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Harmonizing EU Health Legislation for New Genomic Techniques

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Abstract

This article examines the regulation and application of New Genomic Techniques (NGTs) and genetic testing within the European Union (EU). It scrutinises the detailed aspects of EU data protection laws, underscoring their significance in safeguarding patient privacy and facilitating data sharing in healthcare and research sectors. The paper delves into the ethical dimensions and technological advances in genetic engineering, specifically focusing on gene editing and direct-to-consumer genetic testing, illuminating the complex interplay between technology, ethics, and legal frameworks. The analysis extends to the diverse regulatory environments at both national and EU levels, highlighting the urgent need for legislative updates in response to the rapid advancements in genomic technologies. This necessity accentuates the ongoing challenge of balancing fostering innovation and adhering to ethical and legal standards. Moreover, the article addresses the efforts to harmonise genetic testing regulations across European nations, considering the perspectives of multiple stakeholders. The discourse presented in the article underscores the complexity and critical importance of formulating policies that safeguard public interests and propel scientific advancements in this swiftly evolving domain. The EU should enhance the regulation and standardisation of NGTs in the field of human health and medicine by updating legislation, implementing risk assessment and safety protocols, establishing ethical guidelines, involving various stakeholders, adhering to global standards, promoting public education, and integrating NGTs into healthcare systems, ultimately aiming to promote safe and ethical NGTs development and advance public health objectives.

Keywords: NGTs; new genomic techniques; legislation; European Union.

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Armonización de la legislación sanitaria de la UE para las nuevas técnicas genómicas

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Resumen

Este artículo examina la regulación y aplicación de las Nuevas Técnicas Genómicas (NTG) y las pruebas genéticas en la Unión Europea (UE). Analiza los aspectos detallados de las leyes de protección de datos de la UE, subrayando su importancia para salvaguardar la privacidad de los pacientes y facilitar el intercambio de datos en los sectores de la atención sanitaria y la investigación. El artículo profundiza en las dimensiones éticas y los avances tecnológicos de la ingeniería genética, centrándose específicamente en la edición de genes y las pruebas genéticas directas al consumidor, iluminando la compleja interacción entre la tecnología, la ética y los marcos jurídicos. El análisis se extiende a los diversos entornos normativos, tanto a escala nacional como de la UE, y pone de relieve la necesidad urgente de actualizar la legislación en respuesta a los rápidos avances de las tecnologías genómicas. Esta necesidad acentúa el reto permanente de encontrar un equilibrio entre el fomento de la innovación y el respeto de las normas éticas y jurídicas. Por otra parte, el texto aborda los esfuerzos por armonizar la normativa sobre pruebas genéticas en todos los países europeos, teniendo en cuenta las perspectivas de las múltiples partes interesadas. El discurso presentado subraya la complejidad y la importancia crítica de formular políticas que salvaguarden los intereses públicos e impulsen los avances científicos en este ámbito que está en rápida evolución. La UE debería mejorar la regulación y la normalización de los NTG en el ámbito de la salud humana y la medicina actualizando la legislación, aplicando protocolos de evaluación de riesgos y seguridad, estableciendo directrices éticas, implicando a las distintas partes interesadas, respetando las normas mundiales, fomentando la educación pública e integrando los NTG en los sistemas sanitarios, con el fin último de promover un desarrollo seguro y ético de estos y avanzar en los objetivos de salud pública.

Palabras clave: NTG; nuevas técnicas genómicas; legislación; Unión Europea.

Introduction

The evolving landscape of genetics and its intersection with law and ethics presents a complex matrix of considerations, especially in the European context. In May 2016, the European Union adopted Regulation (EU) 2016/679 to enhance personal data protection. This regulation, advocated for by the European Patients' Forum, strikes a balance between safeguarding patient privacy and enabling the sharing of patient data for healthcare and research purposes. It empowers citizens with more rights regarding their data. It clarifies the responsibilities of entities handling this data, significantly impacting patients' rights to privacy, data sharing, and access to health data.[1]

In parallel, genetic engineering has seen breakthroughs, like modified viruses for vaccinations and the controversial gene editing of human embryos, as seen with the 2018 report of edited twins in China. These developments triggered a global debate in philosophy, theology, public ethics, and research ethics, highlighting the necessity for human genome editing regulations.[2] The ethical dimensions of therapeutic gene editing in human embryos remain a contentious and critically important area of study.[3]

Furthermore, the accessibility and affordability of commercial gene sequencing and editing technologies have brought ethical considerations to the forefront, especially concerning gene editing (specifically germline) and genetic selection. These technologies raise profound questions about manipulating the human genome, underscoring the urgency for ethical dialogues and regulatory frameworks.[4, 5]

Genetic testing has transformed, expanding into the direct-to-consumer (DTC) market with diverse tests. This sparks controversy over consumer autonomy versus concerns about medical supervision, result interpretation, and genetic data privacy. The lack of comprehensive European regulation highlights the need for a harmonised approach covering medical supervision, genetic counselling, and informed consent.[6]

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1 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, 4.5.2016, 1, 38.

2 Antara Barman et al., "A Glance at Genome Editing with CRISPR–Cas9 Technology," *Current Genetics* 66, no. 3 (2019): 457.

3 Qi Zhou et al., "Human Embryo Gene Editing: God's Scalpel or Pandora's Box?" *Briefings in Functional Genomics* 19, no. 3 (2020): 157.

4 ESHG - European Society of Human Genetics, "Statement of the ESHG on Direct-to-Consumer Genetic Testing for Health-Related Purposes," *European Journal of Human Genetics* 18, no. 2 (2010): 1273.

5 SIENNA, *D2.4: Ethical Analysis of Human Genetics and Genomics. Report of the SIENNA project – Stakeholder-informed ethics for new technologies with high socio-economic and human rights impact* (European Commission, 2019), 4.

6 Louiza Kalokairinou et al., "Direct-to-Consumer Genetic Testing," in *Encyclopedia of Life Sciences* (Wiley, 2014): 127.

Additionally, the European Union is revising its GMO legislation, reflecting a need to adapt existing laws to the realities of new genomic techniques (NGTs). This process involves reassessing the adequacy of current legislation in regulating research and marketing of NGT products, aiming to align them with the objectives of the EU Green Deal and Farm to Fork strategies.[7] Critiques of the current EU regulatory system for GMOs underscore the need for a more proportionate, risk-based approach that balances precautionary measures with the principle of proportionality.[8, 9, 10] This ongoing legislative evolution in the EU, alongside international dialogues and shifts in regulatory approaches in EU countries, underscores genetic technology regulation's complex, dynamic nature.

This article will delve into these multifaceted issues, focusing on the broad spectrum of national laws regulating genetic tests and their potential impact on DTC genetic testing in European countries. We will particularly emphasise medical supervision, genetic counselling, and informed consent, discussing the desirability of a harmonised regulatory framework across Europe.

Overview of the European Union's regulation on personal data protection

Historical context and development of Regulation (EU) 2016/679

The GDPR (General Data Protection Regulation), or Regulation (EU) 2016/679, is a crucial milestone in EU data protection. It emerged in response to digitalisation challenges and builds upon earlier data protection laws, including the 1970s laws and the 1995 EU Data Protection Directive.[11] As technological advancements continued, especially in social media and cloud computing, the European Commission proposed a comprehensive reform in 2012.[12] After extensive negotiations and amendments

7 European Commission, "Commission staff working document. Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/1," (2021), 2.

8 Dennis Eriksson et al., "Options to Reform the European Union Legislation on GMOs: Post-Authorization and Beyond," *Trends in Biotechnology* 38, no. 5 (2020): 465.

9 Dennis Eriksson et al., "Options to Reform the European Union Legislation on GMOs: Risk Governance," *Trends in Biotechnology* 38, no. 4 (2020): 350.

10 Dennis Eriksson et al., "Options to Reform the European Union Legislation on GMOs: Scope and Definitions," *Trends in Biotechnology* 38, no. 3 (2020): 231.

11 Council of Europe, *Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data"* (1981), 2.

12 European Commission, *Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)*, Document No. 52012PC0011 (2012).

addressing the balance between individual rights and business interests, the GDPR was adopted in 2016 and enforced in 2018, marking a significant overhaul of data protection laws in the EU.[13] Its global influence is evident, as it has set high privacy and data protection standards worldwide.[14]

Implications for patient privacy and data sharing in healthcare and research

Implementing the GDPR has had profound implications for patient privacy and data sharing in healthcare and research. The GDPR enhances patient privacy by introducing stricter consent requirements for processing personal data, particularly sensitive health data.[15] The WHO has formed a global expert panel to address human genome editing challenges, including scientific, ethical, social, and legal, with members from diverse regions. This enhances patient data control and transparency in the patient-provider relationship. Strict penalties for non-compliance ensure data protection and confidentiality standards are maintained.[16]

In the realm of healthcare and medical research, the GDPR has necessitated a re-evaluation of data-sharing practices. While aiming to protect individual privacy, the regulation also recognises the importance of data sharing for advancing medical research and public health objectives.[17] It provides a framework for legally processing personal health data for research under certain conditions like anonymisation or pseudonymisation of data. It also ensures data processing aligns with the public interest.[18] This nuanced approach attempts to balance the ethical necessity of patient privacy with the collective benefits of medical research.

However, the implications of GDPR on healthcare and research are not without challenges. Researchers and healthcare professionals need increased administrative

13 Regulation (EU) 2016/679, 1–88.

14 Chris Jay Hoofnagle et al., "The European Union General Data Protection Regulation: What It Is and What It Means," *Information and Communications Technology Law* 28, no. 1 (2019): 66.

15 Bocong Yuan and Jiannan Li, "The Policy Effect of the General Data Protection Regulation (GDPR) on the Digital Public Health Sector in the European Union: An Empirical Investigation," *International Journal of Environmental Research and Public Health* 16, no. 6 (2019): 4.

16 Consumers, Health, Agriculture and Food Executive Agency, *Assessment of the EU Member States' Rules on Health Data in the Light of GDPR* (LU: Publications Office, 2021), 122.

17 John Mark Michael Rumbold and Barbara Pierscionek, "The Effect of the General Data Protection Regulation on Medical Research," *Journal of Medical Internet Research* 19, no. 2 (2017): 3.

18 Denise Amram, "Building up the 'Accountable Ulysses' Model. The Impact of GDPR and National Implementations, Ethics, and Health-Data Research: Comparative Remarks," *Computer Law and Security Review* 37 (2020): 2.

burdens to ensure compliance, potentially hindering the pace and scope of research activities.[19] There is also the concern that the stringent requirements of the GDPR might impede cross-border data sharing, which is crucial for large-scale international research projects.[20] These concerns highlight the ongoing need to refine and adapt data protection policies to support both patient privacy and the dynamic needs of healthcare and medical research in the digital era.

Advancements and ethical challenges in genetic engineering

Case studies: gene editing

Genetic engineering has revolutionised medical science, offering ground-breaking tools for treating and preventing diseases like cancer. Developments in gene editing technologies, particularly CRISPR-Cas9, have opened new avenues for genetic manipulation with precision and efficiency.[21] Despite these advancements, ethical considerations remain at the forefront, particularly concerning the implications of altering human DNA in current generations and for posterity. The recent public attention on modifying human embryos has generated much discussion on the ethics of such research, but also the ethical issues raised by genetically modifying human cells more generally.[22, 23] The CRISPR-Cas9 technology, a key development in gene editing, allows for specific targeting and modification of DNA sequences in living organisms. Its potential applications range from correcting genetic defects to enhancing disease resistance.[24] A landmark case involving CRISPR gene editing in human embryos sparked global ethical debates. Gene editing shows promise in treating hereditary diseases, infections, and cancers, with trials for conditions like sickle cell anaemia and cystic fibrosis showing potential for long-term solutions. Ethical concerns revolve around accessibility, long-term effects, and the risk of eugenics.[25]

19 Pamela Herd and Donald Moynihan, "Health Care Administrative Burdens: Centering Patient Experiences," *Health Services Research* 56, no. 5 (2021): 751.

20 Laura Bradford et al., "International Transfers of Health Data between the EU and USA: A Sector-Specific Approach for the USA to Ensure an 'Adequate' Level of Protection," *Journal of Law and the Biosciences* 7, no. 1 (2020): 3.

21 Fatima Akram et al., "RETRACTED: CRISPR/Cas9: A Revolutionary Genome Editing Tool for Human Cancers Treatment," *Technology in Cancer Research & Treatment* 21 (2022): 153303382211320.

22 Megan Munsie and Christopher Gyngell, "Ethical Issues in Genetic Modification and Why Application Matters," *Current Opinion in Genetics and Development* 52 (2018): 8.

23 Barry S. Coller, "Ethics of Human Genome Editing," *Annual Review of Medicine* 70, no. 1 (2019): 290.

24 Coller, "Ethics of Human Genome Editing," 291.

25 Penticuff, Joy, "Ethical Issues in Genetic Therapy," *Journal of Obstetric, Gynecologic and Neonatal Nursing* 23, no. 6 (1994): 500.

The ethics of human genome editing: global perspectives and debates

The global debate over human genome editing, especially using CRISPR-Cas9, centres on its potential to eradicate genetic diseases but raises significant ethical concerns. Germline editing, which affects future generations, is particularly contentious. Ethicists and scientists worldwide discuss the moral implications, with many urging a global moratorium until ethical guidelines are in place.[26]

Human gene editing, mainly using the new CRISPR/Cas9 technology, will significantly increase the capability to make precise changes to human genomes. Human gene editing can be broken into four categories: somatic therapy, heritable gene editing, genetic enhancement, and basic and applied research.[27]

The sharing of genomic data holds great promise for advancing precision medicine and providing personalised treatments and other interventions. However, privacy concerns exist, as data misuse may lead to privacy infringement for individuals and their blood relatives.[28]

Data collected and stored in biobanks are promising for improving health care. However, improperly handling these vast amounts of biodata raises unresolved legal and ethical issues.[29]

The global debate intensified with the birth of gene-edited babies in China, highlighting transparency and premature technology application issues. Regulatory disparities between developed nations like the US and EU, with stringent guidelines and others needing comprehensive regulations, led to ethical dilemmas and international tensions in biotechnology.[30]

[26] National Academy of Sciences (NAS) and National Academy of Medicine (NAM), *Human Genome Editing: Science, Ethics, and Governance* (National Academies Press, 2017).

[27] Gary, E. Marchant, "Global Governance of Human Genome Editing: What Are the Rules?" *Annual Review of Genomics and Human Genetics* 22, no. 1 (2021): 387.

[28] Luca Bonomi et al., "Privacy Challenges and Research Opportunities for Genomic Data Sharing," *Nature Genetics* 52, no. 7 (2020): 646.

[29] Esra Demir, "The Protection of Human Biodata: Is There Any Role for Data Ownership?" *Computer Law and Security Review* 51 (2023): 105905.

[30] Cyranoski David and Heidi Ledford, "Genome-Edited Baby Claim Provokes International Outcry," *Nature* 563, no. 7733 (2018): 607–608.

The UN and other organisations stress global cooperation for genome editing guidelines. The WHO's committee aims to establish ethical standards and equal access. The goal is to ensure genome editing benefits global health without worsening inequalities.[31]

Adding to these considerations, genetic techniques such as gene editing and cloning present significant ethical dilemmas, including potentially misusing genetic information. Genetic discrimination is a primary ethical concern, where misuse of genetic data could lead to discrimination in employment, insurance, and other life areas. Scientists underscore the necessity of stringent laws to prevent such discrimination and protect genetic privacy and rights.[32]

Germline editing using CRISPR raises questions about future generations, as changes would be heritable. The US National Academy of Sciences[33] recommends cautiously using germline editing only to prevent serious diseases and under strict oversight. On the other hand, cloning raises ethical questions about identity and individuality. Some scientists argue against this practice due to concerns over the psychological well-being of clones.[34]

Commercialising genetic technologies, such as DTC genetic testing, risks misusing and misinterpreting genetic data. Some authors stress the need for regulation to ensure consumer protection.[35] Regulatory frameworks like the EU's GDPR[36] and UNESCO's Universal Declaration on the Human Genome and Human Rights (1997)[37] are crucial in addressing these challenges.

Summarising these facts, while genetic techniques offer significant benefits, they also pose ethical dilemmas and risks of misuse. A balanced approach, incorporating ethical considerations and robust regulatory frameworks, is essential to harnessing these technologies responsibly.

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31 World Health Organization (WHO), *WHO expert advisory committee on developing global standards for governance and oversight of human genome editing* (2019), 5.

32 Lawrence O. Gostin and James G. Hodge Jr., "Genetic privacy and the law: an end to genetics exceptionalism," *Jurimetrics* 40, no. 1 (1999): 23.

33 NAS and NAM, *Human Genome Editing*.

34 Leon R. Kass, "The Wisdom of Repugnance: Why We Should Ban the Cloning of Humans," *Valparaiso University Law Review* 32, no. 2 (1998): 694.

35 Amy L. McGuire and Wylie Burke, "An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing," *JAMA* 300, no. 22 (2008): 2669.

36 Paul Voigt and Axel von dem Bussche, *The EU General Data Protection Regulation (GDPR)* (Springer International Publishing, 2017).

37 Unesco, *Universal Declaration on the Human Genome and Human Rights* (UNESDOC, 1997).

The rise of DTC genetic testing

Evolution from clinical to consumer settings

The rise of DTC genetic testing marks a significant shift from traditional clinical settings to a consumer-driven approach. Initially, genetic testing was conducted exclusively within the healthcare system, where tests were ordered by medical professionals, often as part of a broader diagnostic or therapeutic process. However, the advent of DTC genetic testing companies has democratised access to genetic information, allowing consumers to obtain genetic data without a healthcare provider's intermediary.[38, 39] This shift is fuelled by advancements in genomic technologies and a reduction in the cost of gene sequencing, enabling companies to offer these tests directly to the public. DTC genetic testing is a new way of obtaining genetic testing outside a traditional clinical setting.[40]

DTC genetic testing provides ancestry and health risk information but raises concerns about data accuracy, interpretation, and privacy. Consumers risk making crucial decisions based on unverified results, leading to misunderstandings and anxiety. Commercial entities handling genetic data also pose risks to personal privacy and data security.[41]

The regulatory landscape for DTC genetic testing varies significantly across jurisdictions, reflecting different cultural and ethical standards. In the United States, the Food and Drug Administration (FDA) has begun to exercise oversight, approving specific DTC genetic tests for health risks.[42] In contrast, European countries have generally adopted more stringent regulations, with some nations outright banning health-related DTC genetic testing without a prescription.[43] These contrasting approaches highlight the challenge of balancing consumer autonomy and interest in genetics with the need for accurate, reliable, and ethical genetic testing practices.

38 Kathryn T. Hock et al., "Direct-to-Consumer Genetic Testing: An Assessment of Genetic Counselors' Knowledge and Beliefs," *Genetics in Medicine* 13, no. 4 (2011): 327.

39 Mary A. Majumder et al., "Direct-to-Consumer Genetic Testing: Value and Risk," *Annual Review of Medicine* 72, no. 1 (2021): 152.

40 Pascal Borry et al., "The Challenges of the Expanded Availability of Genomic Information: An Agenda-Setting Paper," *Journal of Community Genetics* 20, no. 1 (2012): 104.

41 "Direct-to-Consumer Genetic Testing FAQ," Nih National Human Genome Research Institute, accessed November 16, 2023.

42 "Direct-to-Consumer Tests," FDA. U.S. Food and Drug Administration, accessed October 25, 2023.

43 Pascal Borry et al., "Legislation on Direct-to-Consumer Genetic Testing in Seven European Countries," *European Journal of Human Genetics* 20, no. 7 (2012): 716.

The main advantages and disengages of DTC genetic testing include:

Advantages:

- Enhances awareness of genetic health risks.
- Offers personalised health insights, disease risks, and trait information.
- Encourages proactive health management.
- Eliminates the need for medical or insurance provider approval.
- Results are private and not automatically included in medical or insurance records.
- Generally, more cost-effective than provider-obtained tests, increasing accessibility.
- Simple, non-invasive DNA sample collection with quick result turnaround.
- Anonymous data contributes to research databases, potentially featuring millions of participants.

Challenges and Constraints:

- Not all health conditions or traits may be covered by the tests.
- Cannot provide definitive predictions for disease development.
- Results typically require confirmation through clinical genetic testing.
- Only examines a limited range of genetic variations, possibly missing disease-causing variants.
- May uncover unexpected and potentially distressing information about health, family, or ancestry.
- Lacks the in-person genetic counselling and informed consent found in clinical settings.
- Important decisions may be based on inaccurate, incomplete, or misunderstood information.
- Minimal oversight or regulation over testing companies.
- Risk of misleading results from unproven or invalid tests due to insufficient scientific evidence.

- Potential compromise of genetic privacy through unauthorised use of data or data breaches.
- Genetic testing results may affect eligibility for life, disability, or long-term care insurance.
- Provides a partial picture of health, not accounting for other genetic, environmental, lifestyle, or familial factors often discussed with doctors or genetic counsellors.

Controversies and ethical considerations in DTC genetic testin

The controversies and ethical considerations in DTV genetic testing include, for example:

- Privacy and data security problems
- Informed consent problems
- Clinical validity of this testing
- Regulatory problems
- Negative psychological impact on customers and patients
- Health disparities
- Genetic discrimination

The adequacy of informed consent is questionable in the DTC genetic testing model. Due to the absence of counselling and the complexity of the information presented, consumers may need adequate information to make informed decisions about testing implications.[44]

Many DTC genetic tests have yet to undergo rigorous clinical validation. This raises questions about the accuracy of the risk assessments and the clinical utility of the tests, potentially leading to misinterpretation of results and misinformed health decisions.[45]

[44] J. Scott Roberts and Jenny Ostergren, "Direct-to-Consumer Genetic Testing and Personal Genomics Services: A Review of Recent Empirical Studies," *Current Genetic Medicine Reports* 1, no. 3 (2013): 183.

[45] Amy L. McGuire and Wylie Burke, "Health System Implications of Direct-to-Consumer Personal Genome Testing," *Public Health Genomics* 14, no. 1 (2010): 56.

The level of regulatory oversight for DTC genetic testing companies varies widely, with some countries having minimal to no specific regulations. This leads to a market where not all tests are equal in quality and reliability.[46]

Receiving genetic information about potential health risks without proper context or support can have a significant psychological impact on individuals, leading to anxiety or distress. Furthermore, it may affect family dynamics if undisclosed familial relationships are revealed.[47]

There is a concern that DTC genetic testing may increase health disparities. Individuals from higher socio-economic backgrounds are more likely to afford and access these services, potentially widening the gap in health literacy and outcomes between different segments of the population.[48]

Consumers fear genetic discrimination, particularly concerning life insurance and employment. The lack of comprehensive legal protection against such discrimination in many regions fuels this concern.[49]

Regulatory landscapes: national and EU-level responses

Comparative analysis of national laws on genetic testing in Europe

The landscape of national laws governing genetic testing in Europe is diverse, reflecting the continent's varied cultural, ethical, and legal perspectives. A comparative analysis reveals that while some European countries have specific regulations that directly address genetic testing, others rely on broader health and privacy laws to govern the practice.[50] Rules on health data in the light of GDPR were established in many European countries.[51]

46 Alexandra Cernat et al., "Considerations for Developing Regulations for Direct-to-Consumer Genetic Testing: A Scoping Review Using the 3-I Framework," *Journal of Community Genetics* 13, no. 2 (2022): 165.

47 Serena Oliveri et al., "A Systematic Review of the Psychological Implications of Genetic Testing: A Comparative Analysis Among Cardiovascular, Neurodegenerative and Cancer Diseases," *Frontiers in Genetics* 9, (2018).

48 Juan R. Canedo et al., "Racial and Ethnic Differences in Knowledge and Attitudes about Genetic Testing in the US: Systematic Review," *Journal of Genetic Counseling* 28, no. 3 (2019): 597.

49 Jane Tiller et al., "Community Concerns about Genetic Discrimination in Life Insurance Persist in Australia: A Survey of Consumers Offered Genetic Testing," *European Journal of Human Genetics* 32 (2023): 293.

50 Franziska Rössler and Johannes R. Lemke, "Legislation on Genetic Testing in Different Countries," in *Pediatric and Adolescent Medicine*, ed. W. Kiess, C. G. Bornehar and C. Gennings (S. Karger AG, 2017), 38.

51 Consumers, Health, Agriculture and Food Executive Agency, *Assessment of the EU Member States' Rules on Health Data in the Light of GDPR: Country Fiches for All EU MS* (LU: Publications Office, 2021).

The landscape of genetic testing legislation in European countries presents a diverse and complex picture. In France, the regulations are notably stringent, mandating that genetic testing be conducted solely for medical reasons and under strict medical supervision.[52] This contrasts sharply with the United Kingdom's approach, where access to genetic testing is more liberalised. The UK offers these services through the National Health Service (NHS) and private entities, supported by robust data protection laws.[53]

Germany takes a different path with its Genetic Diagnostics Act (GenDG), which focuses on safeguarding individual rights and explicitly prohibits genetic discrimination.[54] Meanwhile, countries like Italy and Spain, while lacking specific legislation for genetic testing, manage the practice within the broader scope of health service regulations and data protection laws.[55] In Belgium, Italy, and the UK, there is no specific legislation that forbids or regulates the provision of DTC-GT, while in France, Germany, Portugal, and Switzerland, there is specific legislation that dictates that genetic tests can only be carried out by a medical doctor after the provision of sufficient information and appropriate genetic counselling.[56]

This varied regulatory environment across Europe significantly impacts the availability and practice of genetic testing. It also challenges the flow of genetic data across borders and hampers collaborative efforts in genetic research.[57]

The EU seeks uniformity through directives like GDPR to protect personal data, including genetic information. However, implementation varies among member states, leading to inconsistent protection and consent requirements.[58]

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52 Louiza Kalokairinou et al., "Legislation of Direct-to-Consumer Genetic Testing in Europe: A Fragmented Regulatory Landscape," *Journal of Community Genetics* 9, no. 2 (2017): 119.

53 Victoria Chico, "The Impact of the General Data Protection Regulation on Health Research," *British Medical Bulletin* 128, no. 1 (2018): 113.

54 Matthias Orth et al., "Praktische Umsetzung Des Gendiagnostikgesetzes (GenDG) in Der Laboratoriumsmedizin, Dem Humangenetischen Laboratorium Und Der Humangenetischen Beratung/Practical Implications of the German Genetic Diagnostics Act (GenDG) for Laboratory Medicine, the Human Genetics Laboratory and for Genetic Counseling," *Laboratoriums Medizin* 35, no. 5 (2011): 245.

55 Kalokairinou et al., "Direct-to-Consumer Genetic Testing," 117-132.

56 Serena Oliveri et al., "Genetic Testing Consumers in Italy: A Preliminary Investigation of the Socio-Demographic Profile, Health-Related Habits, and Decision Purposes," *Frontiers in Public Health* 8, (2020).

57 Pormeister, Kārt, "Genetic Research and Applicable Law: The Intra-U Conflict of Laws as a Regulatory Challenge to Cross-Border Genetic Research," *Journal of Law and the Biosciences* 5, no. 3 (2018): 711.

58 Fruzsina Molnár-Gábor et al., "Harmonization after the GDPR? Divergences in the Rules for Genetic and Health Data Sharing in Four Member States and Ways to Overcome Them by EU Measures: Insights from Germany, Greece, Latvia and Sweden," *Seminars in Cancer Biology* 84, (2022): 278.

Summarisation of the regulatory landscape in the EU

The regulatory landscape for genetic testing in Europe is characterised by a mix of national laws, reflecting diverse cultural, ethical, and legal perspectives. While some European countries have specific regulations for genetic testing, others rely on broader health and privacy laws.[59] For instance, Austria requires consent and specialist involvement for particular tests, while Belgium has legislation for human genetics centres and genetic data processing. In contrast, countries like Cyprus, Estonia, Finland, and Malta lack specific regulations for genetic testing. Countries like the Czech Republic follow international conventions and protocols, and Denmark has established the National Genome Centre for genetic sequencing and data maintenance. Germany's Genetic Diagnosis Act governs genetic testing for medical and parentage purposes, while Greece and Hungary have specific genetic diagnosis and research regulations. Ireland's Disability Act protects individuals with genetic disorders, and Italy has guidelines for medical genetics and genomics in healthcare. Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden have varying regulations, from general requirements to specific genetic testing laws. The UK, however, has yet to establish specific rules for genetic testing. The regulatory environment impacts the availability and practice of genetic testing across Europe, influencing the flow of genetic data and collaborative research efforts. The EU aims for uniformity with directives like the GDPR for personal data protection, but member states implement these differently, leading to varied protection and consent requirements. This situation highlights the need for adaptable regulations that balance individual rights with research and innovation, considering future challenges like genetic editing and data misuse.

The role of EU legislation in shaping genetic testing practices

EU legislation is essential for standardising genetic testing and safeguarding data privacy. It ensures consistent regulations across member states, preventing unequal access and varying standards. The GDPR provides a unified legal framework, explicitly addressing personal data, including genetic information, to ensure privacy and data protection throughout the EU.[60]

[59] "EC study on new genomic techniques. Stakeholders' consultation," European Commission, accessed November 1, 2023.

[60] Regulation (EU) 2016/679.

EU legislation should address genetic testing ethics, including consent, genetic discrimination, and data use in employment and insurance. Specific directives or regulations on these ethical aspects could promote responsible and ethical genetic testing across member states.[61]

The EU plays a role in fostering collaboration and research in genetics. By standardising regulations, the EU can facilitate cross-border genetic research, enabling the sharing of genetic data and resources. This advances scientific knowledge and ensures that the benefits of genetic testing, such as personalised medicine, are accessible to a broader population.[62]

The EU's legislative framework needs to adapt to the rapid advancements in genetic technology, including gene editing. Regulations should be flexible to accommodate new developments while ensuring safeguards for individuals and society. As gene-editing technologies, which change an organism's DNA, are globally competitive, there is a need for legal frameworks that protect users while allowing developers to be flexible.[63]

The EU's role in shaping genetic testing practices is multifaceted and essential for creating a harmonious, ethical, and scientifically progressive environment for genetic testing and research within Europe. The challenge lies in balancing the rapid advancements in genetic technology with ethical considerations and data protection, ensuring equitable access, and facilitating scientific collaboration.

Revising EU legislation in the context of new genomic techniques

The need for reassessment and adaptation of existing laws

The rapid advancement in genomic technologies has precipitated a need to reassess and adapt existing EU laws. The current legal framework, primarily based on the understanding and capabilities of genetic modification from decades past, must be more comprehensive in addressing the complexities and ethical considerations presented by NGTs.[64]

61 European Commission Directorate General for Research and Innovation, *European Group on Ethics in Science and New Technologies Opinion on the Ethics of Genome Editing* (LU: Publications Office, 2021).

62 European Commission, *Declaration of Cooperation. Towards access to at least 1 million sequenced genomes in the European Union by 2022* (2022).

63 Aurélie Mahalatchimy et al., "Framing and Legitimating EU Legal Regulation of Human Gene-Editing Technologies: Key Facets and Functions of an Imaginary," *Journal of Law and the Biosciences* 8, no. 2 (2021).

64 Tarja Laaninen, *New genomic techniques. European Commission study and first reactions* (2021).

NGTs, such as CRISPR-Cas9 and other gene-editing tools, offer unprecedented precision and efficiency in genetic modification. These advancements have significant implications for medicine and provide potential solutions to longstanding challenges such as targeted therapies. However, they also raise complex ethical, safety, and regulatory concerns that the existing EU legislation may need to address fully.[65]

The global landscape of genomic technologies is rapidly changing, with non-EU countries adopting flexible regulations for NGTs. This regulatory disparity hinders international trade and research collaboration. To stay competitive in genomic research, the EU must update its framework to match current science and align with global standards.[66]

Scientists and policymakers see a need to reform current definitions and risk assessments for NGTs to ensure safety, trust, and innovation. Reevaluating EU laws for new genomic techniques is crucial, striking a balance between safety, ethics, innovation, and international alignment. Collaboration among experts and the public will maintain the EU's leadership in genomic research. The European Commission proposed a Regulation on new genomic techniques in July 2023, and a similar approach may be considered for NGTs in medicine.[67]

Potential impacts of revised legislation on research and health services

Revised legislation for new genomic techniques can profoundly impact research and health services. It can boost EU research by providing clear, updated boundaries, reducing ambiguities, and attracting investment. Enhanced regulatory frameworks may increase funding, resources, innovation, and development in genomics.[68]

Revised legislation can enable personalised medical treatments for genetic disorders and diseases using genomic technologies, especially in gene editing and therapy. Updated legal frameworks can expedite treatment approval and integration, enhancing patient outcomes, healthcare efficiency, and medical science progress.[69]

65 European Commission, "Commission staff working document."

66 İbrahim Erdoğan et al., "Recent Developments in CRISPR/Cas9 Genome-Editing Technology Related to Plant Disease Resistance and Abiotic Stress Tolerance," *Biology* 12, no. 7 (2023): 1037.

67 "New genomic techniques - what lies ahead?" EURACTIVE, accessed October 25, 2023.

68 Charles Auffray et al., "Making Sense of Big Data in Health Research: Towards an EU Action Plan," *Genome Medicine* 8, no. 1 (2016).

69 OECD, *OECD Science, Technology and Industry Working Papers* (OECD iLibrary, 2023).

However, these legislative changes also need to address ethical and safety concerns. For instance, gene editing issues like germline modification require careful ethical consideration. Laws that balance enabling innovation and safeguarding against potential ethical violations are crucial. Such balance ensures that research progresses responsibly, maintaining public trust and upholding ethical standards.[70]

The Commission's study assesses the EU's NGT legislation via consultations with Member States and stakeholders. Revised laws impact global research and health services collaboration. Harmonizing EU laws with international standards boosts cross-border collaboration, speeding up medical research and treatment development and benefiting a global population. It positions the EU as a genomics leader, influencing global practices and standards in this evolving field.[71]

The potential impacts of revised EU legislation on research and health services will be significant. They offer the opportunity for enhanced research and innovation, improved health outcomes, and greater international collaboration. However, achieving these benefits requires a careful and balanced approach to legislative reform, addressing the potential of genomic technologies and their ethical, safety, and societal implications.

Balancing risk, precaution, and innovation in NGT regulation

Critiques and recommendations for the current EU regulatory system

The EU's NGT regulation must balance risk, precaution, and innovation more effectively. Critics argue its process-oriented approach, focusing on techniques rather than final products, may hinder the adoption of beneficial technologies like CRISPR-Cas9 in medicine.[72]

Another concern is the rigidity of the current risk assessment protocols. While ensuring safety is paramount, the existing protocols might not adequately differ-

70 Zabta Khan Shinwari et al., "Ethical Issues Regarding CRISPR Mediated Genome Editing," *Current Issues in Molecular Biology* 26, (2018): 108.

71 Laaninen, "New genomic techniques."

72 Hellen Mbaya et al., "Regulatory Frameworks Can Facilitate or Hinder the Potential for Genome Editing to Contribute to Sustainable Agricultural Development," *Frontiers in Bioengineering and Biotechnology* 10, (2022).

entiate between varying levels of risk presented by different applications of NGTs. A more nuanced, case-by-case assessment could better balance safety concerns with the potential benefits of NGTs. This approach could encourage responsible innovation while maintaining high safety standards.[73]

Several recommendations have been proposed to address these critiques. Firstly, updating the regulatory framework to focus more on the characteristics and safety of the end product rather than the process used to create it could be more appropriate for assessing NGTs. This shift would align the EU's regulatory approach more closely with scientific advancements and global standards.[74]

Secondly, enhancing public engagement and transparency in the regulatory process is crucial. Building public trust through transparent decision-making and clear communication about the benefits and risks of NGTs is essential for accepting and successfully integrating these technologies into society.[75]

Additionally, it is recommended that international collaboration in regulatory standards be facilitated. Aligning EU regulations with international counterparts can facilitate global research collaboration, trade, and knowledge exchange, thereby enhancing the development and safe use of NGTs.[76]

Regulating NGTs requires balancing risk, precaution, and innovation. The EU's regulatory system, criticised for potentially stifling innovation, could improve with a product-focused approach, nuanced risk assessments, increased public engagement, and international collaboration. This would create a framework that ensures public safety while promoting scientific advancement.[77]

Case studies: risk assessment and proportionality in NGT authorisation

Case studies on NGTs' risk assessment and proportionality are crucial in medicine. For example, gene therapy for genetic disorders like Duchenne Muscular Dystrophy

73 Franziska Koller et al., "The Need for Assessment of Risks Arising from Interactions between NGT Organisms from an EU Perspective," *Environmental Sciences Europe* 35, no. 1 (2023).

74 European Commission, *Commission staff working document impact assessment report. Brussels, 5.7.2023. Proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625* (2023).

75 Sigfrid Kjeldaas et al., "With Great Power Comes Great Responsibility: Why 'Safe Enough' Is Not Good Enough in Debates on New Gene Technologies," *Agriculture and Human Values* 40, no. 2 (2022): 536.

76 Mikhail P. Kirpichnikov and Alexander M. Kudryavtsev, "Safe Use of Genetic Technologies," *Herald of the Russian Academy of Sciences* 92, no. 3 (2022): 225.

77 European Parliament, *Regulating genome editing: Societal hopes and fears. Study of the Panel for the Future of Science and Technology* (EPRS European Parliamentary Research Service, 2021).

involves assessing safety and efficacy, considering unintended genetic alterations and immune responses. Proportionality evaluates if the benefits outweigh the risks, highlighting the need for a nuanced authorisation approach.[78]

Another case study involves CRISPR-Cas9 in cancer research, aiming to enhance precision oncology by modifying immune cells. Risk assessment examines side effects like off-target genetic changes and immune system impact, while proportionality assesses treatment potential for resistant forms of cancer. This emphasises the necessity of a flexible regulatory framework for advanced cancer treatments using NGTs.[79]

In both cases, prioritising ethics and patient safety is crucial. The authorisation process needs transparent, peer-reviewed risk assessments. Proportionality should evaluate broader healthcare system impact, cost-effectiveness, and treatment accessibility. By addressing NGTs' risks and transformative potential in medicine, regulatory authorities can encourage innovation while safeguarding public health.[80]

These case studies demonstrate the intricate balance required in regulating NGTs in medicine. Effective risk assessment and proportionality measures are critical for harnessing NGTs' benefits in human health while minimising potential risks and ethical concerns.[81]

Harmonisation of genetic testing regulations across Europe

Challenges and prospects for a unified regulatory framework

Harmonising genetic testing regulations in Europe, particularly in medicine and human health, faces challenges due to diverse healthcare systems, ethical standards, policies, and cultural attitudes across countries. Variations exist in DTC testing, data sharing, and consent protocols, making harmonisation a significant hurdle.[82]

78 Nertiyan Elangkovan and George Dickson, "Gene Therapy for Duchenne Muscular Dystrophy," *Journal of Neuromuscular Diseases* 8, no. s2 (2021): 312.

79 Ali A. Rabaan et al., "Application of CRISPR/Cas9 Technology in Cancer Treatment: A Future Direction," *Current Oncology* 30, no. 2 (2023): 1956.

80 M. Khair ElZarrad et al., "Advancing an Agile Regulatory Ecosystem to Respond to the Rapid Development of Innovative Technologies," *Clinical and Translational Science* 15, no. 6 (2022): 1333.

81 Tomasz Zimny, "New Genomic Techniques and Their European Union Reform. Potential Policy Changes and Their Implications." *Frontiers in Bioengineering and Biotechnology* 10, (2022).

82 Molnár-Gábor et al, "Harmonization after the GDPR?" 280.

A key challenge is updating the regulatory framework to match the fast advancements in genetic testing technologies. Genomics is rapidly evolving with new techniques and applications. Therefore, a unified framework must be adaptable and flexible yet maintain high safety and ethical standards.[83]

Despite challenges, harmonisation offers significant prospects. A unified framework could boost collaboration and data sharing across Europe, enhancing genetic testing research. This could lead to evidence-based medical genomics, improving patient care. Streamlined test approval could make them more accessible to European patients.[84]

One potential prospect is developing a centralised European database for genetic information, which could be instrumental in advancing personalised medicine. Such a database would enable more comprehensive research, facilitating the development of targeted therapies based on a diverse genetic dataset. However, this would require rigorous data protection and privacy regulations to ensure patient confidentiality and trust.[85]

Stakeholder perspectives and policy recommendations for NGTs

Understanding stakeholder perspectives and formulating NGT policy recommendations for medicine and human health is crucial. Medical professionals stress the need for practical guidelines, training, ongoing education, and resources to keep up with NGT advancements. They also emphasise ethical considerations, particularly in gene editing with unknown long-term effects.[86]

Patients and patient advocacy groups: these stakeholders generally support the potential benefits of NGTs, such as personalised medicine and treatments for previously incurable diseases. However, they also express concerns about accessibility, equity, and informed consent. Policies that ensure equitable access to these advanced treatments and safeguard patient rights are a priority for this group.[87]

83 HM Government, *Genome UK. The future of healthcare* (2020).

84 Consumers, *Assessment of the EU Member States' rules.*

85 "10. April 2018 EU countries will cooperate in linking genomic databases across borders," European Commission, accessed October 28, 2023.

86 Jodie Rothschild, "Ethical Considerations of Gene Editing and Genetic Selection," *Journal of General and Family Medicine* 21, no. 3 (2020): 40.

87 Bjørn K. Myskja and Kristin S. Steinsbekk, "Personalized Medicine, Digital Technology and Trust: A Kantian Account," *Medicine, Health Care and Philosophy* 23, no. 4 (2020): 580.

Researchers and academics: this group emphasises the need for a regulatory framework that balances safety with the flexibility to innovate. They recommend policies that streamline the approval process for clinical trials and facilitate collaborative research while maintaining rigorous safety and ethical standards. Main ethical principles, including beneficence, nonmaleficence, autonomy, and justice, must be observed in scientific research. Academics also call for public funding to support independent research in NGTs.[88]

Industry representatives: stakeholders from the biotechnology and pharmaceutical industries are interested in a regulatory environment conducive to developing and commercialising NGT-based therapies. They advocate for policies that reduce bureaucratic hurdles, protect intellectual property, and provide incentives for research and development in this field.[89]

Policy recommendations:

- Develop a balanced regulatory framework that ensures safety and efficacy while promoting innovation in NGT applications in medicine.
- Foster collaboration and data sharing among EU countries to accelerate research and development in medical genomics.
- Implement policies that ensure equitable access to NGT-based treatments and address disparities in healthcare.
- Enhance public engagement and education about NGTs to build trust and informed understanding among patients and the general public.
- Provide support for independent research and ongoing professional development for healthcare providers in the field of NGTs.

These stakeholder perspectives and policy recommendations highlight the multifaceted considerations in regulating and implementing NGTs in medicine and human health. A collaborative, balanced approach is necessary to harness NGTs' potential while addressing ethical, safety, and accessibility concerns.[90]

88 Basil Varkey, "Principles of Clinical Ethics and Their Application to Practice," *Medical Principles and Practice* 30, no. 1 (2020): 20.

89 European Commission, "EC study."

90 Wageningen Food Safety Research, *Policy scenarios for new genomic techniques* (University of Wageningen, 2022).

Conclusion

The European Union should take significant steps to effectively regulate and harmonise its regulatory framework for NGTs in the human health and medicine sector. This entails revising legislation to accommodate technological advancements, establishing detailed risk assessment and safety protocols, and developing ethical guidelines for NGTs. Additionally, it involves engaging diverse stakeholders for inclusive policy-making, aligning with international standards, fostering public education for greater transparency, and integrating NGTs-based treatments into healthcare systems. Implementing these measures will enable the EU to promote a regulatory environment that supports safe, ethical NGT development and innovation while advancing public health goals.

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