

# The Impact of AI on the Global Health Data Ecosystem

Immense change is happening across the Life Science sector with emerging Health Data and AI Regulation changing the Data Ecosystem

KPMG Life Science Solutions

**Global technological advancement powered by AI is changing global Life Science Regulation. The KPMG Life Science Solutions Practice supports organisations to transform their enterprise and operational strategies and ensure regulatory readiness and compliance. To prepare for these changes Life science organisations should focus on the following areas: Enterprise & Operational Data Governance; Regulatory Intelligence; R&D Primary and Secondary Use of Health Data; Privacy Standards and R&D procedures; AI&ML Governance; and Data Ethics.**

Governments across the world are developing new AI, Cyber, Privacy, Data and Human Research regulation and evaluating how new technology may be controlled without stifling innovation and economic growth. Recent Research identified 37 AI-related laws in 127 different countries was enacted in 2022.

Global Regulators expect life science organisations to demonstrate security of technology systems, compliance, control, quality and utility of data, and to have appropriate technical and organisational measures in place to protect sensitive information, and the rights of individuals.

There are important concepts outlined in forthcoming global legislation that life science organisations should be considering when future proofing their procedures to avoid audit challenges with regard to Health Data and to meet regulatory requirements.

One example of future legislative proposals is the European Union's plans to create an EU Health Data Regulation and European Health Data Space which will build on the GDPR, Data Governance Act, draft Data Act and the Network and Information and Systems Directive. Life Science organisations should understand their entire health data lifecycle and ecosystem from Ingestion, Acquisition, Processing, Retention and Destruction.

The EHDS will create a central Health Data Ecosystem with common standards, practices, infrastructure and Data Governance for primary (Electronic Health Records EHR), and secondary health data. The proposals hope to empower individuals by giving them increased digital access and control over their electronic personal health data across the EU. We anticipate that the global individual health data rights discourse will continue to grow in importance in the next few years, preparation now is critical for Life Science organisations.

## The Regulatory Environment is Changing for Health Data Use



### China Data Act PIPL

This act provides data subjects more rights to use their data. There are more stringent requirements for data sharing and data transfer.



### Japan's APPI

The most recent amendments to the APPI in 2020 introduced additional regulation of cross-border transfers of information.



### South Korea

Personal Information Protection Commission (PIPC) October 2023 will launch an artificial intelligence (AI) privacy task force. Personal Information Protection Act (PIPA) underwent extensive amendments in early 2023 increasing the rights of data subjects, data portability and the right to be excluded from automated decision-making. It also set new requirements for overseas personal data transfer.



### Singapore

July 18, 2023, the Personal Data Protection Commission PDPC published its proposed advisory guidelines on the use of personal data in artificial intelligence (AI) for public consultation.



### US Executive Order on Safe, Secure, Trustworthy AI

US aims to protect consumers from the potential risks of AI systems through creating transparency among developers to share information with federal government, develop standards and tools to ensure AI is safe and secure, establish and advance cybersecurity program to fix vulnerabilities among other critical initiatives.



### Good Machine Learning Principles (GMLP) & the EU AI Act

Manufacturers must evaluate current procedures against GMLP for best practice development

Risks relating to re-training of deployed models must be managed in a real-world setting



### European Health Data Space (EHDS)

Data governance procedures must align with the EHDS, where there is significant potential for secondary use of data for industry

Draft adopted in April 2022 for an EU wide health specific ecosystem comprised of rules, standards and practices.



### GCP Regulation

Regulation contains Data Integrity Risk Assessment (DIRA) where each data source is mapped out where their controls are identified and their criticality, and their inherent risks are documented.



### Nature and Biodiversity

A growing number of biodiversity-related frameworks and regulations apply to the life science sector e.g. the Kunming-Montreal Global Biodiversity Framework and the Taskforce on Nature-related Financial Disclosures.

The Nagoya Protocol and Access and Benefit Sharing regulations apply where genetic material is utilised.



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## KPMG’s Life Science experts have supported organisations to prepare for the changing health data regulatory landscape.

Life science organisations are Data Holders and Data Users of sensitive health data and must re-design their Regulatory Intelligence, Global Data Enterprise Standards and Operational Data Governance Procedures at speed, to be ready for imminent global regulatory change. The research and development (R&D) space will be an important area for focus with this change in the regulatory data landscape.

**Our expertise spans Regulatory Affairs, Privacy, Data Governance, Cyber Security and Strategy. We have supported R&D organisations and across the entire Enterprise Health Data Governance Transformation:**

Diagnostic Workshops - readiness for changing Data Regs

Policy and Procedure Re-design Optimisation

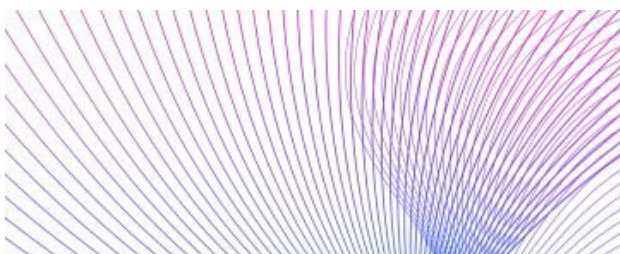
Change management to embed new operational data governance frameworks

External Benchmarking to understand landscape best practice, maturity

People, Process, Data Tech Alignment Design & Build & Optimise

Project Management including - Change, Communications and training content and roll-out

Learning Services - Optimisation of Training Curricula



## Case studies

1

Data Operational Governance, A Multidisciplinary Approach For R&D Transformation to able to advise on the development of a new over-arching policy related to the complete lifecycle of Health Data from Acquisition/Ingestion to Retention and Destruction

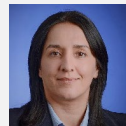
2

Supporting a global organization to create a AI Governance Framework consisting of principles, polices, and guidelines, to address the challenges and opportunities associated with AI, guiding stakeholders to create a trusted AI ecosystem that aligns with societal values and protects the well-being of individuals and communities.

3

A global firm seeking a regulatory roadmap for various geographical locations through evaluating the existing level of compliance and creating strategy to remediate documentation as necessary.

## Meet the Team



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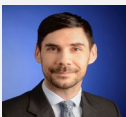
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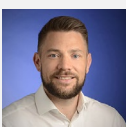
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