




European Federation of Pharmaceutical Industries and Associations

EFPIA

Oncology data landscape in Europe

Trends affecting health data
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A.T. Kearney

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

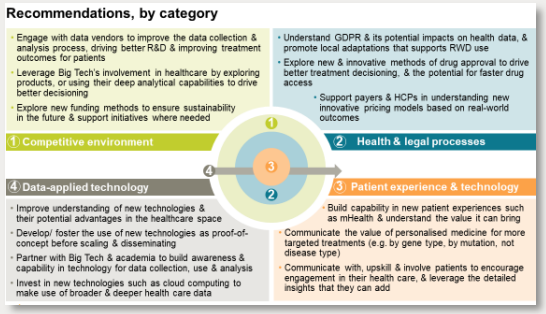
- This document outlines the **key trends in the healthcare landscape** and their potential impact on health data
- We conducted a **landscape review and ~40 interviews** (16 internal interviews with oncology and RWD experts across 11 pharmaceutical companies and 22 external interviews across 8 countries)
- The key trends fall into four categories:
  - **Competitive environment** (e.g. integration of Pharma and data vendors, emergence of Big Tech) – trends will affect data in the short-term and policy has limited scope to influence, but the impact will be positive (except for 'financial sustainability')
  - **Health and legal processes** (e.g. outcomes-based models, regulatory use of RWD) – trends will affect data in the short-term, but policy influence scope is high and the impacts on health data will be largely positive (except for 'GDPR')
  - **Patient experience and technology** (e.g. PROs & patient empowerment, mHealth) – trends have the potential in the short-term to improve the health data landscape, but scope for policy influence is moderate
  - **Data-applied technology** (e.g. AI and machine learning, blockchain) – trends will have a positive affect on health data in the mid to long-term, but scope for policy influence is low
- Policy action should **focus on short-term trends** that will have a **negative impact** on health data, such as **GDPR and financial sustainability,** as well as **health and legal processes**
- At the request of EFPIA, **additional insights into the new GDPR** have been detailed

Contents

Trends have been categorised by theme and rated based on criteria; further detail on risks and opportunities has been outlined

Method of trend analysis

Categorisation



1. **Competitive environment**
2. **Patient experience & tech**
3. **Health & legal processes**
4. **Data-applied technology**

Ratings by criteria & maturity

Potential impact: Negative · Neutral · Positive

Critical timing[1]: Long-term · Mid-term · Short-term

Scope for policy: Low · Medium · High

Gartner[2] evolution stage

1. **Technology trigger** – conceptualisation
2. **Peak of inflated expectations** – implementation by early adopters
3. **Trough of disillusionment** – flaws & failures lead to disappointment
4. **Slope of enlightenment** – further applications are understood & implementation increases
5. **Plateau of productivity** – wide-scale implementation & good understanding

Detailed trend analysis

- What is the trend?
- How is it evolving?
- What are the opportunities?
- What are the risks?
- Where is it being used?

1. Short-term = <2 years; mid-term = 2-5 years; long-term = >5 years
2. Gartner hype cycle

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

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

Method of trend analysis: interviews

Internal 'trend' interviews

- **16** interviews conducted
- **11** companies covered

AstraZeneca, Pfizer, Boehringer Ingelheim, MSD, Roche, Bayer, Lilly, abpi, Novartis, Merck, Takeda

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

External 'trend' interviews

- **21** interviews conducted

European Medicines Agency, The Christie, KV Hessen, SciLifeLab, Università di Roma Tor Vergata, Servizio Sanitario Regionale Emilia-Romagna, European Cancer Patient Coalition

- **8** countries covered + EU

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

External 'initiative' interviews

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

Global Alliance for Genomics & Health, Genomics England, My Clinical Outcomes, wise breast cancer, InSite, NHS The Christie NHS Foundation Trust, WEB-RADR, Public Health England, code, EUROCARE

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

Source: EFPIA; A.T. Kearney; IQVIA

Contents

Several trends are currently affecting the healthcare space and will have a critical impact on health data in Europe

Overview of current & future trends, by category

1 Competitive environment

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

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

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

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

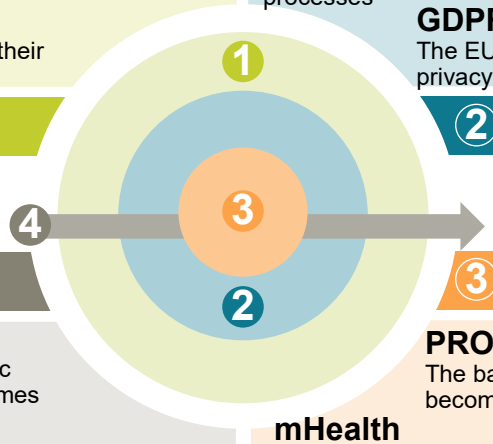
2 Health & legal system

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

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

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

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



3 Patient experience & technology

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

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

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

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

4 Data-applied technology

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

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

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

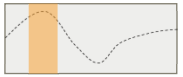
Big Data
Large volumes of fast, complex & varied data require advance methods to collect, distribute, store & manage it, & can be applied to health data

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

The commercial value of health data is clear, but European stakeholders are reluctant to turn data into a commodity

Trends 'deep-dive': monetisation of health data

Peak of inflated expectations



What is it?
- Health data has intrinsic value to numerous stakeholders due to its multiple uses & applications (R&D, treatments, genomic medicine) so by trading data on an open marketplace, stakeholders (e.g. patients, HCPs, data sources) can realise this value

What are the potential applications?
- **Patient ownership & benefit** – patients can have greater control over their data through agreed purchase contracts
- **Transparent marketplace** – clear audit trails & authentic data is available for trading on a secure marketplace
- **Increased data quality & sharing** – by incentivising patients & HCPs to share data, data quality is improved (fewer gaps, better representation) & data ownership is made clear
- **Enriched data used to improve medical diagnosis** – by selling insights from patient data to Big Tech firms, HCPs ensure data is used for clinical research & machine learning

What are the potential risks?
- **Ethical concerns** – patients prefer to share data altruistically for the benefit of future health care, especially in publicly-funded systems
- **Weakening position of trust** – by pursuing commercial interests in data monetisation, health companies put their trust & integrity with consumers at risk
- **Hacking risks** – the data market could tempt fraudsters to monetise illegally obtained & sensitive personal data
- **Strict regulation** – e.g. anti-monetisation legislation in Finland prevents companies selling patient data

Where is it being used?
- Longenesis, a US healthcare AI company, has partnered with an Estonia start-up, **Neuromation**, to develop a **global data marketplace** enabled by **blockchain technology;** patients can sell blood data for cryptocurrency
- Nebula Genomic is a **marketplace enabled by blockchain**, allowing patients to **monetise their genomic data**; it **improves the availability** of genomic data for research purposes & **supports the building of Big Data** genomic databases

How is it evolving?
- **Blockchain** will **enable monetisation** of health data, but ethical issues & data privacy & security concerns create an adverse mindset
- This is taking place in the US, but **unlikely to find root in the EU**

Potential impact	●
Critical timing	🕒🕒🕒
Scope for policy	■■□

AI = artificial intelligence; HCP = health care professional
Source: R& "RWD L&scape in Europe" (2014); Foley "Tapping into the Big Value of Heath Data"; PLDW Healthcare "Monetising Health Care Data"; HealthManagement Website; Motherboard.vice Website; A.T. Kearney analysis

The focus on realising short-term value and cost-containment hinders investment in initiatives that give long-term sustainability

Trends 'deep-dive': financial sustainability

Trough of disillusionment

What is it?
- Governments & payers, faced with ageing populations & unfavourable dependency ratios, are cutting down costs instead of supporting long-term investment in public health & technology

What are the potential applications?
- **Increased focus on value** – the growing demand for RWD to inform regulation & enable HTAs & payers to monitor efficiency will encourage focus on the value of innovation
- **Increased use of mHealth** – automating care administration & disease monitoring via apps & devices will enable more detailed, real-time data to be collected
- **Increased self-management of disease** – better health literacy & understanding of chronic disease management will reduce the burden on healthcare systems & empower patients in the use & application of their health data

What are the potential risks?
- **Lower willingness to invest in RWD** – current attitudes focus on realising returns faster, rather than on developing RWD & infrastructure which requires a long-term view
- **Lower willingness to invest in innovation** – a stringent focus on cost-containment & concerns around budgetary impacts could limit investment in innovations such as outcome-based models, which depend on the creation of RWD

Where does it apply?
- In Portugal, the use of MEAs for new medicines is **increasing year on year** (12% of all new compounds in 2011); three quarters of all agreements in Europe are aimed at **addressing budgetary impacts**
- Across Europe, the use of mHealth is delivering more **cost-effective activities such as the training of HCPs;** in France, training on **computerised systems** for doctors & nurses is obligatory

How is it evolving?
- In the wake of the 2008 crash, the **EC, ECB and IMF** put in place policies to help Ireland, Greece, Portugal & others to **limit drug budget impact**
- Today, **reimbursement** of new drugs can be delayed to manage affordability

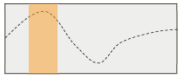
Potential impact	●
Critical timing	◷
Scope for policy	■■□

HCP = health care professional; HTA = health technology assessment; MEA = managed entry agreements
Source: Global Health "Operationalising mHealth to improve patient care"; Ferrario "MEAs in Europe"; "mHealth sub-group - Report on national mHealth strategies": A.T. Kearney research

By acquiring or partnering with data vendors, Big Pharma can leverage data expertise, but current activity is confined to the US

Trends 'deep-dive': integration of data vendors

Peak of inflated expectations



What is it?
- The advent of digital startups & dedicated tech companies in health have introduced dedicated capabilities & innovative solutions to extract more value from health data; Pharma companies are increasingly investing in or buying these companies

What are the potential applications?
- **Faster & easier access to health data** – partnerships with data vendors specialising in the collection & process of health data will speed up access where it has been traditionally slow
- **Greater analytical ability** – leveraging the core analytical capabilities of vendors will extract more value from data
- **Enhanced R&D for drug development & personalised healthcare** – Big Pharma can enhance its R&D efforts, & focus on patient-specific treatments for complex disease by utilising greater insights from data

What are the potential risks?
- **Patient involvement issues** – recruitment of patients for clinical trials is a significant hindrance to oncology drug development; issues around consent management & a lack of visibility discourage engagement via an intermediary
- **Faster tracking of drug efficacy** – RWD increases the patient monitoring speed, thus highlighting an ineffective drug almost immediately; Pharma must move to accommodate the new, heightened sensitivity of tracking to small signals

Where is it being used?
- **Roche** acquired **Flatiron Health** in 2018, an oncology EHR vendor & curator of RWD data, to develop **personalised treatments &** improve the RWD **regulatory landscape**
- **Foundation Medicine**, a molecular information company, entered into a strategic collaboration with Roche in 2015 to develop more **personalised cancer treatment through deep genomic analysis**
- **Cota** collects oncologists' data via **automation & manual extraction** for **personalised cancer care**; **Novartis** was a 2nd round investor

How is it evolving?
- Healthcare M&A is at a **10-year high ($39bn to start 2018),** but Pharma are focusing on consolidating due to a **loss of key patents**, rather than health data
- **US tax reform** may spur global activity from 2018 due to repatriated cash

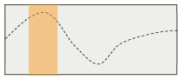
Potential impact	●
Critical timing	◷◷
Scope for policy	■□□

Source: Forbes Website; Roche Website; Morgan Stanley Website; Harvard Business Review; A.T. Kearney analysis

The emergence of Big Tech could disrupt the health paradigm, but products are still at early pilot stage with limited application

Trends 'deep-dive': emergence of Big Tech

Peak of inflated expectations



What is it?
- Big technology players such as Google & Amazon, are beginning to leverage their expertise in Big Data & deep analytics, as well their large footprint across traditional digital consumer products & services to enter the health industry

What are the potential applications?
- **Improved data landscape** – existing fragmented Big Datasets are easily integrated into new global cloud solutions, creating vast networks of easily-shared data
- **Better understanding of complex diseases** – the deep analytical abilities & decision algorithms of Big Tech enable complex diseases to be treated in new ways
- **New health services** – existing capabilities in consumer products & other data services allows Big Tech firms to launch new health services, improving upon the efficiency & costs of current healthcare systems & services

What are the potential risks?
- **Threat of monopoly** – large, powerful entities such as Google have the financial stability to sidestep regulation & limited incentives to share data with other stakeholders
- **Unproven health expertise** – Big Tech firms are unfamiliar with the healthcare as a heavily regulated industry which could lead to mismanagement, errors & poor solutions with a bad reputation
- **Unknown territory** – entering the health space is outside the comfort zone of Big Tech firms & the response of the public, regulator & other incumbent players is unknown

Where is it being used?
- Verily, Alphabet's health data research unit, developed a **study watch in 2017 to collect heart rate, gait & skin temperature data**, & launched a **study on 10,000** patients called Project Baseline
- Apple launched the **Apple ResearchKit in 2015** to enable health researchers to **enroll participants in mass;** GSK is an early adopter
- In 2018, Google has launched its **Cloud Healthcare API** which provides a **robust, scalable infrastructure** for linking various healthcare data types (e.g. HL7, FHIR, DICOM)

How is it evolving?
- **Big Tech M&A activity** in healthcare has **increased** ($277m in 2012, $2.7bn in 2017[1]), but products are in **early pilot stage**
- **Core capabilities** of Big Tech firms are not in health so **evolution is slow**

Potential impact	●
Critical timing	◷
Scope for policy	▮▯▯

1. In the United States; DICOM = Digital Imaging and Communications in Medicine; FHIR = Fast Healthcare Interoperability Resources; HL = Health Level
Source: NY Times Website; Freedom Lab "Big Tech & the Healthcare System" (2018); HealthCare Website; Google Cloud API Website; A.T. Kearney analysis

Outcomes-based agreements could increase flexibility around value, but complexity and uncertainty in implementation limit use

Trends 'deep-dive': outcomes-based models

Trough of disillusionment

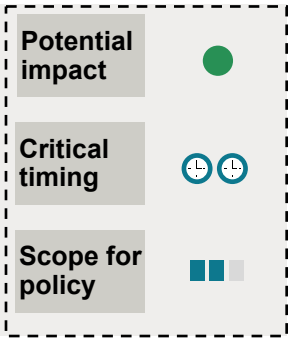
What is it?
- Models that focus on patient outcomes & value delivered to determine the remuneration that companies receive for their health products & to enable a wider range of drug availability, are being adopted as part of new innovative contracts

What are the potential applications?
- **Evidence-based approval of innovative medicines** – the focus on patient outcomes instead of cost promotes the collection & use of RWD
- **Better coverage decisions** – by using outcomes-based models, payers can review the P&R of innovations based on real patient outcomes & adjust their approaches
- **Improved RWD quality** – the use of RWD for outcomes-based decisioning requires & will foster greater quality standard

What are the potential risks?
- **Lack of experience** – few countries have experience with complex contracting & outcome tracking so negotiating MEAs is challenging
- **Data complexity** – collecting & processing of RWD for evidence-based decisions is expensive & time-consuming
- **Resistance from payers** – the additional resources required to support RWD is seen as an admin burden by HCPs & payers
- **Restrictive regulation** – some countries (e.g. Germany & France) have restrictive data requirements for payer decision purposes & if made mandatory, they could be burdening & prevent use

Where is it being used?
- **Zilveren Kruis** has agreed a 10-year deal with **Diabeter** to prioritise **long-term patient outcomes** by taking a **value-based approach** towards care for Type 1 diabetes; the patient & HCP choose which care would be best, based on **100 patient outcome metrics**
- In **Italy**, a cancer drug called cetuximab has been agreed under an MEA which includes **payment by results**, **monitoring of a registry** & **risk-sharing** for both head & neck, & colorectal cancers
- In **France, Italy & Spain**, a **hepatitis C cure**, Sovaldi, was agreed between **Gilead** & payers based on an **outcomes-based MEA**

How is it evolving?
- Some countries (**Italy**, **Netherlands**) are **pioneers** & adoption is **rising at a comfortable pace**
- A **strategic commercial unit** has been set up to encourage 'novel risk-sharing agreements' between the **NHS & innovators** in the UK



1. A metastatic colorectal cancer treatment; HCP = health care professional; MEA = managed entry agreement

Source: PharmPhorum (2015) "Does RWD matter in health technology assessments?"; DataMonitor Health care. (2016). Key Trends in the European Market Access; "Outcomes-based reimbursement of Medicines"; Zilveren Kruis Website; A.T. Kearney analysis

Regulatory bodies are adopting RWD to drive decision making, but issues with datasets are prevalent and RCTs are preferred

Trends 'deep-dive': regulatory use of RWD

Plateau of productivity

What is it?
- RWD has been primarily used in regulatory systems for pharmacovigilance, to monitor products' safety after they reach the market, but opportunities exist to leverage RWD at a large scale could pioneer its use for granting new market authorisations

What are the potential applications?
- **Supplementation of evidence with real-life impact** – RWD can continue to contribute to post-approval safety & effectiveness profiling, & track long-term outcomes
- **Evidence development where other methods impractical** – in rare diseases the potential sample size is small & single-arm RCTs are not reliable; RWD bypasses this issue allowing data to be filtered on specific sub-populations
- **Provision of preliminary data for accelerated pathways** – RWD can be provided earlier on in the approvals process accelerating access to certain drugs

What are the potential risks?
- **Methodological limitations of RWD** – by design, RWD lacks consideration for the risks of drugs in the real world
- **Increased burden to collect & analyse** – to enable RWD use for regulation, additional resources must be focused on collecting quality data & analysing it appropriately
- **Limited regulator capabilities** – the additional onus on the regulator to assess & manage RWD is burdening
- **Unclear hierarchy of evidence** – RCTs remaining the 'gold standard' limits the trust in regulatory assessments relying heavily on RWD

Where is it being used?

- In the UK, NICE **advises the use of registry data** for data mapping & definition of clinical data, but it is **not a requirement**
- The **FDA** has made progress using RWD for **rare disease drug development & post-market safety surveillance**
  - To date it has been used for the **approval of NDA submissions** for rare diseases or in small population settings

How is it evolving?
- The use of RWD for regulatory purposes is **growing rapidly in the US**, but more **slowly in the EU** due to ethical **concerns around patient safety**

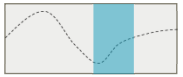
Potential impact	●
Critical timing	◷
Scope for policy	■■■

EMA = European Medicines Agency; NDA = new drug application
Source: Margols Centre for Health Policy "A Framework for Regulatory Use of RWE" (2017); A.T. Kearney analysis

Use of RWE can accelerate regulatory processes and allow complex diseases to be treated sooner, but is not yet the norm

Trends 'deep-dive': accelerated & adaptive pathways

Slope of enlightenment



What is it?

- Adaptive pathways are a flexible approach to the regulation of drugs & biologics to improve the timely access for patients to new & innovative medicines. Accelerated pathways entail the review of current processes to find ways of speeding up access

What are the potential applications?

- **Faster regulatory approval** – a commitment to faster pathways will allow faster access to innovative drugs for seriously ill patients
- **More efficient drug development** – by highlighting the most-effective drugs earlier in the process, further costs to pass through lengthy regulatory channels will be reduced
- **International regulatory harmonisation** – the approval of innovations by at least two international benchmark agencies will standardise processes & save costs/resources when assessing for real-world use

What are the potential risks?

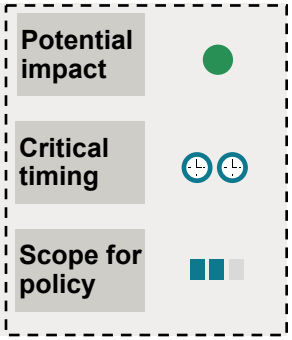
- **Diversity in member state interests** – differences in approval requirements & treatment paradigms will hinder universal standardisation of regulatory approval
- **Ethical issues & patient consent** – the access to drugs not yet approved presents ethical questions around choice of which sub-population to choose for treatment
- **Drug recalls** – where a drug has had early approval for treatment, patients may lobby to keep it even if it is later proven to be unsafe

Where is it being used?

- The European **adaptive pathways approach** is designed to improve **timely access for patients to new medicines**; post-market authorisation decisioning & use in medical practice forms part of an extension to the **Medicines Adaptive Pathways to Patients (MAPPs)**
- The EMA has **reduced the limit for approval** of new products from 210 to 150 days as part of its **Accelerated Assessment Program**
- In France, an antidiabetic drug called Glitazone was introduced **contingent on performance** (which is measured using RWE)

How is it evolving?

- Currently offered in situations of **serious conditions**, major public **interest** or where there is **significant improvement** over existing treatments
- The number of drugs **approved** via adaptive methods by the EMA & FDA is increasing year on year

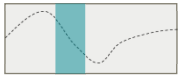


EMA = European Medicines Agency; MDSAP = Medical Device Single Audit Program
Source: RAND "Early Adoption of Medical Innovations" (2015); A.T. Kearney analysis

GDPR replaced the previous directive in May 2018, covering all EU countries with some national-level flexibility

Trends 'deep-dive': GDPR

Trough of disillusionment



What is it?
- The GDPR is a new data law in the EU that aims to harmonise data privacy laws across Europe; protect & empower all EU citizens; & reshape the way organisations across the region approach data privacy

What are the potential applications?
- **Data harmonisation & codes of conduct** – opportunities exist to define clear standards for health data & demonstrate leading compliance in the industry
- **Patient ownership & empowerment** – greater control over data & rights to access & rectification will improve data quality & potentially accessibility
- **Increased protection & accountability** – GDPR will tighten data protection laws ensuring a greater level of protection for sensitive patient data & ensure those who handle data are accountable & must conform

What are the potential risks?
- **Restricted ability to collect data deemed sensitive** – increased scrutiny & disparities arising from local interpretation could hinder research & innovation
- **Increased onus on data controller** – greater consent, ownership & control privileges may overburden patients
- **New investment is needed** – in order to to implement & adopt laws (e.g. DPO) thus straining economic resources
- **Threat of fines** – fines could weaken public trust (if issued publicly), prevent data collection & sharing, as well as hinder data processors & innovators

Where does it apply?
- European-level application of GDPR defines **more types of sensitive data** but country autonomy allows **differing conditions & requirements** to be developed
- Laws apply to **biometric, genetic & personal health data**
- **Exceptions** for HCPs **processing patient data** for **health care** will apply
- A **European Data Protection Board** will have powers to **enforce application of GDPR** across EU member states, & **data protection officers** will need to be appointed at the **national level & across large institutions**

How is it evolving?
- Legislation took effect across Europe on **25th May**
- Devolves legislation to local level; **open to interpretation**
- **Baseline impact** from May that can change radically once countries start implementing their own laws

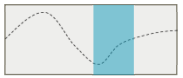
Potential impact	●
Critical timing	🕒
Scope for policy	■■■

GDPR = General Data Protection Regulation; DPO = data protection officer
Source: Hogan Lovells 'The Final GDPR Text & What It Will Mean for Health Data' (2016); Noerr. 'Taking advantage of patient data – an outlook on the upcoming General Data Protection Regulation' (2017); BHBIA 'GDPR Quick Guide' & 'GDPR Legal Grounds for Data Processing' (2017); IGA. 'The GDPR: What's New'; A.T. Kearney analysis

Patient involvement is improving R&D and treatment; mHealth and Big Data will disrupt the traditional PRO process

Trends 'deep-dive': PROs & patient empowerment

Slope of enlightenment



What is it?

- Power is shifting from HCPs to patients through the involvement of: patients in patient reported outcomes (PROs) for disease management & quality of life monitoring; patient associations in HTA decisions; & general patient engagement with care

What are the potential applications?

- **R&D enhancement** – increased enrollment & retention rates in clinical studies leads to a greater trust in HCPs & more relevant research to address observed patient outcomes
- **Better health literacy** – improving patient health education
- **"Democratisation" of the clinical process** – an ethical mandate for patient participation & ownership of data, leads to greater credibility of results & a more transparent clinical practice
- **Tracking treatment response** – real-time tracking of responses enhanced by mHealth data leads to improved treatment decisions & predictive & preemptive care

What are the potential risks?

- **Micro-level view of health decisions** – patients are often preoccupied with their own health interests & do not take a more comprehensive view of the wider situation
- **Overburdening of patients** – where digital literacy is low & patient lack the required skillset to engage with PROs, patients may feel overburdened with the process
- **HCP mindset** – HCPs lack widespread engagement in the value of PROs; fundamental attitude change is needed across healthcare to foster support & buy-in

Where is it being used?

- In Sweden, a **new platform** for access to health information **assigns data ownership rights** to the patient & allows clear consent rules
- **23andMe** offers a consumer-facing mail-order saliva test to determine a patient's **genetic predisposition to disease** as well as additional services such as **genealogy to track ancestry**
- In the **UK, NICE** has recommended the **use of patient scores** (QoL-AGHDA) as one of three criteria when **judging suitability for treatment** with a recombinant human growth hormone

How is it evolving?

- Both the EMA & FDA are **calling for increased use of PROs** (e.g. Biomarker Qualification program)
- However, use & **recognition is currently limited** – fewer than 30% of data sheets include PROs

Potential impact	●
Critical timing	◷◷
Scope for policy	■■■

PRO = Patient Reported Outcomes; EMA = European Medicines Agency; QoI – AGHDA = quality of life in adult growth hormone deficiency scale

Source: "Patient empowerment: for better quality, more sustainable health services globally" (2014); Gartner "Hype Cycle for Consumer Engagement With Healthcare & Wellness" (2017); Domeck "Patient Engagement in Research" (2014); Scot "Patient Advocate Perspectives on HTA Involvement" (2017); MedCare "Putting Patient Perspective in Patient-Centred Outcomes Research"; A.T. Kearney analysis

mHealth is nearing widespread use as innovative devices to track health are launched, but rapid growth may overload analysts

Trends 'deep-dive': mHealth

Plateau of productivity

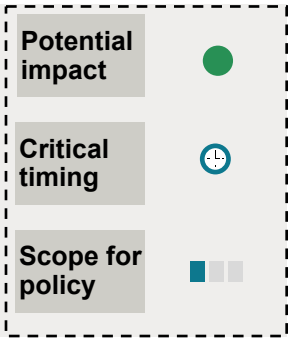
What is it?
- An abbreviation for "mobile health", mHealth refers to the practice of using mobile devices such as smartphones, PDAs & wearables, to provide access to various healthcare services, information & for health data collection

What are the potential applications?
- **Improved patient data landscape** – applications that allow patients to report outcomes will make health data reporting easier, improving availability & quality
- **Real-time diagnosis, disease tracking & drug effectiveness** – sensors & devices that monitor health signals will allow in real-time: diagnosis of disease based on signal patterns; tracking of disease development to support research; & efficacy of drugs
- **Adherence to treatment** – wearable technology will enable HCPs to track & improve patients' adherence to treatment, enabling more drug effectiveness data for monitoring

What are the potential risks?
- **Information overload & poor linkage** – multiple devices per patient & differing vendors & systems will make linkage difficult & interpretation of data complex
- **Public mindset** – concerns around data privacy & security may prevent widespread adoption of devices such as smart pills & body sensors as patients feel they lack control over data collection & management
- **Increasing data regulation** – GDPR laws will require careful navigation as data collection & patient consent frameworks become more complex & strict

Where is it being used?
- **Apples' Health App** allows US patients to access **EMRs from 39 different health systems** (e.g. Kaiser), improving patient involvement & reducing medical errors
- **GSK** partnered with **Propeller Health** to develop a **sensor** for the Ellipta inhaler to **collect data in clinical trials** of asthma & COPD patients
- **Cenvigo**, has developed an **mHealth application**, P&A, enabling **real-time communication between neurologist & patient**

How is it evolving?
- Connected devices are forecast to **grow at 23%** per year over the next 5 years
- For healthcare, that means **$410bn in value by 2022** from the monitoring & tracking of patient health

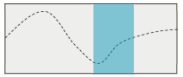


COPD = Chronic Obstructive Pulmonary Disease; P&A = Parkinson's Digital Assessment; PDA = personal digital assistant
Source: PwC "Socio-economic impact of mHealth" (2014); The Verge Website; The Medical Futurist Institute; mHealthIntelligence Website; A.T. Kearney analysis

Genetic sequencing will enable faster and more effective treatment based on gene type, but genetic data is highly sensitive

Trends 'deep-dive': genomics

Slope of enlightenment



What is it?

- Genomics is the mapping of genetic information using new sequencing methods. By understanding chromosomes down to the genetic level, scientists can understand the interactions of various diseases & treatment options with different gene types

What are the potential applications?

- **Personalised therapy** – sequencing genomic make-up allows drug development to become more tailored to genetic type rather than disease category, improving & tailoring patient outcomes & prognoses
- **Preemptive treatment** – patients predisposed to certain diseases can be treated earlier, before the disease develops
- **Faster understanding of drug effectiveness** – a clearer understanding of patient response to drugs according to gene type, effectiveness is determined quickly by monitoring gene type & disease response through EHRs & PROs

What are the potential risks?

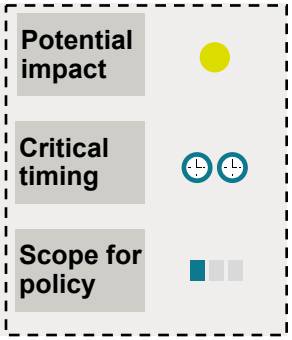
- **Complexity of treatment** – the vast array of genome types & disease interactions will lead to complex datasets for treatment decisions, requiring robust analytical skillsets
- **Genetic profiling risks** – by creating genetic profiles of patients, data may be misused to discriminate against certain genetic types (e.g. in insurance decisions)
- **Ethical issues regarding gene-specific treatment** – as use of preemptive treatments to correct for genetic defects becomes more widespread, concerns arise around genetic altering & the impacts on offspring

Where is it being used?

- **Google Genomics** uses the raw data power of its Cloud Platform to process, share & analyse large biological datasets with researchers
- **Pfizer** developed a cancer drug called **Xalkori** to target a small sub-set of non-small lung cancer patients with a **defect** in the ALK gene
- Devices such as **Inano's Bio Sensor** allow **faster genome sequencing** for early disease detection; **DNA Electronics' Genalysis** allows **POC diagnostic** without needing to send biological samples for testing

How is it evolving?

- Genetic sequencing will become **commonplace** as commercial attractiveness increases with a **fall in price**
- Innovative solutions entering the market will **bring down technology & processing costs**

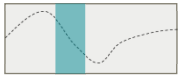


EHR = electronic health record; PRO = patient reported outcome; POC = point of care
Source: Medical Futurist; A.T. Kearney analysis

Personalised medicine has the potential to revolutionise patient-care, but the right infrastructure and use of Big Data are lacking

Trends 'deep-dive': personalised medicine

Trough of disillusionment



What is it?
- Personalised medicine is a new paradigm based on the use of smart technology & greater patient participation to assist in disease treatment, enabling targeted treatment options (including based on gene profile) & promoting general wellbeing

What are the potential applications?
- **Development of genome-specific treatments** – tailored treatments can be developed for specific gene profiles, driving better outcomes & fewer side-effects
- **Improved patient empowerment** – by signalling to patients that their individual disease & treatment matters could build trust & foster increased sharing of individual health data
- **POC personalisation** – understanding patients' genetic make-up could build more detailed datasets that enable a greater personalisation of care & treatment plans, including follow-ups & ongoing advice
- **Big Data & AI** – the rise of machine learning & use of big data will make the process of personalised medicine more efficient & cost-effective

What are the potential risks?
- **Limitations of RCTs** – the reliance on RCTs as the 'gold standard' means testing for highly-specific drugs in small sub-populations is limited
- **Financial burden** – the increased number of complex drugs developed requires high investment costs, though this may be addressed by innovations in 3-D drug printing

Where is it being used?
- Research into **specific gene mutations** of melanoma tumours has allowed the development of **targeted therapies,** such as **vemurafenib**, to be approved by the FDA
- **Crescendo's Vectra DA** is a multi-biomarker blood test that allows HCPs to **stratify patients genetically**, allowing **targeted RA therapy**
- Personal genetic services using **mail-order saliva tests** developed by **23&Me** have enabled **personalised, targeted medicine** according to genome, & the **monitoring & prediction of adverse outcomes**

How is it evolving?
- **Specific disease types** are being treated on a **small scale** (gene-specific cancers)
- **Predicted adoption is relatively low** – 8% of eHealth professionals in Europe see it as a big trend in the next 2-3 years

Potential impact	
Critical timing	
Scope for policy	

FDA = food and drug administration; POC = point of care; RA = rheumatoid arthritis
Source: 23&Me Website; Crescendo Biosciences Website; European Commission "Personalised Medicine Conference 2016"; A.T. Kearney analysis

Simulated datasets have low momentum to replace RCTs as the 'gold standard', but uses for eLearning could improve care quality

Trends 'deep-dive': simulation

Technology trigger

What is it?
- By using raw processing power, simulations can run millions of scenario analyses on virtual patients, whose characteristics, treatment approaches, environmental conditions, etc. are all informed by but distinct from real patients

What are the potential applications?
- **Bypassing privacy concerns** – by running simulations on virtual patients, sensitive data concerns are addressed
- **Simulated clinical trials** – clinical trials can be run quickly & cheaply, without putting clinical trial patients at risk
- **Faster drug efficiency checking** – the potential efficacy of a drug can be estimated earlier in the development stage, thus saving time & wasted resource from further development
- **Simulated eLearning platforms** – the quality of treatment can be improved by creating a simulated learning environment for HCPs to engage with virtual patients

What are the potential risks?
- **Ethical issues** – there is public concern around trusting a drug that has never be trialed on a living human & Pharma's incentives to save on cost through simulation; HCPs & regulators are lacking in buy-in
- **Complexity of biological systems** – the complexity in mathematical modelling required to simulate biological systems such as the human body, requires enormous computing power & available quality "seeding" data

Where is it being used?
- Simulacrum is an **AI simulation model** that uses health data to test the **feasibility of drugs before entering the strict approval process**; it is owned by Health Data Insight, a UK social enterprise
- The ADA engaged Archimedes Inc to **simulate a 30-year clinical trial** to **test treatment effectiveness** by calibrating maths equations with empirical data to carry out scenario analysis for a new diabetes drug
- During the **2009 influenza epidemic**, the FDA approved a **simulation to test the safe dosage** of Peramivir on children without trial

How is it evolving?
- Whilst the technology to enable simulation exists, **ethical concerns** & a **lack of regulatory buy-in** are preventing widespread use
- Datasets can take **up to a decade** to be suited for use in simulations

Potential impact	●
Critical timing	●●
Scope for policy	■□□

ADA = American Diabetes Association; MVSP = Multilingual Virtual Simulated Patient; P&R=pricing & reimbursement; RCT = Randomised Control Trial
Source: WHO "eHealth in the European Region" (2016); Applied Clinical Trials Online website; "Simulation of Clinical Trials" (2012); A.T. Kearney analysis

AI and machine learning could quicken diagnoses and enable predictive medicine, but concerns around accuracy and cost exist

Trends 'deep-dive': AI & machine learning

Technology trigger

What is it?

- AI is the use of computer intelligence to automate tasks & develop complex decision-based processes that can adapt & learn over time using machine learning, by mining Big Data & spotting processes & patterns on a large scale

What are the potential applications?

- **Data gaps** – automation of data collection & monitoring of data quality will fill data gaps in patients' medical records
- **Universal language** – machine learning can decipher differences in coding & language across datasets, including from unstructured data
- **Predictive, personalised healthcare** – deep learning from millions of patient data points could enable predictive & personalised health care for chronic conditions
- **Faster diagnosis** – new methods of diagnosis using AI can hasten the diagnosis time & improve accuracy

What are the potential risks?

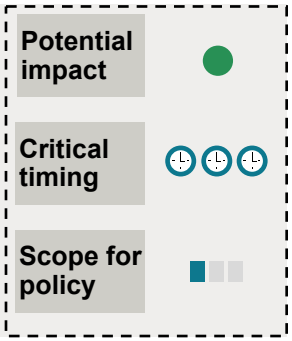
- **Accuracy of predictions** – the accuracy & reliability of long-term predictions is untested in healthcare
- **Lacking capabilities** – the technical skills needed are rare, costly & sought after
- **Low consistency & quality** – when presented with new & untested datasets, AI systems lose reliability; their current infancy means wide-ranging application is limited
- **Imperfect data-collecting devices** – devices to collect Big Data are lacking in accuracy (e.g. FitBits have a 20% error vs ECG readings, making calibration difficult)

Where is it being used?

- A university hospital in Indiana is using a Health Catalyst EDW & machine learning from catalyst.ai to **enrich EMR data** where **gaps are present**, to better inform the risks to patients from CLABSI
- **Lumiata have developed a clinical decision making algorithm called Risk Matric** that uses 160m data points from textbooks, journals & public data to predict the risks of disease to patients

How is it evolving?

- The industry is making sense of how to use vast amounts of data for **decisioning to improve treatment**
- **Predicted uptake is low** – 5% of eHealth professionals in Europe see it as a big trend in 2-3 years



AI = artificial intelligence; CLABSI = central line-associated bloodstream infection; ECG = electrocardiography EDW = enterprise data warehouse; PAC = Picture Archiving & Communications; Source: R& "RWD L&scape in Europe"; "Growing Impact of RWE" (2017);"The Opportunities & Risks of AI in Healthcare" (2016); HiMSS "Annual European eHealth Survey" (2017); Lumiata website; Enlitic Website'; Health Catalyst Website; A.T. Kearney analysis

Blockchain could revolutionise access and sharing of eHealth data, but current application is limited and risks are significant

Trends 'deep-dive': blockchain

Technology trigger

What is it?

- Blockchain is a list of data blocks that are linked & secured by complex codes & passwords, & accessed via an open, distributed ledger that is hosted & managed across a peer-to-peer community network with decentralised ownership rights

What are the potential applications?

- **EHRs** – blockchain could allow patients & HCPs to quickly access multiple medical records on an open-source, community-wide, trusted ledger, with a clear audit trail
- **R&D** – by developing a secure sharing platform, patients can share sensitive data via an open-source API with researchers to assist with drug development
- **mHealth** – by enabling large scale, Big Data collection in a secure & transparent platform, blockchain can magnify the potential of data collect through mHealth & wearables

What are the potential risks?

- **End-point vulnerability** – information is only as secure as the users accessing the end of the chain
- **Untested at scale** – the use of blockchain at a large scale is unknown territory – threats from mass fraud & exponential storage capacity growth may threaten scalability
- **Risk from blockchain systems & users** – weak systems, poor code & personnel vulnerabilities all threaten security
- **Lack of national standards & regulations** – the need for regulation will become stronger as blockchain is used for sensitive, personal data; currently, it does not exist

Where is it being used?

IBM Watson

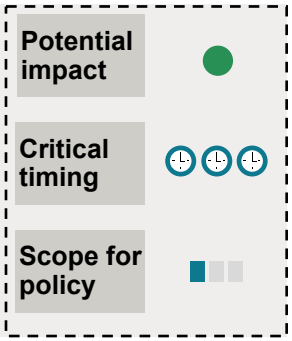
MEDICALCHAIN

MediLedger

- The **FDA is partnering with IBM Watson** to explore the use of blockchain for EHRs, clinical trials & genetic sequencing
- **MedicalChain** is a blockchain for EHRs that allows clear access control for patients; the **UK NHS has partnered** with the technology
- The **MediLedger** project brings together industry stakeholders to develop a process to improve the track & trace capabilities of prescription medicine; in 2017, it launched an **audit trail called ConnectingCare**

How is it evolving?

- Few startups have developed blockchain in healthcare, with limited application
- Predicted **uptake in the health industry is low** – 1% of eHealth professionals in Europe see it as a big trend in the next 2-3 years

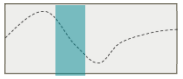


Distributed Ledger = consensus of shared digital data spread across multiple geographies; by design it has no central administrator or storage
API = application program interface; DLT=distributed ledger technology; EHR = electronic health record
Source: HiMSS "Annual European eHealth Survey" (2017); MedicalChain website; MediLedger website; A.T. Kearney analysis

Big Data know-how exists, but a lack of public buy-in and insufficiently advanced incumbent systems prevent uptake

Trends 'deep-dive': Big Data

Trough of disillusionment



What is it?
- Big Data represents large volumes of fast, complex & varied data from across countries & industries, that requires advanced technologies & techniques to collect, store, distribute, manage, & analyse it

What are the potential applications?
- **Improved R&D** – linked databases provide new research opportunities to analyse disease patterns & detect associations between exposures
- **Patient outcomes** – a greater understanding of specific disease responses & patterns improves public health surveillance & strategic decisions around health care
- **Improved efficiency** – big data can identify the most cost-effective treatments, enable care co-ordination (e.g. using linked EHR systems) & accelerate the development of innovative drugs, potentially reducing waste

What are the potential risks?
- **Risk of data overload** – using Big Data to drive decisioning can become overburdening if robust processes aren't in place to handle vast amounts of data
- **Data breaches** – the potential impact of a Big Data breach is much more damaging due to the linked network of datasets
- **Wasted data collection/irrelevant data** – overcollection of data may lose the focus on what data is actually required
- **Data & privacy concerns** – public & HCP concern for data security & privacy hinders the collection & sharing of patient-level data for Big Data networks

Where is it being used?
- **Eureka Health Oncology**, a new platform by **Precision Health.AI**, uses EMR **Big Data to aid R&D** with targeted therapies for cancer
- Molecular & physiological data is being collated by **Google X's** "Baseline Study" to drive **proactive medicine** focusing on **prevention**
- **GenieMD** uses IBM Watson to deep mine data from EMRs, wearables & lab to enable patients to ask health questions using natural language
- **Twitter** is trialing the **tracking of drug effectiveness** by filtering tweets for reported patient response to various treatments

How is it evolving?
- There is a **lack of political will** to invest in & commit to Big Data as part of eHealth strategies
- Analytical **skillsets are insufficient** currently
- **13% of EU member** states have a policy on **Big Data**

Potential impact	●
Critical timing	◷◷
Scope for policy	■■□

Source: MobiHealthNews Website; WHO "Policy Implications of Big Data in the Health Sector" (2017); Genie MD Website; Raghupathi "Big Data Analytics in Healthcare: promise & potential"; A.T. Kearney analysis

The GDPR replaced the previous directive in May 2018, applying to all EU countries but leaving some national flexibility

Overview of the GDPR

- **Description**: the GDPR (General Data Protection Regulation) is the new legal framework in the EU that aims to:
  - Harmonise data privacy laws across Europe
  - Protect & empower all EU citizens
  - Reshape the way organisations across the region approach data privacy

- **Date**: it came into force on 24th May 2016, but did not take effect until May 25th 2018

- **Implementation**:
  - Replaces the Data Protection Directive 95/46/EC
  - Establishes minimum mandatory requirements across the EU
  - Provides a limited ability for Member States to legislate locally on certain discrete matters, including the use of health data

- **Key points of the GDPR**
  - A Clarification of data definition & rationale for use
  - B Expanded monitoring & liability
  - C Strengthened individual rights & consent
  - D Processing accountability & compliance mechanisms

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Source: Hogan Lovells 'The Final GDPR Text and What It Will Mean for Health Data' (2016); Noerr. 'Taking advantage of patient data – an outlook on the upcoming General Data Protection Regulation' (2017); BHBIA 'GDPR Quick Guide' & 'GDPR Legal Grounds for Data Processing' (2017); IGA. 'The GDPR: What's New'

Although the GDPR can improve data security, transparency and subject rights, many of its requirements hinder data development

GDPR key points & impact

Extent of impact: Large threat | Small threat | Small opportunity | Large opportunity

A	Clarification of data definition & rationale for use	1	Clear justification needed to process health data
		2	Restriction of automated decision-making, including profiling
		3	Definition of more types of health data as sensitive (inc. genetic & biometric)
B	Expanded monitoring & liability	4	Increased codes of conduct & certifications
		5	Application of GDPR to more stakeholders
		6	Stronger data protection agencies
C	Strengthened individual rights & consent	7	Clarification of individual rights for data subjects (to access, to rectification, to data portability)
		8	Clarification of individual rights for data subjects (to be forgotten, to restrict processing, to object)
		9	Additional info. required to explain context for use ("transparency & fair processing")
		10	More stringent definition of consent
D	Processing accountability & compliance mechanisms	11	Qualified compliance framework & derogations for scientific research
		12	Stronger data protection & impact assessments
		13	Mandatory data breach reporting
		14	Mandatory appointment of data protection officers
		15	Accountability & increased reporting of processing
		16	Higher threshold for anonymization

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Processing of data is allowed under three provisions – consent, medical and public health grounds

A GDPR: data definition & rationale

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Clear justification needed to process health data	• Allowed only: – If data subject has given **explicit consent** – **On 'medical care' ground** – i.e. for "preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems & services" – **On 'public health' ground** – i.e. for "reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality & safety of health care & of medicinal products or medical devices"	● • **Flexibility** beyond explicit consent that provides further opportunities to collect data without consent • **Uncertainty** around what constitutes legitimate 'medical care' or 'public health' grounds, which could lead to disagreements & fines	• **Leverage consent** where possible, including **additional** uses from early on (e.g. secondary purposes, linkage, etc.) • **Work with local politicians & regulators** to establish clarity around 'medical care' & 'public health' grounds, to ensure cover the widest possible usage & does not hinder data initiatives • **Partner with patient associations** to ensure their interests are respected & supported in derogations

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The definition of biometric, genetic and health data as particularly sensitive could significantly impair current data initiatives

A GDPR: data definition & rationale

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Restriction of automated decision-making, including profiling 2	• Ability to not be subject to a **decision based solely on automated processing** (including profiling, risk stratification), which produces legal effects concerning or similarly significantly affects them • Possibility to **opt out** (though not if individual originally consented to profiling or where the profiling is necessary for reasons of substantial public interest & in both instances, suitable measures to safeguard the individuals' rights & freedoms are implemented) • **Written notice** no longer necessary	●	• May increase **trust** in use of data & lack of discrimination against patients • **Resources** required to review existing processes & ensure that comply (or establish procedures so that subjects can object before processing) • Likely to be particularly relevant for **specific stakeholders** (e.g. insurance providers), limiting their data	• **Review of existing processes** to ensure compliance • **Obtain clear consent** for profiling where necessary
Definition of more types of health data as sensitive 3	• Data concerning health, "**genetic data**" & "**biometric data**" subject to a higher standard of protection than personal data • "Genetic data" & "biometric data" are additions vs the Directive • Member states can introduce **further conditions relative to biometric, genetic or health data**	● ●	• Increased **scrutiny** of genetic & biometric data can inhibit innovators & research • Susceptibility to **local interpretation & derogations**, leading to disparities	• **Work with local politicians & regulators** to limit additional restrictions, & support derogations where possible • **Partner with patient associations** to ensure their interests

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The application of GDPR to a broader range of stakeholders, including international ones, will limit the development of data

B GDPR: monitoring & liability

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Increased codes of conduct & certifications 4	• Encouraged development of **codes to take account of the specific features of particular industries** & sectors • Where a data protection authority approves a code, adherence potentially to be used to **demonstrate compliance** with other aspects of the GDPR (an alternative being to obtain a certification that is recognised under the GDPR)	●	• Opportunity to **define standards** for the healthcare industry • Could **facilitate demonstration of compliance** if approved	• **Develop the code for the healthcare industry**, in collaboration with multiple stakeholders
Application of GDPR to more stakeholders 5	• **Processors** now subject to direct legal obligations (although not as wide-ranging as the obligations on controllers) • **Organisations that are not established in the EU** but offer goods or services to individuals in the EU or monitor their behaviour now also required to comply	● ●	• **Resources** will be required for processors to come up to speed (vs controllers), potentially limiting extent of stakeholders able to continue handling data • Application to international stakeholders may **limit non-EU involvement & analysis**, potentially limiting extent of stakeholders providing insights	• **Review existing processes** to ensure compliance • **Have non-EU stakeholders collaborate with EU entities** already following rules, to benefit from insight & limit changes required

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The ability of data protection agencies to impose fines for any breach of GDPR presents one of the most significant threats

B GDPR: monitoring & liability

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Stronger data protection agencies 6	• Data protection authorities in each of the Member states with **supervisory role** but given **more powers** • Can **fine** organisations (controllers & processors) up to **€20 million or 4% of total worldwide annual turnover** for GDPR breaches • **European Data Protection** Board with wider powers to ensure consistent application of the GDPR across the EU	● ● • **Fear of fines** will limit stakeholder willingness to process & connect data • **Actual fining** will lead to loss of public trust, thereby limiting further possibility to handle data	• **Obtain legal advice on an ongoing basis** for data initiatives to ensure compliance • **Establish ongoing consultation with local & European data protection agencies** to test feasibility & ensure research can continue • **Partner with patient associations** to ensure their interests are respected & accounted for by local data protection authorities

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Increased individual rights will empower individuals and provide patients with opportunities to gain value from their data

C GDPR: individual rights & consent

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Clarification of individual rights for data subjects (1/2) 7	• **Right of access by data subject** -- removal of charges, in most cases, for providing copies of records to patients or staff who request them; to be provided within one month • **Right to rectification** -- ability to request rectification of inaccurate personal data; obligation to reply to request within one month • **Right to data portability** -- can receive personal data in a commonly-used & machine-readable format (only where processing is based on consent / execution of a contract & is automated)	● • **Resources** required to review existing processes & ensure that they enable these rights • Right of access & data portability that may **promote patient ownership** & may give them more weight to take their data to other processors / providers • **Increased administrative burden** due to right to access & rectification, but eventually improvement in **data quality & accuracy** • **Budget change** to deal with free responses for right of access	• **Review existing processes** to ensure they fully support new rights • **Dedicate resources** for processes & administration to support new rights • **Partner with patient associations** & ensure patients are informed & make the most of their data • **Collect case studies** of where this has led to improved data quality & patient outcomes

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Increased patient rights relating to being forgotten or to oppose processing will limit the quality and availability of data

C GDPR: individual rights & consent

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Clarification of individual rights for data subjects (2/2) 8	• **Right to be forgotten** -- available where subject withdraws consent, subject objects & there are no overriding legitimate overriding groups, personal data have been collected in relation to info. society services, or personal data are no longer necessary for the purposes for which they were collected • **Right to restriction of processing** -- available where accuracy is contested by data subject, processing is unlawful & subject opposes erasure, data controller no longer needs the data but subject requires it to be kept, or data subject has objected (pending verification of legitimate grounds) • **Right to object** -- objection must be respected (unless can demonstrate compelling legitimate grounds that override individual rights)	● • **Resources** required to review existing processes & ensure that they enable these rights • Will **limit availability of data**, in terms of breadth & history • Will **increase administrative burden** to handle requests	• **Dedicate resources** for processes & administration to support new rights • **Partner with patient associations** to support comms. around patient rights & their impact on data & outcomes • **Set clear criteria for & documentation** of "compelling legitimate grounds"

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More stringent requirements for information and consent will increase trust but place a burden on patients and data collectors

C GDPR: individual rights & consent

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Additional info. required to explain context for use 9	• Must include **more information** than in Directive (e.g. whether data will be transferred, how long it will be kept for, & information about any profiling individuals will be subject to) • Similar info to be provided **where data has not been collected directly** from individuals (unless providing notice renders impossible or seriously impairs the research)	● • Good opportunity to **increase patient ownership** if done well • May **add to existing patient concerns** & **burden** (i.e. will have to be crafted in a user-friendly manner) • Will require further **resources** to adjust & implement (unless can prove that seriously impairs research)	• **Collaborate with patient associations & legislators** to determine the right balance between information & burden • **Dedicate resources** to support expanded information & consent processes (as needed)
More stringent definition of consent 10	• Must be a **freely given, specific, informed, verifiable & unambiguous** indication of an individual's wishes (i.e. as in the Directive) • Must be phrased in an **easily accessible** form, using **clear & plain language**, prominent & **obvious** (i.e. not bundled up) • Must enable individuals to **withdraw their consent** easily	● ● • **Onus on controller / processor** to demonstrate that consent was given • May increase **patient empowerment** in decision-making • Will require **effort / adjustment** to develop appropriate forms & processes without over-burdening patients or data collectors • Can readily be addressed moving forward, but will be challenging to collect &/or prove **retrospectively**	• **Review processes** to ensure compliance • **Evaluate impact on past data** & discuss with legislators ability to limit data loss • **Collaborate with patient associations** to develop joint standards & templates for consent forms

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Special provisions for scientific research can be supportive, but will need to be defined to benefit all stakeholders

D GDPR: accountability & compliance

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Qualified compliance framework & derogations for scientific research 11	• Special provisions for **scientific research**: – **Qualified compliance framework** (inc. safeguard such as processing minimal personal data or pseudonymisation) for processing of health data if necessary for scientific research – Possibility to use scientific research grounds to **limit the right to be forgotten & right to object** to data processing – **Further / secondary processing of data permitted** if safeguard framework is respected • **No clear definition of "scientific research"** provided (inc. whether it covers research for commercial gain) • Member states or EU law may set out **derogations where these can render impossible or seriously impair** the achievements of scientific research	● • Susceptibility to **local interpretation & derogations**, leading to disparities • If handled properly, can be **supportive of data collection** & usage within the limits of the compliance framework & derogations	• **Review processes** to ensure compliance & development of qualified compliance framework • **Work with local politicians & regulators** to establish clarity around 'scientific research', to ensure cover the widest possible usage & does not hinder data initiatives • **Partner with patient associations** to ensure their interests are respected & supported in derogations • **Set clear criteria** for & documentation of "rendering impossible or seriously impairing"

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Stronger data protection and breach reporting will improve transparency but increase admin. and psychological burden

D GDPR: accountability & compliance

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Stronger data protection & impact assessments 12	• Introduction of **data protection by design & default** into controllers' processing systems when building databases & systems (i.e. only personal data necessary specific purpose of processing should be used) • **Mandatory data protection impact assessments** (DPIA) where proposed data processing is likely to result in a **high risk** to the rights & freedoms of individuals (inc. all large-scale processing operations) • **Not mandatory where the processing of health data by a doctor or healthcare professional concerns patients**	●	• **Resources** required to review existing processes & involve data protection officer early in the process • May have **limited impact on smaller initiatives** (depending on what constitutes "large scale") or those **already complying** with existing guidance of privacy impact assessments	• **Review processes** to ensure compliance & embed data protection by design / default • **Dedicate resources** to embed data protection & conduct DPIA • **Develop standards, templates & trainings** for DPIA
Mandatory data breach reporting 13	• Obligation to **report breaches to data protection authorities & affected individuals** within 72 hours • Requirement to inform affected individuals only triggered where the **breach could result in a high risk to individuals**, and if the breach was not subject to **measures to reduce the risk** (e.g. encryption) or would involve disproportionate effort	●	• Could be a good opportunity to **increase general trust** in transparency • **Resources** required to review existing processes for breach reporting & to report as / when data breaches occur	• **Review & adjust processes** for data breach reporting • **Dedicate resources** • **Set clear criteria** for & documentation of "disproportionate effort"

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Many entities already have data protection officers, but smaller stakeholders may lack resources to hire and train these

D GDPR: accountability & compliance

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Mandatory appointment of data protection officers 14	• **Data protection officer** (DPO) to be appointed by controllers & processors where: – **Core processing activities require regular & systematic monitoring** of individuals on a large scale – Core activities consist of the **processing of sensitive data** on a large scale	● ● • Will have **limited impact at the national level for most EU countries** (already mandatory) & large institutions (already have these) • Will require **investment from smaller innovators & data sources**, potentially limiting innovation • Will entail **training** to ensure that DPOs are up-to-date with requirements	• **Establish pan-European, low-resource DPO training curricula** (e.g. online courses & qualifications) to develop & maintain skills across stakeholders • **Consider funding for cross-initiative DPO roles** to limit burden on smaller innovators & data providers

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Higher thresholds for anonymisation and recording of processing requirements will increase the resources required

D GDPR: accountability & compliance

Extent of impact: ●● Large threat ● Small threat ● Small opportunity ●● Large opportunity

Category	Details	Impact	Mitigating actions
Account-ability & increased reporting of processing 15	• Controllers required to **implement appropriate data protection policies** & **demonstrate compliance** with principles • Both controllers & processors required to **keep a record** of processing activities • Provisions to be **included in controller-processor contracts** specifically set out by the GDPR • Does not apply to organisation employing less than 250 people, unless data processing carries high risk or includes **special categories** (inc. health data)	● ●	• **Resources** required to review existing processes, assess whether meet requirements, & **plan / assess** if not (including for smaller stakeholders, e.g. GPs)	• **Review processes** to ensure compliance • **Dedicate resources** to monitor processing & ensure appropriate compliance
Higher threshold for anonym-isation 16	• Data considered anonymous if **re-identification is not possible or impractical**, taking into account all means reasonably likely to be used, either by the person or entity that has anonymized the data, or by any third party • Process of **pseudonymisation explicitly defined** (processing is not forbidden, but must have an established lawful basis & comply with the GDPR)	● ●	• Increasing **difficulty to anonymise data** due to rapid technological developments & growing number of entities collecting data / combining databases, may limit data that is accessible as defined by the GDPR	• **Review processes** to ensure sufficient anonymization • Investigate **new techs.** to enable anonymisation • **Sensibilise decision-makers** to current trends in personal data sharing, enlisting patient support

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Given the scope for local interpretation and possible derogations, several actions can be taken to mitigate the impact of the GDPR

Mitigating actions to handle the GDPR

Review & adjust	• **Review & adjust processes** to ensure compliance & best practice • **Dedicate resources to support new requirements** (e.g. individual rights, data protection impact assessments, documentation of reporting, etc.)
Consult & discuss	• **Work with local politicians & regulators at the European & international levels**, to establish clarity around specific terms & limit risk / fines while maximising ability to collect & use data • **Set clear criteria & ongoing documentation** for interpretable elements (e.g. "scientific research", "disproportionate effort", etc.) • **Establish ongoing consultation with local & European data protection agencies** to test feasibility & ensure research can continue • **Obtain legal advice on an ongoing basis** for data initiatives to ensure compliance
Inform & train	• **Issue joint information statement / Q&A on the GDPR** to explain its content & impact on health data • **Collect case studies of health data on patient outcomes & GDPR impact on data collection**, to sensitize all relevant stakeholders to the importance of health data (inc. impact on historical data) • **Develop standards, templates & trainings** for DPIAs & DPOs
Collaborate & partner	• **Collaborate with all relevant stakeholders to develop health industry code** of conduct • **Partner with patient associations** to ensure their interests are respected & supported in applications of the law & derogations at the national level, & to develop consent / information forms that best address legal & patient requirements • **Have EU & non-EU processors collaborate** to enable best practice sharing & ensure compliance with new rules • **Investigate new technologies** for anonymisation & analysis to protect patient data & privacy

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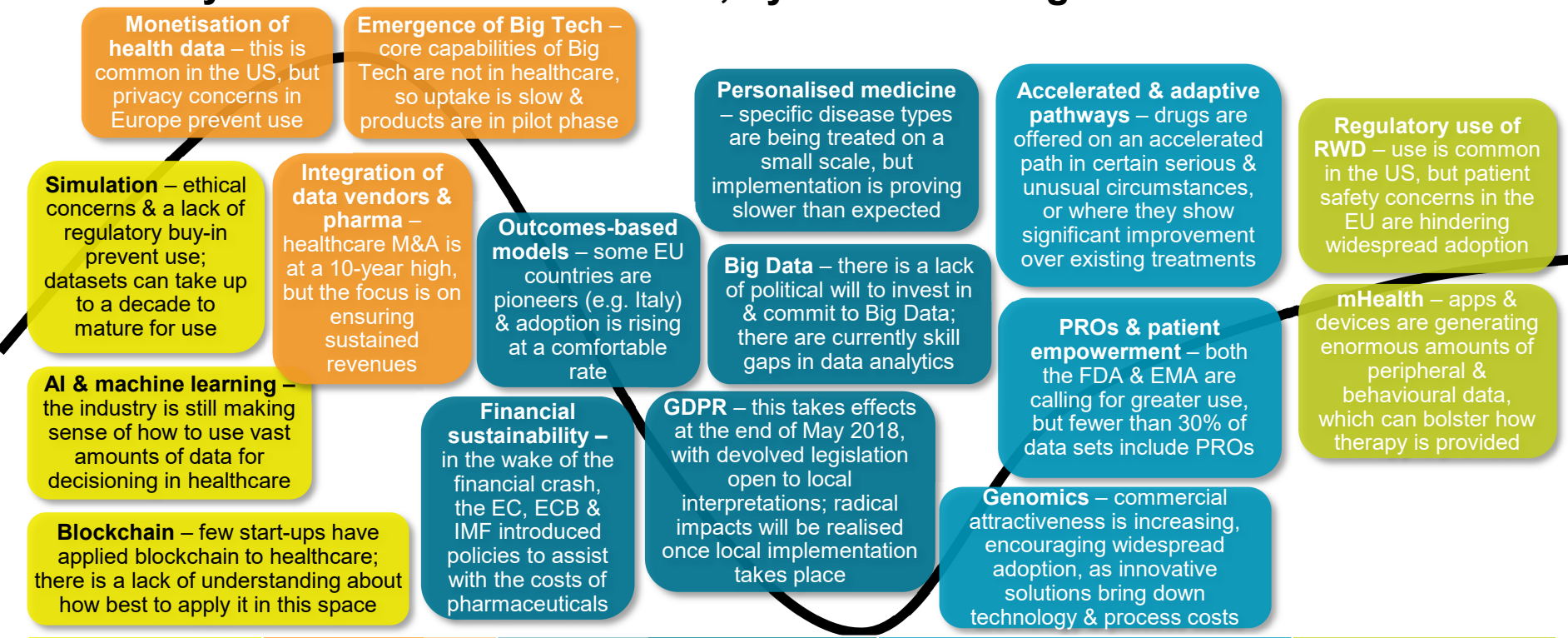
Contents

- Background & method
- Overview of trends
- **Conclusion**

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

Summary of current & future trends, by evolution stage



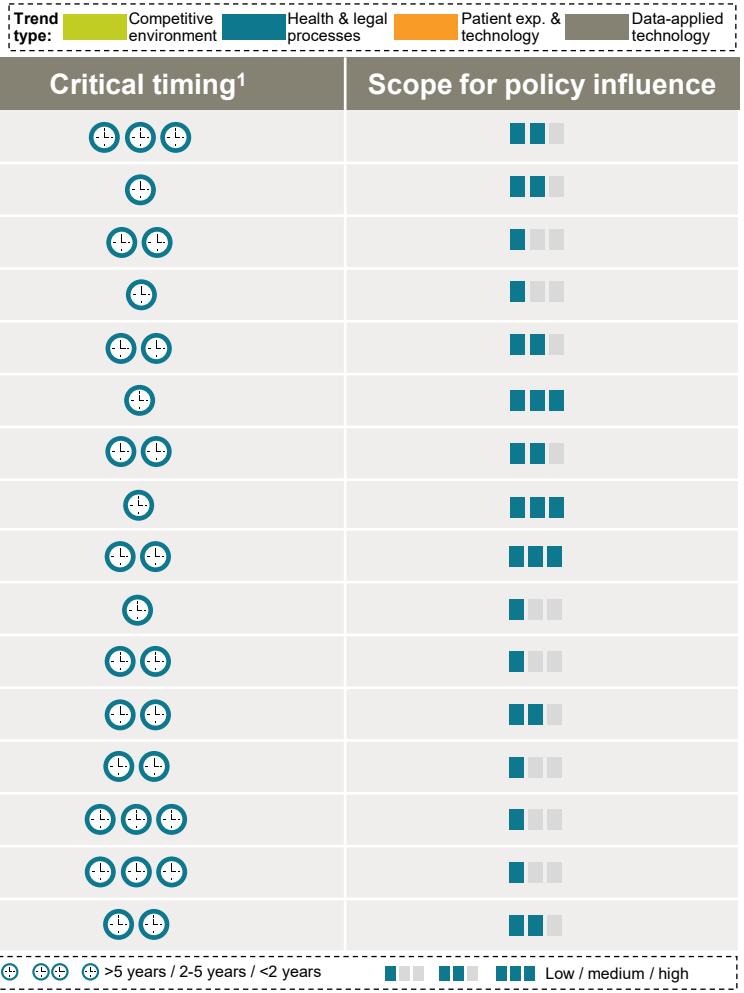
Technology trigger	Peak of inflated expectations	Trough of disillusionment	Slope of enlightenment	Plateau of productivity
Conceptualisation of idea	Implementation by early adopters	Flaws & failures lead to disappointment in the idea	Further applications are understood & implementation increases	Wide-scale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

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

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

In the short term, financial sustainability and GDPR will have a negative impact; mHealth and RWD use will have a positive one

Summary of current & future trends, by criteria



GDPR = General Data Protection Regulation; RWD = real-world data; AI = artificial intelligence; mHealth = mobile health; PRO = patient recorded outcome
Source: A.T. Kearney analysis

Legal barriers will be strengthened by environmental and process trends; economic barriers will be reduced

Overview of trends & impacts on barriers (1/2)

Strong negative impact ↘ → ↗ Strong positive impact

Trends	Political	Economic	Societal	Technical	Legal
Monetisation of health data	• Political will may be restrictive due to concerns around ulterior commercial incentives →	• New sources of funding for stakeholders helps address some of the funding constraints ↗	• Drives increased involvement & ownership of health data • Makes a better case for the value to specific patients ↗	• Commercial use of data may enforce minimum quality standards as part of contractual agreements →	• Outdated regulation may not address the commercial use of data & needs updating ↘
Financial sustainability	• Pressures to address sustainability concerns & adopt a long-termist view →	• Requirement for long-term, sustainable funding is not met by current funding models ↘	• Affordability concerns mean stakeholders want to see better value for money from investment (i.e. proof) ↘	• This has limited impact →	• Updating legislation is costly & time consuming, thus regulations tend to be outdated ↘
Integration of data vendors	• This has limited impact →	• Strong cash position of Big Pharma supports data quality improvement by reducing financial stress ↗	• Fears around commercial incentives for collecting health data may limit engagement ↘	• Improves data quality & consistency from approved third-party vendors ↗	• Monopolises the data source market, creating disparity in access ↘
Emergence of Big Tech	• Big Tech firms have lobbying power, but regulation is tightening around them in Europe →	• Strong cash position of Big Tech firms reduces financial stress on certain stakeholders ↗	• Fears around commercial incentives for collecting health data & threat of monopoly, offset by willingness to share →	• Advanced data capabilities overcome data linkage & quality issues ↗	• Big Tech firms have the financial stability to sidestep or challenge regulations they find restrictive ↘
Outcomes-based models	• New value propositions for drugs may improve political will & commitment to ensuring RWD is part of national health strategy ↗	• Creates a clearer linkage between investment & value, including socioeconomic factors ↗	• Performance tracking & monitoring places additional burden on HCPs ↘	• Incentives to collect good quality RWD that is suitable for sharing, are built into innovative pricing models ↗	• Outdated regulation may not address use of RWD in pricing models & needs updating →
Regulatory use of RWD	• Increasing regulatory requirements for use of RWD pushes politicians to consider the value of health data ↗	• Increasing regulatory requirements requires investment, but skills & capability may improve →	• Use of RWD for post-marketing monitoring increases decision accuracy & better aligns it to real patient outcomes →	• Stricter requirements for RWD improves the quality & reliability of data ↗	• This has limited impact →
Accelerated & adaptive pathways	• This has limited impact →	• Reduces trial funding pressures • Where drugs are cost-effective, it reduces overall financial pressure ↗	• Faster access to drugs improves mindset & outcomes • Concerns around safety of patients limits value →	• Faster access may overshadow data quality assurance as a top priority →	• Disparity in regulatory process for access makes the law more complex & cumbersome ↘
GDPR	• Shift of will to commit to protecting sensitive health data may be restrictive & increase fragmentation ↘	• Financial pressures as GDPR requires investment (e.g. for data controllers) ↘	• Addresses some concerns on data privacy & security • HCPs may lack time to comply with new measures →	• National-level interpretations may fragment technical requirements across Europe & hinder linkage ↘	• Gives greater clarity on data protection laws; but national-level interpretation opens up disparity ↘

GDPR=General Data Protection Regulation
Source: A.T. Kearney analysis

Trend type: Competitive environment; Health & legal processes; Patient ex & technology; Data-applied technology

Technical and societal barriers will be overcome by patient experience and technology trends; legal barriers may worsen

Overview of trends & impacts on barriers (2/2)

Strong negative impact ↘ → ↑ Strong positive impact

Trends	Political	Economic	Societal	Technical	Legal
PROs & patient empowerment	• Public & HCP mindset change positively influences political will ↑	• Improves digital literacy & the negative image of commercial entities ↑	• Mindset shift reduces data privacy concerns & ensures value of data is understood ↑	• Fills data gaps & improves consistency through increased engagement ↑	• This has limited impact →
mHealth	• Shift of political will through public mindset change & rapid adoption of devices ↑	• Decreasing investment costs are stimulating demand & if cost-effective, mHealth frees up resources ↑	• Greater patient engagement in health data collection empowers patients in their care & thus data ownership ↑	• Automated data collection improves consistency, quality & sharing of health data ↑	• Sensitive personal information presents new privacy risks & encourages tighter regulation ↘
Genomics	• Creates ethical concerns around profiling & gene editing →	• High investment costs may prevent funding availability & hinder scalability ↘	• More effective care, but concerns around gene editing may reduce interest →	• Vast amount of genetic data may overburden current systems & processes →	• Detailed genetic information presents new privacy risks & encourages tighter regulation (e.g. GDPR) ↘
Personalised medicine	• This has limited impact →	• Highlights capability gaps, but encourages more training of HCPs →	• Empowers patients with more involvement in health, & drives better outcomes for patients & HCPs ↑	• May increase complexity of treatment putting pressure on systems & software →	• Greater focus on personal data may be met with increasingly restrictive legislation ↘
Simulation	• Basing decisioning on simulations may be met with political resistance →	• This has limited impact →	• Increases approved drugs' efficiency thus improving patient outcomes ↑	• Automates manual data processing ↑	• Improves data access as datasets are not based on real patients ↑
AI & machine learning	• Raises concerns around physicians being replaced by machines & thus lowering employment →	• Automation of manual tasks reduces the burden on HCPs to collect & manage health data ↑	• May be met with resistance from HCPs & patients due to loss of jobs & use of data for decisioning →	• Automated processing & decisioning improves data quality • Suited to complex disease prediction & treatment ↑	• May require new laws for AI-based decisioning as current laws are outdated →
Blockchain	• Need for blockchain regulation increases focus on national e-Health strategies →	• Automation of eHealth services reduces technical skillset requirement ↑	• Appeases patient & HCP data security concerns • Increases ease of participation in health data ↑	• Facilitates linkage & common standards as these are required for the Blockchain process ↑	• Provides IT security • Consent is clear & ownership decentralised ↑
Big Data	• Influences national strategies to address Big Data as viability grows ↑	• Value in sharing & linkage of Big Data drives commercial interest ↑	• Concerns around data privacy & security may increase if not addressed →	• Linking multiple data sources using common systems improves usability ↑	• Concerns around data privacy & security for large, linked datasets tightens regulation ↘

Source: A.T. Kearney analysis

Trend type: Competitive environment | Health & legal processes | Patient ex & technology | Data-applied technology

Supporting investment in tech, leveraging patient experiences and engaging with stakeholders to improve process is key

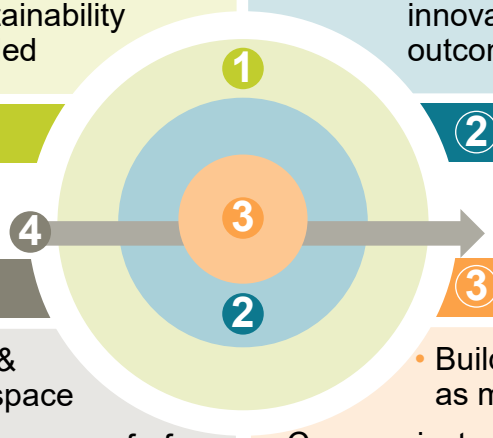
Recommendations, by category

① Competitive environment

- Engage with data vendors to improve the data collection & analysis process, driving better R&D & improving treatment outcomes for patients
- Leverage Big Tech's involvement in healthcare by exploring products, or using their deep analytical capabilities to drive better decisioning
- Explore new funding methods to ensure sustainability in the future & support initiatives where needed

② Health & legal processes

- Understand GDPR & its potential impacts on health data, & promote local adaptations that supports RWD use
- Explore new & innovative methods of drug approval to drive better treatment decisioning, & the potential for faster drug access
- Support payers & HCPs in understanding new innovative pricing models based on real-world outcomes



③ Patient experience & technology

- Build capability in new patient experiences such as mHealth & understand the value it can bring
- Communicate the value of personalised medicine for more targeted treatments (e.g. by gene type, by mutation, not disease type)
- Communicate with patients, upskill & involve them to encourage engagement in their health care, & leverage the detailed insights that they can add

④ Data-applied technology

- Improve understanding of new technologies & their potential advantages in the healthcare space
- Develop & foster the use of new technologies as proof-of-concept before scaling & disseminating
- Partner with Big Tech & academia to build awareness & capability in technology for data collection, use & analysis
- Invest in new technologies such as cloud computing to make use of broader & deeper health care data

Source: A.T. Kearney



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