Incorporating ELSI as a core support for international genomic data access and sharing

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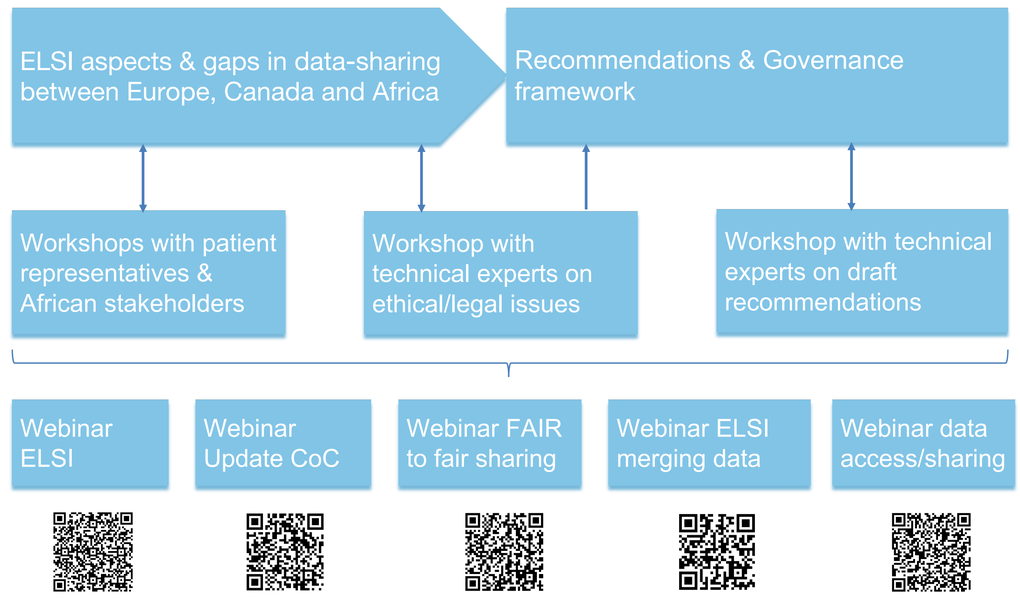
Introduction

Health data collected in cohort studies are valuable sources for knowledge generation and the advance of biomedical research. However, the use of these data for research projects beyond the initial purpose raises several ethical, legal, and societal questions regarding the sensitivity of genomic data sourced from vulnerable and ethnic groups, such as African genetic data and material.

Federated data infrastructures have become a key approach to make population-scale genomic and biomolecular data accessible across international borders. While the FAIR principles have become a guiding technical resource for data sharing, legal and socio-ethical considerations are equally important for a fair data ecosystem for further uses of genomic data.

The Horizon 2020 project CINECA aims to provide a federated cloud-based infrastructure for the discovery, access, and analysis of human genetic and phenotypic data, based on a virtual cohort of 1.4 million individuals from 10 cohorts in Europe, Canada, and Africa. Beside technical solutions, CINECA addresses and provides valuable experience and input on essential ethical, legal, and societal implications and requirements for transnational health data access, sharing and secondary processing for research purposes.

Methodology



Informed consent and further use of data

According to the EU General Data Protection Regulation (GDPR, 2016) informed consent is one of the possible legal basis for personal health/genetic data processing (to be considered in addition to the consent required for participation in research). In case of further processing of previously collected data for a purpose different from that originally intended at the time of the collection, the presumption of compatibility (under art. 5, GDPR) means that no consent is needed if adequate safeguards are in place to ensure research participants data integrity and transparency (information). From an ethical perspective, consent can still be used as one of these safeguards. In any case, attention should be paid to cultural differences and professional behaviours when seeking consent.

Recommendations[1]

- Clear provision of information
  - On what is going to happen to the data and how they will be used, on the governance framework and on their possible exchange/transfer.
  - On research participants' rights including opt-out and withdrawal possibilities, return of results and the responsible person to contact in case of questions.
- Informed consent and appropriate alternatives
  - Provide a continuous ethical assessment for the further use of the data.
  - Use informed consent not as a legal basis but more as an ethical requirement and an appropriate safeguard to be implemented in various forms (broad , tiered, consent) that are respectful of fundamental rights.
  - Assess the risks related to future use and data sharing in various countries taking especially into account re-identifiability and stigmatisation of vulnerable groups).
  - Consider ethical acceptability of consent use in low- and middle-income country (spec. Africa) and facilitate community engagement after discussions about possible re-identification, benefit sharing and commercial use of research results.

Tools

- CINECA Webinar "Ethical, legal and societal issues in international data sharing"
- GA4GH Regulatory & Ethics Toolkit
- BBMRI-ERIC ELSI Knowledge Base

Safeguards and respect for privacy

The potentials of research with genomic data, particularly improvements in genetic analysis, has led to a change in the risk profile, especially regarding re-identifiability, stigmatisation, and discrimination on both the individual and group level (Kasperbauer et al. 2018, Helgesson 2012). Risks related to further processing of genomic data in multiple ways and across countries have raised concerns about potential harms related to the protection of privacy. Respective mechanisms and safeguards need to be put in place to ensure privacy and to protect patient data from misuse and exploitation.

Recommendations

- Implement respective mechanisms and safeguards to ensure privacy and to protect patient data from misuse and exploitation.
- Maximise the potential and promote the development of technology as a means of enabling the availability, re-use, and analysis of personal health data while, at the same time, protect privacy and security.
- Implement monitoring and evaluation mechanisms.
  - Track chain of data access and/or exchange to its source.
  - Continuous ethical review process, evaluations of whether that research is in the scope of the consent model.
  - Adapt to changing conditions.
  - Assess benefits and risks of harm in data sharing.
  - Mitigate risks and establish mechanisms for handling complaints related to data misuse, for identifying reporting and managing breaches, and for instituting appropriate sanctions.

Tools

- GA4GH Regulatory & Ethics Toolkit
- BBMRI-ERIC ELSI Knowledge Base

Further uses and data-access

Building cohorts means building a resource available for the scientific community. This resource aims to be shared and reused for various purposes that where not all identified at the time of the data collection. Then, researchers have duties towards research participants such as the respect for their privacy (information including on the sharing), to avoid misuse of the data (discrimination) and to ensure data integrity (security measures). In practice, the responsible for the data processing must implement procedures and mechanisms to ensure proper and responsible governance regarding the access to the data.

Recommendations

- Ensure the data in the catalogue are updated.
- Implement clear procedures for the assessment of the data users' protocol (e.g., through the appointment of a Data Access Committee).
- Review and approval procedures for the use of health/genetic personal data for research
  - consider duties from the national laws.
  - rely on the compatibility principle for further use and implement the required additional safeguards.
- Increase transparency through public information mechanisms while respecting health/genetic data confidentiality and legitimate interests.

Tools

- CINECA Webinar "Status Update Code of Conduct: Teaming up & Talking about it"
- GA4GH Beacon project

Engagement and benefit sharing

Stakeholder engagement at early stages of the research process is key for the establishment of good governance structures. This is even more important when researchers and genomic data from low- and middle-income countries are involved. Engaging with patients and communities to discuss potential re-identification of genomic data, benefit sharing and commercial use of research results, strengthens fair and responsible use of data. Good governance structures must also ensure equal partnerships between the researchers involved for a fair sharing of data, research outputs, and benefits.

Recommendations

- Encourage common policies and procedures that minimize barriers to sharing data for health system management, statistics, research, and other health-related purposes that serve the public interest while protecting privacy and data security.
- Establish appropriate training and skills development in privacy and security measures for those processing personal health data, that are in line with prevailing standards and data processing techniques to improve data quality.
- Facilitate engagement and participation of a wide range of stakeholders at early stages of the research process and throughout a project's lifecycle, and consider ethical, legal, and societal implications (ELSI) for the establishment of appropriate governance structures for fair data sharing.

Tools

- CINECA Webinar "From FAIR to fair data sharing"
- GA4GH Regulatory & Ethics Toolkit
- BBMRI-ERIC ELSI Knowledge Base

Outlook

- Synthetic data: can overcome part of the reuse questions regarding GDPR compliance but can still raise ethical issues ⇒ discrimination or stigmatisation
- Artificial Intelligence (AI): will raise and extend questions regarding informed consent, risks regarding data privacy and protection, further uses, or governance more broadly

⇒ In case of questions regarding GDPR application, identify existing internal structures and expertise that could offer support (DPO, legal department)

You can find some guidance here:

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[1] All recommendations are based on the OECD Recommendation of the Council on Health Data Governance (OECD 2019), the GA4GH Framework for Responsible Sharing of Genomic and Health-Related Data (Global Alliance for Genomics and Health 2019), FAIR principles (Wilkinson et al. 2016, Holub et al. 2018), and CINECA research findings.

Common Infrastructure for National Cohorts in Europe, Canada, and Africa

www.cineca-project.eu

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