European Federation of Pharmaceutical Industries and Associations

Data as a foundation for value and access: the oncology data landscape in Europe

Author: Vincent Clay * **Date:** 04/10/2018 * **Version:** Draft






Presentation

From the ‘Taking action on cancer together’ paper

Idea C: Map initiatives to improve data collection and usage, share experiences of successes and blockages and consider what action can be taken to accelerate progress

Data collection and analysis is already improving the quality and affordability of cancer care. Industry is committed to making further progress in the collection and use of cancer data across Europe through a detailed health data mapping exercise. The project will bring together different initiatives on cancer data collection currently under way across Europe and compare their scope and content; examine potential blocks to the collection, sharing and usage of data and consider ways to coordinate and accelerate future progress.

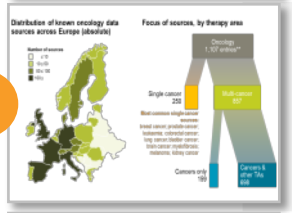
The Oncology Data Landscape materials

1 

Report

2 

Narrative

3 

Data sources & initiatives

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Barriers

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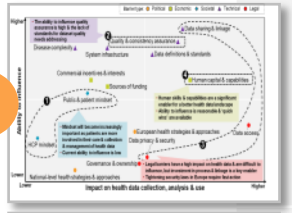
Trends

6 

Strategic solutions

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Country profiles
BE, CH, DE, ES, FR, IT, NL, PL, SE, UK

https://www.efpia.eu/about-medicines/use-of-medicines/disease-specific-groups/fighting-cancer/

Source: A.T. Kearney; IQVIA

What is oncology data used for?

Use cases

Application	Description[1]
R&D enablement	To support identification of promising compounds, investigation of the genome & smarter clinical trials
Healthcare context	To understand the context of the disease & patient populations (e.g. population, biomarkers / genetic characteristics & unmet need)
Treatment patterns	To understand real-world usage of anti-cancer treatments, including by patient group, line of therapy & geography
Real-world clinical value	To measure the delivery of cancer interventions' clinical promise in a real-world setting (including outcomes & safety, quality assurance, etc.)
Socio-econ value	To measure the value of cancer interventions beyond that provided to patients & health systems (inc. lost employment, absenteeism…)
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 (inc. Patient Reported Outcomes), covering aspects of care beyond clinical outcomes

Source: 1. EFPIA

Where does oncology data come from?

Types of data sources

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*

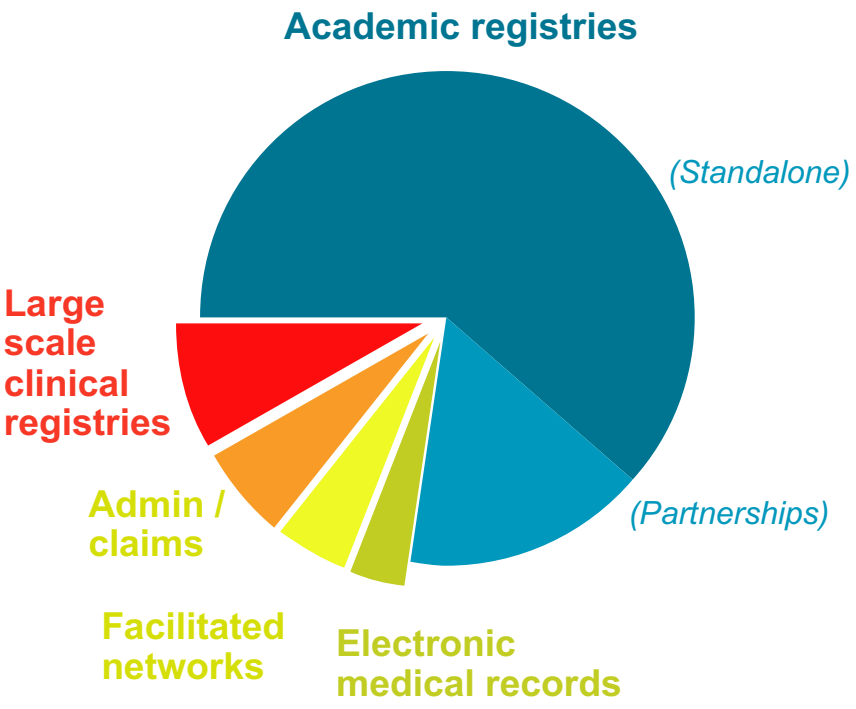
Re-type refers to the process of copying existing information out of an original EMR system into a secondary database for secondary use rather than having to utilise the original data system directly

Source: IQVIA RWD Catalogue; IQVIA research

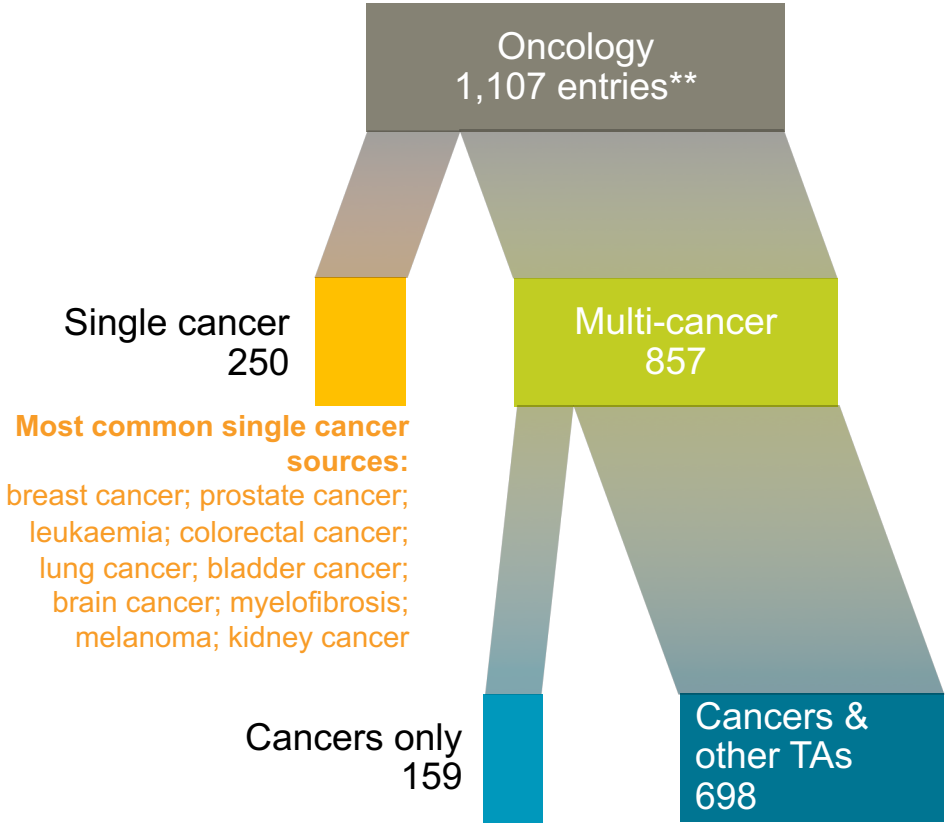
Where does oncology data come from?

Overview of data sources in Europe*[1]

Types of sources



Focus of sources, by therapy area

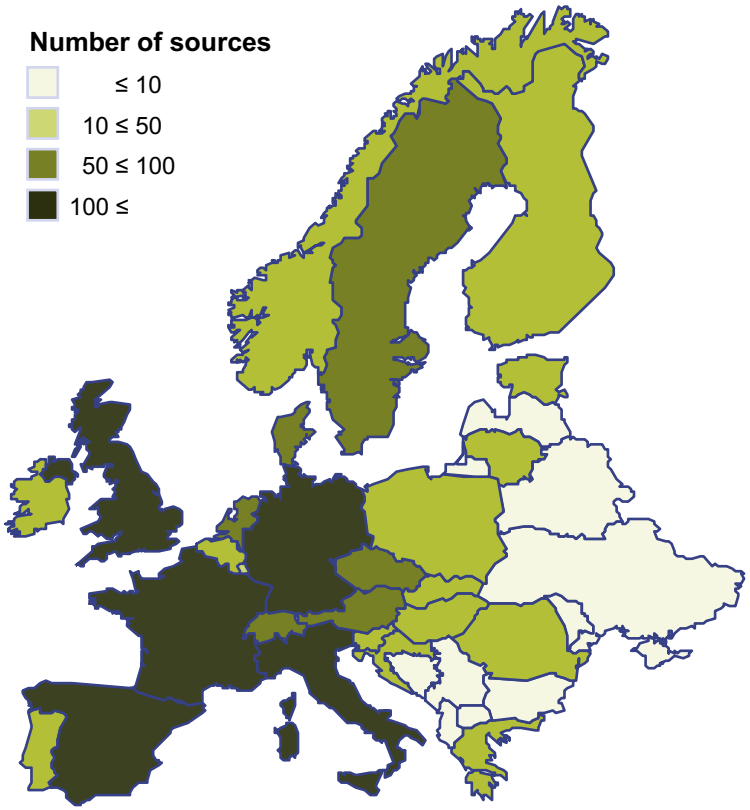


*Data sources used in analysis are those captured within the IQVIA RWD catalogue (>1100); does not account for size of database nor country population; **Entries reflect sources listed in the IQVIA RWD catalogue; EHR = electronic health record

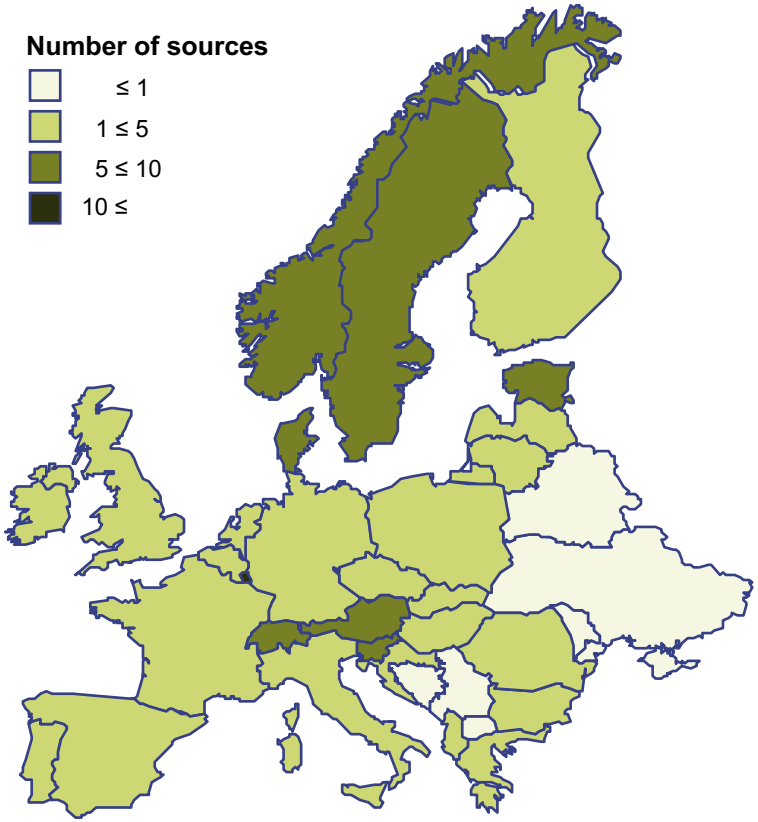
Source: 1. IQVIA RWD Catalogue & IQVIA research

Where does oncology data come from?

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

What are the barriers to more effective use of oncology data?

Data

- Limited collection of relevant data (e.g. PFS, ECOG score, DNA)
- Lack of recognition of certain endpoints
- Inability to consider unstructured data
- Different coding for structured data
- No standards in minimum data required
- Insufficient quality control mechanisms

Structure

- Lack of aligned European & national approach to data, inc. ability to legislate locally on health data
- Insufficient, short-term funding
- Fragmentation of funding sources
- Complexity in accessing funding
- Limited linkage due to lack of single identifying numbers and complex processes / legislation to link data

Process

- Diversity & lack of clarity in rationale needed for data collection & use
- Diversity & complexity of access requirements, inc. need to go via third party
- Large number of stakeholders controlling access, with divergent interests
- Complexity & lack of timeliness of patient consent processes
- Need for inbuilt data protection & associated burden

Technology

- Lack of interoperability due to numerous systems & lack of clear rules
- Low user-friendliness of software & high requirement for manual processing
- Outdated technology surpassed by new processing requirements

People

- Lack of data science skills & related training
- Vested interests in limiting access to & sharing of data
- Concerns around data privacy & protection

ECOG=Eastern Cooperative Oncology Group; PFS=progression-free survival
Source: 1. A.T. Kearney analysis; 2. IQVIA analysis

Several trends will have a critical impact on oncology data in Europe

Overview of current & future trends, by category

① Competitive environment

Monetisation of health data
Health data has intrinsic value to multiple stakeholders which can be leveraged by trading it on a marketplace

Financial sustainability
Facing ageing populations & unfavourable dependency ratios, governments & payers are cutting costs instead of supporting investment

Integration of data vendors & pharma
Digital startups & tech companies have introduced capabilities suited to extracting more value from data & Pharma are investing in these companies

Emergence of Big Tech
Big Tech players such as Google & Amazon are leveraging their expertise in data analytics to enter the health industry

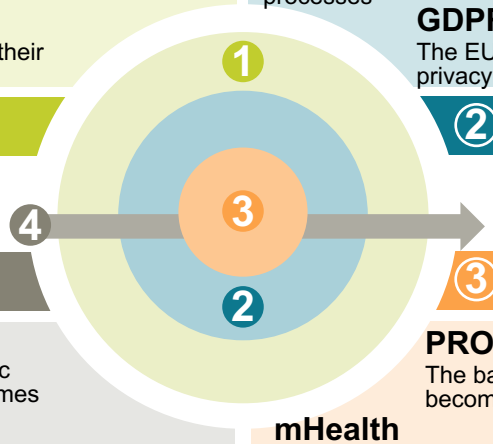
② Health & legal system

Outcomes-based models
New & innovative contracts are being adopted that include models focusing on patient outcomes & value delivered to determine remuneration

Regulatory use of RWD
RWD can be leveraged to grant new market access on a large scale

Accelerated & adaptive pathways
Access to new & innovative drugs can be sped up by reviewing current processes

GDPR
The EU has launched a new data law aiming to harmonise data privacy laws across Europe



③ Patient experience & technology

PROs & patient empowerment
The balance of power is shifting from HCPs to patients as they become more involved in their personal health care

mHealth
Mobile apps & devices are being used to provide access to healthcare services & assist the collection of health data

Genomics
Genetic mapping is being used to understand chromosomes down to the gene level, allowing various diseases to be treated by gene type

Personalised medicine
Smart technology & greater patient participation allows diseases to be treated on a more personal level, using targeted treatment options

④ Data-applied technology

Simulation
Using raw processing power, simulations can be run to mimic patients in a clinical trial setting & to observe potential outcomes

AI & machine learning
Using computer intelligence, tasks & complex decisioning can be automated, & computers can learn over time by using Big Data & mining to spot patterns

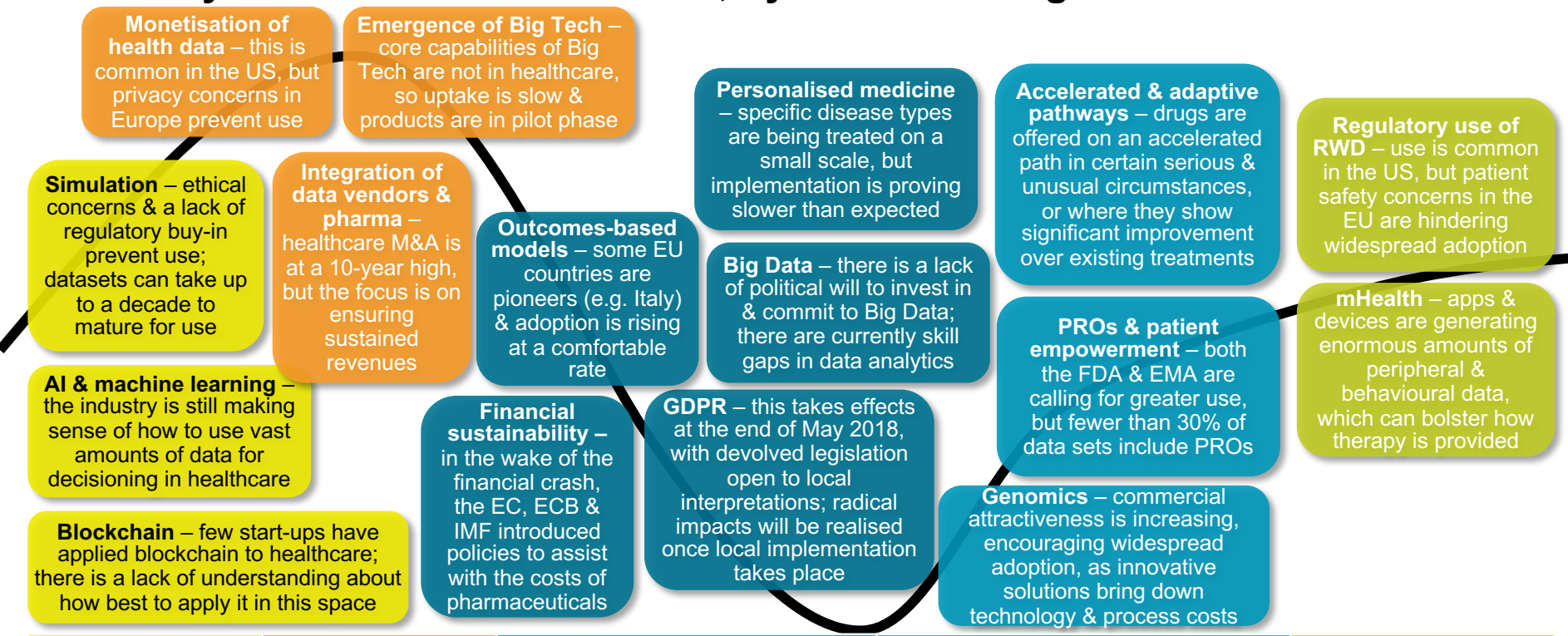
Blockchain
Using secure data blocks, linked in a chain with decentralised ownership, provides new ways to ensure data security & auditing

Big Data
Large volumes of fast, complex & varied data require advance methods to collect, distribute, store & manage it, & can be applied to health data

GDPR = General Data Protection Regulation; HCP = health care professional; HTA = health technology assessment; MEA = managed entry agreement; PRO = patient reported outcome
Source: 16 interviews with oncology & RWD experts across 11 pharmaceutical companies (April 2018)

The trends affecting the oncology data landscape are at various stages of evolution, from early concept to full-scale use

Summary of current & future trends, by evolution stage



Technology trigger	Peak of inflated expectations	Trough of disillusionment	Slope of enlightenment	Plateau of productivity
Conceptualisation of idea	Implementation by early adopters	Flaws & failures lead to disappointment in the idea	Further applications are understood & implementation increases	Wide-scale implementation & understanding

GDPR = general data protection regulation; HCP = health care professional; HTA = health technology assessment; MEA = managed entry agreement; PRO = patient reported outcome

Source: 16 interviews with oncology & RWD experts across 11 pharmaceutical companies (April 2018)

What existing initiatives are trying to make this data more usable?

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

19 initiatives profiled, with insight into the aims, scope and impact of this effort

Initiative Profile

Owise by Px Healthcare

Dr Anne Bruinvels (Founder, Px Healthcare)

owise breast cancer

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	Human capital and capabilities
2	Sources of funding
3	HCP mind-set (engagement)

Source: IQVIA research

To overcome these barriers, several solutions can support both oncology and general health data, led by different stakeholders

28 possible initiatives identified, in nine focus areas

Prioritised focus areas	Rationale
1 Patient & HCP mindset	• Patient & HCP misconceptions around personal health data use negatively impacts mindset • There is a need to build transparency & empower patients in their health care
2 Quality & consistency assurance	• There is a lack of consistency & uniformity in data conventions, including dataset structures, standards, definitions & terminology; this prevents linkage & sharing of data across Europe
3 Access, privacy & sharing	• Rules & regulations concerning access varies across Europe & often it is restricted as a result • Data privacy is a sensitive issue & a major concern for HCPs & patients; new regulation will lead to further complications at the local level, as regulation is not completely understood
4 Human skills & capabilities	• Data science skillsets are a significant enabler for a better health data landscape, but gaps exist
5 Socio-economic value	• An increased focus on health system expenditure & patient perspective means that a holistic approach to cancer treatments is needed to allow access to innovations more comprehensively
6 Pricing enablement	• Understanding the value of health data to develop more innovative pricing models is essential to improve the financial sustainability of certain drugs & improve coverage decisions
7 Patient perspective	• Patients are becoming increasingly engaged in their personal health & the new, detailed insights that can be drawn from patient perspectives can to be leveraged to inform treatment decisions
8 R&D enablement	• New technology can be leveraged for more effective R&D, but a focus on the data sciences as a core capability required to enable more innovative research methods & outcomes
9 Strategic enablers	• The longevity of funding is a key issue & often it runs dry before a dataset has gained traction • Health data is dispersed across multiple sources, with few efforts to enable simple linkage • Initiatives lack manpower, skillsets & funding to scale up, thus collaborating is key

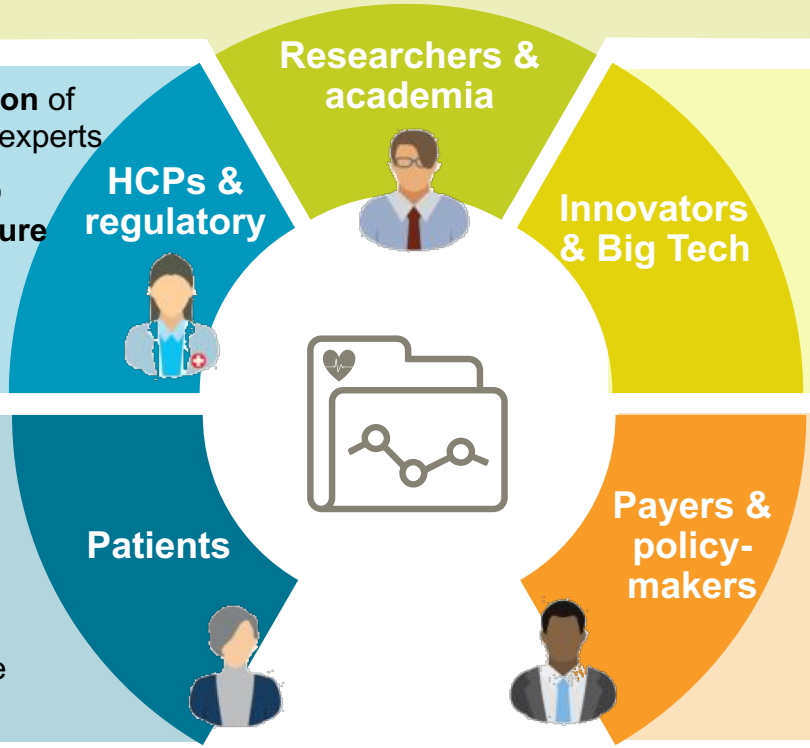
Prioritised area: Use case | Sub-barrier | Strategic enabler

HCP = health care professional;
GDPR = general data protection regulation
Source: A.T. Kearney; IQVIA analysis

All stakeholders have a role to play in implementing solutions to improve the oncology health data environment

Actions for health data stakeholders[1]

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



HCPs & regulatory

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

Researchers & academia

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

Patients

1. **Develop a patient data donation platform** to enable ownership & sharing
2. **Inform reflection on patient consent** processes & forms to improve transparency & ease-of-use

Payers & policy-makers

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

Source: 1. EFPIA

What further actions could help to improve the effective use of oncology data?

Recommendations to improve data[1]

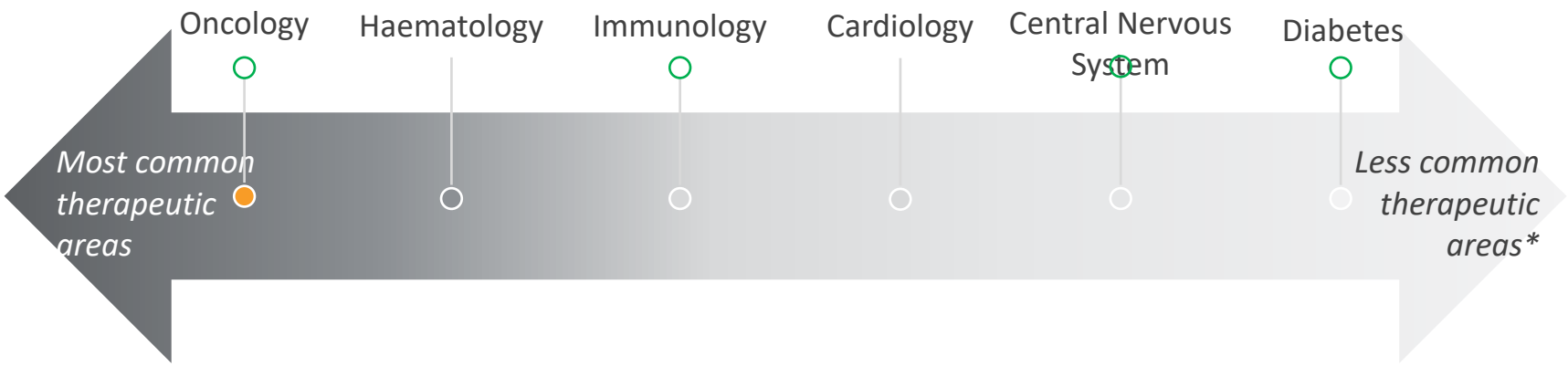
Build awareness	Develop standards	Build infrastructure	Develop skills
✸ **Understand the benefits** of sharing & using oncology data ✸ **Have support for innovative pricing** based on data & outcomes ✸ **Improve the understanding of the technologies** that can enhance health data ✸ **Recognise data science** as a core health skill	✸ **Define clear guidelines & best practice** for working with health data (inc. privacy protocols, anonymisation, access governance, minimum dataset, linkage, etc.) ✸ **Establish a quality accreditation framework** to support the implementation of best practice ✸ **Foster the transparency & ease-of-use of patient consent processes** ✸ **Define & test measures of socio-economic benefit** ✸ **Refine & test PRO definitions** in cancer	✸ **Achieve full, 'live' visibility & comparability of RWD sources** in Europe ✸ **Have an established approach to govern, fund, manage & scale** healthcare data projects ✸ **Enable the collaboration of cancer experts** across countries & centres ✸ **Support patients** in owning, sharing & benefiting from their data ✸ **Enable the sharing & linkage of 'raw' data** ✸ **Support the preparation of regulatory-compliant data** ✸ **Have aligned EU & national grants** ✸ **Consider local GDPR interpretations** that support data use & benefits	✸ **Develop key data skills** across industries & **sectors** ✸ **Facilitate the collection of complete, high-quality data** by HCPs

Source: 1. EFPIA


Any assessment
of the value of an intervention
is based on a selection of data.

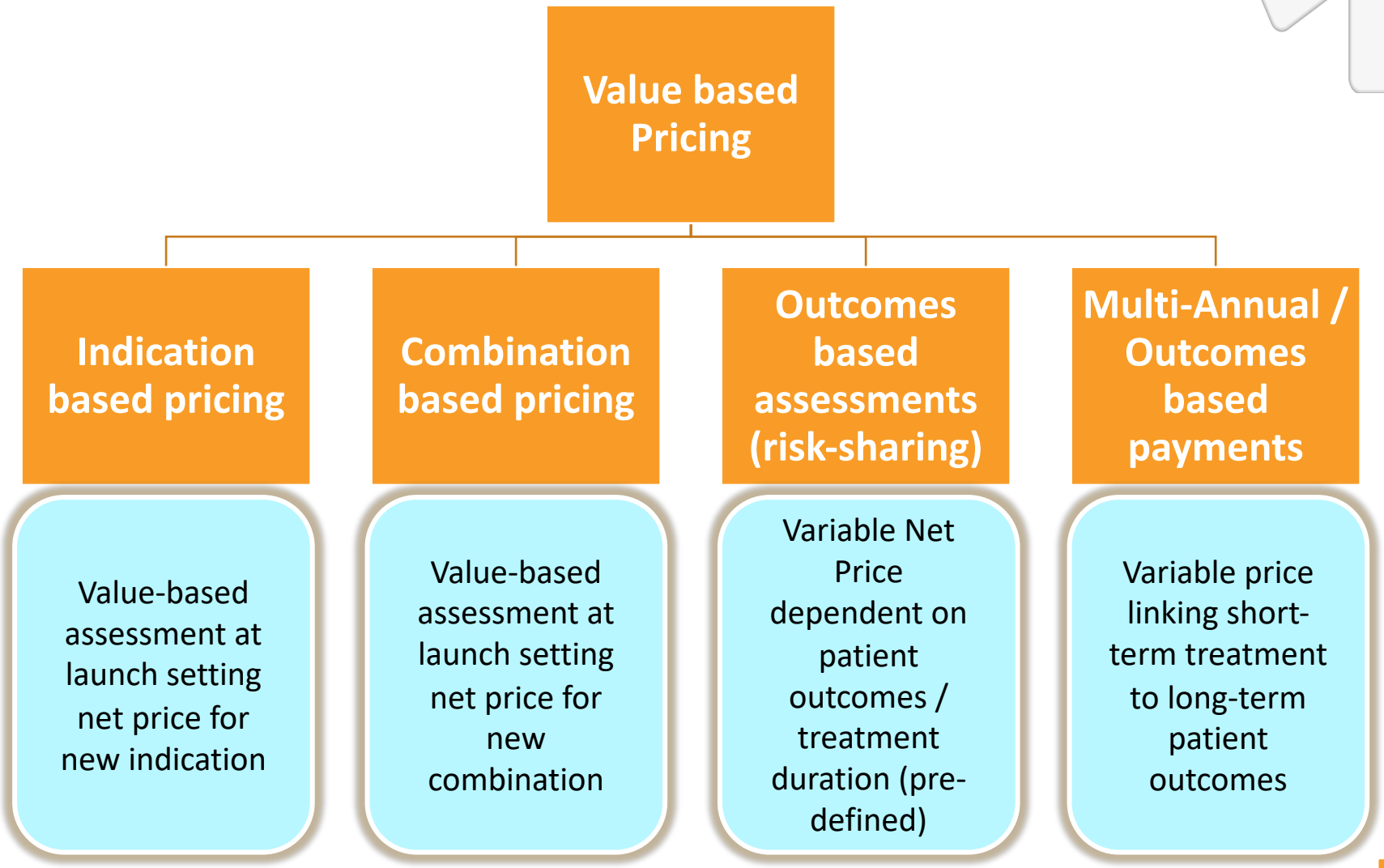
Most common therapeutic areas for products with outcomes based Managed Entry Agreements

- Oncology = most common therapeutic area, followed by haematology and immunology, may be overlaps (e.g. immuno-oncology).



Notes: = mentioned by previous studies as common therapeutic areas (EMiNet, Ferrario et a.,l 2017, Gerkens et al., 2017; Gonçalves et al., 2016) ; * Osteoporosis and Orphan medicines were also mentioned.

Innovative pricing models: types and definitions



Examples of how innovative pricing models can be implemented

Innovative pricing model	Negotiation considerations	Data Needs	Examples of types of "Enablers"
Indication based pricing	• Value-based assessment of new indication • Data collection to facilitate net price according to use of indication	• Product utilisation across multi-indications	• Prescription data systems • Real World data sources • Payer willingness
Combination based pricing	• Value based assessment of new combination • Data collection to facilitate net price according to use of combination	• Product utilisation across indications & Combination	• Prescription data systems • Real World data sources • Payer willingness • Value sharing
Outcomes based assessment	• Pre-defined patient outcomes used to settle price contract • Rebates / discounts according to patients meeting criteria	• Patient Outcomes • Treatment duration/ Clinical response • Survival / QOL outcomes	• Observational research (prospective) • Patient outcomes integrated into routine data collection systems
Multi-annual / Outcomes based Payments	• Curative therapies based on short treatment duration • Payments (net price) linked to long-term outcomes	• Long-term patient outcomes • Survival • Other	• Observational research • Routine patient surveillance linked to payment systems

1. The materials are yours to use

2. Recommendations for everyone

Build awareness	Develop standards	Build infrastructure	Develop skills

3. Relevance for medicines

- **Better data → Better assessment of value**
- **Better data can support improved access to effective interventions**
  - Indication-based pricing a useful step
  - Outcomes-based pricing as the destination

  → ***Better outcomes for patients***



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