EFPIA

Oncology data landscape in Europe

Barriers to the collection and use of health data
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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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European Federation of Pharmaceutical Industries and Associations

Executive summary

* This document focuses on **identifying the key barriers** to collection, analysis, and use of oncology data in Europe

* We have conducted a **landscape review** and **16 internal interviews** with Oncology and RWD experts across 11 pharmaceutical companies, **22 external interviews** across 8 countries, and **22 interviews covering 18 initiatives**

* **Five key barriers**, with associated sub-barriers and possible solutions, have been identified and mapped to the **potential negative outcomes on health data**

  – A **lack of national eHealth strategies** and a **restrictive political will** is common across many European countries

  – Funding for data sources and initiatives tends to be **fragmented and lacks longevity**, and **skills and capabilities needed for data use**, collection and analysis are often **lacking**

  – Both HCPs and patients currently have a **mindset that does not always support** the collection and use of personal health data; data **security and privacy concerns prevail**

  – Technical **infrastructure and standards are not fit for the purpose** and quality assurance and **auditing is not always practised**

  – **Data access, ownership, consent and governance** are all **legal barriers** to health data

* For Pharma, **legal barriers are the strongest**, particularly around **access to data and data privacy issues; technical barriers** are generally being addressed by ongoing initiatives

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Background & method

Overview of barriers

Detailed barriers

Conclusion

Five key barriers have been identified and mapped to outcomes; case-studies outline the current situation and possible solutions

Method of barrier analysis

Identification of barriers & sub-barriers

- Based on stakeholder interviews & desk research, **five key barriers** were identified with associated sub-barriers

1. Political
2. Economic
3. Societal
4. Technical
5. Legal

Likelihood of negative outcomes, by barrier

- Across the five key barriers, **negative outcomes were identified** & mapped by their **frequency**

1. Risk of data breach
2. Delayed or restricted access
3. Lack of data comparability
4. Limited data relevance
5. Limited data sharing or transfer
6. Low data quality or completeness

Detailed sub-barrier situation & possible solutions

- For each sub-barrier, the **current situation** & **potential solutions** to overcome the sub-barrier have been outlined, driven by:

1. **Case-study examples** (with a European focus)
2. **Stakeholder interview quotes**

Source: 16 interviews with oncology & RWD experts across 11 pharmaceutical companies (May 2018); A.T. Kearney analysis

Research entailed internal and external interviews, covering a wide range of stakeholders and geographies

Method of barrier analysis: interviews

Internal 'trend' interviews

- **16** interviews conducted
- **11** companies & assoc. covered

- **Several functions addressed**
  - Market access
  - Medical affairs
  - Data science
  - RWD
  - Epidemiology
  - …
  - Oncology TA

External 'trend' interviews

- **21** interviews conducted

- **8** countries covered + EU

- **Wide range of stakeholders**
  - Regulators
  - Policy experts
  - HTA
  - Academia
  - Payers
  - Tech/ innov.
  - Patient reps.
  - Oncologists

External 'initiative' interviews

- **22** interviews conducted
- **18** initiatives covered

- **Wide range of profiles**
  - **19** full profiles
  - Additional 21 short profiles

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Several barriers have been identified that currently hinder the collection, analysis and use of oncology data across Europe

Health data barriers

Not exhaustive

Political	Economic	Societal	Technical	Legal
European health strategies & approaches (e.g. existence of data or cancer strategies, member state interests) **National-level health strategies & approaches** (e.g. focus on national cancer strategies, will & commitment to health data, fragmentation of EHR implementation across regions & settings of care)	**Sources of funding** (e.g. fragmentation of funding sources, funding availability, short-term funding) **Commercial incentives & interests** (e.g. information sharing, image / reputational issues) **Human capital & capabilities** (e.g. skillset, training, digital literacy, analytic methodologies)	**Public & patient mindset** (e.g. data protection concerns, involvement of patient associations, buy-in & commitment) **HCP mindset** (e.g. data protection concerns, commitment & interest, engagement & awareness)	**Disease complexity** (e.g. genetic information, treatment shifts) **System infrastructure** (e.g. transfer & linkage, system complexity) **Data definitions & standards** (e.g. coding, language) **Data processing & linkage** (e.g. data sharing, data collection methods, data warehouses) **Quality & consistency assurance** (e.g. data auditing, accreditations)	**Ownership & consent** (e.g. consent management, data control) **Governance & data access** (e.g. access rules, access rights for stakeholders) **Data privacy & security** (e.g. IT & cybersecurity, data legislation)

Outcomes from the sub-barriers' issues has been identified, and their frequency across the five barriers, mapped

Barriers & associated outcome frequency

Higher frequency to lower frequency[1]

Key barriers		Risk of data breach	Delayed and / or restricted access	Associated outcome			
				Lack of data comparability	Limited data relevance[2]	Limited data sharing / transfer	Low data quality[3] & completeness
Political				●	·	●	●
Economic				●	●	●	●
Societal				●	●	●	●
Technical		·	●	●	●	●	●
Legal		·	●	·		●	●
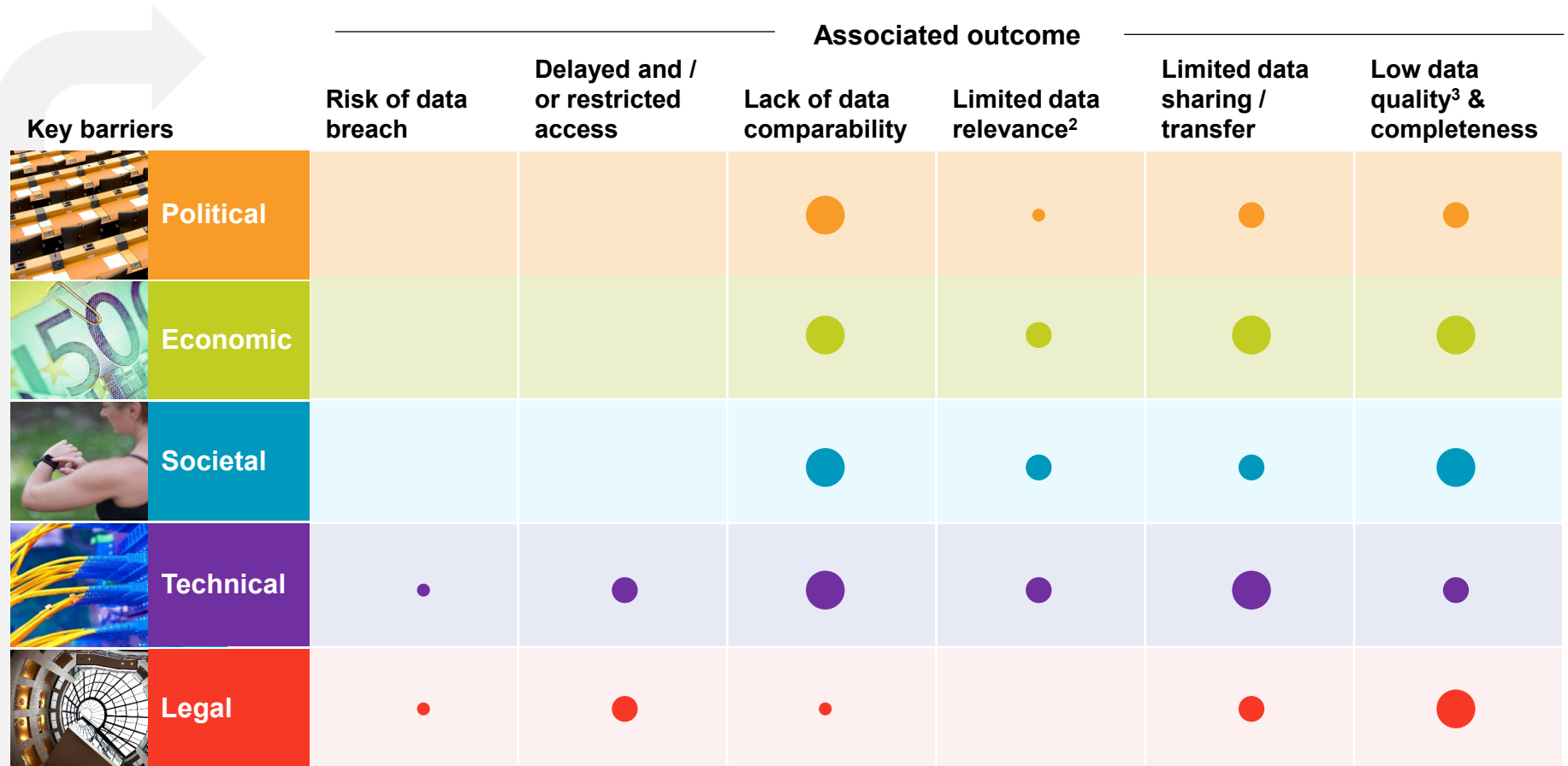
1. Based on frequency of outcomes from the issues across each key barrier
2. Due to untimely datasets, lack of scale & granularity in light of complex diseases
3. Due to the low-quality of available data, and data gaps
Source: A.T. Kearney; IQVIA

Contents

A lack of political will and leadership is seen as hampering the ability to maximise the benefits of health data

Overview of barriers: political

Sub-barrier	Issues	Quotes
European health strategies & approaches	Lack of European-wide data or cancer strategies	
	Inability to overcome Member state interests to harmonise data	
National-level health strategies & approaches	Limited political will & commitment to develop health data	
	Limited focus on health data in national cancer strategies	
	Fragmentation of EHR implementation across regions & settings of care	

"There is a lack of intellectual leadership and political will to address the barriers in place"

"Political will is lacking – you need someone to say it is not evil to share clinical data"

"We can't share data – except for healthcare purposes only, and we can't share data outside the EU" – Initiative Interviewee

"The politicians will follow the people"

"They have done a great job on political and patient engagement"

"There are national programmes and contracts that get in the way"

Source: initiative interviews

National strategies and political initiatives are beginning to shift the will to adopt and invest in e-health data infrastructure

Health data barriers: political

Barrier case studies

Uneven EHR implementation
- 73% of states are not using EHRs to their full, intended use

Diversity in Member state interests
- Member countries can implement national-level regulation in addition to EU laws & have done so (e.g. the French DPA)

Limited political will to develop health data
- 70% of member states in Europe have a national e-health strategy or policy
- Only 13% have a policy on the use of Big Data

Limited focus on health data in cancer strategies
- Most initiatives are still in pilot stage (e.g. 'Système national des données de santé' in France; Medical Informatics Initiative (MI-I) in Germany)

Example solutions

Strategy for standardisation
- The 2nd Programme of Community Action in the Field of Health '08- '13 supports IT infrastructure

Facilitation of healthcare access
- The epSOS project ('08-'14) developed a European e-health infrastructure, involving 22 member & three non-member states

National strategies around e-health data
- Denmark's 'Making E-Health Work' strategy ('13-'17) aims to develop a national standardised framework for the collection of e-health data

Shift in political will
- The Belgian healthdata.be initiative recognises the benefits from linking existing systems together; a new centre for the integration of data was created as part of the national plan

The EU is supporting the development of frameworks to counter the lack of harmonisation – IT and data access are on the agenda

Overview of barriers: political (European health strategies & approaches)

🟢🟡🔴 Impact of barrier (lower – medium – higher)   ↑↗→ Susceptibility to change (higher – medium – lower)

Current situation 🟢

Lack of European-wide data or cancer strategies

- A lack of a systematic & proactive framework across Europe prevents e-health from being built up at the speed required by the advances in e-health technology
- **Ministerial Conferences**, the **MIE conference** & several communities / not-for-profits (**EUROREC, EHTEL, Calliope, IHE, CEN & Continue**) are not coherent enough

Inability to overcome Member state interests to harmonise data

- Member countries can implement national-level regulation in addition to EU laws & have done so (e.g. an amendment to the **French Data Protection Act (DPA)** has allowed the government keep the existing structure, despite having some older clauses that will no longer apply under GDPR)
- This lack of harmonisation across data laws undermines European-level legislation

Possible solutions →

EU-wide strategy for methodological standards for data collection, both regionally & nationally

- **Cancon, co-funded by the EU Health Programme** ('14-'17), produced a guide on improving the quality of cancer control across Europe, including recommendations on cancer data
- The **2nd Programme of Community Action** in the Field of Health 2008-2013 explicitly focuses on IT infrastructure

Facilitation of healthcare access & Member cooperation at a European level

- The **European e-health Action Plan** (2004), followed by the **e-health Initiative** (2007), encourages cooperation between all EU member states to facilitate access & improve care quality across Europe
- The **European Patient Smart Open Services (epSOS)** project (2008-2014) is the latest iteration to develop a European e-health infrastructure, involving 22 member states & three non-member states; the results of the pilot have been used in projects such as Expand, e-SENS & Stork 2.0

The Nordics and Netherlands are most advanced in their national e-health data strategies and implementation of EHRs

Overview of barriers: political (national-level health strategies)

🟢🟡🔴 Impact of barrier (lower – medium – higher)　　　↑↗→ Susceptibility to change (higher – medium – lower)

Current situation 🟢

Limited political will & commitment to develop health data
- **70% of member states** in Europe have a national e-health strategy or policy
- Only **13% of member states** have a national policy on the use of Big Data to drive their e-health strategy

Limited focus on health data in national cancer strategies
- Efforts have been made across Europe to invest in national health data platforms (e.g. **Mina VårdKontakter (MVK)** in Sweden)
- Most initiatives are still in pilot stage (e.g. '**Système national des données de santé'** in France; **Medical Informatics Initiative (MI-I)** in Germany) & the landscape remains fragmented

Fragmentation of EHR implementation across regions & settings of care
- EHRs for primary care are widespread across Europe, but **73% of implementations are not using** the system to its full, intended use
- Use for secondary & social care is limited

Possible solutions →

Shift in political will
- The Belgian **healthdata.be initiative** recognises that a vast amount of data improvement can come from linking existing systems together
- A new **centre for the integration of existing data** was created as part of the national plan, requiring a shift in political will – hundreds of stakeholders came together to agree on the approach

National strategies around e-health data
- Denmark's '**Making E-Health Work**' strategy (2013-2017) aims to develop a national framework for collection of e-health data that allows cross-database linkage at the national level

Successful EHR implementation nationally
- By 2010, more than **95% of primary healthcare providers across Spain** had used the electronic records; **Andalusia** is piloting providing access to electronic health records on mobile devices
- **NHS England** has committed to linking EHRs across primary, secondary & social care by 2020

Resourcing projects is a constant concern with skilled individuals in short supply and funding difficult for small entities

Overview of barriers: economic

Sub-barrier	Issues	Quotes
Sources of funding	Fragmented sources of funding at the national level	*"The elephant in the room is who is going to pay for this long-term"*
	Lacking of funding availability for health data	*"Pharma can't continue leaving the tap running"*
	Complex & unclear process to obtain funding to develop health data	*"If you were small, costs would be an issue"*
Commercial incentives & interests	Lack of commercial interests to share data for private stakeholders	*"These projects themselves are quite helpful in proving that this (pharma) industry, which has been perceived with quite a lot of suspicion, can actually engage on things that are not focused on commercial/pushing their own products"*
	Lack of interests to share data for public stakeholders	
	Image problem of private / commercial entities	
Human capital & capabilities	Limited technical skillset to collect & analyse data (e.g. analytics, machine learning)	*"There are very few people who understand how to work with clinical data, very few who understand how to work with genetic data, and virtually no-one who understands how to work with both"*
	Uneven digital literacy across patients & public	*"There is a lack of skilled people to do the work; while there are some very good people, there are not nearly enough"*
	Lack of HCP education & training for data collection & monitoring	

Incentive schemes align conflicts of interest, whilst initiatives for info. sharing and national-level funding prevent fragmentation

Health data barriers: economic

Barrier case studies	Example solutions
Fragmented funding sources 🇬🇧	**Sponsorship schemes** 🇦🇺
• Funding for EHRs in NHS England stems from a variety of different sources (e.g. Integrated Digital Care Fund, NHS Innovation Scheme, Vanguard)	• The Managed Health Network Grant Programme in Australia supported a managed health network in the South with AUD 1.8m of funding
Limited technical skillset/literacy 🇬🇧	**National-level funding** 🇪🇸
• 14% of HCPs find hiring workers with data skills an issue • Only 0.4% of patients use the NHS' online health service	• The Ministry of Health in Spain provides national & regional funding for EHR system development
Image problem of pharma. companies 🇪🇺	**Information sharing initiatives** 🇪🇺
• Amongst 600 international, national & regional patient groups, only 34% give pharma a "good" or "excellent" rating (vs. 62% for retail pharmacists)	• i-HD is a non-profit organisation supporting efficient sharing of data for health & knowledge discovery across Europe
Lack of funding availability for health data 🇮🇹	
• Fragmented heath care system leads to a lack of transparency, so that a government partner is needed to understand funding process	

Fragmentation and lack of funding clarity are being addressed by some countries through national grant and sponsorship schemes

Overview of barriers: economic (sources of funding)

● ● ● Impact of barrier (lower – medium – higher)   ↑ ↗ → Susceptibility to change (higher – medium – lower)

Current situation ●

Fragmented sources of funding at the national level
- EHR funding in NHS England stems from several schemes: Integrated Digital Care Fund; Nursing Technology Fund; NHS Innovation Scheme; Vanguard sites. Each has its own funding source & objective

Lack of funding availability for health data
- Across Europe, 14% of healthcare providers see **funding as the main eHealth challenge** they face
- This reaches 28% in Ireland, 30% in Austria & 31% in the UK (relative to 8% in the Netherlands & 9% in Italy & Spain)

Complex & unclear process to obtain funding to develop health data
- The fragmented, administrative nature of the Italian healthcare system results in a **lack of transparency** in the approvals process for funding
- A government partner is needed to understand how granting agencies **evaluate proposals & what funding is available**

Possible solutions ↑

National-level funding availability
- Spain's Ministry of Health supports EHR system development both at the **European & national level**, including via cohesion funds for regional investment
- Any region receiving funding must conform to the same national standards & requirements as public healthcare networks

Dedicated grant & sponsorship schemes for health data
- Australia's Managed Health Network Grant Programme awarded AUD 1.8m in **start-up funding** for the Managed Health Network in the South to develop a web-based electronic messaging system for sharing health data
- **Sponsorship of implementation** costs has incentivised Austrian HCPs to adopt EHR systems

Provision of short-term or initiative-specific funding
- Health Data Research UK has committed **£54m in funding for six separate data research sites** to collect & analyse health data to derive new knowledge for patient benefits
- The funding supports partnerships with NHS bodies & patient groups

Careful commercial messaging and reputation management are key to achieving data sharing and stakeholder buy-in

Overview of barriers: economic (commercial incentives & interests)

🟢🟡🔴 Impact of barrier (lower – medium – higher)　　　　⬆↗➡ Susceptibility to change (higher – medium – lower)

Current situation 🟢

Lack of commercial interests to share data for private stakeholders

- Private entities (e.g. pharma., insurances) see health data as a commercial advantages & have been pursuing options to gain exclusivity, e.g. with Roche buying **FlatIron Health**, an oncology-focused electronic health records company

Lack of interests to share data for public stakeholders

- Data sources & HCPs spend a lot of time / effort to collect data, & gain publications / grants on this basis so are reluctant to share
- The **GetReal melanoma case study** was funded by EFPIA, EMA, the UK NICE & Dutch ZIN, participating Dutch registries restricted access to enable PhD students to publish their theses on data

Image problem of private / commercial entities

- Amongst 600 international, national & regional patient groups, only 34% give pharma. a "good" or "excellent" rating (vs. 62% for retail pharmacists)
- Patients are concerned about Big Pharma **use of data** being at odds with **public interests**, but use for insurance & marketing is deemed unacceptable

Possible solutions ↗

Careful management of public relations & governance arrangements to promote ownership & sharing

- In Denmark, a **national coordination effort of clinical registries** has been framed by the government as a means to fulfil high-quality care responsibilities through careful promotion & PR
- In the Netherlands, the **Dutch Upper GI Cancer Group** has a committee reviewing applications to access their data; members can oppose access, but this rarely happens & the data is readily shared

Initiative dedicated to or requiring information sharing between stakeholders groups

- **i-HD**, the European Institute for Innovation through Health Data, is the latest iteration of the EHR4CR initiative, a not-for-profit organisation to support efficient & timely sharing of health data for health & knowledge discovery across Europe
- It is co-funded by the **European commission**
- The **Human Brain Project**, co-funded by the EU, provides access to its data in exchange for the data held by entities seeking access; it currently has 118 collaborating universities & centres

EHR4CR = Electronic Health Records for Clinical Research

Relevant data skills are currently lacking across Europe and particularly in the public sector, though this is changing

Overview of barriers: economic (human capital & capabilities)

🟢🟡🔴 Impact of barrier (lower – medium – higher)   ⬆️↗️➡️ Susceptibility to change (higher – medium – lower)

Current situation 🟢

Limited technical skillset to collect & analyse data (e.g. analytics, machine learning, data science)
- **7% of healthcare providers** in Europe report finding & hiring sufficiently-skilled employees as a key issue
- This reaches 14% in Germany & the UK

Uneven digital literacy across patients & public
- Despite 96% of GPs allowing patient access to SCRs online, book appointments & prescriptions, **only 0.4% of patients** have used this service
- Across Europe, **78% of patients consult the Internet** to find information on a specific injury, disease, illness or condition; 58% look for information on pharmaceuticals

Lack of HCP education & training for data collection & monitoring
- Roll-out of 2.1m patient EHRs in the **Cambridge University Hospital Trust** in 2014 was hindered due to governance & planning issues for staff engagement & training
- This ultimately led to poor quality & ultimately the reversion to paper records

Possible solutions ⬆️

International initiatives to support skills development in digital health
- **SEPEN** aims to map national health workforce policies across the EU, foster the exchange of knowledge & good practice, & provide tailored advice to countries
- An **action plan has been developed by the European Commission** to improve health workforce planning, anticipate future skills needs & improve continuous professional development; this includes digital & key enabling technology skills

Education programmes in digital & data analytics
- Several countries (e.g. Netherlands, Switzerland, Italy, Spain) offer **eHealth training** to health sciences students &/or health professionals
- **Imperial College** has established a course for 'data analytics in health', to understand emerging issues in eHealth & how to manage technology initiatives

Industry-sponsored training programmes for employees
- In the US, Celgene is running a **company-wide information & knowledge initiative** to support employees in accessing & leveraging data
- This involves using better analytics tools, interfaces, data visualisation techniques & cloud-based sharing platforms
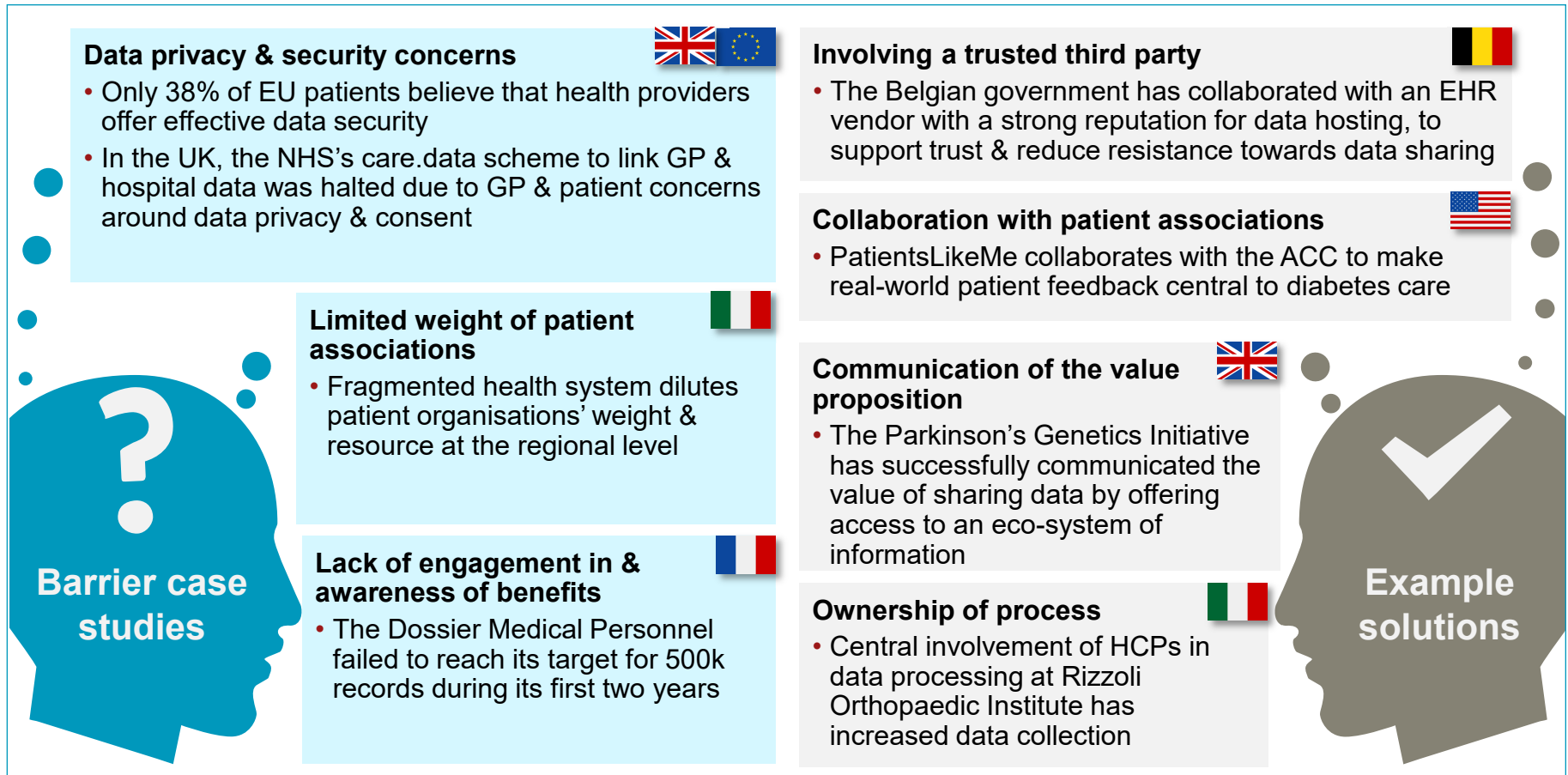
Cultural norms and lacking capabilities amongst HCPs and patients' data privacy concerns are seen as key barriers

Overview of barriers: societal

Sub-barrier	Issues	Quotes
Public & patient mindset	Lack of engagement in & awareness of health data benefits to the public / patients	*"New generations of HCPs are trained by the old HCPs who still use older books and dated paradigms of medicine"* *"HCPs don't have an issue with data collection and sharing but there is no tradition of recording information so capabilities are lacking"*
	Concerns around data privacy & security	
	Limited weight & involvement of patient associations / communities	*"In a public health system, is it wrong to make money from health?"* *"HCPs are the stronger partners to form partnerships, but their mindsets are archaic"*
HCP mindset	Lack of HCP time & resources to support data collection & reporting	*"People need to trust the data generated by others, which is why an unbiased intermediary third party might be a good middle-ground to solve the data trust issue"*
	Lack of engagement in & awareness of benefits from health data analysis & use	*"The value of health data to society is not fully understood - people only hear about research or monetary-based benefits"* *"People are afraid of a 'Big Brother' scenario and sceptical about having their country hold the data for them"*
	Concerns around the risks to patient privacy & anonymity	

Third party involvement can appease data privacy concerns, while communicating the value proposition is key for engagement

Health data barriers: societal

Barrier case studies

Data privacy & security concerns
- Only 38% of EU patients believe that health providers offer effective data security
- In the UK, the NHS's care.data scheme to link GP & hospital data was halted due to GP & patient concerns around data privacy & consent

Limited weight of patient associations
- Fragmented health system dilutes patient organisations' weight & resource at the regional level

Lack of engagement in & awareness of benefits
- The Dossier Medical Personnel failed to reach its target for 500k records during its first two years

Example solutions

Involving a trusted third party
- The Belgian government has collaborated with an EHR vendor with a strong reputation for data hosting, to support trust & reduce resistance towards data sharing

Collaboration with patient associations
- PatientsLikeMe collaborates with the ACC to make real-world patient feedback central to diabetes care

Communication of the value proposition
- The Parkinson's Genetics Initiative has successfully communicated the value of sharing data by offering access to an eco-system of information

Ownership of process
- Central involvement of HCPs in data processing at Rizzoli Orthopaedic Institute has increased data collection

Patients lack awareness of the benefits of health data, but some initiatives are beginning to communicate the value proposition

Overview of barriers: societal (public & patient mindset)

● ● ● Impact of barrier (lower – medium – higher)   ↑ ↗ → Susceptibility to change (higher – medium – lower)

Current situation ●

Lack of engagement in & awareness of health data benefits to the public / patients
- 60% of UK patients would rather commercial entities have access to data rather than miss out on benefits, but not if there is **no clear public benefit & solely commercial motivation**

Concerns around data privacy & security
- Despite the public seeing the importance of health data for treatment purposes, only **38% of patients** believe that healthcare providers offer effective data security
- The UK had the highest concern level (40-60%), & the Nordics the lowest (20%)
- A publicly-funded initiative in the Netherlands failed due to **firm opposition from patient groups** over data privacy issues during information exchange

Limited weight & involvement of patient associations / communities
- In Italy there is **no legislation for patient participation** & empowerment, which is compounded by the fragmented healthcare system that dilutes the capacity & resources of patient groups

Possible solutions ↗

Communication of the data value proposition
- In the UK, the **Parkinson's Genetics Initiative** has successfully communicated the value of sharing data by offering access to an eco-system of information about diseases to help manage patients' conditions & have the opportunity to engage with similar patients

Appeasement of data privacy & security concerns
- Disease, patient group & intervention data from 16 million care episodes across 18 years & hundreds of initiatives have been coordinated in Denmark
- Significant **investment in people & time to engage with stakeholders** has helped to minimise unease & reduce the risk of backlash

Collaboration with patient associations / communities to enrich & access health data
- **PatientsLikeMe** is collaborating with the ACC to make real-world patient feedback more central to diabetes research & care, & sharing data with pharmaceutical companies

Public awareness campaigns
- #datasaveslives is a campaign to **communicate the importance of health informatics** on public health

HCPs are resistant due to patient privacy concerns, but across Europe the involvement of third parties is addressing this issue

Overview of barriers: societal (HCP mindset)

● ● ● Impact of barrier (lower – medium – higher)   ↑ ↗ → Susceptibility to change (higher – medium – lower)

Current situation ●

Lack of HCP time & resources to support data collection & reporting
- Increase of nurses & physicians' workload is **mentioned in 11 of 38 papers** surveyed on EMR implementation (one of the top 5 barriers)
- Across Europe, **11% of health providers struggle** with EMR implementation; this reaches 15% in Switzerland & 14% in the Netherlands

Lack of engagement in & awareness of benefits from health data analysis & use
- In France, after two years' implementation of the **Dossier Médical Partagé** (an initiative to ensure every French patient has a medical record), collection of 400k records was below the first year target of 500k; lack of awareness or campaigns targeted towards GPs was seen as the main cause for this

Concerns around the risks to patient privacy & anonymity
- The NHS's **care.data scheme**, designed to unify patients' care across GPs & hospitals into one central database, was postponed due to GPs & the BMA resisting over data privacy & consent concerns
- The programme was delayed to allow patients to properly consider opt-out options

Possible solutions →

Involvement of a third party to address privacy issues
- The Belgian government's collaboration with a **Custodix**, a trusted **third party EHR vendor** with a strong reputation for data hosting & transfer, has inspired trust amongst HCPs & reduced resistance towards collecting & sharing data

Use of automation in data collection
- The **Clermont-Ferrand University Hospital** has implemented a system from Capsule Technologie & Microsoft in its ICU & General Medicine practices
- This uses artificial intelligence to automatically collect data from medical devices, converts it into a standard format & sends to an EMR system for monitoring by HCPs

HCP managements & patient control of data
- The **Cancer Drug Fund** in the UK collects data on cancer treatments
- Where data analysis on established databases is led by **Public Health England (PHE)**, control lies with PHE & ownership with the patient whose data is being used

Working in oncology data is regularly made more difficult by the lack of standards for sharing, coding and quality of data

Overview of barriers: technical
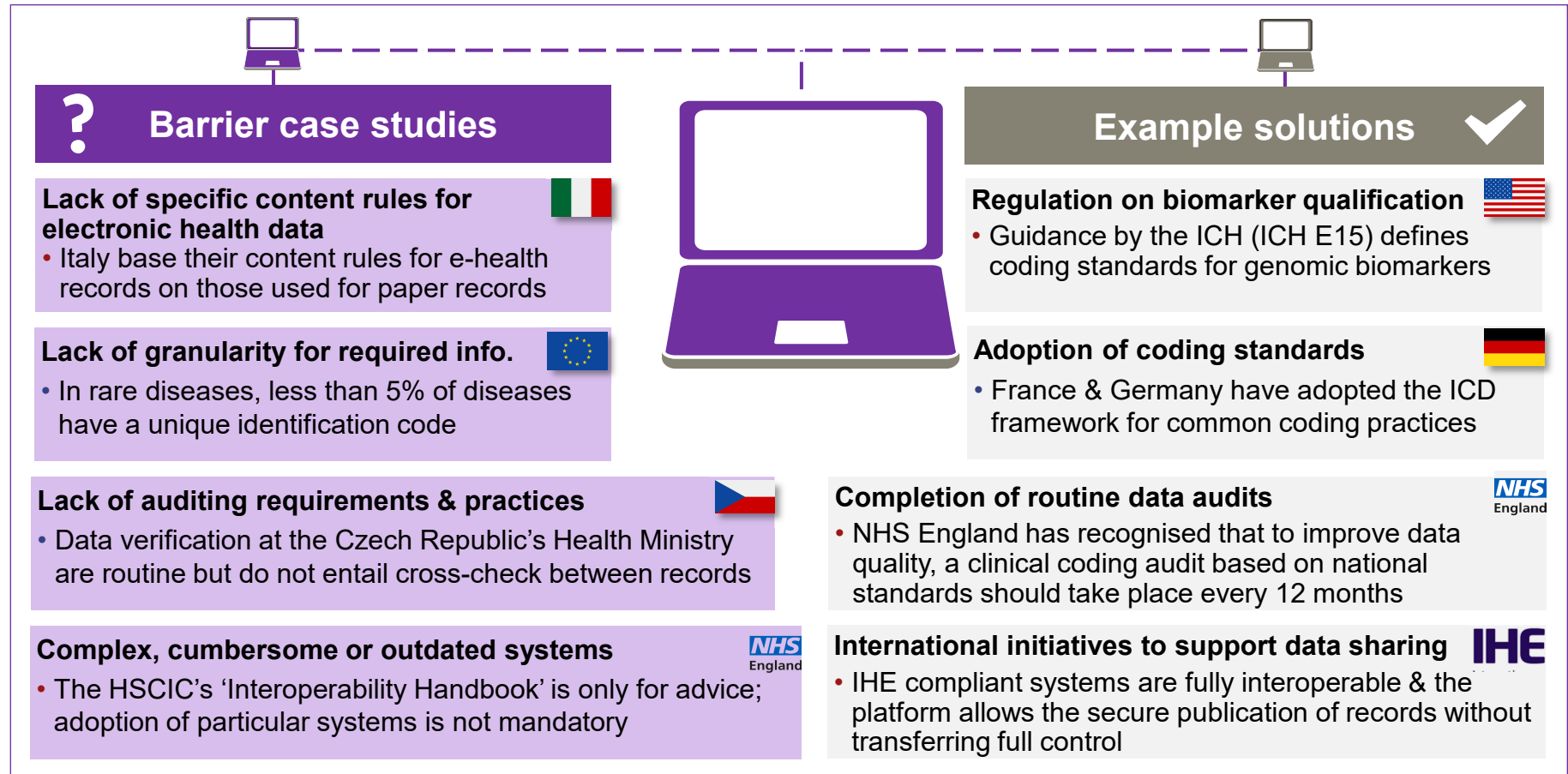
Sub-barrier	Issues	Quotes
Disease complexity	Lack of granularity in collected evidence Limited collection of genetic, biomarker & histological information Limited collection of non-standardised data	*"The biggest barrier is the inherent complexity of the data"*
System infra-structure	Archaic or insufficiently-powerful infrastructure Complex or outdated software (e.g. requiring manual processing)	*"Some hospitals don't want to admit that their data is not in order"* *"…for us to get over this transition period where there is suspicion and anxiety over technology and data, so, we get to appoint where data-driven healthcare has become the mainstream"*
Data processing & linkage	Numerous software providers with low interoperability Lack of standards & mechanisms to support interoperability & transfers across countries Lack of a single identifying number to link relevant data in a secure & informative way	*"There isn't even data sharing across the street, let alone across provinces and countries"*
Quality & consis-tency assurance	Unclear responsibility for quality assurance Lack of auditing requirements & practices Limited certification & alignment for EHR vendors	*"Even though there is a common data model, some of the sites don't load it all in"* *"I'm not convinced there are a lot of countries using large health datasets well – there are some good examples"*
Data definitions & standards	Lack of specific content rules for electronic health data Inconsistent use of coding & language standards	

Biomarker regulation and partnerships with big-data firms are enabling patient-specific treatments for complex diseases

Health data barriers: technical

? Barrier case studies

Lack of specific content rules for electronic health data
- Italy base their content rules for e-health records on those used for paper records

Lack of granularity for required info.
- In rare diseases, less than 5% of diseases have a unique identification code

Lack of auditing requirements & practices
- Data verification at the Czech Republic's Health Ministry are routine but do not entail cross-check between records

Complex, cumbersome or outdated systems
- The HSCIC's 'Interoperability Handbook' is only for advice; adoption of particular systems is not mandatory

Example solutions ✔

Regulation on biomarker qualification
- Guidance by the ICH (ICH E15) defines coding standards for genomic biomarkers

Adoption of coding standards
- France & Germany have adopted the ICD framework for common coding practices

Completion of routine data audits
- NHS England has recognised that to improve data quality, a clinical coding audit based on national standards should take place every 12 months

International initiatives to support data sharing IHE
- IHE compliant systems are fully interoperable & the platform allows the secure publication of records without transferring full control

Partnerships with big tech firms and specific datasets for complex diseases are helping to overcome disease / treatment complexity

Overview of barriers: technical (disease complexity)

🟢🟡🔴 Impact of barrier (lower – medium – higher)　　　⬆️↗️➡️ Susceptibility to change (higher – medium – lower)

Current situation 🟢	Possible solutions ⬆️
Lack of granularity in collected evidence • Lack of data granularity is an issue in The **National Swedish Drug Registry**, which for example does not differentiate between different types of anticoagulants	**Partnership of cancer centres with data firms** • Cancer centres are partnering with big data firms such as Google Deepmind & IBM Watson to develop decision support algorithms for complex, patient-specific cancer treatments based on RWE
Limited collection of genetic, biomarker & histological information • Many datasets currently lack critical information beyond mortality, e.g. ECOG scores, progression, & other **cancer-specific endpoints** • Few databases contain **genetic or biomarker information**, which is lacking from often-used data sources (e.g. SACT in the UK)	**Development of dedicated cancer datasets & initiatives** • **Flatiron Health** has released a dataset allowing visualisation & location of the increase in immunotherapy drugs between 2015-2017 (e.g. inc. PD-1 inhibitors) • Other initiatives are helping to collect genomic data to aid treatment complex strategies, e.g. the 1**00,000 Genomes Project in the UK** which aims embed genomic medicine into clinical pathways through the sequencing of 100,000 genomes from NHS patients with rare diseases & cancer
Limited collection of non-standardised data • Insight to support cancer diagnosis & treatment efficacy increasingly stems from **non-binary inputs**, e.g. imaging • This information is not always collected in a **systematic manner**, e.g. imaging results are collected in DICOM, WADO, HL7, etc. across European countries	**Improved coding standards & technologies for new information** • The FDA's first **guideline on biomarkers** in 2005 has led to a successful Voluntary Exploratory Data Submission programme (VXDS); the **ICH (ICH E15)** defines coding standards for genomic biomarkers • **Machine learning** can be used to improve analysis & comparison of non-standardised data

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Current software and hardware are not adapted to more advanced data processing and analytics, wasting time

Overview of barriers: technical (system infrastructure)

🟢🟡🔴 Impact of barrier (lower – medium – higher)   ⬆️↗️➡️ Susceptibility to change (higher – medium – lower)

Current situation 🟢	Possible solutions ⬆️
Complex or outdated software (e.g. requiring manual processing)	**Development of user-friendly, intuitive software for EMR & databases**
• **7 of 38 papers** surveyed on EMR implementation listed ease of use as a main barrier • In the US, EMR software provided by **Siemens**, **MEDITECH** & **McKesson** were rated as providing the lowest user-friendliness / experience	• In the US, the EMR software **Epic** was rated as having the best interface / visual appeal & experience / ease of use in 2015 • Recent years have seen significant **improvement in the ratings for EMR's interface / visual appeal,** with nearly half of respondents scoring this 8, 9 or 10 out of 10
Archaic or insufficiently-powerful infrastructure	**Use of new technologies to improve infrastructure, processing & storage**
• Between 100mn to 2bn human genomes could be sequenced by 2025, requiring **2-40 exabytes** of storage capacity & to processing that is **6 orders of magnitude faster** than possible today	• **Cloud computing** could be used for large-scale analysis & storage of health data – e.g. **C3-Cloud** in Europe will enable a continuous coordination of patient-centred care activities & seamless integration with existing systems • **Blockchain** can offer a shared database, managed through the consensus of participants in the network (e.g. patients, HCPs) • The **Hadoop Distributed File System** divides the data into smaller parts and distributes it across various servers/nodes

Within and across countries, standards and mechanisms to support linkage and sharing are growing but remain limited

Overview of barriers: technical (data processing & linkage)

● ● ● Impact of barrier (lower – medium – higher)   ↑ ↗ → Susceptibility to change (higher – medium – lower)

Current situation ●	Possible solutions ↑
Numerous software providers with low interoperability	**Implementation of national-level initiatives to support interoperability**
NHS England • In the UK, there are **100+ commercial suppliers of EHR software** (e.g. EMIS, TPP & inPractice for GPs; Cerner, CSC, BT for hospitals); IT systems do not always communicate across suppliers, leading staff to revert to paper records	**UK** • The UK **Transfer of Care Initiative** aims to ensure common standards are during the patient journey
• In France & Spain, most hospitals use different software	**Implementation of international initiatives to support interoperability & data sharing**
Lack of standards & mechanisms to support interoperability & transfers across countries	**IHE** • **Integrating the Healthcare Enterprise** (IHE) is an HCP-led programme to build upon existing standards (HL7, SNOMED, CT, etc.); Turkey, Austria & the US are using IHE for EHR & the UK NHS is planning to
• The EU's 28 member states have different **systems**, **collection practices** & **storage methods**	**EMIF** • The **European Medical Information Framework** (EMIF) is an initiative designed to enable the sharing of health databases (e.g. case studies, bio-banks & EMRs), encompassing 48 million records from seven European countries
• Only **13 countries** have set up specific rules & standards on interoperability (e.g. Austria, Belgium), & only 6 for cross-border interoperability (e.g. Spain)	
Lack of a single identifying number to link relevant data in a secure & informative way	**Linkage of dataset via national ID numbers or matching of different identifiers (e.g. tokenization)**
• Most countries do not have a unique identifier within healthcare, let alone beyond – e.g. the French '**numéro d'identification au répertoire**' is only used by medical authorities & social security	• The **Personal Identity Number** in Sweden & Central **Person Register Number** in Denmark collate both health & non-health information, with good coverage
• Germany & Poland do not **enable linkage at the national level**	• In many countries, linkage must be enabled by a **dedicated authority** or a law (e.g. the Privacy Commission in Belgium)

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A lack of incentives and audit legislation impact the quality of data; routine data audits and accreditation are not common

Overview of barriers: technical (quality & consistency assurance)

🟢🟡🔴 Impact of barrier (lower – medium – higher)　　　⬆🡕➡ Susceptibility to change (higher – medium – lower)

Current situation 🔴	Possible solutions ⬆
Unclear responsibility for quality assurance	**Completion of routine data audits**
• There is no clear **responsibility** for quality, between EU-wide standards & legislation, compared to Member state autonomy & legislation	• The NHS England has recognised that to improve data quality, a **clinical coding audit** based on national standards should take place every 12 months by a Clinical Classifications Service
• Many countries have **no specific legislation** on data quality (e.g. Bulgaria, Estonia, Greece)	• Some EU countries have **implemented quality audits** of EHR records, e.g. Belgium, Estonia, Iceland, Portugal
Lack of auditing requirements & practices	**Introduction of accreditation processes**
• Many European countries do not have **quality audits** of EHR records (e.g. Austria, France, Germany, Netherlands, Sweden, Switzerland)	• In the UK & Australia, accreditation processes are being developed for stakeholders wishing to process eHealth data; they must detail a data governance framework in order to gain accreditation status & be audited for compliance
• In the Czech Republic, providers are **not incentivised** to prioritise quality when they submit health data to the Health Ministry (IHIS); data verification processes at the Health Ministry are a simple **routine** & do not cross-check records against original health records	• Several countries (e.g. Belgium, France, Sweden) have **certifications for vendors of EHR systems**, many of which require vendors to adopt terminology standards
Limited certification & alignment for EHR vendors	**Incentives for HCPs to ensure quality & completeness**
• Austria, Finland, the Netherlands, Poland & other countries do not have a **certification process**	• In Belgium, the government has **incentivised HCPs with €875 per head** to subscribe to an EHR system that is coded with decision aids & categories to help HCPs input the correct data to drive the best outcomes for patients; other vendors may help populate missing info. in a practice's database
• Some countries establishing these certifications (e.g. Sweden) **do not require vendors to adopt technology standards**	

Internationally recognised language and coding standards encourage greater specificity of EHR content and better linkage

Overview of barriers: technical (data definitions & standards)

● ● ● Impact of barrier (lower – medium – higher)   ↑ ↗ → Susceptibility to change (higher – medium – lower)

Current situation ●	Possible solutions ↑
Lack of specific content rules for electronic health data	**Development of national standards for the structure & content of EHRs**

Lack of specific content rules for electronic health data

- Whilst many European countries do specify general **electronic record content**, some (e.g. Italy & Latvia) base these on dated **paper records**
- Some (e.g. Bulgaria, Belgium, Cyprus) rely on general content rules for both **shared EHR systems & internal electronic records**, but others do not (e.g. Cyprus)
- Much content is entered in the form of notes & clinical observation, but this **unstructured data** cannot be readily compared

Inconsistent use of coding & language standards

- France & Austria use **ICD-10** for diagnosis, while Denmark & Finland also use **ICPC** & **ICPC2**; Belgium uses **SNOMED-CT**
- Development of standards to refer to **specific medical conditions** for data comparison amongst stakeholder groups is in its infancy across Europe –e.g. in rare disease, less than 5% of diseases have a unique identification code

Development of national standards for the structure & content of EHRs

- The **UK NHS COPD project** has highlighted ICD10, OPCS4 & HRG as the primary enablers to interpreting & linking data
- In the UK, the **Professional Standards Body** has been established, with the endorsement of the HSCIC, to ensure that standards for the structure & content of EHRs are adopted nationally; this fosters the use of **SNOMED CT** when HCPs input clinical terms into EHRs

Adoption of internationally-recognised coding standards

- France & Germany are leading the way with the adoption of the **International Classification of Disease** (ICD) framework which provides a common coding language
- The **WHO** is due to publish guidelines to encourage a wider adoption of the ICD & allow international comparisons of disease data

New technologies to enable alignment & use of data

- In 2018, Google launched a **cloud open application interface (API)** enabling HCPs to manage various medical datasets covering DICOM, HL7 & FHIR standards
- **Federated querying** can pool comparable available data from different sets, while **machine learning** can extract relevant info. from unstructured notes

Uncertainty around data access and privacy remains a concern for many with inefficient governance adding further delays

Overview of barriers: legal

Sub-barrier	Issues	Quotes
Governance & data access	Complex & non-standardised access rules across datasets (e.g. for legal / ethical reasons)	
	Limited access rights for non-academic stakeholders	
Data privacy & security	IT & cybersecurity risks	
	Limited data protection, IT & cybersecurity preparation & enforcement	
	Restrictive & rapidly-outdated data legislation (especially for data linkage & transfers)	
Ownership & consent	Complexity & burden of consent forms	
	Lack of clear & appropriate patient consent framework	
	Uncertainty around data ownership & control	

"We can't share data – except for healthcare purposes only, and we can't share data outside the EU"

"To not have all of the Trusts using different health systems that require bespoke software to translate to ours"

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

"GDPR has had a huge impact in terms of resource [drain/cost]"

"We needed to move from a 30 person meeting to a 4 person executive, with a steering committee meeting quarterly. A more nimble governance structure, that is accountable"

"There is confusion in the minds of government and the service about the responsibilities to patient confidentiality"

Patient access frameworks simplify the consent management process and the latest systems decentralise data control

Health data barriers: legal

Complex access rules across datasets 🇬🇧
- Data application processes differ depending on which type of data is being accessed (e.g. HSCIC, patient level data)

Limited access rights for non-academics
- Access to some RWD databases will be reliant upon academia, such as the Farr Institute database

Lack of a clear patient consent framework 🇫🇷
- In France, the MR-001 is overly-restrictive on patient consent due to consent management issues

IT & cybersecurity risks 🇬🇧
- From 2011-2014, 7,255 cases of NHS data breaches have been reported

Government-backed frameworks for patient access 🇸🇪
- In Sweden, a central platform called 1177 gives patients a clear method of access to their health information

Opt-in consent management solutions 🇩🇪
- In Germany, a Regional Health Information Network led the development of opt-in consent management tools (Rhine-Neckar Region)

Data environment not tied to a centralised data controller 🇪🇪
- Estonia's "X-road" environment does not require a central data owner / controller

Barrier case studies

Example solutions

Governance and consent management can be cumbersome, but new processes and frameworks are helping limit the burden

Overview of barriers: legal (ownership & consent)

● ● ● Impact of barrier (lower – medium – higher)　　　　↑ ↗ → Susceptibility to change (higher – medium – lower)

Current situation ●	Possible solutions →
Complexity & burden of consent forms • At the Columbia Uni. Medical Center, consent forms for research have **3-28 pages** (avg. of 10) & have an average readability score of 11.6 (i.e. easily understood by a **college graduate**) **Lack of clear & appropriate patient consent frameworks** • 13 of the 28 EU countries have **specific rules regulating patients' consent** for EHRs • In France, Portugal & Spain, there are regulations mandating informed consent for the use of medical information (e.g. **declaration MR-001 in France**) **Uncertainty around data ownership & control** • EU patients have a number of **data rights** (e.g. to access, to download, to know who accessed, to modify or access), but this differs by country • Data sharing platforms such as the 'Enigma' project at MIT **fragment data** in the cloud; as the data controller is the only person able to bring the data together, control lies with them & this raises questions around data ownership	**Development of manageable consent forms (e.g. standards, opt-in consent management solutions)** • In Germany, a health information network in the Rhine-Neckar region led the development of **opt-in consent management tools**; the Consent Management Service stores info. & answers consent queries, & the Consent Creator Service enables new patients to create consent • The **Moffitt Cancer Center** in the US has developed a 5-min video of the research & a form with three consent questions, achieving more than 98% sign-up rates **Revision of data frameworks to streamline consent requirements & clarify ownership** • **Identifiable personal data** (non-sensitive) has been made available to researchers without prior consent in the Nordics & Belgium, allowing sharing & processing for research purposes • The GDPR enables the use of data without consent for **scientific research or medical / public health interest**; it also **clarifies data rights** (subject to local change) & holds **data processors** (e.g. HCPs) accountable **Use of a data environment not tied to a centralised controller** • Estonia's "X-road" links up public & private sector e-Services but does not require a data owner / controller

Partnerships with academic institutions allows for greater data access, whilst government-backed networks simplify the process

Overview of barriers: legal (governance & data access)

🟢🟡🔴 Impact of barrier (lower – medium – higher)

⬆️↗️➡️ Susceptibility to change (higher – medium – lower)

Current situation 🔴	Possible solutions ➡️
Complex & non-standardised access rules across datasets (e.g. for legal / ethical reasons) • In the UK, **data application processes** differ depending on which type of data is being accessed (e.g. HSCIC, patient level data, linked CPRD data, Welsh health data, UK audit data) • Various **bodies may be required to approve** access (e.g. DAAG, SAIL Data Management Committee, ISAC, IGRP, HQIP) & different evidence types required (ISO 27001 security, patient consent, SAIL form, etc.) **Limited access rights for non-academic stakeholders** • Most databases in Europe are accessible to **academics upon request**, but give limited access to private & industry stakeholders • Access to certain RWD databases currently in development will be reliant upon academia's involvement, e.g. for the **Farr Institute database** in the UK	**Existence of government-backed universal network for health data access** • In Estonia, an **e-Government platform** allows patients to view & request changes to their EMRs as well as restrict & monitor access; data protection is ensured using encryption in a network environment • A similar system in Sweden, called **1177**, allows patients a clear method to access their EMRs across both public & private health sectors **Involvement of third party private / public companies** • Private companies are buying the services of data consultancies specialising in RWD such as **Evidera**, **Cegedim** & **Optum** to access data • **Pfizer** recently partnered with **Optum** to collect lung cancer data from a French hospital • In the UK, **18 of the 22 top pharma.** companies use CPRD to access patient data **Partnership with universities to gain access to data** • In the UK, **AstraZeneca** & **MINAP**, which is managed by **UCL**, have partnered to look at treatment for post-acute myocardial infarction & gain access to HES & Office of National Statistics Mortality data

Governments are imposing record fines on those accountable for data breaches, and outdated laws will be addressed by GDPR

Overview of barriers: legal (data privacy & security)

● ● ● Impact of barrier (lower – medium – higher)   ↑ ↗ → Susceptibility to change (higher – medium – lower)

Current situation ●

IT & cybersecurity risks
- Between 2011-2014, **7,255 cases of NHS data breaches** have been reported, including incidences of inappropriate access & misplaced hardware
- Modern **AI techniques** can identify most individuals by matching various pieces of info.

Limited data protection, IT & cybersecurity preparation & enforcement
- **64%** of European countries surveyed have to notify regulators &/or subjects of data beaches; in effect, mandatory notification legislation in case of a breach is **rarely implemented**
- Only Germany & Ukraine require **DPOs**, while only France, Germany, the Ukraine & Czech Republic have separate **cyber security laws**

Restrictive & rapidly-outdated legislation on processing, linkage & sharing
- 15 of the 28 EU countries have set specific rules for **hosting & processing** of EHRs (e.g. Spain, France, Poland, the UK, Sweden, Czech Republic)
- The 'Loi Informatique et Libertés' in France & UK Data Protection Act in the UK set the process for **data linkage**

Possible solutions →

Strengthening of data protection & breach reporting requirements
- The **GDPR** mandates the establishment of DPOs,
- It also requires **Data Protection Impact Assessments** where data processing presents a high risk & the introduction of **data protection "by design & by default"**
- **Breaches must be reported** to data protection authorities & affected individuals, with exceptions

Fines for data breaches or failure to comply with the law
- A £325,000 fine was imposed on the **Brighton & Sussex University Hospital NHS Trust** by the ICO, when 252 hard drives were stolen after the Trust failed to carefully dispose of 1,000 hard drives, leading to 68,000 records being exposed

New technologies to support data privacy & security (e.g. simulated datasets, pseudonymisation, blockchain)
- **Simulacrum**, a partnership between Health Data Insights & AstraZeneca, develops artificial data based on properties from the NCRAS
- **Medicalchain** uses blockchain technology to securely store health records & maintain a single version of the info., accessible by key stakeholders

Contents

📬 Background & method
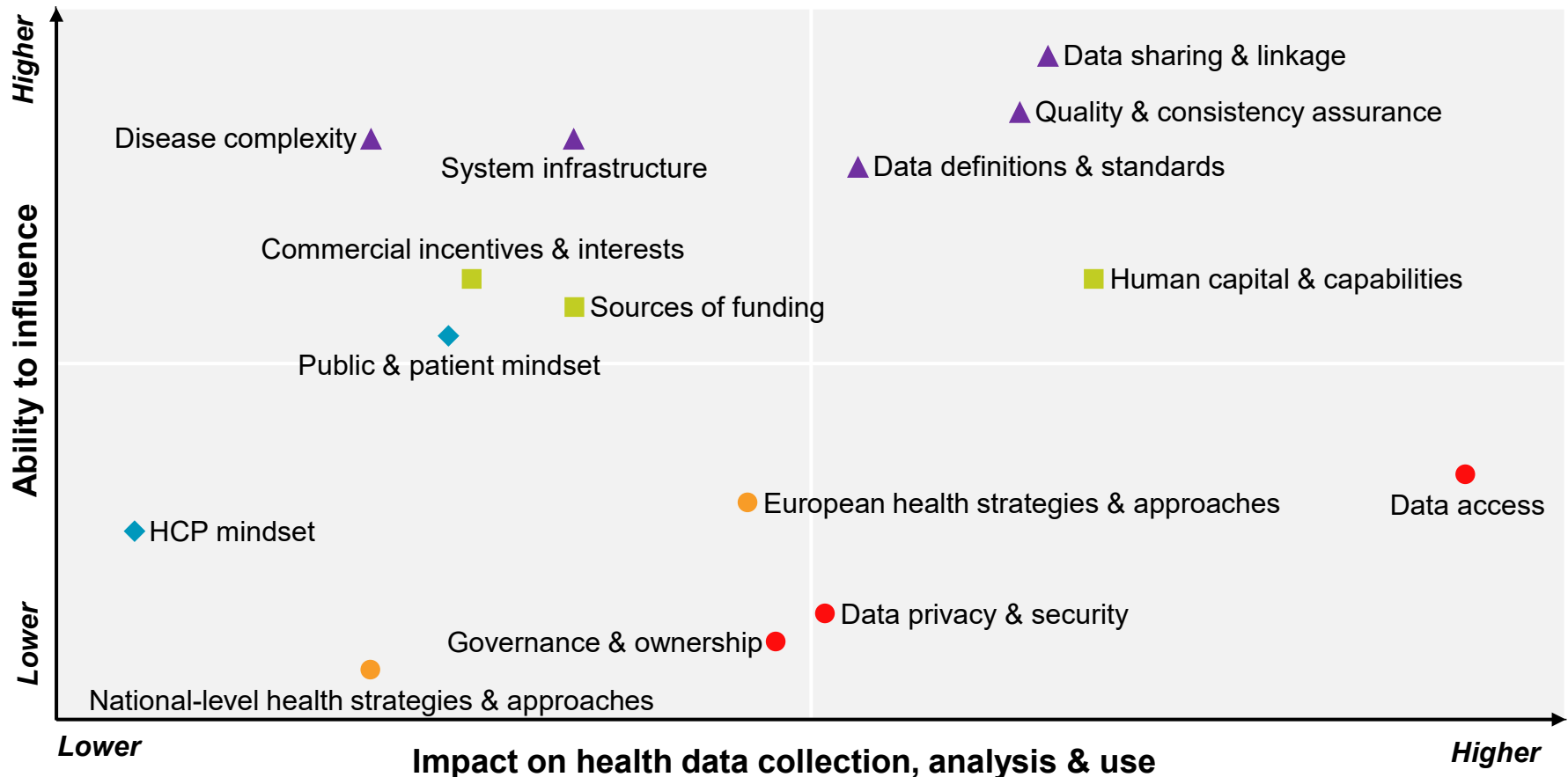
📬 Overview of barriers

📬 Detailed barriers

📬 **Conclusion**

Technical topics present a good opportunity, while legal barriers – the most impactful – have low susceptibility to change

Prioritisation of barriers

Legend: ● Political ■ Economic ◆ Societal ▲ Technical ● Legal

Y-axis: **Ability to influence** (Higher / Lower)
X-axis: **Impact on health data collection, analysis & use** (Lower / Higher)

Data points:
- ▲ Data sharing & linkage
- ▲ Quality & consistency assurance
- ▲ Disease complexity
- ▲ System infrastructure
- ▲ Data definitions & standards
- ■ Commercial incentives & interests
- ■ Sources of funding
- ■ Human capital & capabilities
- ◆ Public & patient mindset
- ● European health strategies & approaches
- ● Data access
- ◆ HCP mindset
- ● Data privacy & security
- ● Governance & ownership
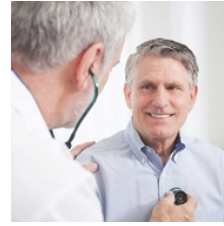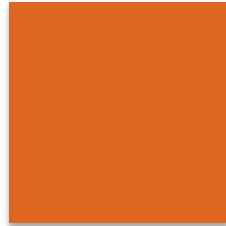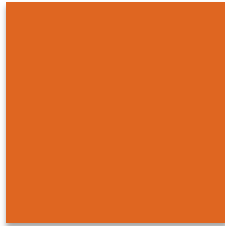- ● National-level health strategies & approaches

Pharma. company respondents tend to see stronger barriers than other stakeholders, particularly around legal issues

Comparison of barrier ratings, by stakeholder type

Legend:
- Non-pharma respondents
- Pharma respondents
- Average
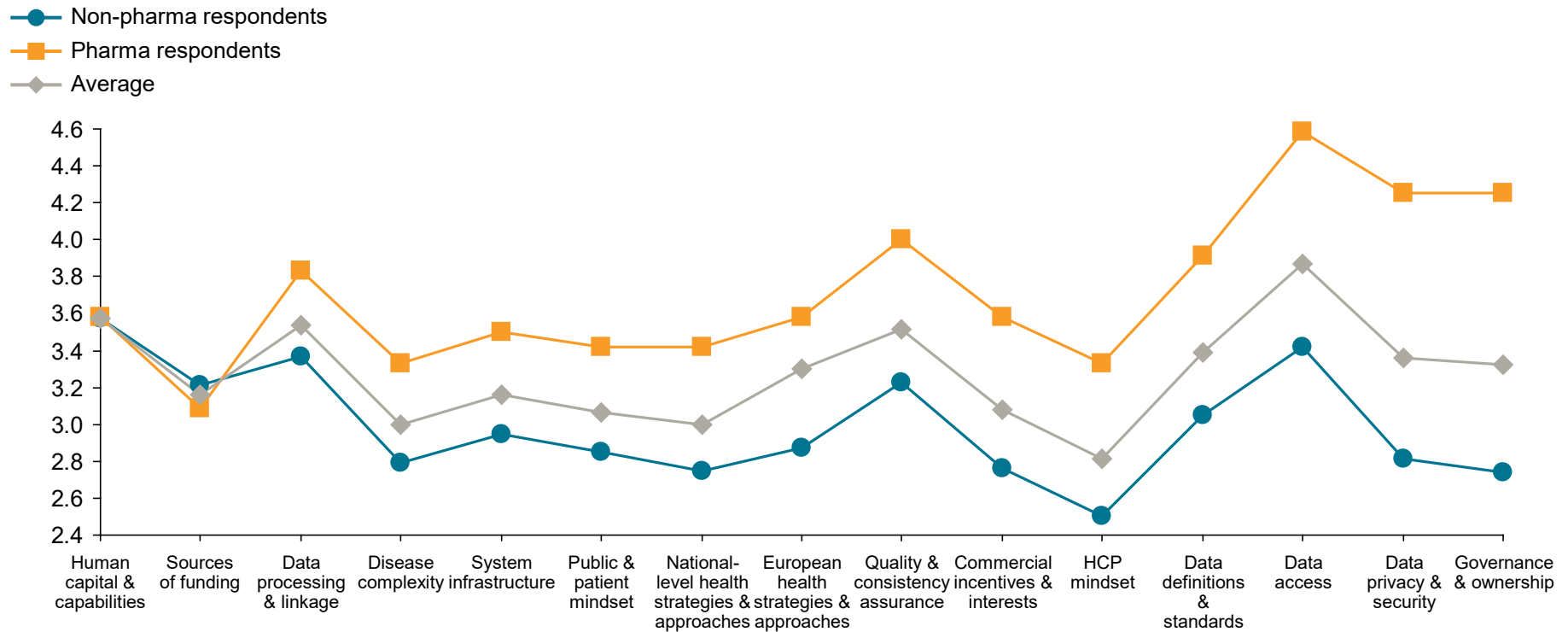
Top 4 barriers mentioned by interviewees

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European Federation of Pharmaceutical
Industries and Associations