

## Task Force 4: Science and Digitalization for a Better Future



# An Integrated Global Bio-data Governance Framework Enhancing Human Rights and Prosperity

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## Abstract

The rapid advancements in biotechnology and the increasing generation, collection, and use of biological data (biodata) have revolutionized scientific research and healthcare. However, the current landscape of biodata governance is fragmented, with varying regulations and norms across jurisdictions, hindering international collaboration and raising concerns about data owner-

ship, access, benefit-sharing, privacy and potential misuse.

This policy brief urges the G7 nations to lead this effort through convening an international summit, establishing a multi-stakeholder working group and integrating biodata governance.

Specific recommendations include:

- 1) Fund social research to address imbalances in biodata communication.
- 2) Proactively align industry and commercial stakeholder incentives in biodata governance nationally and transnationally.
- 3) Encourage Track II science diplomacy through convening international summits and working groups.
- 4) Enable FAIRify data at scale through pilot interdisciplinary capacity building for practitioners.

Urgent action and international cooperation are imperative to uphold human rights, facilitate responsible innovation transnationally, promote public trust and health equities, and contribute to the UN Sustainable Development Goals.

## Introduction

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Biobanking and biodata are inextricably connected, with biobanks serving as the vital bridge between the collection, storage, and management of biodata derived from human biological samples. Human biodata, collected and processed by biobanks, encompasses biological and health information, such as genetic material, clinical outcomes, personal records, and associated digital data. The field of biobanking is entering a new era marked by expanded scientific possibilities for processing big data networks, rapid growth of private and community-based ventures worldwide, and an increasing societal consciousness of human rights and social justice implications (Beneduce and Bertolaso 2022).

However, the misuse of biodata poses significant threats to human rights in the rapidly evolving landscape of biobanking. Biobanks around the world are amassing vast quantities of human biodata, including genetic material, clinical outcomes, personal records, and digital data. While this biodata holds immense potential for scientific advances, we cannot overlook the grave risks it poses to the fundamental rights and freedoms of individuals and communities.

It is crucial to emphasize that the current state of biodata governance is inadequate. The absence of a comprehensive, internationally recognized framework leaves the door open for abuse and exploitation. If not properly safeguarded, biodata can be weaponized to enable genetic discrimination in employment, insurance, and law enforcement. Furthermore, the increasing commodification of biodata by profit-driven entities raises serious concerns about data privacy, consent, and the equitable distribution of benefits to those who contribute their biological samples.

Biobanks have a solemn responsibility to ensure that biodata is used ethically and in accordance with human rights principles. However, they are grappling with navigating the complex web of regulatory uncertainties, particularly in the international context. This challenge cannot be addressed by any single nation alone.

While G7-led initiatives have promoted the ethical and free use of biodata, such as the Fort Lauderdale Agreement (Wellcome Trust 2003) and Global Alliance for Genomics and Health (<https://www.ga4gh.org>), significant challenges remain, hindering biobanking's sustainable development and responsible biodata use. These obstacles necessitate urgent international cooperation to develop an integrated, human rights-based governance framework (Knoppers and Thorogood 2017; Dove 2015). Such a framework is essential to foster public trust, enable scientific advances that benefit humanity, and, crucially, protect the fundamental rights of individuals and communities in an era of rapid biodata-driven innovation.

## Challenges of biodata governance

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Participation bias in biobanks is widening health inequalities, as lack of diversity in data pools leads to unequal distribution of research benefits and distorted scientific associations. This results in a “silent crisis” where research fails to translate into healthcare improvements for marginalized groups (Schoeler et al. 2023; Shepherd and Zhang 2023).

The rise of private and societal biodata ventures, enabled by new technologies, complicates efforts to promote public trust due to social scepticism, regulatory gaps, and perceptions of commercial profiteering. Community-based initiatives using blockchain remain inadequate to fully address public concerns about equitable benefit-sharing (Lysaght et al. 2021; Sánchez et al. 2023; Grishin et al. 2018; Kulemin et al. 2017).

Legal hurdles persist for international bio-data sharing, intensified by growing geopolitical tensions and stricter national controls on foreign access to genomic data. This hinders scientific collaboration and worsens global data biases (Aymé et al. 2023; Zhang 2023).

A capacity gap exists among bioscience practitioners and institutions in making bio-data FAIR, with deficiencies in ensuring interoperability, shareability and accountability. In-depth interdisciplinary training is urgently needed for future biobankers and researchers (Rainey et al. 2023; Aarestrup et al. 2020; Kinkorová 2021).

## G7's role

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The G7 has a pivotal role in data stewardship, fundamental to realizing the G20's Rome Declaration goals of facilitating data sharing, capacity building, global solidarity, equity and enhanced multilateral cooperation. Initiatives like the US "All of Us" project (Mayo et al. 2023) and European BBMRI-ERIC exemplify commitments to improving biomedical research through data stewardship and resource sharing.

However, considering historical issues of biopiracy, bio-exploitation, IP debates and epistemic injustice, it is imperative for G7 nations to lead in developing coordinated governance frameworks that champion health equity and social fairness globally. The framework must be compatible with G7's idea of data governance with trust, prioritize inclusivity and empowerment, benefiting practitioners and societies, particularly marginalized groups, to set a precedent for a more equitable global bioeconomy (Zhang 2023).

## Principles for a rights-based biodata governance framework

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The framework should be rooted in upholding human dignity, autonomy, and privacy, preventing misuse and discrimination. Key principles include:

- Individual control & ownership over personal biodata: Ensuring meaningful control through informed consent, right to access, correct, delete, and port personal data (Kaye et al. 2015; European Parliament and Council of the EU 2016).
- Robust data protection and security measures: Implementing strong safeguards, encryption, access controls, secure storage, and privacy-by-design (Shabani and Marelli 2019; Cavoukian 2011).
- Ethical oversight and accountability mechanisms: Independent ethics committees assessing implications, monitoring compliance and holding actors accountable for breaches (Blasimme and Vayena 2020; World Medical Association 2013).
- Equitable benefit-sharing: Transparent arrangements based on justice and solidarity (Chadwick and Berg 2001; UNESCO 2003).
- Transparency and public participation: Open and inclusive decision-making with clear public information (Lemke et al. 2010; Laurie 2017).

## Key components and implementation

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- Global governance body and national implementation: Coordinating and overseeing practices, developing standards, engaging diverse stakeholders. Countries implementing through national laws, entities (Gottweis and Lauss 2012; Dove 2015; Rothstein et al. 2015) and regulated data intermediaries (Martignago 2024).

- Legally binding international treaty/convention: Providing common principles, rights, obligations, and mechanisms for cooperation, dispute resolution and compliance monitoring (Debussche et al. 2019; Slokenberga et al. 2021).
- Minimum standards and guidelines: Setting standards based on human rights and best practices for data quality, access, sharing, retention and ethical research conduct (Knoppers et al. 2014; Dove 2015).
- Capacity building for developing countries: Technical assistance, training, resources for strengthening legal, regulatory, institutional, scientific, and technological capacities. Collaborative partnerships for knowledge transfer (Helmy et al. 2016; Munung et al. 2016; Yakubu et al. 2018).
- Incentives for compliance and impartial dispute resolution: Trade and economic benefits to encourage adherence. International arbitration or specialized courts for enforcement (Chalmers et al. 2016).

## Benefits and impacts

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- Upholding human dignity and rights: Protecting autonomy, privacy, preventing misuse and discrimination, promoting social justice and inclusive progress (Dove 2015; Mittelstadt and Floridi 2016).
- Facilitating responsible innovation: Stable regulatory environment reducing uncertainties, enabling investment, scientific discoveries, and medical breakthroughs while respecting rights and minimizing harms (Dove and Özdemir 2015; Rothstein et al. 2015; Blasimme and Vayena 2020; Caulfield and Murdoch 2017).
- Boosting public trust and equitable progress: Transparency, accountability, and engagement building confidence, addressing concerns, promoting inclusive benefit-sharing, reducing health disparities (Kraft et al. 2018; O'Doherty et al. 2016; Munung et al. 2016; Yakubu et al. 2018).
- Enabling cross-border data sharing and collaboration: Harmonized standards and interoperable systems for large-scale diverse datasets advancing research, personalized medicine, and knowledge transfer (Knoppers et al. 2014; Auffray et al. 2016; Helmy et al. 2016; Capps and Lederman 2015).
- Contributing to UN Sustainable Development Goals: Supporting affordable interventions, strengthening health systems, universal coverage and pandemic preparedness (Stevens and Huys 2017).

## Recommendations

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- Fund social research to address imbalances in biodata communication: Current public engagement tends to overstate risks and downplays the benefits of bio-data sharing (Aymé et al. 2023; Nunes Vilaza et al. 2021). More qualitative research into public attitudes – particularly those of patients and users – towards genomic and personalised medicine is in dire need to

inform inclusive and balanced public engagements.

- Proactively align industry and commercial stakeholder incentives in biodata governance nationally and transnationally to foster new public-private partnerships and implement regulatory oversight, ensuring public trust and driving innovation for all populations (Aarestrup et al. 2020).
- Encourage Track II science diplomacy through convening international summits and working groups to develop common ethical guidelines for human right protection in cross-border biodata sharing (Zhang 2023). Such shared ethical vision will serve as the foundation for tailored bilateral or multilateral governance agreements.
- Enable FAIRify data at scale through pilot interdisciplinary capacity building in clinical and laboratory scientists, statisticians, and algorithm developers. There is also an urgent need to equip healthcare providers with genetic counselling skills to serve the public at scale (Ahalt et al. 2023; Bettio et al. 2023; Kinkorová 2021; Mayo et al. 2023).

## Conclusion

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Developing and implementing an integrated global biodata governance framework grounded in human rights is imperative to address the challenges and seize the opportunities presented by biotechnology advancements. The G7 must lead urgent international action and cooperation to shape an ethical, equitable and beneficial future for biodata governance (Knoppers and Joly 2018; Chadwick and Berg 2001).

By convening a summit, establishing a working group, committing to capacity building, and integrating biodata governance into broader agendas, the G7 can spearhead a framework that protects rights, promotes responsible innovation, enables collaboration, reduces inequities and advances sustainable development goals. The time for action is now – the well-being of current and future generations depends on realizing biodata's transformative potential in a manner that respects human dignity and serves the common good of all humanity.



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