State of the Situation in EU for Oncology RWD

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CDDF Workshop – July 6, 2016

Outline of presentation

- Unlocking the potential of RWD

- EU-level initiatives to increase the utility of RWE
  - Patient registries
  - Electronic Health Records
  - Cancer networks & initiatives

- Challenges to realising the full potential of RWE in Europe

What is RWD & what is its role in a product's lifecycle?

Real World Data (RWD)

Healthcare data collected in real life practice settings and so, outside the context of RCTs

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To generate Real World Evidence (RWE)

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Drug development
- To determine natural history
- To define subpopulations with better benefit-risk profiles
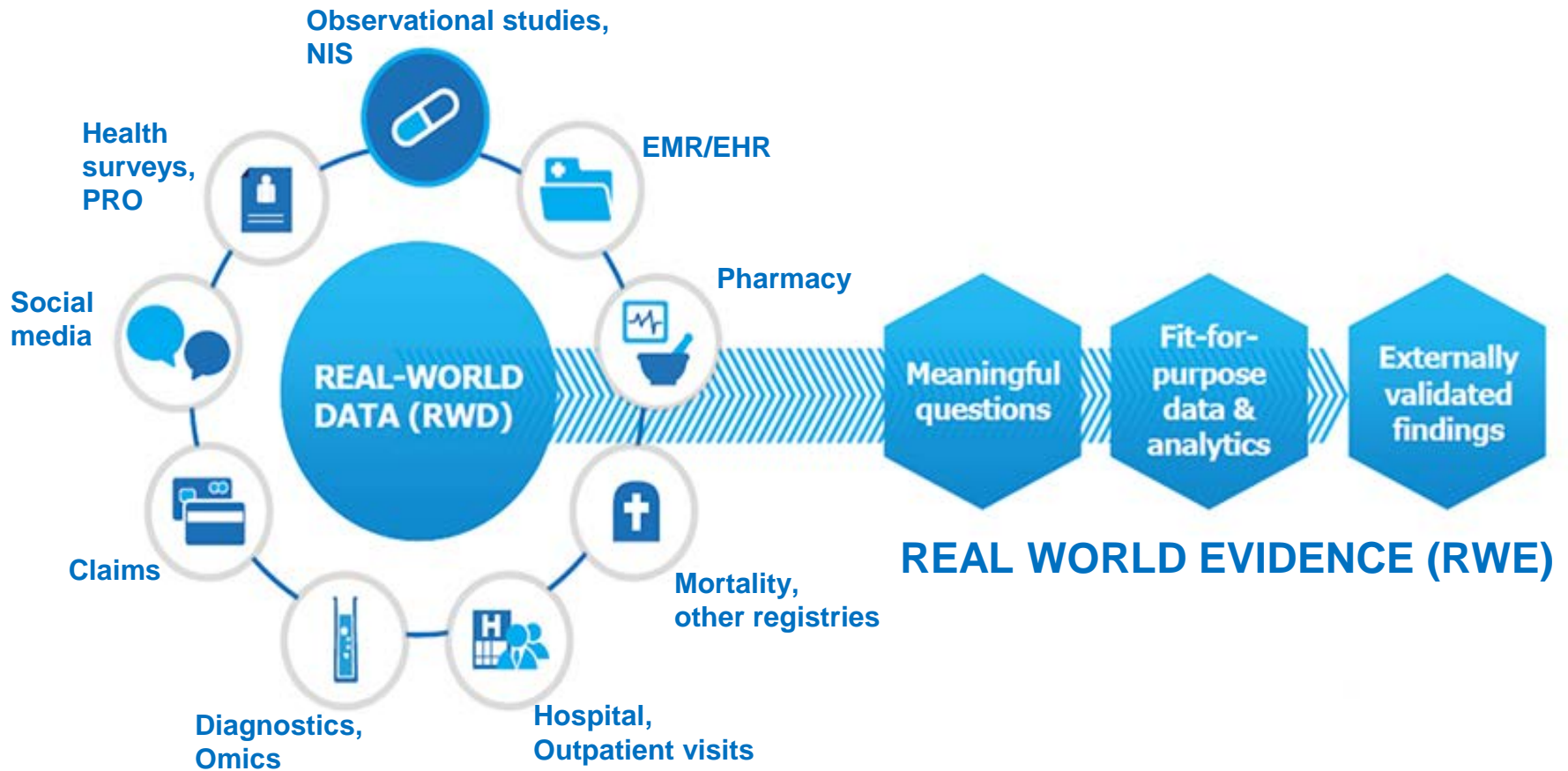- To inform the design of pivotal trials

Regulatory
- Fulfilment of post-marketing commitments (RMP, PAES, PASS)
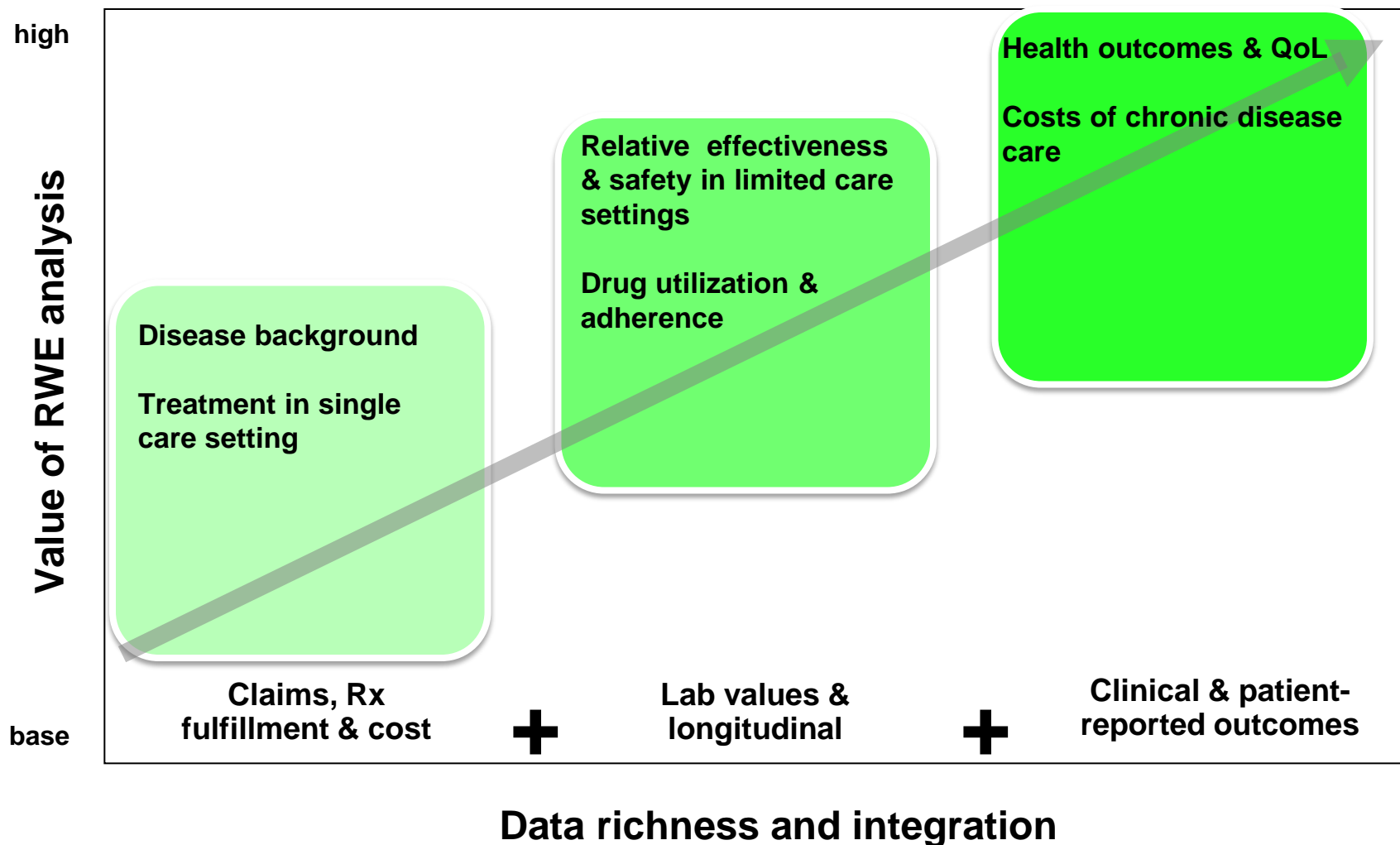- Conditional marketing authorisations, adaptive pathways

HTA assessment
- Relative effectiveness assessment
- Input pharmacoeconomic models
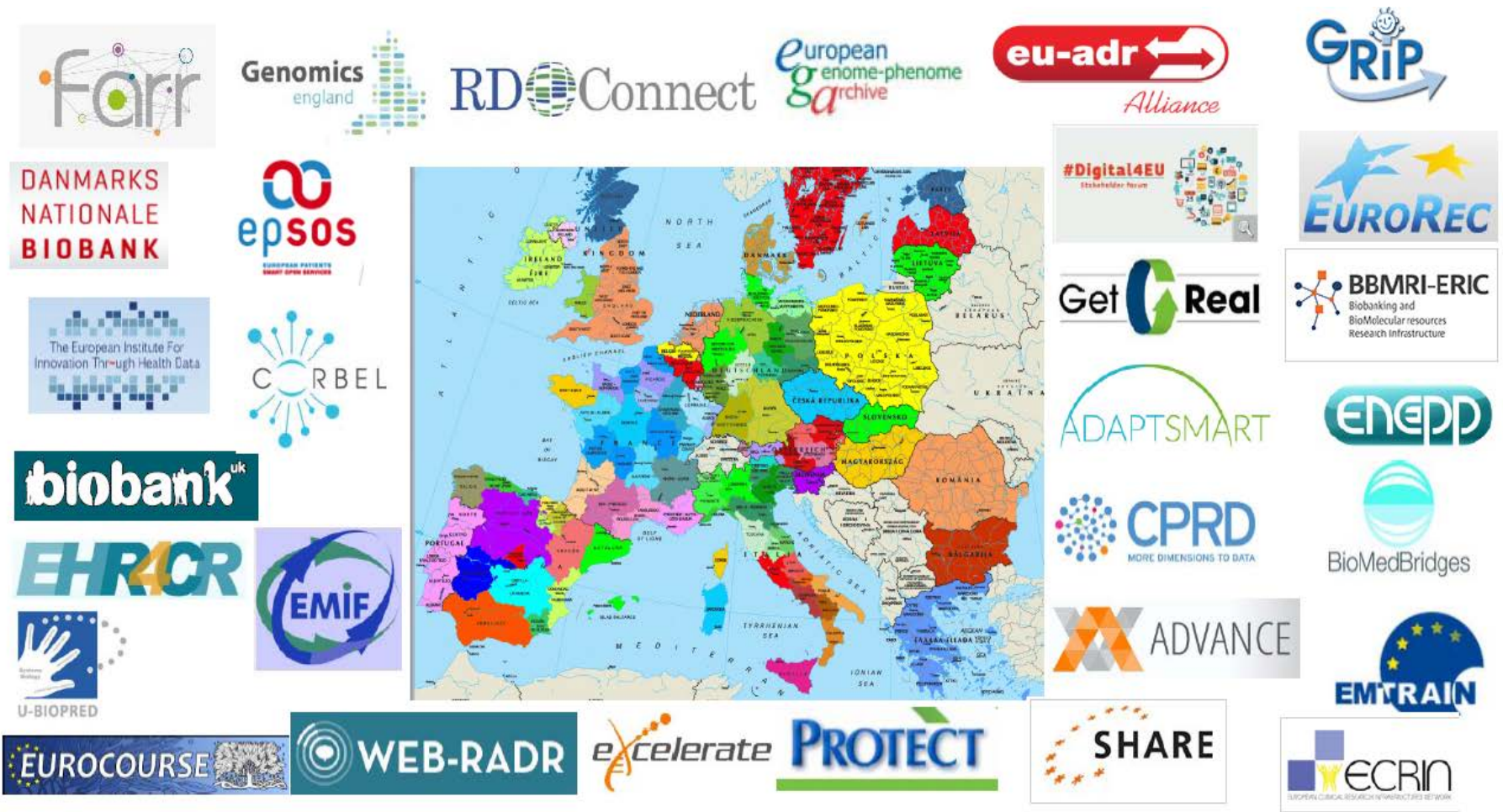- Provide inputs on the drug prescription and use

Data integration can unlock the full potential of RWD

Integration of different RWD sources increases utility of RWE

Value of RWE analysis (vertical axis, from base to high)

- Disease background

  Treatment in single care setting

- Relative effectiveness & safety in limited care settings

  Drug utilization & adherence

- Health outcomes & QoL

  Costs of chronic disease care

Claims, Rx fulfillment & cost **+** **Lab values & longitudinal** **+** **Clinical & patient-reported outcomes**
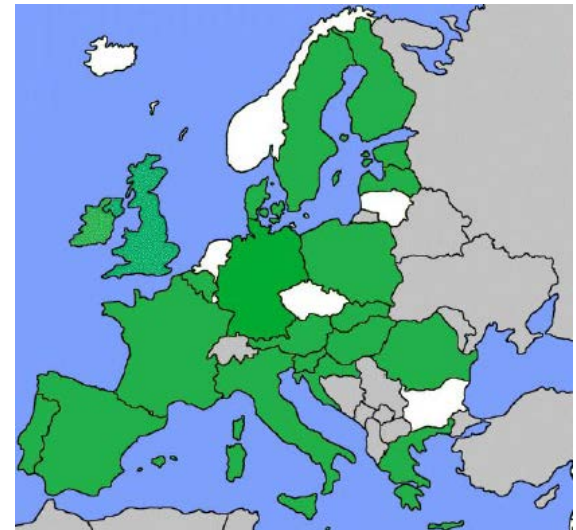
Data richness and integration

Many EU-level initiatives to increase the utility of RWE

EU-level initiatives to increase the utility of RWE

- Initiatives on **patient registries** (such as PARENT Joint Action, ENCR - European Network of Cancer Registries, Eurocourse and the EMA Initiative on Patient Registries)

- Initiatives on **electronic health records** (such as EH4CR, EMIF, EU-ADR Alliance, RD-Connect, epSOS, EuroRec)

- Initiatives aimed at **establishing methods and platforms to enable and facilitate data access, analysis and collaboration** (such as IMI GetREAL, IMI PROTECT, IMI ADAPT SMART, IMI ADVANCE, the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance - ENCePP)

- Initiatives on **HTA** (EUnetHTA JA3 aims to conduct pilots on post-launch evidence generation and to develop a tool to support permanent collaboration on post-launch evidence generation)

PARENT set up to promote cross-border secondary use of data at EU level

PARENT – PAtient REgistries INiTiative (05/2012 - 11/2015)

PARENT may provide **framework for accessing RWD**

The PARENT RoR is envisioned as a Web service to ensure up-to-date information about patient registry metadata

Guidelines, Recommendations, Methodologies

Best practices

Common information model, ontologies, vocabularies

Services, SW tools repository

Registry of Registries (RoR), Assessment tool

Knowledge Management Platform

PARENT Framework

http://patientregistries.eu/ (accessed July 2016)

European Network of Cancer Registries (ENCR)

The network was established in 1990 within the framework of the Europe Against Cancer Programme of the European Commission.

ENCR Objectives:

- to improve the quality, comparability and availability of cancer incidence data

- to create a basis for monitoring cancer incidence and mortality in the European Union

- to provide regular information on the burden of cancer in Europe

- to promote the use of cancer registries in cancer control, health-care planning and research

EHR systems throughout Europe

Legend:
- Countries currently implementing national eHealth strategies
- Countries with a national eHealth strategies (pre-implementation phase)
- Countries with regional eHealth strategies only
- Countries without eHealth strategies

Majority of European countries are designing or implementing strategies for development of **national EHR systems**

National initiatives aimed at **harmonisation** of RWD

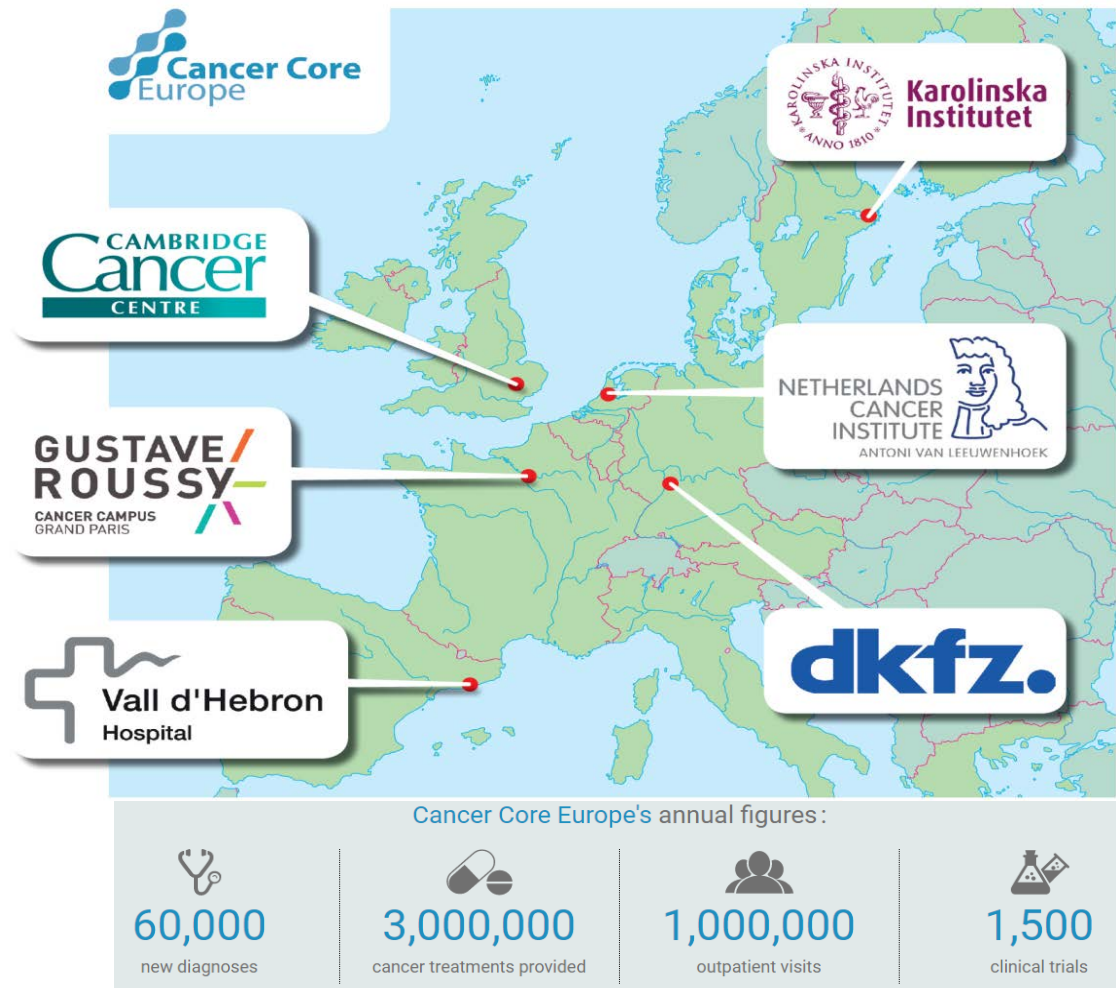Several Initiatives aimed at **increasing accessibility and utility of EHR** for clinical research and drug safety

Map country labels: Iceland, Norway, Sweden, Finland, Estonia, Latvia, Lithuania, Denmark, Ireland, Great Britain, Netherlands, Germany, Belgium, Poland, Czech Republic, Slovakia, Austria, Hungary, France, Switzerland, Slovenia, Romania, Spain, Portugal, Italy, Bulgaria, Greece

Stroetmann, 2011; RAND 2014 Assessing the RWD Policy Landscape in Europe

Cancer Core Europe – a virtual "e-hospital"

Cancer Core Europe was established in 2014

Create platform allowing the **exchange of data** (genomic, imaging, clinical, treatment outcomes) across centers

Harmonisation of diagnostics, imaging, omics, biobanking, shared databases

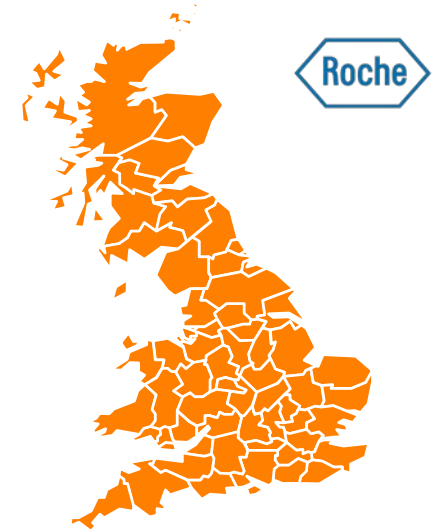Use **common standards** to ensure data interoperability

Cancer Core Europe's annual figures:

60,000	3,000,000	1,000,000	1,500
new diagnoses	cancer treatments provided	outpatient visits	clinical trials

http://www.cancercoreeurope.eu/ (accessed July 2016)

SACT Systemic Anti-Cancer Therapy
Chemotherapy Dataset

Roche

National collection of all cancer chemotherapy in the NHS in England since 2012

SACT Systemic Anti-Cancer Therapy
Chemotherapy Dataset

- DEMOGRAPHICS AND CONSULTANT
- DRUG DETAILS
- PROGRAMME AND REGIMEN
- CLINICAL STATUS
- CYCLE
- OUTCOMES

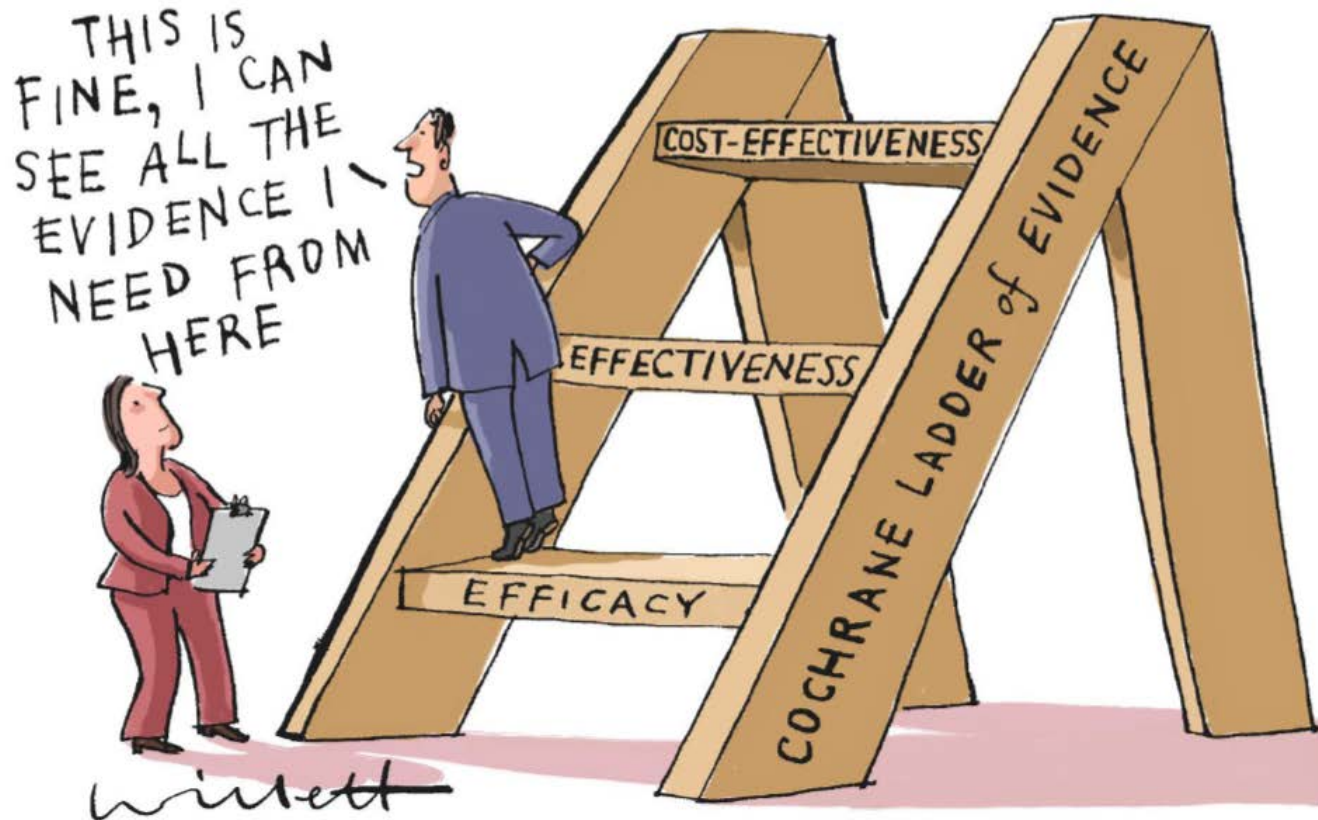**Real world 43-field oncology drug registry that is linkable via the unique NHS number**

NHS developed and owned

Every NHS funded treatment is recorded

Has ~ 200,000 patients

http://systems.hscic.gov.uk/data/nhsdmds/faqs/datasets/sact (accessed July 2016)

Challenges to realising the full potential of RWE in Europe

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- Fragmentation and quality of data sources constitute a challenge for RWD access

- New data protection regulations in the EU may lead to a restrictive environment for data access

- Agree best mechanisms for governance of RWD collection efforts and develop policies accordingly

- Standardise and provide guidance on tools, methodologies and strategies for RWD collection and analysis

Doing now what patients need next