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Oncology data landscape in Europe

Strategic solutions
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Disclaimer

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

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Executive summary

- This document **outlines key interventions** needed to improve the European oncology health data landscape
- We conducted **three webinars** and a **survey with 34 responses**, to inform the prioritisation of interventions in a workshop with the core team
- Amongst ~30 interventions, three were deemed most critical and implementation plans developed for these:
  - **Launch of an oncology summit to increase RWD acceptability**
  - **Creation of an open RWD catalogue**
  - **Development of a quality framework & self-accreditation**
- **Additional interventions that were deemed of high importance** (including a “best practice” playbook for data handling, the definition and testing of broader value measures, and support for innovative pricing) can be pursued at a later stage

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This document focuses on the barriers to health data in Europe, as part of the research and landscaping phase

Summary of deliverables

Research & landscaping

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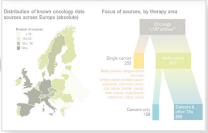
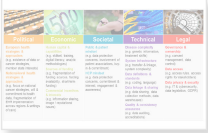
Country profiles

b 
Data sources & initiatives

c 
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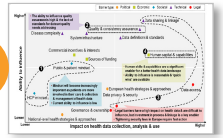
e 
Strategic solutions

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Oncology health data narrative

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Oncology health data white paper

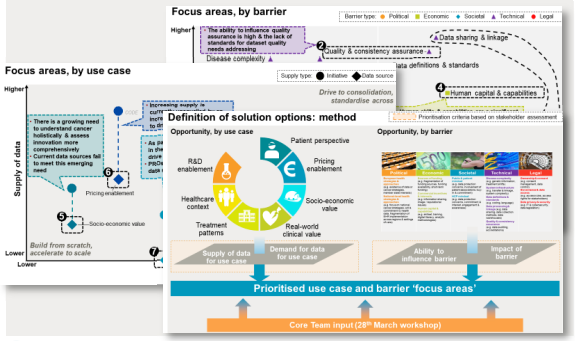
Source: A.T. Kearney; IQVIA

To reach a set of recommendations, five steps have been undertaken to identify focus areas and prioritise accordingly

Method to identify strategic recommendations

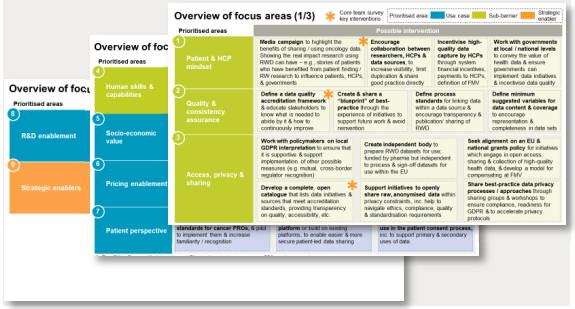
1 Identification of focus areas

- **Focus areas identified**, by use case & barrier, based on gaps & opportunities



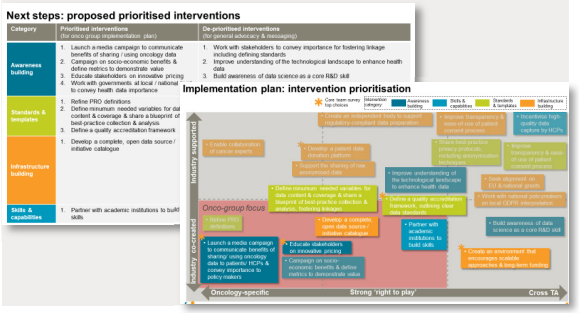
2 High-level overview of interventions

- **Complete list of potential macro interventions** detailed, across use cases, barriers, and key strategic enablers



3 Prioritisation of strategic recommendations

- **Recommended interventions** prioritised based on industry "right to play" in oncology

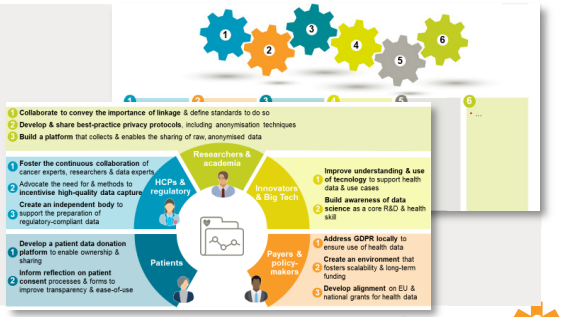


4 Implementation plan detail

- **Implementation plan** per prioritised recommendation detailing:
  - Background & overview
  - Steps, KPIs & deliverables
  - Communications plan
  - High-level roadmap

5 Key actions & considerations

- **Actions by stakeholder group** required to influence the wider data landscape
- **Critical success factors**



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

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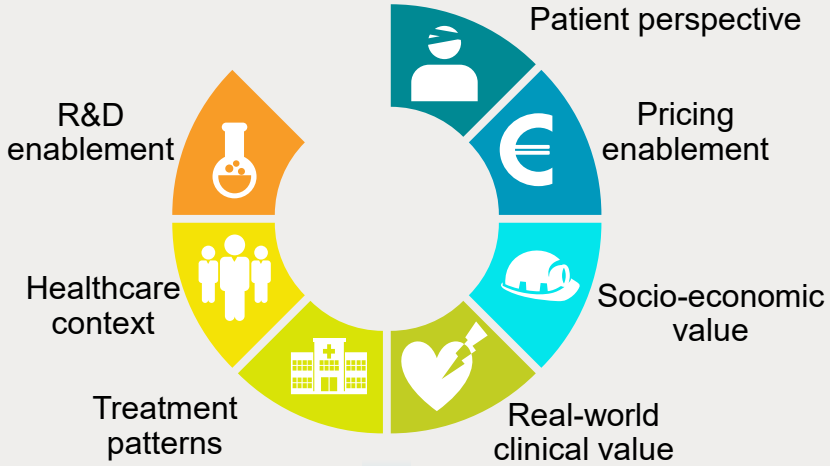
The landscape is fragmented across use cases and barriers; we have prioritised based on interviews and core team input

Definition of solution options: method

Prioritisation criteria based on stakeholder assessment

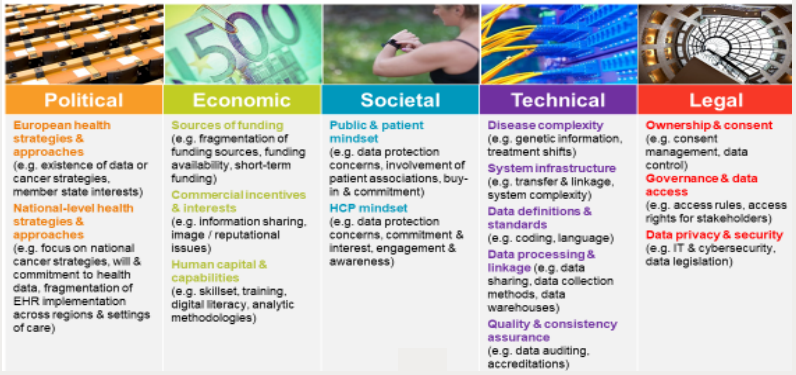
Opportunity, by use case



Supply of data for use case

Demand for data for use case

Opportunity, by barrier



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)

Ability to influence barrier

Impact of barrier

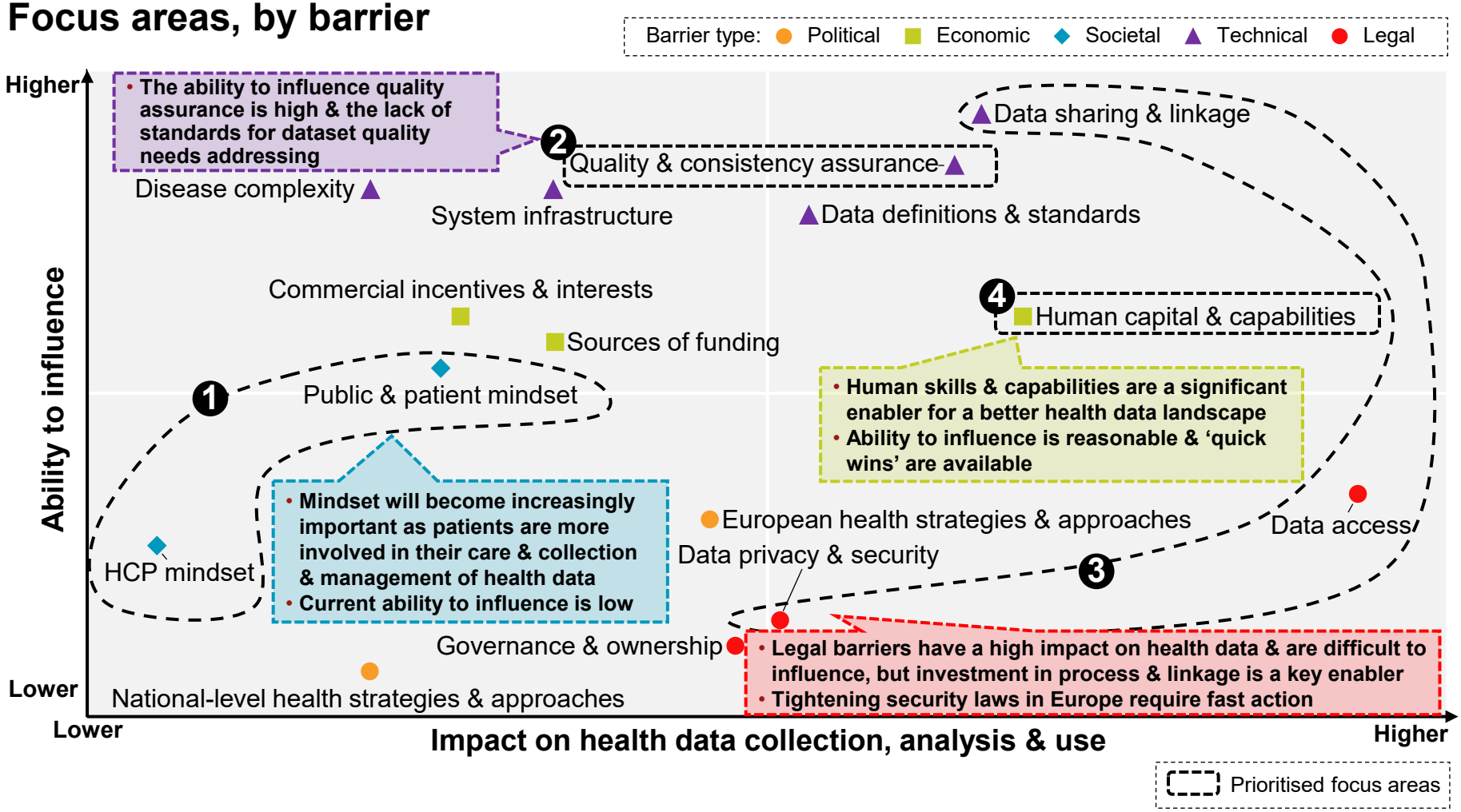
Prioritised use case and barrier 'focus areas'

Core team input (28th March workshop)

Source: A.T. Kearney; IQVIA

The core team have prioritised barriers based on the impact on health data and the ability of industry to influence improvements

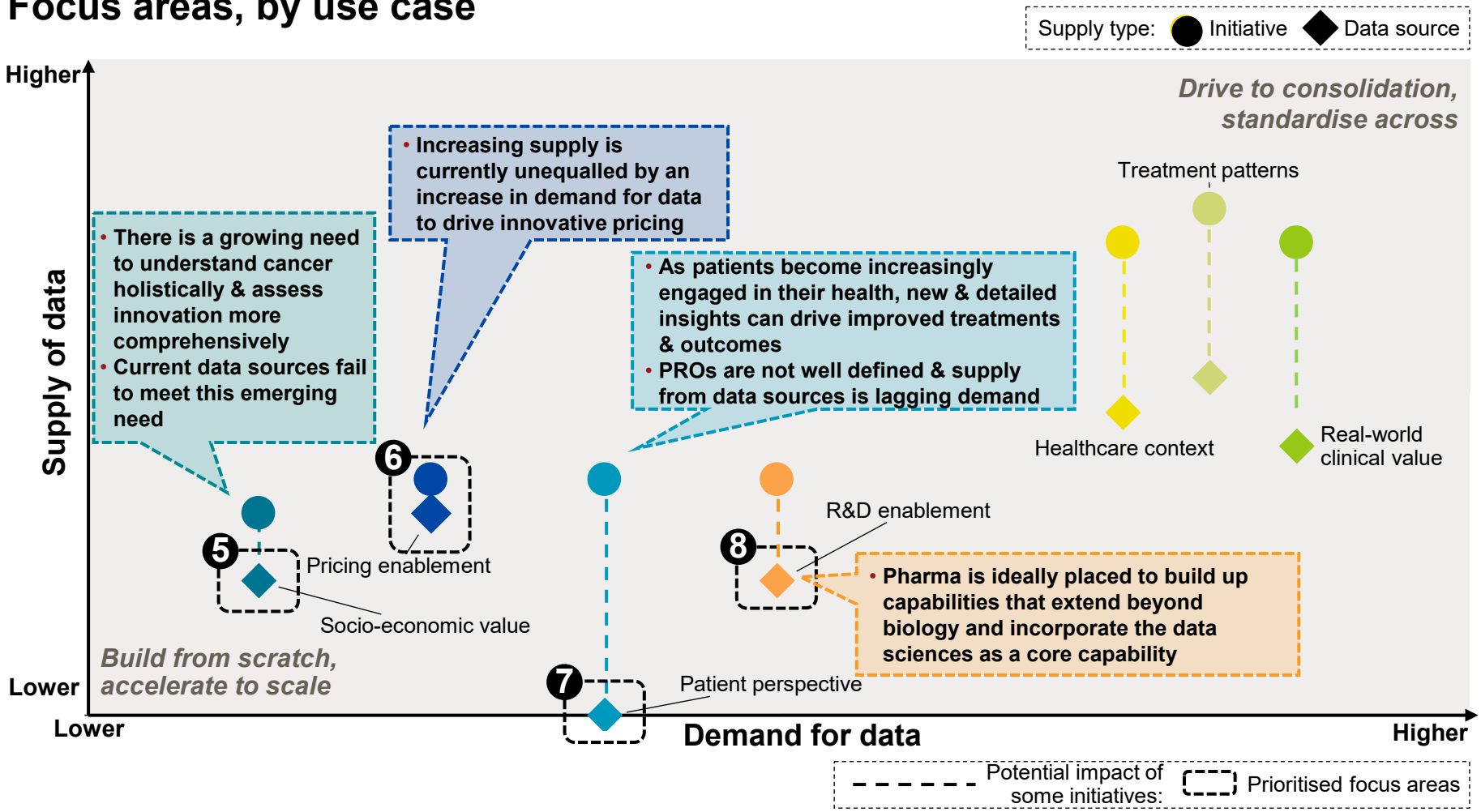
Focus areas, by barrier



Source: survey conducted following interviews in March 2018 (9 internal responses, 9 external responses)

Initiatives are creating opportunities where sources lack supply but gaps still exists; priorities are where demand is unmet

Focus areas, by use case



Stakeholder demand for data by taken as an average across all stakeholder groups
Source: A.T. Kearney analysis; IQVIA analysis

Nine ‘focus areas’ have been identified, across use cases and barriers, as key to improving the health data landscape

Summary of 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

On the basis of gaps in use cases and barriers to health data, several groups of macro-level interventions can drive change

Proposed interventions for focus areas (1/3)

Prioritised focus areas	Possible interventions			
1 Patient & HCP mindset	**Launch an awareness campaign** to highlight the benefits of sharing & using oncology data. Showing the real impact research using RWD can have. Targeting patients, HCPs and government bodies	**Encourage collaboration between researchers, HCPs & data sources**, to increase visibility, limit duplication & share good practice directly	**Incentivise high-quality data capture by HCPs** through system financial incentives, payments to HCPs, definition of FMV	**Work with governments at local & national levels** to convey the value of health data & ensure governments can implement data initiatives & incentivise data quality
2 Quality & consistency assurance	**Define a data quality accreditation framework** & inform stakeholders to know what is needed to abide by it & how to continuously improve	**Develop a "playbook" of best- practice for working with health data** through the experience of initiatives to support future work & avoid reinvention	**Define process standards** for linking data within a data source & encourage transparency & publication & sharing of RWD	**Define minimum suggested variables for data content & coverage** to encourage representation & completeness in data sets
3 Access, privacy & sharing	**Work with national policymakers on local GDPR interpretation** to ensure that it is supportive & support implementation of other possible measures (e.g. mutual, cross-border regulator recognition)	**Create an independent body to support regulatory-compliant data preparation** funded by pharma but independent to process & sign-off datasets for use within the EU	**Seek alignment on an EU & national grants policy** for initiatives which engage in open access, sharing & collection of high-quality health data, & develop a model for compensating at FMV	
	Develop a complete, open RWD source & initiative catalogue that lists data initiatives & sources, providing transparency on quality, accessibility, etc.	**Support initiatives to openly share raw, anonymised data** within privacy constraints, inc. help to navigate ethics, compliance, quality & standardisation requirements	**Share best practice data privacy processes & approaches** through sharing groups & workshops to ensure compliance, readiness for GDPR & to accelerate privacy protocols	

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

Prioritised area: Use case Sub-barrier Strategic enabler

On the basis of gaps in use cases and barriers to health data, several groups of macro-level interventions can drive change

Proposed interventions for focus areas (2/3)

Prioritised focus areas	Possible interventions		
4 Human skills & capabilities	**Partner with academic institutions to build key skills** for future HCPs & data analysts, including via courses & apprenticeship schemes	**Improve understanding of the technological landscape to enhance health data** for multiple stakeholders including data sources and end-users	
5 Socio-economic value	**Define socio-economic outcomes & metrics** & **pilot a framework** to test these, with parameters suggested by the EMA, national & regional HTAs & payers to ensure relevance	**Launch an advocacy campaign on the socio-economic benefits** of cancer management, publishing case studies that show where real value has been delivered	
6 Pricing enablement	**Create demand & support for innovative pricing** with multiple stakeholders to inform & build awareness on how to improve decision making		
7 Patient perspective	**Refine definitions & agree on standards for cancer PROs,** & pilot to implement them & increase familiarity & recognition	**Develop a patient data donation platform** or build on existing platforms, to enable easier & more secure patient-led data sharing	**Improve transparency & ease-of-use in the patient consent process,** including to support primary & secondary uses of data

EMA = European Medicines Agency; HTA = health technology assessment; PRO = patient reported outcome
Source: A.T. Kearney; IQVIA analysis

Prioritised area: Use case Sub-barrier Strategic enabler

On the basis of gaps in use cases and barriers to health data, several groups of macro-level interventions can drive change

Proposed interventions for focus areas (3/3)

Prioritised focus areas	Possible interventions		
8 R&D enablement	**Work with the industry & academia** to promote the importance of the data sciences as a new core capability to enable smarter & more efficient R&D processes	**Raise awareness & use of technology to enhance R&D** in treatment centres, e.g. to facilitate patient recruitment	**Openly tackle issues around anonymising** patients in clinical trials by supporting necessary processes (e.g. algorithmic approaches within treatment centre firewalls)
9 Strategic enablers	**Create environment for longer term funding** (influencing funders & EFPIA members) to enable data sources to invest in data, processes & standards beyond 1-2 year horizon	**Work with stakeholders nationally & locally to convey the importance of fostering linkage of datasets**, including developing an independent data clearing house & using methods to protect anonymity	**Create an environment that encourages scalable approaches** across the industry; supporting expansion rather than reinvention for each new activity (influencing funders & EFPIA members)

Source: A.T. Kearney; IQVIA analysis

Prioritised area: Use case Sub-barrier Strategic enabler

For all of the interventions listed, several are “quick wins” with low effort and high impact which industry can pilot within oncology

Intervention ratings, by effort, impact, TA focus & industry role

“Best” option

‘Macro’ intervention	Effort	Impact	TA focus	Industry role
Launch an awareness campaign	Low	High	Onco-specific	Co-create
Enable collaboration between cancer experts	Low	High	Onco-specific	Support
Incentivise high-quality data capture	Medium	Low	Cross TA	Support
Work with governments to convey the value of data	High	Low	Cross TA	Co-create
Define a data quality accreditation framework	High	High	Strong onco focus	Co-create & support
Share a “playbook” of best practice for working with data	Medium	Medium	Strong onco focus	Co-create & support
Define process standards for linkage	Low	Medium	Strong onco focus	Support
Define minimum suggest variables for content	Medium	Medium	Strong onco focus	Support
Work with policymakers on local GDPR interpretation	Low	High	Cross TA	Co-create & support
Create an independent body to support data preparation	Low	Medium	Strong onco focus	Support
Seek alignment on EU & national grants	Medium	Medium	Cross TA	Support
Develop a complete, open RWD source &initiative catalogue	High	Medium	Strong onco focus	Co-create
Support initiatives to share ‘raw’ data	Low	Medium	Onco-specific	Support
Share best practice data privacy process & approaches	Low	Medium	Strong onco focus	Co-create
Partner with academic institutions to build data skills	Low	High	Strong onco focus	Co-create
Improve understanding of technology for stakeholders	Low	Medium	Strong onco focus	Support
Define socio-economic outcomes & metrics	Medium	High	Onco-specific	Co-create
Launch a campaign on socio-economic benefits	Low	High	Onco-specific	Co-create
Create demand & support for innovative pricing	Low	Medium	Onco-specific	Co-create
Refine definitions & agree on standards for cancer PROs	Medium	High	Onco-specific	Co-create
Develop a patient data donation platform	High	Medium	Strong onco focus	Support
Improve transparency & ease-of-use in the consent process	Medium	Low	Cross TA	Support
Promote importance of data sciences as a core capability	Low	Medium	Cross TA	Co-create
Raise awareness of technology to enhance R&D	Medium	High	Strong onco focus	Support
Openly tackle anonymisation issues	Medium	High	Cross TA	Co-create
Create an environment for longer-term funding	High	High	Cross TA	Co-create
Convey the importance of fostering linkage of datasets	Medium	High	Cross TA	Co-create
Create an environment that encourages scalable approaches	High	Medium	Cross TA	Co-create

TA=therapy area
Source: A.T. Kearney; IQVIA analysis

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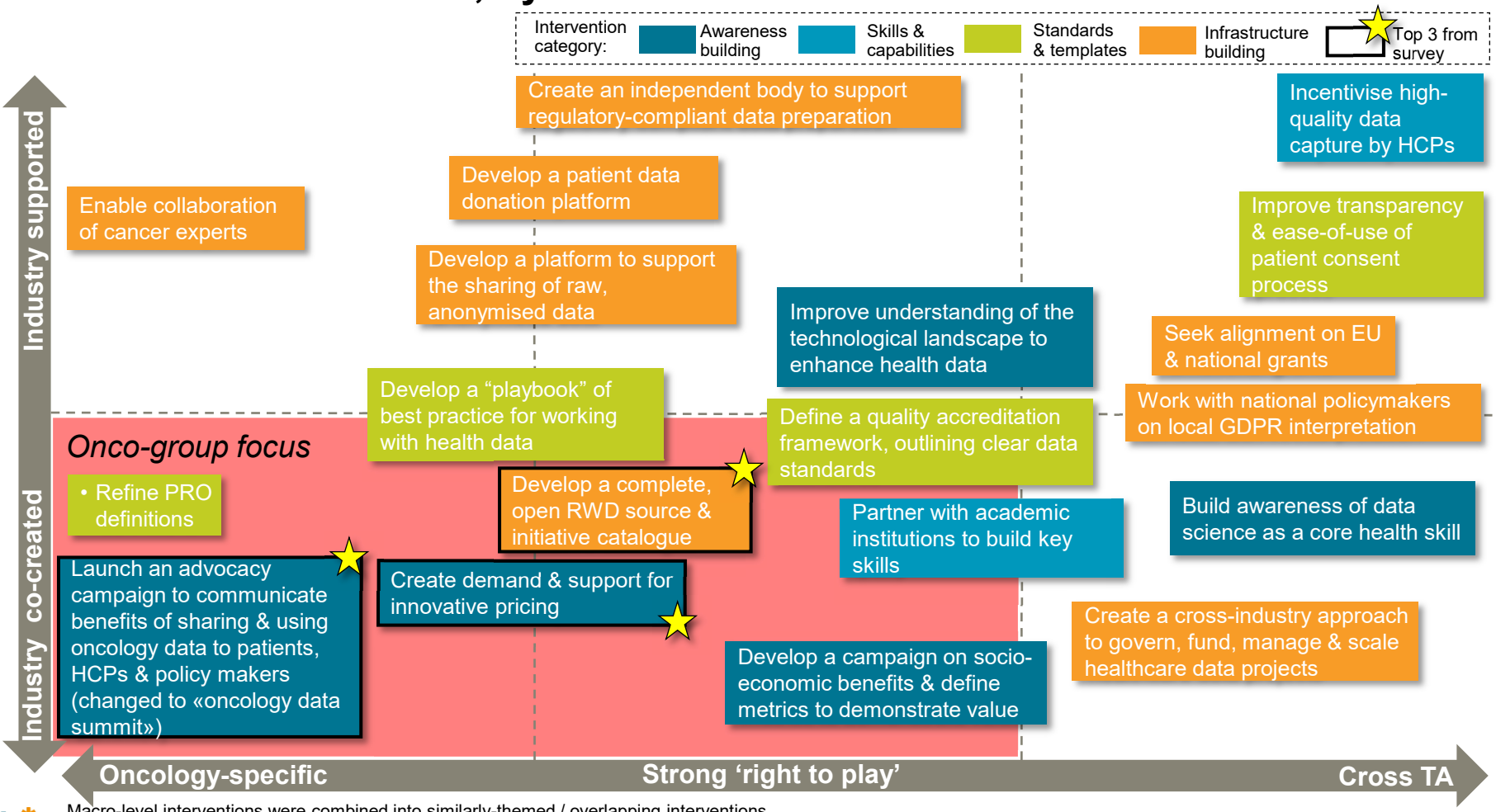
Across the interventions outlined, several are suitable for industry to play a leading role from an oncology standpoint

Overview of interventions, by TA & stakeholder lead



Macro-level interventions were combined into similarly-themed / overlapping interventions
PRO = patient reported outcome; TA = therapy area; note that earlier 'macro' interventions may have been combined here
Source: 34 responses from survey of EFPIA companies; A.T. Kearney analysis; IQVIA

Certain interventions have been prioritised by the core team, and fall within the specific scope of the oncology group

Interventions, prioritised & de-prioritised

Category	Primary interventions	Secondary interventions	De-prioritised interventions
Awareness building	A Launch an oncology data summit	Create demand & support for innovative pricing Foster the use of broader data metrics (i.e. PROs & socio-economic benefits)	Build awareness of data science as a core health skill Improve understanding of the technological landscape to enhance health data
Standards & templates	B Define a quality accreditation framework, outlining clear data standards for data sources & users	Develop a «playbook» of best practice for working with health data (inc. privacy protocols, access governance, min. dataset, linkage, anonymisation techniques, etc.)	Improve transparency & ease-of-use of patient consent process
Infra-structure building	C Develop a complete, open RWD source/ initiative catalogue		Create a cross-industry approach to govern, fund, manage & scale health data projects Enable collaboration of cancer experts Develop a patient data donation platform Build a platform enabling raw data sharing Create an independent body to support regulatory compliant data preparation Seek alignment on EU & national grants Work with national policymakers on local GDPR interpretation
Skills & capabilities			Incentivise high-quality data capture by HCPs Partner with academic institutions to build key skills

Source: based on 2 F2F workshops & 34 survey responses

The oncology data summit will bring together stakeholders to commit to using oncology RWD to transform cancer care

A Oncology data summit: overview

Rationale & description

- Need to **change perceptions** & have a **common agenda** on RWD in oncology (i.e. value beyond RCTs, costs beyond pricing)
- Lack of **acceptability** & **trust** in RWD (e.g. RWD vs RCTs, proxy data)
- Need to build a foundation of **shared knowledge**

Goal/objective

- **To raise awareness** of lack of RWD use in oncology
- **To build commitment** to developing principles & guidelines on better use of oncology RWD, to build trust (inc. quality, PROs, socio-econ, etc.)
- **To communicate a clear case for change** & co-create solutions with all relevant stakeholders*

Key stakeholders

- **Industry**
- **Oncology stakeholders**
- **Data source, HTA, regulators, oncologists & medical communities**, etc. to attend & be informed

TA focus

- **Oncology-specific**, though some themes (e.g. trust, quality, governance) apply to other TAs

Strategy

- **Build on collaborations**
- **Leverage expertise**

Time to value

- **Short-term**
- Mid-to-long term follow-up depending on outcomes from summit

Key resources

- **Vendors, contacts & methods**

Actions

1. **Define objectives, agenda & overall direction**
2. **Inform & invite roundtable stakeholders**
3. **Connect with comms & key functions**
4. **Oversee logistics & communications**
5. **Develop agenda, topics & content**
6. **Run the summit**
7. **Review & consider further actions**

Strategic considerations

- **Synergies**
- **Inspiration**
- **Risks & mitigating actions** – agreement without commitment, requiring more long-term collaboration; need to retain continuity & connection with other interventions; differences in physician perceptions between 3° & 1/2° centres

* Regulators, HTA, payers, oncologists, data source owners, patient organisations, scientific associations providing recommendations on best practice
WG=working group; source: EFPIA website; Farr Institute website; A.T. Kearney, IQVIA

A bi-lateral data quality framework, evolving into an accreditation, will certify data sources and users to build quality and trust

B Data quality accreditation: overview

Rationale & description

- Low **quality of data &/or processes** across data sources that limit usability & trust
- **Limited recognition of RWD** from payers, regulators, & other decision-makers
- **Time wasted** & **quality of insights** diminished across all RWD use cases

Goal/objective

- **To align criteria & standards** for data collection & use, acknowledging differences for stakeholders or use cases
- **To certify acceptable sources & users of data** based on agreed criteria, providing support as needed
- **To increase acceptance & trust** in certified sources, facilitating review processes

Key stakeholders

- **Industry** to initiate effort & build awareness
- **Independent body** to lead
- **Regulators, payers & HTA** to co-develop the principles for data & processes
- **Data source & clinical community** to co-develop principles & inform feasibility

TA focus

- **Oncology-specific** initially to manage scope, but can be expanded to other TAs

Strategy

- **Encourage independent body** to lead this effort
- **Develop initial framework** that is expanded into self-certification or accreditation
- **Build on extensive existing work**

Time to value

- **Medium-term** (limited value/ differentiation from framework in the short-term, but necessary to achieve value via accreditation)

Key resources

- **Advisory Committee**
- **Existing partnerships** with data sources
- **Developers** (for portal)

Actions

1. **Identify intervention lead**
2. **Consult externally**
3. **Develop & pilot framework of quality accreditation**
4. **Adjust framework & socialise**
5. **Expand framework to self-certification portal**

Strategic considerations

- **Synergies** –consider EC & DG Connect work on interoperability
- **Inspiration** – look into existing frameworks, e.g. GEKID, Primis Hub, i~HD
- **Risks & mitigating strategies** – incentivise data sources to get them involved; retain neutrality towards private entities (especially if lead is public); consider motivations & incentives for payers, regulators etc. to align when disagreeing can help negotiate prices

Source: A.T. Kearney, IQVIA

An open, “live”, self-sustaining and web-based onco. RWD source catalogue will provide transparency on existing data sources

C Oncology RWD source catalogue: overview

Description & rationale

- Lack of **visibility** around availability, quality & accessibility of current data sources, leading to duplication
- Limited **scope**, **completeness**, **accessibility** or **timeliness** of current data catalogues

Goal/ objective

- **To provide greater transparency** of the data available in the landscape & its relative usability, quality & accessibility
- **To encourage more collaboration** across data sources & with private entities
- **To reduce duplication** of effort in data source identification activities

Key stakeholders

- **Industry** could **initiate** the intervention & may be responsible for platform maintenance/curation
- **Data source owners** will submit information to the open platform
- **Pharma** will be able to suggest new entries
- **Wider scientific community** will be informed

TA focus

- **Oncology-specific**, but can be considered across other TAs & regions* in the future

Strategy

- Launch **new initiative** but **partner with existing catalogues** to provide initial leads
- **Pool information** from existing pharma databases collected

Time to value

- **Short-term “light” option** can be devised with top-line info.
- **Long-term version** expanded to include an accreditation process & relationship & contract mgmt.

Key resources

- **Personnel to build** & manage platform
- Expert advisors & **relationship managers** to get data source input & support contracting

Actions

1. **Establish industry role & catalogue business model**
2. **Determine catalogue scope**
3. **Develop ‘proof of concept’ platform**
4. **Recruit data source owners**
5. **Sustainably maintain platform**

Strategic considerations

- **Synergies & dependencies** – leverage existing catalogues to provide initial leads & foundational information; catalogue can serve as a “shop front” for the later accreditation process & be supplemented with guidance
- **Inspiration** – catalogues in other TAs (e.g. Orphanet, ISPOR SpecimenCentral, Global Health Data Exchange) can help identify key success factors & pitfalls
- **Risks & mitigating strategies** – catalogue value will be linked to its ability to continue to be updated, requiring incentives; partnership & stakeholder mgmt. with data sources will be required to mitigate impact of ratings & accreditation

*Consider EU legal implications
Source: A.T. Kearney, IQVIA

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Stakeholders in the health data landscape have different preoccupations, which must be considered moving forward

Stakeholder motivations

Profile	Motivations
Patients	Have increased understanding of their health & ownership of their healthcare Have access to safe, efficacious treatment options that improve quality of life at affordable costs
HCPs & regulatory agencies	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
Researchers & academia	Understand new areas of health and R&D Improve quality, speed and cost-effectiveness of research
Payers, policy-makers & HTA agencies	Ensure the cost-effectiveness of care in the short-term Support financial sustainability of the healthcare system in the long-term
Innovators & Big Tech	Understand unmet needs to develop innovative treatments that are effective & safe Enable returns on investment to fund further innovation

Source: A.T. Kearney

Every stakeholder group has a role to play in order to support the right environment

Communication plan: promote the right environment (1/2)

Audience	Materials / messages shared	Rationale	Channel*
Industry	• The pharmaceutical industry has a strong right-to-play in supporting health data • Member companies should work with other stakeholders to launch or support relevant efforts	• To identify areas of focus • To launch working groups or pilots	• Focus groups • Position paper
General public & patients	• Health data is essential to improve care decision-making and patient outcomes • More, better data is needed and patients have a key role to play in sharing it • Data can be handled safely	• To foster better understanding of the health data situation • To appease concerns around sharing	• Round tables with patient associations • Advocacy campaign*
HCPs & regulatory agencies	• Better quality health data could be made available to improve decision-making and patient outcomes • A wider variety of data, not necessarily from RCTs, is critical and does not endanger patients • Best practice, processes and technology should be leveraged to facilitate use of RWD on a regular basis	• To increase the perceived validity and use of RWD • To appease concerns around the burden of RWD	• Reports • Focus groups / hack-a-thons • Best practice playbook*

*See individual intervention communication plans
Source: A.T. Kearney

Every stakeholder group has a role to play in order to support the right environment

Communication plan: promote the right environment (2/2)

Audience	Materials / messages shared	Rationale	Channel*
Researchers & academia	• Better health data can be obtained to inform research by sharing across sources & initiatives • Data owners have critical expertise and can also learn from others	• To promote collaboration & sharing of data • To enhance best practice	• Reports • Conferences / forums / networking • Best practice playbook*
Payers & HTA agencies	• Comprehensive data is needed to support value assessments & outcomes-based models • RWD can provide high-quality, timely insights to support efficient decision-making	• To increase the perceived validity and use of RWD • To foster willingness to invest in RWD & RWD-fed schemes	• Round tables • Pilots
Politicians & policy-makers	• Long-term, PPP investment is needed to develop the evidence needed for decision-making that supports system sustainability • Private entities have a role to play in collecting, analysis and using RWD, in close collaboration with public entities	• To increase the understanding of RWD and associated efforts needed • To promote PPPs and collaboration with the government	• Round tables • Pilots
Innovators & Big Tech	• Innovators have critical knowledge to improve RWD collection and use, including access to unique data	• To promote collaboration & sharing of data • To enhance best practice	• Reports • Focus groups • Pilots

*See individual intervention communication plans
Source: A.T. Kearney

There are several critical success factors that will enable improvements to the data landscape via interventions & comms

Critical factors for success

1 Vision

Industry can align on the final goal(s) for selected interventions, to ensure that we are all working towards the same objectives

2 Collaboration

Industry can work jointly with their partners, taking account of individual requirements and setting the right example

3 Openness

Industry can strive for transparency and open sharing in their collaborations, to make the most of available knowledge and skills

4 Efficiency

Industry can seek synergies and avoid duplicating efforts, to ensure efficient use of resources

5 Flexibility

Industry can be willing to adjust approaches and find compromises, reflecting the complex and changing nature of health data

6 Patient-centricity

Industry should always put patients first, continuously considering the impact that efforts will have on improving patient experience and access

Source: A.T. Kearney, IQVIA

Contents

Launch campaigns and engage with HCPs and patients to increase understanding, transparency and trust

1 Focus area overview – patient & HCP mindset (1/2)

Effort/ Impact:
Worst – Best

What is the current situation?

- **Patient & HCP mindset** is the conception & attitude of patients & HCPs regarding how patient data is utilised & by whom
- **Impact & ability to influence** negative mindset is perceived to be low; views are that HCPs are harder to influence & with less of a potential impact

What are the gaps & opportunities?

- Patients perceive that work is "*already being done*" involving the sharing of their data for research
- There is **confusion & concern** amongst pts & HCPs surrounding what can be & is shared, what constitutes private information, liability, & with whom data is shared
- Examples exist of poor PR e.g., Google DeepMind
- **Communication, transparency & clear guidelines** & definitions could help inform patients & HCPs

Stakeholders needed?

- HCPs*
- HCP associations/unions*
- Patients*
- Patient associations*
- Governmental organisations

What are the possible interventions?

Launch an awareness campaign to highlight the benefits of using health data

- **Design an awareness campaign** to highlight how the sharing & use of health data can benefit patients
- **Inform the wider population** on the importance of RWD & the impact it can have on research & improved outcomes
- **Identify case studies** of where the use of health data has **specifically helped individuals**
- **Combat the often negative media coverage** that focuses on the improper use & handling of health data

Rationale

- **Transparency & patient empowerment & engagement** is essential to improve patient mindset & overcome misconceptions that data sharing with the pharmaceutical industry, & wider healthcare community is bad – demonstrate how RWD leads to better treatment

Where is it being done?

- **EFPIA** already leads campaigns such as "We Won't Rest" & "The Pledge Wall"
- **#datasaveslives** campaign was launched by the Farr Institute to highlight the importance of data in research

Effort
Impact

*important stakeholders to engage
Source: CMSC Website; IQVIA ; A.T. Kearney analysis

Launch campaigns and engage with HCPs and patients to increase understanding, transparency and trust

1 Focus area overview – patient & HCP mindset (2/2)

Effort/ Impact:
Worst – Best

What are the possible interventions?

Encourage collaboration between researchers, HCPs & data sources

- **Initiate open forums, engagement activities, workshops**, etc., to enable cancer experts from different specialties to engage, share & collaborate
- Personally **introduce experts** of different specialties where combined efforts & communication would be beneficial to the wider healthcare context & **incentivise partnerships** between them
- **Regular publications**, **highlight features & expert interviews** with experts distributed amongst wide spectrum of cancer specialists

Rationale

- **Increased awareness** & collaboration between cancer experts would lead to **reduced duplication** of effort, shared learning of what works & what doesn't, **sharing** & **creation** of innovative ideas, & adoption of **good practice** at site level
- **Increased collaboration** will generate better research, better data, & more informed insights

Where is it being done?

- The **consortium of multiple sclerosis centres (CMSC)** is a **membership scheme for health experts, centres & students** to access publications, annual conferences, fellowships & funding

Effort: ●
Impact: ●

Incentivise high-quality data capture by HCPs

- **Mobilise a consensus conference** to discuss appropriate HCP incentives to accurately record data
- **Discuss fair market values** for HCP involvement & support for health data activities

Rationale

- Although HCPs may initially be supportive, **time & understanding** of the commitment involved is often limited, & so data is often **not collected, or reported inconsistently**
- **Embedding good recording practices** at the site level will aid with future work with other HCPs

Where is it being done?

- **CRISP** uses financial incentives to ensure necessary data is captured

Effort: ●
Impact: ●

Work with government at local & national levels

- **Design a country-by-country** public policy maker education programme or round table
- **Educate government** on the value of health data, its utilisation, current barriers, trends, what data is required to achieve outcomes that will benefit patients & contribute to high quality, sustainable healthcare
- **Create an expert group to advise government** on the implementation of innovative initiatives through provision of industry knowledge, financial contributions, national programme support, proposal support & backing of government health campaigns

Rationale

- **Government backing** of initiatives aids HCP & patient buy-in & increases participation
- **Supporting government** may help **overcome the stigma** that surrounds the image of pharma
- **Transparency** over what data is used & how it is used will help gain government support to pass the necessary legislation to benefit all

Where is it being done?

- **The 100,000 Genomes Project** was backed by UK government leading to increased **recognition & buy in** from stakeholders

Effort: ●
Impact: ●

Source: CRISP Website; Genomics England Website; IQVIA ; A.T. Kearney analysis

Formalise definitions, accreditations and processes, and establish networks

2 Focus area overview – quality & consistency assurance (1/3)

Effort/ Impact:
Worst – Best

What is the current situation?

- **Data quality & completeness** is how complete a dataset is & the reliability of the data contained within the dataset
- **Impact of quality & constancy is medium** but there is a **high ability to influence** this barrier

What are the gaps & opportunities?

- **Level of completeness & quality** varies between datasets & within datasets themselves
- Different countries/hospitals/specialties will record the same data by **different conventions & structure data differently**; often using unstructured data/written notes & captured across multiple systems
- Datasets often have no internal **standard conventions**

Stakeholders needed?

- HCPs*
- Data collectors (e.g. clinical coders)*
- Governmental organisations
- Academia
- Pharmaceutical companies*

What are the possible interventions?

Define a data quality accreditation framework

- **Develop a framework supported by independent bodies** whereby a data source is **accredited** according to its level of **quality & completeness**
  - **Involve all stakeholders** during the development of the accreditation framework to ensure transparency, empowerment & feasibility, & promote the framework itself
  - **Educate all stakeholders** on the requirements for an accreditation process & how to abide by it
- **Work with data source** owners to test framework & **improve the quality** of data through **highlighting inconsistencies & deviations from benchmarks,** highlighting how to undertake continuous improvement
- **Actively engage** with data source owners & **promote data sources** of high quality

Rationale

- **Increased data quality** for both data source owners & data processors leading to more **accurate reporting of data to payers** & more **accurate insights** to influence future healthcare
- **Increased promotion** of datasets through accreditation allows others to **identify the necessary data** more easily
- **Increased consistency** across industry stakeholders over **data expectations**
- **Buy-in** of stakeholders due to involvement through conception to implementation of framework

Where is it being done?

- **PRIMIS Hub**, support by the Health Quality Improvement Partnership (HQIP) is an online platform that **supports GPs & HCPs with auditing data quality** in health centres to meet GP appraisal requirements & revalidation

Effort
Impact

*important stakeholders to engage
Source: PRIMIS Website; IQVIA ; A.T. Kearney analysis

Formalise definitions, accreditations and processes, and establish networks

2 Focus area overview – quality & consistency assurance (2/3)

Effort/ Impact:
Worst – Best

What are the possible interventions?

Develop a "playbook" of best practice

- **Develop a recommended** approach that new initiatives can refer to & follow based on the **collective experience** of current & historic initiatives; create a forum for discussion to drive the **knowledge capture & dissemination**
- **Involve a broad group** of stakeholders & initiative participants to draw on as much experience as possible before disseminating into a "blueprint"
- Additional to standard approach include **examples of best practice** for inspiration, identify historic issues with potential resolution options
- **Create a forum for continuous discussion** & revision of "blueprint", best practice examples & issues/resolutions, supporting future work & preventing re-invention

Rationale

- Too often initiatives are left to navigate the landscape based on the **limited experience** of those involved leading to similar issues being tackled multiple times; this leads to **inefficiencies & inconsistency** across the field

Where is it being done?

- **GA4GH** aims to identify & support the best approach for sharing genomic data with reference to format, regulations, security, etc.

Effort
Impact

Define process standards

- **Work with a selection of stakeholders & leading initiatives to create & publish a list of data management standards** that are agreed across stakeholders for the internal management of data through collection, recording, storage, extracting, linking & analysing of data
- **Set out required standards** for good data management including the processes & required documentation; build in a requirement for continuous quality control & improvement, allowing publication & sharing of RWD

Rationale

- Agreed standards will support collaboration with partners having greater assurances relating to data being provided & actions to expect
- Creates an environment to encourage continually improved standards of data partners

Where is it being done?

- **The Data Coordination Board (DCB)** is a NHS governance group that **defines processes & assures the quality** of information standards

Effort
Impact

Source: GA4GH Website; NHS Website;; IQVIA ; A.T. Kearney analysis

Formalise definitions, accreditations and processes, and establish networks

2 Focus area overview – quality & consistency assurance (3/3)

Effort/ Impact:
Worst – Best

What are the possible interventions?

Define minimum needed variables for data content & coverage

- **Launch a program of forums & workshops** that demonstrate the value of complete, high quality data & how this is used to generate insights engaging data source owners over feasibility of capturing necessary data, encouraging representation & completeness
- **Build on work already underway with IMI to launch** a multi-stakeholder effort to **define a list of minimum required variables & coverage** & a desirable variable list with an **incentive** to fulfil the desirable variables by use case

Rationale

- **Increased understanding from both sides**: data source owners understand the need for the dataset; industry understands the availability of data

Where is it being done?

- **InSite** conducts **quality checks** before data source owners can be part of a network

Effort
Impact

Source: InSite Website; IQVIA ; A.T. Kearney analysis

Foster more collaborations and transparency to increase access by ensuring secure data privacy and sharing

3 Focus overview – access, privacy & sharing (1/3)

Effort/ Impact:
Worst – Best

What is the current situation?

- **Access** refers to a user's ability to access or retrieve data stored within a database or other repository
- **Privacy** determining which data can be shared
- **Sharing** is the ability to share the same data resource with multiple applications or users
- Access, privacy & data sharing has **medium to high** impact, with **data access having the biggest impac**t, & the ability to influence ranges **low to medium**

What are the gaps & opportunities?

- **Rules & regulations concerning** accessing data varies from source to source & country to country
- **Linkage** of data sources is difficult, therefore much valuable information is lost in silos
- **Data privacy** is a sensitive issue, now expected to be influenced by new regulations, yet there is uncertainty amongst all stakeholders

Stakeholders needed?

- Data science companies*
- Pharmaceutical companies
- HCPs
- Governmental organisations*
- Patient associations
- Data sources/ initiatives*
- Policy regulators*

What are the possible interventions?

Work with policymakers on GDPR interpretation

- **Work with national policy-markers** to support & guide interpretation of GDPR regulation & obtain clarification on the new compliance requirements, & transition periods for implementation
- **Push for universal recognition** of an organisation's GDPR compliance, once acknowledged in one, or more, participating country (i.e. mutual, cross-border regulator recognition)
- **Establish a forum** that aids organisations to be compliant & provides assistance

Rationale

- This would **reduce complex bureaucracy** that halts expansion of data sources into various countries & aid organizations to smoothly adopt new expectations

Where is it being done?

- The IGA has set up a **GDPR working group** to help organisations **adapt to the new regulation**

Effort
Impact

Create independent body for regulatory-compliant data preparation

- **Creating an independent centralised health data preparation factory** where sources can provide 'raw' data for **independent de-identification/ transformation** to meet regulatory standards & "transformed" data can be then provided to stakeholders with a **quality mark**
- Independent body can be **sponsored/ funded by stakeholders** to secure its future but its **governance & management remains truly independent** to guarantee trust in its work

Rationale

- Trust is a major factor in ensuring all stakeholders involved in health data are comfortable with its use; providing an independent organisation that has no interest other than ensuring data privacy is maintained will help build the trust

Where is it being done?

- Process applied to **clinical trial sponsorship** demonstrates a model for pharmaceutical companies sponsoring activities but not being involved in the execution to ensure outputs are independent of the interested parties

Effort
Impact

*important stakeholders to engage
GDPR = General Data Protection Act; IGA = Information Governance Alliance
Source: NHS Website; IQVIA ; A.T. Kearney analysis

Foster more collaborations and transparency to increase access by ensuring secure data privacy and sharing

3 Focus overview – access, privacy & sharing (2/3)

Effort/ Impact:
Worst – Best

What are the possible interventions?

Seek alignment on EU & national grants to support best practice use of health data

- **Encourage review of award criteria to ensure EU & national grants encourage** access, sharing or collection of high-quality health data
- **Work with policy bodies & data initiatives** to define Europe-wide principles for fair market value (FMV) for access to data sources

Rationale

- There is a great amount of valuable information that could be extracted if data sources were more comprehensive, or in depth. **Incentivising data sharing** would enable linking data sources to provide **better insights** for use cases
- Currently, **no benchmarks exist** on the amount that data sources can charge for access & this can be detrimental to smaller, less funded initiatives who therefore cannot obtain necessary data due to **financial constraints**
- No view on what **fair market value** for data is, leading to uncertainty & potential conflict of interest

Where is it being done?

- **Simulacrum** is an initiative that gives open access to all parties equally & was **jointly funded** in its pilot phase by Public Health England, IQVIA, HDI & AstraZeneca

Effort
Impact

Develop a complete, open RWD catalogue

- **Sponsor the development of a catalogue in conjunction with the European Commission** (especially DG Sante & DG Connect) that provides up-to-date lists of all data initiatives & sources, outlining GDPR compliance, ensuring transparency on quality & information on accessibility
- **Establish an interactive forum** where data source owners can collaborate & share ideas, & where potential data users can ask questions

Rationale

- **Having transparency** in what work is already underway, to what quality data exists & who owns it, would not only lead to **more collaboration but also would ensure that efforts are not replicated**
- **Listing** will promote lesser known/up & coming data sources, thus **promoting future collaborations**
- Key aspect will be the **provision of an accreditation** or means of benchmarking the different sources in the catalogue – existence does not equate to quality & suitability

Where is it being done?

- Several data catalogues exists to give **open, free access to data sources worldwide** (e.g. RoPR, Parent, Orphanet, ISPOR SpecimenCentral, Global Health Data Exchange, Healthcare Quality Improvement Partnership)

Effort
Impact

DG SANTE = Directorate-General for Health and Food Safety EC = European Commission; GDPR = General Data Protection Regulation
Source: IQVIA; A.T. Kearney analysis

Foster more collaborations and transparency to increase access by ensuring secure data privacy and sharing

3 Focus overview – access, privacy & sharing (3/3)

Effort/ Impact:
Worst – Best

What are the possible interventions?

Support initiatives to openly share 'raw', anonymised data

- **Support initiatives** that collect their own data to openly share this at a 'raw' level, whilst removing all identifiable patient information
- **Encourage a platform** by which raw data can be interrogated at a deidentified level
- **Incentivise initiatives** that engage in open access, sharing or collection of high quality health data, via grants & also through legal & ethical support

Rationale

- Some initiatives **collect good-quality, high-value data**, that could be used by academia, healthcare institutions & industry

Where is it being done?

- The **InSite** initiative both allows researchers to **submit queries** & return to them aggregated results
- **CODE** is an initiative that will make **data accessible to all who pay for subscription** with a limited fee for academia

Effort
Impact

Share best practice data privacy protocols & approaches

- **Organise sharing groups &** workshops to ensure GDPR readiness
- **Engage stakeholders** in the agreement & the publication of best practices guidelines to help data sources, & other organisations, in following guidelines

Rationale

- GDPR guidelines are new to the whole market; every data source & organisations storing & using data will have to learn how to be compliant

Where is it being done?

- **CODE** is "*privacy by design*" & has **adopted all GDPR requirements** from the outset

Effort
Impact

Source: InSite Website; CODE Website; IQVIA ; A.T. Kearney analysis

Partner with academic institutions to increase human skills and capabilities and raise awareness of technology

4 Focus overview – human skills & capabilities

Effort/ Impact:
Worst – Best

What is the current situation?

- **Human skills & capabilities** are he ability to collect, analyse & use health data for a variety of purposes
- The impact of **increasing human capital** & **capabilities** is high & the ability to influence is also high

What are the gaps & opportunities?

- Human **skills & capabilities are currently lacking**, & there are few training programs to fill the gap
- Artificial Intelligence (AI)/ machine learning has **not sufficiently developed** yet to fill in the gaps
- **Partnering with academics** to train professionals in human data science will enable timely & secure information gathering & analysis

Stakeholders needed?

- Pharmaceutical companies
- Academic partners*
- HCPs
- Technology experts*
- Data sources/ initiatives*

What are the possible interventions?

Partner with academic institutions

- **Partner with a selected group of academic institutions** to develop the required skillsets for future data analyst experts through industry-funded courses, scholarships, apprenticeships, graduate schemes & PhD funding & expand to further centres in a second wave
- **Shape the development of academic curricula** (e.g. Masters in data sciences) to focus on the specific skills required to improve capabilities for health data collection & analysis (especially around overcoming the limitations of RWE)

Rationale

- There is a **lack of training opportunities & incentives** for people who would otherwise be interested in data sciences in healthcare
- Current skills **do not address some health data issues** that are prevalent today

Where is it being done?

- **Imperial College** has established a course for **'data analytics in health',** to understand emerging issues in eHealth & how to manage technology initiatives
- **ECIBC & ECIS** both provide **training to their employees** to gain the necessary skills for data extraction

Effort ●
Impact ●

Improve understanding of the technological landscape

- **Hold a series of industry co-sponsored events to improve understanding** of how the latest technology can enable better health data use, collection & analysis through **conferences & webinars**
  - **Publish feature insights** into best practices & technological advances in academic journals & industry magazines to generate awareness of new available resources

Rationale

- **Increased awareness** of the technology available & its possible uses

Where is it being done?

- The **HiMSS annual exhibition** brings together 45,000+ healthcare professionals & **explores cutting-edge technology** solutions & **educates attendees** solve some of the biggest health technology challenges

Effort ●
Impact ●

*important stakeholders to engage
AI = Artificial Intelligence; ECIBC = European Commission Initiative on Breast Cancer; ECIS = European Cancer Information System
Source: Imperial College Website; ECIBC & ECIS Websites; InsideBIGDATA Website; IQVIA ; A.T. Kearney analysis

Launch campaigns to highlight the importance of socio-economic value and test metrics to demonstrate relevance

5 Focus area overview – socio-economic value

Effort/ Impact:
Worst – Best

What is the current situation?

- **Socio-economic value** is the value that drugs bring to society beyond clinical outcomes (economic contributions, ethics, carer burden, preferences)
- **Supply & demand are currently low** across initiatives & data sources for determining value
- **EFPIA** is an expert group & key partner in **IMI's Socio-Economic Impact Assessment**

What are the gaps & opportunities?

- Socio-economic value is currently **not valued** & is **poorly defined**
- The growing focus on expenditure & patient perspectives are such that a more **holistic approach to costs** could become more relevant
- Clear, jointly-determined socio-economic metrics & supporting facts could help **inform this shift**

Stakeholders needed?

- Pharmaceutical companies*
- HCPs
- Payers & HTAs*
- Patients & patient associations
- Governmental organisations*

What are the possible interventions?

Define socio-economic metrics & pilot them to demonstrate value exists

- **Commission research** into parameters by which socio-economic value can be measured & quantified (e.g. work productivity) & **test with the EMA & national HTAs & payers** to ensure relevance
- **Finance & launch a pilot** to test these on cancer treatments to demonstrate value

Rationale

- There is a **lack of understanding** of how treatments deliver a wider social value, particularly as long-term survivorship increases, & limited scope to quantify it; by demonstrating value, drug development & approvals are **better aligned to true societal needs**, beyond purely medical requirements

Where is it being done?

- The Health Foundation has launched a £1.5m funding program in the UK to **support research into developing new knowledge & expanding understanding** of how impacts to a patient's health affects their **economic & social outcomes**

Effort ●
Impact ●

Launch an advocacy campaign & publish case studies

- **Conduct a stakeholder engagement round table program** to raise awareness of the important of socio-economic value in approving, reimbursing & prescribing cancer treatments & interventions
- **Publish case studies** to show where & how socio-economic value has been delivered & the data that was collected to demonstrate it

Rationale

- **Limited buy-in** from key stakeholders (payers, HCPs & Pharma) due to a belief that socio-economic value **isn't important** so there is **low demand for data** to understand it

Where is it being done?

- PhRMA's "Prescription Medicine: Costs & Context" campaign outlines **additional benefits to society** from advances in prescription medicine (**innovation, reduced cost & quality of life**)

Effort ●
Impact ●

* important stakeholders to engage
EMA = European Medicines Agency; IMI = Innovative Medicines Initiative
Source: PhRMA "Prescription Medicines: Costs in Context"; IMI "Socio-economic Impact Assessment"; Health.org Website; A.T. Kearney analysis; IQVIA

Raise awareness of the value of innovative pricing machanisms to build demand and improve decision making

6 Focus area overview – pricing enablement

Effort/ Impact:
Worst – Best

What is the current situation?

- **Pricing enablement** is the use of drug & treatment indications &/or outcomes to enable a flexible pricing mechanism
- **Currently demand** for data to drive innovative pricing decisions is low & limited by a lack of understanding
- **Current data sources** do not provide much suitable data for pricing enablement activities

What are the gaps & opportunities?

- There is a **lack of understanding** from stakeholders as to the **value of health data** to develop innovative pricing models, thus by building **awareness & educating stakeholders**, pricing enablement will gain traction
- The **CODE initiative, a dedicated oncology data network,** aims to fill the gap(s) in terms of providing the data to support innovative pricing

Stakeholders needed?

- Pharmaceutical companies*
- Funding bodies*
- Government organisations*
- HCPs

What are the possible interventions?

Create demand & support for innovative pricing

- **Collaborate with multiple stakeholders** to demonstrate what is possible in terms of pricing enablement & create an understanding of what the broad needs and benefits are beyond pharmaceutical companies, for example: the ability of indication based pricing to align drug spend against areas of greatest impact
- Build an awareness of how to use innovative pricing to **improve decision making**

*** Rationale**

- The desired approach for pricing enablement application is **not agreed between all stakeholders**, therefore demand is uncertain & lacking
- This could be resolved through first **demonstrating what is possible** & then **establishing what is required** to improve pricing decisions
- Offers the ability to address the financial sustainability of pharmaceutical spend

*** Where is it being done?**

- **The Roche Innovative Pricing Solutions** initiative is working with Roche's stakeholders to ensure that payers & healthcare authorities have **more flexibility** when it comes to reimbursement decisions

Effort
Impact

* important stakeholders to engage
CODE = Collaboration for Oncology Data in Europe
Source: CODE Website; Roche Website; A.T. Kearney analysis; IQVIA

Refine PRO definitions and support patient data sharing through transparent, innovative platforms

7 Focus area overview – patient perspective

Effort/ Impact: Worst – Best

What is the current situation?

- **Patient perspective** is the insight gained from patients on quality of life, covering aspects of care beyond clinical outcomes
- **Current supply is very low**, with no data source consistently offering data fit for this purpose, & **demand is limited**
- **The EFPIA Patient Think Tank** is an **open forum** to share perspectives between patients & the industry

What are the gaps & opportunities?

- A **lack of understanding** on how to **engage patients & use insights** to inform better treatment decisions is common across stakeholders
- Patients are becoming **increasingly empowered & involved** in their personal health, opening up opportunities to **gain detailed insights** into the effects of disease & treatments, & collect new data points to better understand patients' experiences

Stakeholders needed?

- Patients & patient associations*
- HTAs
- Pharmaceutical companies
- HCPs*
- Policy regulators*

What are the possible interventions?

Refine definitions & standards for PROs

- **Conduct stakeholder engagement & round tables to refine & agree** on the required definitions, content (including language use) & format for cancer PROs & **pilot on a multi-national, heterogeneous group** to gather feedback

Rationale

- Although PROs are well established in some fields, cancer stakeholders **have differing definitions** for what they should look like

Where is it being done?

- IMI's PRO-active **created new tools** to monitor patients' experiences with COPD, **merging questionnaires** with **physical activity monitor data**

Effort: Impact:

Develop a patient data donation platform

- **Work with patient associations to sponsor the development of a secure platform** that facilitates uploading of data from existing sources but for new purposes, with clear ownership & **transparent protocols**

Rationale

- Patient awareness of the importance of health data is improving, but they **lack tools** to engage with it & **doubt the incentives** of many who attempt to capture it

Where is it being done?

- In Sweden, the 1177 national patient portal allows patients to **contribute to their health records** & set **clear consent rules** for data access & sharing

Effort: Impact:

Improve transparency & ease-of-use in the patient consent process

- **Work with patient associations & academic centres to review protocols** of patient consent for collection & use of their personal data, & **establish a paradigm of transparency** to build trust & empower patients, promoting the new standard

Rationale

- Consent rules & frameworks are **not clearly understood** & often **more restrictive** that necessary, thus **hindering data sharing**

Where is it being done?

- In Germany, the Consent Management Service **developed an opt-in consent management tool** & addresses **consent queries** from patients

Effort: Impact:

* important stakeholders to engage
COPD = chronic obstructive pulmonary disease
Source: IMI Website; The Medical Futurist "Digital Health Best Practices"; RAND "RWD landscape in Europe" (2014); EFPIA Website; A.T. Kearney analysis; IQVIA

Build awareness of data science as a core asset and utilise technology for recruitment to enhance R&D

8 Focus area overview – R&D enablement

Effort/ Impact: Worst – Best

What is the current situation?

- **R&D enablement** is the enhancement of research outcomes by finding efficiencies in the R&D value chain & making use of new techniques to inform more accurate drug development & testing
- **Current supply is low**, with few data sources fit for this purpose, but **demand high & expected to rise**
- **EFPIA** & PhRMA jointly launched the **Principles for Responsible Clinical Trial Data Sharing**

What are the gaps & opportunities?

- The global market for R&D is well-functioning, but there is a **lack of data skill** & **recognition of data science** which could **enable more innovative research** methods & outcomes
- As **traction grows** in cutting edge techniques (i.e. genome sequencing, simulated clinical trials), opportunities to **leverage data sciences** to enhance R&D efforts will become more lucrative

Stakeholders needed?

- Pharmaceutical companies*
- Patients & patient associations
- HCPs
- Academic partners
- Health centres*
- Technology vendors*

What are the possible interventions?

Build awareness of data science as a core capability in the R&D process

- **Co-sponsor a joint industry & academia initiative to promote the importance** of data sciences as a new core capability to enable smarter & more efficient R&D processes, & **fill the emerging skill gap**

Rationale

- As the availability & potential of health data grows, **traditional medical skills** will be supplemented by data science as a new, essential set of health skills

Where is it being done?

- Korea's Gov 3.0 Master Plan is building a multi-pronged Big Data framework that includes a strategy for **developing data science skills**

Effort: Impact:

Raise awareness & use of technology

- **Partner with selected vendors to raise awareness of the new technologies** available & how they can be used to **enhance the R&D value chain** (greater patient recruitment, better patient segmentation)

Rationale

- Stakeholders are **unfamiliar with current technology**, & even more so with emergent tech & its potential – education & **awareness will help bridge this gap**

Where is it being done?

- CCTI's Recruitment Project **identifies barriers to trial recruitment** & **recommends best practice solutions** (e.g. Using e-communication tools)

Effort: Impact:

Openly tackle anonymisation issues & provide support to overcome them

- **Support the development of a best practice sharing forum targeted at major health centres** to review the complexity of patient data anonymisation, by developing new algorithms & training users

Rationale

- The onus of (de-) anonymisation of patients' clinical trial data is on health centres who **lack the skills & abilities** to handle the **complexity of the process,** whilst respecting privacy laws

Where is it being done?

- The CPFT runs a **training module** for HCPs to use CRATE – a software tool to **anonymise & extract clinical record data** for research purposes

Effort: Impact:

* important stakeholders to engage
CCTI = Clinical Trials Transformation Initiative; CPFT = Cambridge & Peterborough Foundation Trust;
Source: Applied Clinical Trials Online Website, NHS Website; Research Gate "Big Data Strategies of World Countries"; EFPIA Website; A.T. Kearney analysis; IQVIA

Undertake strategic interventions to facilitate an environment promoting funding, data linkage and scalability

9 Focus area overview – strategic enablers (1/3)

Effort/ Impact:
Worst – Best

What is the current situation?

- Data funding is usually in the form of **short to medium-term grants**
- **Impact of funding sources** is **low-medium** & ability to influence this barrier is **medium**
- **EFPIA** is currently supporting the funding of projects through the **Innovative Medicines Initiative (IMI)**

What are the gaps & opportunities?

- Many initiatives face issues surrounding funding, **particularly in the early days**
- **High profiles & recognition** attract funding from commercial parties
- Public initiatives often involve **external collaboration** in respect to funding
- **It takes time** for a data source to flourish

Stakeholders needed?

- Pharmaceutical industry*
- Government organisations*
- Other commercial entities with healthcare interest
- Funding bodies*
- Data sources/ initiatives*

What are the possible interventions?

Create an environment that facilitates longer term funding

- **Building on IMI experience, work with the Commission** to promote public-private partnerships whereby private entities can provide initial funding for public sector initiatives & where public sector & charitable funding can provide initial funding for private endeavours
  - **Outline the process** of transferring funding obligations from the private to the public sector, & vice versa
- **Create an investment fund** that initiatives & data sources can apply to for activities related to data quality improvement, process improvement & standardisation, & ensure that its investments extend beyond a 1-2 year horizon

Rationale

- **Increased funding availability for key processes** such as implementation of standardisation & data quality improvement
- Ensures **longevity** of initiatives
- **Multi-stakeholder investment** increases amount of funding available to an initiative
- Transferring funding from private to public sector entities, & vice versa, aids in ensuring **continuation** of an initiative, & makes funds available for other initiatives at different stages of the project lifecycle

Where is it being done?

- **InSite** initially had **IMI** funding, which was extended to the **Champion Programme** & is now working with **pharmaceutical companies**
- Projects such as **IMI** & the **Cancer Innovation Challenge** provide funding & recognition for innovative initiatives that aim to promote healthcare

Effort
Impact

*important stakeholders to engage
Source: InSite Website; IMI Website; Cancer Innovation Challenge Website; IQVIA; A.T. Kearney analysis

Undertake strategic interventions to facilitate an environment promoting funding, data linkage and scalability

9 Focus area overview – strategic enablers (2/3)

Effort/ Impact:
Worst – Best

What is the current situation?

- Different data sources need to be linked in order to **gain valuable analyses**, but, patient identifiable information cannot be shared
- **Impact of data sharing** is **high**, & ability to influence is **high**

What are the gaps & opportunities?

- Individual patient's health data is often **split across multiple data sources**
- There is **no simple approach for identifying patient overlap** between similar data sources
- Definitions & approaches for **data de-identification & anonymisation vary greatly**

Stakeholders needed?

- Governmental organisations
- HCPs & hospital staff*
- Pharmaceutical companies
- Any other organisation collecting healthcare data*
- Data sources/ initiatives*

What are the possible interventions?

Work with stakeholders nationally & locally to convey the importance of fostering linkage of datasets

- **Create a independent patient data clearing house** that is owned by the industry & managed by an independent body & can act as a third party where data source owners send patient lookup reference tables & data receivers can receive details of which patients are the same, allowing clear linkage across datasets
  - **Fund training programmes** for data handlers & information governance staff to engage with the third party
  - **Establish good practice procedures** within industry for linking datasets using the third party
  - **Communicate clearly the security & trustworthiness of the third party**, & outline that the data is non-attributable

OR

- **Create centralised networks** whereby a system algorithm (or artificial intelligence) can assign **randomised IDs to patient identifiable information** whilst maintaining consistency between datasets

*** Rationale**

- **Awareness** will aid in reducing linkage issues
- **Patient identifiable information** is not shared outside of agreed arrangements
- Staff are **trained** to work with data & the processes involving de-identification & linkage

*** Where is it being done?**

- Universal Patient Key (UPK) is a software tool that integrates with existing systems to provide a **secure patient data de-identification** process using an encrypted 'token'; the software allows the **linking of patient datasets** without sharing protected health information

Effort
Impact

*important stakeholders to engage
Source: Universal Patient Key Website; IQVIA; A.T. Kearney analysis

Undertake strategic interventions to facilitate an environment promoting funding, data linkage and scalability

9 Focus area overview – strategic enablers (3/3)

Effort/ Impact:
Worst – Best

What is the current situation?

- **Scalability** is the capacity to accommodate **increased workload, demand & geographies** in order to grow
- Most data sources tend to **be local & isolated**: they lack scale & would struggle to reach it
- The impact of **scalability is high** & the ability to influence it is **high**

What are the gaps & opportunities?

- Lots of initiatives are trying to achieve similar goals
- Different markets have **different rules & regulations** that need to be adhered to
- **Scalability** requires **manpower, skillsets & funding** in order to be successful
- Hospital sites are often **ill-equipped** in terms of resource, therefore, impeding recruitment processes

Stakeholders needed?

- Governmental organisations
- Pharmaceutical industry*
- HCPs & healthcare institutions*
- Academia
- Data sources/ initiatives*

What are the possible interventions?

Create an environment that encourages scalable approaches

- **Create a pan-European, multiple stakeholder initiative** with the specific objective to facilitate the growth of innovative & scalable oncology data projects & provide support navigating international markets, promotional activity, grant proposal writing, etc.
  - **Encourage initiatives with similar objectives** & subject area to **join forces** & provide financial incentives/legal assistance to facilitate this
  - **Incentivise large treatment centres** to participate in research through recognition, provision of insights into their data, aiding in the improvement of data quality, on-site representatives recording data & recruiting
  - **Actively collaborate** with initiatives & data sources to assist in **expanding their capacity**

Rationale

- **Merging & collaboration** between initiatives & data sources allows resources to be pooled & facilitates growth
- **Buy in** from treatment centres, & HCPs, aids recruitment, enhances recognition & in the long term facilitates growth
- **Support of new & growing initiatives** (not just through funding) will aid them to **address barriers &** enable them to flourish

Where is it being done?

- **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; experts working in their spare time develop the tool
- **IRONMAN** is launched in America & is expanding into European & other markets

Effort
Impact

*important stakeholders to engage
Source: OMOP Website; Ironman Website; IQVIA; A.T. Kearney analysis

Contents

For each intervention, knowledge of existing or past initiatives can provide insight and/or help avoid duplication

Areas of synergies & inspiration for interventions (1/5)

Focus area	Interventions	Areas of synergies & inspiration
Patient & HCP mindset	Launch an awareness campaign/ oncology summit	• Farr Institute's "#datasaveslives" • EFPIA's "We Won't Rest" & "The Pledge Wall" • EFPIA Digital Task Force "stakeholder engagement platform", principles for responsible use • EFPIA WG on Data Protection (i.e. chain of custody on data stewardship & responsibility) • EFPIA Board-level initiative on regulatory acceptance of RWD
	Enable collaboration between cancer experts	• Consortium of Multiple Sclerosis Centres (CMSC) • EUSOMA • Big Data 4 Better Outcomes (BD4BO)
	Incentivise high-quality data capture	• CRISP • Pfizer's collaboration with Optum • Rizzoli Orthopaedic Institute in Italy
	Work with governments to convey the value of data	• 100,000 Genomes Project • Farr Institute's "#datasaveslives" • PatientsLikeMe collaborating with the FDA & ACC
Quality & consisten-cy assurance	Define a data quality accreditation framework	• PRIMIS Hub (supported by the Health Quality Improvement Partnership (HQIP)) • GEKID in the UK • Big Data 4 Better Outcomes (BD4BO) • European Institute for Innovation through Health Data (i~HD) • Clinical Classifications Service • EFPIA Digital Task Force "stakeholder engagement platform"

Source: A.T. Kearney; IQVIA analysis

For each intervention, knowledge of existing or past initiatives can provide insight and/or help avoid duplication

Areas of synergies & inspiration for interventions (2/5)

Focus area	Interventions	Areas of synergies & inspiration
Quality & consistency assurance	Share a "playbook" of best practice for working with data	• Global Alliance for Genomics and Health (GA4GH) • European Health Data Network (EHDN) • European Network of Cancer Registries • Germany's GEKID • International Consortium for Health Outcomes Measurements (ICHOM) • Observational Health Data Sciences and Informatics (OHDSI, inc. OMOP) • Simulacrum • European Institute for Innovation through Health Data (i~HD) • INCEPP • EFPIA Digital Task Force
	Define process standards for linkage	• NHS Data Coordination Board (DCB) • European Institute for Innovation through Health Data (i~HD) • OHDSI
	Define minimum suggested variables for content	• OHDSI • InSite • International Consortium for Health Outcomes Measurements (ICHOM) • European Institute for Innovation through Health Data (i~HD) • Professional Record Standards Body (endorsed by the HSCIC)
Access & privacy	Work with policymakers on local GDPR interpretation	• UK Information Governance Alliance • EFPIA WG on Data Privacy & Data Protection

Source: A.T. Kearney; IQVIA analysis

For each intervention, knowledge of existing or past initiatives can provide insight and/or help avoid duplication

Areas of synergies & inspiration for interventions (3/5)

Focus area	Interventions	Areas of synergies & inspiration
Access, privacy & sharing	Create an independent body to support data preparation	• Professional Record Standards Body (endorsed by the HSCIC)
	Seek alignment on EU & national grants	• European Commission
	Develop a complete, open RWD source/ initiative catalogue	• Bridge2Data • Epi Aviesan • RoPR • Parent • Orphanet • ISPOR SpecimenCentral • Global Health Data Exchange • Healthcare Quality Improvement Partnership • Big Data 4 Better Outcomes (BD4BO)
	Support initiatives to share 'raw' data	• InSite
	Share best practice data privacy process/ approaches	• European Health Data Network (EHDN) • Simulacrum
Human skills & capab.	Partner with academic institutions to build data skills	• IBM Academic Initiative & Big Data and Analytics Faculty Awards • BBC Data Science Research Partnership • IMI GetReal • EFPIA Working Group on Data Privacy

Source: A.T. Kearney; IQVIA analysis

For each intervention, knowledge of existing or past initiatives can provide insight and/or help avoid duplication

Areas of synergies & inspiration for interventions (4/5)

Focus area	Interventions	Areas of synergies & inspiration
Human skills	Improve understanding of technology for stakeholders	• Healthcare Information and Management Systems Society (HiMSS annual exhibition)
Socio-economic outcomes	Define socio-economic outcomes/ metrics	• Health Foundation's £1.5m funding program to support research into patients' economic & social outcomes
	Launch a campaign on socio-economic benefits	• PhRMA's "Prescription Medicine: Costs & Context" campaign
Pricing enablemnt.	Create demand & support for innovative pricing	• Roche Innovative Pricing Solutions • CODE
Patient perspect-ive	Refine definitions & agree on standards for cancer PROs	• IMI's PRO-active • Big Data 4 Better Outcomes (BD4BO) • MyClinicalOutcomes • IMI PREFER • O-Wise • My Clinical Outcomes • EFPIA WG on Data Protection
	Develop a patient data donation platform	• Sweden's 1177 national patient portal • Universal Cancer Databank • 23&Me • PatientsLikeMe

Source: A.T. Kearney; IQVIA analysis

For each intervention, knowledge of existing or past initiatives can provide insight and/or help avoid duplication

Areas of synergies & inspiration for interventions (5/5)

Focus area	Interventions	Areas of synergies & inspiration
Patient perspect-ive	Improve the consent process	• Germany's Consent Management System • EFPIA WG on Data Protection
R&D enable-ment	Promote importance of data sciences as a core capability	• Korea's Gov 3.0 Master Plan, inc. to develop skills • Health Data Research UK's "Future Talent Programme"
	Raise awareness of technology to enhance R&D	• Clinical Trials Transformation Initiative (CTTI) Recruitment Project
	Openly tackle anonymisation issues	• Cambridge & Peterborough Foundation Trust training modules on anonymisation software • EFPIA WG on Data Protection
Strategic enablers	Create an environment for longer-term funding	• Innovative Medicines Initiative • Cancer Innovation Challenge • European Network of Cancer Registries
	Convey the importance of fostering linkage of datasets	• European Medical Information Framework (EMIF) • EFPIA WG On Data Protection
	Create an environment that fosters scalable approaches	• Germany's Consent Creator Service • EC's eHealth Initiative 2007 • Health Data Research UK

area
Source: A.T. Kearney; IQVIA analysis