

Big Data in Healthcare

Opportunities, emerging risks and potential liabilities



Dive into Big Data

Undeniably, all digital health innovations rely on Big Data – they collect, store, exchange, synthesize and/or produce substantial amounts of health data.

The promise of Big Data to transform healthcare is identical to the promise of digital health innovations: reduced costs, increased efficiency and improved outcomes and access.

Therefore, it is important for digital health companies to explore and consider the emerging areas of concerns and potential liability related to Big Data within their organizations.



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What is Big Data?

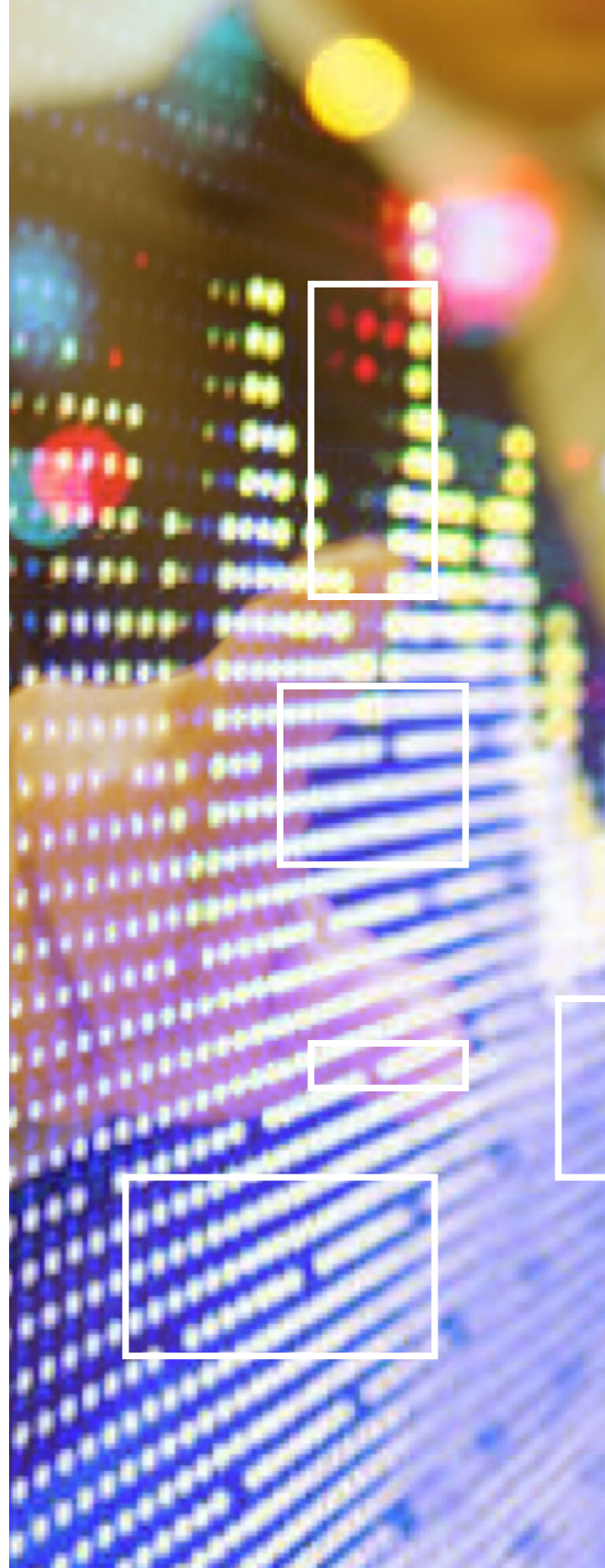
There is no universal agreement on the definition of 'Big Data'; the term is generally used to describe the growth and availability of large datasets. Big Data is frequently characterized in terms of the 7Vs: volume, variety, velocity, validity, value, volatility and veracity¹.

Big Data are data whose scale, and complexity require new architecture, techniques, algorithms, and analytics to manage it and extract value and hidden knowledge from it².

In a healthcare context the term often has a multidimensional meaning that incorporates:

1. the volume and diversity of data available from disparate sources with
2. the efficient real-time linking and analysis of those data in order to
3. provide actionable insights and enable informed decision making.

Consequently, 'Big Data' in healthcare is not wholly focused on the flood of data; rather, the emphasis is on the analysis, parsing and synthesis of the data into knowledge and understanding.



¹Khan, M., Uddin, M., and Gupta, N. (2014) Seven V's of Big Data Understanding Big Data to Extract Value. Accessed at: <http://www.asee.org/documents/zones/zone1/2014/Professional/PDFs/113.pdf>

²Bellazzi R. Big Data and biomedical informatics: a challenging opportunity. Yearb Med Inform. 2014;9:8-13. doi: 10.15265/IY-2014-0024. <https://pubmed.ncbi.nlm.nih.gov/24853034/>

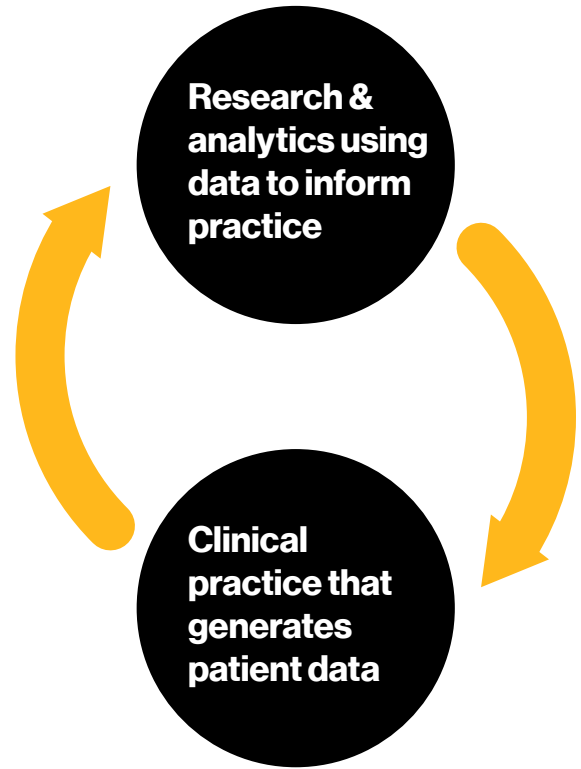
Why does it matter?

Many healthcare systems, though often data rich, do not properly utilise existing datasets to generate a better understanding of how to improve access to better quality care and to reduce waste.

Such missed opportunities result in unnecessary patient harm and serve to increase the gap between the cost of healthcare and the outcomes achieved.

These system limitations could be overcome by the development of a continuous learning healthcare system that harnesses Big Data to 'fuel' a virtuous cycle in which research informs and influences clinical practice and clinical practice informs and influences research.

Virtuous cycle of continuous learning



In such a system, Big Data can help facilitate a more empirically driven healthcare system, ideally, free from bias, to drive lowered costs, improved quality of care and patient safety and ultimately better outcomes. This is the promise of 'Big Data'.



Yet, the pathway to these potentially transformational changes is littered with challenges.



Key challenges in the use of data in healthcare

Interoperability challenges

Health data are unstructured, from variant sources (i.e. financial, billing, pharmaceutical, durable medical, laboratory, etc.), they do not utilize standardized terminology and require great collaboration among all stakeholders.

Accuracy and quality of data needs to be established and issues addressed. Improving the interoperability of healthcare data and systems is a top priority in many countries.

Data governance

Once data is validated, global privacy regulations often require that policies and procedures protect health information.

From a compliance perspective, there are more limitations on data disclosure than on data collection.

There is need for access control, authentication and security during transmission; cloud storage can solve some of these issues.

Policy and procedures regarding how devices, employee access/use and data are managed are critical to the modern healthcare system.

Data storage

The volume of healthcare data is massive and growing unimaginably as more and more electronic information is captured.

On premises storage is almost antiquated as the volume, hardware and power requirements to store the data on site has become very costly to organizations.

On site storage is vulnerable and upkeep of security is precarious as many organizations do not have sufficient IT staff.

It is not easy to add physical space to increase storage capacity and the backup batteries that it requires.

Data accessibility/mobile competency

Downtime or inability to access data presents a substantial risk to care in the modern, and increasingly digitized, healthcare system.

Proactive risk management strategies are essential to protect data. One mitigation strategy is cloud storage; a scalable less capital-intensive way to transfer and provide patient / provider access to complex data without compromising security – even as more mobile devices are used.



Data ownership

It is important to help both providers and patients understand that the medical record, whether paper or electronic has levels of ownership.

The individual data (i.e. vital signs, laboratory values, radiologic images) are typically owned by the patient.

However, the media in which the information is recorded and stored are typically considered the property of the organization or individual provider (who is the legal custodian and has a duty to protect that information). Simply stated, medical Big Data is somewhat of a shared ownership³.

Data mining liability

Within healthcare there is a continuously (and necessarily) changing standard of care.

Will the wide availability of large datasets and the proliferation of technological capabilities to synthesize data lead to an expansion on our understanding of the standard of care – one that will eventually evolve to include Big Data analytics?

Management challenges/need for healthcare analytics talent

The healthcare system needs data scientists and IT staff with healthcare knowledge in order to run meaningful analytics.

Healthcare risk managers need to recognize new and different risks that are emerging due to the transformational influence of Big Data.

Further, physicians and administrators alike require education about the clinically relevant input that Big Data analytics can generate⁴.

Cybersecurity

Cybersecurity encompasses a myriad of potential hazards, including: malware/phishing attempts, ransomware, vendor selection, unsecured mobile devices that may not meet security standards (leaving networks vulnerable), lost and stolen devices, online medical devices (potential for interception and manipulation of data), unrestricted access to computers and inadequate disposal of old hardware⁵.

The need for continuous monitoring and ongoing improvements

Organizations can feel like they are drowning in data. The challenge however is not just volume but also the integrity and quality of data.

Strong organizational data governance, with continuous monitoring, is integral to creating ongoing improvements with Big Data analytics.

End-users should receive regular training and reminders about optimal data integrity, data entry practices, and organizations should conduct frequent internal audits and assessments to ensure they are maintaining a high level of data quality and appropriate usage of the data⁶.

³Shama, R. (April, 2018) Who really owns your health data? Forbes Technology Council. Accessed at: <https://www.forbes.com/sites/forbestechcouncil/2018/04/23/who-really-owns-your-health-data/?sh=6da592c16d62>

⁴Ibid.

⁵Security Threats in Healthcare Systems. (March, 2019) Accessed at: <https://consoltech.com/blog/security-threats-healthcare-systems/>

⁶Bresnick, J. (July, 2016) The Role of Healthcare Data Governance in Big Data Analytics. Health IT Analytics. Accessed at: <https://healthitanalytics.com/features/the-role-of-healthcare-data-governance-in-big-data-analytics>

The health data ecosystem and data reuse

Despite these challenges, health-related Big Datasets hold great promise in the eyes of multiple stakeholders that seek to harness their power.

Each want to use health data generated through digital health innovations in varying ways and to differing purposes, including research, public health surveillance, system analysis and/or marketing and commercial activities.

Through these activities, stakeholders hope to achieve some of the well recognized benefits of secondary uses within the healthcare industry: reductions in systems costs, improvements in system quality, better health outcomes and overall advancements in clinical care and practice.

Whatever the impetus, use of data beyond their originally intended use (typically personal medical care) is often referred to as secondary use or data reuse. A few notable data sharing projects include: Electronic Health Records for Clinical Research (EHR4CR)⁷ and eMERGE Consortium⁸.

Core to the desire to derive better insights from large healthcare data sets is data linking – a practice distinct from data reuse, but closely related to it.

Data linking entails the aggregation of different data related to the same individual, family, place or event from multiple diverse sources.

The main goal of data linking is to create richer datasets that enable the user to gain deeper insights through the synthesis and aggregation of data.

Data being linked with health records:



Population registries



Census data



Education system data



Prison service data



Genomic data (direct to consumer genetic tests)



Social media



Credit card data



⁷i-HD. EHR4CR: Electronic Health Records for Clinical Research [Internet]. 2016 [cited 2020 Sep 24]. Available from: <https://www.i-hd.eu/index.cfm/resources/ec-projects-results/ehr4cr>

⁸National Human Genome Research Institute. Electronic Medical Records and Genomics (eMERGE). Network [Internet]. Genome.gov. 2020 [cited 2020 Sep 24]. Available from: <https://www.genome.gov/Funded-Programs-Projects/Electronic-Medical-Records-and-Genomics-Network-eMERGE>

Shifting reimbursement models, legislative incentives, health system policies and goals and commercial goals are all driving a surge in secondary use and data linking projects.

Some key focuses areas of these projects include:

Research

- **Public health research** - monitoring Big Data to identify disease trends and health strategies based on demographics, geography and socioeconomics.⁹
- **Medical research**- data-driven medical and pharmacological research to cure disease and discover new treatments and medicines

The vast promise of data reuse and data sharing has prompted many bodies, including the Institute of Medicine¹⁰, the International Committee of Medical Journal Editors¹¹ and the National Institutes of Health¹² to release statements advocating data sharing as a method to accelerate and advance clinical knowledge. In certain circumstances these institutions require results sharing as a stipulation of funding.

Clinical care

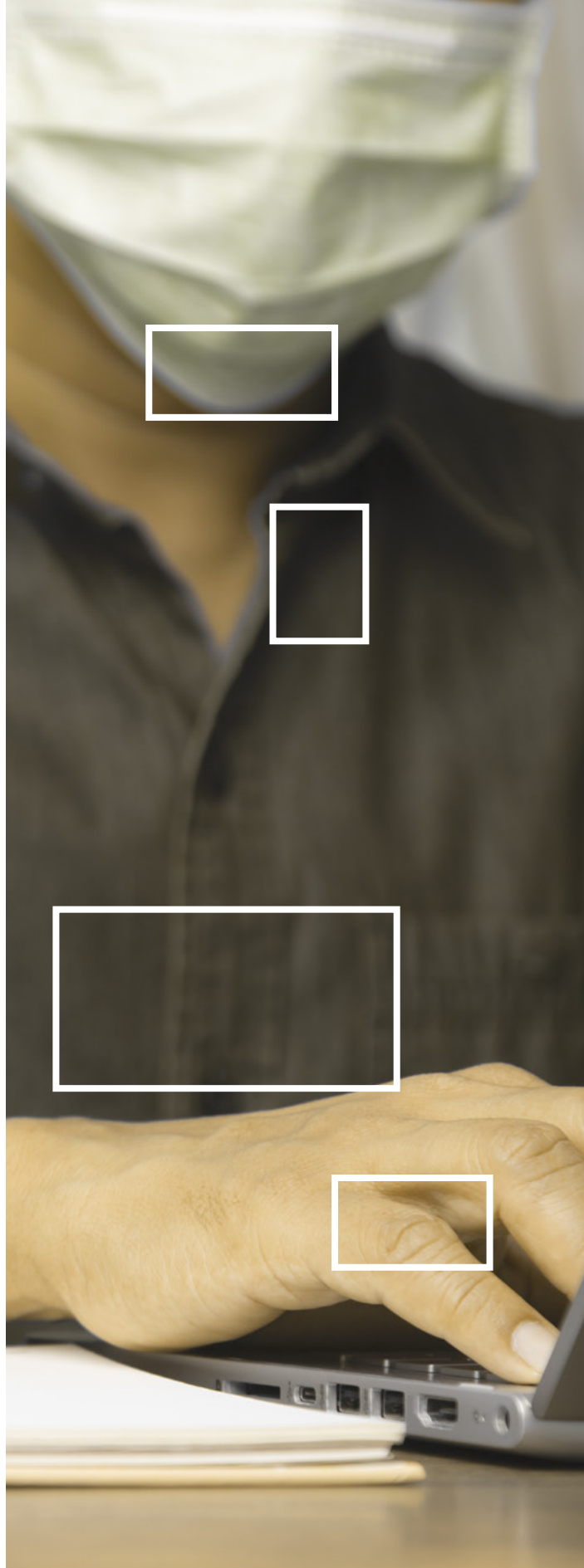
- **Diagnostics** - mining data to analyze and identify causes of illness.
- **Preventative medicine** - predictive analytics and data analysis of genetic, lifestyle, and social circumstances to prevent disease.
- **Precision medicine** - leveraging aggregate data to drive hyper-personalized care.

Risk reduction and compliance

- **Reduction of adverse events**, e.g. medication errors - Big Data can be used to spot medication errors and flag potential adverse reactions.
- **Prevention of opioid abuse** - Big Data can be used to identify risk factors that can predict whether someone is at risk for abusing opioids.
- Big Data can also be used to determine what **healthcare employees may need more support** or training and to encourage continuous learning.

Finance and operational efficiencies

- **Cost reduction through optimised business decision support**- e.g., fraud reduction within the healthcare system or identification of value that drives better patient outcomes for long term savings.
- **Improved supply chain** - leverage Big Data to track supply chain performance and drive better data-informed operational decisions.



⁹New England Journal of Medicine Catalyst (January, 2018) Healthcare Big Data and the Promise of Value-Based Care. Accessed at: <https://catalyst.nejm.org/doi/full/10.1056/CAT.18.0290>

¹⁰Institute of Medicine. Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk [Internet]. 2015 [cited 2020 Aug 29]. Available from: <https://www.nap.edu/catalog/18998/sharing-clinical-trial-data-maximizing-benefits-minimizing-risk>

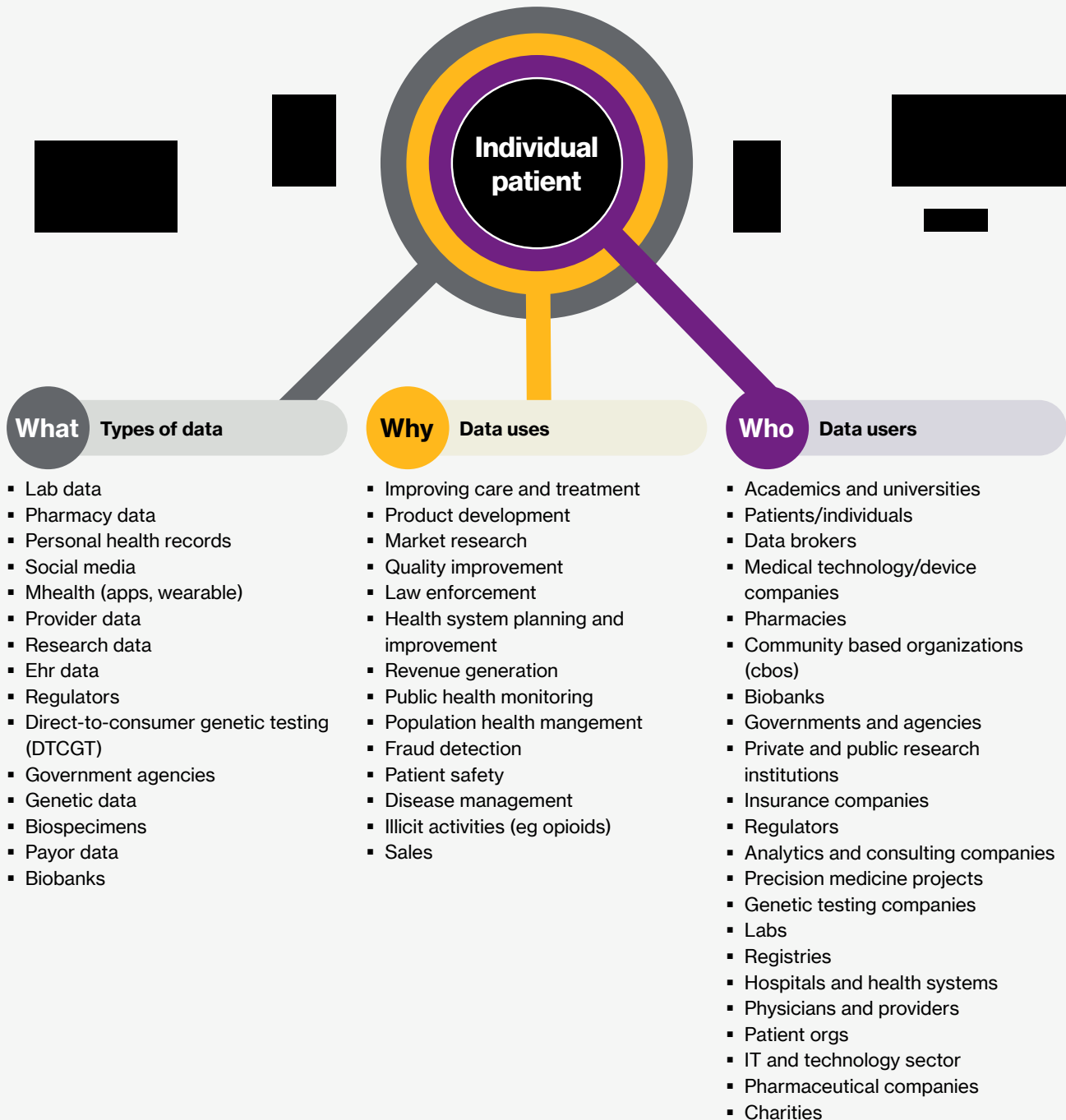
¹¹Research Councils UK, Higher Education Funding Council for England, Universities UK, Wellcome Trust. Concordat on Open Research Data [Internet]. 2016 [cited 2020 Aug 29]. Available from: <https://www.ukri.org/files/legacy/documents/concordatonopenresearchdata-pdf/>

¹²National Institutes of Health. NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information [Internet]. 2017 [cited 2020 Aug 29]. Available from: <https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm>

Health data ecosystem

It is imperative to understand the health data ecosystem as a complex network with numerous participants that utilize and find value in health data in diverse ways.

However, the potential benefits and harms of data reuse are not universally agreed and may shift according to one's perspective and context.



Often, within such practices (reuses and linking of datasets) there is inherent tension between the vast prospective benefits for the community and potential for individual harms – including the risk to privacy and possible misuse of sensitive data.

This tension is evidenced by the growing number of public controversies related to data sharing initiatives and the growing global discussion surrounding the ethical challenges of COVID-19 related contact tracing apps.

Secondary use project	Nature of data share	Objections
A data program	A program aimed at extracting data from GPs for a central database.	Lack of 1) patient awareness of the program and 2) clarity around opt-out options.
Social network company	The social network's personal data was harvested for political advertising.	Lack of consent and transparency.
Consulting company and a government agency	180,000 lung cancer patients' anonymized data were shared with the consulting firm for a study on lung cancer trends.	Consent of the patients was not obtained.
Artificial intelligence (AI) company	1.6M patients' data were transferred to the AI company to test an acute kidney injury altering system (streams).	Inadequate public engagement, awareness and lack of transparency.
A healthcare organization and a technology company	Identifiable patient data was shared with a technology company to pilot an electronic health record (EHR) search tool.	Lack of notification to patients; federal inquiry to ensure compliance with The Health Insurance Portability and Accountability Act of 1996 (HIPAA).
A healthcare company and a technology corporation	Agreement to share identifiable patient data to develop cancer algorithms.	Identifiable data utilized; how has consent been obtained?
Online pharmacy	Names and addresses of >20,000 customers were sold to a marketing company.	Breach of data protection rules by not seeking customers' consent.





There are a few critical questions to contemplate:

Do patients know how much of their health data are being used, by whom and for what purpose(s)?

What liability does ‘Big Data’ and corresponding sharing, linking and reuse practices pose to an organization?

Some liability considerations of health data reuse:

- **Privacy concerns:** some privacy regulations rely heavily on deidentification as the main mechanism to protect patient privacy.

With the continued progression of reidentification science and data linking projects, standards and regulations that rely on deidentification provide an increasingly inadequate privacy protection.

Alongside the reidentification risks, are increasing public concerns surrounding the commercial exploitation of data.



Global privacy related laws

US HIPAA's Privacy rule (as expanded by the HITECH Act) and various state laws

UK and EU General Data Protection Regulation (GDPR)

Australia Federal Privacy Act 1988 and Amendment Bill and various State Privacy Bills

Canada Personal Information Protection and Electronic Documents Act (PIPEDA) and provincial

- **Lack of transparency:** consumers don't understand or are unaware of the full extent of the collection and reuse of their health data. This makes it difficult for people to assess the risks and benefits of sharing their data.

This limited understanding must be addressed in order to have a transparent system that fosters truly informed consent. Notably, not all countries require informed consent for secondary use of patient data – particularly deidentified data.

E.g., while GDPR sets a high threshold for achieving consent, consent is not an absolute requirement and there are several legal bases for exceptions.

There is great potential for abuse and misuse of patient data in any system that lacks transparency and public awareness.

¹⁹Mazor KM, Richards A, Gallagher M, Arterburn DE, Raebel MA, Nowell WB, et al. Stakeholders' views on data sharing in multicenter studies. J Comp Eff Res. 2017 Sep;6(6):537–47 <https://pubmed.ncbi.nlm.nih.gov/28805448/>
²⁰Vezyridis P, Timmons S. Resisting Big Data exploitations in public healthcare: free riding or distributive justice? Social Health Illn. 2019 Nov;41(8):1585–99. <https://onlinelibrary.wiley.com/doi/abs/10.1111/1467-9566.12969>

▪ **Data monetization: a word of caution about monetization and profit-making within the health data ecosystem.**

There is widespread concern and caution about the involvement of commercial companies or profit-related motives within the health data ecosystem. Public trust and willingness to consent decrease when societal benefits are murky, or profit may be derived.

Many members of the public are concerned that profit-making, particularly covert profit-making, potentially incentivizes companies to misuse data for their own gain and to the disadvantage of the patient/public^{13/14}.

Within the health data ecosystem, data brokers are one segment that is laser focused on how to monetize health data.

The definition of what a data broker is varies between the different regulatory authorities, but in its broadest sense a data broker is an operation/company that aggregates disparate information (about consumers) from a wide variety of sources; often for the purpose of analysis and reselling/licensing that data to a third party.

An in-depth discussion on data brokers is beyond the scope of this whitepaper, however it is important to note that, in general, the data broker industry has had little oversight and lacks transparency around their data collection, aggregation and selling practices.

Internationally, there is increasing regulatory attention to data brokering practices, but current regulations vary greatly from country to country and even the robust protections that GDPR offers provide several legal bases for processing a consumer's personal data.

What is important to note is that data are increasingly being viewed as a commodity to be sold and traded.

Consider the recent news that Israel has traded the data generated from their health system to Pfizer in return for rapid and continuous access to Pfizer's COVID-19 vaccine¹⁵.

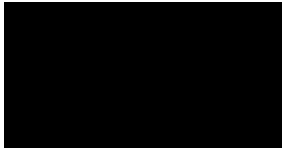
Past examples of sensitive data sets sold:

- Lists of rape victims
- Seniors with dementia
- HIV patients
- Patients with erectile dysfunction¹⁶

Additionally, some member of the public, (particularly minorities, the socially disadvantaged and vulnerable populations) are concerned about the potential for commercial companies to use these health datasets to stereotype and discriminate.

Financial discrimination (e.g., denial of mortgages), insurance (life and health) discrimination (e.g. raised premiums) and denial of employment are some top concerns related to commercial use of health data. The evidence shows that the public have a limited awareness and understanding of commercial access and use of health-related data¹⁷.

Furthermore, the presence of commercial companies in the data reuse equation amplifies public desire for greater control over their data reuse preferences. This presents a challenge that the digital health industry (alongside every other stakeholder) must address.



¹⁵<https://www.pbs.org/newshour/science/israel-trades-pfizer-vaccine-doses-for-medical-data>

¹⁶<https://www.forbes.com/sites/kashmirhill/2013/12/19/data-broker-was-selling-lists-of-rape-alcoholism-and-erectile-dysfunction-sufferers/?sh=5a3a68201d53>

¹⁷Beasley, K. (September 2020) Patient and public attitudes towards secondary use of health-related data, with particular focus on themes of commercialism: a two-phased scoping review

Conclusion

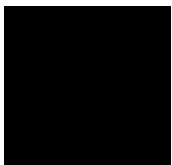
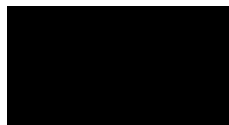
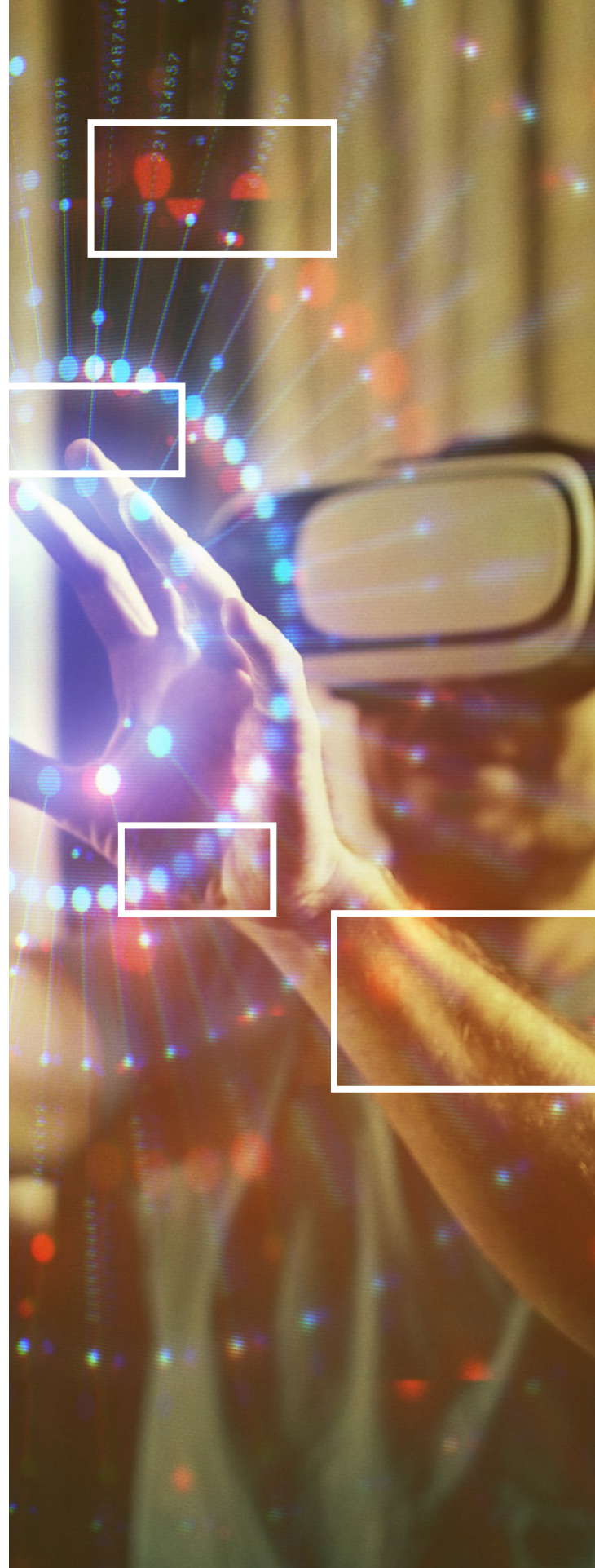
Clearly, health-related longitudinal data sets hold great promise in the eyes of multiple stakeholders seeking to harness their power in varying ways and to differing purposes.

However, organizations must recognize that when tapping into that potential there is a responsibility to ensure that the public's health-related data is not abused.

There should be a concerted effort to be proactively transparent about health data reuse in order to increase public awareness and understanding.

The individual is at the core of the health data ecosystem, thus prioritizing their views enables the construction of data reuse policies that will better reconcile the inherent frictions that exist within data sharing.

Improved public awareness about data sharing and linking in conjunction with more transparency about commercial involvement will lay a path towards equitable, sustainable and community-centric secondary use strategies.



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