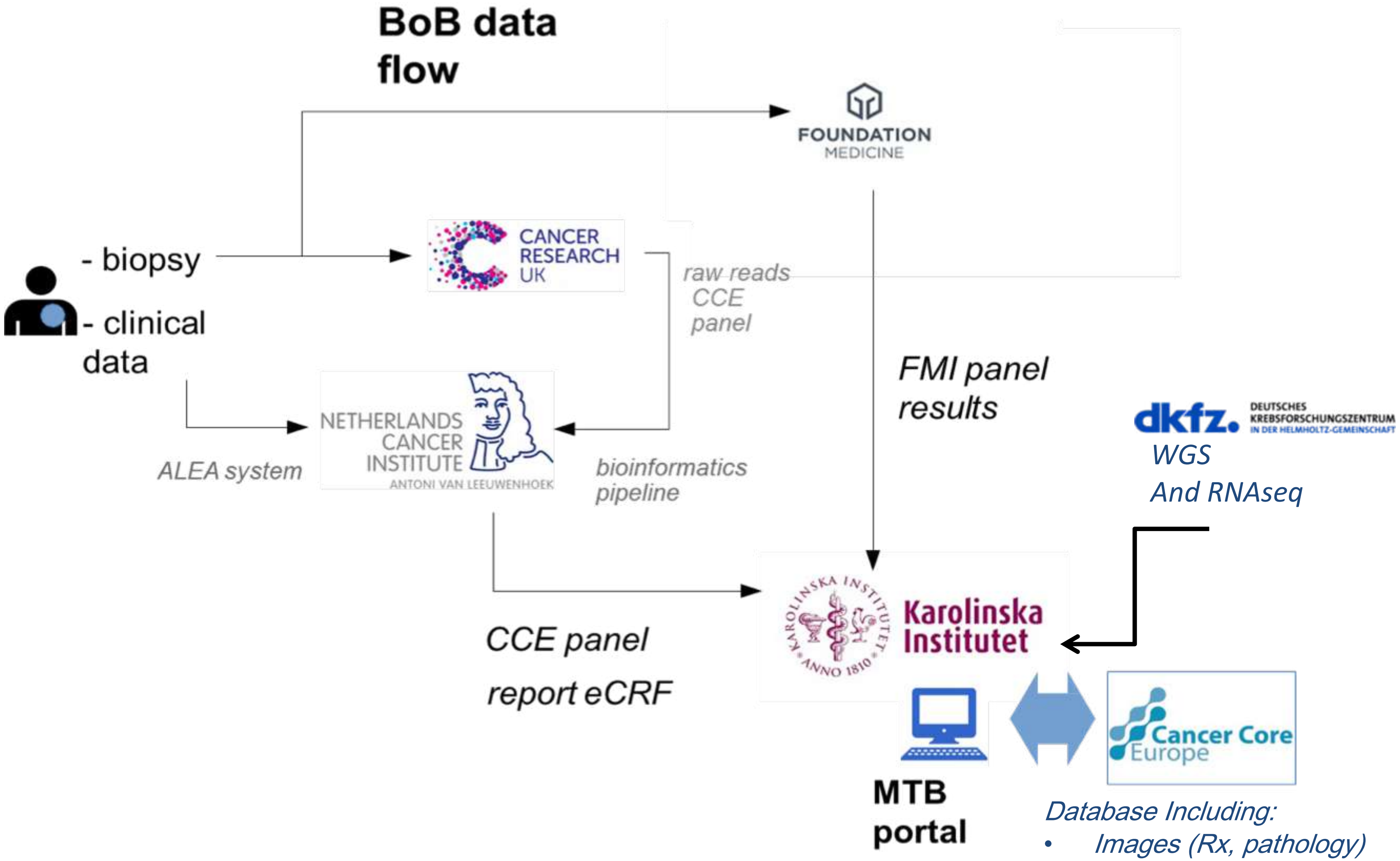
Treated according to mutation analystics

Multiple Partners (16-20M)

Mutations in MAPK pathways	Pan Raf Ki
Mutations in PI3K-AKT-mTOR pathways	PIK3CAi, AKTi, Pan Raf Ki
Mutations in MET	Met i
Hypermutation and repair defects in tumours	Anti-PDL1 + others
Mutations in FGFR	FGFRi

- ➢ Clinically-annotated Genomic Database
- ➢ Companion Diagnostics
- ➢ Cancer Core Europe Translational Research
- ➢ Fast conclusions for efficacy with limited numbers of patients
- ➢ **Open to new targets/ drugs when discovered**

Basket of Basket data flow



BoB data flow

- biopsy

- clinical data

ALEA system

raw reads CCE panel

bioinformatics pipeline

FMI panel results

CCE panel report eCRF

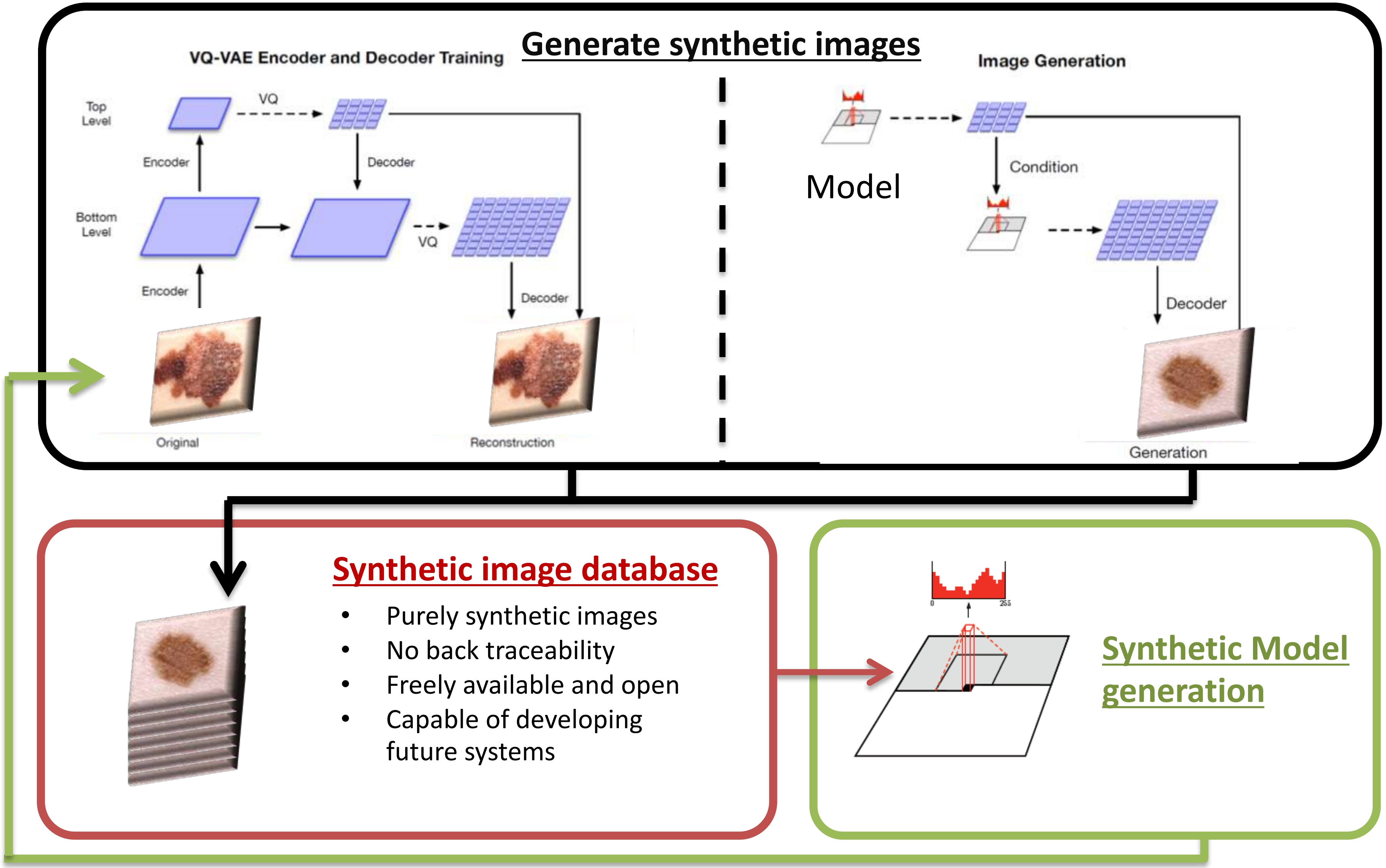
WGS
And RNAseq

MTB portal

Database Including:

- *Images (Rx, pathology)*
- *Immunobiology*
- *outcomes*

Artificial Intelligence may contribute in reducing the burden of data sharing through artificial datasets



Generate synthetic images

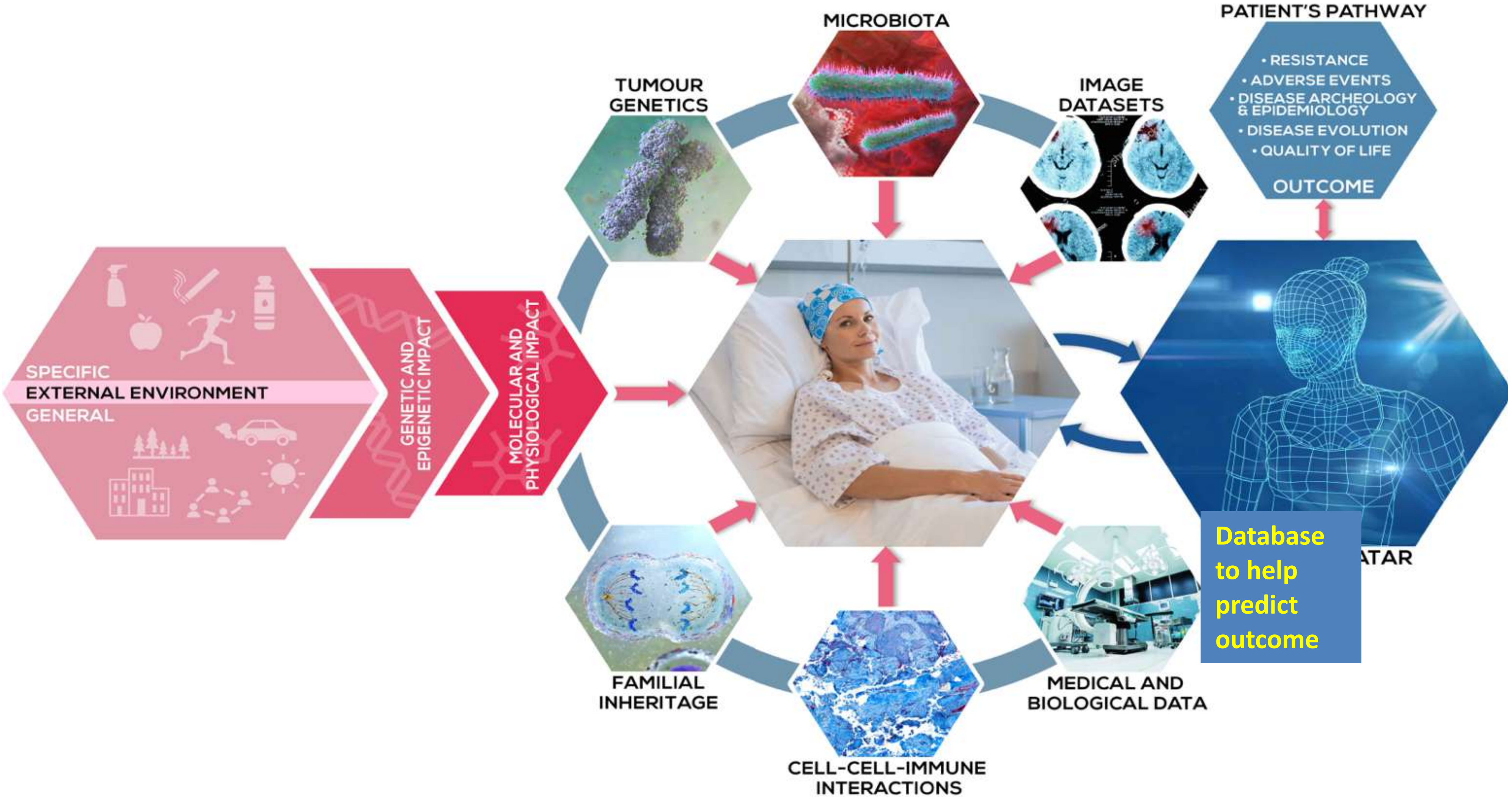
Synthetic image database

- Purely synthetic images
- No back traceability
- Freely available and open
- Capable of developing future systems

Synthetic Model generation

Validation with the original images

Cancer Complexity in the 21st Century needs databases … and good data (+/- completeness but quality +++ !

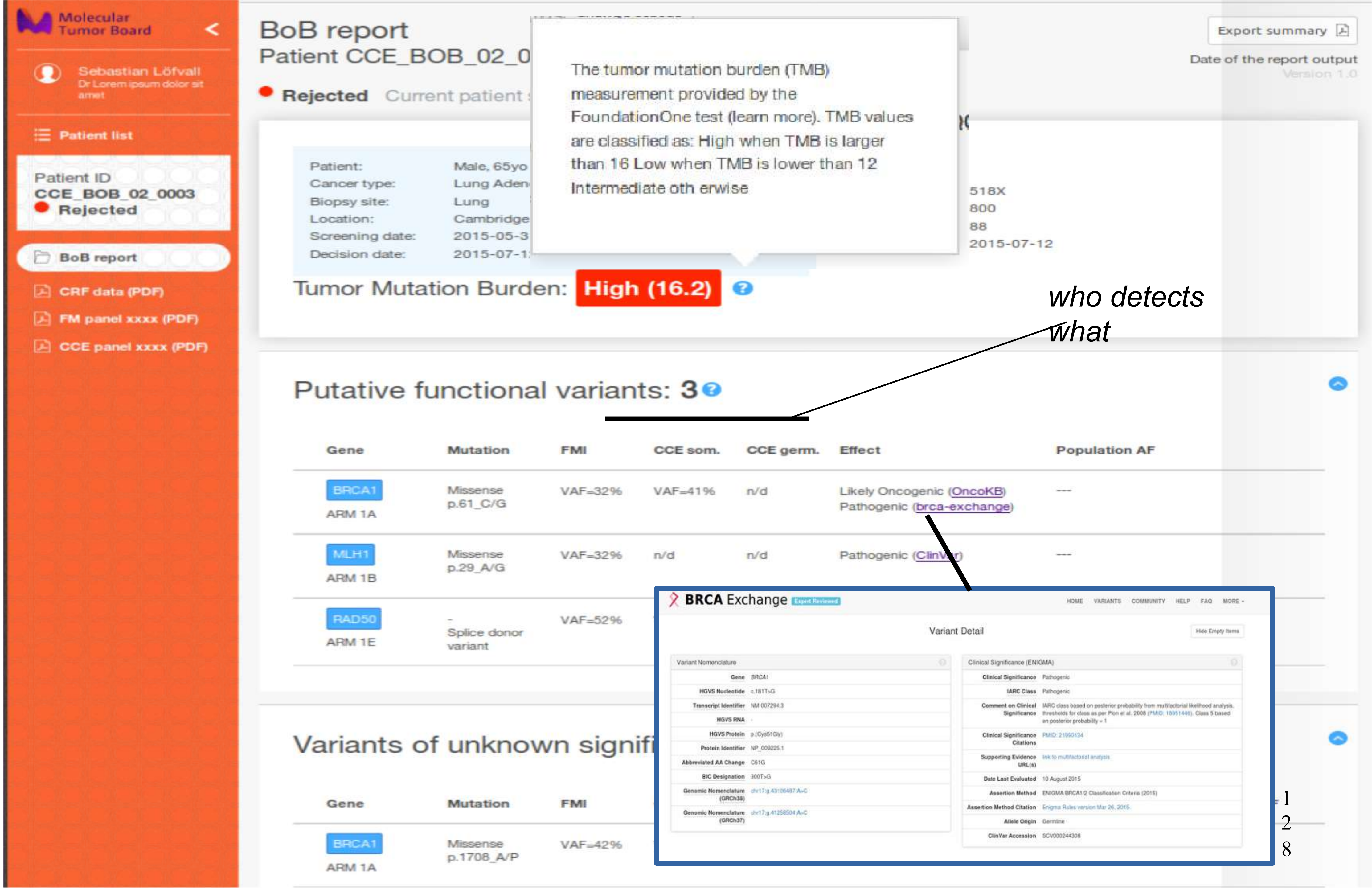


Database to help predict outcome

Cancer is not only genomics: immunity, metabolism, exposome, genetics, lifestyle, outcomes … are to be present and explored in databases

Access to data

- Restricted to clinicians- geneticists- biologists of CCE until the completion of each clinical trial module
- Open to researchers through a Data Access committee (authorization through request - different levels)
- With the aim of making it public 6 Mo end of each module
- Inclusion of 1000 patients each year in an evolutive clinical trial (addition of different modules and different arms) – several years
- Additional projects through specific challenges
- Main difficulties related to variability of GDPR understanding accross countries (found solutions…)
- Inclusion of AI projects, imaging, immunity, genomics… through data addition
- Cancer is not only genomics: immunity, metabolism, exposome, genetics, lifestyle … are to be present in data



Patient ID
CCE_BOB_02_0003
Rejected

BoB report
Patient CCE_BOB_02_0

Rejected Current patient

Date of the report output
Version 1.0

Patient:	Male, 65yo
Cancer type:	Lung Aden
Biopsy site:	Lung
Location:	Cambridge
Screening date:	2015-05-3
Decision date:	2015-07-1

518X
800
88
2015-07-12

The tumor mutation burden (TMB) measurement provided by the FoundationOne test (learn more). TMB values are classified as: High when TMB is larger than 16 Low when TMB is lower than 12 Intermediate oth erwise

Tumor Mutation Burden: High (16.2)

who detects what

Putative functional variants: 3

Gene	Mutation	FMI	CCE som.	CCE germ.	Effect	Population AF
BRCA1 ARM 1A	Missense p.61_C/G	VAF=32%	VAF=41%	n/d	Likely Oncogenic (OncoKB) Pathogenic (brca-exchange)	---
MLH1 ARM 1B	Missense p.29_A/G	VAF=32%	n/d	n/d	Pathogenic (ClinVar)	---
RAD50 ARM 1E	- Splice donor variant	VAF=52%				

Variants of unknown signifi

Gene	Mutation	FMI
BRCA1 ARM 1A	Missense p.1708_A/P	VAF=42%

BRCA Exchange

Variant Detail

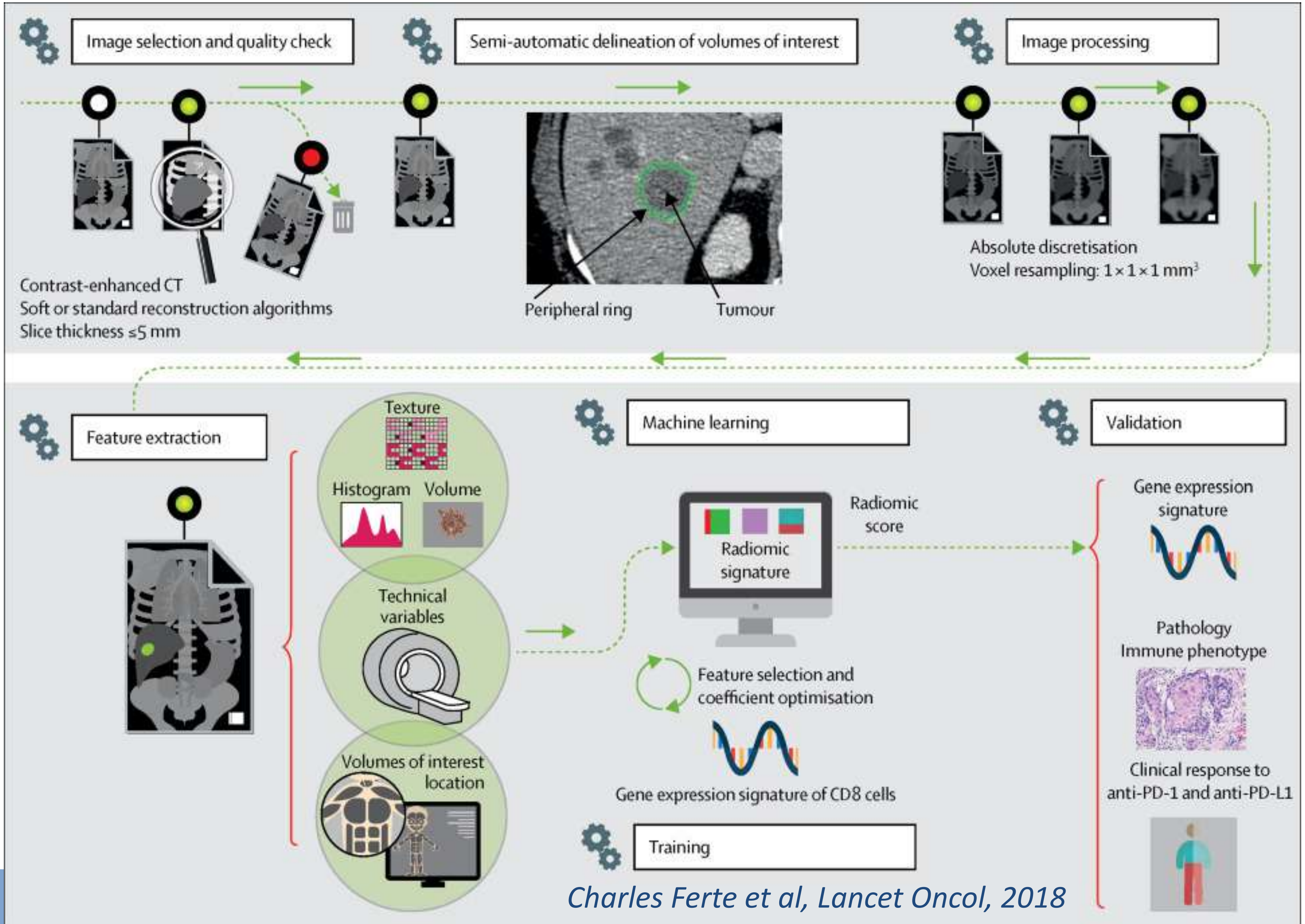
Variant Nomenclature

Gene	BRCA1
HGVS Nucleotide	c.181T>G
Transcript Identifier	NM 007294.3
HGVS RNA	-
HGVS Protein	p.(Cys61Gly)
Protein Identifier	NP_009225.1
Abbreviated AA Change	C61G
BIC Designation	300T>G
Genomic Nomenclature (GRCh38)	chr17:g.43106487:A>C
Genomic Nomenclature (GRCh37)	chr17:g.41258504:A>C

Clinical Significance (ENIGMA)

Clinical Significance	Pathogenic
IARC Class	Pathogenic
Comment on Clinical Significance	IARC class based on posterior probability from multifactorial likelihood analysis. thresholds for class as per Plon et al. 2008 (PMID: 18951446). Class 5 based on posterior probability = 1
Clinical Significance Citations	PMID: 21990134
Supporting Evidence URL(s)	link to multifactorial analysis
Date Last Evaluated	10 August 2015
Assertion Method	ENIGMA BRCA1/2 Classification Criteria (2015)
Assertion Method Citation	Enigma Rules version Mar 26, 2015.
Allele Origin	Germline
ClinVar Accession	SCV000244308

Artificial Intelligence may contribute in reducing the burden of data sharing through artificial datasets



Charles Ferte et al, Lancet Oncol, 2018

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EHDEN

EUROPEAN HEALTH DATA & EVIDENCE NETWORK

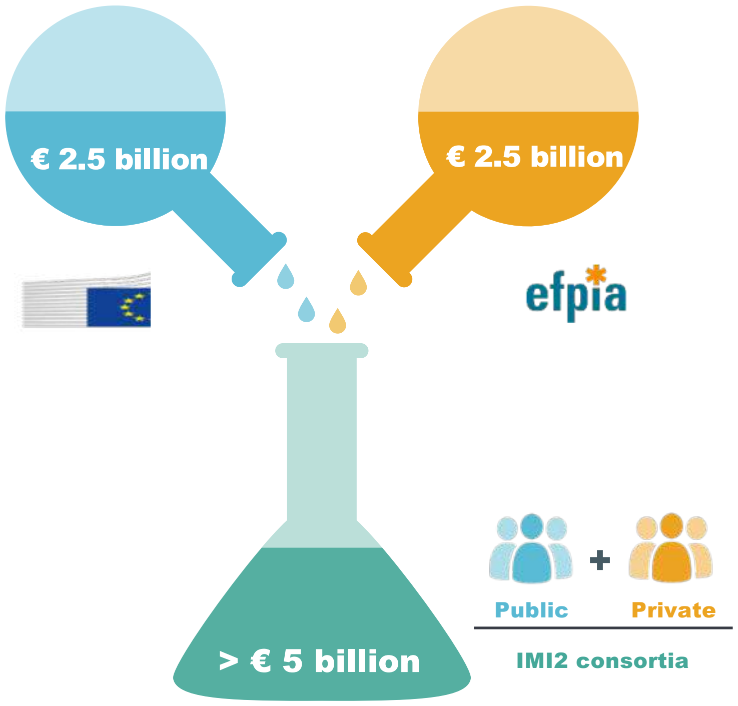
EFPIA Oncology Data Summit

Nigel Hughes 18th September 2019

imi innovative medicines initiative efpia

INNOVATIVE MEDICINES INITIATIVE

www.imi.europa.eu



€ 2.5 billion

€ 2.5 billion

efpia

Public + Private

IMI2 consortia

> € 5 billion

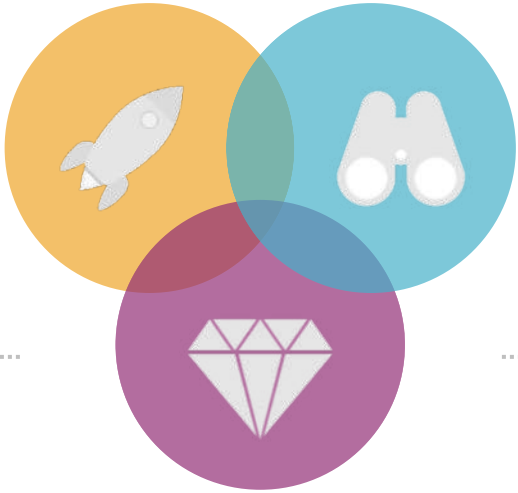
Carlos Moedas

EU commissioner for research, science and innovation

*"**Radical collaboration** where multinational companies work together and share data instead of keeping it secret is helping to change the model of the pharmaceutical industry and solve problems more quickly." (Source)*

- Accelerate research and development.
- Speed up patient access to innovative treatments.
- Improve patient outcomes and safety of medicines.

MISSION & VISION



Mission

Develop a federated network, standardised to a common data model that more smartly manages and shares research methodologies, and expands education in open science and collaboration.

Vision

The European Health Data & Evidence Network (EHDEN) aspires to be the trusted observational research ecosystem to enable **better health decisions, outcomes and care**

Values

- Community
- Education
- Sustainability
- Open science
- Quality
- Inclusiveness

FOUNDATIONAL PILLARS

Infrastructure

Creation of an **EU-wide** federated network architecture

Privacy by design

Data harmonisation to the OMOP common data model

Training & certification of **SMEs**

Research & Outcomes

Use cases to evaluate the EHDEN federated network

Collaboration on consistent **methodologies**

Collaboration with the global **OHDSI** research network

Incorporation of the **ICHOM** health outcome standards

Education & Community

Establishment of an **EHDEN Academy**

Expansion of the **OHDSI network** in Europe

Collaboration on **collective memory** for research use cases

EHDEN CONSORTIUM

Start date: 1 Nov 2018
End date: 30 Apr 2024
Duration: 66 months

22 partners

Almost €29 million

Universities, public bodies and research organisations

Erasmus MC
Universitair Medisch Centrum Rotterdam

Academic coordinator

Uppsala Monitoring Centre

universidade de aveiro

NICE
National Institute for Health and Care Excellence

Universitas Tartuensis 1632

University of Oxford

SME & Mid-sized companies

SYNAPSE
Research Management Partners

thehyve

Non-profit organisations

EPF
European Patients Forum

ICHOM

EFPIA & Associated partners

Janssen
Pharmaceutical Companies of Johnson & Johnson

EFPIA Lead

Bayer

Celgene

Pfizer

abbvie

AstraZeneca

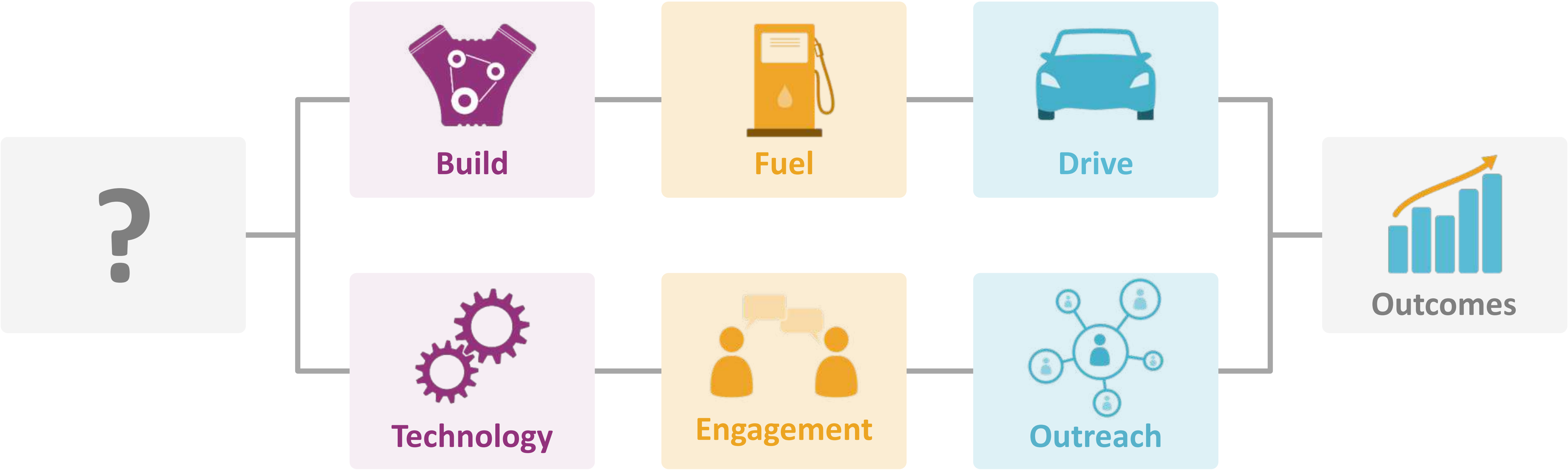
Sanofi

ucb

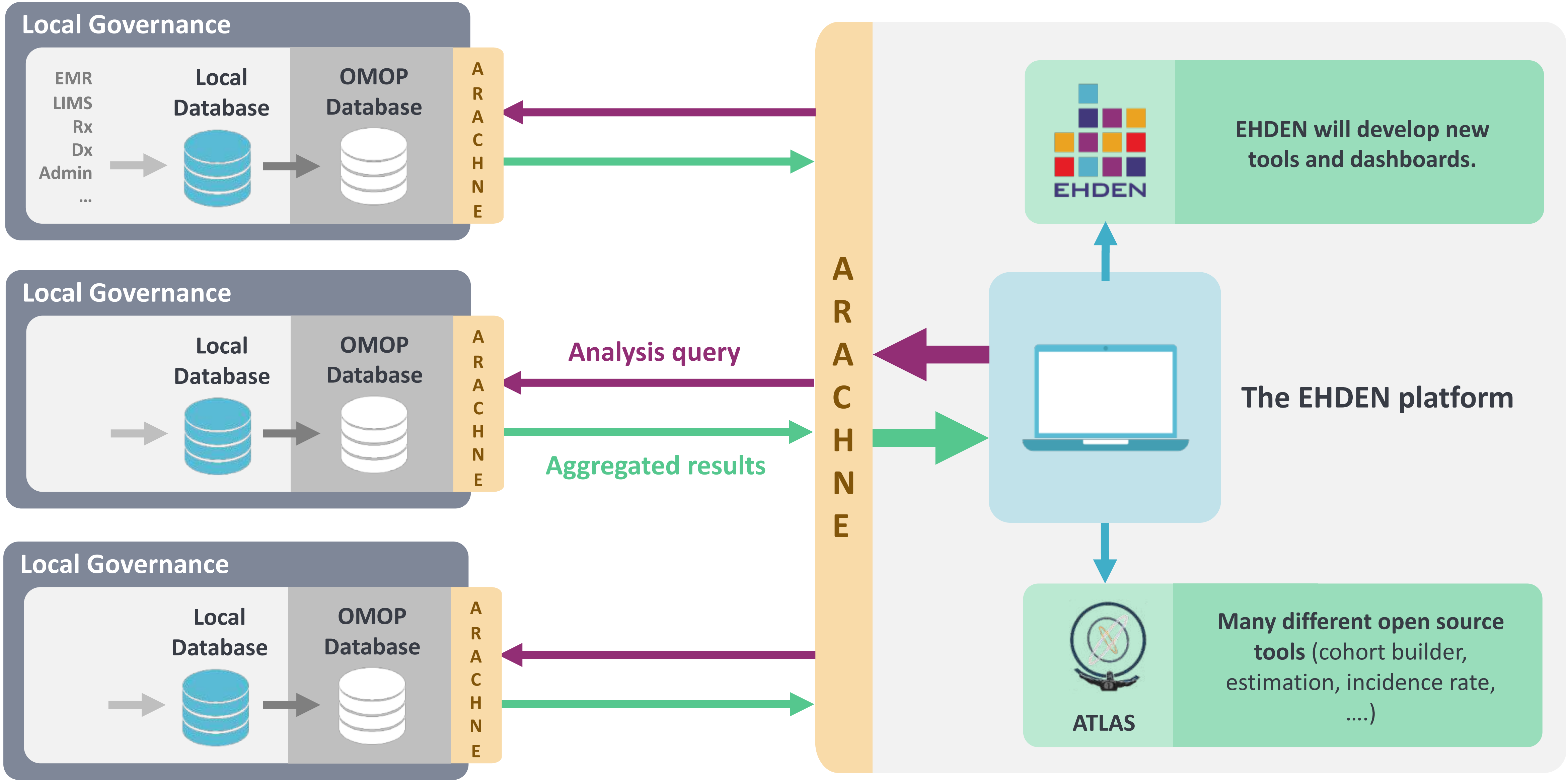
Novartis

Servier

KEY COMPONENTS FOR EHDEN



THE EHDEN FEDERATED DATA NETWORK



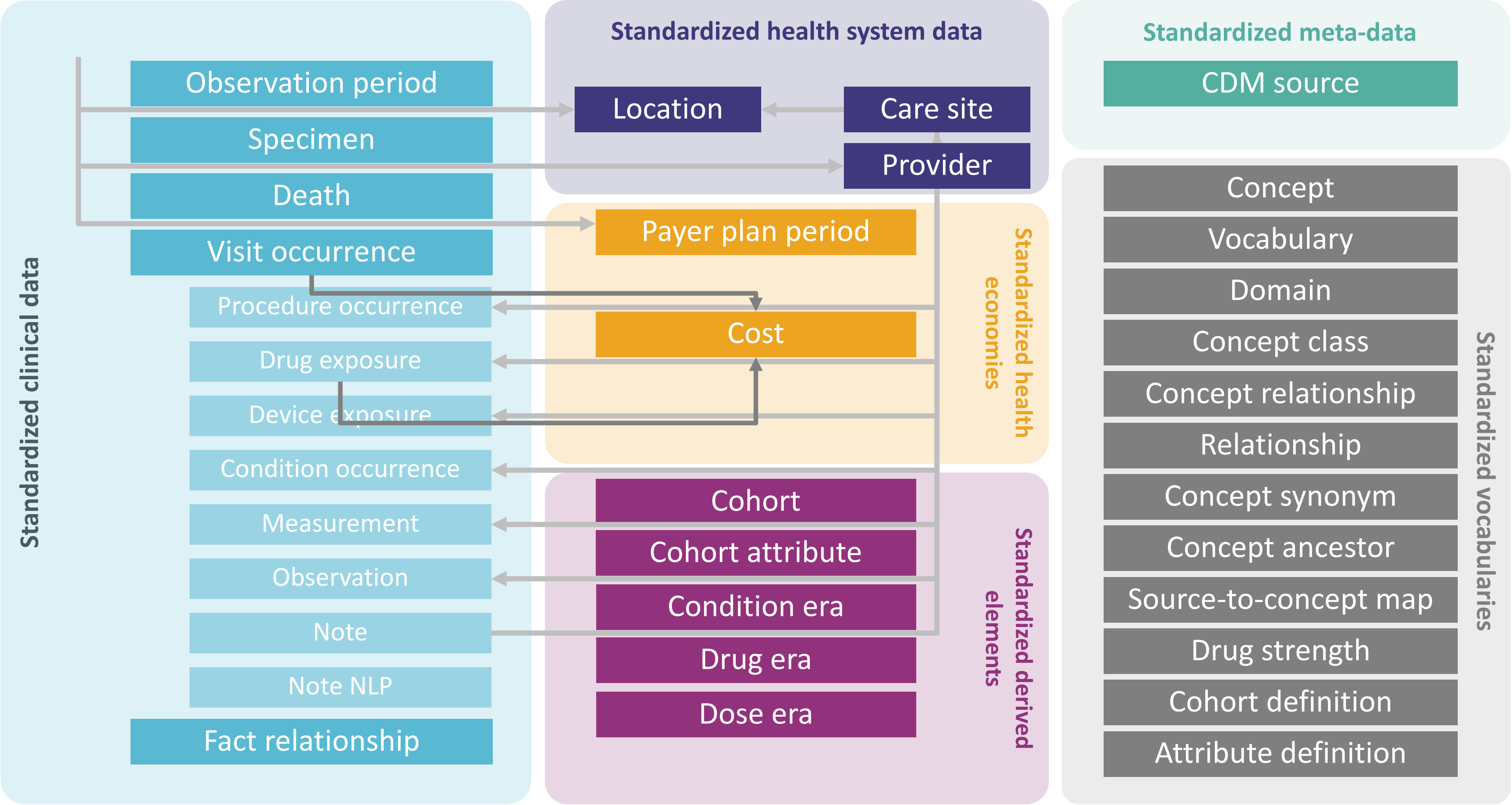
EHDEN will develop new tools and dashboards.

The EHDEN platform

Many different open source tools (cohort builder, estimation, incidence rate, ….)

THE OMOP COMMON DATA MODEL

v 5.0.1



Standardized clinical data

- Observation period
- Specimen
- Death
- Visit occurrence
  - Procedure occurrence
  - Drug exposure
  - Device exposure
  - Condition occurrence
  - Measurement
  - Observation
  - Note
  - Note NLP
- Fact relationship

Standardized health system data

- Location
- Care site
- Provider

Standardized health economies

- Payer plan period
- Cost

Standardized derived elements

- Cohort
- Cohort attribute
- Condition era
- Drug era
- Dose era

Standardized meta-data

- CDM source

Standardized vocabularies

- Concept
- Vocabulary
- Domain
- Concept class
- Concept relationship
- Relationship
- Concept synonym
- Concept ancestor
- Source-to-concept map
- Drug strength
- Cohort definition
- Attribute definition

Patient-centric

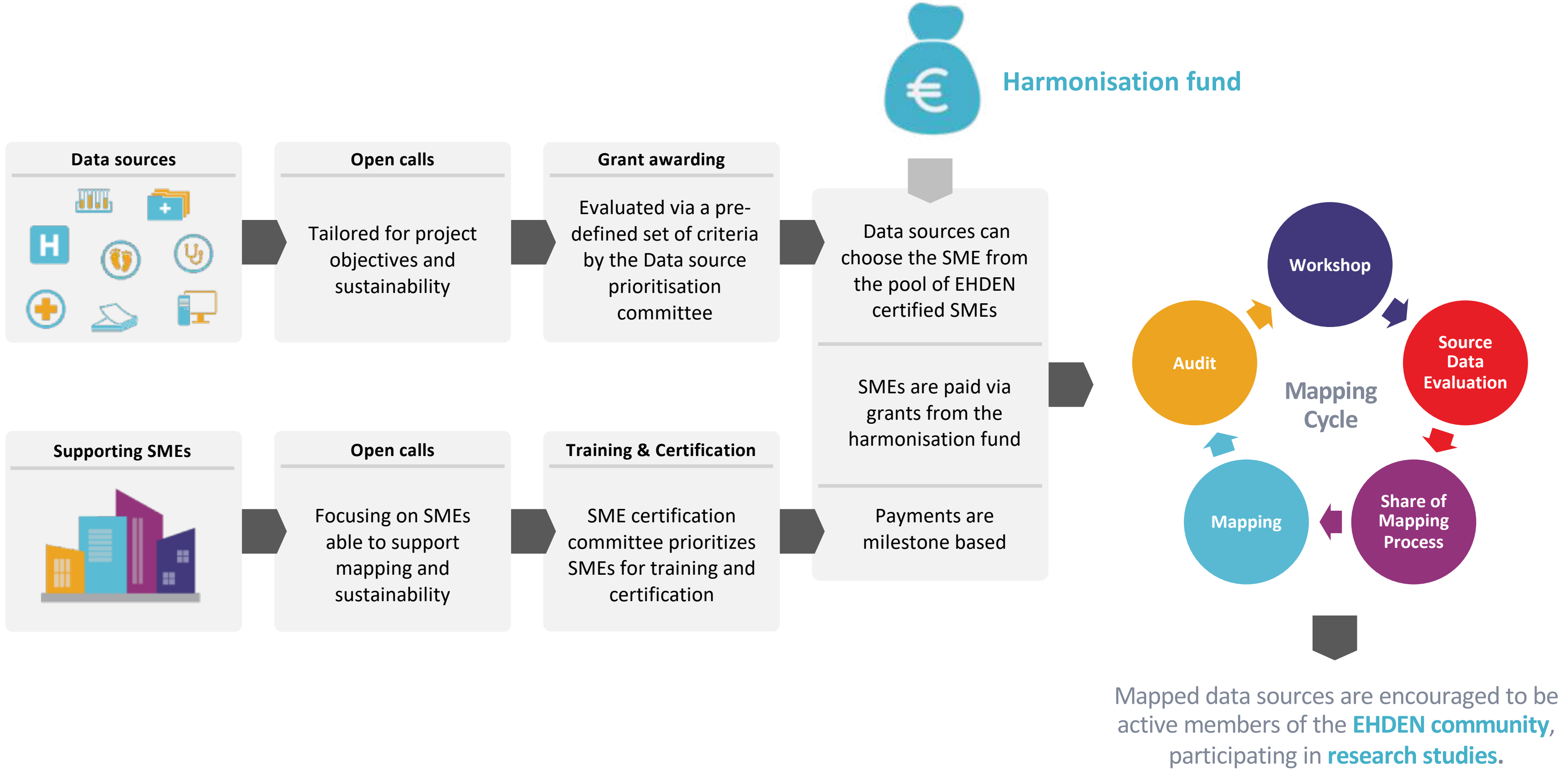
Tabular

Extendable

Built for analytics

Relational design

CALL PROCESS OVERVIEW



Harmonisation fund

Data sources

Open calls

Tailored for project objectives and sustainability

Grant awarding

Evaluated via a pre-defined set of criteria by the Data source prioritisation committee

Data sources can choose the SME from the pool of EHDEN certified SMEs

SMEs are paid via grants from the harmonisation fund

Payments are milestone based

Supporting SMEs

Open calls

Focusing on SMEs able to support mapping and sustainability

Training & Certification

SME certification committee prioritizes SMEs for training and certification

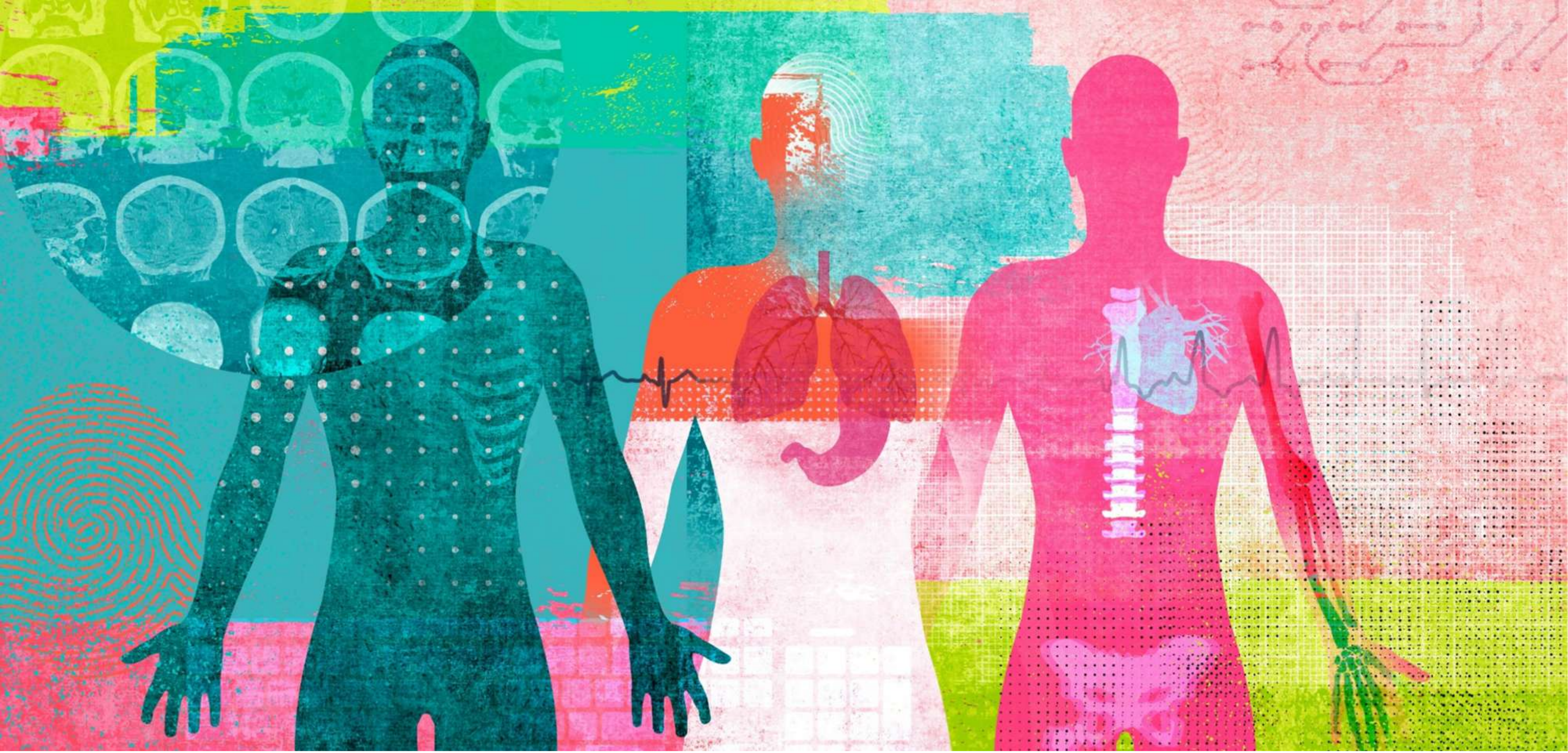
Mapped data sources are encouraged to be active members of the **EHDEN community**, participating in **research studies.**

EHDEN: 21ST CENTURY REAL WORLD RESEARCH

EHDEN is a bold step in recognising that a **flagship project** is needed to address conducting real world research for the 21st century

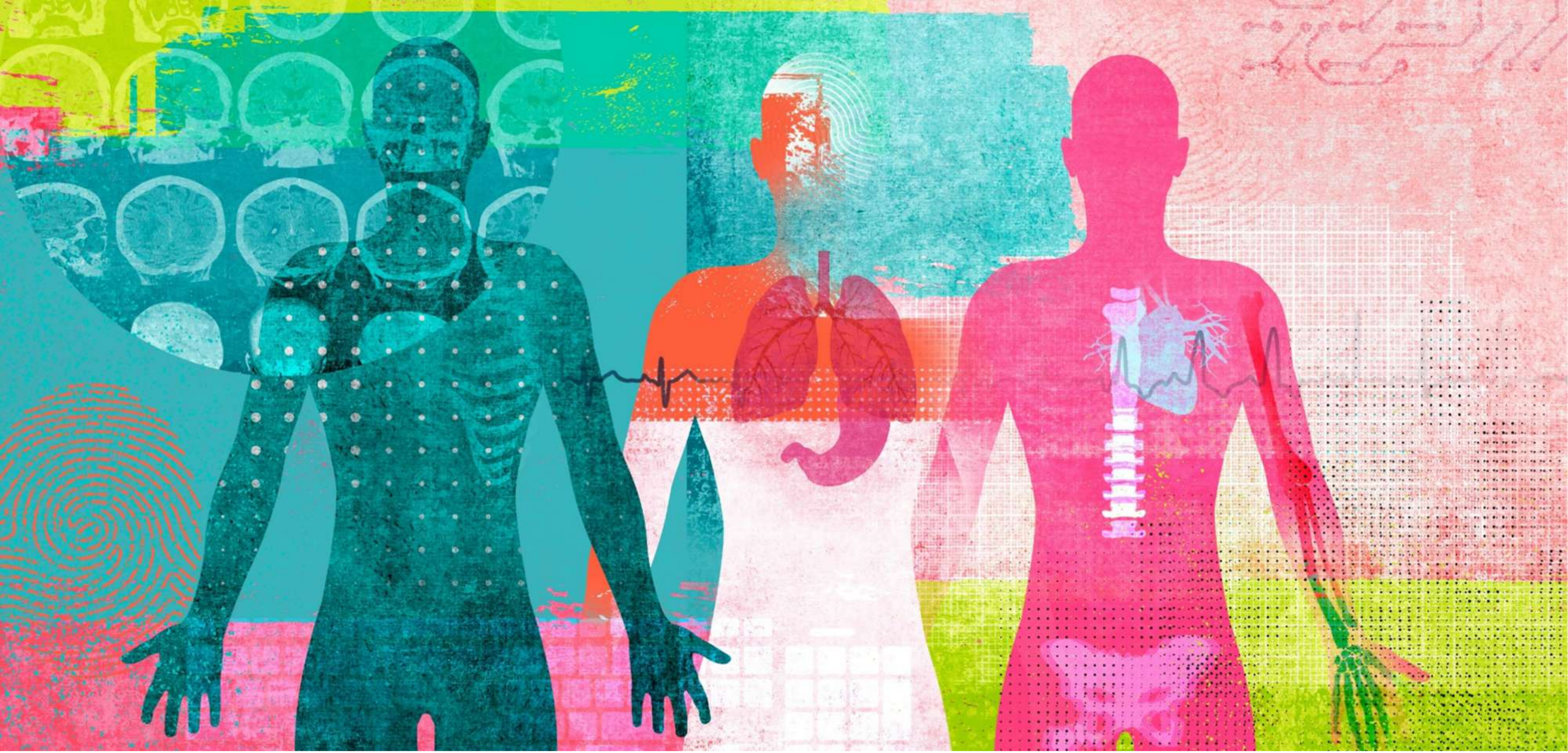
At its heart is the acknowledgement that we need to develop a **community** via a **federated network**, within an ecosystem, all based on a quid pro quo around data for research use

The **Open Science/Open Source** community of **OHDSI**, and the OMOP CDM, are critical enablers and partners for EHDEN in this endeavour



QUESTIONS & ANSWERS

#OncologyDataSummit



SPOTLIGHT ON THE USE OF DATA

#OncologyDataSummit

PANEL: ACCEPTANCE OF REAL-WORLD DATA BY REGULATORS & HTA

Nicole Mahoney

Senior regulatory policy Director, Flatiron Health

Ritu Nalubola

Director, Food and Drug Administration (FDA) Europe Office

Flora Musuamba Tshinanu

Vice Chair Person, European Medicine Agency (EMA) Scientific Advice Working Party & Pharmacometrics Expert, Federal Agency for Medicines and Health Products (Belgium)

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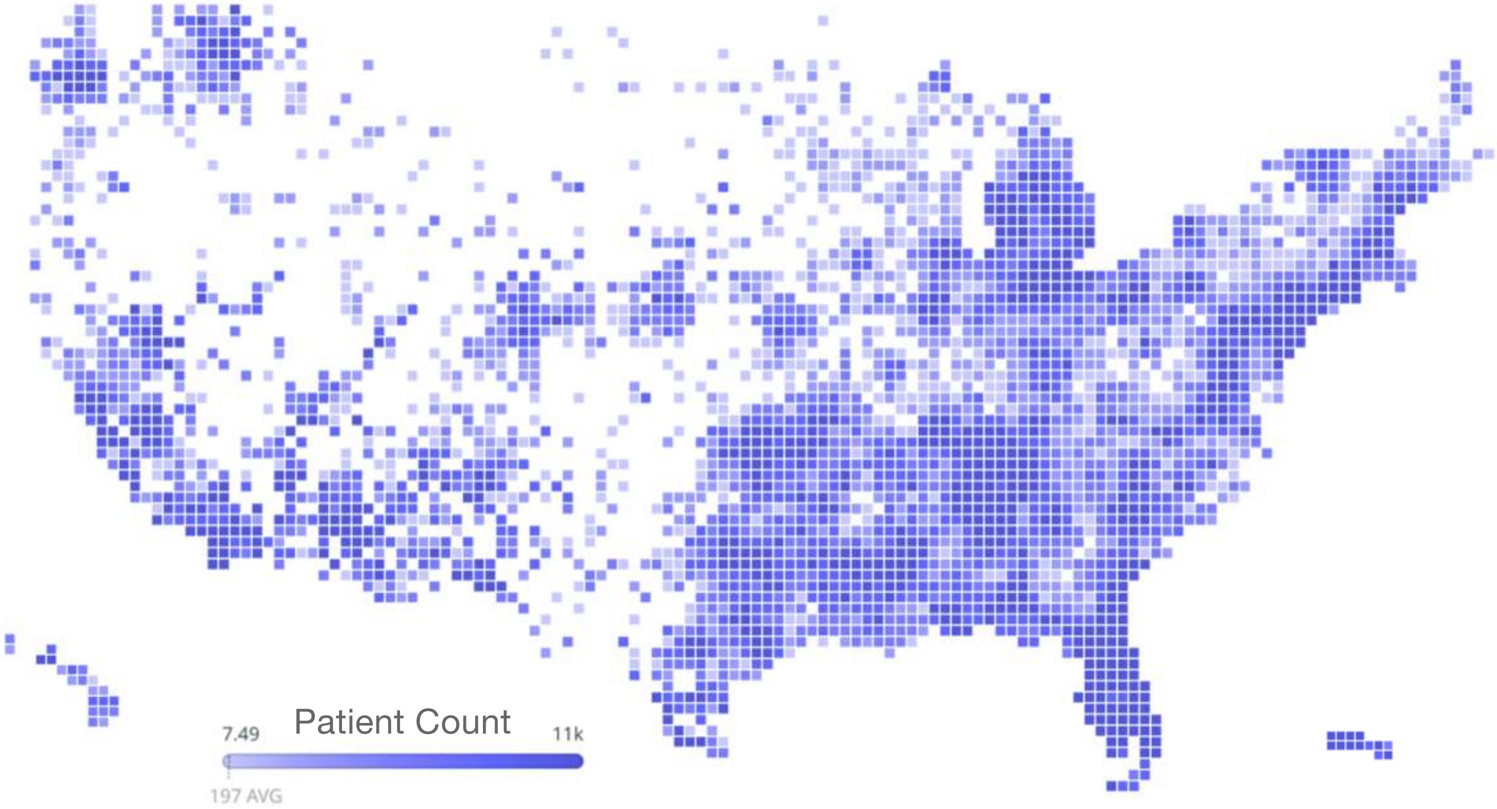
Acceptance of Real World Data for Use by Regulators and HTA

Nicole Mahoney, Ph.D.
Senior Director, Regulatory Policy
Flatiron Health
https://flatiron.com/

flatiron

The Flatiron Network



2.2M
Active Patients

2,500+
Clinicians

280
Cancer Clinics

800
Unique Sites of Care

RWD from EHRs can help support regulatory decisions

New Filing

Label Update or Expansion

Post-Marketing Studies

To provide disease context/natural history

To characterize unmet need

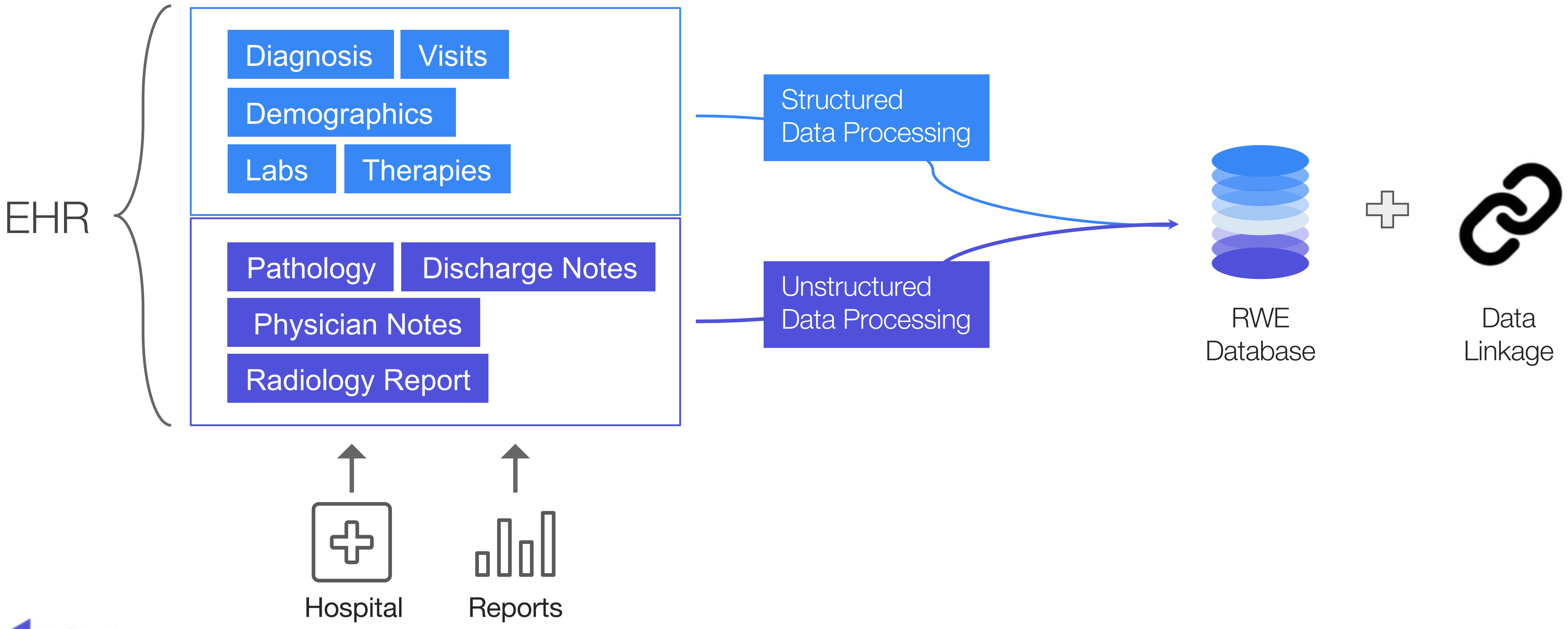
To evaluate safety and/or effectiveness

To compare or provide context for a treatment arm in single arm trial

To modify indication (e.g., dose)

Provided that the data is relevant, well-characterized, reliable and fit-for-purpose

High-quality data collection, curation and characterization



EHR

Diagnosis

Visits

Demographics

Labs

Therapies

Pathology

Discharge Notes

Physician Notes

Radiology Report

Structured Data Processing

Unstructured Data Processing

RWE Database

Data Linkage

Hospital

Reports

flatiron

© Flatiron Health 2017

Transparent quality assurance & control processes

Upfront

- Feasibility
- Policies & Procedures
- Training & Testing

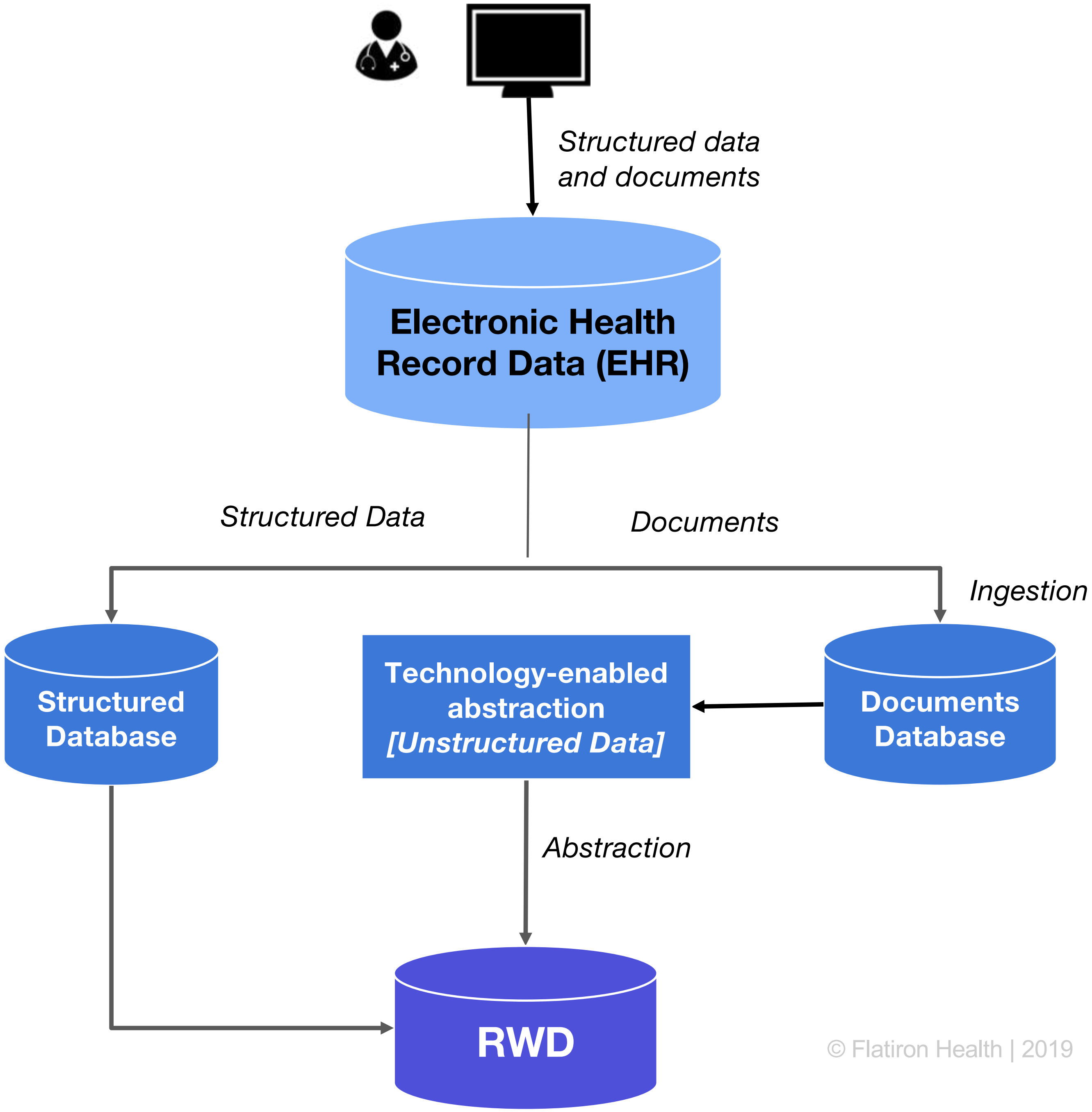
Ongoing

- Auditing & Monitoring
- Performance Management
- Review Panel

Dataset QA

- Cohort QA
- Data Alignment
- Clinical Assertions

Traceability back to source data



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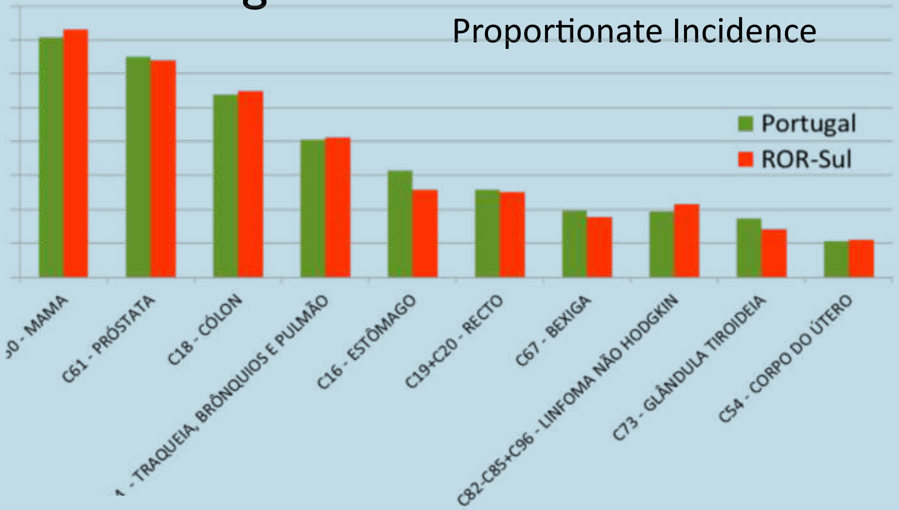
- Same functions wider coverage

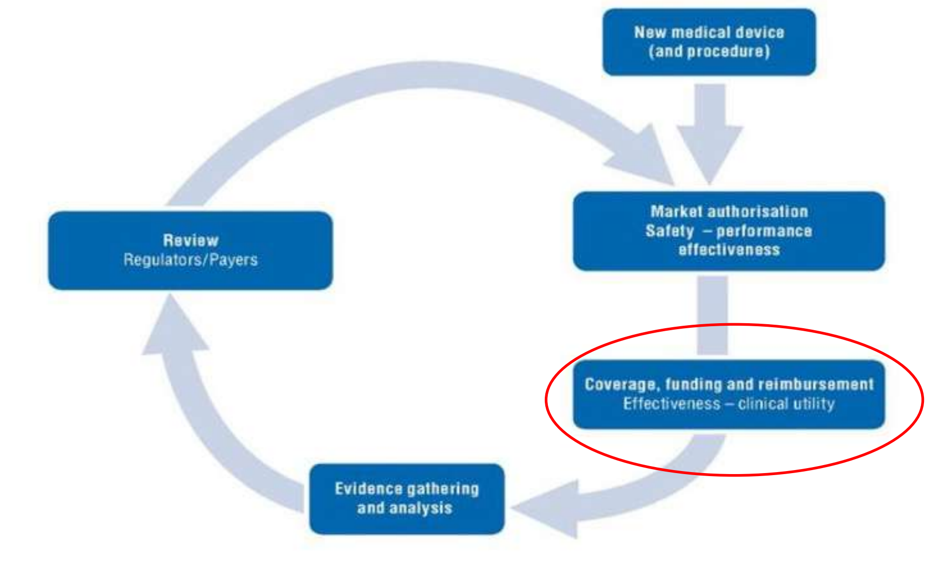
Lei n.º 53/2017

Cria e regula o Registo Oncológico Nacional

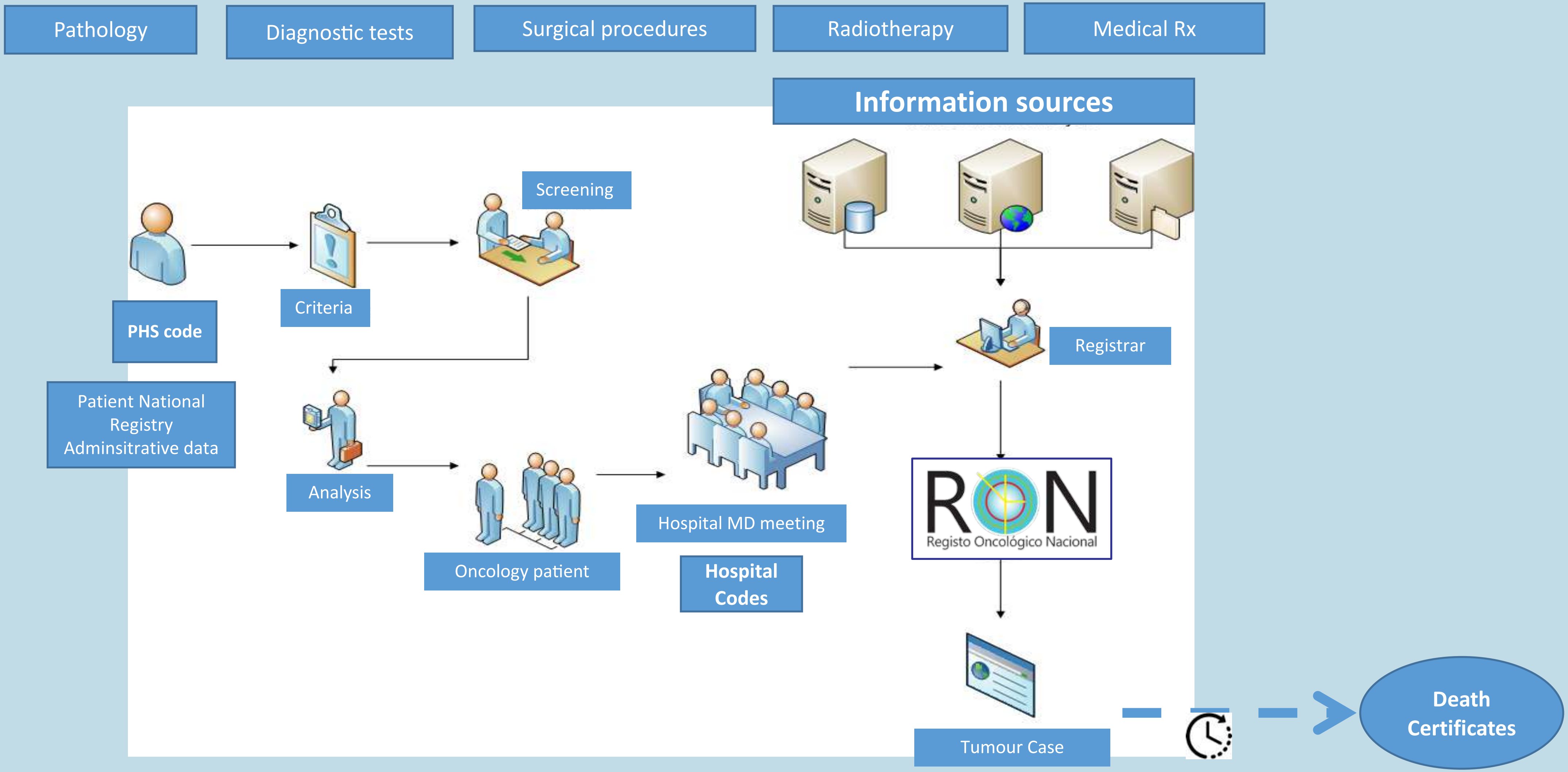


- New functions

Figure 4.1. **Illustration of the regulatory cycle**



New Health Technologies *Managing Access, Value and Sustainability.*
DOI:https://dx.doi.org/10.1787/9789264266438-en



Pathology

Diagnostic tests

Surgical procedures

Radiotherapy

Medical Rx

Information sources

Screening

PHS code

Criteria

Patient National Registry Adminsitrative data

Registrar

Analysis

Oncology patient

Hospital MD meeting

Hospital Codes

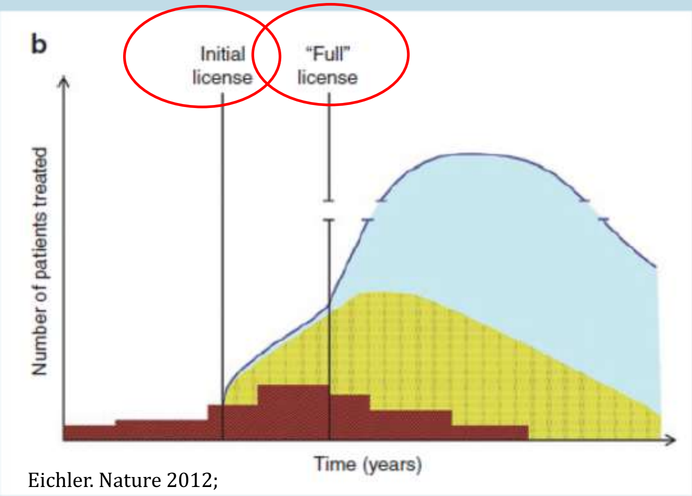
RON Registo Oncológico Nacional

Tumour Case

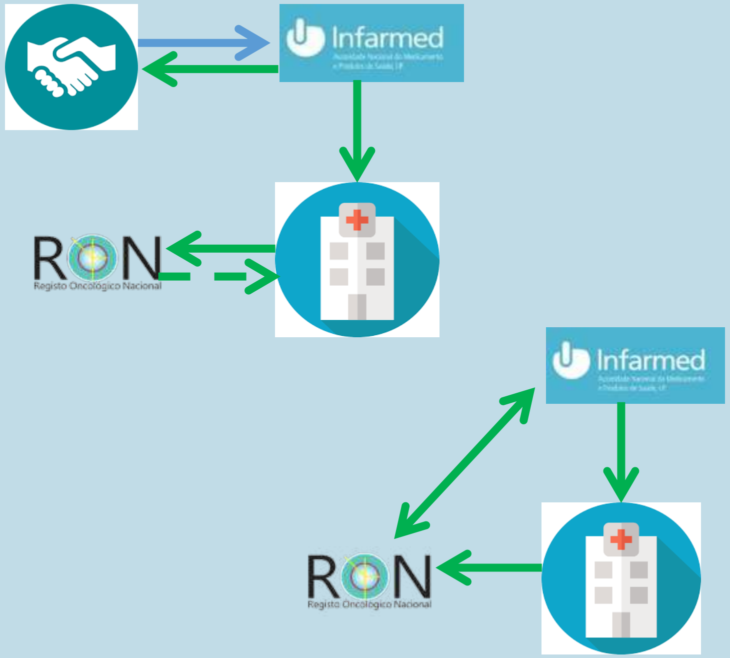
Death Certificates

SNS SERVIÇO NACIONAL DE SAÚDE

RON Registo Oncológico Nacional

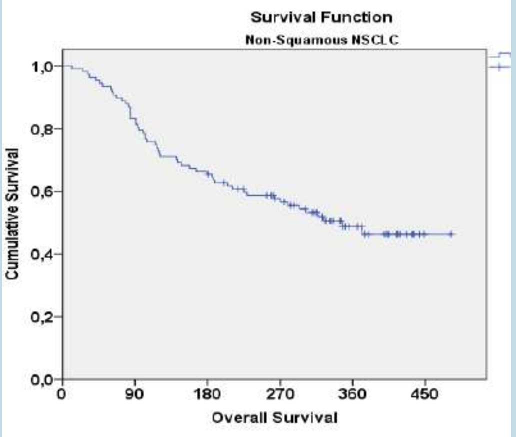


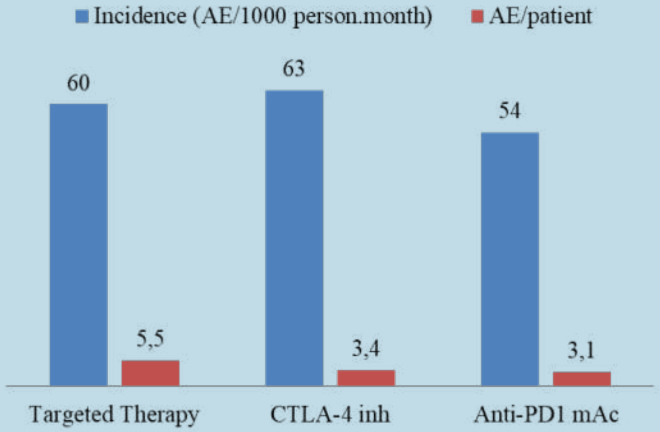
Eichler. Nature 2012;



*Median **Overall survival** among exposed patients was **11.4 months**, slighly inferior to that reported in published clinical trials (**12.2 months**). However, the characteristics of patients in our sample indicate they had a **worse prognosis**.*

Borghaei et al. N Engl J Med 2015





42 (11.6%) AEs not described in SmPCs

OUTCOMES	KEYNOTE-006 (n=277)	RON (n=125)
OS, median ($_{95\%}$ CI) 1-year OS*	Not reached 68.4%	16.6 months (11.8; 31.0) 58.0%
PFS, median** ($_{95\%}$ CI)	4.1 months (2.9; 7.2)	4.7 months (3.8; 6.7)
ORR ($_{95\%}$ CI)**	36.0% (30.0%-42.0%)	28.0% (20.3%-36.7%)
EFS, median ($_{95\%}$ CI) 1-year EFS	Not available	4.2 months
AE, n (%)** Any grade Grade 3 or 4 Leading to treatment discontinuation	 213 (76.9%) 46 (16.6%) 30 (10.8%)	 102 (81.6%) 28 (22.4%) 11 (8.8%)

Costa et al, Pulmonology 2019; Aguiar et al, Int J Clin Pharm 2018; Borges et al, in press.

*Robert et al, NEJM. *2015;* **Shachter et al, *Lancet,. 2017*

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NICE National Institute for Health and Care Excellence

The Cancer Drugs Fund and experience from NICE

Thomas Strong, CDF Technical Advisor

The CDF recommendation since 2016

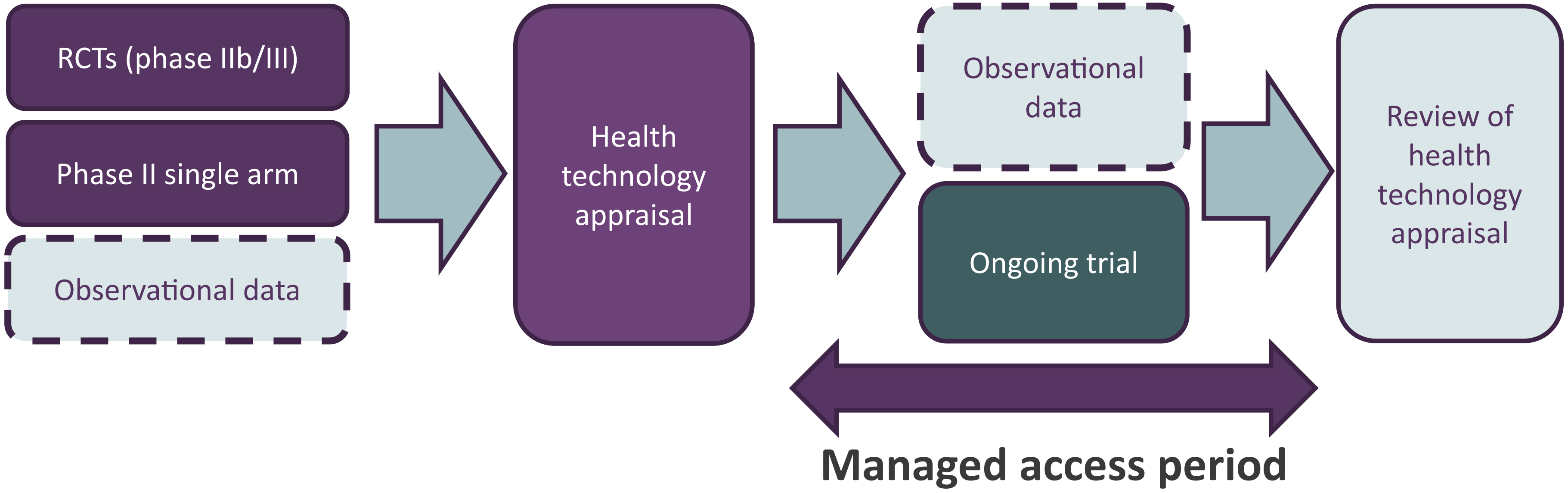
For promising drugs that cannot get routine commissioning due to clinical uncertainty NICE works with the Company, NHS England and Public Health England to agree a time-limited **Managed Access Agreement** comprised of 2 key components:

Commercial agreement (CAA)

Data Collection Agreement (DCA)

Managed access agreement

What outcome data is collected whilst a drug is available on the CDF?



RCTs (phase IIb/III)

Phase II single arm

Observational data

Health technology appraisal

Observational data

Ongoing trial

Review of health technology appraisal

Managed access period

NICE

Blueteq and SACT

Blueteq: NHS England system used by **all** trusts to request high cost drugs

SACT (systemic anti-cancer therapy): a national **mandated** dataset managed by Public Health England

Can collect real-world **retrospective** and **baseline** data **(Blueteq)** and **prospective** data **(SACT)**

Does not collect **quality of life** data or **comparative** data

But

are

we

making

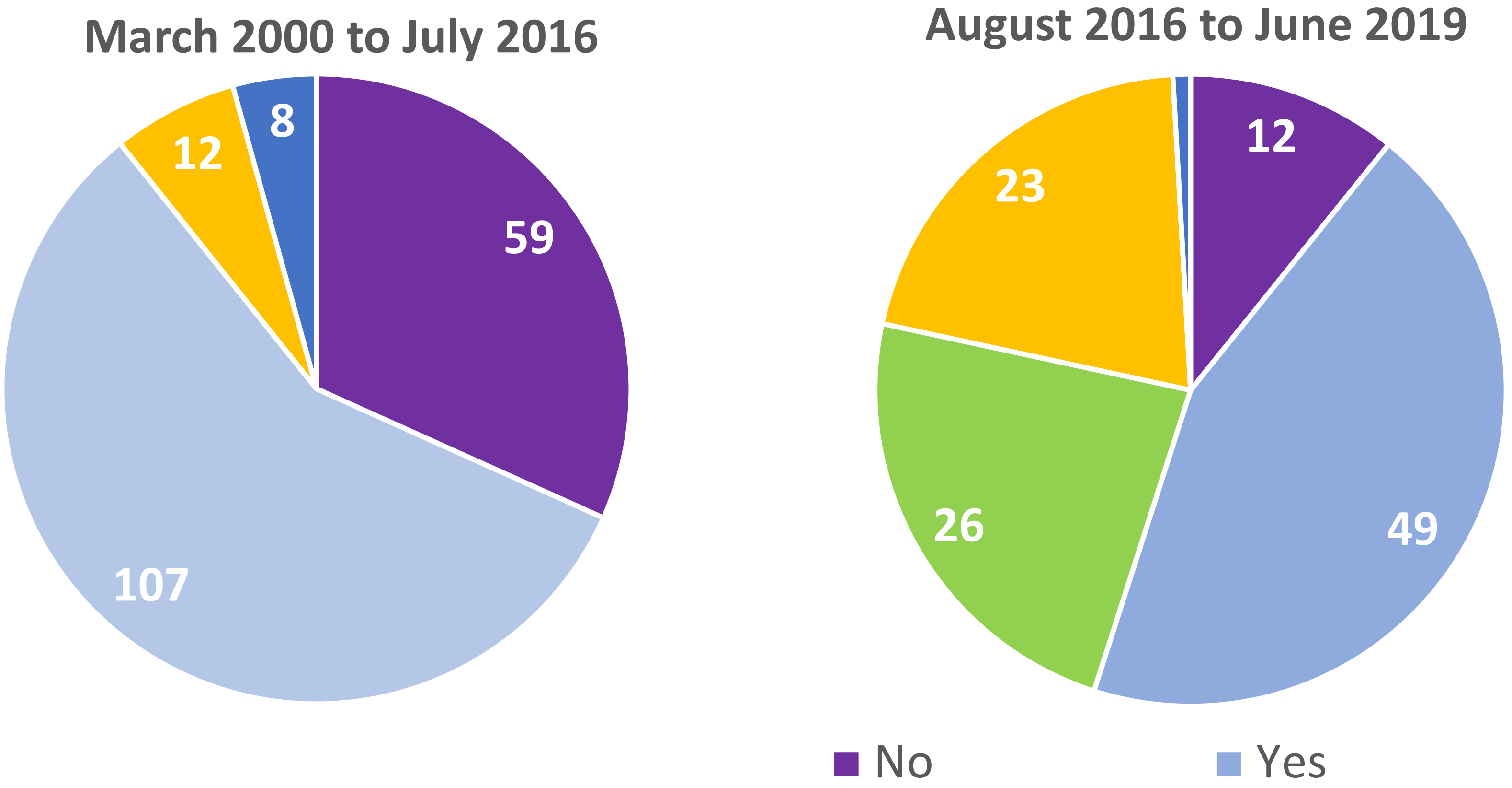
a

difference?

CDF by numbers

Over 13,000 patients have accessed CDF treatments

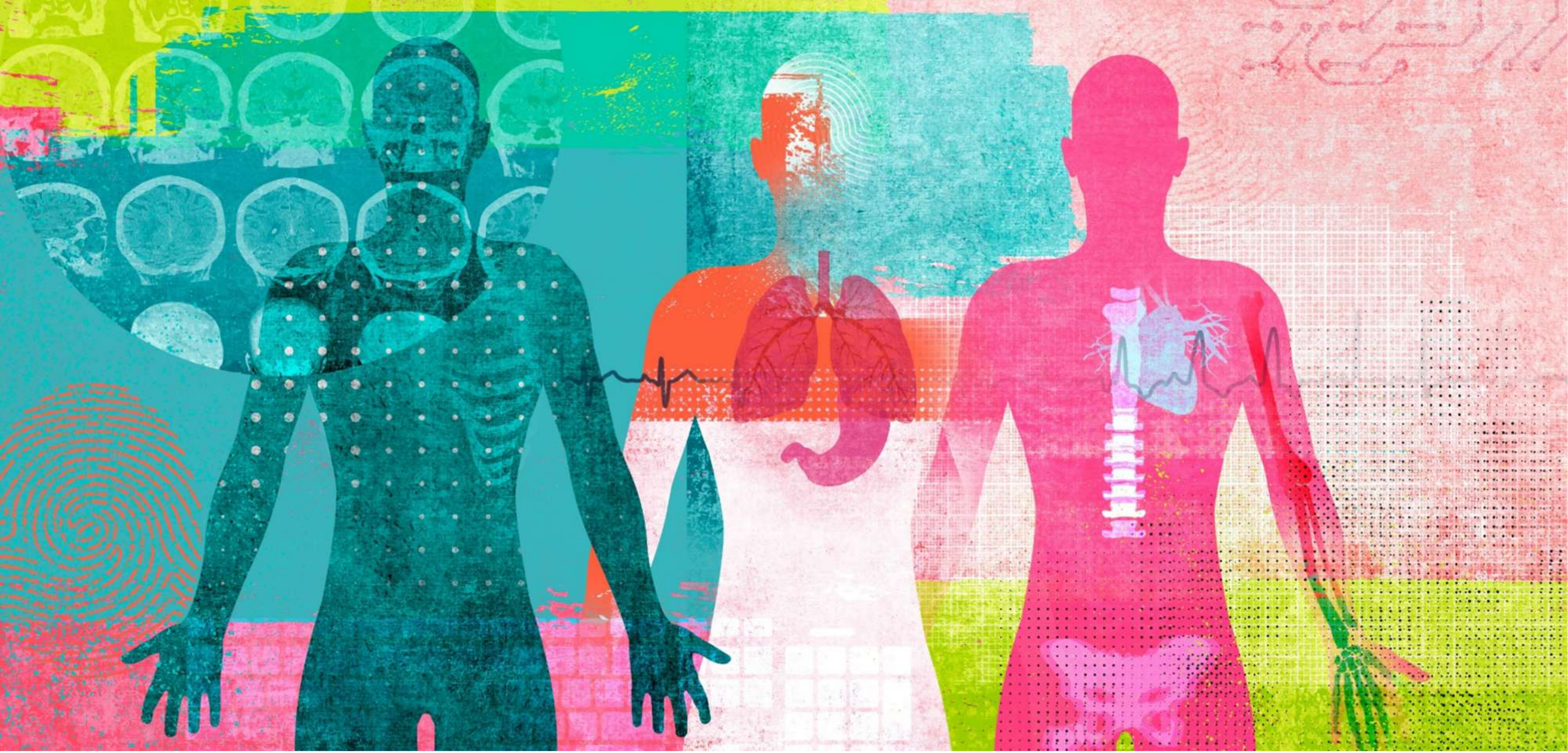
Strong appetite for data collection from all stakeholders



March 2000 to July 2016

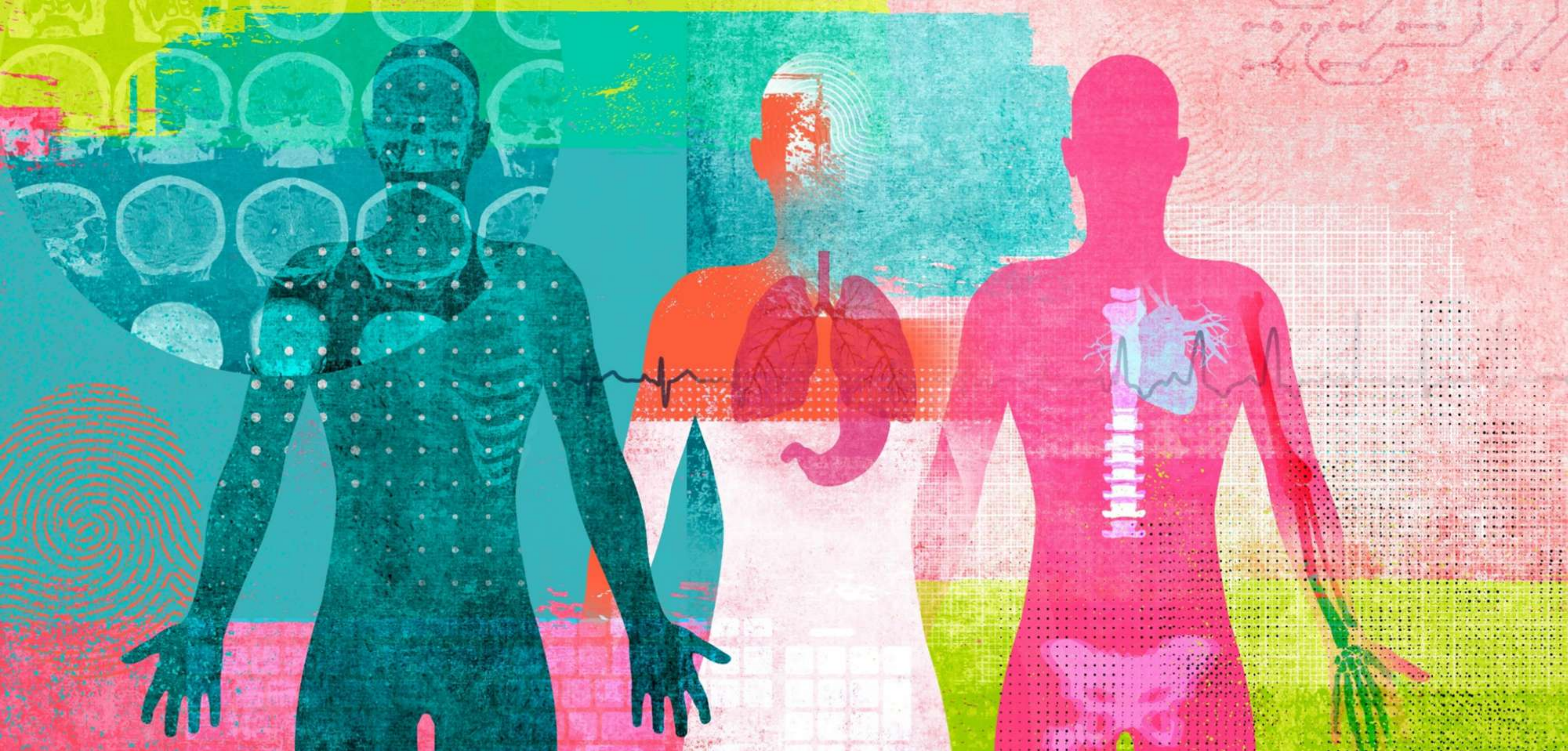
August 2016 to June 2019

Future challenges?



QUESTIONS & ANSWERS

#OncologyDataSummit



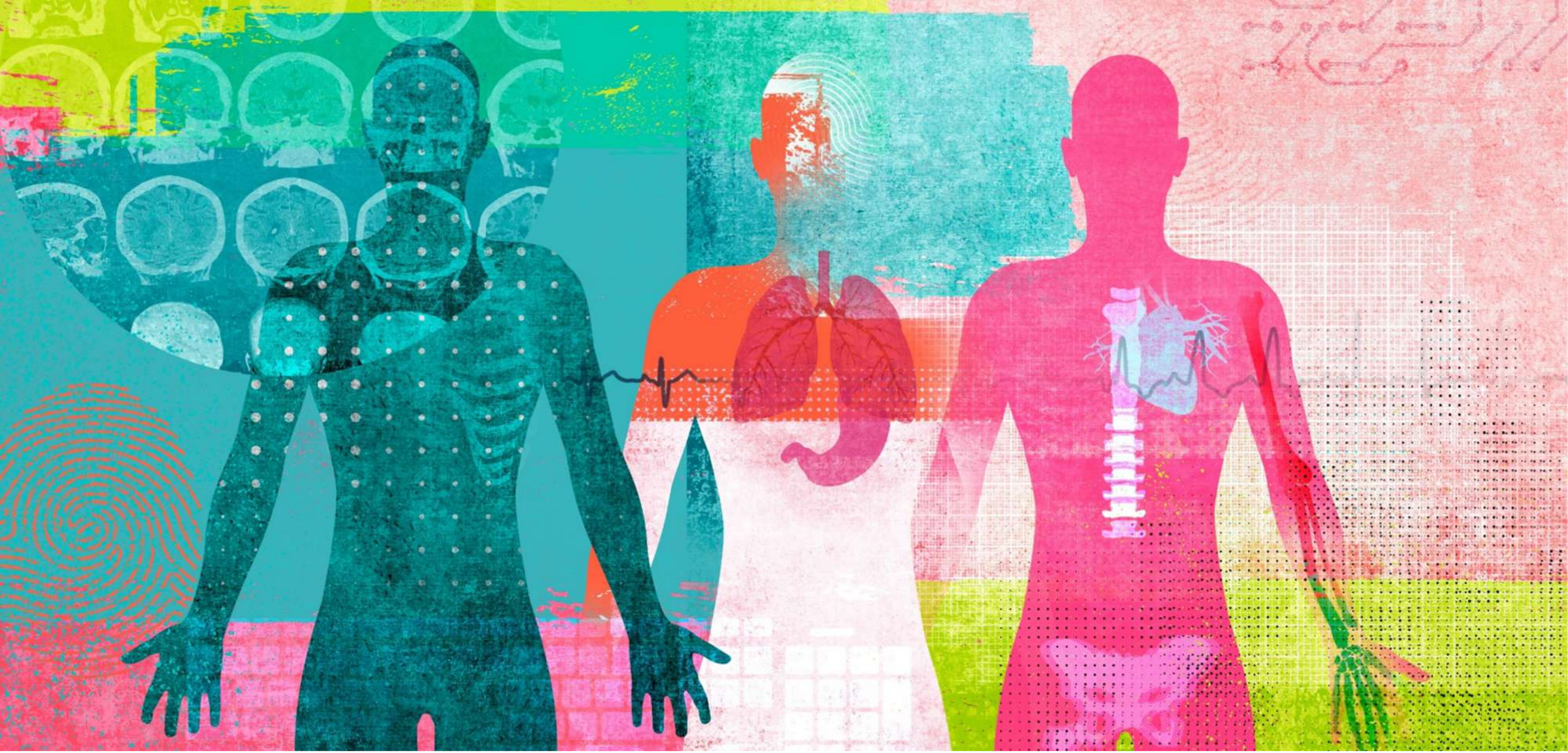
NETWORKING COFFEE BREAK & POSTERS

#OncologyDataSummit

Keynote speech

Vera Katalinić-Janković

MD, Assistant Minister, Croatian Ministry of Health of Croatia



SPOTLIGHT ON THE USE OF DATA – Part II

#OncologyDataSummit

PANEL: USE OF DATA FOR EFFECTIVE AND SUSTAINABLE HEALTH SYSTEMS

Stefan Gijssels

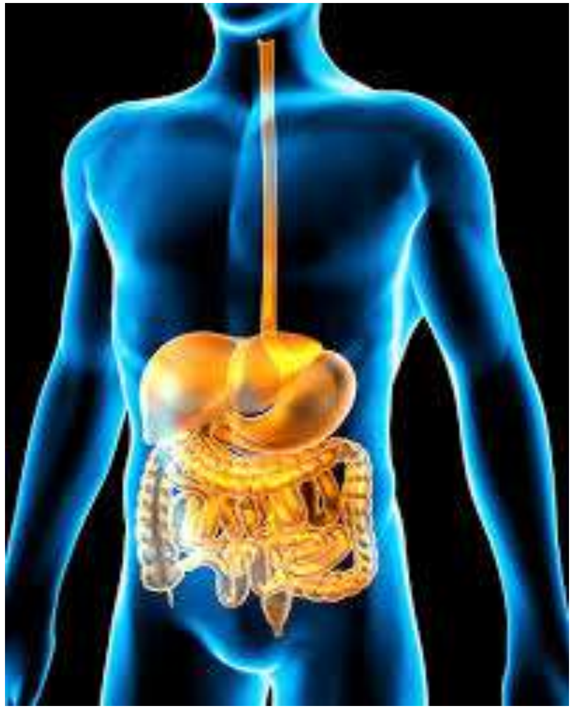
Executive Director, Digestive Cancers Europe

Nils Wilking

PhD Associate Professor Swedish Institute for Health Economics (IHE)

Marius Geantă

President, Centre for Innovation in Medicine



Oncology Data Summit

June, 2019

DIGESTIVE CANCERS
EUROPE

Today’s challenge

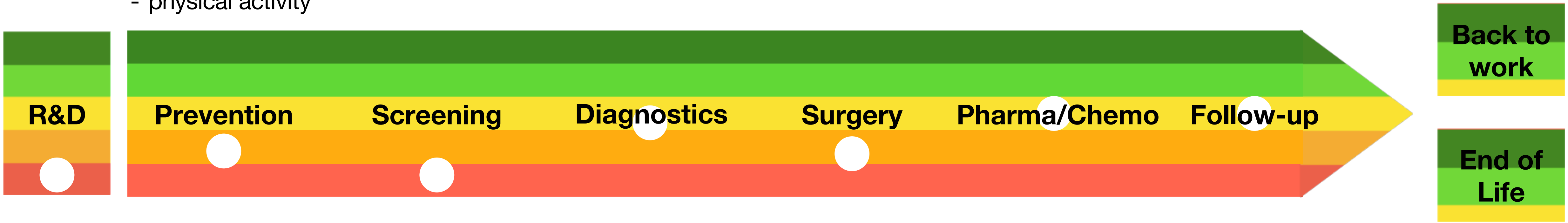
DIGESTIVE CANCERS EUROPE

(Europe : 40 countries)	Number of new cases per year	Number of deaths per year
Oesophagus	52.964	45.061
Stomach	133.133	102.167
Colon	312.495	157.151
Rectum	175.219	81.601
Pancreas	132.559	128.045
TOTAL	806,370	514.025

Source: European Cancer Information System, 2018

The patient journey

DIGESTIVE CANCERS EUROPE



	R&D	Prevention	Screening	Diagnostics	Surgery	Pharma/Chemo	Follow-up
Recommendations		Broad education - nutrition - acohol - red meat - physical activity	All citizens 50-74 yrs old	From 4 months to 2 months Primary care education	Specialised hospitals & best practices	Fast approval: 1 yr after EMA	& Digital monitoring
Expected Outcomes		+???	+130,000	+???	+120,000	+???	+???

Back to work

End of Life

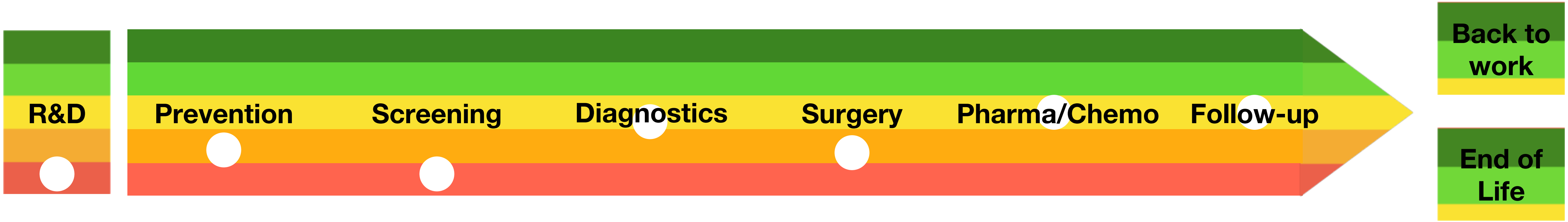
Patient coaching for all medical and non-medical issues: could result in 30% increase in effectiveness and societal savings

The patient journey

DIGESTIVE CANCERS
EUROPE

Recommendations

28%: initial diagnosis is the most inefficient part of their cancer care journey



+??? +130,000 +??? +120,000 +??? +???

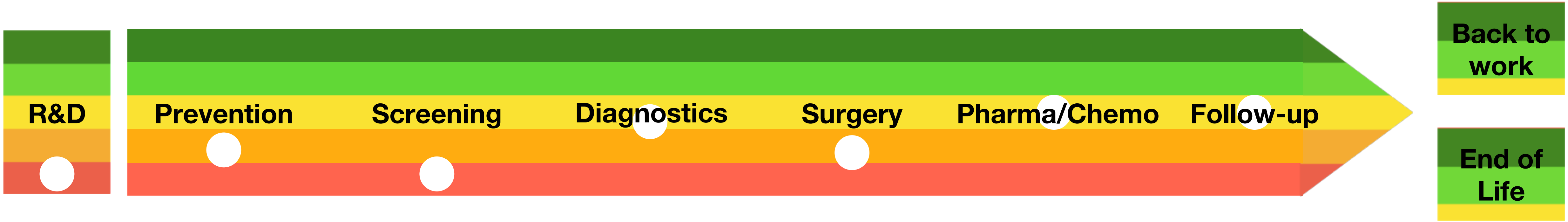
Expected Outcomes

Patient coaching for all medical and non-medical issues: could result in 30% increase in effectiveness and societal savings

The patient journey

Recommendations

32%: cancer is diagnosed as something else – either once or multiple times.



+???	+130,000	+???	+120,000	+???	+???

Expected Outcomes

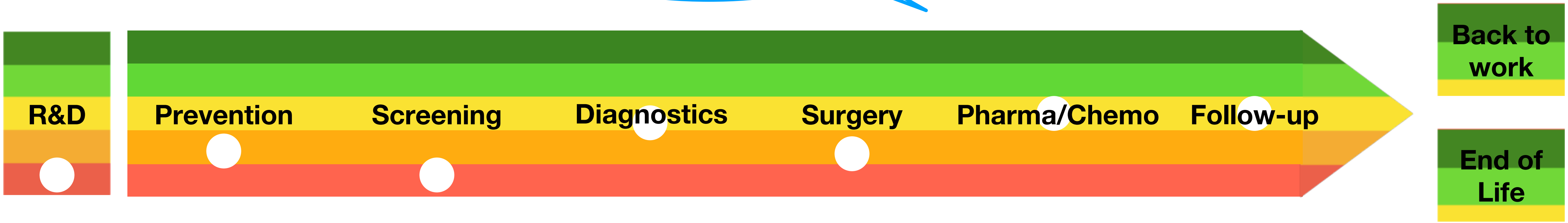
Patient coaching for all medical and non-medical issues: could result in 30% increase in effectiveness and societal savings

The patient journey

DIGESTIVE CANCERS EUROPE

Recommendations

47% not sufficiently involved in deciding about treatment option



+??? +130,000 +??? +120,000 +??? +???

Expected Outcomes

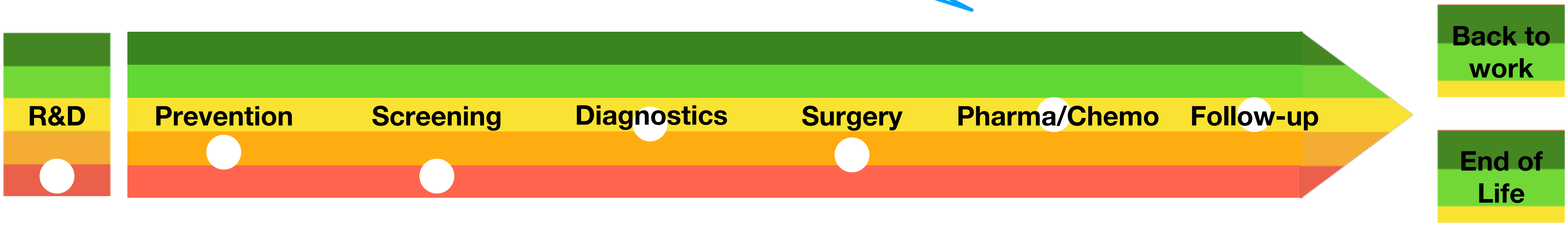
Patient coaching for all medical and non-medical issues: could result in 30% increase in effectiveness and societal savings

The patient journey

DIGESTIVE CANCERS
EUROPE

Recommendations

31% state not to receive an adequate amount of information about their cancer care and treatment.



+??? +130,000 +??? +120,000 +??? +???

Expected Outcomes

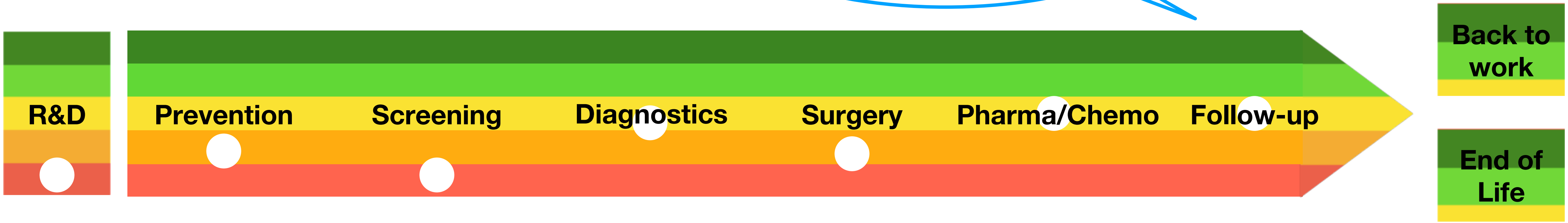
Patient coaching for all medical and non-medical issues: could result in 30% increase in effectiveness and societal savings

The patient journey

DIGESTIVE CANCERS
EUROPE

Recommendations

24% say they do not have access to support from allied healthcare professionals such as dietitians and physiotherapists.


R&D
Prevention
Screening
Diagnostics
Surgery
Pharma/Chemo
Follow-up
Back to work
End of Life

Expected Outcomes

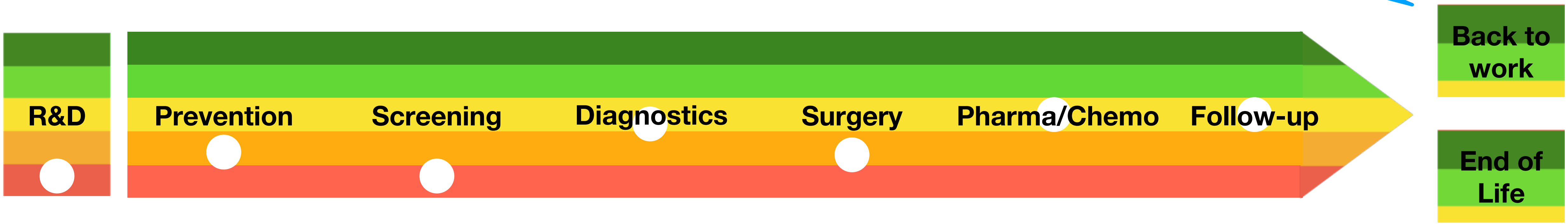
+???
+130,000
+???
+120,000
+???
+???

Patient coaching for all medical and non-medical issues: could result in 30% increase in effectiveness and societal savings

The patient journey

Recommendations

26%: loss of employment income as a result of their cancer care and treatment.



+??? +130,000 +??? +120,000 +??? +???

Expected Outcomes

Patient coaching for all medical and non-medical issues: could result in 30% increase in effectiveness and societal savings

Our Aspiration

DIGESTIVE CANCERS EUROPE

“To save 250,000 lives by 2028”

PANEL: USE OF DATA FOR EFFECTIVE AND SUSTAINABLE HEALTH SYSTEMS

Stefan Gijssels

Executive Director, Digestive Cancers Europe

Nils Wilking

PhD Associate Professor Swedish Institute for Health Economics (IHE)

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President, Centre for Innovation in Medicine

Sweden's National Quality Registries

Personal Identification Number PIN 12 digit unique for each person

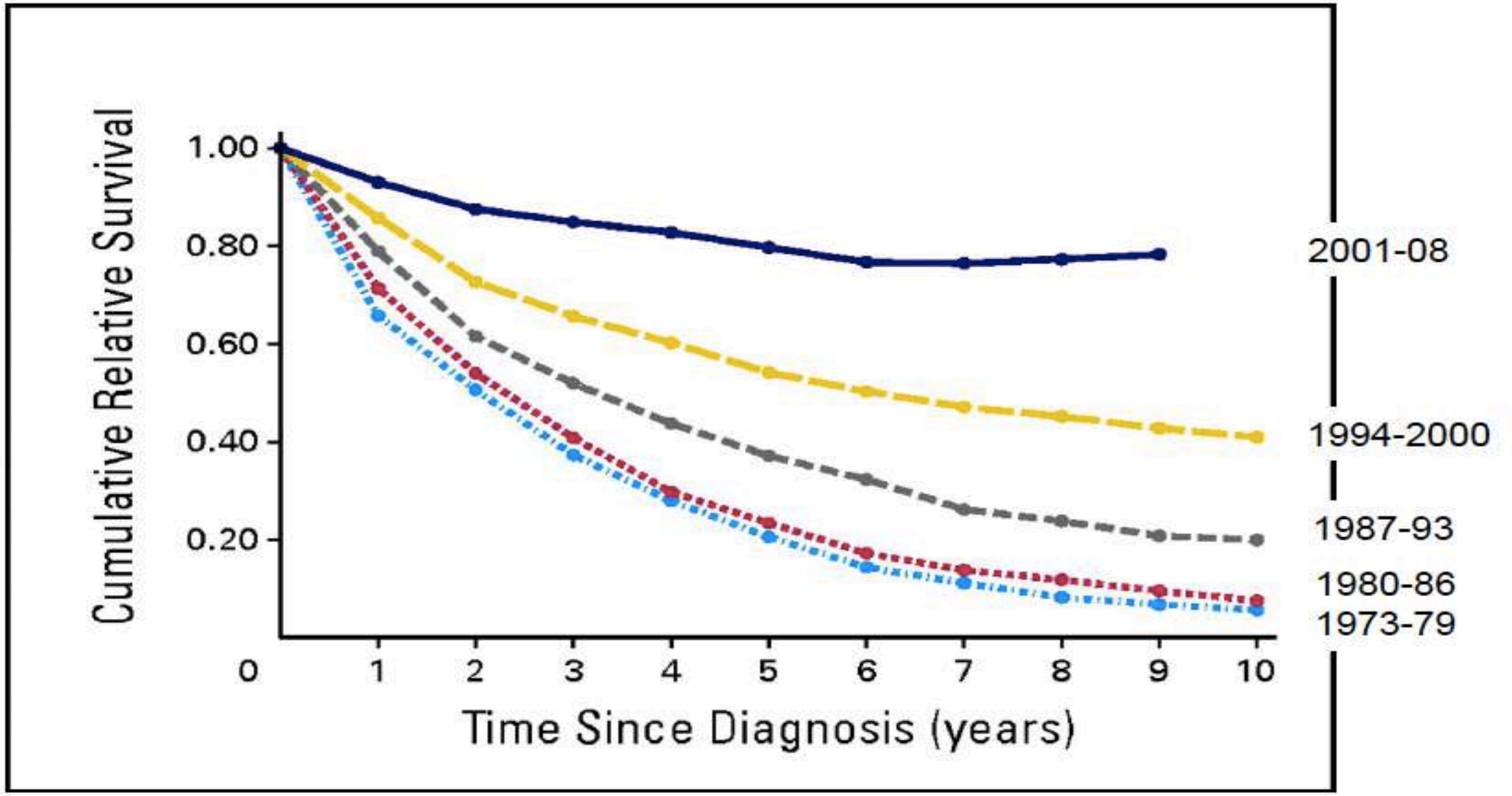
Nils Wilking MD, PhD, KI, Stockholm

The Swedish **PIN** is the tool for linkages between medical registers and allows for virtually 100% coverage of the Swedish health care system.

- All in- and out-patient care is registred. Linked to diagnosis (ICD)
- Register all prescription drugs since 2005.
  - **No national registry for hospital drugs**

- **The PIN provides a unique opportunity to collect RWD/RWE.**

Relative survival ratios for CML in Sweden by 6-year periods from 1973-2008.



Björkholm M et al. JCO 2011;29:2514-2520

PANEL: USE OF DATA FOR EFFECTIVE AND SUSTAINABLE HEALTH SYSTEMS

Stefan Gijssels

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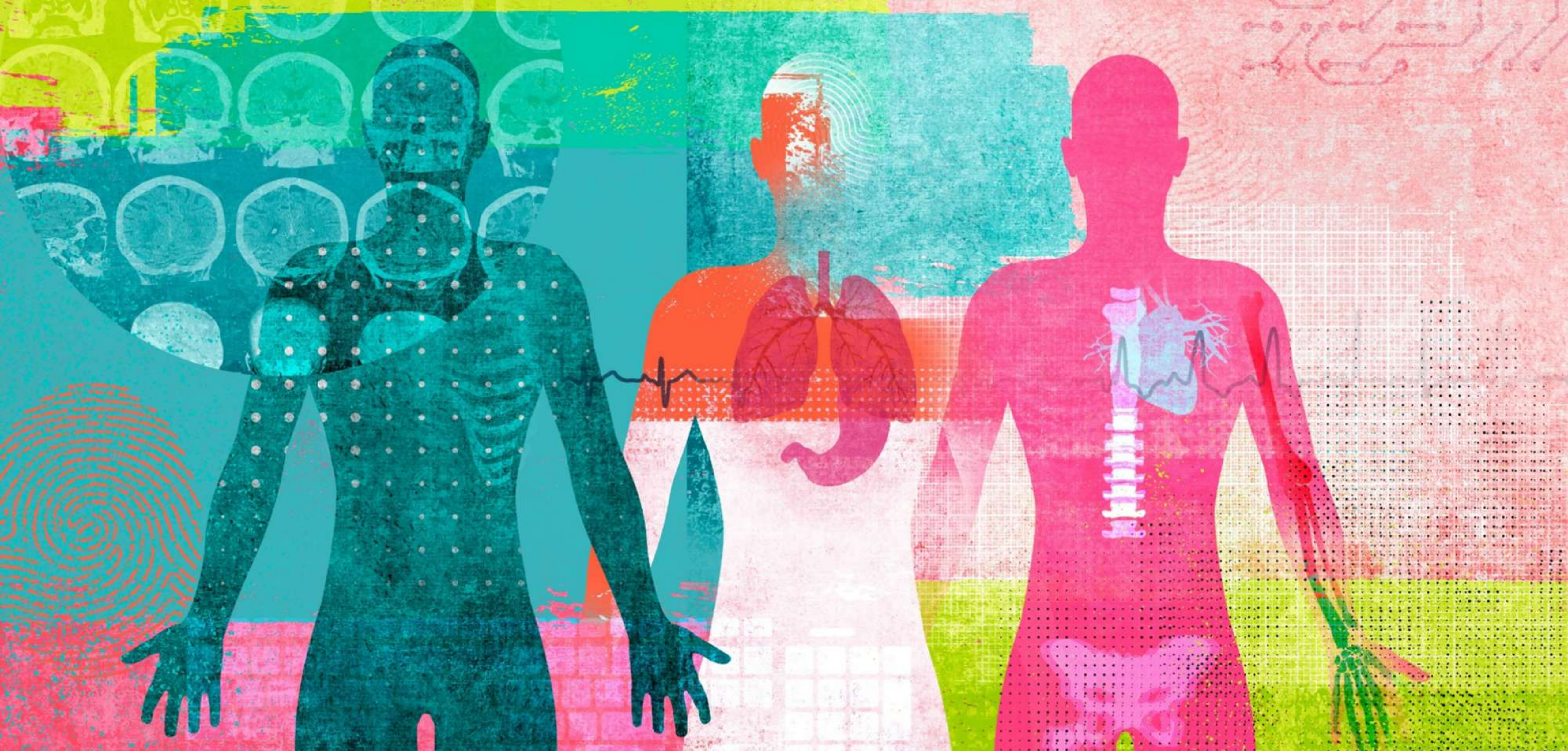
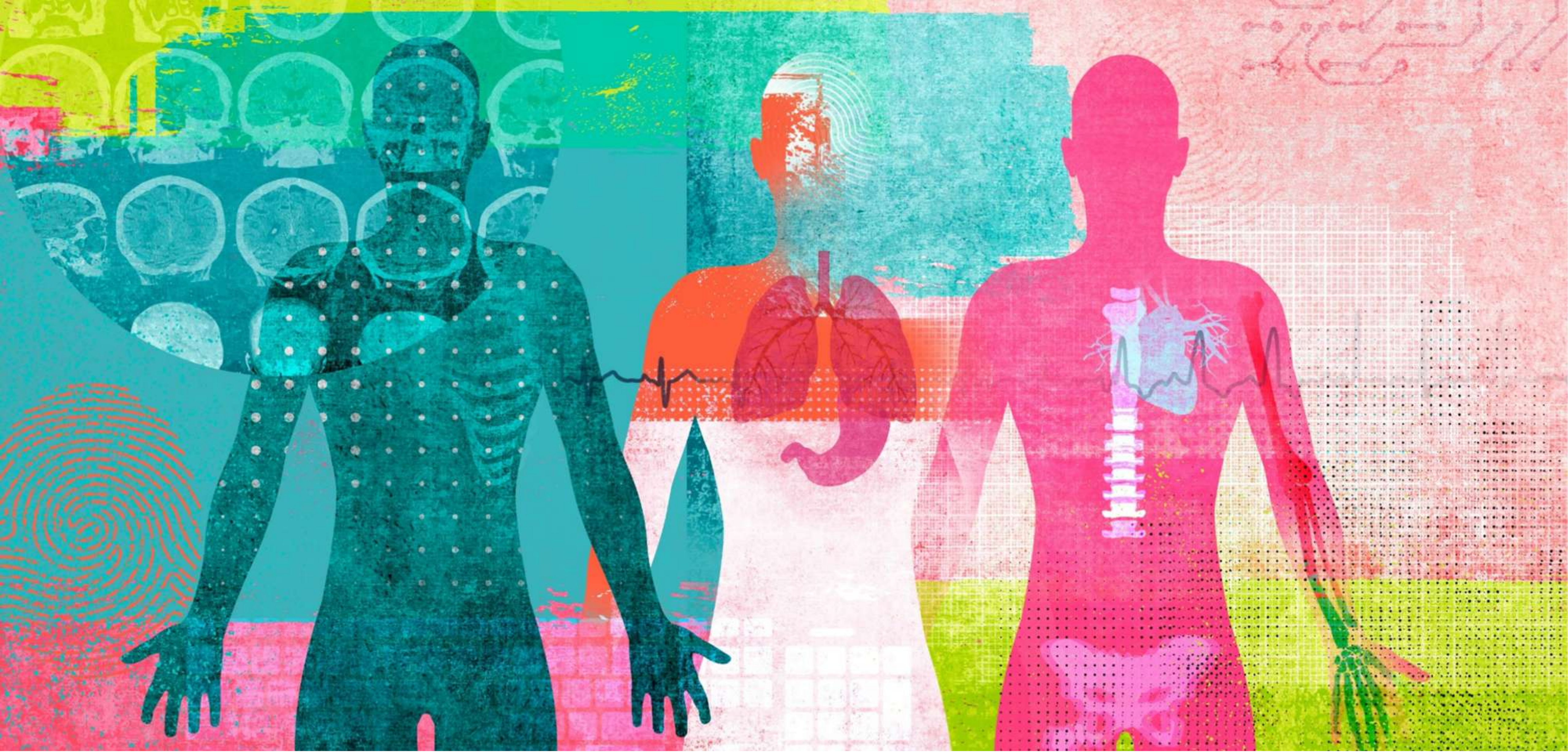
European Innovation Council
TOOLS
MODEL
Visionary E.U. Cancer Plan
Data, Technology and Human Touch
Optimise OUTCOMES for SOCIETY
CENTRE for INNOVATION in MEDICINE
DIGITAL TWINS
APPROACH
RESULTS
MOST EFFECTIVE THERAPY OR PREVENTION
RO2019EU
RE-Think
DATA
COMMON CODING
NETWORKS
QUALITY
TEST
LEARNING HEALTH SYSTEMS
PERSONALISED MEDICINE
Value of Data in ONCOLOGY
Hotel Novotel Bucharest
5.06.2019
marius.geanta@ino-med.ro



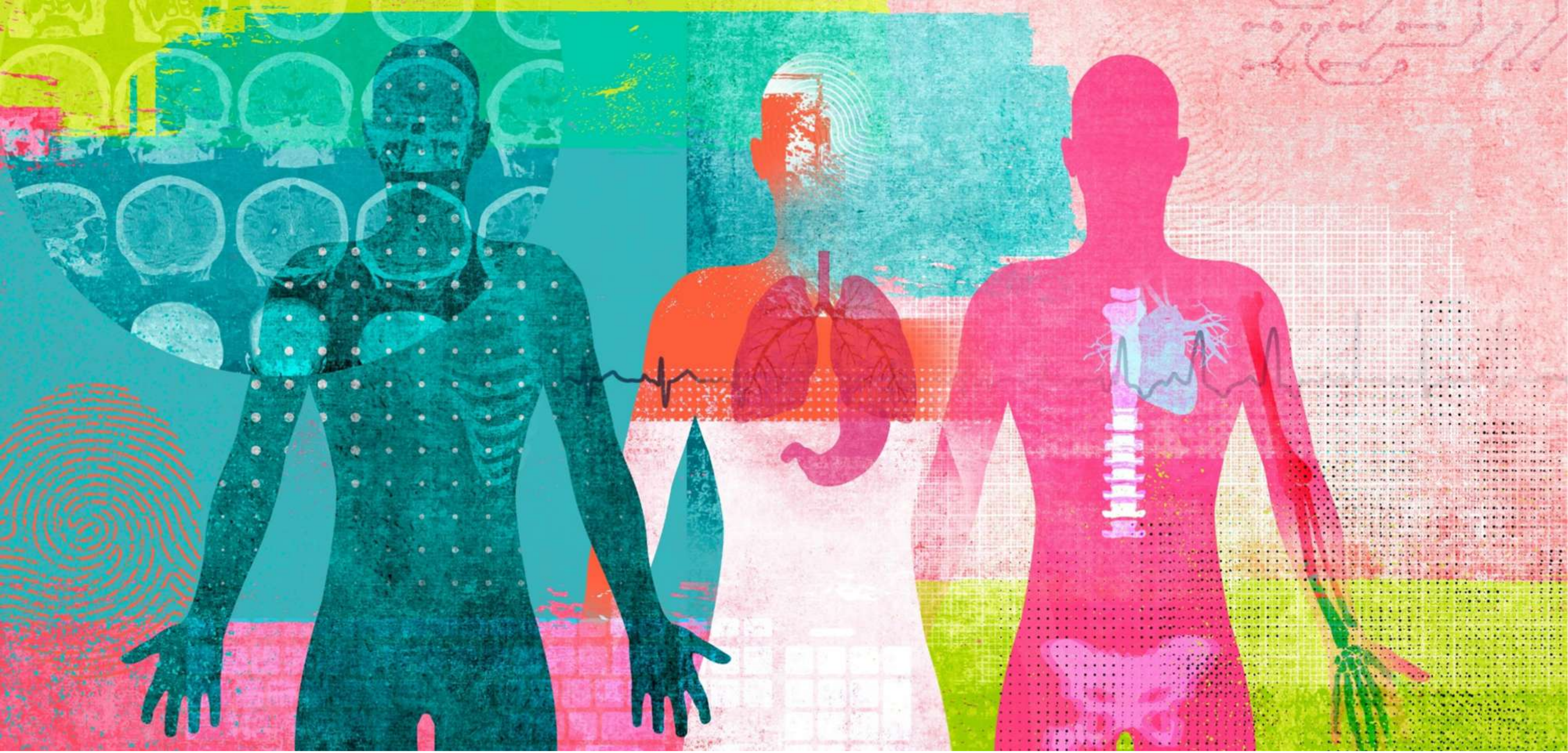
QUESTIONS & ANSWERS

#OncologyDataSummit



VOTING ON POLICY RECOMMENDATIONS

#OncologyDataSummit



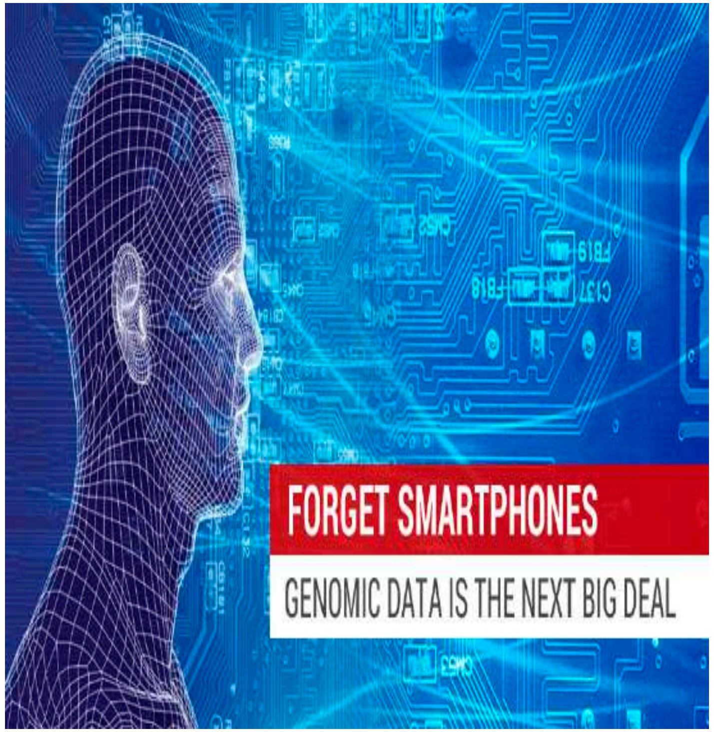
LOOKING AHEAD

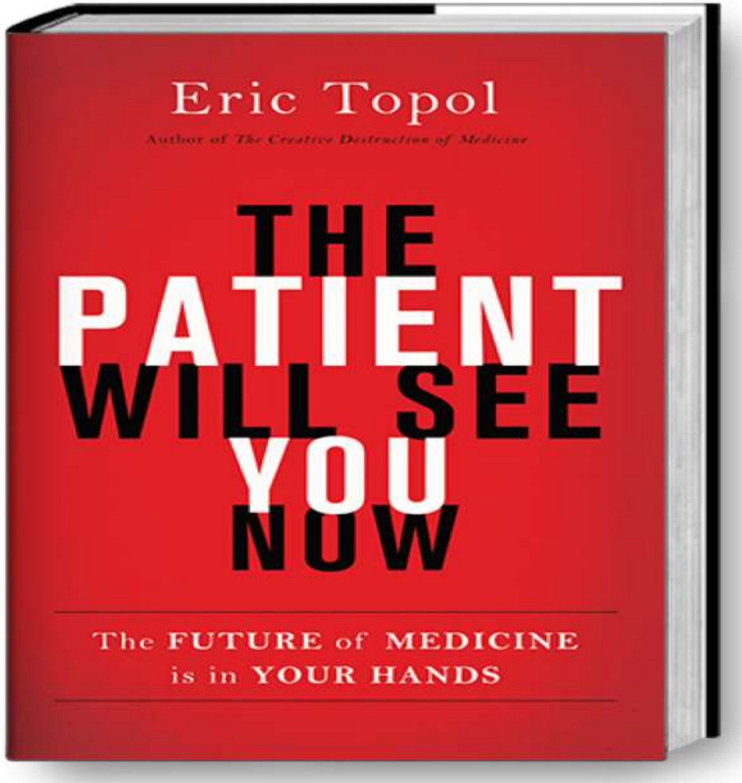
#OncologyDataSummit

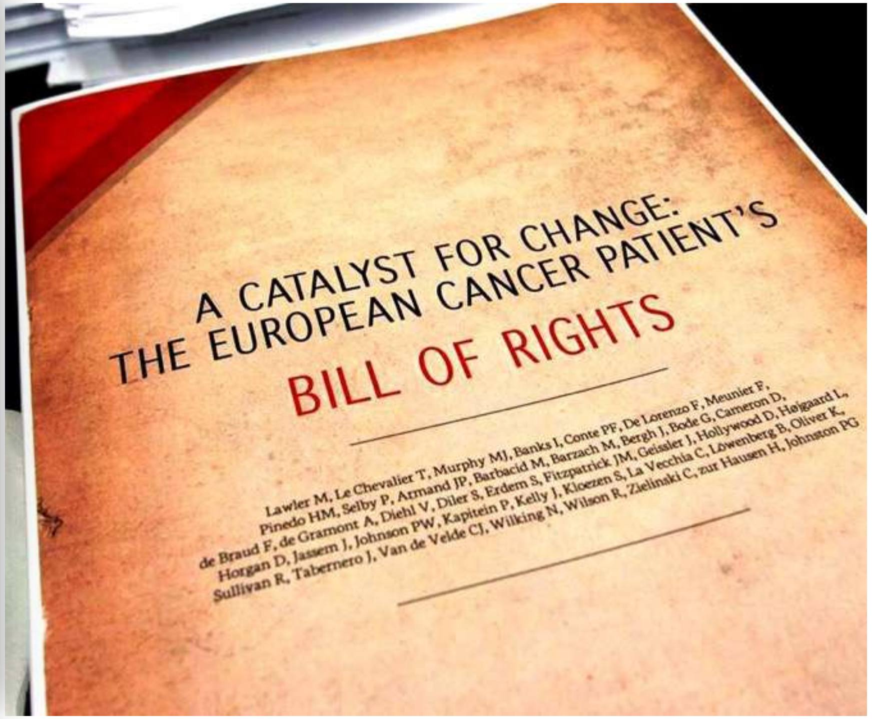
ADRESSING EUROPE’S CANCER CHALLENGES THROUGH A DATA ENABLED LENS

Mark Lawler
PhD, Queen’s University Belfast

Addressing Europe's cancer challenges through a data-enabled lens: the time to act is NOW!







A CATALYST FOR CHANGE:
THE EUROPEAN CANCER PATIENT'S
BILL OF RIGHTS

Lawler M, Le Chevalier T, Murphy MJ, Banks I, Conte PF, De Lorenzo F, Meunier F,
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de Braud F, de Gramont A, Diehl V, Diler S, Erdem S, Fitzpatrick JM, Geissler J, Hollywood D, Højgaard L,
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Sullivan R, Tabernero J, Van de Velde CJ, Wilking N, Wilson R, Zielinski C, zur Hausen H, Johnston PG

Mark Lawler
Chair in Translational Cancer Genomics and Dean of Education,
Faculty of Medicine, Health and Life Sciences, Queen's University Belfast
Associate Director, Health Data Research Wales Northern Ireland
Cancer Data Science Lead, Health Data Research UK (HDRUK)

EFPIA Oncology Data Summit
18th June 2019

QUEEN'S UNIVERSITY BELFAST
CCRCB CENTRE FOR CANCER RESEARCH AND CELL BIOLOGY

A Data Driven Approach to Preserving Health and Wellbeing

- Big data
- Small data
- Personal data
- Clinical data
- Epidemiology data
- Genomic data
- Animal data
- Soil data
- Agrifood data
- (Pseudo)anonymised data
- Multidimensional data
- Metadata
- (Health) Economic data
- Prescription data
- Real world data
- Incomplete data
- Security data
- Encrypted data
- **SMART DATA**

"Why Gramma, what big data you have!"

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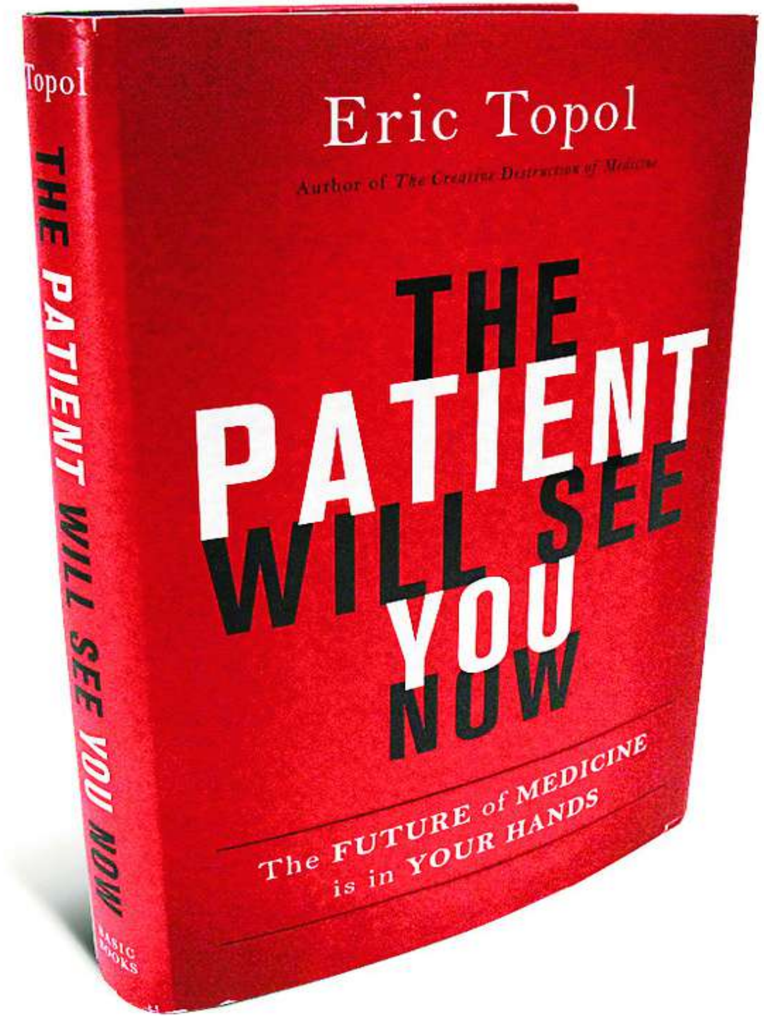
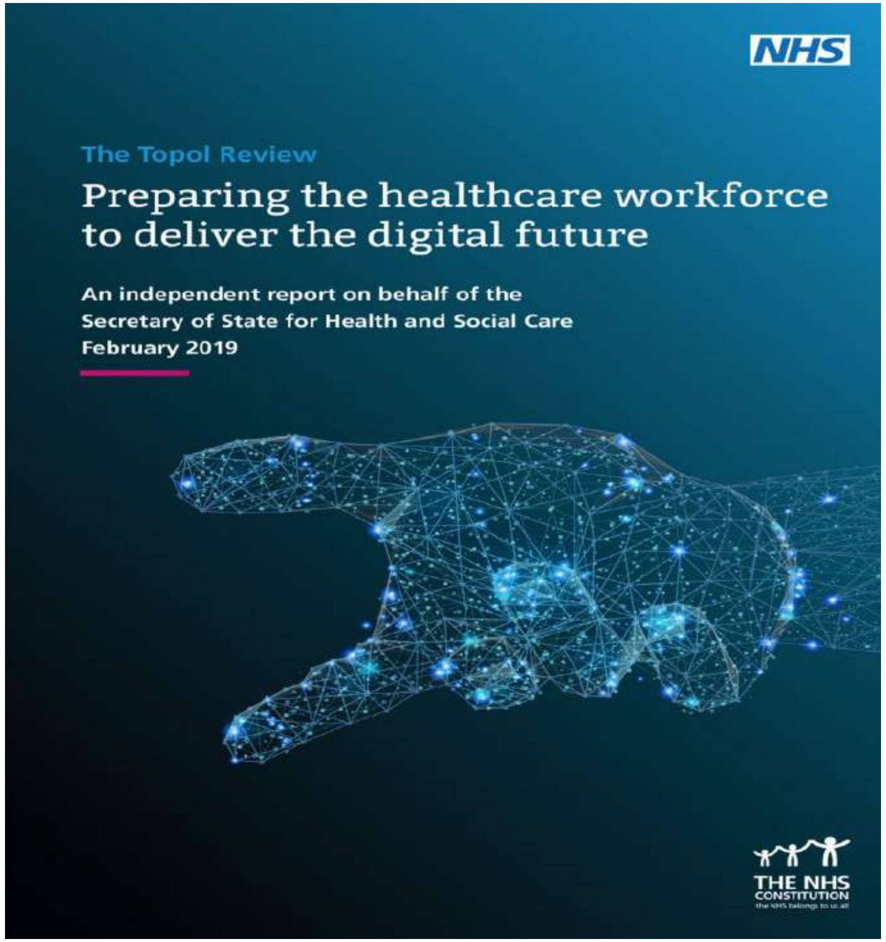
The Rise of the Patient

- **Smartphone-based apps** that will allow patients to **view their own lab results**, monitor vital signs, and **apply artificial intelligent algorithms to diagnose themselves**.
- **Patient autonomy** will be critical
  - … Data
  - … Education
  - … Partnership



The (Grand) Data Challenge

- **Technical**
  - **Scale** (Giga to Peta to Exa!)
  - Data **incompatibility/ Non standardised** Data Analytics Pipelines
  - Linking **Clinical, Epidemiological, Socio-economic** and **'omic** data
  - **Enabling access** to and analysis of data for research
- **Ethical/Legal**
  - **Privacy** and **Data Protection (General Data Protection Regulation (GDPR))**
  - **Benefit:** Individual v Collective
  - **Trust**
- **Cultural**
  - **"Selfish Silo"** Mentality (Control, Credit, IP)
  - Move to a more open source **Collaborative Culture**
  - **Working together in a data collaborative**
  - **Citizen-focussed initiative with citizen/patient input**



NHS

The Topol Review

Preparing the healthcare workforce to deliver the digital future

An independent report on behalf of the Secretary of State for Health and Social Care

February 2019

THE NHS CONSTITUTION

the NHS belongs to us all

Global Alliance for Genomics & Health

QUEEN'S UNIVERSITY BELFAST

Silos are for farms, not for pharma! (nor for patients!)

Image courtesy of Jan Geissler.

Global Alliance for Genomics & Health

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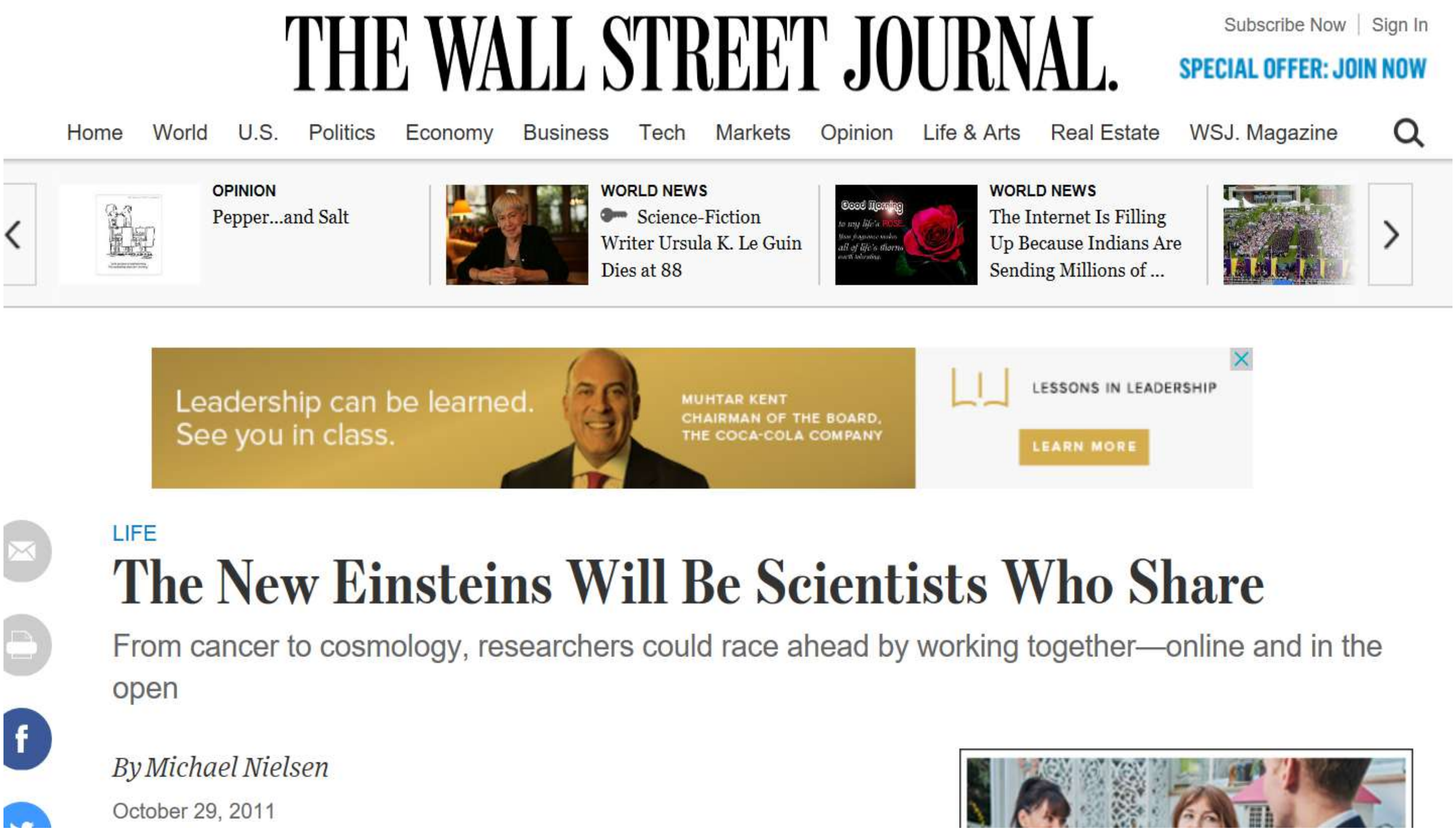

THE WALL STREET JOURNAL.

OPINION
Pepper...and Salt

WORLD NEWS
Science-Fiction Writer Ursula K. Le Guin Dies at 88

WORLD NEWS
The Internet Is Filling Up Because Indians Are Sending Millions of ...

LIFE

The New Einsteins Will Be Scientists Who Share

From cancer to cosmology, researchers could race ahead by working together—online and in the open

By Michael Nielsen

October 29, 2011

Free the data – Cancer patients want to share!

- **Sharing** of data is **increasingly** becoming an **imperative** for patients[1]
- Patients are **no longer passive recipients** but **active participants**[2]
- **BUT…certain** issues must be adequately addressed
- Otherwise, **enthusiasm** for **participating** in **research** and acting as **advocates** for responsible data sharing **may waiver**

1. Rogith D, et al. J Am Med Inform Assoc. 2014;21(e2):e320–e325; 2. Lawler M, et al. Lancet Oncol. 2014;15:258–260.

The ROS1ers: Patient advocacy driving personalised oncology

- **ROS1:** Mutated (in a small %) in different cancers
- **Targetable by an drug**
- **Self aggregation** of patients **online**
- The **ROS1ers** – 120 patients, from 11 countries, in 3 months
- Proactively collect and share **biospecimens** and **genomic** data
- Allows **innovative discoveries** to be translated **“in real time”** for the **benefit of patients**

https://www.lungcancerfoundation.org/patients/ros1/ (accessed October 2018).

BONNIE J. ADDARIO
LUNG CANCER
FOUNDATION

Global Alliance
for Genomics & Health

Driving a “Big Data for Better Health” Agenda at Queen’s

Key issues of relevance for both the science and the patients:

- **Break down the silos:** Get academic researchers, clinicians, industry players, regulators and patients to collaborate
- **Learn from the data:** Use data from diverse sources (‘omic, clinical, epidemiological, socio-economic etc) to increase our understanding of disease
- **Big data for better health:** Use this intelligence to improve health and wellbeing

QUEEN'S
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BELFAST

Developing a Blueprint for sharing of cancer data[1, 2]

- No **single institution** can **“go it alone”**
- **Large data sets** are **rapidly reduced** to **small numbers** when looking for specific genomic profile(s)
- ***Framework for responsible sharing of genomic and health-related data***
- **Embracing** a new **data-enabled** research **cooperative**
- **Involving patients/citizens** in the **co-creation** of health data science resources and the **delivery of patient benefit/impact**
- Ensuring **data access for research**
- Linking **longitudinal clinical, epidemiological, genomic, health economic data**
- Facilitating **accelerated data analytics**

- [1] Lawler et al. All the World's a Stage: Facilitating Discovery Science and Improved Cancer Care through the Global Alliance for Genomics and Health. *Cancer Discov.* 2015; [2] Siu LL*, Lawler M*^ et al Facilitating a culture of responsible and effective sharing of cancer genome data *Nature Med (2016)*

Global Alliance for Genomics & Health

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Championing a citizen-focussed Data Sharing Culture

- Facilitating **access** to **rich** data resources to **enable innovative research**
- Establishing a **Cancer Data Knowledge Network**
- Moving from a Closed **"Selfish Silo"** Mentality to an Open Source **"Collaborative Culture"**
- **Restoring Public Trust in "Big Data"**

The NEW ENGLAND JOURNAL of MEDICINE

25th May 2017

Sharing Clinical and Genomic Data on Cancer — The Need for Global Solutions

Mark Lawler, PhD; David Haussler, PhD; Lillian L. Siu, MD; Melissa A. Haendel, PhD., Julie A. McMurry, PhD; Bartha M. Knoppers, PhD; Stephen J. Chanock, MD; Fabien Calvo, MD., PhD; Bin T. The, MD; Guneet Walia, PhD; Ian Banks, MD; Peter P. Yu, MD; Louis M. Staudt, MD, PhD; and Charles L. Sawyers, MD. For the The Clinical Cancer Genome Task Team of the Global Alliance for Genomics and Health

Global Alliance for Genomics & Health

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Health Data Research UK (HDRUK)
A health and biomedical institute for the digital world

1. Northern Ireland and Wales (Queen's University Belfast and Swansea University)
2. Midlands (Birmingham, Leicester, Nottingham, Warwick)
3. Scotland (Aberdeen, Dundee, Edinburgh, Glasgow, St Andrews, Strathclyde)
4. London (Imperial, Kings, LSHTM, Queen Mary, UCL)
5. Oxford
6. Cambridge (EBI, Cambridge University, Sanger)

https://www.hdruk.ac.uk/

Swansea University
Prifysgol Abertawe

HDRUK
Health Data Research UK

Global Alliance
for Genomics & Health

QUEEN'S UNIVERSITY BELFAST

Transforming the data landscape by Transcending disciplines

- We all need to **work together** to maximise the power of data

Patients
Clinicians
Pathologists
Geneticists
Cell/Molecular Biologists
Biochemists/Microbiologists
Biologists
Animal sciences
Bioinformaticians
Industry
Epidemiologists
Statisticians
Health service researchers
Geographers
Demographers
Social scientists
Economists
Lawyers
Ethicists
Theologians
Image analysts
Computer scientists
Mathematicians
Engineers

Swansea University
Prifysgol Abertawe

HDRUK
Health Data Research UK

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BELFAST

HDRUK triple aim

Data Science

Integration of data science with biomedical and health science expertise to perform ground-breaking research, with an initial focus on **data analytics, enabling precision medicine, 21st century clinical trials and modernising public health.**

Training the next generation

To develop novel approaches to **research training and mentorship** to foster a cadre of health data science researchers, on a substantial scale.

UK wide expert research data services

Development and delivery of **cutting-edge technologies and trusted research platforms** that acquire, store, represent, and process large, **multi-dimensional** research data.

Trustworthy use of data

We will work in partnership with the public, patients, funders, social scientists and legal/ethnical experts to champion the trustworthy use of data.

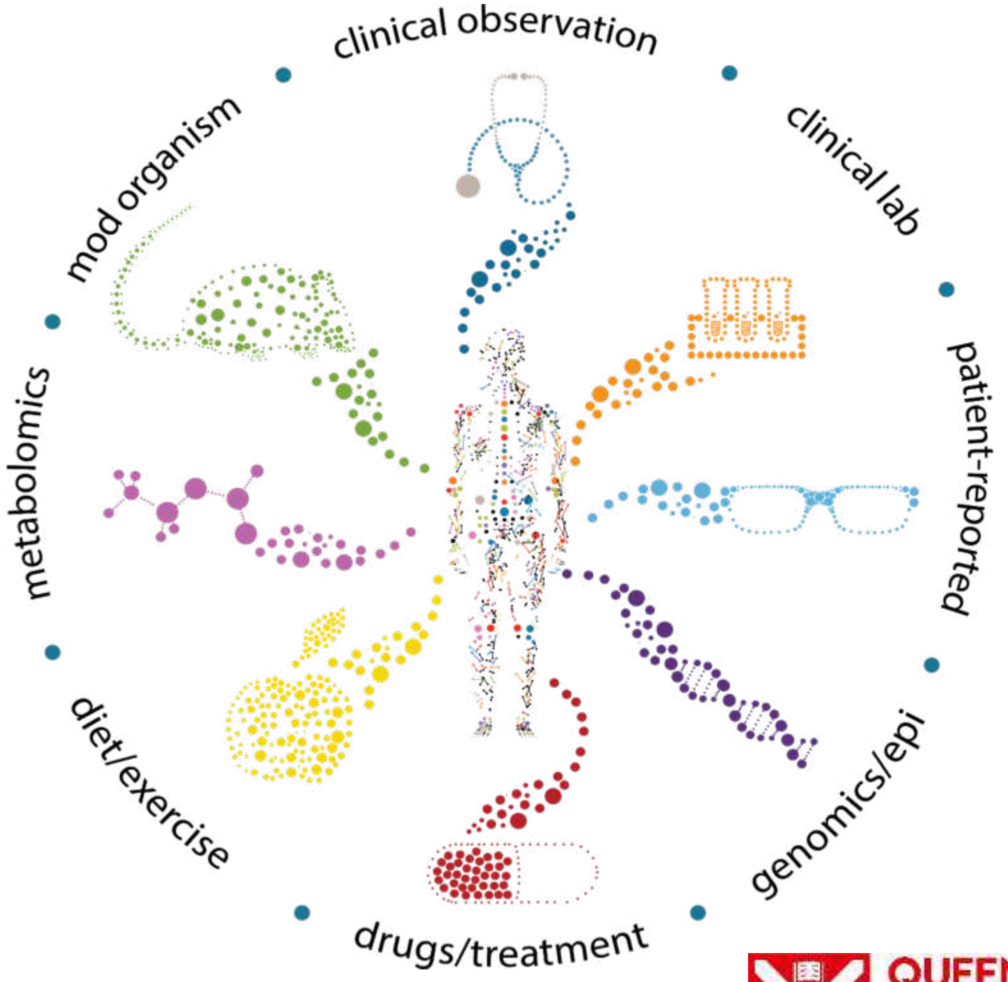
hdruk.ac.uk

HDRUK
Health Data Research UK

QUEEN'S UNIVERSITY BELFAST

Empowering the virtuous data circle

- A **cancer data ecosystem,** built on existing cancer knowledge bases but also generating, incorporating and interrogating new validated information sources
- Enabling **more effective** prevention and early diagnosis approaches
- Facilitating **application of data-enhanced discovery** to deliver innovative therapies
- **Nurturing and empowering** patient recovery and rehabilitation
- Underpinning **enhanced industry partnerships and innovation.**



QUEEN'S UNIVERSITY BELFAST

A Question of Trust: Ensuring a citizen-focussed perspective

THE LANCET Oncology

- Developing a Citizen-focused **Data Sharing Cooperative**
- **Co-development with patients/citizens**
- Articulating a clear **Social Contract**, where citizens (as data donors) are at the heart of decision making.
- Embedding **ethical rigour** in all our data-driven processes
- **Democratising data analysis** for maximum scientific and clinical value
- **Supporting** current data research environments (universities, research institutions, academic medical centres, hospitals) and **enabling data "safe havens"**(where required)
- *"Safe people, working on safe projects, utilising safe data, in safe places, with safe outputs"*
- **Data safe havens** with a **"shop-window"** to the public

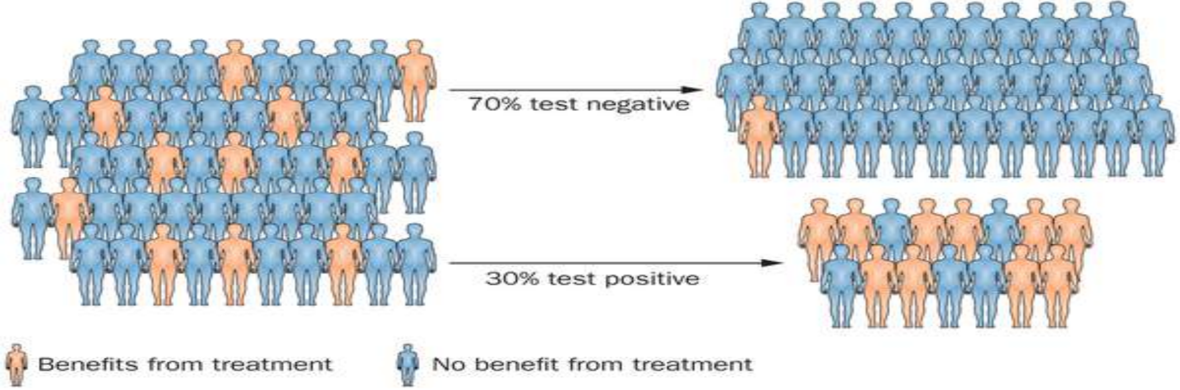
Lawler M, Morris AD, Sullivan R, Birney E, Middleton A, Makaroff L, Knoppers BM, Horgan D, Eggermont A. *Lancet Oncology* 2018 A Roadmap for Restoring Trust in Big Data

HDRUK Health Data Research UK

QUEEN'S UNIVERSITY BELFAST

Stratification in COloRectal cancer
From biology to Treatment Prediction (S:CORT)

S:CORT
Stratification in COloRecTal cancer



MRC Medical Research Council

CANCER RESEARCH UK

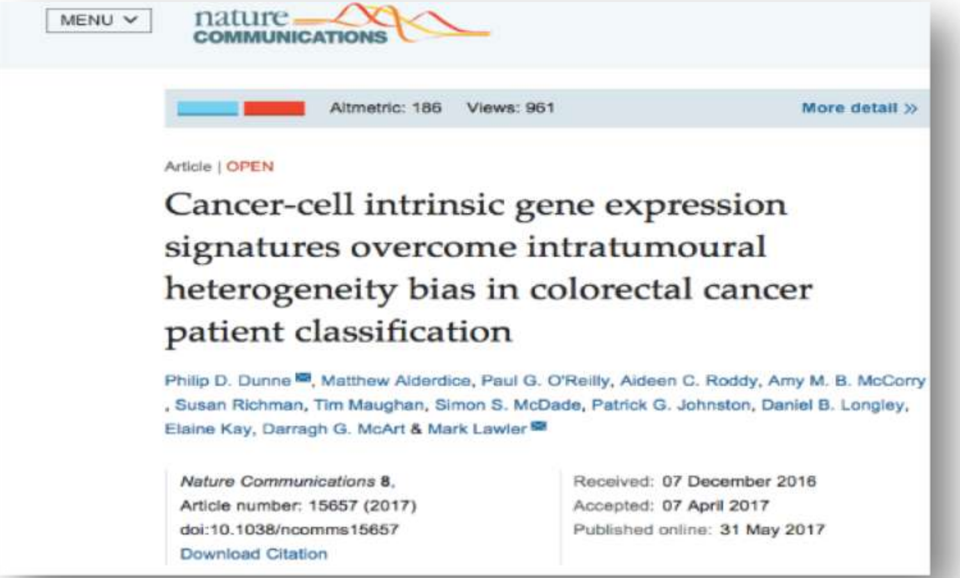
QUEEN'S UNIVERSITY BELFAST

Lawler M, et al. *Oncologist*. 2015;20(8):849–851; Tannock IF, et al. *N Engl J Med.* 2016;375(13):1289–129

Dunne PD, et al. *Nature Comms.* 2017;8:15657; Alderdice M, et al. *J Pathol.* 2018;245(1):19–28.

Enabling precision cancer medicine through Artificial Intelligence and Accelerated Analytics

S:CORT
Stratification in COloRecTal cancer



Article | OPEN

Cancer-cell intrinsic gene expression signatures overcome intratumoural heterogeneity bias in colorectal cancer patient classification

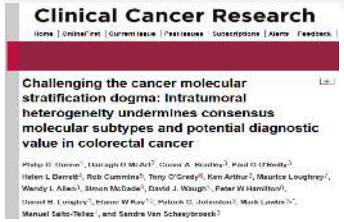
Philip D. Dunne, Matthew Alderdice, Paul G. O'Reilly, Aideen C. Roddy, Amy M. B. McCorry, Susan Richman, Tim Maughan, Simon S. McDade, Patrick G. Johnston, Daniel B. Longley, Elaine Kay, Darragh G. McArt & Mark Lawler

Nature Communications 8, Article number: 15657 (2017)
doi:10.1038/ncomms15657
Download Citation

Received: 07 December 2016
Accepted: 07 April 2017
Published online: 31 May 2017

Stratified analysis reveals chemokine-like factor (CKLF) as a potential prognostic marker in the MSI-immune consensus molecular subtype CMS1 of colorectal cancer

Philip D. Dunne, Paul G. O'Reilly, Helen G. Coleman, Ronan T. Gray, Daniel B. Longley, Patrick G. Johnston, Manuel Salto-Tellez, Mark Lawler, Darragh G. McArt



Challenging the cancer molecular stratification dogma: Intratumoral heterogeneity undermines consensus molecular subtypes and potential diagnostic value in colorectal cancer

Philip D Dunne, Darragh G McArt, Conor A. Bradley, Paul G O'Reilly, Helen L Barrett, Rob Cummins, Tony O'Grady, Ken Arthur, Maurice Loughrey, Wendy L Allen, Simon McDade, David J. Waugh, Peter W Hamilton, Daniel B. Longley, Elaine W Kay, Patrick G. Johnston, Mark Lawler, Manuel Salto-Tellez, and Sandra Van Schaeybroeck

Immune-derived PD-L1 gene expression defines a subgroup of stage II/III colorectal cancer patients with favorable prognosis that may be harmed by adjuvant chemotherapy

Philip D. Dunne, Darragh G McArt, Paul G O'Reilly, Helen G. Coleman, Wendy L Allen, Maurice Loughrey, Sandra Van Schaeybroeck, Simon McDade, Manuel Salto-Tellez, Daniel B. Longley, Mark Lawler, and Patrick G. Johnston

EDITOR'S CHOICE

Validation of a Metastatic Assay using biopsies to improve risk stratification in patients with prostate cancer treated with radical radiation therapy

S Jain, C A Lyons, S M Walker, S McQuaid, S O Hynes, D M Mitchell, B Pang, G E Logan, A M McCavigan, D O'Rourke, D G McArt, S S McDade, I G Mills, K M Prise, L A Knight, C J Steele, P W Medlow, V Berge, B Katz, D A Loblaw, D P Harkin, J A James, J M O'Sullivan, R D Kennedy, D J Waugh

Annals of Oncology, Volume 29, Issue 1, 1 January 2018, Pages 215–222,
https://doi.org/10.1093/annonc/mdx637
Published: 10 October 2017

- Data from over **2,000 patient samples in clinical trials**
- **AI** and **AA** interrogation to deliver **robust data-driven insights** into disease biology
- Underpinned
  - **New molecular classification** for CRC
  - Identification of patient cohorts who could **benefit/be harmed** from particular treatment modalities

QUEEN'S UNIVERSITY BELFAST

Silos Today - Harmonisation Tomorrow

Today

encompass
DELIVERING CARE TOGETHER

2022 & Beyond

8 PAS
14 ED

6 Labs and Rad Order Comms

4 Clinical Noting

10 Theatre Management

10 Maternity

11 Community and Social Care

10 paediatric and Adult diabetes

PAS	HCN's
1	742622
2	677946
3	546009
4	235515
5	48736

Duplicate Processes
Duplicate Patients Records
Paper Everywhere
Silos Pervasive

Harmonised Processes
Minimal Health Records
Whole System Approach

Empowering World Leading Cancer Data Science in the UK

- A **UK-wide enabled research environment** to **better inform** preventative, diagnostic and therapeutic interventions and strategies, thus ensuring **benefits** for the individual **citizen, healthcare providers** and the **UK economy**
  - **Key enablers:**
    - **Partnership and cooperation** between the key data custodians/stakeholders, especially patients
    - **Accessible** data in a timely fashion to **empower research and innovation**
    - **Safe, secure and scalable research environments** to perform high quality cancer data analysis responsibly and effectively

Delivering a bespoke Cancer Data Knowledge Network

- ***The UK Digital Innovation Hub for Cancer Data Analysis (DATA-CAN)***
- Unique **overarching collaboration** between a range of academic, clinical, patient advocacy and industry partners
- **DATA-CAN** will:
- Enable **timely access to data for research,** supported by the right technologies to **empower cutting-edge data science** through optimal collaborations between domain-specific experts, academic and clinical leaders, patients and industrial partners
- Deliver a truly **transformational step change** in our ability to engage meaningfully with industry and drive a **data-enabled innovation agenda** in the UK.
- Provide an excellent opportunity to facilitate the **better adoption of innovative technologies and applications ("innovation to implementation")** within healthcare systems. **(Less breakthrough – more follow through!)**
- **Help train** and **empower** the **next generation of cancer data scientists** in the UK

HDRUK Health Data Research UK

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Belfast Region City Deal (BRCD): A Data-Driven Game Changer for Research and Innovation

- **Once in a life-time** opportunity
- Building a **World leading Innovation Hub** to drive the fourth industrial revolution
- **Data at the heart** of the **Belfast Region City Deal**
- **Global Innovation Institute (GII)** with Northern Ireland **First Peta Scale AI Cloud Supercomputer**, underpinning **Europe's first One Health Innovation Centre (Health, Agri-food)**
- **Institute for Research Excellence in Advanced Clinical Healthcare (iREACH) – data enabled** health preservation and enhancement
- **A citizen and societal focussed initiative**

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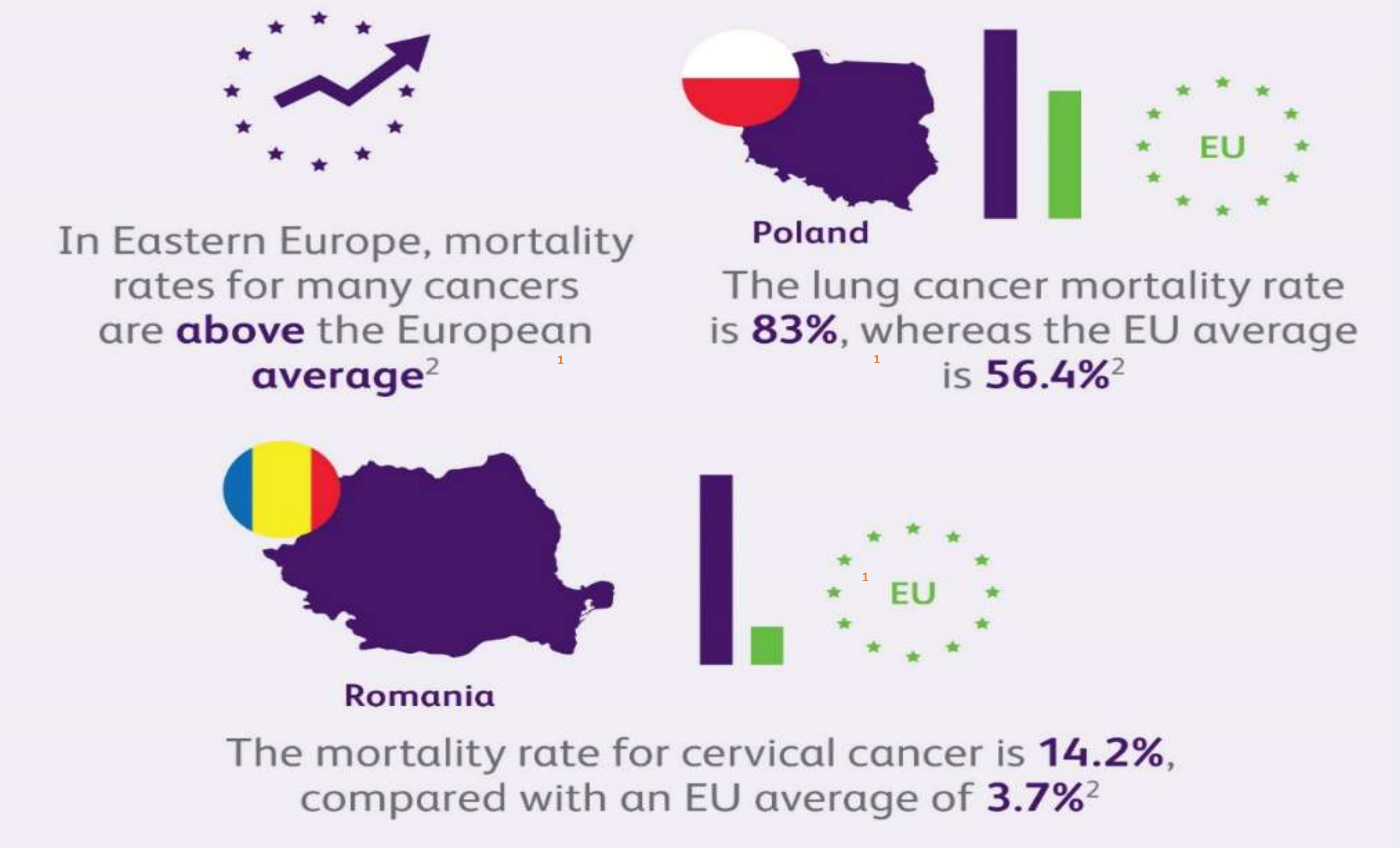
Using Data to Challenge the Europe of Disparities



In Eastern Europe, mortality rates for many cancers are **above** the European **average**[2]

Poland

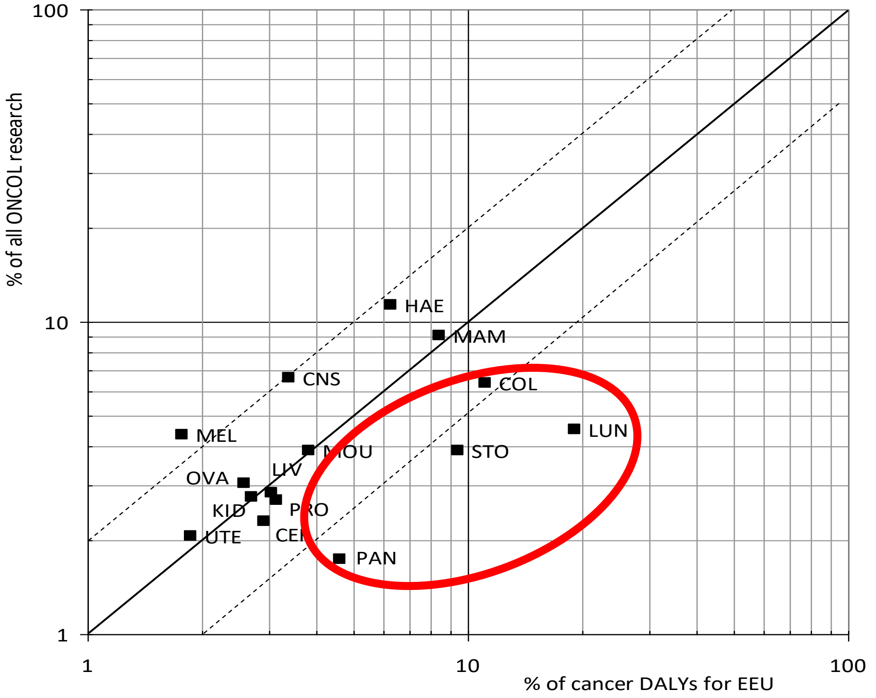
The lung cancer mortality rate is **83%**, whereas the EU average is **56.4%**[2]

Romania

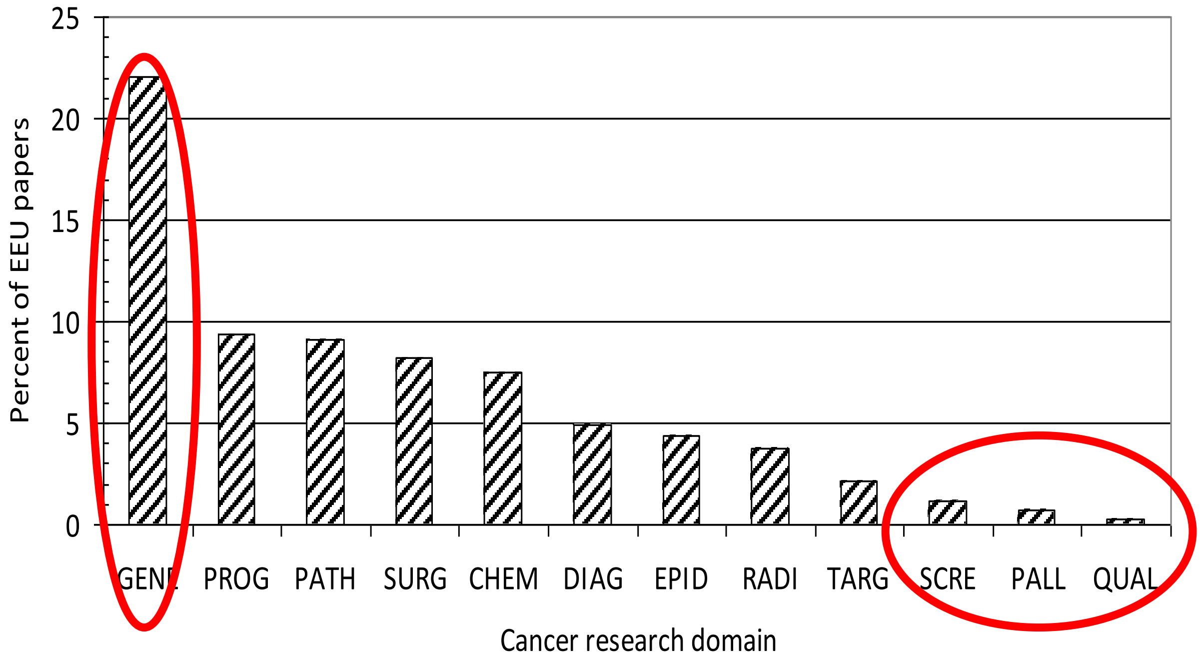
The mortality rate for cervical cancer is **14.2%**, compared with an EU average of **3.7%**[2]

Research by Disease Site and by Research Domain

Research as a function of the disease burden from different cancers

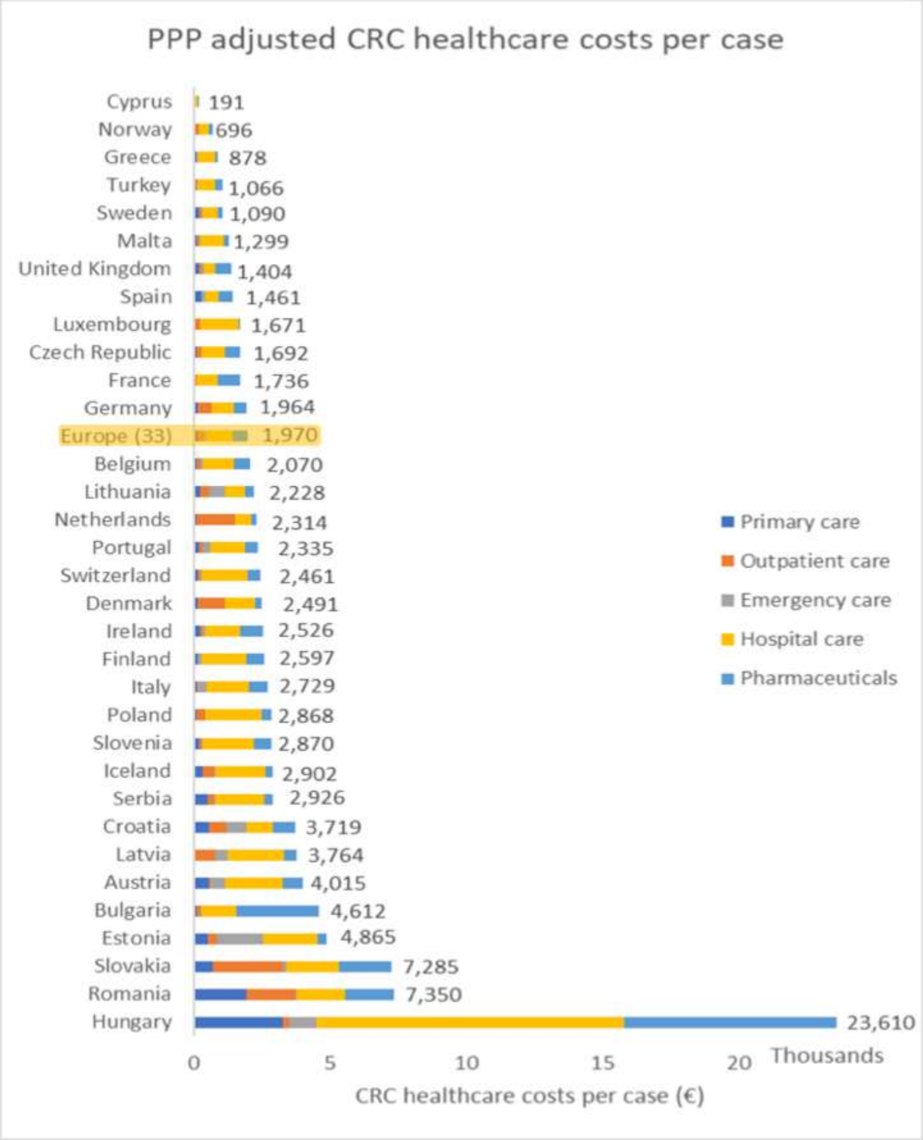


Research as a function of research domain



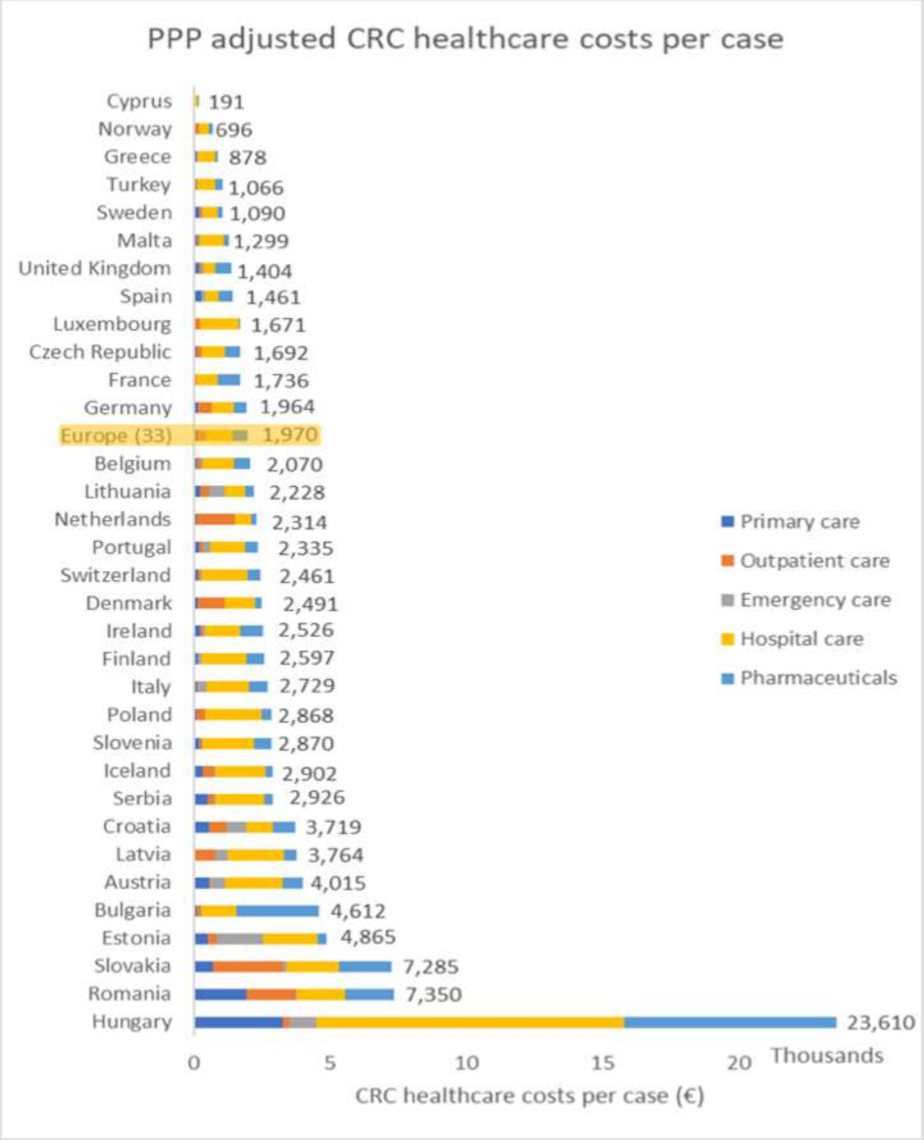
Begum M, et al. Eur J Cancer. 2018 Nov;104:127-136

And it’s not what you spend….

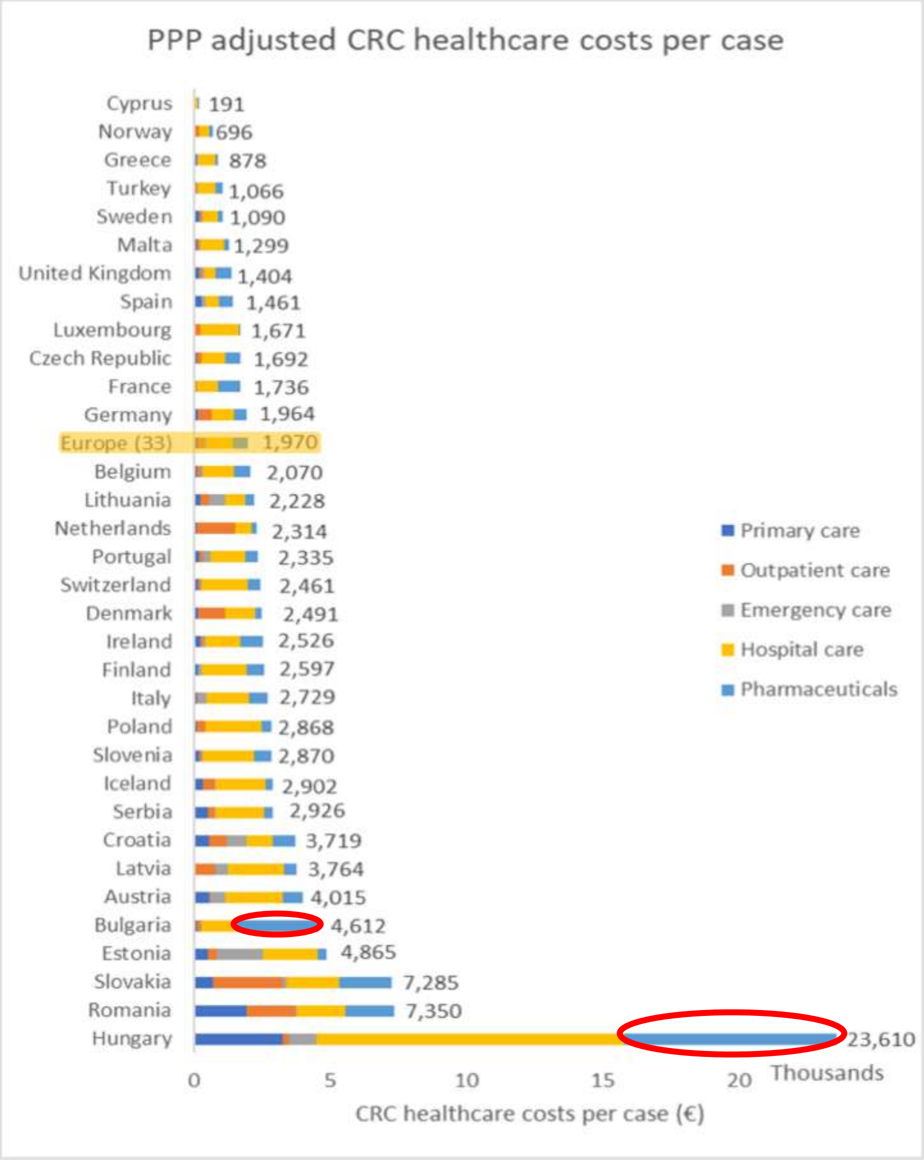


Henderson R, et al. Manuscript in preparation.

It’s the way that you spend it!



Henderson R, et al. Manuscript in preparation.



Empowering enhanced cancer control through the use of Data

- **Access** to reliable data and its robust **interrogation** are **key drivers** for **improved cancer control**
- Data are critical to **underpinning** the introduction of **innovation** within cancer care pathways and health systems
- **Cancer policy** must be **informed** by the use of **reliable, robust data** that **reflect** both local and regional **context**, and national and global **learning**
- Our Data on **cancer disparities** underpinned the development of the **European Cancer Patient's Bill of Rights**[1]
- **Led** to the recent prestigious 2018 **European Health Award**

[1] Lawler et al *Lancet Oncology* 2014;

QUEEN'S UNIVERSITY BELFAST

So is it time for a Cancer Moonshot for Europe?

A Data Informed Cancer Groundshot

THE LANCET Oncology

European Groundshot Commission

QUEEN'S UNIVERSITY BELFAST

PANEL: A EUROPEAN MASTERPLAN FOR CANCER

Antonella Cardone

Director, European Cancer Patient Coalition (ECPC)

Frederico Calado

Head of Real World Evidence Innovation & Partnerships at Novartis Oncology

Collaborative potential between Industry and Member State Cancer Registries

Frederico Calado
Head RWE Innovation & Partnerships, Novartis Oncology

Oncology Data Summit, 18 June 2019, Brussels

Why a closer collaboration between Industry and MS Cancer Registries makes sense

Registries complement RCT data

- High-quality longitudinal data sources
- Reflective of ‘real-world’ clinical practice
- Lower risk of selection bias (when population-based)

Ongoing challenges with Registries

- Incomplete national coverage & linkage issues
- Different data collection standards across MS
- Resource constraints & high dependence on local funding cycles

Shared interest on research questions

- Natural history of disease (e.g. rare cancers)
- Treatment patterns
- Comparative effectiveness and safety

How can these public-private arrangements work in ‘real life’?

- Legal basis & scope?
- Governance?
- Funding?

NOVARTIS

The new proposal for the Public Sector Information Directive (signed by the Council of the EU 6/6/2019)

- Creation of “a list of fundamental **high-value datasets** that should be freely available in all MS”
  - *(...) associated with important socio-economic benefits, notably because of their suitability for the creation of value-added services and applications, and the number of potential beneficiaries of the value-added services and applications based on these datasets*

The EC will work with the MS on identifying high-value datasets and these will be set out in an implementing act; MS have 2 years to implement the new rules before they take effect

Why a closer collaboration between Industry and MS Cancer Registries makes sense… and is possible!

Registries complement RCT data

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Ongoing challenges with Registries

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Shared interest on research questions

- Natural history of disease (e.g. rare cancers)
- Treatment patterns
- Comparative effectiveness and safety

PSI Dir. as a collaboration catalyst

- Provides the legal basis & well defined scope
- MS will develop policies to enable access, including governance and funding
- "High-value" = more investment from MS?

NOVARTIS

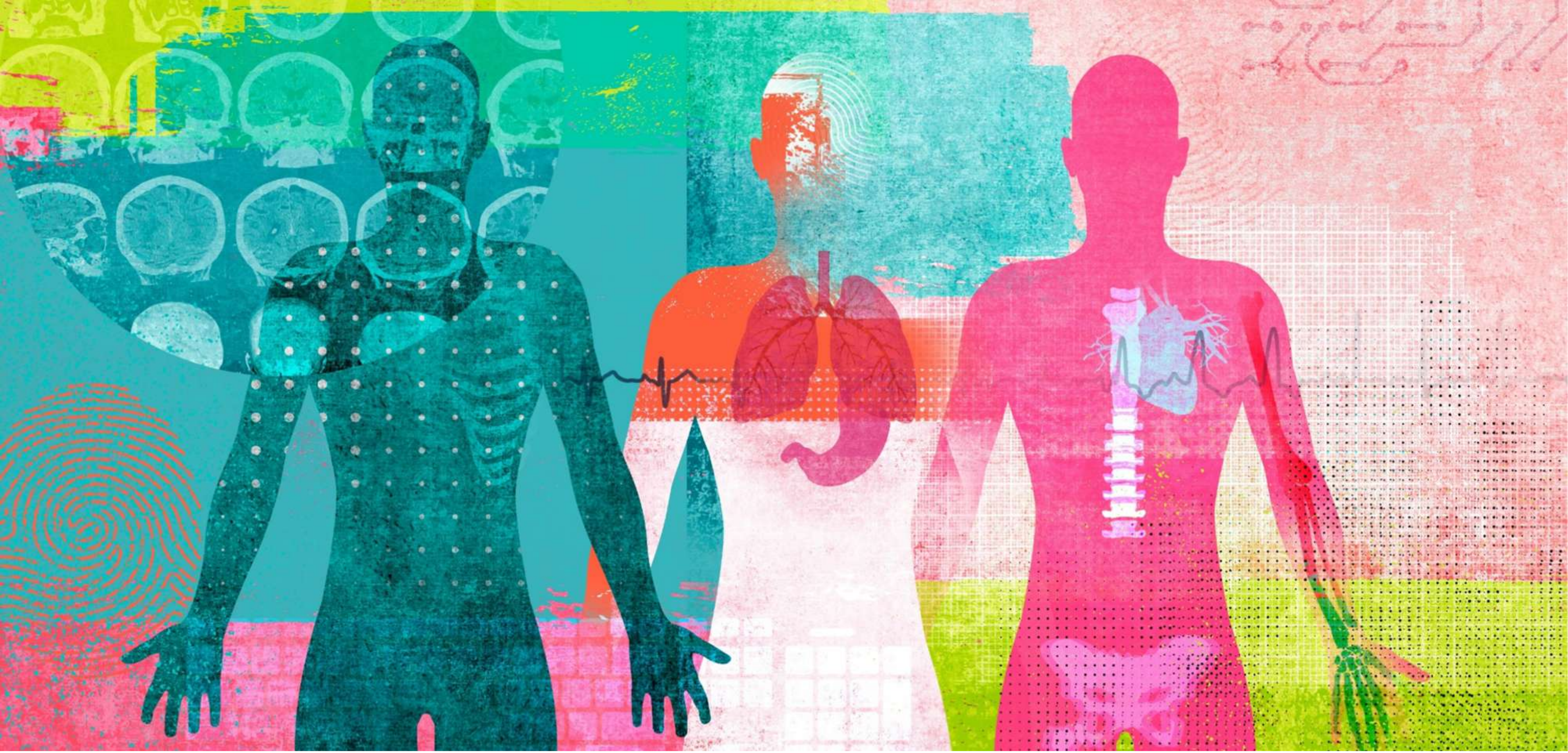
CONCLUDING NOTE AND PRESENTATION OF VOTING RESULTS

Alexander Roediger

Chair of the EFPIA Oncology Steering Committee

Tamsin Rose

Senior Fellow, Friends of Europe



NETWORKING RECEPTION

#OncologyDataSummit