COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Strasbourg, 16 May 2025 CDBIO(2025)7

STEERING COMMITTEE FOR HUMAN RIGHTS IN THE FIELDS OF BIOMEDICINE AND HEALTH (CDBIO)

Draft CDBIO Strategic Action Plan (SAP) (2026-2030)

Prepared by the Drafting Group for the new SAP

Mission Statement

The Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) works to protect and promote human dignity and fundamental rights and freedoms in the fields of biomedicine and health amid ongoing scientific developments and technological innovation. CDBIO works to develop ethical guidance, set standards, and support the effective implementation of human rights obligations across member States. Grounded in a human rights-based approach, the Committee seeks to safeguard individual autonomy while fostering equity and solidarity, both within and across generations recognising the interdependence of human, animal and environmental health.

Preamble

Almost 30 years after the adoption of the Convention on Human Rights and Biomedicine (1997), scientific advancements and social transformations are changing the landscape of biomedicine and healthcare in unprecedented ways. Rapid progress in science and technology is redefining clinical research, as well as the delivery and practice of healthcare. While these developments hold immense promise for improving human health and well-being, they also raise complex ethical, legal, and societal challenges. Particular concern has been raised about the governance of emerging technologies, such as AI in healthcare, synthetic biology, and genomic medicine, highlighting the urgent need for governance structures that evolve in tandem with technological change to prevent harm, uphold human rights, and ensure equitable access to the benefits they offer.

At the same time, important inequities in healthcare remain, both within and across countries, exacerbated by demographic shifts such as ageing populations and migration, the digital transformation of health systems, and growing environmental health risks. The COVID-19 pandemic further exposed vulnerabilities in global and national health systems, underscoring the importance of state of readiness, and cultivating resilient health systems where inclusion and equity are central. As innovation accelerates and structural inequalities persist, the role of bioethics must evolve – not only to respond to new realities, but to proactively shape policy debates and provide strategic foresight to address uncertain futures, protecting the health and rights of both current and future generations.

Compounding these concerns is the growing spread of mis- and disinformation in the health field, amplified by social media and AI-generated content, which threatens the effectiveness of public health responses and erodes trust in science and evidence-based policymaking. More broadly, at a time when democratic values, human rights, and confidence in institutions and expertise are under increasing strain, there is growing concern that principles once taken for granted are under threat, potentially leading to the erosion of human rights and core ethical values.

These issues were identified as the most pressing bioethical challenges of the coming decade through a comprehensive horizon scanning exercise, engaging national ethics bodies, human rights institutions, member State delegations, and leading experts, conducted by CDBIO to guide its strategic priorities for 2026-2030.

Given the scale and complexity of these challenges, reaffirming a human rights-based approach is more important than ever. Human rights are considered in broad terms to

include first-generation (civil and political), second-generation (economic, social, and cultural), and third-generation (collective and environmental) rights. This Strategic Action Plan is grounded in that approach, which is firmly anchored in the Convention on Human Rights and Biomedicine – the only legally binding international instrument on human rights in the biomedical field. The Convention establishes the fundamental principle that the interests of the human being must take precedence over the sole interests of science or society (article 2). This Strategic Action Plan reasserts the Convention's enduring relevance by addressing ongoing, new, and emerging challenges, while ensuring that its core values – human dignity, integrity, autonomy, privacy, and non-discrimination, equity – are upheld in practice.

The Strategic Action Plan has also been developed in alignment with the priorities of the 2024 Reykjavík Declaration and the Council of Europe's Gender Equality Strategy 2024-2029. The Reykjavík Declaration, adopted by the Council of Europe's Heads of State and Government, reaffirmed a shared commitment to the rule of law, democracy, and human rights, while highlighting the importance of social rights as enshrined in the European Social Charter. The Declaration also recognised the right to a healthy and sustainable environment, reinforcing the interconnection between health, environmental justice, and human rights. The Council of Europe's Gender Equality Strategy, which adopts an intersectional approach, reflects a commitment to creating a more equitable society in which all individuals, regardless of background, enjoy equal rights, opportunities, and protection.

Firmly situated within these broader commitments, the Strategic Action Plan has the following ambition:

- First, it aims to ensure that, in the fields of biomedicine and health, human rights and human dignity are effectively upheld and implemented.
- Second, it seeks to apply and strengthen human rights where existing instruments, principles, and procedures require re-examination in light of social, scientific, and technological developments.
- Third, it aims to anticipate and respond to emerging biomedical technologies and healthcare practices to provide timely ethical and legal guidance.
- Fourth, it seeks to foster strong, inclusive engagement by integrating the perspectives of civil society, including young people, strengthening dialogue with the public and professional, ethics, and human rights bodies, and promoting collaboration within and beyond the Council of Europe.

With biomedicine and healthcare systems undergoing profound transformation, this Strategic Action Plan aims to ensure that human rights remain central to policy and practice – not as an afterthought, but as the foundation of responsible governance, innovation, and care. By addressing the pressing bioethical challenges of today, CDBIO aims to contribute to building a resilient, inclusive, and just future for all, now and for generations to come.

Strategic Goals 2026–2030

Over the next five years, CDBIO will continue to be firmly guided by its commitment to human rights and ethical responsibility in an increasingly complex biomedical landscape. Our four strategic goals — Safeguard, Adapt, Anticipate, and Engage — seek to uphold fundamental principles, respond thoughtfully to emerging challenges, prepare for future developments, and foster inclusive dialogue. These priorities will underpin our work as we continue to protect human rights and human dignity, and promote trust in the fields of biomedicine and health across Europe and beyond.

1. Safeguard — Upholding human rights and dignity in biomedicine and health

A core pillar of our work remains safeguarding human rights and human dignity in the fields of biomedicine and health, as well as strengthening the implementation of the principles laid down in the Oviedo Convention and its protocols. This includes promoting the effective adoption and application of existing legal instruments, guidance documents, and other tools, and contributing to the implementation of the European Court of Human Rights judgments at the national level. Supporting member States in embedding these standards into their legal and policy frameworks will continue to be a priority. By reinforcing the practical implementation of existing norms, we ensure that human rights are respected and upheld across diverse national contexts.

2. Adapt — Strengthening and applying human rights in new contexts

To remain effective in a rapidly evolving biomedical landscape, it is essential to revisit and, where appropriate, clarify, specify and further develop existing instruments, principles, and procedures. This process of re-examination ensures their continued relevance and applicability in light of scientific and technological developments, the evolution of practices, shifting societal values, and diverse cultural and legal contexts. In addressing the ethical and legal challenges raised by these developments, we are committed to ensuring that our standards remain robust, inclusive, and capable of responding to evolving contexts, while remaining firmly grounded in the core principles of human rights and human dignity.

3. Anticipate — Horizon scanning to anticipate future challenges

Looking ahead, we must remain responsive to the needs of member States and the pressing ethical and human rights challenges they are confronting. Horizon scanning will enable us to identify and assess emerging biomedical technologies and healthcare practices, and to provide timely guidance that informs public debate and supports anticipatory governance. In doing so, we aim to ensure that innovation proceeds in a way that respects human rights standards and ethical norms, while supporting member States in navigating complex and fast-moving developments in the fields of biomedicine and health.

4. Engage — Building strong, inclusive engagement

Tackling the ethical and human rights challenges in biomedicine and health requires deep and sustained engagement with a broad range of actors. Given the transnational and multidisciplinary nature of many biomedical issues, we will actively pursue synergies with other Council of Europe committees and international organisations active in the field. We will continue to integrate the perspectives of civil society, including young people across our activities, while strengthening dialogue and

collaboration with relevant publics and professional and ethics bodies. Such meaningful engagement and consultation will reinforce the legitimacy, inclusiveness, and impact of our work.

Safeguard

- **Objective 1: Strengthen the implementation of the Oviedo Convention and its protocols, ensuring that human rights and human dignity remain central to biomedical and healthcare practices**. This objective aims to reinforce the practical application of the Oviedo Convention and its protocols by promoting policies and practices that safeguard human rights and human dignity in all areas of biomedicine and healthcare. Specific actions in this area could include: conducting national reviews of member States' laws for alignment with the Oviedo Convention and its protocols; assessing the reasons why certain instruments have/ have not been adopted, with the aim of pursuing universal ratification of the Convention and protocols through outreach; provision of technical assistance, capacity building programme and encouraging increasing accession by non-member States; and contributing to the execution of relevant case law of the European Court of Human Rights at the national level.

- **Objective 2: Uphold and articulate a human right centred approach to patient rights in accordance with the Oviedo Convention through a patient-centred and safety-first healthcare paradigm.** This objective aims to ensure that patient rights, as enshrined in the Oviedo Convention, are not only formally acknowledged but actively integrated into the fabric of healthcare systems. Specific actions in this area could include: publishing a guide articulating patient rights based on the Oviedo Convention; issuing ethical recommendations for the integration of patient safety principles into relevant legal and clinical frameworks; and developing training programs for healthcare professionals on patient rights, in accordance with the Oviedo Convention.

- **Objective 3: Ensure equitable access to healthcare.** This objective aims to promote equitable access to healthcare in response to increasing challenges confronting health care systems in Europe, including rising costs of medical technologies and treatments, demographic shifts, decreased health system resilience following the COVID-19 pandemic, and geographical disparities in healthcare delivery. Specific actions here could include work relating to addressing structural inequalities and barriers to access for older persons, migrants, persons with disabilities, LGBTQI+ individuals, and those with low socio-economic status; examining the impact of social determinants of health on access and outcomes; and identifying and addressing age and gender bias in biomedical research and clinical practice.

Adapt

- **Objective 1: Re-examine and update existing legal instruments and guidance to ensure continued relevance.** A number of legal instruments and guidance documents issued by CDBIO may require re-examination in light of new developments, including digital transformation and innovative treatments and technologies in healthcare. Specific actions under this objective could include re-examining the following instruments or guidance documents: the Guide for research ethics committee members (2010); the Additional Protocol concerning Biomedical Research (2005); Recommendation CM/Rec(2016)6 on research on biological materials of human origin; the Additional Protocol concerning Genetic Testing for Health Purposes (2006); and the Guide on the decision-making process regarding medical treatment in end-of-life situations (2014).

- **Objective 2: Consider the evolving understanding of rights.** This objective concerns remaining attentive to rapid societal and technological changes that lead to significant shifts in the understanding of existing rights and the development of new legal provisions in the contexts of biomedicine and health. Specific actions under this objective could include: adapting, reinterpreting and specifying existing human rights to address emerging challenges posed by neurotechnologies and AI; examining the balance between individual rights and collective interests, particularly in the context of public health; and exploring the ethical and legal implications of the “One Health” approach, which seeks to sustainably balance and optimise the health of people, animals, and ecosystems.

- **Objective 3: Safeguard individuals’ privacy, autonomy, and integrity in the context of digital health technologies and data-driven healthcare**. This objective aims to explore how digitalisation is reshaping patient autonomy, data control, accountability, and the interpersonal dimensions of the care relationship, and to formulate updated ethical guidance. Specific actions here could include: education and training materials (e.g., on the humanisation of care in the digital age) to help health professionals adapt to the evolving digital landscape while preserving core values; practical tools (e.g., health data protection tips, thematic infographics) to strengthen privacy protections in digital health systems; and guidance on supporting individual decision-making and upholding informed consent in the digital age, and on the ethical use of secondary data and synthetic data.

Anticipate

- **Objective 1: Anticipate and prepare for the human rights and ethical implications of rapid developments in technology and society**. This objective involves regularly scanning the horizon for new technological advancements and societal shifts that may pose challenges to human rights and human dignity in biomedicine and health. Specific actions in this area could include: developing foresight tools to assess potential human rights impacts of biomedical innovations, including synthetic biology and the convergence of AI and genomics; monitoring global trends and coordinating with international partners to support anticipatory regulatory frameworks that align with human rights standards; organising cross-sectoral expert panels to regularly review and discuss ethical risks and governance gaps in new technologies; commissioning targeted research on the ethical, legal, and social implications of emerging biomedical technologies; examining the issue of dual use, and engaging in dialogue with technology developers to raise awareness of human rights and ethical concerns, and to encourage the integration of ethical considerations into the design and development process.

- **Objective 2: Equip Research Ethics Committees for emerging biomedical technologies.** This objective seeks to enhance the knowledge and skills of Research Ethics Committees (RECs) to ensure robust ethical oversight of rapidly advancing biomedical technologies, including AI, gene editing, stem cell research, and neurotechnologies. Specific actions here could include: updating the Guide for research ethics committee members (2010); assessing the current capabilities of RECs and identify resource needs to improve consistency and quality of ethical review processes; establishing a collaborative platform for RECs to share case experiences, best practices, and legal-ethical insights across member States; and organising joint workshops bringing together REC members, researchers working with emerging technologies, and technology developers to foster mutual understanding and dialogue on ethical considerations.

Engage

- **Objective 1: Ensure inclusive and diverse stakeholder engagement.** This objective aims to meaningfully engage with a wide range of stakeholders, including relevant publics, civil society organisations, patient organisations, youth representatives, and professional and ethics bodies, to ensure the Committee's work is inclusive, diverse, relevant, and visible. Specific actions under this objective could include: increasing the number of organisations with observer status; conducting a formal stakeholder mapping exercise; developing a dissemination plan for CDBIO outputs at the national level; mainstreaming youth perspective into the activities of the CDBIO; establishing mechanisms to reach and include the voices of more marginalised groups; and engaging with national delegations to identify priority issues and respond to concrete bioethical challenges in their contexts (e.g., national action plans).

- **Objective 2: Foster synergies within the Council of Europe and strengthen effective collaboration and engagement with international organisations.** This objective seeks to enhance collaboration and streamline activities related to human rights and biomedicine across the various bodies and committees of the Council of Europe, and to actively promote cooperation with international organisations and bodies concerned with human rights and bioethics. Specific actions under this objective could include: strengthening working relationships and methodologies with other Council of Europe committees and bodies; ensuring representation through consultation and physical presence at international meetings; and organising joint meetings or issuing joint statements with other international organisations on emerging global bioethical issues, such as those arising from developments in medically assisted reproduction and end-of-life decision-making.

- **Objective 3: Promote public debate and awareness on bioethical issues.** In accordance with Article 28 of the Oviedo Convention, this objective aims to facilitate and encourage public discussion on the human rights and ethical implications raised by developments in the fields of biomedicine and health. Specific actions under this objective could include: developing tools to enhance health literacy; producing accessible summary materials such as infographics and short videos; and expanding the Council of Europe's HELP (Human Rights Education for Legal Professionals) course.