Policy White Paper

Advancing the promise of data science in healthcare to improve lives

Johnson&Johnson

Worldwide Government Affairs & Policy

The world is at an inflection point; there is an urgent need to address both emerging and longstanding healthcare challenges with new insights and solutions.

The field of data science has exploded. Data science combines expertise in specific fields such as life sciences with concepts from statistics, mathematics, and computer science to turn structured and unstructured data into insights. Data science is an increasingly important strategic capability to meet healthcare needs by driving innovation in science and technology, increasing healthcare access, delivering personalized information and care, and preparing for the next global public health crisis.

> *Every day, Johnson & Johnson works to confront the most complex healthcare challenges of our time. Data science offers remarkable opportunities to advance this commitment. Whether it's powering our research, driving digital innovation in care delivery, or connecting healthcare ecosystems, practitioners, and patients, data science brings us closer to realizing health equity, and changing the trajectory of health for humanity.*

Joaquin Duato
Chairman of the Board and Chief Executive Officer,
Johnson & Johnson

By 2025, healthcare information alone will represent 36% of the global total volume of data.[1] However, there are great challenges such as data integration and the establishment of reliable and unbiased analytics processes that turn data into answers to key questions that can help us tackle healthcare needs. The key is leveraging the "tremendous potential in connecting [the] data and embedding higher-quality, more efficient, and increasingly predictive decision-making tools.[2]"

The digital revolution has been fostered by lessons from the COVID-19 pandemic and the advancement and synergies between life sciences and data science, including new uses of big data, increased computer power, and advancement in both algorithms and artificial intelligence (AI). From the most developed markets to low-to-middle-income countries, data science can bring significant benefits. But policy reforms are needed to help realize its full potential for **societies** and **economies**, **healthcare systems**, **providers**, and most importantly, **patients**. These opportunities include:

- Improving access to care so that everyone can benefit from quality healthcare services that they need, when they need them, regardless of where they live.

- Enabling efficient health systems to deliver value-based care through optimized service delivery and fast and accurate disease diagnosis.

- Connecting across the healthcare ecosystem to increase collaboration, leading to greater healthcare provider resilience and a better patient experience.

- Fostering precision medicine by personalizing care, improving patient outcomes, and delivering innovative healthcare solutions that serve unmet patient needs.

1. RBC Capital Markets, "The Healthcare Data Explosion — The Convergence of Healthcare and Technology," found at https://www.rbccm.com/en/gib/healthcare/episode/the_healthcare_data_explosion
2. Johnson & Johnson: Bettering Health Through Tech in a New COVID-19 World," found at https://deloitte.wsj.com/cio/2020/04/28/johnson-johnson-bettering-health-through-tech-in-a-new-covid-19-world/

J&J

Policy opportunities in data science applications for healthcare

Public policy can enable consistent regulatory frameworks that foster responsible data access and use by ensuring the construction of robust and efficient data ecosystems. The data architecture we build today will be the infrastructure that supports future innovations for improved health and wellbeing. Building this digital healthcare ecosystem will require clear and coherent policies across borders that remove unnecessary barriers to data access and utilization for good while respecting and protecting personal data. This data-driven revolution can only be realized if we base our progress on a culture of ethics, collaboration, respect, and accountability, where literacy, skills, and access help us all master the possibilities offered by data science.

Policymakers are uniquely positioned to help unlock the potential for data science in healthcare. COVID-19 has been a leading example showing how it is possible to construct a conducive environment for innovation through public-private partnership, novel collaboration models, and collective engagement. Public policy can help in the construction of trustworthy data ecosystems if focused on these foundational pillars by governments across the world:

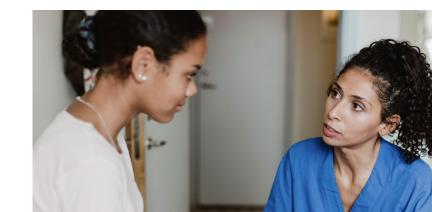## 01 Harmonization, privacy, security, and legal certainty:

We advocate for strong policies that support the access, use, and sharing of health data that are both foundational to public trust and promote sustainable health data ecosystems. We call for policies that address:

- The need for implementation of privacy safeguards in a manner that is proportional to the risks and sensitivity of the data, and takes into account existing regulatory protections that apply to personal health information.

- The current fragmentation of data protection and localization practices – those country-specific rules requiring data to stay local, preventing cross-border data flows – with diverse classifications for sensitive data. We call for clear, harmonized rules on permitted national and international data access, sharing, and use that protect patient privacy and provide for a predictable legal framework where stakeholders, including civil society, are involved through public consultation. These rules should apply to access and use of data in the delivery of healthcare as well as in research and innovation.

- The need for more shared data assets. We encourage public and private efforts enabling responsible data sharing which would comprise a data ecosystem in healthcare. Our own commitments include participation in the European Health Data Space and participation in the Yale Open Data Access (YODA) Project. By responsibly sharing our data, we aim to pave the way for better healthcare data sharing practices to improve health outcomes for the greatest number of people.

- The need for standardized data security. We call for a robust health data security framework, including obligations for critical infrastructure, network, and information systems, as well as minimum required security standards in the healthcare sector, such as protecting hospitals and health systems. Such a framework requires global cooperation to harmonize standards for improved security and data control, which can also drive innovation for the healthcare sector.

J&J

02 Connectivity, interoperability, and standards:

We need **federated FAIR[3] (Findable, Accessible, Interoperable, Re-usable) health data ecosystems** where appropriate access to data by individuals, industry, healthcare providers, and researchers is enabled.

- Connectivity and interoperability are key to data-based innovation, data-driven solutions, and delivery in healthcare. Public investment in healthcare data infrastructure and connectivity must ensure that no patient is left behind (e.g., broadband networks and hospital data infrastructure) in order to overcome the digital divide. We also call for more inclusiveness and representativeness in data pools and approaches that address structural discrimination. To increase effectiveness, the design of these data-driven solutions should take users and their technological environment into consideration. It should also provide adapted approaches (e.g., digital solutions optimized for mobile phones).

- Data science depends on the availability of a sufficient volume of high-quality data.

We need **healthcare data ecosystems based on federated network approaches[4]**, which are inclusive and benefit from individual, private sector, and public healthcare data based on the qualification of data relative to the FAIR model.

- A critical step is to ensure data systems are interoperable by encouraging the adoption of existing open technical and data exchange formats[5] for Electronic Health/Medical (semantic) standards for all health-related data such as clinical data, including high-dimensional (e.g., -omics) data, or patient-generated healthcare data.

03 Evidence-driven healthcare ecosystems:

Data collected in real-life settings (Real-World Data, or RWD) can help drive new understandings of value and generate insights (Real-World Evidence, or RWE). This can support healthcare decision-makers faced with varied data needs from pre- to post-market and the challenge of utilizing different forms of technology and treatments in the context of finite healthcare budgets. An explosion of genetic, lifestyle, and environmental data will help researchers, innovators, health care providers, public health officials, and others to draw new inferences and accelerate interventions. This can include a range of routinely collected data from electronic health records, hospital databases, electronic registries, and administrative insurance claims; to wearables, applications (or "apps"), and device-generated data, among other sources. Greater trust and acceptability of RWD/RWE[6] will enable the shift toward value-based healthcare models and systems and improved regulatory decision-making, enabled by:

- Regulatory agency coordination and guidance to scale up initiatives that support the use of RWE and connected databases to inform decision making.

- Policy measures fostering the quality and integrity as well as the aggregation of RWD (e.g., responsiveness to treatment, diet, exercise, co-morbidities, and co-treatments) joined, categorized, and used in the context of RWE, sharing back with HCPs and individuals the potential links between disparate data sets.

- Using RWE to understand the value of healthcare solutions and to innovate in our approaches to review and regulate products throughout their life cycle, including assessing their safety and efficacy.

3. Wilkinson, Mark D, et al, "The FAIR Guiding Principles for scientific data management and stewardship," Scientific Data, March 15, 2016, found at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4792175/
4. For an example of Federated Data Network, please visit: https://portal.honeur.org/documents/20126/0/HONEUR_Brochure.pdf
5. Examples include OMOP (part of OHDSI) and FIHR, among others
6. RWE: Evidence created by addressing specific research questions through the scientific analysis of RWD

J&J

04 Inclusiveness and empowerment for all:

Investments in a skilled, diverse healthcare workforce

Healthcare professionals need to have a thorough understanding of data science for healthcare systems to effectively guide patients. We support policies to empower and diversify both the data science and provider workforce, support educational advancement, and drive access to the full range of healthcare providers to reduce health inequities and ensure that all have access to innovations, such as:

- Training diverse healthcare professionals to read, analyze, and interpret data is essential to increase efficiency of care, achieve better outcomes, increase equity, and help patients understand and consider their care options. Healthcare workforce planning and education are important tools for policymakers to anticipate future skills shortages and take remedial action in education and training policies early on.

- Diversifying the data science and technology workforce and increasing training in the field for underrepresented minorities is critical for bias reduction and inclusivity in data ecosystems. We also need more life science education and training programs for data scientists to improve the application and customization of data science to healthcare needs.

- Workforce skilling via lifelong learning programs and university education, equipping the workforce with the reskilling and continued learning opportunities required to embrace ongoing technological developments to maximize the positive impact of data science. For example, investments to enhance the digital skills of healthcare professionals (HCPs) could be done through pre-certification by medical societies and advancement of AI curricula for both HCPs and hospital managers.

- Provider education on implicit bias, racial, and other disparities, and culturally appropriate approaches in healthcare and communication with patients. Diverse participation throughout is needed, from the analysis of available data to those working directly with patients, to assure that the algorithms used to interpret data minimize bias from preconceived beliefs or misrepresentative data.

Further, we know that we face tremendous shortages of frontline healthcare workers, something that is expected to continue[7]. If we include healthcare workers as a critical group when designing, deploying, and assessing solutions, and have broad, sustainable funding from governments, we can use data science to support the healthcare workforce, including their work experience and resiliency, and improve outcomes for all members of the ecosystem.

Investments in digital access and literacy

Digital access and literacy are critical to ensure citizens and patients are empowered to manage their own data, understand the benefits of data science, and have the tools to make informed decisions.

- This should extend to both the use and the governance of digital health technologies. This can help the public understand the benefits of data and appropriate data sharing, and the ramifications of safety and ethical frameworks.

- This will be critical to overcome the "digital divide," bridging socio-demographic disparities, such as gender, race and ethnicity, age, and geography, so that populations who might benefit the most from data applications are both involved in, and have access to, these developments. Allowing various populations to participate will help enable data generation that simultaneously improves the authenticity of data sets and the inclusivity of data-driven insights.

7. "Health Workforce," World Health Organization, found at https://www.who.int/health-topics/health-workforce#tab=tab_1

J&J

Data science enables our commitment to improve the trajectory of health for humanity
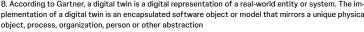

At Johnson & Johnson, we embrace using data science to drive improvements in healthcare and reflect Our Credo commitments, which begin with our responsibility to patients, doctors, and nurses. These are fundamental principles which can enable a trustworthy data science ecosystem.

Innovations in data and technology must lead to new benefits for both patients and healthcare providers
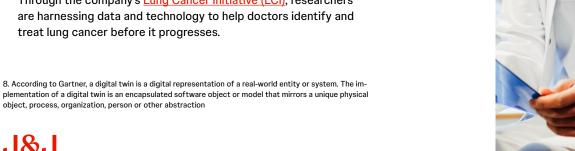
By tearing down silos and connecting previously segregated information, data science opens new horizons to deliver better medicines, diagnostics, medical technologies. From using real-world studies and external control arms for clinical trials, to digital twins[8] improving the quality and efficiency in our supply chain, to predictive analytics to improve HCP experiences and patient outcomes, to digital surgery, Johnson & Johnson has made significant progress in integrating and maximizing the use of data science:

- Data science is becoming an essential part of how we design clinical trials, select clinical trial sites, and recruit patients. By applying AI and machine learning to real-world data, we're able to increase our understanding of patients impacted by diseases, enabling us to determine which patients could potentially benefit the most from specific medicines, and then designing clinical trials and geographically siting them to meet those needs. This also helps ensure our trials are diverse and representative, with the goal of accelerating clinical development and bringing the latest scientific innovations to those in need faster. We are starting to scale this approach across our portfolio.

- We are also developing and deploying digital solutions that support patient care and experience before, during, and after surgery, helping medical intervention to be smarter, less invasive, and more personalized. These solutions leverage data analytics to provide better insights to surgical teams, enable remote care, improve workflows, and predict and reduce variability of outcomes.

- Catching lung cancer early can make all the difference for a patient's prognosis. Yet detecting lung cancer early can be difficult. Symptoms such as persistent cough for fatigue can be vague, and not everyone has access to screening resources to find the disease early, when it is most treatable. Our data scientists are working to help reduce delays in diagnoses. Through the company's Lung Cancer Initiative (LCI), researchers are harnessing data and technology to help doctors identify and treat lung cancer before it progresses.

8. According to Gartner, a digital twin is a digital representation of a real-world entity or system. The implementation of a digital twin is an encapsulated software object or model that mirrors a unique physical object, process, organization, person or other abstraction

J&J

Data science for healthcare requires respect for human relationships and a commitment to earning trust, starting at the very earliest stages of design

For Johnson & Johnson, we approach data science in an ethical, compliant, and secure manner, as we understand that public trust is the cornerstone of unleashing the potential of data science and achieving a truly patient-centric experience in the healthcare ecosystem. For instance, we continue to work with our businesses to integrate privacy and information security controls into designated data-driven initiatives (including data science, clinical operations, digital surgery and robotics, and e-commerce) and implement key standardized processes across Johnson & Johnson, designed to consistently support the rights of patients for the management of their personal data. Through our Information Security and Risk Management organization, we safeguard the Company's networks, systems, products and information against evolving cyber threats to ensure the availability of critical systems and prevent unintended or unauthorized access to both business and personal information. We have obtained ISO 27001 certifications for multiple products, including products from both our MedTech and Innovative Medicines business segments. This helps to increase confidence that cybersecurity controls are in place to safeguard the confidentiality and integrity of data. Respecting the patient and healthcare provider, using the data in an appropriate and secure manner, and ensuring data will be handled responsibly and ethically through the entire process is essential, and especially critical, given the sensitive and confidential nature of healthcare data.

Johnson & Johnson is fully committed to protecting the privacy of those who entrust us with their personal information. In addition to all the laws that apply to our operating companies' handling of personal information, we also maintain global privacy policies to which all our businesses worldwide must adhere. Our policies reflect our commitment to fair and transparent information practices.[9]

Our teams are guided by Our Credo and Business Code of Conduct, an Ethical Code for the Conduct of Research and Development, our white paper on AI & Ethics and commitments to Diversity, Equity and Inclusion. Our bioethical principles include transparency, integrity, and respect for the rights and welfare of all persons and for championing ethical decision-making and policies. We are a leader in initiatives to improve clinical trial data transparency through the Yale University Open Data Access (YODA) Project–a data-sharing model that provides a fair and unbiased approach for assessing external requests for the use of data from the Johnson & Johnson Family of Companies.

Equity and inclusion are critical to achieving optimal outcomes in data science

Recognizing and understanding the rich diversity of patients is critical in designing and implementing data ecosystems. The use of data and approach to data science must be sensitive to historic and structural discrimination, both in the data and in those who analyze it, which is particularly important for predictive modeling. Constant vigilance is needed to identify and address the potential for bias or underrepresentation in data sets and to ensure diversity in data science teams. This will ensure a diversity of viewpoints and help mitigate unconscious bias.

Our commitments also extend to promoting diversity and empowering those who are underrepresented in data education and careers, including women. We have been driving a WiSTEM2D initiative (Women in Science, Technology, Engineering, Mathematics, Manufacturing and Design) since 2015, where we have selected female STEM2D tenure-track professors who are making key STEM2D discoveries and shaping the future of tomorrow as part of our ongoing WiSTEM2D Scholars Award Program.[10]

9. Please see here our positions on privacy and information security
10. Johnson & Johnson Health for Humanity Report, found at https://healthforhumanityreport.jnj.com/our-employees/employee-engagement and "What WiSTEM2D Is—and Why It Matters," found at https://www.jnj.com/wistem2d

J&J

Together, data science will allow us to go further than ever before

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

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

For more information, contact:

Carla Cartwright
Global Digital and Regulatory Policy
+1 202 589 1060 | ccartwr@its.jnj.com

Angel Martin
Digital Health Advocacy, EMEA
+32 474 295889 | AMart357@its.jnj.com

J&J