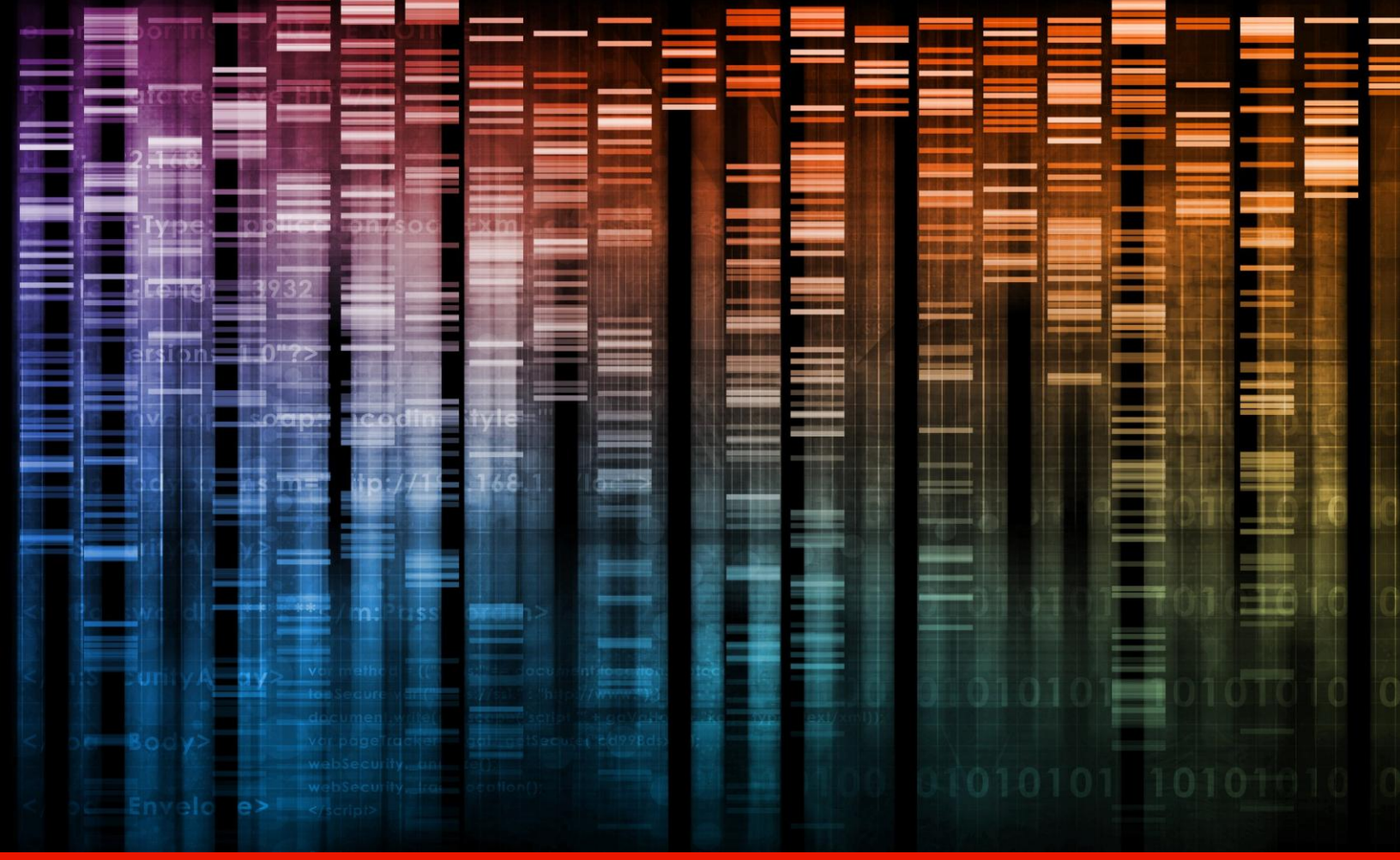


Policy White Paper

Strengthening Health Data Governance to Accelerate Responsible Innovation

Worldwide Government Affairs & Policy

Johnson&Johnson

AI is only as effective as the data that fuels it and thoughtful data governance is vital for healthcare innovation

Health data is foundational to modern healthcare innovation, from advancing scientific discovery and improving patient outcomes to enabling safe, effective, and trustworthy artificial intelligence (AI). As health systems become increasingly digital and interconnected, the volume, variety, and uses of data continue to grow—along with the responsibility to govern it well. Strong data governance is therefore not simply a technical exercise, but a strategic and ethical imperative, ensuring that health data is used responsibly, securely, and in ways that maintain public trust while delivering societal benefit.

As Johnson & Johnson continues to scale the use of AI across the enterprise, strong data governance is foundational to turning innovation into impact. AI is only as effective as the data that fuels it, which is why data management, quality, security, and interoperability are strategic priorities.

By investing in reliable foundational data architecture, robust data governance, and "security by design" practices, we help ensure that AI systems are trustworthy, compliant, and fit for use in a highly regulated healthcare environment. This approach allows us to move beyond experimentation and focus on high value AI applications that deliver meaningful benefits for patients, healthcare professionals and healthcare systems.

Looking ahead, effective health data governance requires clear, coherent, and forward-looking policy frameworks. Policymakers play a pivotal role in promoting harmonized standards, protecting privacy, enabling responsible data access, and supporting data quality and interoperability at scale. By aligning governance principles with technological progress and workforce digital literacy, governments, healthcare actors and industry together can unlock the full value of health data—supporting innovation, strengthening health systems, and ensuring that AI delivers meaningful, long-term benefits for patients and society.



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Responsible Data Use and Privacy

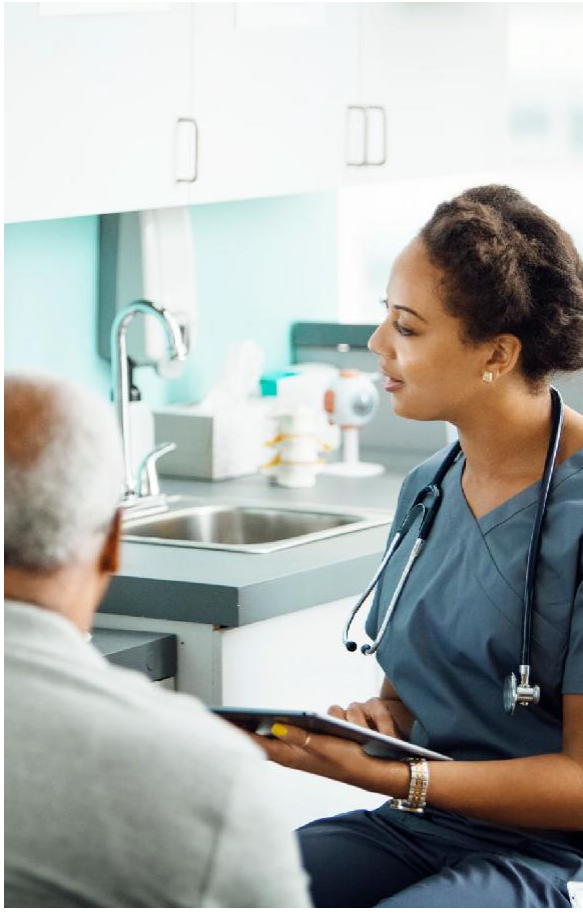
Health data plays a central role in scientific progress, improved patient outcomes, and more efficient health systems. As data use and governance become more complex, the need to protect privacy becomes critical. Privacy is both a legal requirement and a cornerstone of public trust, ensuring that health information is collected, used, and shared in ways that respect individual expectations while enabling societal benefit and powering research and development.

At Johnson & Johnson, we integrate ethical principles across our governance framework, guided by Our Credo, bioethics commitments, local requirements and global regulatory standards. We limit data collection to what is necessary for legitimate business or research purposes, retain data only as long as required, and communicate clearly about how personal information is collected, used, shared, corrected, or deleted. Safeguards such as encryption, anonymization, pseudonymization, and controlled access help protect sensitive data, while annual training and internal audits reinforce compliance across the enterprise.

Responsible data use also relies on rigorous due diligence and continuous monitoring to preserve privacy. J&J examines the provenance of health data, the validity of consent, and whether proposed secondary uses are consistent with what individuals were informed, consented to, when applicable, and could reasonably expect.

This approach is present in our commitment with responsible sharing of clinical trial data under independent oversight models and broad trial transparency through registration and publication of results. Through research and health data partnerships, J&J works to responsibly expand access to high-quality data, strengthening trust, improving care, and supporting robust innovation ecosystems.

To support broader data governance, policymakers can promote harmonized privacy frameworks which balance usage with trust, with clearer rules for data provenance and consent, and well-defined parameters for secondary use. Independent oversight models for sensitive data can reinforce accountability, while policies that encourage privacy enhancing technologies can help reduce re-identification risks. Transparent and ongoing discussion among stakeholders about how data is used, shared, and protected remains essential to unlock the power of health data while safeguarding its use.



Data Ethics in Practice:
Clinical Trial Data Transparency at Johnson & Johnson Innovative Medicine

J&J Innovative Medicine (J&J IM) supports broad clinical trial transparency as a core ethical obligation, including:

- Public registration of Phase 1b–4 clinical trials and timely disclosure of results in global registries.
- Publication of results from company-sponsored Phase 2–4 trials and Phase 1 trials in patients, including discontinued programs where findings have scientific value.
- Sharing Clinical Study Reports and participant-level data, subject to independent review through the YODA Project.
- Providing Plain Language Summaries (PLS) of clinical trials to participants and the public. Since 2024, J&J IM has offered PLSs for all new Phase 2–4 interventional trials on Trialsummaries.com.

This approach reflects our commitment to data transparency, participants' rights, and the advancement of science, while maintaining the highest standards of privacy and data protection.

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Data Stewardship and Access

Strong data stewardship and access are fundamental to realizing the full potential of health data. As health systems grow more digital and interconnected, the ability to access and use data across borders safely and effectively becomes a key driver of public health progress, scientific discovery, and operational efficiency. Moving from narrow concepts of ownership to frameworks that enable responsible use is essential, as fragmented or inaccessible data ultimately limits benefits for patients and society.



Johnson & Johnson is modernizing its stewardship practices through secure, cloud-based infrastructure that supports data governance and access. Our centralized cloud-based solutions such as Orion and Nebula support efficient storage, metadata tagging, and rapid insight generation. These initiatives support our mission to provide safe and effective healthcare solutions while maintaining the highest standards of data integrity. In the Asia-Pacific region, J&J Innovative Medicine uses Collibra Data Quality & Observability, a powerful tool that enables us to systematically assess and ensure the integrity of our data. With Collibra, we automate the monitoring process, allowing for real-time evaluation of data quality across various datasets.

MedTech PubPRO is a digital solution that simplifies how we manage scientific publications. By storing only relevant scientific content and keeping it distinct from marketing materials, we ensure that our communications remain accurate and support informed decision-making within the medical community. Our hybrid multi cloud strategy across leading cloud providers platforms supports real-time insights into Research & Development (R&D), manufacturing, and distribution environments while enabling scalable, data-driven innovation.

Policymakers can reinforce responsible stewardship by developing harmonized rules for data standardization, quality, confidentiality, and oversight of secondary use. In addition, helping to drive the adoption of globally recognized standards such as HL7 FHIR (Fast Healthcare Interoperability Resources), Observational Medical Outcomes Partnership (OMOP), Common Data Model (CDM) and IHE Profiles can promote consistent, clinically meaningful data exchange across borders and systems. Governance frameworks also need to anticipate emerging data types as technologies and therapies evolve. Clear and accessible communication about data practices is critical for maintaining trust, and investments in digital infrastructure and workforce skilling are key to supporting high-quality data stewardship across health systems.

Coordinated approach to data management: **J&J MedTech Data Office**

- **Drives the creation of a standardized J&J MedTech data catalog and data marketplace:** Enhancing data discoverability and accessibility, significantly accelerating time-to-insight and enabling faster digital product innovation.
- **Leads the standardization of data policies & procedures:** Advancing our data maturity, strengthening compliance, improving efficiency, and driving innovation for a competitive edge.
- **Coordinates the implementation of the J&J Data Management Council Data Quality Framework across J&J MedTech Transformational programs:** Enhancing data reliability, streamline decision-making, and support strategic business growth.
- **Oversees Change Review for critical data attributes:** Enhance integrity, compliance, efficiency, and strategic decisions.
- **Fosters data ownership and accountability across critical data domains:** Driving a culture of responsibility enhances decision-making and accelerates business performance.



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Data Quality in Health: Building a Trusted and AI-Ready Ecosystem



High-quality health data is essential for safe and effective use of digital health tools, technologies and AI systems. As healthcare organizations adopt advanced analytics and machine learning methods, the precision, traceability, and integrity of the underlying data become a fundamental determinant of reliability. When datasets are incomplete, inconsistent, or poorly documented, they undermine clinical insights, weaken regulatory submissions, introduce operational inefficiencies, and increase the risk of AI outputs that are inaccurate, biased, or unsafe.

The central challenge for health systems is no longer accumulating larger volumes of data but ensuring that the information they use is accurate, well-documented and governed according to consistent and privacy-respecting standards. Clear provenance — showing how data was collected, processed, and transformed — is critical for establishing trust. Without established provenance, permissibility, and quality, organizations cannot determine whether datasets, including those purchased from third-party vendors, are suitable for clinical, regulatory, or AI related applications. As AI becomes embedded across healthcare delivery, supply chains, regulatory interactions, and real-world evidence generation, public confidence depends heavily on whether the data supporting these systems is managed transparently, ethically, and with strong governance.

Across Johnson & Johnson Innovative Medicine, de-identified health data plays a central role in advancing scientific understanding and delivering innovative medicines. It supports early-stage research, development programs, safety monitoring, real-world evidence generation, and post-market insights. Each year, J&J scientists contribute extensively to the scientific community through peer-reviewed publications based on these datasets, reflecting the company's commitment to R&D, research priorities, and therapeutic innovations. Access to this information requires navigating a complex and often costly health data marketplace, yet these assets are indispensable to generating evidence, meeting regulatory expectations, and improving patient outcomes. For example, J&J led the ATHENA project aimed at overcoming the hurdles of Real-World Data (RWD) access and generating high-quality RWD, while respecting data privacy with a focus on bladder cancer and multiple myeloma.

Policymaking plays a vital role in shaping trusted, AI-ready health data ecosystems:

- Clear national and sector-wide standards for data provenance can ensure that health and AI applications depend on traceable and appropriately consented data, especially as systems increasingly rely on third-party providers and digital platforms.
- Minimum data quality requirements for high-risk datasets can reinforce accuracy and completeness through proportional monitoring, routine audits, and transparent reporting.
- Public sector adoption of data catalogues and standardized metadata frameworks can further improve consistency and support the development of safe, explainable AI systems.
- Governments can strengthen oversight by promoting risk-based classification frameworks that focus regulatory attention where it is most needed, reducing unnecessary burdens for lower-risk data categories.
- Responsible innovation depends on availability of curated and well-governed public datasets, which play a valuable role in research, benchmarking, and AI validation. Ensuring that these datasets are accompanied by robust privacy protections and clear rules for use will allow wider reuse of data for advancing R&D and public health.

By advancing coherent frameworks that prioritize provenance, quality, classification, transparency, and accountability, policymakers can help build a future-ready health data environment that supports safe AI deployment, reinforces system integrity and delivers meaningful benefits for patients and society. The private sector also plays an important role by aligning internal processes with existing frameworks for trusted data use, engaging policymakers in dialogues about emerging technology and data usage, and efficient adoption of standards and requirements.

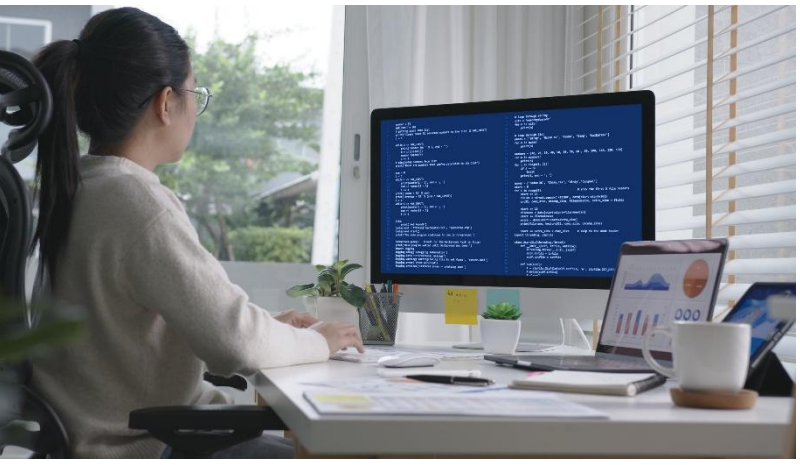
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Data Literacy

As digital tools, AI and advanced analytics become integral to healthcare, data literacy is increasingly essential. It includes the ability to understand health data types, assess provenance and quality, interpret analytical and AI-generated outputs, and apply insights responsibly. Without strong literacy across the workforce and the general public, digital tools are more susceptible to misunderstanding, misuse, or mistrust.

Johnson & Johnson invests in data literacy by training employees to evaluate data provenance and quality, use de-identified data appropriately, interpret analytical models and AI systems with an understanding of their assumptions and limitations, and integrate privacy considerations into daily decision making. These competencies support robust evidence generation, transparent decision processes, and trustworthy use of digital and AI technologies across the enterprise.

Policymakers can strengthen national capabilities by establishing data literacy frameworks for health professionals, integrating data literacy into clinical and health science education, and fostering public understanding of how digital and AI systems work. Continuous learning within health institutions and incentives for responsible data practices will help ensure that literacy keeps pace with innovation. In the long run, strong data literacy policy contributes to a more trusted, effective, and equitable digital health ecosystem.



Digital Upskilling: Critical focus for the next generation of technology leaders

We define AI fluency as the ability to responsibly and effectively apply AI in real work. That means employees have the skills to reimagine how work gets done with AI. Our approach to upskilling employees in digital is multifaceted, focusing on education, experience, and exposure. We believe that training is critical, but it is through experience that people can reach their full potential.

We are taking a strategic approach to build AI fluency across three employee populations:

- **Leaders**: We are equipping senior leaders to set direction, act as role models, and hold themselves and their organizations accountable for driving AI outcomes. AI leadership skills are now embedded in Executive Committee success profiles, and we are partnering with institutions like Carnegie Mellon and Harvard to deepen executive AI capability.

- **Specialists**: Our 7,000+ technology workers lead the way in embedding AI. For these specialists, we provide immersive upskilling approaches, including a learning program that drove a 22% increase in GenAI fluency. We're also evolving technology roles, training people to manage teams of AI agents and leveraging GenAI to develop code.

- **J&J workforce** (~140,000 employees): We are scaling fluency through sustained practice in real work, not one-time training. In addition to offering curated learning pathways, we have enabled enterprise-wide AI tools and created peer-led AI accelerator networks to reinforce everyday usage. Today, we have more than 130,000 active GenAI users, and 79% of our employees report that AI allows them to focus on more impactful work.



Collaboration on health data policy issues will allow us to go further together, transforming the future of healthcare

At Johnson & Johnson, we recognize the power and promise of data in healthcare and believe that effective data governance is a collective, collaborative effort. We value our role as collaborator and innovator in healthcare, contributing new ideas, solutions, technology, partnerships, and perspectives on policy. We are focused on increasing engagement and collective action with patients, providers, and policymakers to raise awareness on how harnessing the potential of data in healthcare can help everyone.

We believe healthcare stakeholders have an important role to play serving as a trusted partner for policymakers by engaging in multistakeholder dialogue, on challenges faced by the industry, and building solutions through collaborative mechanisms, such as regulatory sandboxes and consortia, and driving the responsible use of AI.

With so much untapped yet critical potential, an open conversation about responsible data governance in healthcare is crucial. We are committed to continuing the dialogue and collaboration, igniting policy changes for the good of patients and our communities.

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