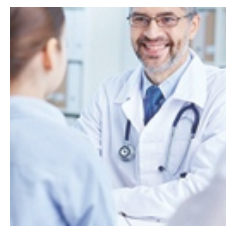


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Oncology data landscape in Europe

Data narrative
July 2018

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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Purpose

This slide deck outlines the importance of health data in Europe, barriers to its use, and possible solutions to those barriers.



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A number of innovations are transforming the management of oncology

Overview of innovation in oncology

Improved screening & detection

- **Better understanding of cancer and its causes** helps offer better care – 50 years ago, blood cancers were categorised into leukaemia & lymphoma; today, 40 unique leukaemia types & 50 unique lymphoma types have been identified¹
- Through nutrition, lifestyle change & other interventions, cancer can now be prevented – in 2006, the first **vaccine for the prevention of cervical cancer** was launched¹
- **Personalised biopsies, ultrasound imaging & digital pathology** are improving diagnosis²



Non-pharmaceutical advances

- Thanks to **mHealth**, cancer patients can be at the center of their care – for example, ChemoWave is an app that collects vitals (e.g. symptoms, drugs, exercise) from chemo. patients & shares it with HCPs³
- **Digital platforms** (e.g. Syapse, Flatiron) are integrating genomic & clinical data to inform & improve treatment paradigms²



Pharmaceutical advances

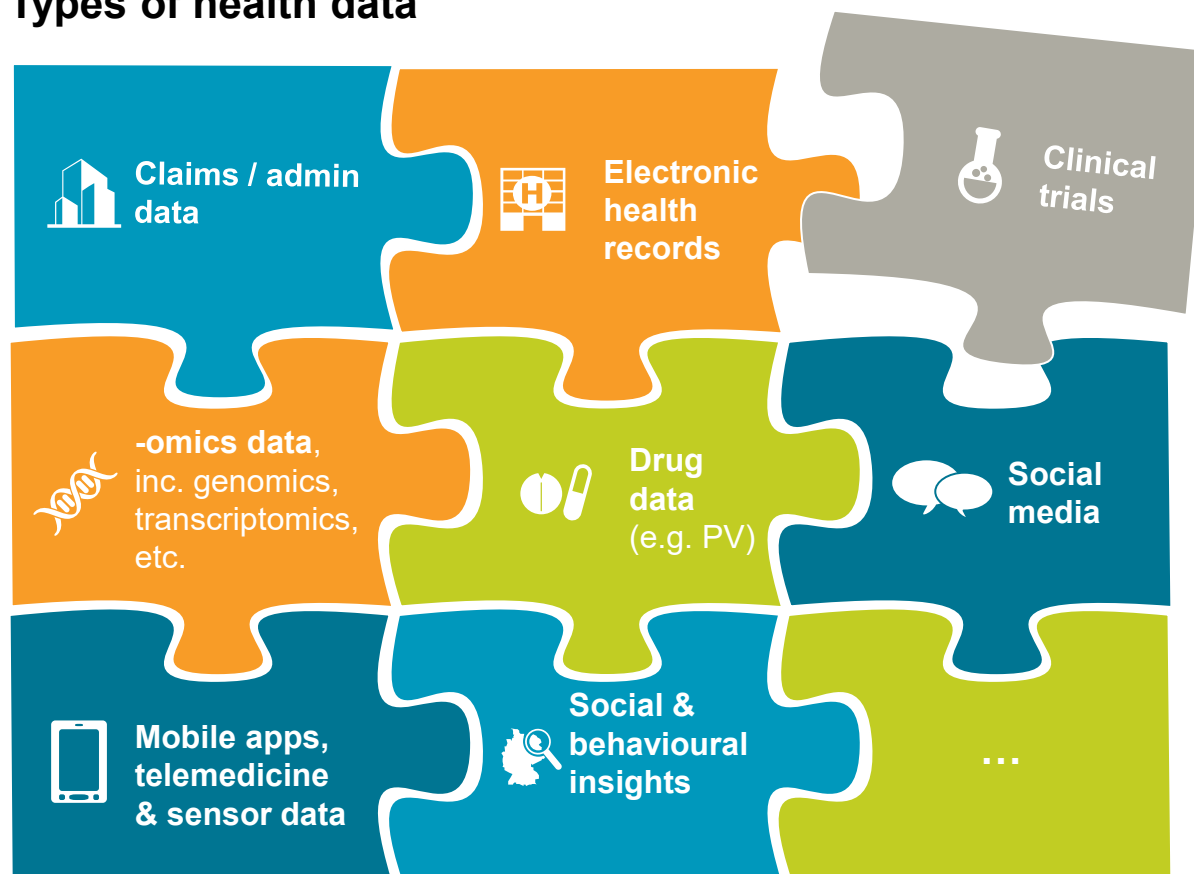
- **Personalised treatment**, increasingly based on mutation rather than organ, leads to improved outcomes – in lung cancer, EGFR & ALK inhibitors work best in patients with corresponding mutations⁴
- **Immunotherapies** help target & kill cancer cells by “releasing the brakes” on the immune system – although 5-year survival with chemotherapy was 15-20% for melanoma in 2011, new therapies show 40% of patients surviving after 3 years⁴
- **CRISPR gene editing** allows researched to manipulate cancer cell function; **CAR T-cell adoptive cell therapy** involves the modification of individuals’ immune-boosting T-cells to target & kill blood cancer cells⁵



While clinical trial data continues to be important, it has limitations and new data sources are emerging

About health data in oncology¹

Types of health data



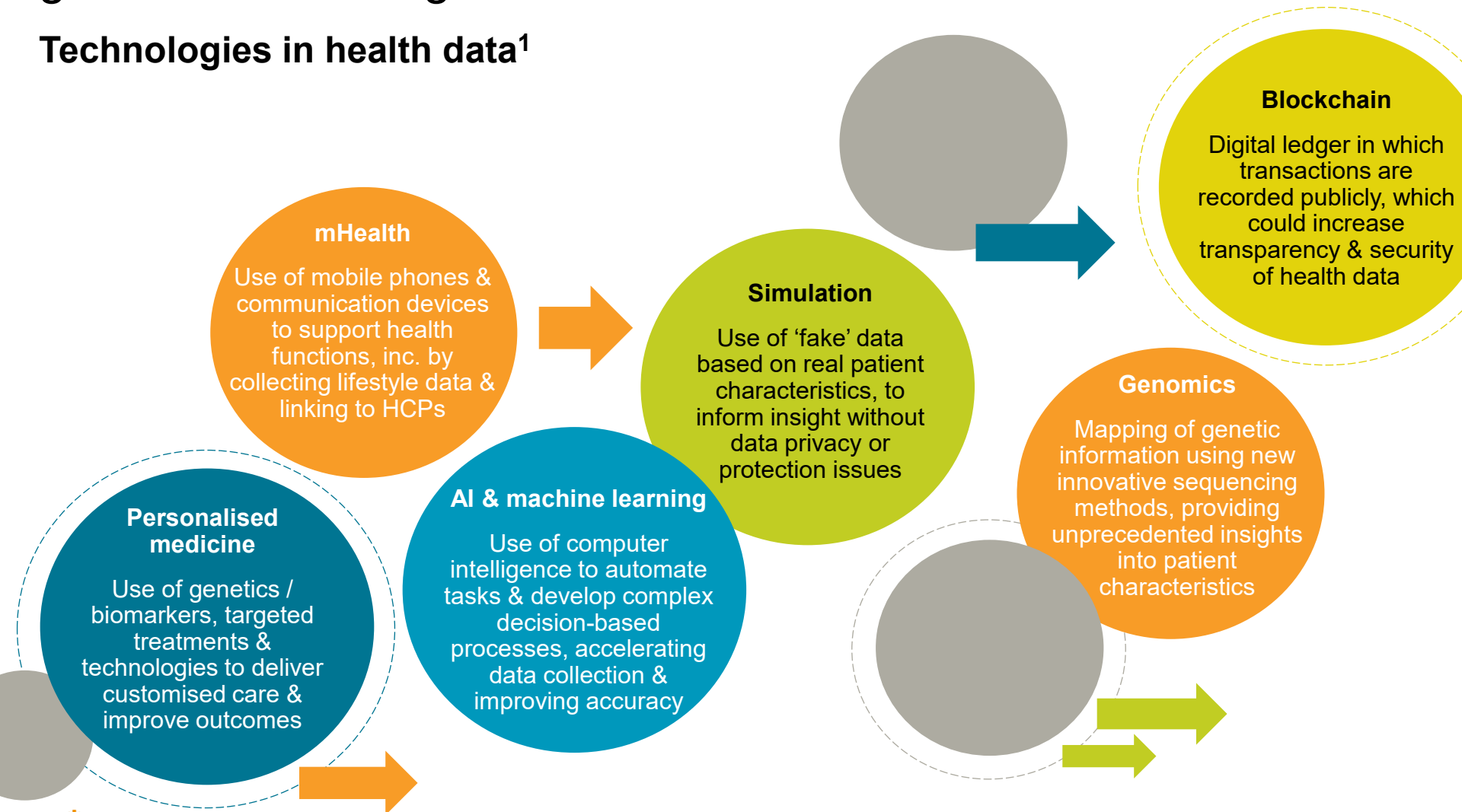
Limitations of clinical trials²

Oncology clinical trials only provide part of the picture because:

- 📖 Current treatment regimens involve **multiple lines and combinations of treatment**, which cannot be reproduced in a controlled setting
- 📖 Highly-innovative therapies are increasingly approved through **accelerated / adaptive pathways**, with limited time to run clinical trials
- 📖 Clinical trials are conducted for **certain indications**, but not all potential uses
- 📖 Some rare forms of cancers can only be studied in **one-arm trials for ethical reasons**, to ensure patients receive treatment and support continued anonymity








The availability of new technologies is transforming our ability to gather and interrogate health data

Technologies in health data¹




Health data can be used for different purposes, from providing insight into the healthcare context to R&D and drug assessment

Applications of health data

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 QoL(inc. PROs), covering aspects of care beyond clinical outcomes

There are many examples of increased data availability improving patient access to care and better outcomes


Benefits of health data


Application	Sample benefits
 R&D enablement	 The EHR4CR initiative enables more precise recruitment, retention & site-selection strategies via better patient-level data ¹
 Healthcare context	 In Italy, IBM & the National Cancer Institute of Milan use genomics to improve the treatment cancers, leading to personalised care & better outcomes ¹
 Treatment patterns	 In Hungary, a national health app has been used to detect inefficiencies in charging & reimbursement for cancer therapy, leading to pathway adjustment & increased detection ¹
 Real-world clinical value	 In the US, the FDA granted accelerated access to avelumab based on an open-label, single-arm study supported by RWD in metastatic Merkel cell tumour ²
 Socio-econ value	 In Sweden, the societal & humanistic value of new drugs is considered as part of the health technology assessment process
 Pricing enablement	 In Italy, MEAs established from 2006-2008, mostly for oncology drugs, showed that they helped decrease the time to market by 75% (from 343 to 84 days) ³
 Patient perspective	 The PatientsLikeMe epilepsy portal allows better involvement of patients in clinical trial processes, facilitating research that responds to patient needs ¹


All stakeholders stand to benefit from better health data in oncology


RWD benefits for health stakeholders¹


 Understand new areas of health and R&D

 Improve quality, speed and cost-effectiveness of research

 Achieve a better understanding of their patients & of the real-life effectiveness / safety of their treatments

 Monitor performance & identify best practice to continuously provide the best quality of care


 Have increased understanding of their health & ownership of their healthcare


 Have access to the right treatment options at appropriate costs


Researchers & academia



Innovators & Big Tech

 Understand unmet needs to develop innovative treatments that are effective & safe

 Support flexible pricing arrangements to ensure that treatments deliver value-for-money

 Increase the cost-effectiveness of care & support long-term sustainability of health systems

 Support evidence-based reimbursement for outcomes

HCPs & regulatory



Patients



Payers & policy-makers

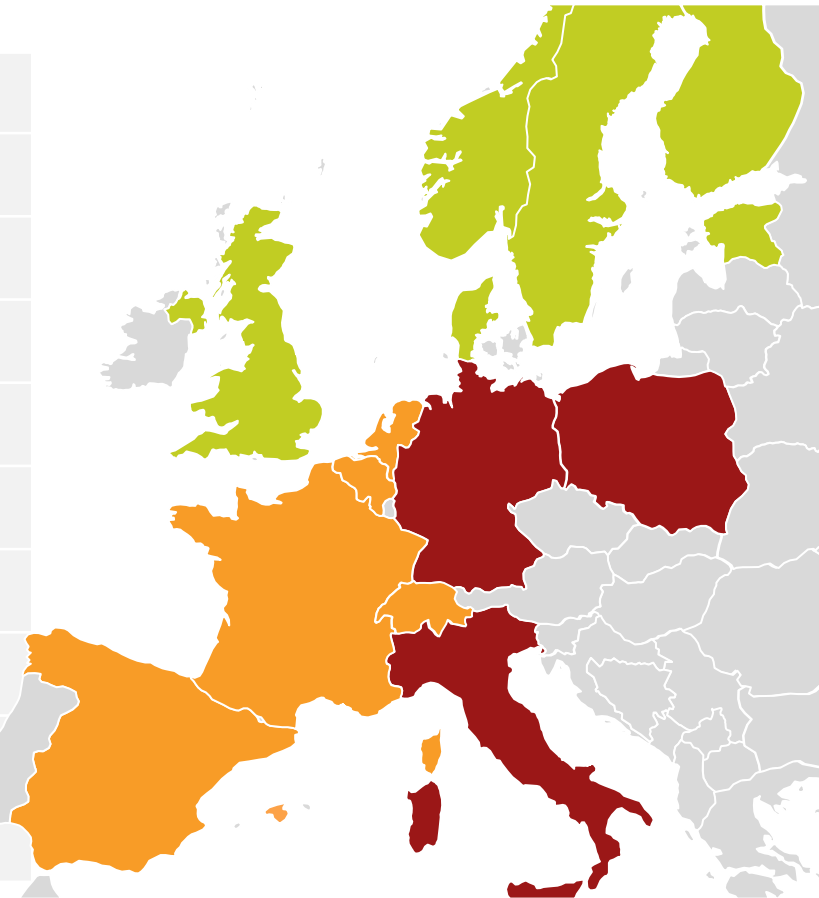


The availability and quality of health data varies across European countries, due to differences in systems and infrastructure

Overview of EHR infrastructure in Europe¹⁻⁶

Country	Comments
	eHealth platform introduced in 2008; data sharing limited to regional level; limited legislation on use of health data
	Country-wide EHR system in place; initiative underway to enable a shared oncology database; lacking standards & data quality
	EHRs owned by SHIs; poor linkage due to strict privacy rules; lack of standards
	Regional EHR systems; lack of national eHealth and/or oncology plan; several managed-entry agreements in place for new oncology drugs
	Gaps in a national EHR plan (but being solved); widespread use of EHRs; limited sharing across healthcare centres or quality standards
	Mandatory EHRs; plans to introduce a national patient account & ID system; legal issues around access
	Regional EHRs despite national strategy; limited data sharing; lack of legal procedures that hinders widespread access
	National EHR strategy that allows linkage across health centres & databases using a patient ID; clear & well-understood patient consent
	National plan for EHRs but regional disparities; limited country-wide sharing; ad hoc access approval, with few process standards
	Widespread EHR adoption; independent body to establish national cancer databases; well-developed data quality & linkage across datasets

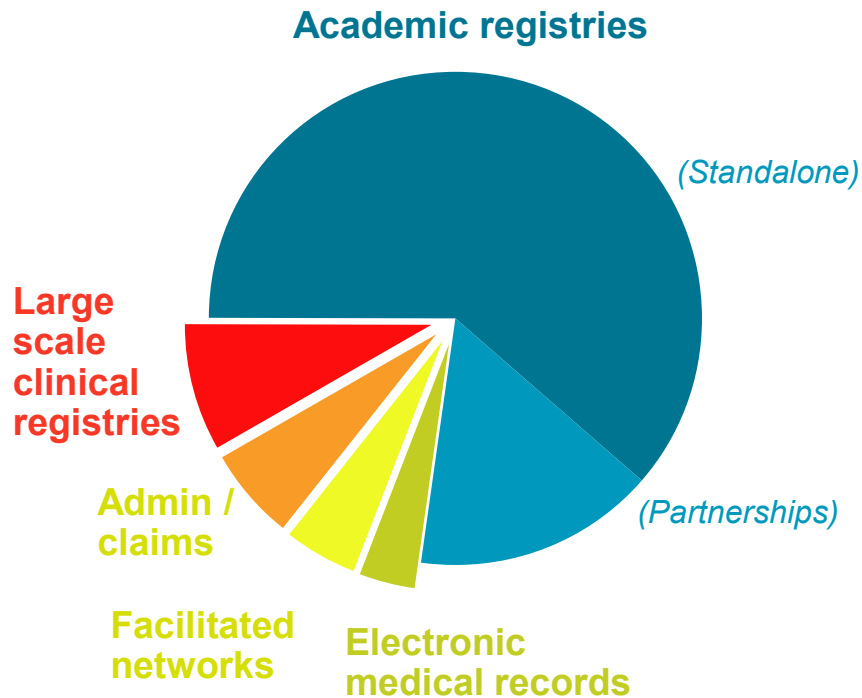
Maturity:  Leading  Emerging  Lagging



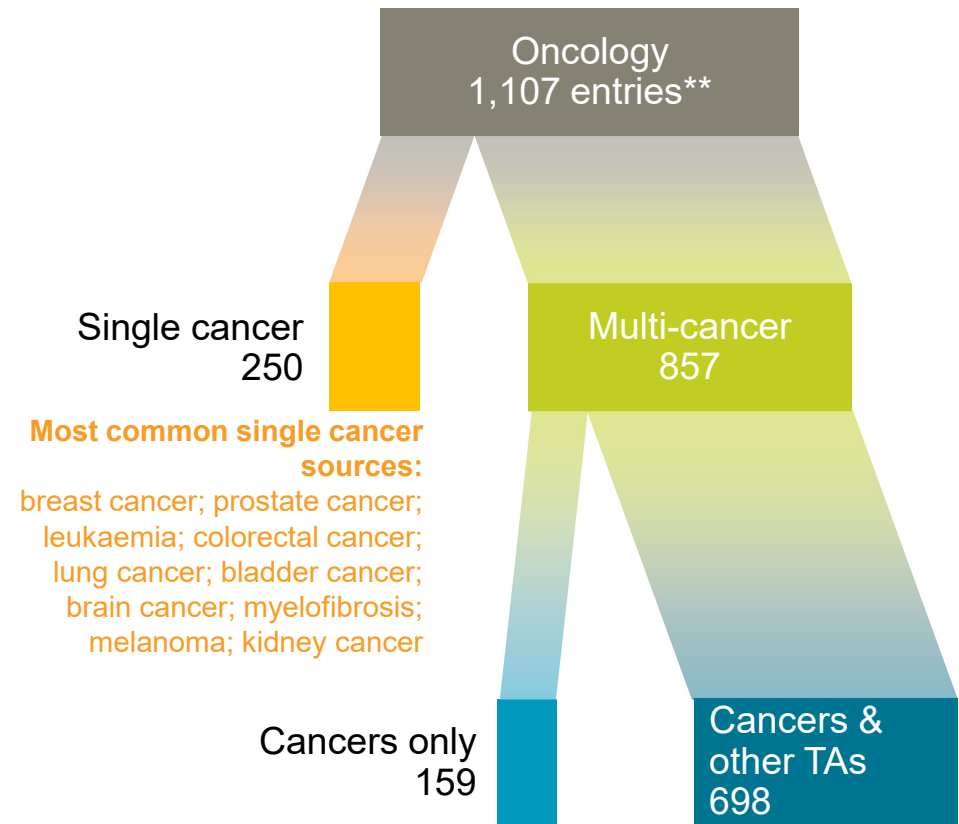
Oncology data sources across Europe include academic registries, EHRs and networks, and remain fragmented

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




Despite their number and variety, most current European data sources lack scale and robustness to support decisions

Strength of oncology data sources¹

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

While a number of initiatives have been launched and scaled to address this, data, standards and access remain fragmented

Data initiatives in Europe*1

Improve access 	Improve collation 	Standardise data 	Collect new data types 
<p>Aims to improve access to existing datasets or allow their interrogation</p>	<p>Aims to incorporate existing datasets into a central repository</p>	<p>Aims to standardise how data is collected so that datasets are comparable</p>	<p>Aims to collect data that does not yet exist, often via novel approaches</p>
<ul style="list-style-type: none">  Big Data for Better Outcomes (BD4BO)  Collaboration for Oncology Data in Europe (CODE)  Innovative Medicines Initiative (IMI)  INSITE 	<ul style="list-style-type: none">  European Commission Initiative on Breast Cancer (ECIBC)  European Cancer Information System (ECIS)  European Network of Cancer Registries (ENCR) 	<ul style="list-style-type: none">  European Health Data Network (EHDN)  International Consortium for Health Outcomes Measurement (ICHOM)  Observational Medical Outcomes Partnership (OMOP) Oncology 	<ul style="list-style-type: none">  EUROSTAT  IRONMAN  OWise  SCAN-B  WEB-RADR

These challenges apply across countries and data sources, leading to poorer patient outcomes and inefficiencies

Current challenges around health data use^{1,2}

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

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

Example solutions

Solution	Rationale	
 Build awareness	To communicate the importance & value of health data to all stakeholders, highlight current ongoing challenges & illustrate possible solutions	 #datasaveslives is a media campaign launched by the Farr Institute in the UK, to communicate the importance of health data & informatics in public health ¹
 Develop standards	To harmonise practices in data collection & use, thereby accelerating & limiting the burden of data analysis, linkage & sharing	 OMOP is standardising data variables with a staged approach taking each segment (e.g. diagnosis, treatment, outcomes) in turn rather than standardising everything at once ²
 Build infrastructure	To establish systems & networks where data & best practice can be collected, stored, analysed & shared with all relevant stakeholders	 The e-Government platform 1177 allows patients to access their EMRs across public & private sectors; patients own their records ³ .
 Develop skills	To ensure the quality & efficacy of data gathering processes, accuracy & adequacy of analyses, & use of the latest technologies	 Imperial College London has established a 5 week course for “ data analytics for health ” to educate students on emerging issues in eHealth & how to use technology ⁴

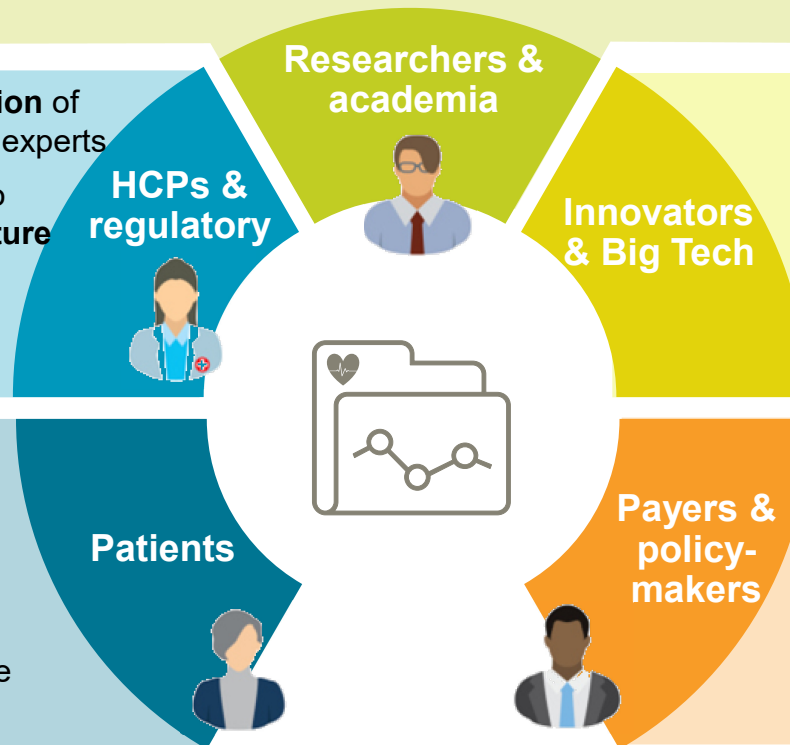
All stakeholders have a role to play in implementing solutions to improve the oncology health data environment

Actions for health data stakeholders¹

- 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

- 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

- 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






















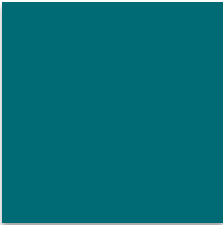
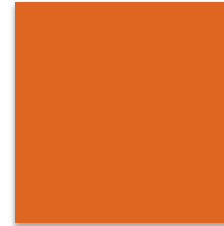
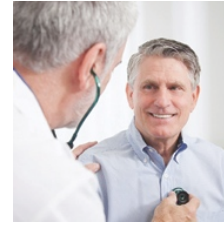
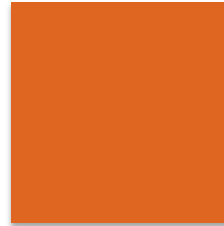
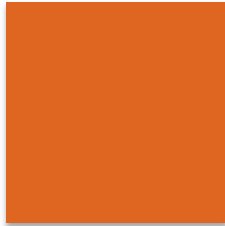
- 1 Improve understanding & use of technology to support health data & use cases
- 2 Build awareness of data science as a core R&D & health skill

- 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

EFPIA is committed to partnering with all stakeholders to enable oncology health data use and improve patient outcomes

Recommendations to improve data¹

Build awareness	Develop standards	Build infrastructure	Develop skills
<ul style="list-style-type: none">  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 	<ul style="list-style-type: none">  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 	<ul style="list-style-type: none">  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 	<ul style="list-style-type: none">  Develop key data skills across industries & sectors  Facilitate the collection of complete, high-quality data by HCPs



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