




European Federation of Pharmaceutical Industries and Associations

EFPIA

Oncology data landscape in Europe
Data sources & initiatives

Research Report
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Disclaimer

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

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Executive summary

- This deliverable focuses on:
  1) *Characterisation of the current data landscape, and its strengths and weaknesses, providing a macro-view of European data sources grouped by archetypes*
  2) *Characterisation of current European oncology initiatives looking at their aims and methods, unique approaches, as well as the barriers they face*
- We have conducted a bottom-up assessment of the current data landscape using the IQVIA RWD catalogue to identify data source archetypes
  - **Research databases** [standalone / partnerships]
  - **Facilitated networks**
  - **EMR-linked sources**
  - **Administration and claims sources**
  - **Large scale clinical registries**
- Interviews were conducted with initiative experts to gain first-hand knowledge of both the initiatives themselves and the barriers they believe exist in the landscape
- Initiatives provide insights into “what good looks like” and how EFPIA Oncology might consider collaborating or replicating to help develop future interventions

Contents

Introduction

The health data landscape is diverse with many data sources and some standout initiatives; all with varying abilities to tackle the use cases

European Health Data Landscape Definitions

Data Sources

An organised repository of information that can be managed, updated and queried for a variety of purposes; individual characteristics vary greatly between data sources

Data Source Archetypes

A typical data source, illustrating features that may be common amongst similar data sources but that any individual data source may not align to completely

Health Data Initiatives

Are projects working with health data that have a clearly defined purpose driving all their activities and an innovative approach for achieving their aims

Overview of use cases

Use case	Description
R&D enablement	• To support identification of promising compounds, investigation of the genome & smarter clinical trials (e.g. through better design & recruitment, or provision of historic control groups)
Healthcare context	• To understand the context of the disease & patient populations • Can include population characteristics, biomarkers/ genetic characteristics & unmet need, but also non-health related aspects (e.g. microbial, ecological); can be used to prioritise resource allocation
Treatment patterns	• To understand real-world usage of anti-cancer treatments, including by patient group, line of therapy & geography • Can be used to prioritise resource allocation, avoid wastage &over-treatment, & modify treatment guidelines based on evidence rather than experience
Real-world clinical value	• To understand the use of anti-cancer treatments (including drugs & combinations) & delivery of their clinical promise in a real-world setting (including outcomes & safety, quality assurance, etc.) • Can be used to prioritise resource allocation
Socio-econ value	• To measure the value of a drug or intervention beyond that provided to patients & health systems; includes indirect costs (e.g. lost employment, absenteeism & presenteeism)
Pricing enablement	• To provide a mechanism for flexible pricing, based on use, indication and/ or outcomes
Patient perspective	• To offer insight into quality of life (including PROs), covering aspects of care beyond purely clinical outcomes, to support patient empowerment

Source: A.T. Kearney; IQVIA

Contents

IQVIA's RWD Catalogue supported the creation of a macro-level view of Europe's oncology health data landscape

Overview of the RWD Catalogue:

RWD Data Sources

- 3025 sources across 110 countries
  - 1/3 EU5
  - 1/3 Europe outside EU5
  - 1/3 rest of the world
  - **58% include oncology**

Oncology Data Sources

- 1749 oncology data sources world wide
  - **1107 are within Europe**
    - 675 are within the EU5
    - 31% are multi-country

RWD Catalogue: 3025 entries

Approach for using the RWD Catalogue:

Methodology

- A systematic approach was used to analyse the oncology health data landscape:

1. Identification of driving characteristics within the RWD Catalogue
2. Segmentation into preliminary archetypes
3. Validation and refinement using expert opinion
4. Detailed archetype characterisation including assessment vs. use cases

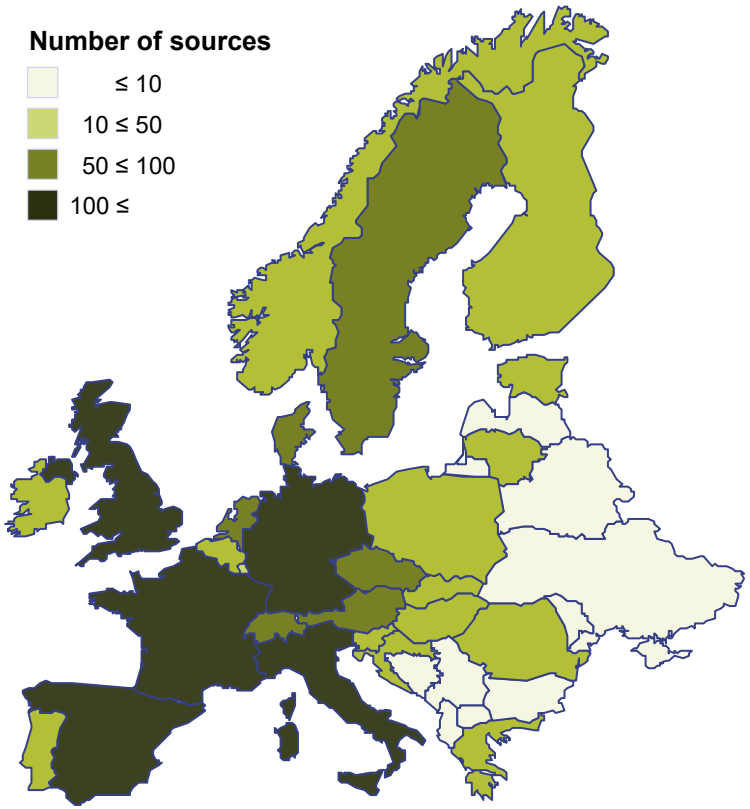
Outputs

1. This report provides macro-level views of the data sources by country and by cancer focus
2. Through the characterisation of health data source archetypes we demonstrate some of the limitations of the current data landscape
3. Whilst not a guide to engaging with individual health data sources, the information can help inform future approaches and initiatives to improve the landscape

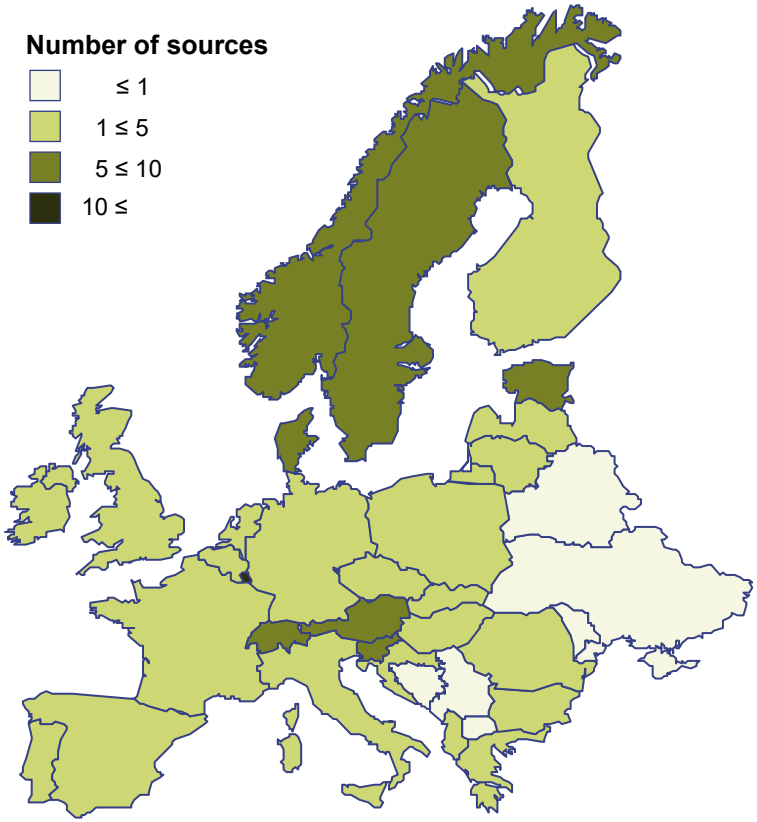
Note: values denoting entries in the RWD Catalogue are latest counts as of Q1 2018
Source: IQVIA RWD Catalogue; IQVIA research

Sources are predominantly in the EU5 markets but concentration is strongest in Scandinavia and some central European countries

Distribution of known oncology data sources across Europe (absolute)



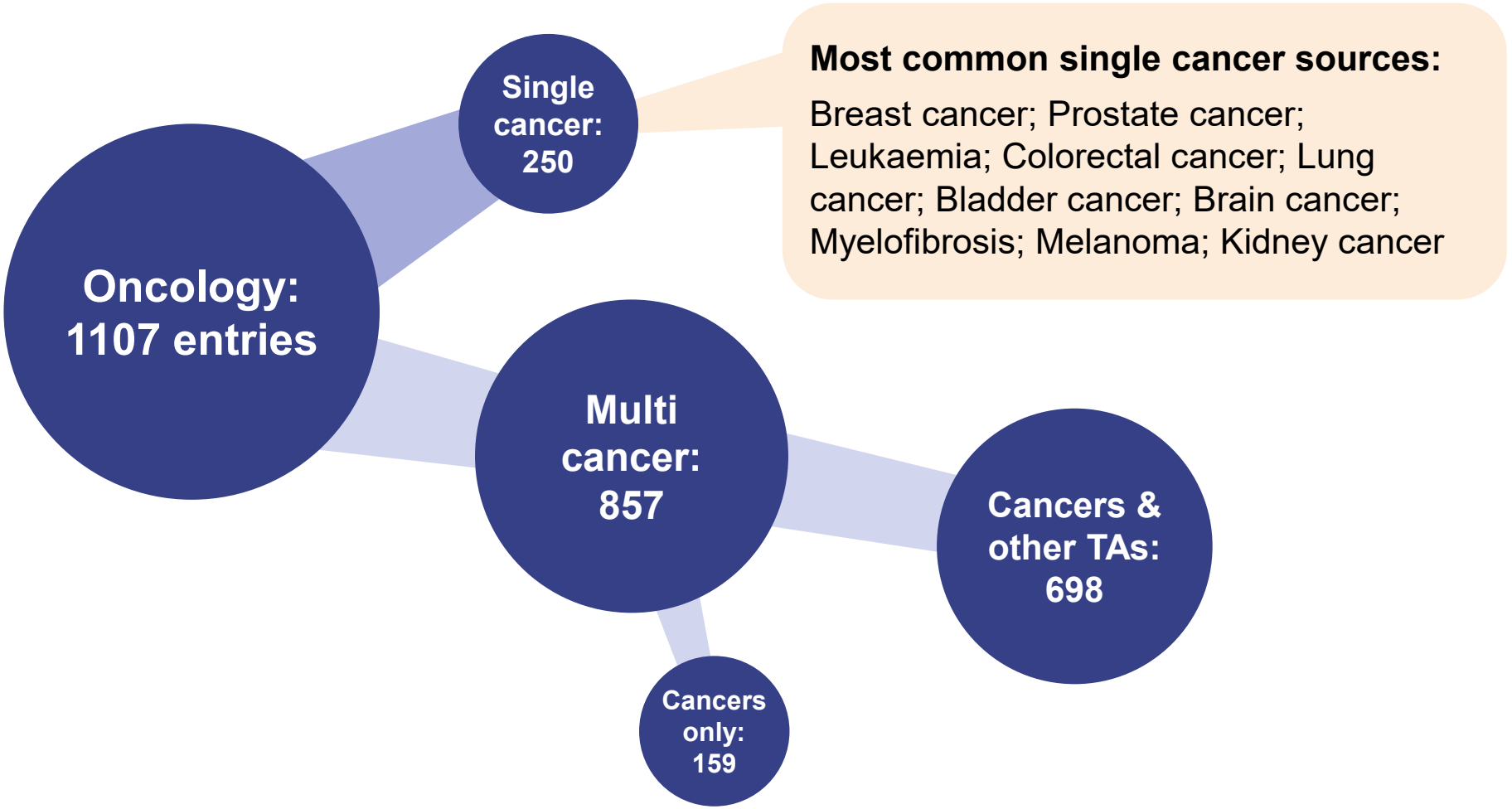
Distribution of known oncology data sources across Europe per capita (millions)



Note: the analysis does not account for # patients per data source nor potential overlap between data sources

Source: IQVIA RWD Catalogue; IQVIA research

The majority of health data sources are not specific to single cancers, or cancers in general but cover many therapeutic areas (TAs)



Source: IQVIA RWD Catalogue; IQVIA research

Five distinct archetypes have been developed to describe the variety of data sources found across Europe

Primary focus of data source*

	Archetype	Summary
Research	**Research database** • *Standalone* • *Partnerships* 	Secondary data collated from primary sources (re-type) for a **specific research purpose**; can be either standalone or a partnership formed around common research interests. Commonly these data sources are time-limited and have an uncertain duration. Combination of government, pharma and 3rd sector funding via specific and non-specific grants. Access is typically granted for protocolised studies.
Research	**Facilitated networks** 	Centred around a 3rd party (usually commercial) to coordinate a network of data sources. They are able to serve the **varied research needs** of many stakeholders. The 3rd party acts to support both the sources and stakeholders. Typically syndicated offerings funded by commercial engagements. Access is granted via formal contracting, in some cases requiring a protocol.
Healthcare System	**EMR-linked database** 	Data sitting in existing EMRs, created to **support the healthcare system** (both primary and secondary care), that have been developed to allow direct extraction to support a variety of research purposes. Funded typically by hospitals or administration services. Access for primary care is typically well established and commercialised; in secondary care they are uncommon and without established access approaches.
Healthcare System	**Admin/ claims** 	Created to capture data to **support healthcare administration** purposes such as tracking activities within healthcare, supporting insurance companies and reporting to governmental authorities. Funding is by central or regional government and health authorities. Where available, access is typically provided by established protocolised process.
Healthcare System	**Large scale clinical registries** 	Typically government funded registries collecting data at a national or international level to generate clinical evidence to **support the healthcare system**. Funding often by national government. Access is through a protocolised process and typically only for medico-scientific or public-interest research.

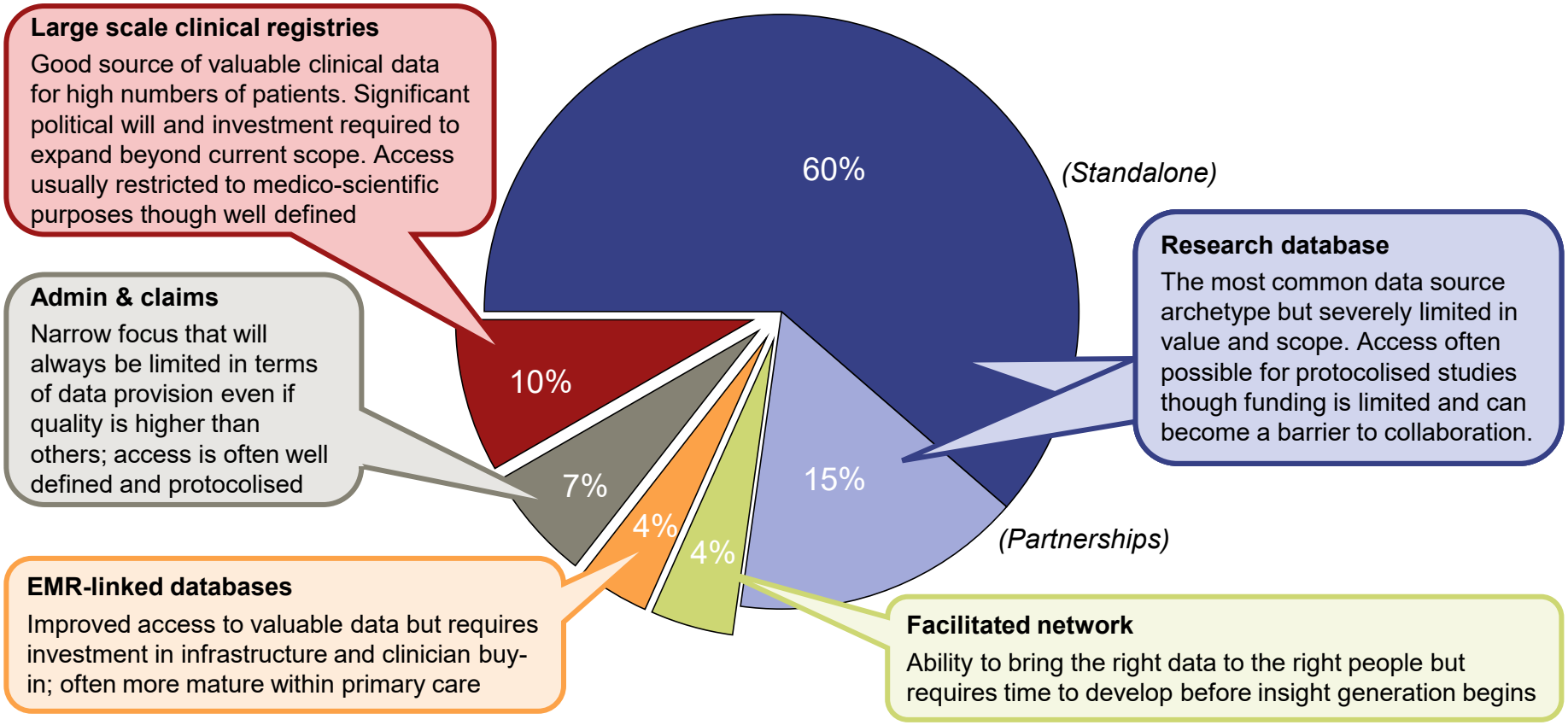
**Data sources are not restricted to a single focus and will support secondary functions in addition to their primary focus*

Re-type refers to the process of copying existing information out of an original EMR system into a secondary database for secondary use rather than having to utilise the original data system directly

Source: IQVIA RWD Catalogue; IQVIA research

Research registries are the most numerous but the most value can be found in some of the other archetypes

Distribution of data sources in RWD catalogue across archetypes*



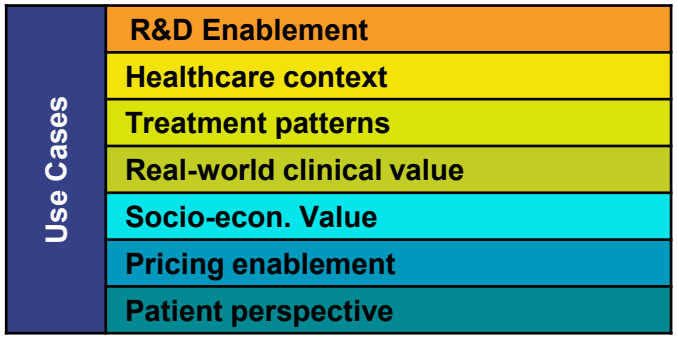
Understanding each archetype in detail can highlight their value for insights and research collaboration

*Approximate, based on assessment of the IQVIA RWD catalogue
Source: IQVIA RWD Catalogue; IQVIA research

Each archetype has been profiled based on common characteristics commonly found with data sources aligned to each archetype

1. The following characteristics were used to profile the archetypes:
   - Access to source
   - Funding
   - Coverage
   - Depth of data variables
   - Quality of data
   - Latency

2. Archetypes' anticipated ability to support the use cases was also considered



Assessments were rated in high, medium or low categories dependent on the characteristic

Good/ Deep/ Secure	Variable/ Moderate/ Sufficient	Difficult/ Poor/ Insufficient

Source: IQVIA RWD Catalogue; IQVIA research

Archetype Profile
Research database (standalone)

Characteristics:
- Data sources **typically local or regional**; centred around a **single academic** hospital or institute, with most capturing fewer than 10,000 patients
- **Data fields can be variable** and are often focused on a subset of information based on the source's own research interests. This often centres on patients, treatments and outcomes data with very few collecting cost & resource data
- Whilst many will collect longitudinal data the proportion is lower compared to data sources captured in other archetypes
- **Publication rate is high** compared to other archetypes and often the only way to identify data sources as they do not routinely have an external presence (e.g., website) beyond that of the institute they sit within

Access and funding:
- Access is typically for **protocolised studies** – for which either blanket ethical approvals exist or case-by-case approval is required through an established process. Many have the right to transfer data based on consents collected at the point of first data capture
- **Funding is fragmented** and time-limited through a combination of government, pharma and charity (3rd sector) funding both via specific studies and non-specific grants

Strengths:
- ✓ Targeted data provision for focussed research questions allowing for insight delivery/ publications for protocolised research studies
- ✓ Quantity of data sources ensures that they collectively cover a broad scope of markets/ regions and therapeutic areas

Weaknesses:
- × Data provision usually struggles beyond **narrow scope** with quality often low for many variables; often lacking standardisation & internal coding
- × Often lacking data beyond 1st line treatment; with line of therapy difficult to infer
- × Resourcing often not available to manage data quality issues or the capture of additional variables without significant support; difficulties can be had in attempting to go back to original source
- × Decision & delays decisioning

Examples:
- *Brighton & Sussex university hospitals trust* mBCa information system
- *Manchester children's tumour registry*
- *Ege university dept. of urology database*
- *University of Belgrade CLL database*

Characteristic	Rating
Access to source	Difficult
Funding (amount)	Insufficient
Funding (duration)	Insufficient
Coverage	Narrow
Depth of data variables	Moderate
Quality of data	Poor
Latency	Moderate

Use Cases	Rating
R&D enablement	Poor
Healthcare context	Variable
Treatment patterns	Variable
Real-world clinical value	Variable
Socio-econ. value	Poor
Pricing enablement	Poor
Patient perspective	Poor

Source: IQVIA RWD Catalogue; IQVIA research

Archetype Profile
Research database (partnerships)

Characteristics:
- Initiated through a **partnership** of existing standalone registries, or where new registries are created independently but intended to work with other registries from the outset
- Partnerships span a **broad mix of geographic scales** from regional through to international dependent on the current members of the partnership; patient numbers also vary dependent on members' size
- Data are **able to address specific questions** regarding healthcare, treatment, pricing enablement and real-world clinical value; with a good ability to collect diagnostic information, however with a varying ability to collect longitudinal data
- Collaborations are maintained through **shared research interests** but can develop into more formal self-managed arrangements with shared governance structures and shared study funding

Access and funding:
- Access is more established compared to standalone research databases but remains **driven by the submission** of study protocols for ethical or scientific review
- **Funding is fragmented** and time-limited through a combination of government, pharma and charity (3rd sector) funding both via specific studies and non-specific grants

Strengths:
- ✓ Targeted data provision as with other academic registries but with the additional value of have more representative data over a large geog.
- ✓ Working in a partnership will encourage improvements in governance and a degree of standardisation within the databases
- ✓ Willingness to collaborate with 3rd parties can be higher given the pre-existing inclination to form partnerships to benefit research impact

Weaknesses:
- × Latency across networks can be an issue where satellite centres are required to transfer data to a central hub at defined periods
- × Data provision often remains limited with no internal resourcing to improve quality and data capture concerns; often lacking data beyond 1st line treatment; with LOT difficult to infer
- × Sites' funding can be independent creating risk to partnership's stability

Examples:
- *Bart's Cancer Institute*
- *The Czech leukaemia study group for life*
- *Rete Ematologica Lombarda (Lombardy Hematologic Network)*
- *EU ADR Network*

Characteristic	Rating
Access to source	Variable
Funding (amount)	Sufficient
Funding (duration)	Sufficient
Coverage	Moderate
Depth of data variables	Deep
Quality of data	Moderate
Latency	Poor

Use Cases	Rating
R&D enablement	Poor
Healthcare context	Variable
Treatment patterns	Variable
Real-world clinical value	Variable
Socio-econ. value	Poor
Pricing enablement	Poor
Patient perspective	Poor

LOT = length of treatment
Source: IQVIA RWD Catalogue; IQVIA research

Archetype Profile
Facilitated network

Characteristics:
- The data source consists of a **3rd party organisation** that manages access to a network and provides access to a variety of stakeholders; the network's constituent parts can be varied to allow a broader variety of research uses
- The networks cover **large geographical regions** with many having national or international scopes; coverage within the geographies is not always good with a focus on select deep insights from many locations
- Networks will have a **broad scope** but are usually still focused on a common effort – not trying to do everything
- **Publication rates are low** compared to other archetypes,
- Compared to other archetypes they **proactively seek collaboration** and as such are most likely to have a website providing details on the data source

Access and funding:
- Funding is typically through **commercial engagements** for the provision of data from the network to interested partners
- Access will often be **well defined contracting** and in some cases requiring a protocol

Strengths:
- ✓ Targeted data provision for focused research questions for commercial partners and multi-sector collaborations
- ✓ Resourcing is more secured allowing investment into the data sources within the network
- ✓ Governance processes are clear and there is a good degree of standardisation across the network

Weaknesses:
- × Time to build the networks requires upfront investment with little initial reward
- × Not suited for broad epidemiological studies due to limited patient coverage across geographies
- × Network facilitating 3rd parties will retain a degree of autonomy which will limit the ability of users to influence changes for individual needs

Examples:
- *iOMEDICO*
- *IQVIA Oncology Dynamics*

Characteristic	Rating
Access to source	Good
Funding (amount)	Sufficient
Funding (duration)	Sufficient
Coverage	Moderate
Depth of data variables	Moderate
Quality of data	Good
Latency	Good

Use Cases	Rating
R&D enablement	Poor
Healthcare context	Variable
Treatment patterns	Good
Real-world clinical value	Variable
Socio-econ. value	Poor
Pricing enablement	Variable
Patient perspective	Poor

Source: IQVIA RWD Catalogue; IQVIA research

Archetype Profile
EMR-linked database

Characteristics:
- EMR data sources **can be accessed directly** to utilise primary and secondary care data for research purposes (though predominantly primary care)
- Patient numbers can be limited with **EMRs restricted to specific clinics**; though some exist where third parties are able to support access to large-scale EMR data
- Data is usually **focused on clinical data** with the specifications decided by the needs of the healthcare provider that initiated the EMR; this includes patient and treatment data as well as outcomes and occasionally resource utilisation data; data is usually longitudinal though can be limited to stage in healthcare system (e.g., primary care clinic)

Access and funding:
- In **primary care, access is typically well established** and commercialised; **secondary care EMRs set up as data sources for research purposes are rare** but there is an increasing interest from healthcare providers to find ways to access them.
- Typically **requires protocols** but the contracting process is often ad hoc.
- **Funded either by hospitals** to enable paid research or basic administration of case-load; or by third party intermediaries hoping to create PoCs and enable sell-on; or in primary care as a by-product of bought-in case management software. Once initial free of charge implementation is carried out, funding often becomes insecure

Strengths:
- ✓ Able to capture detailed patient level data including treatment patterns, outcomes, and often cost and diagnostic information
- ✓ Most data sources collect longitudinal data
- ✓ Latency of data capture can be minimal as sourced directly from EMR

Weaknesses:
- × Most EMRs are not utilised for research purposes with significant cost & effort required to create access for secondary purpose
- × Linking across 1º and 2º care data is difficult which may impact, among other issues, the ability to get truly longitudinal data through EMR-linked databases
- × Governance structures are not aligned for research activities and it can be a slow process to achieve scientific/ethical approval
- × Single site 2º care EMRs are uncommon and often not suitable for broad epidemiological studies due to limited patient numbers and representativeness

Examples:
- *IQIVA RWD EMR - disease analyser (multiple countries)*
- *HEMSYS*
- *MOSAIC*

Characteristic	Rating
Access to source	Variable
Funding (amount)	Sufficient
Funding (duration)	Secure
Coverage	Narrow/ Mod.
Depth of data variables	Moderate
Quality of data	Moderate
Latency	Moderate

Use Cases	Rating
R&D enablement	Variable
Healthcare context	Variable
Treatment patterns	Variable
Real-world clinical value	Variable
Socio-econ. value	Poor
Pricing enablement	Variable
Patient perspective	Poor

Source: IQVIA RWD Catalogue; IQVIA research

Archetype Profile
Admin & claims

Characteristics:
- Created to capture data for **administrative purposes** such as tracking activities within healthcare, supporting insurance companies and reporting to governmental authorities
- Data sources have a **large-scale scopes** that capture information millions of patients usually over **regional or national scopes**; almost none are either locally focussed or international
- Data will **include patient and treatment information** as well as **substantial resource utilisation data**; unlikely to include richer clinical data

Access and Funding:
- Access typically via **established contracted approach** requiring review including protocol submission
- **Funding is by central and regional government** and often more secure than other archetypes due to the role of the data sources within the applicable healthcare system

Strengths:
- ✓ Rich source of data for select research interests e.g., resource utilisation
- ✓ Quality of the data is usually reliable and well organised
- ✓ Population coverage is usually high
- ✓ Longer-term historic records are usually available and expectation of future data capture is more secure than other archetypes

Weaknesses:
- × Defined list of data fields captured, with little flexibility to add to these
- × Often does not provide longitudinal data with individual patients not tracked over time due to "snapshot" nature of capture
- × To make use of data for broader research interests, it often has to be linked to other data sources as data sources are unlikely to expand their data capture beyond original narrow remit

Examples:
- *Danish national prescription registry*
- *Italian local health authority admin. claim databases*
- *Programme de médicalisation des systèmes d'information (PMSI)*
- *Hospital Episode Statistics (HES)*

Characteristic	Rating
Access to source	Variable
Funding (amount)	Sufficient
Funding (duration)	Secure
Coverage	Broad
Depth of data variables	Limited
Quality of data	Good
Latency	Good

Use Cases	Rating
R&D enablement	Poor
Healthcare context	Variable
Treatment patterns	Good
Real-world clinical value	Poor
Socio-econ. value	Poor
Pricing enablement	Variable
Patient perspective	Poor

Archetype Profile
Large clinical registries

Characteristics:
- **Created by governmental bodies** or organisations **to support the healthcare systems** through the monitoring of clinical practise to identify patterns and help improve services
- Some pharmaceutical companies have previously funded large clinical registries to support submissions e.g., post launch safety records
- Data sources have a **national or international scope**, collecting information on a large population
- Depth of **data fields is often limited** due to balancing need for geographic scale and resource and logistical expense
- Collaborations with 3rd party researchers are common leading to a **high level of associated publications**, though this is not a primary aim for the data source itself

Funding and access:
- Access approach is often established though usually **restricted only for medico-scientific or public-interest research**; **access unlikely to be provided to pharma** funded sources
- Typically **funded by the government bodies** though pharma can occasionally fund

Strengths:
- ✓ Provides high level understanding on epidemiology for a population
- ✓ Often willing to provide access for scientific research
- ✓ Provides ground for international comparisons and policy reviews
- ✓ Quality of data for selected data fields is often high

Weaknesses:
- × Defined list of data fields captured, with little flexibility to expand these within existing data sources
- × The creation of new equivalent data sources requires significant political will and resources, and would require significant build up time to implement
- × To make use of data for broader research interests, it often has to be linked to other data sources as data sources are unlikely to expand their data capture beyond original remit

Examples:
- *PHE Cancer Analysis System*
- *Scottish Cancer Registry*
- *Association of Nordic cancer registries*
- *World Health Organisation Cancer Mortality database*
- *GSK Study Register*

Characteristic	Rating
Access to source	Variable
Funding (amount)	Sufficient
Funding (duration)	Sufficient
Coverage	Broad
Depth of data variables	Limited
Quality of data	Moderate
Latency	Poor

Use Cases	Rating
R&D enablement	Poor
Healthcare context	Variable
Treatment patterns	Variable
Real-world clinical value	Variable
Socio-econ. value	Poor
Pricing enablement	Poor
Patient perspective	Poor

Source: IQVIA RWD Catalogue; IQVIA research

All archetypes face significant challenges, and are limited in their value across the use cases

Common characteristics of sources within archetypes, and ability to support use cases:

		Research database *(standalone)*	Research database *(partnerships)*	Facilitated networks	EMR -linked source	Admin/ claims	Large clinical registries
Characteristics	Access to source	Difficult	Variable	Good	Variable	Variable	Variable
	Funding (amount)	Insufficient	Sufficient	Sufficient	Sufficient	Sufficient	Sufficient
	Funding (duration)	Insufficient	Sufficient	Sufficient	Secure	Secure	Sufficient
	Coverage	Narrow	Moderate	Moderate	Narrow/ Mod.	Broad	Broad
	Depth of data variables	Moderate	Deep	Moderate	Moderate	Limited	Limited
	Quality of data	Poor	Moderate	Good	Moderate	Good	Moderate
	Latency	Moderate	Poor	Good	Moderate	Good	Poor
Use Cases	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

Contents

There is a wide spectrum of data initiatives across the European oncology landscape working to improve health data use

Initiatives were defined as:

"projects working with health data that have a clearly defined purpose and an innovative approach for achieving their aims"

Initiatives can be grouped into four broad categories based upon their purpose

Four Categories

- **Improve Access**
- **Improve Collation**
- **Standardise Data**
- **Gather New Data Types**

Methodology

- Initiatives were identified, researched and profiled to provide insight into what people are currently doing to advance the use of oncology health data and understand some of systemic barriers faced

40 initiatives were short-listed as "of interest"

Input and approval was sought from EFPIA during short-listing process

19 initiatives were fully profiled* via interviews & desk research

Outreach was conducted for all short-listed initiatives

1 initiative was selected for an in-depth case study

Data access requirements and approaches across different EU markets

Short profiles for remaining initiatives were created

Non-respondents profiles generated using publicly available information

* For profiles, please see Appendix

Source: IQVIA research

Initiatives broadly fall into four categories based upon their primary aims and intended outputs

For full profiles please see Appendix following hyperlinks on select initiatives listed below

Improve Access	Improve Collation	Standardise Data	Collect New Data Types
Aims to improve access to existing datasets or allow their interrogation	*Aims to incorporate existing datasets into a central repository*	*Aims to standardise the ways in which data is collected so that datasets re comparable*	*Aims to collect data that does not yet exist, often via novel approaches*
• BD4BO • CODE • GOBDA • HemoBase • IMI Harmony • INSITE • PHEDRA • POI • Simulacrum	• Cancer Core Europe • ECIBC • ECIS • EUROCARE • HMRN • ENCR • EUCAN • EUSOMA • Greater Manchester Cancer • IMI Protect • Innovative Pricing Solutions • I-O Optimise • REAL Oncology • Sarcoma BCB	• EHDN • GA4GH • GEKID • FRANCIM • Health Informatics Collaborative • ICHOM • OMOP Oncology	• 100,000 Genomes Project • AURORA • EUROSTAT • CRISP • IRONMAN • OWise • My Clinical Outcomes • SCAN-B • Universal Cancer Databank • WEB-RADR

A number of initiatives touch upon a second category. For example, CRISP, a cohort study, has found that they will need to set up a standardisation framework in order to proceed with work

Initiative profile summaries (1 of 10)

AURORA

Launched in 2014

Aims to understand molecular aberrations in breast cancer

Incorporates molecular tumour profiles from metastatic breast cancer patients across 14 European countries

Collaboration between Breast International Group, ICR and academia

BIG against breast cancer

BD4BO

Big Data for Better Outcomes

Big Data for Better Outcomes launched in 2016 under IMI

Aims to put the patient at the centre of healthcare, drive improvement and improve data access

Incorporates EMRs

Made up of three projects: Harmony, Roadmap and BigData@Heart

Cancer Core Europe

Network launched in 2014

Aims to share data, develop biomarkers and harmonise clinical trail procedures

Incorporates EMR, clinical databases, genomics and immune biology databases

Collaboration between six cancer centres across Europe

Cancer Core Europe

CODE

code collaboration for oncology data in europe

Launched in 2017

Aims to inform patient treatment and facilitate new models of access

Incorporates EMRs from participating sites in seven European countries

Collaboration with IQVIA and six pharmaceutical companies

Full profile located in Appendix for initiatives in **underlined**

Initiative profile summaries (2 of 10)

CRISP

Launched in 2015

Prospective cohort study aiming to capture patient characteristics, biomarkers, treatments and outcomes via a clinical registry, establish biobank of samples

Covers metastatic NSCLC patients in Germany

Collaboration between AIO and ten pharmaceutical companies

ECIBC

European Commission on Breast Cancer launched in 2012

Aims to improve and harmonise care in breast cancer throughout Europe

Objectives: quality assurance scheme, guidelines, training template, patient facing platform

Incorporates patient data from each country and anticipates future PROs

ECIS

European Cancer Information System launched in 2009

Provides information on cancer burden across Europe

Aims to support research and public-health decision making processes

Incorporates data from national registries, via the ENCR

EHDN

European Health Data Network launched in 2017

Aims to support better quality healthcare systems with focus on value-based, outcome-focused and sustainable healthcare across in Europe

Will provide standard model to address data and structural heterogeneity

Part of IMI's BD4BO programme

Full profile located in Appendix for initiatives in **underlined**

AIO = Arbeitsgemeinschaft Internistische Onkologie; ENCR = European Network of Cancer Registries
Source: IQVIA research

Initiative profile summaries (3 of 10)

EUCAN

Launched in 2009
Aims to disseminate cancer burden information across Europe
Multi-tumour focus
Incorporates registry data and WHO mortality database

EUCAN

1995-2018 (terminated due to lack of funding)
Aimed to provide population based survival information across the EU
Incorporated >100 registries across 23 European countries
Initially founded by European Commission

EUROCARE

ENCR

European Network of Cancer Registries launched in1989
Aims to improve data quality, comparability and availability in addition to defining standards
Incorporates data from multiple registries
Secretariat provided by European Commission Joint Research Centre

Launched in 2006
European health survey focusing across on healthcare across Europe
Aims to assess health status, healthcare utilisation, determinates and socio-economic background variables
Incorporates survey results

EUROSTAT

Full profile located in Appendix for initiatives in **underlined**

Initiative profile summaries (4 of 10)

EUSOMA

Launched in 1986
Aims to promote scientific research and contact between science and healthcare professionals
Breast cancer focus across Europe
Incorporates EMR

FRANCIM

France Cancer Incidence and Mortality Launched in 1997
Aims to harmonise registration practice, publish epidemiological indicators, coordinate French cancer registries
Incorporates data from 14 main registries and ten specialised registries
Data access subject to Francim-HCL-InVS-INCa approval (some open source)

GA4GH

Launched in 2013 after a white paper led to the formation of the initiative
Aims to identify and support best approach for standardisation of genomic data and promote data sharing
Collaboration with 500 organisations including IARC, CRUK, DKFZ

GEKID

Launched in 1996
Association of population-based cancer registries in Germany
Aims to establish uniform cancer registration standards across the different German federal states (different states have different registration laws)

Full profile located in Appendix for initiatives in **underlined**

Initiative profile summaries (5 of 10)

100,000 Genomes Project

Launched in 2012
Aims to transform NHS care and embed genomics into clinical pathways through sequencing of 100,000 genomes of cancer and rare disease patients
Incorporates genomic, HES, registry, mental health, mortality and imaging data
Collaboration between NHS, Genomics England and academia

Genomics england

Merck

Project Data Sphere

Global Oncology Big Data Alliance announced in 2017
Worldwide, pan-healthcare focus
Aims to analyse RWD
Collaboration between Merck and Project Data Sphere

GOBDA

Greater Manchester Oncology

Launched in 2013
Aims to provide a single system provider for Greater Manchester cancer services with a focus on breast cancer
Incorporates CAS, HES and PLICS data
Collaboration between NHS, Novartis, NIHR and IQVIA

Greater Manchester Cancer | Vanguard Innovation

NHS National Institute for Health Research

Launched in 2013 with focus on five solid tumours (and non-cancer areas)
Aims to improve healthcare through catalogued, comprehensive, patient data
Incorporates clinical data through Metadata Catalogue
Collaboration between five UK hospitals

Health Informatics Collaborative

Full profile located in Appendix for initiatives in **underlined**

CAS = Cancer Analysis Service, HES = Hospital Episode Statistics, NIHR = , National Institute for Health Research, PLICs = Patient Level Information and Costing System; source: IQVIA research

Initiative profile summaries (6 of 10)

HemoBase

Query based platform launched in 2000
Focuses on Dutch haematological cancers
Aims to improve data access
Incorporates EMRs from multiple sites

Launched in 2014
Haematological Malignancy Research Network aiming to follow up haematological cancer patients from point of diagnosis
Incorporates HES data, cancer registry data, national administrative datasets
Collaboration with NHS with funding from NIHR, Bloodwise, CRUK, Wellcome

HMRN

ICHOM

International Consortium for Health Outcomes Measurements launched 2012
Worldwide, pan-healthcare focus
Aims to transform healthcare through standardised measuring and reporting
Incorporates registry data & perspectives from patients and healthcare professionals

Full profile located in Appendix for initiatives in **underlined**

Initiative profile summaries (7 of 10)

IMI Harmony

- IMI project launched in 2017
- European, haematological cancer focus
- Aims to improve patient care through sharing of RWD
- Incorporates multiple sources of RWD

HARMONY

PROTECT

- Pharmacoepidemiological Research on Outcomes of Therapeutics launched in 2009 as an IMI project and ended in 2015
- Aimed to monitor medicine benefit-risk and facilitate early detection of ADRs
- Consortium of 35 academics, regulators, SMEs, EFPIA entities

IMI Protect

Innovative Pricing Solutions

- Roche initiative as part of the Access to Healthcare programme
- Aims to broaden access to medicine and improve sustainability
- Implementing personalised reimbursement models and international differential pricing
- Incorporates EMRs and prescription data

Roche

InSite

- Launched in 2016, InSite now run by Custodix
- Network of 24 hospitals to create on-site databases linked to InSite system
- Aims to aid clinical trial protocol feasibility and optimisation, patient recruitment and directly transfer EMR data to trial records
- Collaboration between nine pharmaceutical companies and Custodix

InSite

Full profile located in Appendix for initiatives in **underlined**

Initiative profile summaries (8 of 10)

I-O Optimise

Launched in 2017

Aims to improve outcomes for patients with thoracic cancers through development of a RWD network and research framework

Incorporates EMRs and registry data

Collaboration led by BMS

IRONMAN

Soft launch in 2017 with global launch in 2018

Aims to increase understanding of prostate cancer

Incorporates medical history, treatment information, blood samples, PROs from prostate patients worldwide

Collaboration with Movember and Prostate Cancer Clinical Trials Consortium

My Clinical Outcomes

Launched in 2011

Aims to facilitate patient engagement with clinicians and hospitals

Incorporates PROs from patients across healthcare

SME with private funding

OMOP Oncology

Launched in 2017 with first outputs expected 2018

Aims to transform data into a common format with common terminology across oncology

Incorporates EMRs histology records, diagnostic/treatment/outcome data

Collaboration with academia

Full profile located in Appendix for initiatives in **underlined**

Initiative profile summaries (9 of 10)

OWise

Launched in 2012
Aims to provide support for breast cancer patients via a mobile device App
Links PROs with EMR data
Funds from Cancer Innovation Challenge & seeking commercial collaboration

Owise breast cancer

janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Platform launched in 2015
European, haematological cancer focus
Aims to source RWD at the patient level and understand treatment patterns and provide control arm for clinical trials data

PHEDRA

POI

Pharmaceutical Oncology Initiative launched in 2005
Aims to evaluate medicines, optimise medicines, address inequalities & improve healthcare services
Incorporates SACT data and cancer registry data
Collaboration between pharmaceutical companies (ABPI) and NHS

abpi Bringing medicines to life

IQVIA™

Launched in 2016
Solid tumour focus in North East England
Aims to generate RWE for unmet patient needs, improve safety & healthcare
Incorporates EMR data, demographics, SACT, radiotherapy, surgery and outcome data

REAL Oncology

Full profile located in Appendix for initiatives in **underlined**

Initiative profile summaries (10 of 10)

Sarcoma BCB

French, sarcoma database launched in 2012

Aims to improve molecular diagnosis, reinforce databases, develop research and disseminate information

Incorporates databases: Conticanet, ConticGist, RRePS, NetSarc, ReoOs, ConticaBone

Sarcoma Database

SCAN-B

Sweden Cancerome Analysis Network launched in 2014

Swedish, breast cancer focus

Aims to develop new molecular diagnosis assays for breast cancer

Multi-centre hospital collaboration with support of Berta Kamprad Foundation, South Swedish Breast Cancer Group, Swedish Regional Cancer Centre South

SCAN-B

Simulacrum

Launched in 2016

Aims to provide a publicly-available simulated dataset

Incorporates simulated data modelled from the Cancer Analysis System

Collaboration between PHE, HDI, IQVIA, AstraZeneca

HDI

WEB-RADR

Launched in 2014

Aims to exploit new technology to report adverse drug reactions

Runs across healthcare in UK, Croatia, Netherlands and Africa

Collaboration between IMI, EFPIA, regulatory agencies, pharma, academia, patient groups and technology companies

Web-RADR

Full profile located in Appendix for initiatives in **underlined**

The barriers faced by initiatives are associated with their data, processes or resources

Barriers were assigned to one of three categories: **Data**, **Processes** or **Resources**

During interviews, respondents were asked to rate how much of an issue each barrier was

Specific barriers considered with initiatives

Data	Processes	Resources
• Ability to **identify** suitable data • **Scale** and **granularity** requirements to generate evidence • Biological **complexity** of cancer • Number of **patients covered** • Data **quality** and **completeness** • **Standardisation** across datasets • **Fragmentation** and the requirement to **link** datasets for **enrichment** • **Latency** of data collection	• Ability to **access** data • Ability to **use and share** data • Data **privacy** steps to meet legal regulations • **GDPR** impact on data use • Costs and implementation of **data security** • Scientific and ethical **sign-off** • **Governance** and consent management • **Political will** and direction • Managing multiple stakeholders within **collaborations**	• Ability to source **funding** • Access and data infrastructure/management **costs** • Length of **time** to complete aims • Number of **people** required • People with the necessary **skillsets** • Availability of necessary **technology** • Ease of creating **valued partnerships** • **HCP** perceptions and awareness • **Patient** perceptions

These barrier discussions were linked back to the key barriers types used in other modules

Source: IQVIA research

Initiatives consistently reported issues with finding data of sufficient quality and coverage, and in a timely fashion

- The top three barriers associated with data were **Latency***, **Coverage** and **Quality**
- **Scale and Granularity,** and **Fragmentation** were also identified as significant barriers
- Most barriers were seen to be as variable as the underlying sources

"It depends on the source, the site"

Top Three Barriers

Latency

- Just under half of initiatives reported issues with data latency
- Latency can be up to four years
- When information is required for decisions, latency becomes an issue
- Whilst some initiatives find latency to be an issue others are not impacted
- Latency was seen as an issue not just for initial data access but to build the quality of data over time

Coverage

- Patient coverage issues vary within initiatives depending on the dataset
- Some coverage issues are associated with HCP reluctance (based upon existing clinical processes and legitimate concerns over inclusion/exclusion criteria)
- Can lead to significant impact on original scope and timelines

Quality

- Over half of initiatives reported issues with data quality
- Quality issues vary between datasets, though completeness was a key issue with it never clear what level to expect from sources
- Networks often required minimum quality requirements of data sources

"Some hospitals don't want to admit that their data is not in order"

Other Barriers

Tumour heterogeneity, and its recording, adds **complexity** to data

Disease complexity: *"The biggest barrier is the inherent complexity of the data"*

The ability to **link** different datasets and records was an issue

Fragmentation: *"The information we need is out there, it's in the heads of the clinicians, the notes, the EHR, the specialty medical systems. The issue is that it is atomised, we need to understand all of those different pieces of information pulled together"*

There are initiatives where their primary aim is to address **standardisation**

Standardisation: *"People do great stuff in an informal way"*

*Latency refers to the time between an event occurring and it being available for use by an initiative
Source: IQVIA research

The processes involved in working with health data cause significant issues related to access, privacy and general governance

- The top three barriers associated with processes were **Access**, **Privacy** and **Governance**
- **GDPR** was not identified as a particular issue or concern; initiatives did share that it had been addressed (often at significant cost) and processes had been updated accordingly

Top Three Barriers

Access

- 40% of initiatives had access issues
- Perception that funding for data access may be less of a barrier for larger companies
- Instances where some initiatives have stopped using data due to changes in third party access requirements
- The access requirements for different datasets varied greatly

"There is a patchwork of approaches required for the different sources"

Privacy

- Approximately half of the initiatives found data privacy a barrier
- Patient identifiable information causes issues – you can de-identify but this may not be 100% guaranteed
- Aggregating data addresses some issues but wasn't always preferable
- Genomic data provides information on blood relatives – a unique issue

"If something goes wrong, will my name be on the front of the Daily Mail?"

Governance

- 40% had governance issues
- More organisations involved in initiatives creates more issues
- Initiatives stated that they felt the balance between bureaucracy and delivering their work was not always balanced correctly
- Transparency between all governing members is crucial
- Different governing members may be more conservative than others within the same initiative

Other Barriers

GDPR was the smallest barrier in relation to processes

Collaboration: *"Taken time & resource to get right governance in place but been necessary to create expertise & credibility for initiative"*

Some **national health strategies** have not materialised and act as a barrier to new initiatives

Political will: *"There is confusion in the minds of government & the service about the responsibilities to patient confidentiality"*

Contract signing and **ethical approval** process can be very slow

Information use: *"There isn't even data sharing across the street, let alone across provinces and countries"*

Source: IQVIA research

The biggest resources issues for data sources were finding the right people for the work and having sufficient secure funding

- The top three barriers associated with resourcing were **Skillset**, **Manpower** and **Funding**
- All initiatives reported moderate to high issues with either **Skillset** or **Manpower** and lack of these resources has knock on impacts by triggering other barriers e.g., maintaining quality

Top Three Barriers

Skillset

- Not enough with right skillsets
- Some initiatives provide specific training for employees
- Being able to have the people at (hospital) sites with the right skillsets is an issue
- High profile helps when recruiting

"We had to move to the UK from Netherlands to find enough people with the right skills"

"Difficult to identify people with the right skills because of the short term nature, you lose experts"

Manpower

- Initiatives tend to be labour intensive
- As scales increase, more people are needed – creating a potential limit
- Not having enough people can impact the ability to apply for funding
- Getting people using the technology on site is a challenge
- Feedback to participants requires extensive manpower

Funding

- Over half of initiatives faced issues with funding
- Some centrally funded initiatives cannot apply for external funding
- Although industry contributes in early phase, question remains as to who will pay in the long term
- Initiatives terminate when funding dries up

"Funding is always a challenge, particularly in the early days"

Other Barriers

Patients Cultural Shift is not a major issue - patients expect work to be "*already being done*"

Patient cultural shift: *"Patients are usually asking to share data to help with research"*

Approx. half of initiatives faced moderate to high issues with **HCP Cultural Shift**

HCP cultural shift: "It is a challenge particularly in some countries to engage the public sector/academic stakeholders with industry-sponsored initiatives"

Technology is not a significant barrier "*It is there.*" It is more about skills to use technology

Technology: *"Fundamentally, IT [required to do most things well] was already ready in the early 2000's - tech is massively overhyped as a solution"*

Source: IQVIA research

Case Study: CODE (Collaboration for Oncology Data in Europe) (1/2)
Multi-country initiative is navigating a diverse regulatory environment requiring different undertakings for the same action

Requirement

- CODE aims to develop a dedicated Oncology Data Network to provide access to data on the use of anti-cancer medicines. The network is working with multiple hospital sites across 7 countries in Europe
- As a case study, CODE demonstrates how it, as a single initiative, has approached data access across multiple markets and highlights the fragmented approach all initiatives face when working across Europe

General Approach

CODE has been able to implement some general approaches that apply across their network:

Managed Information Flow
- Data are initially de-identified before leaving the healthcare provider (HCP) site
- Data are securely transferred to an in-country trusted third party acting on behalf of HCPs

Consent / Transparency
- Scope of current work fits within regulatory characterisation of public interest
- Requires patient notification of use and option to “opt out”

Data Retention
- Strict rules are applied to minimise the scope of data collection and retention according to the approved information uses

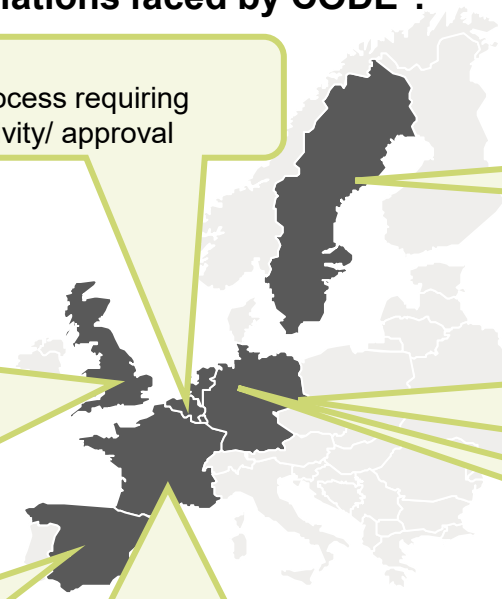
Pharmacovigilance
- Data specifications limit ability to identify adverse events, etc.

Case Study: CODE (Collaboration for Oncology Data in Europe) (2/2)
Multi-country initiative is navigating a diverse regulatory environment requiring different undertakings for the same action

Country Specific Approaches to Data Access

Despite the consistent data requirement of CODE from each country, individual countries/regions possess their own data privacy requirements adding to the complexity and cost of the initiative as well as limiting the ease of replicating "best practice" across countries

Examples of Country/Region Variations faced by CODE*:



Belgium
- Official process requiring formal activity/ approval

Sweden
- Required to abide by local secrecy laws and data protection and confidentiality specific to healthcare

England
- Official authority and process by which users of process can identify if authorisation is required
- Adopts a more risk-based approach than considering absolute guarantee
- Also required to consider common law duty of confidentiality

Germany
- 16 regional data protection agencies, each requiring approval (CODE approach approved by all)
- Hospital manager personally liable for data breaches

Spain
- Specific regulatory requirements that need to be followed
- No official process or approval
- Conservative approach

France
- Official process requiring formal sign-off; HCP is classified as the primary data controller and IQVIA is a secondary data controller

Netherlands
- No approval process but must be compliant with rules and regulations
- Necessary to work with HCP recognised company

*Variations are not specific to CODE and will be faced by other iniatives
Source: IQVIA research

Initiatives saw human resourcing as the most common barrier to success either because of a lack of skills or sheer numbers

Barrier Significance

		% with significant barrier	Key Points
Resource	**Skillset**	82%	• "Skillset" barriers were linked with "manpower" barriers • Not enough people with appropriate skills to undertake work • Not enough people at sites (external to initiative) with skillsets to comply with initiative's requirements • Short term nature means that people with skillsets move on • Specific training provided by some initiatives (e.g. ECIBC, ECIS) • High profile initiatives face less challenges than new/low profile ones
Resource	**Manpower**	76%	• Initiatives are labour intensive • As scale increases, more manpower is required • Funding applications takes manpower, and, lack of manpower means ability to apply for funding is impacted upon negatively • Getting people to use technology on site is an issue, and, this takes manpower from the initiative to install confidence in the technology • Feedback to participants requires extensive manpower resource
Data	**Quality**	59%	• Patient coverage is variable within and between datasets • HCP reluctance can result in issues with coverage • Based on HCP concerns surrounding inclusion and exclusion criteria • Poor quality can impact on initiative original scope and timelines • Some initiatives define quality standards before a data source can be included (e.g. InSite)

Source: IQVIA research

Initiatives can be examples of “what good looks like” but continue to face barriers themselves impacting their ability to succeed

Initiatives tend to focus on the use cases of **Healthcare Context** (82%), **Treatment Patterns** (94%) and **Clinical Value** (88%)

Barriers faced by initiatives fall under three categories: **Data**, **Process**, or, **Resourcing**

The biggest barriers facing initiatives are:

- **Manpower**
- **Skillsets**
- **Funding**
- **Quality**
- **Access**
- **Privacy**
- **Governance**
- **Coverage**
- **Latency**

30% of initiatives aim to **collate existing data** as their primary objective

Preparing for **GDPR**, despite a need to be addressed, has not been a significant issue or concern when compared to other barriers

Some initiatives have been specifically designed to address particular barriers, such as **standardisation** and **data access**

More mature initiatives have often mitigated barriers that existed when they started up

- Initiatives provide a great way to learn and better understand what future solutions and interventions may look like
- They also help identify some of the continuing barriers that exist when working with oncology health data to help plan mitigations or resolutions

Source: IQVIA research

Whilst data sources face a multitude of issues, initiatives are starting to find improved ways of working but still face barriers to success

Key Insights

Data Source Archetypes	• The majority of data sources would fit within a "Research Database" archetype. They tend to be small entities and are associated with issues relating to the scope and quality of data, funding uncertainty and poor governance structures • Other archetypes, covering the other health data sources, bring additional issues • Across all archetypes the greatest issue is the level of variability across the key characteristics (e.g., quality, access, funding, scope); variation is large even within the individual archetypes leaving little room for certainty • For those seeking to work with data sources, the uncertainty created by this variability prevents stakeholders from fully benefiting from the actual data available
Initiatives	• The are a growing number of initiatives working with oncology health data • Studying the initiatives helps identify "what good looks like" providing a toolbox of possible options for replication, support, or evolution • The initiatives themselves also face barriers similar to those faced by the individual data sources that often underpin the initiatives • Tackling the barriers faced by initiatives should be a priority for EFPIA, policymakers & other stakeholders as appropriate • Focussing on issues faced by the initiatives will help them and the broader health data landscape bringing increased benefit

Source: IQVIA analysis

Contents

Initiative Profile
100,000 Genomes Project

Simon Thompson and Amanda O'Neil (Clinical Data Scientist; Clinical IT Lead, Genomics England)

Started: 2012 **Status:** Active – should reach 100,000 by close of 2018

Aim & Objective:
- Aims to transform NHS care, embed genomic medicine into clinical pathways, and, ultimately benefit patients
- Objective is to sequence 100,000 genomes from NHS patients with rare diseases (along with their families), and, patients with cancer
- Additional aim to drive up research involving genomic medicine

Scope:
- UK based
- Patients with rare disease, their families, and, patients with common cancers

Health data:
- Genomic data from patients
- Linkage to HES, cancer registry data, mental health, ONS mortality data and imaging data
- Quarterly follow up survey data from patients

Collaboration: Yes
- Collaboration between NHS England, Genomics England
- Also involves collaboration with academia and genomic medicine centres
- Funding: Department of Health with additional grants from Medical Research Council (MRC) and National Institute for Health Research (NIHR)
- Governance: Board and executive team comprised of NHS England and Genomics England representatives
    - Also consults with a scientific advisory group

GDPR Ready: Nearly
- Will be ready by the time of GDPR deadline but there is still work to be done to achieve this
- Will not impact on what the initiative does

Impact:
- **Patient:** Influence patient outcomes, faster diagnosis, treatment identification
- **Research:** Drive research, understand association between disease and genetics, public health, health economics
- **Commercial:** Identify patients who are eligible for clinical trials that otherwise would not have been identified, promote industry-academic collaboration

Use Cases:

★ ★ Main focus
★ Additional

R&D enablement	★ ★
Healthcare context	★ ★
Treatment patterns	★ ★
Real-world clinical value	★ ★
Socio-econ. value	★ ★
Pricing enablement	★ ★
Patient perspective	★ ★

Barriers (top 3):

1	Latency for some data sets
2	Manpower
3	Technology

NHS – National Health Service; HES – Hospital Episode Statistics; ONS – Office for National Statistics
Source: Interviews; IQVIA research

Return to initiatives overview

Initiative Profile
BD4BO (Big Data for Better Outcomes)

Dr Shahid Hanif (Head of Health Data & Outcomes, ABPI)

Big Data for Better Outcomes

Started: 2016 **Status:** Active (Aims to run until 2024)

Aim & Objective:

- Aims to improve health outcomes and transform healthcare systems through maximising the potential of "big data" whilst being collaborative and patient-centric; support the drive towards value based healthcare
- Multiple themes and enablers:
  - Implement standard outcomes; Increase high quality outcomes data access; Utilise data to improve healthcare delivery value; Utilise technology to increase patient engagement
- Acts as an umbrella for multiple disease-specific projects:
  - ROADMAP (Alzheimer's disease) – Platform and health economics modelling
  - HARMONY (haematological cancers) – Alliance of data sources and platform
  - BigData@Heart (cardiovascular disease) – Characterise atrial fibrillation and explore precision medicine
  - Launching soon: PIONEER (prostate cancer)
- Coordinating projects involved to manage work:
  - DO->IT for coordination and support activities
  - Launching soon: European Health Data Network (EHDN) aiming to develop a network enabling researchers to access data which is mapped onto a common data model

Scope:

- European
- Pan-healthcare with cancer specific projects

Collaboration: Yes; Public private partnership: EC & EFPIA (& members) through IMI

- DO->IT coordinated by LSE; ROADMAP coordinated by Uni. of Oxford, Uni. of Edinburgh, Uni. of Maastricht, and others; HARMONY coordinated by Institute of Biomedical Research of Salamanca (IBSAL), Instituto de Investigacion Sanitaria LaFe; BigData@Heart coordinated by University Medical Center Utrecht

Use Cases:

★★ Main focus
★ Additional

R&D enablement	★★
Healthcare context	★★
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	★★
Pricing enablement	★★
Patient perspective	★★

Barriers (top 3):

1	Data privacy
2	Patient cultural shift
3	Political will

Impact:

- **Patient:** Increased patient engagement; improved standards of care
- **Research:** Better data access
- **Commercial:** Better data access; implementation of standards

ABPI – The Association of the British Pharmaceutical Industry; ROADMAP – Real world Outcomes across Alzheimer's Disease spectrum for better care; HARMONY – Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in Haematology; IMI – Innovative Medicines Initiative: LSE – London Scholl of Economics and Political Science
Source: Interviews; IQVIA research

Initiative Profile
CODE (Collaboration for Oncology Data in Europe)

Ashley Woolmore (CODE Lead, IQVIA)

Started: 2017 at ESMO **Status:** Active

Aim & Objective:
- Collaboration for Oncology Data in Europe
- Aims to collaborate with 200 cancer treatment centres over first three years and extend this to 2,000 across Europe over ten years
- Aims to help inform patient treatment
- Aims to enable new models of access to medicines

Scope:
- Patients receiving anti-cancer medicines across all tumour types in participating centres
- Across England, France, Spain, Belgium, Sweden, Netherlands and Germany

Health data:
- Works with electronic medical records (EMRs) from participating centres
- Automated, structured data collection approach

Collaboration: Yes
- Collaborating partners: IQVIA, BMS, Lilly, Merck, Pfiser, AstraZeneca, Amgen
- Oncology Data Network – network of treatment centres who chose to share information
- Led by IQVIA with support from all Collaboration members
- Governance: Project oversight and direction through Collaboration Board (comprised of all partners) and clinical governance through Clinical and Analytical Steering Committee of European KOLs

GDPR Ready: Yes
- Followed GDPR path from project outset
- Designed to comply with data privacy regulations

Impact:
- **Patient:** Access to medicines, informed patient care, improved care and outcomes
- **Research:** Address and inform research questions such as treatment patterns and variability, address information gaps
- **Commercial:** New models of access, understand product utilisation, inform research and development, development of flexible payment agreements, financial sustainability

Use Cases: ★★ Main focus ★ Additional

R&D enablement	
Healthcare context	
Treatment patterns	★★
Real-world clinical value	★
Socio-econ. value	
Pricing enablement	★★
Patient perspective	★

Barriers (top 3):

1	Data standardisation
2	Data access
3	Skillsets

ESMO – European Society for Medical Oncology; BMS – Bristol Myers Squibb; KOL – Key Opinion Leader
Source: Interviews; IQVIA research

Return to initiatives overview

Initiative Profile
CRISP (Clinical Research Platform into Molecular Testing, Treatment, Outcome of NSCLC Patients)

Professor Frank Griesinger (Director of Haematology and Oncology, Pius-Hospital)

Started: 2015 **Status:** Active (expected to conclude 2022)

Aim & Objective:

- Prospective cohort study currently in recruitment phase:
  - Aims to capture patient characteristics, including biomarkers, treatments, treatment outcomes via a clinical registry
    - In parallel – set up interaction between CRISP and other clinical cancer registries
  - Aims to monitor quality of life through patient questionnaires
  - Aims to build up a central biobank of tissue samples with well annotated patients

Scope:

- Metastatic NSCLC patients
- Across Germany
- 8,250 patients over a four year recruitment with follow-up (initial aim was for a three year recruitment window)

Health data:

- Electronic Case Report Form

Collaboration: Yes

- Governance: Executive steering committee of academic clinicians, with consultation from sponsor (AIO) and pharmaceutical companies
- Funding: Supported by ten pharmaceutical companies and European Commission
  - Funding from pharmaceutical companies will last until recruitment is completed
  - Additional funding sought – potentially through a public-private partnership

GDPR Ready: Yes

Impact:

- **Patient:** Address quality of life, understand treatment variation
- **Research:** Understand treatment variation and treatment outcomes
- **Commercial:** Understand treatment outcomes and therapy utilisation

Use Cases:

★★ Main focus
★ Additional

R&D enablement	
Healthcare context	★★
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	★
Pricing enablement	
Patient perspective	★★

Barriers (top 3):

1	Ethical approval
2	Scale and granularity
3	Skillsets

NSCLC – Non Small Cell Lung Cancer; AIO – Arbeitsgemeinschaft Internistische Onkologie
Source: Interviews; IQVIA research

Initiative Profile
ECIBC (European Commission Initiative on Breast Cancer)

Dr Luciana Neamtiu (Project Officer, Joint Research Centre, European Commission)

Started: 2012 **Status:** Active

Aim & Objective:
- Aims to improve and harmonise care across Europe
- Development of evidence-based guidelines for screening and diagnosis of breast cancer
- Development of a Guidelines Platform which collates existing evidence-based guidelines spanning breast care processes relating to treatment, rehabilitation and palliative care
- Propose European training template for digital breast screening
- Develop web hub hosting to inform patients

Scope:
- Breast cancer
- Europe

Health data:
- Patient data collected in each breast cancer service
- Anticipates future use of patient reported outcomes

Collaboration: Yes
- Commission's Directorate-General for Health and Food Safety, Joint Research Centre
- Involvement of some European Commission services

GDPR Ready: Yes
- No impact

Impact:
- **Patient:** Improved and standardised healthcare, informed decisions for patients, increased and effective treatment
- **Research:** Assess quality of treatment, model application to other health-related issues
- **Commercial:** Assess quality of treatments

Use Cases: ★★ Main focus ★ Additional

R&D enablement	★
Healthcare context	★★
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	★★
Pricing enablement	
Patient perspective	★★

Barriers (top 3):

1	Data Latency
2	Data Privacy
3	Skillsets

Source: Interviews; IQVIA research

Initiative Profile
ECIS (European Cancer Information System)

Dr Luciana Neamtiu (Project Officer, Joint Research Centre, European Commission)

Started: 2009 **Status:** Active

Aim & Objective:
- Provide cancer incidence and mortality information across Europe
- Illustrate effects of health policy interventions
- Establish a reference base for cancer epidemiological research
- Host and manage a portal which allows interrogation of anonymised data by geography and tumour type parameters

Scope:
- Pan-oncology
- Europe

Health data:
- Incorporates data from > 150 regional and national registries

Collaboration: Yes
- European Network of Cancer Registries (ENCR), Joint Research Centre (JRC), EUROCARE, International Agency for Research on Cancer, other projects and DG SANTE (part of the European Commission)
- Pharmaceutical companies are informed of work and findings

GDPR Ready: Yes
- Data is anonymised

Impact:
- **Patient:** Indirect - potential future treatment improvements/better outcomes, address regional variation
- **Research:** Treatment quality assessment, epidemiological research studies, improved access to data
- **Commercial:** Improved access to data, understand trend survival, informed market analysis

Use Cases: ★ ★ Main focus ★ Additional

R&D enablement	★
Healthcare context	★ ★
Treatment patterns	★ ★
Real-world clinical value	★ ★
Socio-econ. value	★
Pricing enablement	
Patient perspective	★ ★

Barriers (top 3):

1	Data Latency
2	Data Linkage
3	Skillsets

Source: Interviews; IQVIA research

Initiative Profile
EUROCARE
Gemma Gatta (Istituto Nazionale Tumori di Milano)

Started: 1995 **Ended:** 2018 – *writing final manuscript after funding dried up*

Aim & Objective:
- The programme aimed to provide population based survival information for countries across the EU; starting with a paper in 1995 including 30 registries and 11 countries is grew to cover > 100 registries across 23 countries
- EUROCARE is run by four members from two institutes (Istituto Nazionale Tumori di Milano and of the Istituto Superiore di Sanità) who work together; the registries are represented by regional representatives that attend a Steering Committee annually (and ad hoc as required); registries are not compensated financially but participate in publications
- Data is collected every 4-5 years from each registry, analysed and then reported; before each collection each registry involved in coordination efforts; once collected data has undergone quality control and errors addressed with the corresponding registry (manual process)

Scope:
- Pan-oncology
- 23 European countries

Health data: clinical data covering epidemiology, treatment patterns and outcomes

Collaboration: Yes [see above]
- Funding: Initially EU commission; then Italian bank foundations; currently none

GDPR Ready: Yes / N/A
- Data is captured anonymously without patient identifiers; though project future uncertain

Impact:
- **Patient:** See improved services in markets where politicians have used outputs to inform healthcare policy (e.g., UK, Italy); EU improved guidance for childhood cancer care
- **Research:** Large EU wide network connecting registries to share data for greater insights and research; multiple publications including presentations to the European parliament
- **Commercial:** Data available to show country variations for need and provision of cancer care

Use Cases: ★ ★ Main focus ★ Additional

R&D enablement	
Healthcare context	★ ★
Treatment patterns	★ ★
Real-world clinical value	★ ★
Socio-econ. value	
Pricing enablement	
Patient perspective	

Barriers (top 3):

1	Sources of funding
2	Data quality
3	Skillsets

Source: Interviews; IQVIA research

Return to initiatives overview

Initiative Profile
GA4GH (Global Alliance for Genomics & Health)

Lena Dolman and Peter Goodhand (Strategy and Outreach Manager; CEO, GA4GH)

Global Alliance for Genomics & Health
Collaborate. Innovate. Accelerate.

Started: 2013 **Status:** Active

Aim & Objective:
- Originally a white paper that led to a meeting which kicked off an initiative
- Aims to identify and support the best approach for sharing genomic data with reference to format, regulations, security and storage
- Aims to mobilise the genomic community towards the principal of data sharing

Scope:
- Worldwide, pan-healthcare with a genomic focus

Health data:
- Genomic data

Collaboration: Yes
- 500 organisations (40% from the private sector) including IARC, CRUK, DKFZ, Wellcome Sanger Institute, and 200 individuals across 70 countries
- Patient groups, insurance companies
- Governance by four executives, three funding agencies, three host centres (Toronto, Harvard, Cambridge)
- Launched alliance to better manage governance

GDPR Ready: Yes
- Responding and adapting as required

Use Cases: ★★ Main focus ★ Additional

R&D enablement	★
Healthcare context	★★
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	★
Pricing enablement	★
Patient perspective	★

Barriers (top 3):

1	Standardisation
2	Data sharing
3	Data privacy

Impact:
- Patient: Prevention and screening
- Research: Adoption of standards by early adopters and these standards becoming international and ubiquitous, allow data sharing between organisations, data instantly available through a network
- Commercial: Development of tool allowing the interaction with standards

IARC – International Agency for Research on Cancer; CRUK – Cancer Research UK; DKFZ – Deutsches Krebsforschungzentrum
Source: Interviews; IQVIA research

Return to initiatives overview

Initiative Profile
Greater Manchester Cancer

Steve Jowett (Country Lead, IQVIA)

Started: 2013 **Status:** Active

Aim & Objective:

- Originally part of cancer vanguard in colorectal cancer with focus on: evidence-based analysis, treatment variation, patient experience, patient centric service redesign
- Aims to address inconsistencies in breast cancer pathway
- Aims to provide a single system provider for Greater Manchester cancer services
    - Support the Christie NHS Foundation Trust in developing a business case that demonstrates the Trust's superior service delivery and outcomes compared to the rest of Manchester, whilst also demonstrating capacity and sustainability
- Aims to improve services and patient experience for breast cancer patients

Scope:

- Breast cancer, however, was originally part of a cancer vanguard in colorectal cancer focusing on evidence-based analysis, treatment variation, patient experience
- Manchester area

Health data:

- Incorporates data from: Cancer Analysis Service (CAS), Hospital Episode Statistics (HES), Patient Level Information and Costing Systems (PLICS)

Collaboration: Yes – joint working arrangement between pharma and the NHS

- Governance: The Christie
- Funding: Novartis, National Institute for Health Research (NIHR)
- Also: IQVIA, patient groups

GDPR Ready: Yes

Impact:

- **Patient:** Better breast cancer services, improved patient outcomes, improved patient experience through health promotion, diagnosis and care, build clinician relationships across Manchester
- **Research:** N/A
- **Commercial:** Understand capacity and demand at The Christie, better use of cancer medicines

Use Cases:

★ ★ Main focus
★ Additional

R&D enablement	
Healthcare context	★ ★
Treatment patterns	★ ★
Real-world clinical value	
Socio-econ. value	
Pricing enablement	
Patient perspective	★ ★

Barriers (top 3):

1	Data access
2	Data latency
3	Fragmentation

Initiative Profile
HMRN (Haematological Malignancy Research Network)

Alexandra Smith and Professor Eve Roman (Deputy Director; Director, University of York)

Started: 2004 **Status:** Active

Aim & Objective:
- Haematological Malignancy Research Network
- Patient cohort with patients recruited at diagnosis and followed up comprehensively
- Aims to link diagnostic and prognostic data to treatments and outcomes

Scope:
- Haematological cancers and related blood disorders
- UK – Regional to Leeds/York area

Health data:
- Hospital Episode Statistics (HES) data, cancer registry data, national administrative datasets
- Centralised diagnostic system – local area
    - This was identified as essential as enabling HMRN to conduct their work

Collaboration: Yes
- NHS
- Funding: charities and other organisations including National Institute for Health Research (NIHR), Bloodwise, CRUK, Wellcome Trust
- Governance: Audit committee involving each participating hospital

GDPR Ready: Yes
- Initiative was already aligned with GDPR requirements

Use Cases: ★ ★ Main focus ★ Additional

R&D enablement	★ ★
Healthcare context	★ ★
Treatment patterns	★ ★
Real-world clinical value	★ ★
Socio-econ. value	★ ★
Pricing enablement	★ ★
Patient perspective	★ ★

Impact:
- **Patient:** Engagement, understand patient experiences, informed decision making
- **Research:** Improved patient information, understand differences between patient cohort and general population, understand tumour genetics and its relation to treatments and outcomes
- **Commercial:** Findings would contribute to NICE approval processes/guidelines

Barriers (top 3):

1	Funding
2	Skillsets
3	Data management costs

CRUK – Cancer Research UK
Source: Interviews; IQVIA research

Initiative Profile
IMI PROTECT (Innovative Medicines Initiative Pharmacoepidemiological Research on Outcomes of Therapeutics)

Started: 2009 **Ended:** 2015

Aim & Objective:
- Pharmacoepidemiological Research on Outcomes of Therapeutics (PROTECT)
- Overall aim was to monitor the benefit-risk of European medicines and hence advance the early detection of adverse drug reactions
- Aimed to address the issues with pharmacoepidemiology and pharmacovigilance methods
  - Outputs have been incorporated into routine pharmacovigilance practice
- Aimed to create a structured adverse reaction database permitting filtering and flagging of reaction monitoring reports
  - Publicly available adverse drug reaction database – PROTECT ADR database

Scope:
- Pan-healthcare, across Europe

Health data:
- Incorporated data collected from patients, electronic medical records, databases, registry data
- Databases incorporated a range of general practitioner data, mortality, cancer, secondary care, socio-economic parameters

Collaboration: Yes, coordinated by European Medicines Agency (EMA) and collaborators
- Involved consortium of 35 academics, regulators, SMEs and EFPIA entities
- Governance: Consortium assembly, external advisory board, steering committee
  - Oversaw workstream performance, budget allocation, making decisions on communication and deliverable dissemination
- Funding: Innovative Medicines Initiative (IMI) funded project

GDPR Ready: N/A – initiative ended

Impact:
- **Patient:** Improved drug safety
- **Research:** Understand adverse drug reactions, increased understanding of pharmacoepidemiology and pharmacovigilance
- **Commercial:** Understand adverse drug reactions, increased awareness of medicine benefit-risk, pharmacoepidemiology and pharmacovigilance prior to clinical trial commencement

Use Cases: ★ ★ Main focus ★ Additional

R&D enablement	
Healthcare context	★ ★
Treatment patterns	
Real-world clinical value	★ ★
Socio-econ. value	
Pricing enablement	
Patient perspective	★ ★

Barriers (top 3):

1	Data quality
2	Data latency
3	Data complexity

ADR – Adverse Drug Reaction; GSK – GlaxoSmithKline; SME – Small Medium Enterprise
Source: IQVIA research

Initiative Profile
InSite
Ketan Patel (Health Informatics Director, AstraZeneca)

Started: 2016 **Status:** Active

Aim & Objective:
- Network of hospitals supported to create on-site databases that are linked to the InSite system
- Utilises electronic medical records to support clinical trials to address:
    1. Protocol feasibility and optimisation (real time) allows collaborators to submit clinical trial inclusion and exclusion criteria to receive estimated patient counts from network's hospitals
    2. Patient recruitment (piloted) is supported the publishing protocols on the network; hospitals identified with potential patients can agree to participate before a site coordinator is able to perform further screening on the potential patients
    3. Collect data direct from electronic medical record to trial records (early phases) to remove the manual effort and risk of error using traditional re-type approach of creating trial records; should provide more frequent data capture and reduce latency

Scope:
- All therapeutic areas, including oncology
- Across Europe (with intent to expand outside Europe); initial "Champion Programme" involved 24 hospitals with > 14M patients

Health data: Electronic medical records

Collaboration: Yes
- Champion programme: Amgen; AstraZeneca; Bayer; Boehringer Ingelheim; Icon; Janssen; Roche; Sanofi
- InSite is now run by a commercial provider Custodix

GDPR Ready: Yes – federated system with patient data remaining at hospitals; aggregate shared

Impact:
- **Patient:** greater access to novel therapies in clinical trials through the network at hospitals not traditionally involved in clinical trials
- **Research:** hospitals able to use their own InSite databases to query for their own research e.g., identify service improvements; future possibility to utilise network for broader real world data (RWD) research, use data for epidemiological and RWD based research
- **Commercial:** ability to optimise clinical trial protocols; identify patients more efficiently; access hospitals not traditionally involved in clinical trials (additional patients; new income for hospitals)

Use Cases:

★★ Main focus
★ Additional

R&D enablement	★★
Healthcare context	★★
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	
Pricing enablement	
Patient perspective	

Barriers (top 3):

1	Data quality
2	Technology
3	Skillsets

Initiative Profile
I-O Optimise
Dr John O'Donnell (Vice President, BMS)

Optimise
European Oncology Real-World Evidence Alliance

Started: Sept 2017 at ESMO **Status:** Active

Aim & Objective:
- Aims to improve outcomes for patients with a thoracic malignancy through the development of a network of real world data (RWD) sources and a multi-national research framework to provide ongoing timely insights into multiple areas of treatment and outcomes

Scope:
- NSCLC, SCLC, mesothelioma
- Across Europe
- All treatments, but, with a particular focus on immuno-oncology therapy

Health data:
- Mix of electronic medical records (EMRs) and registries including SCAN-LEAF (Scandinavian RWD source combining national and site level patient information)
- The data collected falls under five categories: clinical outcomes; treatment patterns; pharmacovigilance; health care resource utilisation; patient reported outcomes (PROs)

Collaboration: Yes
- Led by BMS
- Multi-disciplinary external scientific committee provides independent advice on scientific methods, research prioritisation, results interpretation and publication focus

GDPR Ready: Yes
- All data received by I-O Optimise is already anonymised, or, presented at an aggregate level

Impact:
- **Patient:** Improved understanding of clinical effectiveness leading to improved patient access and care
- **Research:** Research ready network capable of addressing multiple scientific questions
- **Commercial:** Support BMS's understanding of real-world anti-cancer treatments, increased information for payers and policy makers

Use Cases: ★★ Main focus ★ Additional

R&D workbench	
Healthcare context	★★
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	
Pricing enablement	
Patient perspective	★★

Barriers (top 3):

1	Data access
2	Standardisation
3	Data scale & granularity

ESMO – European Society for Medical Oncology; NSCLC – Non Small Cell Lung Cancer; SCLC – Small Cell Lung Cancer; BMS – Bristol Myers Squibb
Source: Interviews; IQVIA research

Initiative Profile
IRONMAN

Adam Friedant (Project Manager, Prostate Cancer Clinical Trials Consortium, Memorial Sloan Kettering Cancer Center)

IRONMAN

Started: 2018 (soft launch 2017) **Status:** Active (2022 anticipated end date)

Aim & Objective:
- Aims to increase understanding of prostate cancer, it's treatments, biomarkers, and, patient perspectives
- Three year recruitment with three year follow up with a > 5,000 recruitment aim

Scope:
- Prostate cancer patients
- Launched in USA, but looking to expand into eight more countries including: Canada, Australia, Sweden, Spain, UK

Health data:
- Clinical data of patients whilst on treatments, blood samples during treatment and following changes, HCP questionnaires, patient reported outcomes
- Data often collected in real-time

Collaboration: Yes
- Coordinated by the Prostate Cancer Clinical Trials Consortium (PCCTC)
- Funding: Movember
- Governance: Executive committee steers project direction, clinical management, financial management, and, ensures completion of initiative's aims and objectives
- Scientific advisory committee will provide insight for registry reports and publications

GDPR Ready: Yes
- GDPR has been a process but not a problem
- Will initiate a privacy review to deal with any issues
- Open dialogue with country leads is ongoing

Use Cases:

★ ★ Main focus
★ Additional

R&D enablement	
Healthcare context	★ ★
Treatment patterns	★ ★
Real-world clinical value	★ ★
Socio-econ. value	
Pricing enablement	
Patient perspective	★ ★

Barriers (top 3):

1	*Not received*
2	
3	

Impact:
- **Patient:** Indirect impact; being able to contribute to future developments without facing invasive procedures, better health outcomes in the future
- **Research:** Access to initiative's collected data (subject to approval by IRONMAN), repository of blood samples for molecular analysis
- **Commercial:** Understand how a drug works in a real world population, clinical outcomes and treatment patterns

HCP – Healthcare Professional
Source: Interviews; IQVIA research

Return to initiatives overview

Initiative Profile
My Clinical Outcomes
Dr Tim Williams (CEO and founder, My Clinical Outcomes)

Started: 2011 **Status:** Active

Aim & Objective:
- Collect Patient reported outcome measures throughout diagnosis, treatment and long-term follow up data via a web-based platform from patients
  - Enables clinicians to make informed clinical decisions for individual patients
- Aims to be a way that hospitals and clinicians can engage patients in the process of submitting regular outcomes data
- Patients can use the platform to understand their treatment

Scope:
- Clinician and patient facing platform
- Pan-healthcare
  - More of a cancer focus over the previous 18 months due to increased demand in oncology area

Health data:
- Patient reported outcome measurements (PROMs)

Collaboration: No
- SME
- Funding: privately funded
  - Received recognition and funding from Cancer Innovation Challenge
- Accreditation: ICHOM, PHIN

GDPR Ready: Nearly
- Will be ready by the time of GDPR deadline
- Huge impact across every aspect in terms of resource
- Big impact on small businesses

Impact:
- **Patient:** Monitor/understand treatments, inform clinical decisions, patient engagement, value for money for payers
- **Research:** Not direct but will allow academics to test an approach in a real world setting, platform to be tailored to client needs in order to capture necessary patient data, facilities hospitals in overcoming patient experience variation
- **Commercial:** Inform development of new products

Use Cases:

★★ Main focus
★ Additional

R&D enablement	
Healthcare context	
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	★
Pricing enablement	★
Patient perspective	★★

Barriers (top 3):

1	Skillsets
2	Forming valued partnerships
3	Political will (national strategies)

ICHOM – International Consortium for Health Outcomes Measurement; PHIN – Private Healthcare Information Network
Source: Interviews; IQVIA research

Initiative Profile
OMOP (Observational Medical Outcomes Partnership)

Dr Christian Reich and Mui Van Zandt (Vice Principal; Principal, IQVIA)

Started: 2017 **Status:** Active

Aim & Objective:
- First outputs are anticipated in 2018
- Transforms data into a common format using common terminology, vocabulary and coding nomenclature
- Aims to standardise healthcare data across different datasets through defining treatments and outcomes and standardising how these are reported
- Overcomes oncology data issues whereby users require a sufficient level of detail from multiple linked datasets in order to realise valuable insight, whilst the data retains a level of abstraction that enables users to query the data

Scope:
- Pan-oncology

Health data:
- Incorporates electronic medical records (EMRs), histology records, treatments, outcomes, diagnostic data
- Staged approach – standardising one data variable at a time

Collaboration: Yes
- Academic research centres (e.g. Memorial Sloan Kettering Cancer Center)
- Involves collaboration and input from oncologists, researchers, IT specialists, academics and data scientists
- A number of pharmaceutical companies are watching with interest

GDPR Ready: Yes
- GDPR will have no impact on the work

Impact:
- **Patient:** Indirect: will identify and address health inequalities; improve patient outcomes
- **Research:** Provide multi-faceted answers to research questions; enable research studies; enable cross-centre; cross-geography data queries and analysis
- **Commercial:** Enable commercial studies; provide multi-faceted answers to research questions; enable cross-centre; cross-geography data queries and analysis

Use Cases:

★★ Primary
★ Secondary

R&D workbench	★★
Healthcare context	★★
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	
Pricing enablement	
Patient perspective	

Barriers (top 3):

1	Funding
2	Skillsets
3	Data quality

Return to initiatives overview

Initiative Profile
Owise by Px Healthcare
Dr Anne Bruinvels (Founder, Px Healthcare)

Started: 2012 **Status:** Active

Aim & Objective:
- Provide education and support for breast cancer patients through the provision of a app for mobile devices. The app allows patients to create a profile and then receive relevant information based on their stage and treatment. It also allows them to securely record conversations with clinicians to allow them to revisit information they might have missed, and report outcomes. The patient reported outcomes (PROs) can be shared with clinicians and played back to the patient in charts to demonstrate changes over time
- Provide longitudinal data by granting access for researchers to the anonymised patient reported outcomes. The initiative is able to link the app to electronic medical records (EMRs) allowing the PROs to be linked to other clinical data and support the healthcare system e.g., earlier identification of side effects

Scope:
- Currently breast cancer; pan-oncology launching 2019
- App launched in Netherlands (2013); UK (2016)

Health data:
- Diagnosis, treatments, side effects, PROs, ability to link to EMRs

Collaboration: Yes
- Funding: Cancer Innovation Challenge; looking for commercial collaborations
- Services: UK regional health authorities are integrating into EMRs

GDPR Ready: Yes
- Data is collected in an anonymised form

Impact:
- **Patient:** Provide information throughout treatment pathway, monitor side effects, give patients control/support, aid in treatment and recovery
- **Research:** Understand which patients have side effects, regional differences, treatment practices and a source of PROs
- **Commercial:** Understand responses to treatments, side effects and PROs, help recruit and monitor clinical trials

Use Cases:

★★ Main focus
★ Additional

R&D enablement	★★
Healthcare context	★★
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	★★
Pricing enablement	★
Patient perspective	★★

Barriers (top 3):

1	Skillsets
2	Sources of funding
3	HCP mind-set (engagement)

Source: Interviews; IQVIA research

Initiative Profile
REAL Oncology (formerly Oncology Data Collaboration)
Dr Geoff Hall (Senior Lecturer and Chief Clinical Information Officer, Leeds Teaching Hospital

Started: 2015 **Status:** Active

Aim & Objective:
- Collaboration between IQVIA and a major English teaching hospital and cancer treatment centre
- Aims to develop research infrastructure in oncology – building off existing high quality electronic medical records (EMRs)
- Mix of industry sponsored and academic research
- Dedicated onsite analytics team delivering research

Scope:
- Pan-oncology
- Regional England

Health data:
- Incorporates treatment and practice patterns, clinical outcomes, healthcare resource utilisation, patient characteristics
- Enrichment possible, for example, with patient reported outcomes (PROs) and tissue sample analysis

Collaboration: Yes
- Joint governance board to oversee research and operations

GDPR Ready: Yes
- No patient identifiable data leaves the hospital site

Impact:
- **Patient:** Improved understanding of anti-cancer treatments leading to improved care
- **Research:** Enhanced research infrastructure at hospital site
- **Commercial:** High quality, research-ready database available for industry use

Use Cases: ★★ Main focus ★ Additional

R&D enablement	
Healthcare context	★★
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	
Pricing enablement	
Patient perspective	★

Barriers (top 3):

1	Skillsets
2	Data access (governance)
3	Scale & granularity of data (e.g. biomarkers)

Source: Interviews; IQVIA research

Return to initiatives overview

Initiative Profile
Simulacrum
Jem Rashbass (National Director for Disease Registration and Cancer Analysis, Public Health England)

Started: 2016 **Status:** Active

Aim & Objective:
- Provide a publically available simulated dataset of high enough quality to allow researchers to run feasibility assessments for studies before formally requesting access to Public Health England's (PHE) data source the Cancer Analysis System (CAS). CAS has a long process before access is granted and historically many have found their study was not suitable only when access was granted wasting significant time and effort.
- Pilot project has successfully created the Simulacrum which is a simulated dataset. This can be used to run test analysis to determine if CAS has suitable data to support a study before access is requested
- Simulacrum will be freely available and success is linked to broad interest and use of the simulated data

Scope:
- Pan-cancer
- UK

Health data:
- None: simulated data based on the Cancer Analysis System (from PHE)

Collaboration: Yes
- Pilot project between PHE, HDI, IQVIA and AstraZeneca
- Pilot funding: joint between collaborators

GDPR Ready: N/A
- Data is simulated; no patient data included

Impact:
- **Patient:** confidence that health data remains secure whilst simulated is more readily used
- **Research:** increased speed to access, allows research into cancer diagnosis and treatment patterns; supports initial protocol writing to provide greater certainty to feasibility early on
- **Commercial:** increase speed to access, allows research into cancer diagnosis and treatment patterns

Use Cases:

★★ Main focus
★ Additional

R&D enablement	★
Healthcare context	★★
Treatment patterns	★★
Real-world clinical value	★★
Socio-econ. value	★
Pricing enablement	★
Patient perspective	

Barriers (top 3):

1	Skillsets
2	Disease complexity
3	Health strategies and approaches

Initiative Profile
Universal Cancer Databank (UCD)

Started: 2018 **Status:** Active

Aim & Objective:
- Overall aim is to support the development of treatments and cures for rare cancers
- Provides a means through which cancer patients can donate their medical data
- Utilises data matching with similar patients to understand other treatment options and aid in clinical trial recruitment
- Collected data will be open-source
- Data will be standardised to permit interoperability

Scope:
- Worldwide
- Pan-oncology

Health Data:
- Patient donated electronic medical records (EMRs)
- Data is anonymised
- EMRs supplemented with patient genome sequencing

Collaboration: Yes
- Philanthropic approach
- Project created by Eliminate Cancer Initiative (ECI)
  - Part funded by the Minderoo Foundation Pty Ltd
- Technology, pharmaceutical companies and research institutions have also expressed their commitment to work with the ECI

Use Cases:

★ ★ Main focus
★ Additional

R&D enablement	★ ★
Healthcare context	★ ★
Treatment patterns	★ ★
Real-world clinical value	★ ★
Socio-econ. value	
Pricing enablement	
Patient perspective	

Impact:
- **Patient:** Increased engagement; potential access to clinical trials; potential alternative treatment options to explore
- **Research:** Clinical trial recruitment; access to information about rare cancers; drug discovery
- **Commercial:** Clinical trial recruitment; access to information about rare cancers; understand treatment patterns for rare cancers; drug discovery

Barriers (top 3):

1	Patient cultural shift
2	Data privacy
3	Standardisation

Source: IQVIA research

Initiative Profile
WEB-RADR (Recognising Adverse Drug Reactions)

Antoni Wisniewski (Safety Surveillance Systems Lead, AstraZeneca)

Started: 2014 **Ended:** 2017 – Now, sustain and maintain

Aim & Objective:

- Aims to improve the exploitation of "new" technology in order to:
  1. Provide an app-based platform for which patients and clinicians to report adverse drug reactions
  2. Utilise social media to identify drug use, effects and safety issues
- Now project has ended, objective is to support and maintain developed App platforms, and collate material to publish findings

Scope:

- Pan-healthcare
- UK (Yellow Card), Croatia (HALMED), Netherlands (LAREB), Africa

Health data:

- App – Adverse drug reactions (ADRs)
- Social Media – off-label use, safety issues

Collaboration: Yes

- Funding: Innovative Medicines Initiative (IMI), EFPIA and other European funds
- Regulatory agencies (e.g. MHRA, EMA), patient groups (EURODIS), technology companies (epidemic), academia (e.g. University of Upsala), pharma (UCB, GSK, AstraZeneca, Novartis, Bayer, Janssen, Sanofi, Amgen)

GDPR Ready: N/A

- Project has now ended and is entering a sustain and maintain phase

Impact:

- **Patient:** Provide patients with the ability to engage, address potential drug safety issues sooner, information/reporting ability across wider patient population
- **Research:** New methods for detecting adverse drug reactions, real-time pharmacovigilance, understand adverse drug reactions, incidence, drug safety, off-label use and niche regimens
  Commercial: Real-time pharmacovigilance, understand drug safety issues sooner, earlier drug launches

Use Cases:

★ ★ Main focus
★ Additional

R&D enablement	
Healthcare context	★
Treatment patterns	★
Real-world clinical value	★ ★
Socio-econ. value	
Pricing enablement	
Patient perspective	★ ★

Barriers (top 3):

1	Data privacy laws
2	Technology
3	Skillsets

HALMED – Agency for Medicinal Products and Medical Devices (Agencija za lijekove I medicinske proivode); LAREB – Bijwerkingencentrum Lareb); MHRA – Medicines and Healthcare Products Regulatory Agency; EMA – European Medicines Agency; EURODIS – European Organisation for Rare Diseases; UCB – Union Chimique Belge; GSK - GlaxoSmithKline
Source: Interviews; IQVIA research






efpia

European Federation of Pharmaceutical Industries and Associations