Enhancing EU legal frameworks for genetics & genomics research

SIENNA project Policy Brief #2 (V2.0)

February, 2021

Highlights

To support and ensure ethical and human rights respectful design, development, deployment, and use of genomic technologies and to advance the right to enjoy the benefits of scientific progress and its applications, we need policy-makers to:

Address **ethics** in regard to **human genomic technologies** in a more stringent and consistent way

Resolve fragmentation and uncertainties regarding **genetic data protection,** and work towards removing obstacles to the sharing of data

Develop guidance on regulation of **human genetics** and **genomics** and enhance human genomics research

Address **dual use** of genomic technology in an effective manner

Capitalise on the EU fundamental **right of data protection** and consider establishing a **right to gen(omic) data**

Who is this for?

European Parliament, European Council and Council of the European Union, the European Commission, Medical Device Coordination Group, European Data Protection Board and European Data Protection Supervisor, EU Member States.

Introduction

The existing EU legal frameworks (e.g., clinical trials and advanced therapy medicinal products, data protection, in vitro diagnostic medical devices, medical devices, and fundamental rights) are relevant for regulating human genomic technologies and should be able to cope with many of the challenges that they pose. However, SIENNA research has identified various gaps and challenges that must be addressed in order to ensure ethical and human rights respectful design, development, deployment, and use of genomic technologies and to further the human right to enjoy the benefits of scientific progress and its applications. This brief presents some of the actions required and recommendations for the European Union institutions, and the Member States.

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Technology, ethics and human rights

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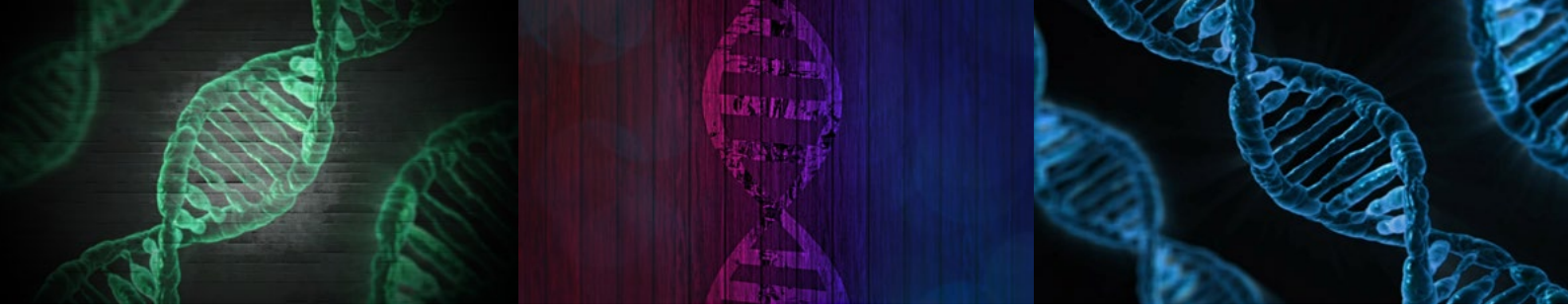

Recommendations

Address ethics of human genomic technologies in a more stringent and consistent way

- Ethics already is an essential requirement in several areas, e.g., clinical trials, studies relating to in vitro diagnostic medical devices. However, these requirements are often vague and their effectiveness depends on diverse national implementation and oversight. SIENNA believes that comprehensive EU action is needed to overcome that. Examples of these steps include considering introducing a particular standard and allocating adequate means to fulfill that.

Resolve fragmentation and uncertainties in genetic data protection, and remove obstacles to sharing of the data

- The General Data Protection Regulation (Regulation (EU) 2016/679) aspired to harmomise divergent EU Member State laws and ensure consistent application of the data protection rules. However, the scientific research regime that is built in the GDPR suffers from considerable fragmentation (e.g., diversity of legal basis for lawful genetic data processing for the purposes of scientific research, dependence on national implementation, multilevel derogations from data subject's rights). Fragmentation in itself, in the absence of straightforward reconciliation measures, constitutes a hurdle for research collaboration and intra-EU data sharing. Empirical studies are necessary to assess the dimensions of this hurdle and implications in the field of concern, and design the most appropriate strategies to address it.
- The General Data Protection Regulation has strengthened the fundamental right to data protection; however, it appears to be significantly different from the protection that personal data are afforded in many third countries. Acknowledging that it is important to maintain high level of personal data protection of the EU data subjects in international collaborations, enhanced dialogue with third countries and international organisations is necessary to overcome the gap between the EU data protection gold standard and differences in the data protection standard in third countries.

Develop guidance on regulation of human genetics and genomics and enhance research

- The EU regulates human genomic technologies to a considerable degree. However, the regulatory field is fragmented. In addition to the natural complexity that the intersection of law and genomics has, regulatory fragmentation makes it difficult to navigate the field. It is essential that continuous, comprehensive, and timely guidance on how EU law regulates human genetics and genomics is provided.
- While it is important to advance biomedical research through research financing, it is equally important to acknowledge that funding alone is not necessarily an effective tool to expand the scientific knowledge. The European research funding agenda needs to include mechanisms that strengthen the expansion of knowledge in a sustainable way. The current discussion on setting up an EU agency for biomedical advanced research and development is an example of such a mechanism.

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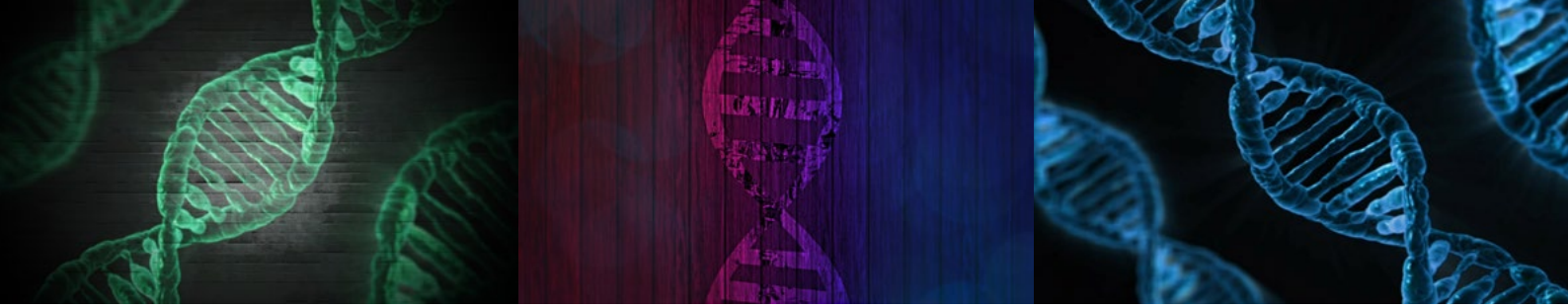

Effectively address the dual use of genomic technology

- Genomic technologies often are regulated as part of health-related legal frameworks, and therefore the non-health application of these technologies risks remaining uncaptured. As implementation of In Vitro Diagnostic Devices Directive (Directive 98/79/EC) has showed, dual use of genetic testing was not addressed by the EU legislator. As far as legally and politically feasible, non-health application of genomic technologies should be addressed by the EU institutions or the institutions should urge the Member States to tackle dual use.

Capitalise on the EU fundamental right of data protection and consider establishing a right to gen(omic) data

- The right to data protection is a fundamental trait of the European Union. However, affording certain level of personal data protection is not sufficient to further genomic medicine and ensure that societal benefit. As the EU competence in the area of health evolves, SIENNA urges it to explore benefits that establishment of a right to (gen)omic data (as a complement to the human rights framework) could deliver to further the development of personalised medicine and create an effective way for the EU society to benefit from scientific progress.

- Further work is required in order to determine the exact role that such a right could play and how it could be achieved given what is on the legislators political agenda at the time such a right would be formulated. Likewise, further research is required to determine what benefits and risks are associated with this right and whether the anticipated benefit outweighs the forseeable challenges.

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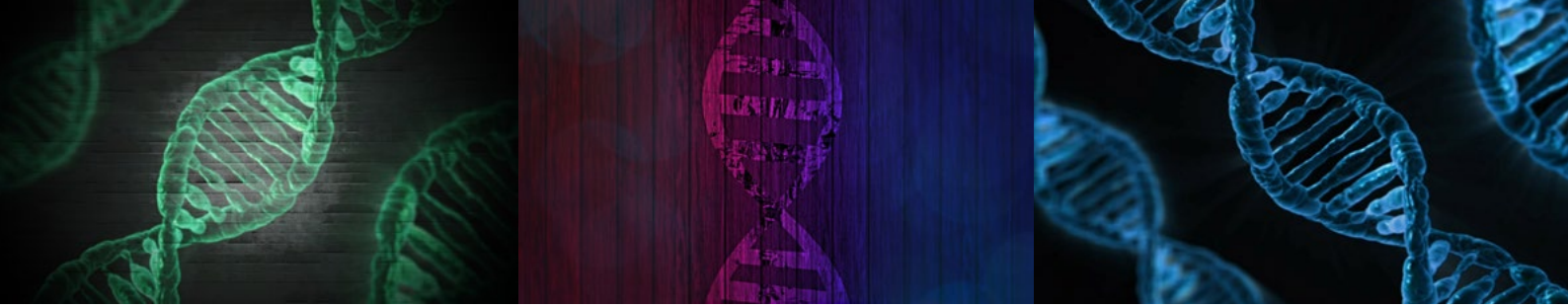

Final thoughts & take-aways

Often challenges in regulating human genomic technologies are attributed to the limitations relating to the principle of conferral, and application of the principle of subsidiarity and proportionality during the legislative stage. Overcoming these challenges will require internal EU commitment, close dialogue with the stakeholders and effective collaboration at all EU levels and with third countries and international organisations.

The EU has the potential to guarantee a high level of protection of health in all EU policies. Building of the European Health Union offers opportunities to enhance the EU's responses to human genomics that should not be missed.

These proposals are limited to what the SIENNA project aspired to and could do in relation to the project design. Although some of these proposals overlap with EU policy agendas, they should not be considered as a general action plan, but rather as pointing out the direction.

Further reading

Siemaszko, Konrad, Rowena Rodrigues, & Santa Slokenberga, "SIENNA D5.6: Recommendations for the enhancement of the existing legal frameworks for genomics, human enhancement, and AI and robotics", 2020 (Version 2.0).

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This policy brief was prepared by Santa Slokenberga, Uppsala University, on behalf of the SIENNA project. This is based on the recommendations in D5.6 (Version 2.0) and intended to support SIENNA recommendations for the ethical management of genetic and genomic research.

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