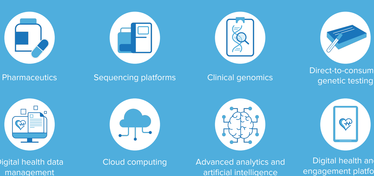
International Genomic Data Sharing by Health Technologies Industries: Points to Consider

This infographic outlines points to consider for the responsible sharing of human genomic and health data internationally by Health Technologies Industries. It was adapted from the 2024 resource "International Genomic Data Sharing by Health Technologies Industries: Points to Consider," developed by the Industry Core Group and the Centre of Genomics and Policy, part of the Victor Phillip Dahdaleh Institute of Genomic Medicine — a GA4GH Host Institution.

Health Technologies Industries (HTI) include...



REGARDING PATIENTS AND RESEARCH PARTICIPANTS

Consent

Consider the following when seeking consent for the processing and sharing of genomic and health data.

- ❑ Define the scope of consent to data sharing.
- ❑ Seek review of consent materials by a research ethics committee or similar entity.
- ❑ Support consent with accompanying safeguards.
- ❑ Notify participants of the right, process, and limitations to withdraw consent to data sharing.
- ❑ Adapt consent to target populations.
- ❑ Obtain consent to any return of results of clinical importance.
- ❑ Use accessible digital environments for e-consent.
- ❑ Document, version, and capture consent in a machine-readable format.

Transparency

Consider the following when providing information to research participants on the processing or sharing of genomic and health data, the use of artificial intelligence (AI), and the possible return of results.

- ❑ Describe the scope of data collection, generation, use, storage, and sharing.
- ❑ Describe any use of AI in health products and services.
- ❑ Describe the plan outlining the scope of return of results to research participants and their families.
- ❑ Where return of results is foreseen, describe the company's responsibility for clinical validation, communication, and re-interpretation over time.
- ❑ Provide sufficient information to participants in plain language.
- ❑ Standardise information elements provided to participants by using voluntary or binding codes of conduct.

Community engagement

Patient and community engagement approaches should consider the following.

- ❑ Encourage greater diversity in research participation that reflects the target community of a study or product.
- ❑ Promote community education, awareness, and understanding of data sharing aims and practices.
- ❑ Involve community representatives in the design and implementation of data sharing policies and practices.
- ❑ Ensure that the views solicited from communities are diverse and representative.
- ❑ Share the benefits of innovation with communities in an equitable manner.

REGARDING GENOMIC AND HEALTH DATA

Privacy and data protection

Data sharing plans should consider the following regarding privacy and data protection rights of individuals.

- ❑ Ensure personal data are shared in a lawful, fair, and transparent manner.
- ❑ Limit collection, storage, and sharing of personal data to what is necessary.
- ❑ Assess and address risks of cross-border data transfer.
- ❑ Employ data localisation strategies in order to reduce the risks of cross-border data transfer.
- ❑ Establish data breach notification procedures in accordance with applicable law.
- ❑ Enable individuals to meaningfully exercise their data protection rights.
- ❑ Ensure data are provided in a common, machine-readable format suitable for analysis and portability.
- ❑ Capture all of the above elements in a data privacy notice accessible to all.

Identifiability

Data sharing plans should consider the following regarding identifiability and the approach to privacy protection.

- ❑ Conduct regular privacy risk assessments.
- ❑ Document and review privacy risk assessments and controls as technology and data contexts evolve.
- ❑ Share data in the least identifiable form necessary to achieve the intended purpose.
- ❑ Establish complementary privacy and security safeguards for better data protection and use.
- ❑ Manage trade-offs between protecting privacy and preserving the utility, quality, and representativeness of data.
- ❑ Take into account practical and legal challenges in some jurisdictions in anonymising and pseudonymising genomic data.

Data security and quality

Data sharing plans should consider the following in protecting the confidentiality, availability, and integrity of genomic and health data.

- ❑ Implement data governance safeguards appropriate for the particular context.
- ❑ Use data sharing platforms and computinge environments that implement cybersecurity standards.
- ❑ Audit and test security measures regularly.
- ❑ Adopt data breach plans.
- ❑ Follow fair, accessible, interoperable, and reusable (FAIR) data principles that facilitate data pooling and linkage.
- ❑ Demonstrate the effectiveness of AI models across the diversity of target populations

Responsible use

Data governance approaches should consider the following when balancing data control for legitimate commercial interests with data sharing for the public good.

- ❑ Maximise commercial, scientific, and societal value of genomic and health data while respecting legal, privacy, and ethical requirements.
- ❑ Limit exclusive control over genomic and health data to the time necessary to protect intellectual property (IP) rights, preserve commercialisation opportunities, or ensure the integrity of studies.
- ❑ Reflect the particular context of a company's activities.
- ❑ Support authorities and researchers in response to public health emergencies.
- ❑ Use open access resources in a manner that does not impede innovation by others.
- ❑ Return derived data and results to data contributors and share such data with the scientific community.
- ❑ Ensure responsible and fair use of AI models.

REGARDING PARTNERSHIPS

Governance of HTI and academic partnerships

Governance of HTI and academic partnerships is vital to translating scientific findings into effective health applications, and should consider the following points.

- ❑ Clarify the nature of the partnership and HTI's role within it.
- ❑ Define the scope of HTI access to data, and the use of data for HTI's own research and IP-development purposes, and any possible or actual onward sharing.
- ❑ Clearly articulate commercialisation goals and how they align with the public good.
- ❑ Establish commitments to scientific best practices, processes to manage conflicts of interest, and publication policies protecting scientific freedom.
- ❑ Ensure platform providers store data in an interoperable form.
- ❑ Establish up-front criteria for estimating the long-run cost of platform services to inform sustainability.
- ❑ Establish contingency plans to safeguard data in case of a termination of platform services.