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

Author: Vincent Clay  *  Date: 04/10/2018  *  Version: Draft
From the ‘Taking action on cancer together’ paper

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

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

1. Report
2. Narrative
3. Data sources & initiatives
4. Barriers
5. Trends
6. Strategic solutions
7. Country profiles
   - BE, CH, DE, ES, FR, IT, NL, PL, SE, UK

Source: A.T. Kearney; IQVIA

## What is oncology data used for?

<table>
<thead>
<tr>
<th>Application</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D enablement</td>
<td>To support identification of promising compounds, investigation of the genome &amp; smarter clinical trials</td>
</tr>
<tr>
<td>Healthcare context</td>
<td>To understand the context of the disease &amp; patient populations (e.g. population, biomarkers / genetic characteristics &amp; unmet need)</td>
</tr>
<tr>
<td>Treatment patterns</td>
<td>To understand real-world usage of anti-cancer treatments, including by patient group, line of therapy &amp; geography</td>
</tr>
<tr>
<td>Real-world clinical value</td>
<td>To measure the delivery of cancer interventions’ clinical promise in a real-world setting (including outcomes &amp; safety, quality assurance, etc.)</td>
</tr>
<tr>
<td>Socio-econ value</td>
<td>To measure the value of cancer interventions beyond that provided to patients &amp; health systems (inc. lost employment, absenteeism…)</td>
</tr>
<tr>
<td>Pricing enablement</td>
<td>To provide a mechanism for flexible pricing, based on use, indication and/or outcomes</td>
</tr>
<tr>
<td>Patient perspective</td>
<td>To offer insight into Quality of Life (inc. Patient Reported Outcomes), covering aspects of care beyond clinical outcomes</td>
</tr>
</tbody>
</table>

Source: 1. EFPIA
Where does oncology data come from?

### Types of data sources

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

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

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

Source: IQVIA RWD Catalogue; IQVIA research
Where does oncology data come from?

Overview of data sources in Europe*1

Types of sources

Focus of sources, by therapy area

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

Source: 1. IQVIA RWD Catalogue & IQVIA research
Where does oncology data come from?

Distribution of known oncology data sources across Europe (absolute)

Number of sources
- ≤ 10
- 10 ≤ 50
- 50 ≤ 100
- 100 ≤

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

Number of sources
- ≤ 1
- 1 ≤ 5
- 5 ≤ 10
- 10 ≤

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

Source: IQVIA RWD Catalogue; IQVIA research
What are the barriers to more effective use of oncology data?

<table>
<thead>
<tr>
<th>Data</th>
<th>Structure</th>
<th>Process</th>
<th>Technology</th>
<th>People</th>
</tr>
</thead>
</table>
| - Limited collection of relevant data (e.g. PFS, ECOG score, DNA)  
- Lack of recognition of certain endpoints  
- Inability to consider unstructured data  
- Different coding for structured data  
- No standards in minimum data required  
- Insufficient quality control mechanisms | - Lack of aligned European & national approach to data, inc. ability to legislate locally on health data  
- Insufficient, short-term funding  
- Fragmentation of funding sources  
- Complexity in accessing funding  
- Limited linkage due to lack of single identifying numbers and complex processes / legislation to link data | - Diversity & lack of clarity in rationale needed for data collection & use  
- Diversity & complexity of access requirements, inc. need to go via third party  
- Large number of stakeholders controlling access, with divergent interests  
- Complexity & lack of timeliness of patient consent processes  
- Need for inbuilt data protection & associated burden | - Lack of interoperability due to numerous systems & lack of clear rules  
- Low user-friendliness of software & high requirement for manual processing  
- Outdated technology surpassed by new processing requirements | - Lack of data science skills & related training  
- Vested interests in limiting access to & sharing of data  
- Concerns around data privacy & protection |

ECOG=Eastern Cooperative Oncology Group; PFS=progression-free survival
Source: 1. A.T. Kearney analysis; 2. IQVIA analysis
Several trends will have a critical impact on oncology data in Europe

Overview of current & future trends, by category

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

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

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

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

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

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

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

**Competitive environment**

**Health & legal system**

**Data-applied technology**

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

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

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

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

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

**Outcomes**
Based models focus on patient outcomes & value delivered to determine remuneration

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

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

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

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

GDPR = General Data Protection Regulation; HCP = health care professional; HTA = health technology assessment; MEA = managed entry agreement; PRO = patient reported outcome

Source: 16 interviews with oncology & RWD experts across 11 pharmaceutical companies (April 2018)
The trends affecting the oncology data landscape are at various stages of evolution, from early concept to full-scale use.

### Summary of current & future trends, by evolution stage

<table>
<thead>
<tr>
<th>Technology trigger</th>
<th>Peak of inflated expectations</th>
<th>Trough of disillusionment</th>
<th>Slope of enlightenment</th>
<th>Plateau of productivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conceptualisation of idea</td>
<td>Implementation by early adopters</td>
<td>Flaws &amp; failures lead to disappointment in the idea</td>
<td>Further applications are understood &amp; implementation increases</td>
<td>Wide-scale implementation &amp; understanding</td>
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<td>AI &amp; machine learning</td>
<td>Simulation – ethical concerns &amp; a lack of regulatory buy-in prevent use; datasets can take up to a decade to mature for use</td>
<td>Integration of data vendors &amp; pharma – healthcare M&amp;A is at a 10-year high, but the focus is on ensuring sustained revenues</td>
<td>Outcomes-based models – some EU countries are pioneers (e.g. Italy) &amp; adoption is rising at a comfortable rate</td>
<td>Personalised medicine – specific disease types are being treated on a small scale, but implementation is proving slower than expected</td>
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<td>Blockchain</td>
<td>Financial sustainability – in the wake of the financial crash, the EC, ECB &amp; IMF introduced policies to assist with the costs of pharmaceuticals</td>
<td>Big Data – there is a lack of political will to invest in &amp; commit to Big Data; there are currently skill gaps in data analytics</td>
<td>GDPR – this takes effects at the end of May 2018, with devolved legislation open to local interpretations; radical impacts will be realised once local implementation takes place</td>
<td>Accelerated &amp; adaptive pathways – drugs are offered on an accelerated path in certain serious &amp; unusual circumstances, or where they show significant improvement over existing treatments</td>
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<td>Regulatory use of RWD – use is common in the US, but patient safety concerns in the EU are hindering widespread adoption</td>
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<td>mHealth – apps &amp; devices are generating enormous amounts of peripheral &amp; behavioural data, which can bolster how therapy is provided</td>
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GDPR = general data protection regulation; HCP = health care professional; HTA = health technology assessment; MEA = managed entry agreement; PRO = patient reported outcome

Source: 16 interviews with oncology & RWD experts across 11 pharmaceutical companies (April 2018)
What existing initiatives are trying to make this data more usable?

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<th>Improve Collation</th>
<th>Standardise Data</th>
<th>Collect New Data Types</th>
</tr>
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<tr>
<td>Aims to improve access to existing datasets or allow their interrogation</td>
<td>Aims to incorporate existing datasets into a central repository</td>
<td>Aims to standardise the ways in which data is collected so that datasets re comparable</td>
<td>Aims to collect data that does not yet exist, often via novel approaches</td>
</tr>
</tbody>
</table>

- **BD4BO**
- **CODE**
- **GOBDA**
- HemoBase
- IMI Harmony
- **INSITE**
- PHEDRA
- POI
- **Simulacrum**
- Cancer Core Europe
- **ECIBC**
- **ECIS**
- **EUROCARE**
- HMRN
- ENCR
- EUCAN
- EUSOMA
- Greater Manchester Cancer
- **IMI Protect**
- Innovative Pricing Solutions
- I-O Optimise
- **REAL Oncology**
- Sarcoma BCB
- EHDN
- **GA4GH**
- GEKID
- FRANCIM
- Health Informatics Collaborative
- ICHOM
- **OMOP Oncology**
- **100,000 Genomes Project**
- AURORA
- EUROSTAT
- **CRISP**
- **IRONMAN**
- **OWise**
- **My Clinical Outcomes**
- SCAN-B
- Universal Cancer Databank
- **WEB-RADR**

A number of initiatives touch upon a second category. For example, CRISP, a cohort study, has found that they will need to set up a standardisation framework in order to proceed with work.
19 initiatives profiled, with insight into the aims, scope and impact of this effort

**Initiative Profile**

**Owise by Px Healthcare**

Dr Anne Bruinvels (Founder, Px Healthcare)

**Started:** 2012

**Status:** Active

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

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

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

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

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

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

**Use Cases:**

- **Main focus**
  - R&D enablement
  - Healthcare context
  - Treatment patterns
  - Real-world clinical value
  - Socio-econ. value

- **Additional**
  - Pricing enablement
  - Patient perspective

**Barriers (top 3):**

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

Source: IQVIA research
To overcome these barriers, several solutions can support both oncology and general health data, led by different stakeholders. 28 possible initiatives identified, in nine focus areas

<table>
<thead>
<tr>
<th>Prioritised focus areas</th>
<th>Rationale</th>
</tr>
</thead>
</table>
| 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                                                                                                                |

HCP = health care professional; GDPR = general data protection regulation  
Source: A.T. Kearney; IQVIA analysis
All stakeholders have a role to play in implementing solutions to improve the oncology health data environment

Actions for health data stakeholders

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

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

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

1. Improve understanding & use of technology to support health data & use cases
2. Build awareness of data science as a core R&D & health skill
3. Address GDPR locally to ensure use of health data
4. Create an environment that fosters scalability & long-term funding
5. Develop alignment on EU & national grants for health data

Source: 1. EFPIA
What further actions could help to improve the effective use of oncology data?

**Recommendations to improve data**

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

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

Notes: = mentioned by previous studies as common therapeutic areas (EMINet, Ferrario et al., 2017; Gerkens et al., 2017; Gonçalves et al., 2016); * Osteoporosis and Orphan medicines were also mentioned.
Innovative pricing models: types and definitions

- **Value based Pricing**
  - **Indication based pricing**
    - Value-based assessment at launch setting net price for new indication
  - **Combination based pricing**
    - Value-based assessment at launch setting net price for new combination
  - **Outcomes based assessments (risk-sharing)**
    - Variable Net Price dependent on patient outcomes / treatment duration (pre-defined)
  - **Multi-Annual / Outcomes based payments**
    - Variable price linking short-term treatment to long-term patient outcomes
Examples of how innovative pricing models can be implemented

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

2. Recommendations for everyone

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3. Relevance for medicines

- **Better data** → **Better assessment of value**

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

→ **Better outcomes for patients**