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DIGITALEUROPE's recommendations for the European Health Data Space

Executive Summary

0.2 – 1.3 years of life expectancy can be added by data-fuelled AI.¹ Fortunately, 30% of the world's stored data is health data.² While we already have strong EU data regulation, these tools are still imperfect. In this response to the EHDS Roadmap consultation we provide a comprehensive overview of the needs for regulatory guidance, technical infrastructure and fundamental issues like skills and trust and investment.

The EHDS Inception Impact Assessment³ sets out ambitious objectives linking together the need for secure and trusted health data sharing for what will be the creation of the first European data space. The EHDS has the potential to be the single market for digital health products and services, and the global centre of development of secure AI powered digital health. Indeed, the EHDS will be a prerequisite for Europe to lead the digital transformation of health and care. DIGITALEUROPE supports these initiatives. We need decisive EU action to harmonise conditions for health data processing for primary and secondary use across Europe, linked to meaningful investment. We would like to highlight the key recommendations from our papers on health data and an increased role for AI in health.

Please find in [here](#) also our **Data Governance Act Recommendations**. This document compiles recommendations from:

4 November 2020 – our paper on [Improving lives and managing diseases through a data driven EU healthcare system](#)

23 January 2020 – our paper on [how to harness the power of AI in health applications](#).

¹ McKinsey Global Institute (2017). [Artificial Intelligence: The Next Digital Frontier?](#)

² EMERJ (2019). [Where Healthcare's Big Data Actually Comes From](#)

³ EC (2020) Digital health data and services – the European health data space ([Roadmap/ IIA](#))



Key recommendations

- ▶▶ **The EHDS requires a robust, secure and interoperable infrastructure with a clear governance framework and defined services.**
 - **A well-defined, common data infrastructure** is fundamental to facilitate a consistent and secure secondary use of health data.
 - **Central health authorities:** We support the establishment of a central health data entity at EU level to select standards and profiles for interoperability, as well as a health data entity in each Member State to implement those standards. The role of the national entities should be to provide controlled data services, like healthcare information sharing and analysis.
 - **EU-level health data entity:** The EHDS should establish the legal foundation of both the EU-level health data entity as well as the national health data entities, and mandate national health entities' adherence to the same set of rules, standards and profiles of standards selected at EU level, and in line with FAIR principles in data sharing and access.⁴

- ▶▶ **We encourage secure and trusted use of the EHDS to build on the creation of an EU Code of Conduct, EDPB guidance on interpreting the GDPR and health data altruism schemes.**
 - **Harmonisation.** A European Health Data Space requires a harmonised framework of health data privacy in Europe. The GDPR made the sharing and cross-border flow of health data possible by establishing the foundations of a trust framework for patients, consumers and other stakeholders. But its interpretation and implementation still diverge among Member States. COVID-19 exacerbated the negative impact from this fragmentation. We need decisive EU action to harmonise conditions for health data processing for primary and secondary use across Europe.

- ▶▶ **Common data models, international standards and best practices already used responsibly by industry are key for swift and broad take-up of EHDS initiatives.** This should build on:
 - **Common data models:** Internationally recognised standards are a critical element to achieve more outcome-based healthcare systems across the EU.

⁴ FAIR stands for Findable, Accessible, Interoperable, Re-usable

- Fulfilling the ambitions in the European Electronic Health Record exchange format recommendation.⁵
 - **A Common data classification framework:** Data classification should enable the use of all classes of healthcare data with cloud technology, with appropriate levels of security and risk mitigation in place which corresponds with the type of data being processed.
- ▶▶ **In addition to liability as covered by the EHDS Roadmap/ IIA, AI will play an important role in the development of the EHDS.** Specifically, as outlined in [our AI health paper](#), we recommend:
- **Avoiding one-size-fits-all approaches for risk assessment** in the design of any future AI policy framework for health. Any such framework should also consider existing international standards, legislation and ethical principles.
 - **Avoiding regulatory overlap.** The EU MDR contains strict requirements, including liability. In case AI specific provisions will still be introduced, it should be done very carefully not to create conflicts or duplications between the various regulations, and new barriers for the development of AI-supported medical devices.
 - **Research, training and data availability:** We should recognise that developing completely bias-free algorithms will never be possible. However, policymakers can incentivise research, training and increase data availability to tackle and reduce potential unintended or discriminatory bias in AI algorithms.

⁵ Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format

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Our recommendations on improving lives and managing diseases through a data driven EU healthcare system

4 November 2020 – these recommendations have been sourced from our paper on [Improving lives and managing diseases through a data driven EU healthcare system](#)



Executive summary

Data-fuelled technologies will lead us to a society where better disease prevention, personalised medicines and faster, more accurate diagnoses and therapy become possible in more efficient care processes. The EU needs to leverage them fully across all Member States. COVID-19 has demonstrated that digital technologies can play an important role to enable health workers in combating the virus, ensure remote care for immunodeficient patients, keep communities informed and empowered, support health population management and accelerate research on treatments, vaccines and cures.

Ultimately, our goal is to accelerate data flows within the EU for better health outcomes for everyone. Health data makes up 30% of the world's stored data.⁶ A single patient generates up to 80 megabytes yearly in imaging and EMR data.⁷ However, such valuable data is often inaccessible, even to the patient, and nationally siloed and shielded. Such non-technology barriers from governments have slowed down the Electronic Health Record (EHR) adoption to 3% in Europe compared to the United States which is 35%.⁸ Understandably, health data is sensitive, but unlocking this wealth of information based on trust and legal certainty can save and improve lives. For instance, a study has shown that AI – which is fuelled by reliable and secure data – can extend average life expectancy by 0.2 -1.3 years.⁹

⁶ EMERJ (2019). [Where Healthcare's Big Data Actually Comes From](#)

⁷ NEJM (2017). [Using It or Losing It? The Case for Data Scientists Inside Health Care](#)

⁸ McKinsey (2019). [Promoting an overdue digital transformation in healthcare.](#)

⁹ McKinsey Global Institute (2017). [Artificial Intelligence: The Next Digital Frontier?](#)

Data driven health innovations are key to saving more lives, which has become ever clearer during the pandemic. Besides the tragic damages from the COVID-19 virus, the disruption this has caused led to unfortunate, yet preventable losses in much needed care everywhere. During the first half of 2020, when the pandemic directly caused half a million deaths in Europe, the block counted 2.7 million new cancer patients – while 1.3 million lost their lives.¹⁰ The pandemic challenged 88% of caregivers in providing care and more than half had to reduce their services.¹¹ Patients with non-communicable diseases did not have access to the treatment they needed; Disruptions mounted up to 49% for treatment for diabetes, 42% for cancer treatment, and 31% for cardiovascular emergencies. These disruptions are preventable. Part of the cause was the lack of data, diagnostics and other technologies.¹²

A truly connected, interoperable and sustainable Common European Health Data Space is a precondition to unlock the potential of health data in the EU. It will ensure that Europe's clinical research and treatments will pivot our society towards value-based healthcare models and systems. For that to happen, the EU should focus on three main areas:

▶▶ A framework of trust and legal clarity

- Harmonise the mechanisms by which personal health information can be shared (e.g. a common approach to pseudonymisation and/or anonymisation) in the EU
- Establish a consistent harmonised model for a central health data authority in each Member State to facilitate the processing of the secondary use of health data for both the private and public research institutions
- Build on responsible data sharing initiatives driven by industry, like YODA,¹³ and guarantee private sector participation in the Data Space, while safeguarding Intellectual Property Rights

▶▶ Interoperability and standardisation

¹⁰ JRC (2020). [Ireland is the country with the highest cancer incidence in the EU](#)

¹¹ ESMO (2020). [Covid-19 Pandemic Halts Cancer Care and Damages Oncologists' Wellbeing](#)

¹² WHO (2020). [COVID-19 significantly impacts health services for noncommunicable diseases](#)

¹³ YODA stands for Yale Open Data Access (YODA) Project. More info [here](#)

- Advance federated data models
 - Foster convergence and acceleration of deployment of Health IT (HIT) interoperability standards such as Fast Healthcare Interoperability Resources (FHIR) building on the Commission Recommendation on a European Electronic Health Record exchange format¹⁴
 - Define a common EU health data classification to help organisations categorise identifiable, anonymised and pseudonymised data
 - Confirm appropriate encryption tools and security standards that should be used to process sensitive health data
- ▶▶ **Increase the potential of digital through investments and ambition**
- Use Next Generation (Recovery and Resilience Facility) funds and the next Multi-Annual Financial Framework (MFF) to radically upgrade the digital capabilities of health systems, including cloud technology, as a secure and economic infrastructure for driving digital transformation
 - Fulfil the ambition and scope lined out in the Commission [Recommendation](#) on a European Electronic Health Record exchange format



A framework of trust and legal clarity

Trust remains the bedrock to build the Common European Health Data Space. Patients, consumers, healthcare professionals and society will unleash the potential of health data only if there is a clear and comprehensive framework of trust and clarity on how health data should be shared consistently across Member States. Addressing the following aspects is crucial for this framework of trust:

Privacy

A Common European Health Data Space requires a harmonised framework of health data privacy in Europe. The GDPR made possible the sharing and cross-border flow of health data by establishing the foundations of a trust framework for patients, consumers and other stakeholders. But its interpretation and implementation still diverge among Member States. COVID-19 exacerbated the negative impact from this fragmentation.¹⁵ We need decisive EU action to

¹⁴ Accessible [here](#)

¹⁵ We also intend to highlight good practices:

harmonise conditions for health-data processing for primary and secondary use across Europe. We urge to:

▶▶ *Create an EU Code of Conduct (CoC) on the processing of genetic, biometric, or health data.* The CoC should accelerate the access to and processing of such data within each, and across all, Member States in cooperation with all key public and private stakeholders. European cooperation to fight diseases and viruses, population health management at scale and support to safe cross-border travel are concrete examples of why we need a CoC. It must entail:

- **Public interest as legal basis for circumstances in Article 9.2 of the GDPR.** The CoC should also give a common interpretation of what is considered “public interest” by national authorities across the EU. Unjustified, restrictive interpretations by Member States of public interest are preventing hospitals from sharing life-saving data with relevant organisations.
- **A consistent legal interpretation of ‘personal data’.** The value of data lies in its use and re-use, which strongly depend on the nature of the data involved (personal data vs. non-personal data). Personal data falls under the GDPR and its processing is subject to numerous data protection legal restrictions, which do not apply to non-personal data. Member States, however, do not hold a unique and aligned position on the legal concept of personal and non-personal data. No adequate and recognised standards exist on the anonymisation of personal (health) data. The CoC should fill this gap.
- **A consistent anonymisation model** that provides traceability back to the source records without presenting a risk for subject identification, using the concept of k-anonymity based on existing international best practice standards. It would facilitate data sharing from institutions to researchers, between pharmaceutical companies (for example to limit the need for a placebo/standard-of-care arm in a clinical trial) as well as from pharmaceutical companies to government-funded research initiatives. Data Protection Authorities are adopting excessively strict and divergent interpretations of what constitutes anonymous or

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- The OpenSAFELY platform researched risk factors for death from COVID-19 using an unprecedented scale of Electronic Health Records from 17 million NHS patients, all in a manner compliant with both the GDPR and the UK Data Protection Act of 2018. More info [here](#).
 - The World Health Organization (WHO) has a COVID-19 interactive map which gives a daily update on the latest global—and country-specific—numbers of COVID-19 cases. This draws on epidemiological data from around the world and relies on automatic web content extraction, data analytics, processing and storage. More info [here](#) and [here](#).

anonymised data. This hinders health data processing and makes it very difficult for entities to agree on whether and how parties can use the data at issue.

- **An opt-out model for secondary use of data in research fields with higher patient identification sensitivities.** This model would suit areas like rare diseases, genomes and personalised medicine, with higher re-identification risks than normal and where complete anonymisation may impact the successful research outcome. A robust ethical and security framework with a strong transparency dimension would build necessary patient trust in this model and guarantee that vital identifiable data for research progress is handled properly. It would entail patient rights to actively object to their data being processed.
- **Practical guidelines** which can support practitioners along the healthcare value chain (including patients, physicians, healthcare managers, industry). They should provide a common data classification framework,¹⁶ providing clarity on how identifiable, anonymised and pseudonymised data should be categorised and where it can be stored and processed.
- **A reduction of fragmentation of local conditions on data processing for scientific research purposes.** The processing of health data for scientific research purposes is authorised by Art. 9 (j) of the GDPR. Yet, Art. 9 (4) of the GDPR allows Member states to introduce further conditions and limitations to the processing of health data. This provision has resulted in the introduction of country- and region-specific constraints to the processing of health data for scientific research purposes, such as those around the concept of “public interest of the research”, the “impossibility or disproportionate effort to obtain consent” and the concept of “research institute or body”. The resulting patchwork of different rules across the EU is hindering health research and cross-country collaboration within the EU. The CoC should create consistency on the use of health data for scientific research purposes and pave the way for a harmonisation of the local implementation of the GDPR.

▶▶ *Issue European Data Protection Board (EDPB) essential guidance on the GDPR in collaboration with industry, the European Medicines Agency*

¹⁶ See section 2.3 for more details

(EMA) and relevant national authorities. It is fundamental to bring harmonisation on:

- the concept of personal data
- the use of public interest, scientific or historical research purposes, legitimate interest and consent as legal basis
- the compatibility of primary and secondary use of data
- the interaction between the GDPR and local and national regulations affecting health data processing
- the use of Real-World Data (RWD) for medicine discovery and development. Data collected in real life settings¹⁷ can help drive new understandings of value.

Data infrastructure

The exponential proliferation of data has the potential to transform healthcare and deliver unprecedented levels of quality and efficiency of care. Although multiple initiatives exist across Europe, we observe a lack of coordination and scale, as well as a fragmentation of resources and funding and an abundance of legal and privacy-related boundaries. The Common European Health Data Space requires a robust, secure and interoperable infrastructure with a clear governance framework and defined services. This is key to unlock the potential of health data in Europe.

A well-defined, common data infrastructure is fundamental to facilitate the consistent and secure secondary use of health data. The EU should therefore establish a central health data entity at EU level to select standards and profiles for interoperability, as well as a health data entity in each Member State to implement those standards. The role of the national entities should be to provide controlled data services, like healthcare information sharing and analysis. FinData in Finland and France's Health Data Hub could inspire the creation of the entities in each Member State.

The Commission should use the planned legislative governance framework for the European Health Data Space to create this infrastructure. It should establish the legal foundation of both the EU-level health data entity as well as the national health data entities, and mandate national health entities' adherence to the same set of rules, standards and profiles of standards selected at EU level, and in line

¹⁷ RWD can include a range of routinely collected data sources from EHR, hospital databases, electronic registries and insurance claims to wearables, apps, and device-generated data, amongst others.

with FAIR principles in data sharing and access.¹⁸ As a core tenet, this entity should exist to promote the frictionless sharing of health data across Europe in a safe, controlled and privacy-preserving environment.

A common, pan-European infrastructure as here suggested would help remove health data-sharing obstacles, boost the exchange of cross-border health data across the EU and guarantee health data interoperability, while optimising scale advantages in global supply markets for healthcare IT and medical devices by building on leading, internationally developed standards and profiles.

Finally, for such a governance framework to be effective, it is also crucial the Commission institutes a broad definition of what constitutes scientific research. In today's AI and big data age, a broad range of commercial activities may qualify as scientific research, and European citizens will benefit from their continued activities, utilising European data as appropriate.

Data altruism

We support health data “altruism” (donation) schemes to give clear, easy and secure ways for citizens to give access to their health data for the public good, in compliance with the GDPR. Control over personal data should remain with the patients/citizens themselves. They should be empowered to access and manage their own health data. Policymakers have an important role in making data donation and altruism a driver for healthcare innovation. We recommend them the following:

- ▶▶ For regular or continued data donation, to create GDPR-compliant, European standard forms between data donors and recipients to establish a legal basis and a strong foundation for long-term data processing activities in areas like research.
- ▶▶ For one-off donations, to develop a standard, GDPR-compliant European consent form to make the approval process by donors quick and efficient. The form could foresee data portability requests where necessary.
- ▶▶ To illustrate data donation use cases for citizen awareness and educate citizens about the benefits of data donation for their health and lives. This is crucial to convey to potential data donors why aggregated data is important to advance research and innovation for society's benefit.
- ▶▶ To encourage data altruism via model contractual clauses or data sharing agreements agreed by individuals.

¹⁸ FAIR stands for Findable, Accessible, Interoperable, Re-usable

Transparency and confidentiality

Data transparency contributes to the framework of trust to unlock the potential of health data in the EU. It can advance medicine knowledge and ultimately improve public health. The biopharmaceutical and medical device industry are playing their part to advance that, by promoting clinical research data sharing that benefits researchers and, ultimately, the healthcare community at large. A relevant example is the Yale Open Data Access (YODA)¹⁹ Project, founded to promote data sharing among the scientific community and develop to advance responsible data sharing. YODA provides increased access to anonymised pharmaceutical and medical device clinical trial data and clinical study reports provided by businesses supporting the initiative. A panel in the project independently reviews and makes final decisions on all requests from qualified researchers, physicians and investigators looking to access such data for the benefit of healthcare innovation.

We support industry-driven initiatives such as YODA which enhance transparency while respecting businesses' rights to data confidentiality.

Ethics

The Commission, Member States and all relevant key stakeholders (industry, academia, health institutions and patients) should develop **ethical principles for healthcare data generation, use, re-use, and curation**. They should address security, transparency and privacy based on the Ethics guidelines for trustworthy AI developed by the European Commission AI High-Level Group.²⁰ These ethical principles should recognise that citizens remain in control over their personal data.

Culture

Trust means also robust data understanding and awareness among officials, payers, practitioners, patients and citizens. As with all technological innovations, including data-driven ones, awareness-raising is key to build acceptance in society. Healthcare stakeholders and policymakers should take a holistic approach to digital health and data literacy. They should create a data culture that encompasses collaboration and partnership amongst healthcare practitioners, payers, patients and citizens. Policymakers should ensure that:

¹⁹ Johnson & Johnson, a DIGITALEUROPE member, is a member of YODA. It is currently making clinical trial data for pharmaceutical, medical device, and consumer products available. More info on YODA [here](#)

²⁰ Available [here](#)

- ▶▶ **Every citizen has access to digital literacy and skills training.** Digital literacy is critical to ensure citizens and patients are empowered to manage their own data and capable of taking informed decisions. This should extend not only to the use of digital health technologies, but also to the ethics, governance and advantages of using healthcare data to benefit all citizens. They should leverage key stakeholder-driven initiatives such as Data Saves Lives.²¹ There are existing training programs available from industry, many of which can be provided free of charge, which Member States could access.
- ▶▶ **Health professionals have the necessary skills to unlock the potential of data.** ICT specialists are just 1% of healthcare workforce and up to 70% of health professionals do not use digital solutions due to gaps in knowledge and skills in data analytics.²²
 - **Member States must prepare tomorrow's healthcare talent with digital-ready university curricula.** Data science and artificial intelligence should be at the centre of a major reform of education systems in Europe, supported by the EU. No health system can be resilient without digital literacy and the necessary digital skills among health professionals.
 - **The update to the Digital Education Action Plan, Erasmus +, Horizon Europe and the upcoming Pact for Skills should make sure no one is left behind in the healthcare workforce** and that practitioners are able to make use of innovative technologies that benefit healthcare. National authorities should design ambitious digital skills programmes tailored to the healthcare workforce.
- ▶▶ **Local officials become ambassadors and ethical advocates of the digitalisation of healthcare in their communities.** This is crucial to raise awareness of digital health innovation at local level across the EU.

²¹ More info [here](#)

²² OECD Health Policy Studies, [Health in the 21st Century: Putting Data to Work for Stronger Health Systems](#), 2019



Interoperability and standardisation

Achieving interoperability among healthcare systems and seamlessly exchanging information and data is critical to improving clinical operations and patient outcomes. 80% of health data remains unstructured and untapped after it is created.²³ Health data siloes prevent practitioners, researchers, authorities and businesses from capturing, analysing and applying valuable information to care delivery, improvements and decisions. Fundamentally, a lack of interoperability directly impedes health systems from providing effective care to citizens, and prevents data from being shared even within health systems. The Common European Health Data Space must ensure data systems are interoperable and therefore data sets are exchangeable and interpretable, and citizens have control of their personal data. Patient-generated data, clinical data²⁴ and data from other sources should all be seamlessly accessible and uniformly interpretable through interoperability of devices and systems to unlock the value of digital in this space.

Common data models

Internationally recognised standards are a critical element to achieve more outcome-based healthcare systems across the EU. The Commission and Member States should advance federated data models, whose goal is to analyse RWD standardised to common data models. Such models would facilitate interoperability and connectivity while respecting GDPR requirements. Their advantage lies in unlocking access to healthcare data and thus facilitating learning healthcare systems,²⁵ all while ensuring the highest level of protection of personal data and commercial IP. Through a federated model, the different sources of healthcare data act as nodes in a network. Importantly, the data remain in an on site, off site or hybrid cloud, unaltered and uncompromised. It is only the final output of the data analysis that is shared within the framework under secure, legally compliant conditions. Actors can use it to inform research, clinical treatment, hospital planning and payment models, and influence the effectiveness of the overall healthcare demand and supply value chain. EU citizens and patients should be at the core of such a network and remain empowered throughout, so no provider can prevent them from managing or accessing their data. A key example of federated data model projects is the Innovative Medicines Initiative (IMI) initiative EHDEN,²⁶ which builds upon the Observational Medical Outcomes Partnership (OMOP) Common Data Model

²³ Kong, Hyoun-Joong. (2019). Managing Unstructured Big Data in Healthcare System. Healthcare Informatics Research.

²⁴ Including high-dimensional (e.g. omics) data

²⁵ Healthcare systems in which knowledge generation processes are embedded in daily practice to produce continual improve in care

²⁶ More info [here](#)

(CDM) launched in the US. The OMOP CDM standardises different structures across disparate health data sources into common tables which harmonise structure, field datatypes and conventions.

There are also other projects on common data models focusing minds of policy-makers and the health community. The EMA and the Heads of Medicines Agencies (HMA), for example, have called²⁷ for the establishment of DARWIN,²⁸ a European network of databases of known quality and content associated by a strong focus on data security. DARWIN's role would be to extract valuable information from multiple, complimentary RWD databases to support regulatory decision-making.

European Electronic Health Record exchange format

Fulfilling the ambitions in Recommendation on a European Electronic Health Record exchange format²⁹ should be key for the Commission. Priority should be given to:

- ▶ **The completion by 2022 of the exchange of electronic patient summaries and ePrescriptions between various Member States.**
- ▶ **Progress on the other baseline domains identified in the Recommendation.** We need profiles providing specifications for interoperability also for laboratory results, medical imaging and reports, and hospital discharge reports. These information domains showed to be vital in the fight against COVID-19 across Europe. The Commission should complete these profiles before 2024 and support their practical implementation to meet clinical needs.
- ▶ **Convergence on specifications selected for data exchanges between health applications.** Convergence will provide strong investment incentives for vendors to comply with prioritised specifications and develop them further. One example are the Existing Fast Healthcare Interoperability Resources (FHIR) standards. They are consistent, easy-to-implement information models used by all major cloud providers and health technology application developers. They also build on similar specifications in related ICT health solutions. Other examples are the DICOM standards and the IEEE Xplore digital library.

²⁷ More info [here](#)

²⁸ DARWIN stands for Data Analysis and Real World Interrogation Network.

²⁹ Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format

Common data classification framework

Europe should encourage a common health data classification framework to help organisations categorise identifiable, anonymised and pseudonymised data. This is especially important as the volume of global healthcare enterprise data is set to grow at a faster rate than the global average data volume.³⁰ Properly managing this growing amount of data becomes crucial as it helps organisations to consistently identify data which belongs to a special category or is potentially high risk for sharing - and take appropriate mitigating actions.

A notable focus area for data classification should be to enable the use of all classes of healthcare data with cloud technology, with appropriate levels of security and risk mitigation in place which corresponds with the type of data being processed. The use of cloud computing is growing in important scenarios like global research collaboration, predictive analytics for early disease detection and population health management. We need a more harmonised approach to utilising cloud technology for healthcare workloads. This could be enabled through a commonly adopted risk assessment framework for different types of health data. It would help data controllers to adopt cloud technologies with the appropriate architecture, security and privacy considerations, and ultimately benefit healthcare innovation. We highlight guidance from NHS Digital³¹ as one among existing good practices and encourage the Commission to also explore others. NHS Digital acknowledges cloud technology's benefits, including for the use of data analytics environments pooling together anonymised data, which is a similar concept to the upcoming Common European Health Data Space. Other healthcare systems across Europe, Data Protection Authorities and the European Commission should define together similar guidance at European level. In Annex I below, we detail the main elements of the NHS Digital's Data Risk Assessment guidance to inspire policymakers' thinking on this issue. We also encourage how the European Open Science Cloud initiative seeks to create a more common understanding of vocabularies and semantic registries to advance data analytics tools in research, including in health.



Investments in digital solutions

The EU has well-tested secure digital solutions from across the globe available for it to build capacity for the Common European Health Data Space. These technologies can deliver advanced services and address areas like interoperability of health IT systems, which require ambition from Commission and Member States to fulfil the goals in the 2019 Recommendation on a European Electronic Health Record exchange format. Large volumes of rich and

³⁰ IDC, [The Digitization of the World: From Edge to Core](#), 2018

³¹ NHS Digital is the statutory body in England with responsibility for national information and technology deployment in the health and care system

quality data will enable transformative technology like AI and machine learning to achieve a precise diagnosis, support personalised therapies, draw new patient- and disease-level insights and advance research in vital areas like genome sequencing. They will enable medicines to deliver their full potential with personalised treatments, and ultimately revolutionise medical science.

We urge policymakers to:

- ▶▶ **Recognise Next Generation EU offers an unprecedented opportunity to transform healthcare systems.** On average, health sectors in developed economies spend just 10% of total expenditure on software and databases, less than other large sectors like finance and machinery.³² Member States' Recovery and Resilience Plans should upgrade medical equipment, IT systems and software used in hospitals, medical centres and research labs. We need a paradigm shift in Europe from investments into legacy infrastructure to investments into future-oriented, well-tested technologies capable to project us towards the sustainable, digitalised healthcare systems we need. Data-driven, personalised care requires a strong technology infrastructure as much as a framework of trust and standardised, interoperable systems and devices.
- ▶▶ **Prioritise resources for setting up EHDS governance.** There should be ample funding reserved in the next MFF (i.e. Health Programme) that is dedicated to the setting up of the governance institutions that will be needed for the creation and functioning of the EHDS. Monitoring and coordinating the implementation of common standardisation will demand meaningful investment. This could be realised with an ambitious Health Programme.
- ▶▶ **Accelerate privacy-preserving machine learning and confidential computing solutions.** To run collaborative data analytics exercises that guarantee the privacy of datasets used. Techniques like homomorphic encryption minimise any risk of re-identifying anonymised patient data, allowing for AI computation directly on encrypted data.
- ▶▶ **Use the Digital Europe Programme (DEP) to establish health-focused, world-reference AI testing facilities.** Placed across the EU, they should partner with healthcare actors to test AI solutions in real operational environments. This is key for health organisations to nurture the growth of data scientists at the forefront of healthcare innovation.

³² Investment in software and databases as a % of non-residential Gross fixed capital formation (GFCF). GFCF is a measure of spending on fixed assets. Source: Calvino et al. (2018[26]), "[A taxonomy of digital intensive sectors](#)"



Annex I: NHS Health and Social Care Risk Framework for data transfer to the cloud

NHS Digital (the statutory body in England with responsibility for national information and technology deployment in the health and care system) has published a risk framework³³ and associated risk model,³⁴ for organisations with health and social care data that wish to make use of public cloud technologies. This guidance acknowledges the benefits of using these technologies, including the use of data analytics environments containing anonymised data: a similar concept to the Common European Health Data Space. It advocates implementing a set of controls which are consistent with the assessed level of risk for processing each dataset. Whilst organisations can never fully remove the risk of processing data using cloud technology, they can build in appropriate controls which are consistent with the risk associated with the data being processed.

Individual organisations retain the responsibility to assess the risk of using public cloud technology with their data. The document provides a high-level overview of the risk classes that should be considered, all of which are relevant to a Health Data Space. The guidance also notes that the construction of the technology solution that is being used to process the data can support the mitigation of some of these risk classes. These risk classes and their description are defined below:

Risk Class	Description
Confidentiality	Data may be subject to loss of confidentiality through breach, through unauthorised access, or through unintended or accidental leakage between environments
Integrity	Data may be subject to loss of integrity through data loss or unintended manipulation
Availability	Ensuring that access to your data is available when required. Network connectivity to cloud becomes a critical dependency and there is a risk of introducing a Single Point Of Failure (SPOF). Public cloud cannot be assumed to be permanently available; cloud availability and SLA [Service Level Agreement] must match the need.
Impact of breach	We cannot assume there can never be any breach, so we need to consider the <i>impact</i> of any unintended breach (unauthorised disclosure into an uncontrolled, or less-well-controlled than intended, environment)
Public perception	There is some degree of public concern over the use of public cloud given that these are widely available, shared, computing environments

³³ NHS Digital, [Health and social care cloud risk framework](#), 2018

³⁴ NHS Digital, [Health and social care data risk model](#)

Lock-in	<p>Flexibility may be impacted (resulting in increased levels of lock-in) by:</p> <ul style="list-style-type: none"> • The adoption of a specific public cloud provider's unique services • The difficulties involved in migrating large quantities of data may make it difficult, in time and/or cost, to migrate to an alternative in the event of future commercial or service changes • An architecture that is not sufficiently tailored to a public cloud model
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Table 1. Risk Classes and Descriptions, from NHS Digital Health and Social Care Cloud Risk Framework, p 5. Copyright NHS Digital, 2018

The guidance then advises the impact of the risk to be considered in terms of the data type, data scale, and data persistence.

- ▶▶ **Data type:** organisations are advised to classify their data into the following categories³⁵:
 - publicly available information
 - synthetic (test) data
 - aggregate data
 - already encrypted materials
 - personal data (including demographic data and personal confidential data)
 - anonymised data (including reversibly - and irreversibly)
 - patient account data
 - data choices
 - patient meta-data (identifiable and linkable)
 - personal user account data
 - audit data
 - key materials
- ▶▶ **Data scale:** organisations are also advised to consider the depth and breadth of the data items they are considering, so that the relative impact of a potential breach can be assessed
- ▶▶ **Data persistence:** the extent to which data will be stored for the long-term versus transitioning immediately out of the environment in which it is being processed. Generally, the risk reduces as the persistence of the data reduces

Organisations are then encouraged to enter information about their data type, scale and persistence into the associated [risk framework](#) tool, which generates an associated Risk Impact Score. These scores are mapped to one of five Risk Profile Levels, which provides organisations with an overall perspective on the

³⁵ More info on the Data classification scheme [at page 7 of NHS Digital Health and Social Care Cloud Risk Framework](#)

“degree of risk or contentiousness” of the data they are considering processing in the public cloud. See Appendix C for a description of these risk profiles.

As part of implementing controls to support the mitigation of these risks, organisations are then asked to refer to the Health and Social Care Cloud Security Good Practice Guide³⁶ (see table below), which documents specific controls that should be put in place for the different Risk Profile Levels of the data that has been assessed. These controls include principles for:

- ▶▶ data in transit protection
- ▶▶ asset protection and resilience
- ▶▶ separation between users
- ▶▶ governance framework
- ▶▶ operational security
- ▶▶ personnel security
- ▶▶ secure development
- ▶▶ supply chain security
- ▶▶ secure user management
- ▶▶ (end user) identity and authentication
- ▶▶ external interface protection
- ▶▶ secure service administration
- ▶▶ audit information for users
- ▶▶ secure use of the service

Risk Profile Levels

Risk Profile Level	Governance Expectation
Class I	All organisations are expected to be comfortable operating services at this level.
Class II	Whilst there may be some concerns over public perception and lock-in, most organisations are expected to be comfortable operating services at this level.
Class III	At this level, risks associated with impact of breach become more significant, and the use of services at this level therefore requires specific risk management across all risk classes described in Section 4, requiring approval by CIO / Caldicott Guardian level.
Class IV	At this level, it is likely to become more difficult to justify that the benefits of the use of public cloud outweigh the risks. However, this case may still be made, requiring approval by CIO / Caldicott Guardian, and would be required to be made visible to the organisation’s Board. Specific advice and guidance may be provided by NHS Digital on request.
Class V	Operating services at this level would require board-level organisational commitment, following specific advice and guidance from NHS Digital.

³⁶ NHS Digital, Health and social care cloud security - good practice guide

Recommendations from our paper on how to harness the power of AI in health applications

23 January 2020 – these recommendations have been sourced from our paper on [how to harness the power of AI in health applications](#).



Executive Summary

AI solutions for health will thrive and benefit patients in Europe only through a coherent and ethical strategy that will prepare governments' health systems and mitigate any unintended consequence of AI use. AI will play an important role as diseases like cancer are expected to rise due to Europe's ageing population.

A study predicts AI alone has the potential to add 0.2–1.3 years onto the average life expectancy.³⁷ AI can improve and accelerate the development of safe and effective medicines, support chronic disease management (such as diabetes), enhance the information available for screening and treatment decisions as well as provide continuous monitoring tools supporting diagnosis or tracking disease progression. They also have the potential to deliver tools to better understand the risk for future diagnoses, stratify patient populations for more precise treatment options and patient management, improve adherence to treatments and ultimately improve clinical and patient outcomes. DIGITALEUROPE calls on relevant policymakers, such as the European Commission, Member States' governments and elected representatives, to:

- ▶▶ Prioritise risk assessments and avoid one-size-fits-all approaches in the design of any future AI policy framework for health. The risk of deploying AI in this domain greatly varies under the specific application considered. Predicting hospital attendance is very different from life-saving AI solutions that diagnose a certain disease. Any future framework should also consider existing international standards, legislation and ethical principles.
- ▶▶ Empower AI development for a health data ecosystem, by earmarking more resources to foster the accessibility and interoperability of health data and addressing its provenance as well as curation. In addition, accelerate health data sharing through FAIR (Findable, Accessible, Interoperable and Reusable) principles.

³⁷ McKinsey Global Institute, Artificial Intelligence: The Next Digital Frontier?, 2017

- ▶▶ Promote policies that encourage the development of AI solutions for clinicians integrating Electronic Health Records (EHRs).
- ▶▶ Tackle the creeping fragmentation and regulatory divergences of health data-processing across the EU, while accelerating the creation of a European health data space. Even if the GDPR allows each Member State to introduce further data-processing conditions for genetic and health data, the Commission and national data protection authorities should strive for a harmonised framework of rules.
- ▶▶ Foster the adoption of initiatives on the secondary use of health data for AI research. They should be deployed at scale across the EU.
- ▶▶ Commit sufficient resources to the development, adoption and implementation of AI in health applications.
- ▶▶ Recognise the benefits of all AI applications for health systems and society. The technology holds potential in a variety of patient treatment solutions. It is equally helpful in areas beyond pure patient care. For example, Natural Language Processing, a branch of AI, can free up precious time for practitioners by dramatically speeding up EHR documentation, one of the most time-consuming tasks in today's health care context.
- ▶▶ Adjust the implementation of the EU health regulatory framework to allow new emerging AI solutions on the market. The overall objective and requirements of existing legislation are generally fit for purpose to cover existing AI products and services in health. The Medical Device Regulation and subsequent guidance will require market assessment bodies who are enforcing the regulation to be regularly trained to understand thoroughly the inner workings of AI, including new mHealth solutions in the EU. Training should also clarify how to exploit the self-learning capabilities of AI systems in health. If practitioners, patients and society are to benefit from AI fully, our regulatory approach to health technology must move in parallel to market innovation.
- ▶▶ Proportionality is the key in the discussion on the explainability of AI decisions specifically with respect to the intended use of the technology, and the corresponding potential risk for the patient. Explaining how the algorithm works should be understood as an occasion for the user to obtain meaningful information. It should not be about sharing source code or training data.

- ▶▶ Recognise that developing completely bias-free algorithms will never be possible. However, policymakers can incentivise research, training and increase data availability to tackle and reduce potential unintended or discriminatory bias in AI algorithms.
- ▶▶ Advance ambitious upskilling and reskilling programmes tailored to the specific needs of all relevant health stakeholders, be them patients, doctors or health market authorities certifying AI technology. Training should be complemented by awareness raising campaigns on the role of AI in health.
- ▶▶ Firmly consider cybersecurity as an essential element for trust in AI in health. We reiterate our support to strengthen cybersecurity across the EU through a framework for the development of voluntary cybersecurity certification schemes based on already internationally recognised schemes.



Introduction

Artificial Intelligence (AI) in health has the potential to bring vast benefits to Europe. If properly harnessed, AI will lead to improved patient outcomes, empowered health practitioners, formidable organisational efficiencies, more productive R&D as well as more sustainable learning health systems. A study predicts AI alone has the potential to add 0.2–1.3 years onto the average life expectancy.³⁸ Turning these predictions into reality will require the commitment of a multitude of stakeholders, including industry, authorities and health professionals, to address challenges and opportunities in the technology.

As an important prerequisite, we need to expand access to health data across Europe — creating an ambitious “common health data space” — to enable a better development and a more effective use of AI systems, all while at the same time increasing patients’ protection through transparency measures and concerted stakeholders’ actions. Policymakers also need to clarify the existing EU regulatory framework as these technologies mature and become increasingly adopted. For instance, legislation such as the Medical Device Regulation (MDR) guarantees trust in the safety and performance of AI technology where risk-assessment is a primary principle. The success of AI in health will ultimately require the EU to develop a coherent strategy in this domain. This document builds upon the work of the High-Level Expert Group on Artificial Intelligence set up by the European Commission. It shows the way forward for authorities across Europe to maximise the benefits of AI in health and, at the same time, minimise its potential risks. The recommendations in this paper have been prepared on the basis of requirements for a trustworthy AI³⁹ which the High-level Expert Group identified as critical for ethical, secure and cutting-edge AI made in Europe.

The technology is poised to be a boon for good patient care, the viability of future public healthcare budgets and prevention. Now it is up to Europe to exploit its capabilities with big investments, ambitious innovation policies and a cautious and nimble regulatory approach that keeps pace with evolving digital health technologies.

³⁸ McKinsey Global Institute, *Artificial Intelligence: The Next Digital Frontier?*, 2017

³⁹ High-Level Expert Group on Artificial Intelligence, *Ethics Guidelines for Trustworthy AI*, 2019



Definitions

As DIGITALEUROPE explained in its Recommendations on AI Policy⁴⁰, AI is not a single technology, nor a specific product or service. It should rather be understood as an indication of the extensive processing capabilities of a machine, robot or indeed software. Its applications can range from performing a very narrow task to conducting a whole set of different activities all at the same time. Specific technology uses have emerged in the health sector, where a form of AI called “augmented intelligence” is particularly prevalent. Augmented intelligence focuses on assisting human operations thereby augmenting, as the name suggests, humans’ performance in a certain task. Importantly, there is no replacement of human input in this form of AI.



AI applications in health

AI-based solutions in health are used in a variety of contexts. They can improve and accelerate the development of safe and effective medicines, support chronic disease management (such as diabetes), enhance the information available for screening and treatment decisions as well as provide continuous monitoring tools supporting diagnosis or tracking disease progression. They also have the potential to deliver tools to better understand the risk for future diagnoses, stratify patient populations for more precise treatment options and patient management, improve adherence to treatments and ultimately improve clinical and patient outcomes.

As an example in medical imaging, AI speeds up the process from image acquisition to patient care by helping to detect diseases like cancer much earlier than conventional technology. Patients, health practitioners and researchers all stand to gain from AI-driven medical imaging, not the least because it will accelerate disease prevention, speed up patient recovery times and ultimately save lives. Other relevant uses of AI in health are in genomics processing, a field of molecular biology investigating on all aspects of a genome, drug and therapy discovery as well as adoption for more personalised patient treatment. Crucially, AI does not deliver only benefits for the patient. The savings these and other similar AI applications allow in budgets should not be overlooked either. The UK’s National Health Service (NHS) predicts using AI models for preventive care could lead to up to £ 3.3 billion savings, as costs on nonelective hospital admissions would be slashed.⁴¹ As demographic trends exert a growing pressure on government health expenditure, the cost-optimisation potential of AI becomes incredibly relevant. What is more, the technology is also a formidable tool in fraud-detection, a less research-intensive but equally important aspect in health.

⁴⁰ DIGITALEUROPE, DIGITALEUROPE Recommendations on AI Policy: Towards a sustainable & innovation-friendly approach, 2018

⁴¹ European Commission, Harnessing the economic benefits of Artificial Intelligence, 2017

By sifting through huge datasets, it can help to strengthen oversight of hospital expenditure and identify cases of corruption. It can prevent, too, burnout felt by health professionals. A survey revealed one in four physicians reported episodes of burnout due to the increasing computerisation of their tasks.⁴² Natural Language Processing (NLP), a branch of AI, can streamline electronic health records (EHRs) systems, limiting the time health professionals spend away from direct patient interactions. In a nutshell, AI will leave more time for human connection that can enable improved doctor-patient communication and more personalised care, which is known to improve patient outcomes.



Building trust

One of the most relevant topics in the public debate on health-based AI is the uncertainty or lack of clarity about its specific applications. Under the assumption that AI is at least partially capable of self-learning and reasoning, some have raised concerns about the safety and effectiveness of decisions or recommendations induced by the technology. Their focus has mainly been on the role of health professionals in an AI-influenced environment, the privacy and security of patient's health data, as well as the overall impact of the technology on the patient. Trust is consequently key in driving the uptake of AI systems in health and allowing many solution providers, including SMEs, to scale in this market. As AI will progress, the importance of autonomous decisions made by algorithms will grow. A health-specific AI ethical approach would allay these concerns. It should maintain transparency and diagnostic reasoning, especially when applications help determine the course of patient care. Integral to this framework is the critical impact that education will have on building trust. Upskilling the healthcare community will be important to ensure that those engaging with AI technology can maintain a healthy level of scepticism/critical thinking when embedding AI outputs into decision workflows. More automation in decision-making must not come at the expenses of lower safety or protection standards in Europe.

Having said that, DIGITALEUROPE also urges to draw sufficient attention to all different use-cases of AI in this domain.

As shown earlier, several existing applications are deployed far from the strictly research-intensive or patient care operations that generate concerns among some. AI models that predict hospital attendance⁴³ or advance drug discovery⁴⁴ are arguably very different from life-saving AI solutions that diagnose a certain disease or recommend a certain course of therapy. Though more mundane or distant from the lab they may be, these uses are similarly beneficial. Adding to

⁴² Advisory Board, Physician burnout in 2019, charted, 2019

⁴³ Nature, Predicting scheduled hospital attendance with artificial intelligence, 2019

⁴⁴ Nature, How artificial intelligence is changing drug discovery, 2018

that, the software into which they are embedded must already meet highly stringent requirements in terms of functionality, reliability, usability and efficiency, just as any other patient-treating software product. It is therefore important to always adopt a risk-based approach to governing the use of AI.

DIGITALEUROPE underlines the following in the debate on trust in health-based AI:

- ▶▶ Health is one of the most highly regulated sectors in Europe. In an overwhelming variety of cases, there are specific requirements which AI-based solutions must observe. The MDR,⁴⁵ recently amended, is one of the main examples in this respect (see below in the Chapter on Safety, Accountability and Liability). It guarantees trust in the safety and performance of AI systems that will be deployed.
- ▶▶ A risk-based approach should always be prioritised by policymakers when designing policy frameworks for health-based AI. Should new regulatory measures be examined, it is crucial to always consider that the level of risk of AI health applications will vary, and that very different considerations will be needed from a policy perspective, in accordance with the specific product or service in question. Descriptive, predictive and prescriptive analytics arguably imply different levels of risk. Diagnostic software, where all the information needed by a doctor is present in the immediate dataset, has a different risk profile than, say, predictive analytics where patient treatment solutions are suggested based on EHR data, which at times can be inaccurate or incomplete. In addition, policymakers should also give appropriate attention to existing legislation, standards and ethical principles.
- ▶▶ Emerging health AI applications need to maintain sufficient transparency (i.e. diagnostic reasoning), flexibility and demonstrate clear improvements over the standard of care in order to reach scale in the EU. AI has the potential to develop decision tools facilitating clinical treatment decision-making. This would boost the growing discipline of precision medicine, where clinicians are required to identify/predict which patients will respond to particular treatments in areas such as cancer care.

⁴⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical

devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

- ▶▶ Providing clinicians with EHRs-integrated AI systems allows for guidance that is personalised to the individual characteristics of the patient. As these AI systems facilitate patient-clinician communication and support shared clinician-patient decision making, they increase the likelihood of patients fully engaging and committing to treatment plans. This can contribute to increased trust between such actors, and therefore foster greater confidence in the use of AI and other digital solutions.
- ▶▶ Trust is a core aspect promoted by initiatives on the secondary use of health data for AI research, some of which are conducted in Europe. They boost research opportunities while making data usage more secure. There would be significant gains if such projects are deployed at scale.
- ▶▶ Cybersecurity remains a critical aspect in generating trust in health AI solutions. DIGITALEUROPE reiterates its support for the EU's efforts on strengthening cybersecurity across the Union through the creation of a framework that will pave the way for voluntary cybersecurity certification schemes based on already internationally recognised schemes.



Human agency

Augmented intelligence, as mentioned above, is one of the most common forms of AI in the health domain. It can, for example, spot abnormal looking cells in an image of a patient's tissue sample that escaped detection by a specialist doctor, therefore enhancing the cognitive performance of the health service provider. In this way, augmented intelligence contributes to high-quality care without replacing humans in strategic patient-related decisions. AI algorithms are not infallible and every stakeholder in the industry has a responsibility to remain critical of its use and application to the decision-making process, regardless of the question being asked and considering the high-stakes nature of the sector.

More of such AI forms will come as the technology continues to improve and be employed for new applications, even beyond the hospital. Lifestyle and diet will indeed be among these. Progress on AI will gradually lead to personalised digital health services; users will be able to take sound health-related decisions based on the recommendations from, say, new diagnostics apps. This being said, more sophisticated usages will continue to be intermediated by a healthcare professional, depending on the purpose.



Safety, accountability and liability

Safety is a primary driver for the successful adoption of the technology in the health domain. This is indeed the case also for AI software that has an intended medical purpose, which in the EU must comply with the MDR. This critical piece of legislation details a series of robust essential requirements which ultimately

provide a very high level of safety and performance during technology deployment. Suppliers of AI solutions must obtain a valid certification from a relevant conformity assessment body if they are to introduce such solutions on the EU market.

Obtaining it is a sophisticated process. Certifying AI software against the MDR criteria requires the AI solution provider to demonstrate that the software's clinical and analytical nature is safe enough. In the case of image recognition software, certification includes direct comparisons between the algorithm's performance and the radiologist's in, say, lung disease detection. Final results on the safety and validity of the AI system are drawn only after the analysis of many samples.

Considerations on the enforcement of the MDR in regard to AI

The implementation of the existing EU regulatory framework will need to catch up with the progresses of AI in health. Concretely, the EU should put in place a more agile, innovation-oriented certification framework for AI healthcare devices, capable of approving more powerful AI systems without eroding trust in their use. As an example, AI systems today used in the sector are “locked”, meaning that once certified for the EU single market, they are prevented from exploiting their inherent self-learning capabilities. This translates, potentially, into huge lost opportunities to improve patient-treatment in the future. As diseases like cancer are expected to rise due to Europe's ageing population,⁴⁶ tackling this serious innovation barrier will be crucial in the future.

Other jurisdictions are taking steps in this direction. For example, the US FDA published a discussion paper titled “Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)” to address the iterative improvement power of AI and machine learning based software as a medical device, while assuring patient safety.⁴⁷

- ▶▶ We invite the European Commission to provide guidance on these issues through the existing initiative of the Medical Devices Coordination Group (MDCG). This will be key to further address the regulatory aspects of health AI in Europe, and to facilitate communication and collaboration between data scientists, health technology experts in academia and private sector, as well as patient organisations.

⁴⁶ European Commission, EU Action on Cancer, 2015

⁴⁷ The FDA discussion paper is available [here](#)

- ▶▶ We also invite Member States to dedicate sufficient resources to train notified bodies responsible for the conformity of medical devices placed on the EU market. It is key that market assessment bodies enforcing the MDR properly understand the inner workings of AI technology.



Accountability and liability

Businesses firmly embed accountability and liability considerations into the development of AI systems for health applications. Industry has prepared product development lifecycles which include impact assessments and balancing tests to measure privacy and security risks in AI. Ethical principles feed into a growing number of businesses' impact assessments. Fittingly, new technologies occupy more and more time of the discussions in ethics councils and firms' ethical review boards. DIGITALEUROPE warmly welcomes organisations that embrace risk-based accountability approaches and put in place technical or organisational risk-minimisation measures.

Adding to that, we underline the robust and balanced EU regulatory framework for liability and safety in new products and technology. Two pieces of legislation in particular, the Product Liability Directive⁴⁸ and the Machinery Directive⁴⁹, prove to offer a comprehensive coverage of AI accountability and liability aspects. They are both currently subjects of review by the European Commission.

DIGITALEUROPE is following these discussions closely while noting the liability, negligence, fault, risk attribution and accountability provisions they contain are part of a complex ecosystem and value chain. Additional evidence-based studies are needed before drawing conclusions, particularly when addressing emerging technologies, including those in health. Policymakers should conduct analyses in an informed manner and primarily seek to answer if existing provisions adequately address risk mitigation and minimisation.

⁴⁸ Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

⁴⁹ Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)



Transparency and explainability

As the technology matures, new AI uses will be accepted in the health sector. Together with an emphasis on safety and effectiveness, adequate levels of transparency will facilitate users' understanding of AI applications and their boundaries. Algorithmic explainability will be crucial, especially when the causal relationship between data and AI decision is not immediately apparent.

Industry fully recognises the need to provide meaningful information and facilitate the interpretation of health-based AI. In particular, DIGITALEUROPE would like to emphasise that:

- ▶▶ For medical devices, including software, extensive testing procedures are conducted prior to introducing these solutions on the market. Whenever these tests demonstrate that an AI medical device is safe as well as clinically and analytically valid, their results are and will continue to be, themselves, strong reassurances for the user. Professional education would, in any case, remain key for health practitioners to understand the functioning as well as the inputs and outputs of the AI system. This will help deploy AI effectively and safely, and support clinicians to appropriately explain the technology, its risks and limitations to patients.
- ▶▶ Proportionality is key. The extent of AI explainability should be in respect to the intended use of the technology and the corresponding potential risk for the patient. Explaining how the algorithm works should be understood as an occasion for the user to obtain meaningful information. It should not be about sharing source code or AI training data, which are crucial elements for security, integrity and IP protection.
- ▶▶ There is still a lot of space for innovation. For example, DIGITALEUROPE points out that "reverse-engineering" an AI decision, that is understanding how the algorithm reached a certain result, greatly depends on the specific AI technique adopted. Explainability of AI processes is an exciting area for businesses and academia to develop techniques aiming to give more contextual and background information behind AI-driven decisions. Principles and guidance are being produced to assist developers in making AI systems auditable right from the moment they are created.



Diversity, non-discrimination and fairness

It is essential that AI and data processes are in line with European social norms. For AI to benefit society at large, we must therefore ensure that AI systems are not skewed by bias hidden in data. This can originate from using inadequate datasets that are incomplete, outdated or not diverse enough. Unwanted discriminatory bias can also be the result of unconscious or historical behaviours and patterns. Just removing sensitive data may not be enough, as the AI model could pick up on or recognise patterns between other proxies.

AI models may never be completely free of unfair bias, as bias permeates our society. However, we can minimise the problem and constantly improve models. Developers and deployers can take action to identify and avoid bias in data, including through analysis and building common criteria and data quality standards. By increasing the quality of input data, paired with thorough scrutiny and diversity of sources, we can greatly improve the output as well.

Furthermore, it is worth noting that many AI applications, including in the health space, are designed to serve a specific population – i.e. a specific disease area, personalised medicine, etc. The design process may require in those instances some level of conscious discrimination to achieve the right result.

Many companies have already set in place constant re-evaluation processes, to detect divergences and anomalies, and to quickly correct these flaws. This also requires diversity across input and high-quality datasets, and among designers and software engineers for assessing and interpreting the output. It is also important to ensure appropriate training for data scientists and software engineers, so they can acknowledge and address their own biases.



Data governance in AI for health – availability, access, use and quality

Data sharing

Data is the building block of health knowledge. Studies estimate the volume of healthcare data will reach 2.134 exabytes by 2020, on the back of growth rates of about 48 percent year-on-year.⁵⁰ In the era of AI and precision medicine, access to quality data has promptly taken a central stage in the debate. As the availability of data increases, so does the potential to provide better services and more effective therapies and treatments.

Important as it is, the digitalisation of patient records can only be considered as one part of the story. The type of data effectively stored its format and possible reusability all are other important factors to enable a real data-based ecosystem.

⁵⁰ PwC, Sherlock in Health: How artificial intelligence may improve quality and efficiency, whilst reducing healthcare costs in Europe

They would all play an instrumental role in better disease understanding and prevention, improved personalised health research, as well as better diagnosis and treatment. Evidence shows there is already appetite for such an ambitious health data ecosystem among citizens. In a 2017 European Commission's survey⁵¹, 80% of respondents said they would agree to share their health data if privacy and security aspects were considered. However, despite citizens' enthusiasm for data-sharing to serve clinical and research purposes, the European Commission and other stakeholders recognise data-sharing mechanisms still fail to materialise in Europe.⁵² The reasons for this are multiple. They include format and accessibility issues, lack of sustained political focus on health data, heterogeneous and time-consuming patient consent frameworks, limited technical interoperability and suboptimal level of digital literacy among health workforce and the general public. On AI research specifically, for example, AI algorithms that mimic the diagnostic or other decisions of a clinician require training on EHR data, which are often incomplete, inaccurate and lack interoperability. The lack of digitalisation of the full healthcare journey remains a critical barrier to implementing AI successfully in healthcare workflows. It will require going beyond diagnostic or other problems of image recognition and classification, where all the information you need to make a decision (e.g. about whether a breast tissue sample has malignant cells or not) is present in the immediate data set. Finally, digitising the healthcare system will also need to consider issues of temporality in decision making and inherent biases within the data.

In this discussion, DIGITALEUROPE emphasises the importance of building a health data ecosystem by guaranteeing FAIR⁵³ principles in any health data governance architecture:

- ▶▶ The principles of Findable, Accessible, Interoperable and Reusable (FAIR). data should be encouraged in the health space. This includes storage according to widely accepted standards to facilitate its search, secure accessibility through technical and organisational measures, interoperability based on standard formats (namely FHIR⁵⁴) and widely agreed metrics, as well as proper attribution to incentivise and reward data-sharing practices.

⁵¹ European Commission, Transformation of Health and Care in the Digital Single Market, 2019

⁵² A 2018 European Commission's [Staff Working Document](#) concludes that "it is widely shared among the stakeholders that access to varied data-sets located across different Member States remains difficult or inexistent, the data is subject to different taxonomies and standards and therefore scientific research invariably builds on relatively limited population cohorts"

⁵³ Nature, The FAIR Guiding Principles for scientific data management and stewardship, 2016

⁵⁴ Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format

We also point out the significance of crafting policies that encourage the use of AI in laboratories. As the volume of health data, already large today, is estimated to double every two years,⁵⁵ there are tremendous benefits in deploying AI for real-world data analysis. In its Communication on Digital Transformation of Health and Care,⁵⁶ the European Commission included real-world data among pilot areas where to dedicate EU funding for testing cross-border health data exchanges for research purposes.⁵⁷ It should continue to step up efforts to tackle the lack of standardised data collection, representative databases and data quality standards, the latter being particularly important to leverage EHR. These are among the barriers that hinder today the potential of real-world data and AI in the health domain.

Getting rid of them will lead to better research findings and ultimately improve patient treatment outcome.

Data processing

Health data processing is regulated by the General Data Protection Regulation (GDPR).⁵⁸ As the European ecosystem for health data develops, so will data collection, collaboration amongst stakeholders and new opportunities for data processing. Privacy and data protection issues will remain equally relevant. DIGITALEUROPE recommends to EU policymakers the following in order to improve health data governance and advance the health data-processing debate:

- ▶▶ Promote EU-wide Codes of Conduct as powerful tools to address data-processing issues in health applications. Codes of Conduct help to ensure the proper application of the GDPR and inject trust in health data-processing. They would contribute, for example, to network effects. More and more endorsement of the Code by stakeholders would lower the barriers to entry into large-scale collaborative health research, thereby triggering a virtuous circle of initiatives.

- ▶▶ Tackle the creeping fragmentation of health data-processing across the EU while accelerating the creation of a European health data space. The GDPR remains an EU-wide provision, but it does not completely harmonise data protection rules across the EU. Member States are interpreting the regulation differently, hindering opportunities for better health outcomes through de-identified patient level data. Even if the GDPR allows each Member State to introduce further data-processing

⁵⁵ PwC, *Sherlock in Health: How artificial intelligence may improve quality and efficiency, whilst reducing healthcare costs in Europe*

⁵⁶ European Commission, *on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society*, 2018

⁵⁷ European Commission, *Real-world data*, 2018

⁵⁸ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

conditions for genetic and health data, the Commission and national data protection authorities should strive for a harmonised framework of rules. It is very important that Member States and the European Commission eliminate or at least minimise regulatory divergences on health data to avoid fragmentation in the Single Market.

- ▶▶ Implement policy approaches that maximise the value of the secondary use of health data. The European Commission and Member States should also ascertain ways in which data can be pooled and made available to improve patients' outcomes while safeguarding patient privacy. A useful example to address this issue comes from Finland.⁵⁹
- ▶▶ Introduce guidance by the European Medicine Agency (EMA) and the Heads of Medicines Agencies (HMA) network on real-world evidence and the use of data sources for regulatory purposes. A framework with guidance on factors to be considered and addressed in a regulatory submission should also be developed. It would encourage exploration by industry of alternative approaches to real world evidence generation.
- ▶▶ Promote a secure, privacy-preserving, access to health data by promoting an EU-level data space where health-focused AI can move forward.
- ▶▶ Strive for a complete digitalisation of health data by 2024 by strengthening data interoperability, facilitating secure data-sharing across multiple data sources and allowing easy and secure access to health data by patients.



Education and Skills

No AI model can be adopted without experts developing and testing it successfully. This holds true for the health domain as well, which shares with other sectors a dire need for AI talent, heavily demanded but in short supply. What distinguishes health from other sectors is its inherent relationship with key public policy objectives. Ensuring a high level of human health protection is indeed a principle enshrined into the EU Treaties.⁶⁰

⁵⁹ Finland's Act on the Secondary Use of Health and Social Data addresses the secondary use of health and social data. It establishes a "one-stop shop" - the Data Permit Authority – to grant data permits for health and social data in a centralised manner, namely when a data enquiry requires collection from several data repositories managed by different organisations. An operating environment with robust cyber security controls will be created in which the data disclosed can be processed in accordance to the permit, although processing in other environments is also foreseen.

⁶⁰ Consolidated version of the Treaty on the Functioning of the European Union – Part Three: Union Policies and Internal Actions - Title XIV: Public Health - Article 168 (ex Article 152 TEC).

This makes it fundamental to craft ambitious educational policies that guarantee Europe's future ability in deploying cutting-edge AI for the benefit of public health. Prioritising STEM education at all levels will be key to encourage more individuals flocking to AI's development.

However, these efforts alone will fall short of expectations if not complemented by AI-based training for all other stakeholders interacting with the technology. Health practitioners will need to assess when to use AI systems and to what extent to capture input from augmented intelligence solutions. They will need to maintain a healthy level of scepticism and critical thinking when integrating AI outputs into decision workflows, and be in the position to accurately explain AI's benefits, limitations and risks to patients, which is a core tenet of building trust in the technology. Regulators will need, too, to comprehensively grasp the technology's inner workings and decide, for instance, about the certification of complex AI devices in highly regulated environments. All this calls for strong upskilling and re-skilling programmes tailored to the specific needs of all relevant health stakeholders.



Investments, uptake and regulatory oversight

AI solutions for health will thrive in Europe only through a coherent strategy that will prepare governments' health systems and mitigate any unintended consequence of AI's use. Industry and regulators will need to strengthen dialogue on whether the current regulatory framework will soon be able to keep up with the pace of innovation. They will need to consider future regulatory models that will provide a more streamlined and efficient regulatory oversight of software-based medical devices.⁶¹ Digitalisation entails a myriad of new opportunities for the health sector. But market authorities across the EU will need to overcome excessive risk aversion in the certification of new digital health solutions if society is to benefit from these.

Together with a supportive regulatory framework, ambitious policies fostering innovation, investments and inclusiveness should be the other pillar for the EU's strategy.

⁶¹ The FDA Pre-cert program is an example of such regulatory reflection. More information [here](#)

Innovation

Innovation should be at the core of all measures taken to boost the uptake of health AI. We call on the EU institutions to:

- ▶▶ Commit sufficient resources to the development, adoption and implementation of AI in health applications. To truly unlock all its benefits for European citizens, Member States and the European Commission should also pour more investments into close-to-market research on health-focused aspects of the technology. Programmes where safely test innovative AI models would clearly boost innovation.

- ▶▶ Deliver on the creation of a European health data space following in the footsteps of the Commission's Communication on digital transformation in health and care⁶² and Commission's recommendations to Member States on complete and personal health records across the EU.⁶³ Tackling health data fragmentation in Europe now needs the strong political leadership of EU governments. They should take stock of these positive developments and launch ambitious health data digitalisation plans where safe, agile mechanisms for data-sharing are outlined. Patients will be the first in line to reap the advantages of more widely available data, in the form of ever-more accurate AI and thus effective therapies.

Inclusiveness

As AI deployment in health expands, its benefits should remain firmly accessible to all. This is why embracing AI responsibly will be essential. For that to happen, industry, government and health practitioners must maintain a regular dialogue on inclusivity in the development and implementation of AI technologies in this context. AI solutions must be designed in way that cater for a heterogeneous population and do not widen, but reduce existing disparities in access to care. Organising training and education activities for patients, health practitioners, organisations and authorities will also prove positive. It is important all groups of stakeholders are reached by initiatives that raise awareness on the technology, illustrate its positive impact in the health domain and address any potential concern.

⁶² European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, 2018

⁶³ European Commission, Commission makes it easier for citizens to access health data securely across borders, 2019



Annex II: examples of AI in health

This section aims to show the variety of AI and machine learning applications across different dimensions of the health domain.

Case Study: Intel Transforming Clinical Trials with AI

The effectiveness of clinical trials in drug development is directly dependent on the quality of the data generated. Ideally, a trial would continuously collect objective data about a patient's response to a drug. But this is often not practical using traditional approaches. Many diseases are monitored sporadically and rely on subjective physician ratings of disease status. For instance, diseases like multiple sclerosis and Parkinson's disease are scored by clinicians roughly two to five times per year, despite the fact that a patient's disease state fluctuates daily or even hourly.

Intel has developed a solution, the Intel® Pharma Analytics Platform, which captures new kinds of data from clinical trial subjects and uses AI technologies to analyse the data. Collecting data from multiple sensors, the platform helps develop objective measures for assessing symptoms and quantifying the impact of therapies, and provide a broader understanding of patient health across a wide spectrum of needs. Working with leading pharmaceutical companies, medical centres and research institutions, this AI –based solution has been used in dozens of trials, comprising more than 1.5 million hours of data collection with over 1,000 patients.

By producing high-quality data and reducing the dropout rate, trial leaders may be able to conduct shorter trials with fewer enrolled participants. With AI and larger, more diverse data sources, analysts can generate more robust evidence for regulatory agencies. Overall, the solution allows for more efficient and productive trials, which can get the latest treatments to patients sooner and more cost-effectively.

Read more: <https://www.intel.com/content/www/us/en/healthcareit/transforming-clinical-trials-with-ai-article.html>

Case study: MSD - AI to Automate Chest Radiograph Interpretation for paediatric pneumonia disease burden studies

Current biological methods to detect bacterial pathogens in nonbacteremic/non-invasive paediatric pneumonia (NBPP) are extremely limited. Diagnostic challenges have limited surveillance of NBPP incidence. Many vaccine impact or disease burden studies have relied on identifying pneumonia outpatient visits or hospitalisations through a range of pneumococcal-specific and non-specific ICD (International Classification of Diseases) codes in administrative healthcare

databases. Both pneumococcal pneumonia and all-cause pneumonia are typically included as outcome measures. However, it is well recognised that pneumococcal pneumonia is under-coded in clinical practice and more likely to represent invasive disease, while the use of non-specific outcomes such as all-cause pneumonia may increase the bias in the estimation of vaccine impact.

Chest radiograph (CXR) on the other hand is a valuable diagnostic tool. The World Health Organisation has developed a standardised methodology for the interpretation of paediatric CXRs, designed to optimise the identification of visual patterns caused by infections related to vaccine-preventable pathogens such as *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). However due to the difficulty of interpretation, inter-viewer concordance rates are typically low and experienced radiologists are needed to adjudicate and validate the interpretation. This makes the CXR approach time consuming and expensive and sometimes infeasible in resource poor areas.

Development in deep learning for image classification has the potential to overcome the resource barrier in carrying out the CXR approach for disease burden estimation. MSD has been trying to automate the image interpretation using deep learning. We trained our neural network based on WHO standardised criteria using retrospective chest x-ray images. The model/algorithm currently achieves an accuracy between 92% - 96% depending on the datasets. The computer-interpreted classification of chest x-ray images may provide a cost-efficient method of determining more accurate disease burden estimates, especially when paediatrician and radiologist-led surveillance cannot be conducted.

Read more: <https://www.ispor.org/heor-resources/presentationsdatabase/presentation/intl2019-1479/89378>

Case study: Philips – AI in clinics and hospitals

With the clinical introduction of digital pathology, pioneered by Philips, it has become possible to implement more efficient pathology diagnostic workflows. This can help pathologists to streamline diagnostic processes, connect a team, even remotely, to enhance competencies and maximise use of resources, unify patient data for informed decision-making, and gain new insights by turning data into knowledge. Philips is working with PathAI to build deep learning applications. By analysing massive pathology data sets, we are developing algorithms aimed at supporting the detection of specific types of cancer and that inform treatment decisions.

Read more: <https://www.philips.com/aw/about/news/archive/standard/news/press/2017/20170329-philips-andpathai-team-up-to-improve-breast-cancer-diagnosis.html>

Further, AI and machine learning for adaptive intelligence can also support quick action to address patient needs at the bedside. Manual patient health audits used to be time-consuming, putting a strain on general ward staff. Nurses need to juggle a range of responsibilities: from quality of care to compliance with hospital standards. Information about the patient's health was scattered across various records, making it even harder for nurses to focus their attention and take the right actions. Philips monitoring and notification systems assist nurses to detect a patient's deterioration much quicker. All patient vital signs are automatically captured in one place to provide an Early Warning Score (EWS).

Read more: <https://www.philips.com/a-w/about/news/archive/casestudies/20180315-early-warning-score-reduces-incidence-of-serious-events-in-general-ward.html>

Case study: Microsoft – Machine learning for tumour detection and genome research

Microsoft's Project InnerEye developed machine learning techniques for the automatic delineation of tumours as well as healthy anatomy in 3D radiological images. This technology helps to enable fast radiotherapy planning and precise surgery planning and navigation. Project InnerEye builds upon many years of research in computer vision and machine learning. The software learned how to mark organs and tumours up by training on a robust data set of images for patients that had been seen by experienced consultants.

The current process of marking organs and tumours on radiological images is done by medical practitioners and is very time consuming and expensive. Further, the process is a bottleneck to treatment – the tumour and healthy tissues must be delineated before treatment can begin. The InnerEye technology performs this task much more quickly than when done by hand by clinicians, reducing burdens on personnel and speeding up treatment.

The technology, however, does not replace the expertise of medical practitioners; it is designed to assist them and reduce the time needed for the task. The delineation provided by the technology is designed to be readily refined and adjusted by expert clinicians until completely satisfied with the results. Doctors maintain full control of the results at all times.

Further, Microsoft has partnered with St. Jude Children's Research Hospital and DNANexus to develop a genomics platform that provides a database to enable researchers to identify how genomes differ. Researchers can inspect the data by disease, publication, gene mutation and also upload and test their own data using the bioinformatics tools. Researchers can progress their projects much faster and more cost-efficiently because the data and analysis run in the cloud, powered by rapid computing capabilities that do not require downloading anything.

Read more: <https://www.microsoft.com/en-us/research/lab/microsoftresearch-cambridge/>

Case study: Hitachi & Vironova – AI for safe and effective therapies for genetic disorders

Biological drugs employ a wide range of substances of biological origin. They include gene therapies, vaccines, recombinant antibodies and biological molecules. They have in common the fact that the drugs themselves are large molecules, far larger than the small chemicals traditionally used. The diversity and heterogeneity of their structure as well as the interaction with the human body and the diversity of all individuals is therefore an extremely complex task to understand and control. The safety and efficacy of a biologic therapy when scaled up depends heavily on the purity and integrity of the large molecules. The possible heterogeneity of a successful therapy exceeds the limits of traditional data analysis, as well as the limits of human cognition. This introduces higher needs for data capacity and computing power for the understanding of the topology of the data, and causal patterns.

Hitachi High-Technologies and Vironova AB initiated a research collaboration to contribute to the efficient development of new biological drugs. Vironova, is an established provider of electron microscopy to the pharmaceutical industry and has developed software and methodologies for transmission electron microscopy systems control and data analysis. Using electron microscopy, the macromolecules and unwanted constituents can be visualised and the morphological data can be extracted and further analysed.

By combining the collected experience and expertise from the biologic field, narrow AI to automate and check the validity of hypotheses of constituents and their morphology and biologic effect with general AI which helps to sort out diversities and variations that is not detectable by human it is possible to accelerate the introduction of biologic precision medicines to a broader public.

Read more: https://www.hitachi.com/rev/archive/2019/r2019_01/gir/index.html
<https://www.linkedin.com/pulse/co-creation-case-sweden-how-makeelectron-microscopy-tom-christensen>

Case study: NVIDIA – Using AI to accelerate drug discovery while protecting data

Bringing a drug to market takes on average 13 years and close to €2 billion. The more data researchers have at their disposal, the better equipped they are to accelerate the drug discovery process. However, pharmaceutical companies have traditionally been reluctant to share data for fear of compromising intellectual property. Pooling the sensitive medical data needed to train AI models also raises concerns about patient privacy.

MELLODDY, a new drug-discovery consortium, aims to demonstrate how an AI technique called federated learning could achieve the best of both worlds: the ability to leverage the world's largest collaborative drug compound dataset for AI training without sacrificing data privacy. Federated learning is a method of decentralised machine learning in which training data doesn't have to be pooled into a single aggregating server, allowing organisations to keep datasets within their own secure infrastructure.

MELLODDY (Machine Learning Ledger Orchestration for Drug Discovery) brings together 17 partners: 10 pharmaceutical companies, including Amgen, Bayer, GSK, Janssen Pharmaceutica (a company of Johnson & Johnson) and Novartis; universities KU Leuven and the Budapest University of Technology and Economics; four startups; and NVIDIA's AI computing platform.

Each pharmaceutical partner will use NVIDIA V100 Tensor Core GPUs hosted on Amazon Web Services. MELLODDY developers will create a distributed deep learning model that can travel among these distinct cloud clusters, training on annotated data for an unprecedented 10 million chemical compounds. As part of the data security mission of MELLODDY, each organisation will keep its research projects confidential. MELLODDY will also employ a blockchain ledger system so pharmaceutical partners can maintain visibility and control over the use of their datasets. By enabling companies to learn from each other's findings without providing competitors direct access to proprietary datasets, the consortium aims to improve the predictive performance of AI-based drug discovery. The \$20 million project will run for three years, at which point the consortium will share learnings with the public.

Read more: <https://blogs.nvidia.com/blog/2019/08/08/pharma-melloddy-aidrug-discovery-consortium/>

Case study: Curelator Inc. – Developing AI to advance personalised, evidence-based medicine

Curelator, based in Barcelona and Cambridge, MA, is actively developing and testing analytical tools and approaches for advancement of personalised, evidence-based medicine. Current clinical analytics favour the use of data typically aggregated from large populations of patients - resulting in "one-size-fits-all" therapies - optimally suitable for only the average patient. In contrast, Curelator captures and preserves the integrity of individual data during the analytical process. The objective is to allow each patient to understand the complex interplay that medications and lifestyle factors have on them as individuals and armed with personalised, actionable information, modify the course of their disease. In our N of 1 strategy, we are applying machine learning and other AI approaches to cluster patients and understand (and eventually predict) optimised individual therapeutic response of tailored treatment pathways - the ultimate goal of personalised, evidence-based medicine.

Read more: <https://n1-headache.com/>

Case study: Bristol-Myers Squibb & Concerto – Advancing real world evidence with AI for regulatory purposes

Bristol-Myers Squibb and Concerto HealthAI, a market leader in oncologyspecific Real-World Data (RWD) and advanced Artificial Intelligence (AI)- enabled insight solutions for Real-World Evidence (RWE) generation, have a multi-year strategic agreement that will cover a diverse range of cancers, integrate multiple data sources, and apply AI and machine learning to accelerate clinical trials, enable robust protocol design and generate insights for precision treatment and improved patient outcomes.

Bristol-Myers Squibb will use Concerto HealthAI's Real-World Data and novel AI insights platform, eurekaHealth™, to accelerate insights through novel health economic outcomes and clinical development synthetic control arm studies. With this agreement, the companies will advance the use of RWE for regulatory purposes, validate clinical application of AI solutions and execute clinical studies to advance patient care. With the increasing importance of Real-World Data and Real-World Evidence, healthcare providers and regulators need to have confidence in the credibility and accuracy of the data sources and methods of evidence generation, it is not just a tool for generating insights into the current standard of care, but a field in its own right that can lead to optimisation of current treatments and new therapeutic innovations. This kind of collaboration supports AI solutions for precision oncology – reinforces our commitment to pursue data science to accelerate disease insights, advance novel study concepts and achieve precision in treatment, with the goal of improving patient outcomes.

Read more: <https://concertohealthai.com/press-releases/bristol-myerssquibb-and-concerto-healthai-announce-strategic-agreement/>

Case study: Johnson & Johnson – Smarter insights to treat complex arrhythmias

Biosense Webster, part of Johnson & Johnson family of companies, has developed CARTOSEG™ in partnership with Siemens AG, which is a Computed Tomography (CT) Segmentation Module using machine learning technology to segment automatically in a few seconds the heart chambers including the Coronary Arteries. This module is part of an integrated solution, the CARTO® 3 System. The CARTO® 3 System is a 3-D mapping system with the integration, scalability and insights to help electrophysiologists make optimal treatment decisions. Advanced 3-D mapping modules integrate multiple data sets and images into one resource for highly detailed, real-time information. The CARTOSEG™ CT Segmentation Module automates the CT segmentation process, providing detailed anatomic 3D image integration in the CARTO® 3

System while highlighting discrete anatomic structures. This module automatically segments all four chambers including papillary muscles and trabeculations and semi-automatically segments the coronary sinus, coronary arteries and esophagus. Having improved accuracy and segmentation of all heart chambers helps electrophysiologists make optimal treatment decisions, which is the main purpose of this AI platform.

Using the machine learning technology in CARTOSEG™ CT Segmentation Module has helped to achieve very accurate results for heart chambers of 1-2mm, which received a high clinical acceptance in the evaluation by physicians. Ultimately, the solution is helping electro physicians to efficiently plan ablation strategies when treating complex arrhythmias.

Read more: <https://www.biosensewebster.com/products/carto-3/cartosegct-module.aspx>

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National Trade Associations

Austria: IOÖ

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Switzerland: SWICO

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United Kingdom: techUK