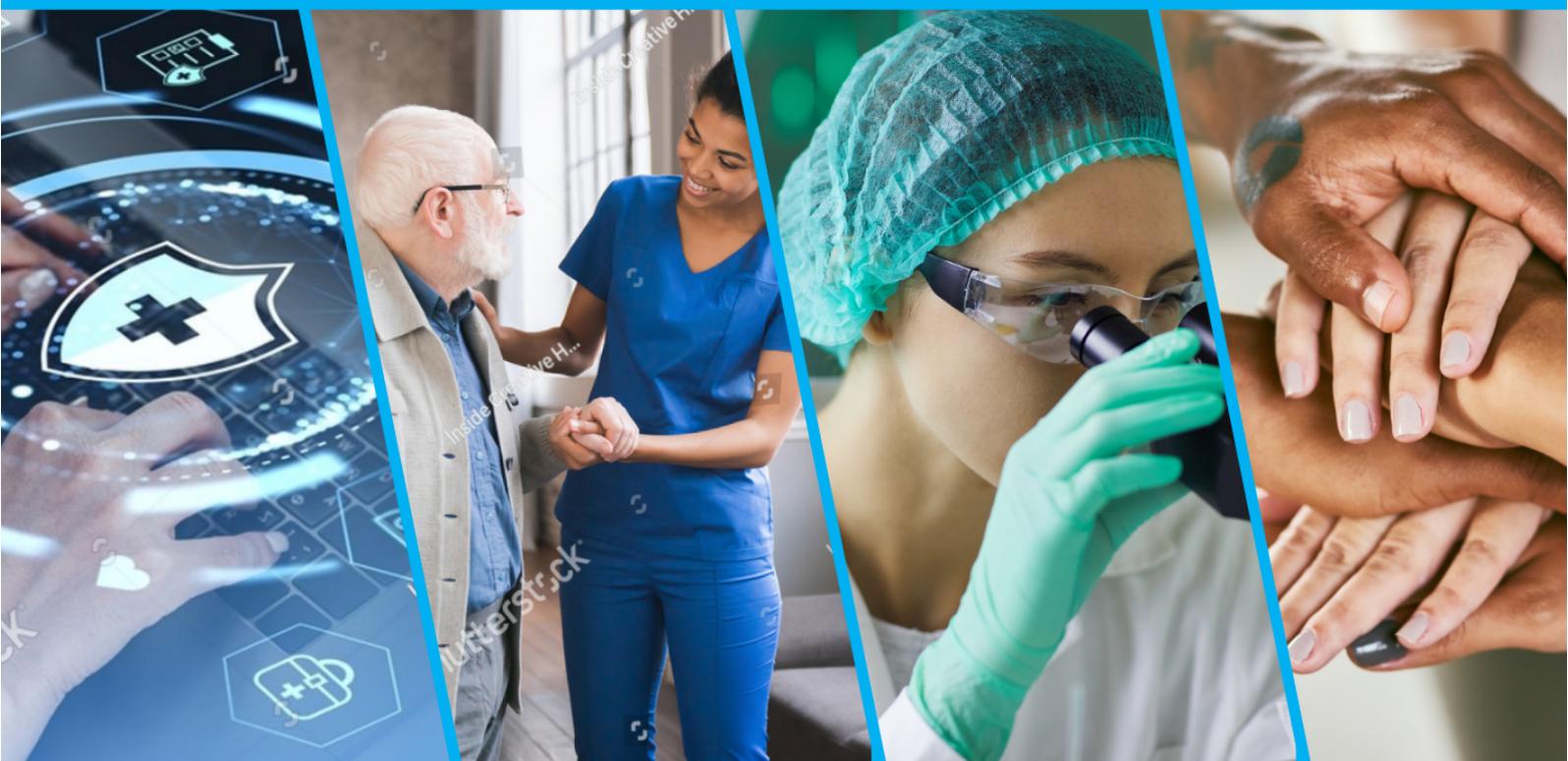


STRATEGIC PLAN FOR HUMAN RIGHTS IN BIOMEDICINE AND HEALTH

KEEPING HUMAN RIGHTS AT THE CORE OF BIOMEDICINE AND HEALTH (2026-2030)



Steering Committee for Human Rights
in the fields of Biomedicine
and Health (CDBIO)

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

STRATEGIC PLAN
FOR HUMAN RIGHTS
IN BIOMEDICINE AND HEALTH
Keeping Human Rights at the Core
of Biomedicine and Health (2026-2030)

Steering Committee for Human Rights
in the fields of Biomedicine
and Health (CDBIO)

December 2025

French version :
*Plan stratégique pour les droits humains dans
les domaines de la biomédecine et de la santé*

*The opinions expressed in this work are the
responsibility of the author(s) and do not
necessarily reflect the official
policy of the Council of Europe.*

The reproduction of extracts (up to 500 words) is authorised, except for commercial purposes, as long as the integrity of the text is preserved, the excerpt is not used out of context, does not provide incomplete information or does not otherwise mislead the reader as to the nature, scope or content of the text. The source text must always be acknowledged as follows “© Council of Europe, year of the publication”. All other requests concerning the reproduction/translation of all or part of this document should be addressed to the Publications and Visual Identity Division (DPIV), Council of Europe (F-67075 Strasbourg Cedex or publishing@coe.int)

All other correspondence concerning this document should be addressed to the Directorate General of Human Rights and Rule of Law. F-67075 Strasbourg Cedex, France Email: DGI-CDBIO@coe.int

Cover photo: Shutterstock

This publication has not been copy-edited by the SPDP Editorial Unit to correct typographical and grammatical errors.

© Council of Europe, December 2025

CONTENTS

PREAMBLE	4
Mission Statement	5
STRATEGIC GOALS 2026–2030	6
SAFEGUARD - UPHOLDING HUMAN RIGHTS AND DIGNITY IN BIOMEDICINE AND HEALTH	8
Objective 1: Strengthen the implementation of the Oviedo Convention and its Additional Protocols, ensuring that human rights and human dignity remain central to biomedical and healthcare practices	8
Objective 2: Foster a human rights-centred approach to healthcare	
Objective 3: Advance equitable access to healthcare as a core human right	9
ADAPT - STRENGTHENING AND APPLYING HUMAN RIGHTS IN NEW CONTEXTS	11
Objective 4: Re-examine existing legal instruments and guidance to assess their continued relevance, coherence, and practical application in evolving biomedical	11
Objective 5: Explore the evolving scope and interpretation of human rights in biomedicine	12
Objective 6: Embed the principles of autonomy, privacy, and integrity within digital health governance and practice	13
ANTICIPATE - HORIZON SCANNING TO ANTICIPATE FUTURE CHALLENGES	15
Objective 7: Anticipate and respond to the human rights and ethical implications of rapid technological and societal developments	15
ENGAGE - BUILDING STRONG, INCLUSIVE ENGAGEMENT	17
Objective 8: Ensure inclusive and diverse stakeholder engagement	17
Objective 9: Strengthen synergies and cooperation on bioethical issues within the CoE and internationally, and foster public debate on developments in biomedicine and health	17
DEVELOPMENT OF THE STRATEGIC PLAN	19
IMPLEMENTATION AND MONITORING	20

PREAMBLE

Scientific and technological advances are transforming the landscape of biomedicine and healthcare. Developments in fields such as artificial intelligence (AI), genomics, neurotechnology, and synthetic biology offer unprecedented opportunities to enhance prevention, diagnosis, and treatment, and to promote more personalised, efficient, and equitable healthcare. These innovations also bring new ethical, legal, and societal questions, underscoring the need for responsive and trustworthy governance frameworks that evolve in step with technological change, uphold human rights, and ensure fair access to the benefits of progress.

At the same time, inequities in access to health and health outcomes persist within and across countries, compounded by demographic shifts, environmental challenges, and potentially the digital transformation of health systems. The COVID-19 pandemic exposed systemic vulnerabilities, reinforcing the critical importance of building resilient, equitable, and inclusive health systems.

The growing spread of mis- and dis-information, amplified by social media and AI-generated content, threatens public health responses and erodes trust in evidence-based policymaking. More broadly, democratic values, human rights, and confidence in institutions and expertise face increasing strain, raising concerns about the potential erosion of core ethical values that define relations between individuals and institutions.

Given these complex dynamics, bioethics must not only address current challenges, but also play a proactive role, offering strategic foresight and shaping policy debates to address uncertain futures.

Building on the achievements and lessons of the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020–2025), the current Strategic Plan is firmly anchored in the Convention on Human Rights and Biomedicine (Oviedo Convention), the only legally binding international instrument in this domain. It reaffirms and advances the Convention's foundational values of human dignity, integrity, autonomy, equity, privacy, and non-discrimination, ensuring their continued relevance and effective application in light of scientific, medical, and technological developments.

Aligned with the broader commitments of the Council of Europe (CoE), the Strategic Plan reflects the priorities of the 2024 Reykjavík Declaration; upholding equality and non-discrimination, protecting social rights including the right to the protection of health under the European Social Charter, ensuring that innovation supports human dignity, inclusion, and democratic values, and emphasising the importance of incorporating youth voices in policy and legal framework deliberations. It also recognises the need to build resilience to disinformation and other threats to democratic integrity, as outlined in the New Democratic Pact for Europe. The Plan further draws on the CoE Gender Equality Strategy 2024–2029, promoting an intersectional approach that ensures equality and protection for all individuals.

A separate implementation plan outlining specific actions, key performance indicators, and timelines will be developed to operationalise and give effect to this Strategic Plan.

This CDBIO Strategic Plan for Human Rights in Biomedicine and Health (2026–2030): *Keeping Human Rights at the Core of Biomedicine and Health* aims to:

- ▶ Ensure the effective implementation and protection of human rights and human dignity in biomedicine and healthcare;
- ▶ Re-examine and strengthen human rights protections where current frameworks require adaptation to new scientific, technological, and societal developments;
- ▶ Provide timely ethical and legal guidance to anticipate and respond to emerging biomedical technologies and healthcare innovations;
- ▶ Promote strong, inclusive engagement by integrating perspectives from civil society, with particular emphasis on youth participation, and strengthening dialogue between the public, professionals, and ethics and human rights bodies; and
- ▶ Support cooperation and capacity-building at the member State level and encourage collaboration with international partners to address shared ethical and human rights challenges.

In pursuing these ambitions, and leveraging the CoE's distinct human rights mandate, the CDBIO will foster robust partnerships both within and beyond the CoE. This collaborative approach will avoid duplication and maximise impact. This Strategic Plan seeks to ensure that ethics and human rights remain central to policy and practice, as the foundation of responsible governance, innovation, and care.

Mission Statement

The Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) is committed to protecting and promoting human dignity and fundamental rights and freedoms in the fields of biomedicine and health amid ongoing scientific and technological developments. Grounded in a human rights-based approach, CDBIO works to develop ethical guidance, set standards, and support their effective implementation across Member States. The Committee seeks to safeguard individual autonomy while fostering equity and solidarity, both within and across generations.

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 – will ensure that we uphold fundamental principles, respond decisively to emerging challenges, prepare for future developments, and foster inclusive dialogue in the field of biomedicine and health. These goals are interdependent and mutually reinforcing, working together to create a coherent and forward-looking approach that strengthens the protection of human rights in health and biomedicine.

1. SAFEGUARD

UPHOLDING HUMAN RIGHTS AND DIGNITY IN BIOMEDICINE AND HEALTH

A core pillar of the work of the Committee remains safeguarding human rights and human dignity in the fields of biomedicine and health, as well as facilitating the implementation of the principles laid down in the Oviedo Convention and its Additional Protocols. This includes promoting and disseminating the relevant legal instruments, guidance documents, and other tools, taking into account the relevant case law of the European Court of Human Rights. Supporting Member States, notably with practical guidance and others tools, to strengthen the implementation of their obligations and in devising policy frameworks in their national context will continue to be a priority.

2. ADAPT

STRENGTHENING AND APPLYING HUMAN RIGHTS IN A RAPIDLY EVOLVING BIOMEDICAL LANDSCAPE

To remain effective in a rapidly evolving biomedical landscape, it is essential to revisit and, where appropriate, clarify and further develop existing instruments, principles, and procedures in the field of biomedicine and health. 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, diverse cultural and legal contexts as well as the impacts that climate change will have on public health and health systems. In addressing the ethical and legal challenges raised by these developments, we are committed to ensuring that our standards continue to be 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 BIOETHICAL 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

Addressing 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 and considering that the CoE operates within a dynamic global institutional landscape, we will place a strong emphasis on building and nurturing partnerships with other CoE committees, international organisations, and networks working in this field. We will continue to integrate the perspectives of young people and wider civil society across our activities, while strengthening dialogue and collaboration with relevant publics and professional and ethics bodies. Such meaningful engagement and inclusiveness will reinforce the legitimacy and impact of the work of the Committee.

SAFEGUARD

UPHOLDING HUMAN RIGHTS AND DIGNITY IN BIOMEDICINE AND HEALTH

Objective 1: Strengthen the implementation of the Oviedo Convention and its Additional Protocols, ensuring that human rights and human dignity remain central to biomedical and healthcare practices.

Almost 30 years after its adoption, the Oviedo Convention remains the only international legally binding instrument exclusively dedicated to protecting and promoting human rights and human dignity in biomedicine and health. Amidst ongoing scientific and technological developments, the Convention and its Additional Protocols continue to serve as a foundational legal and ethical framework for addressing emerging challenges.

- 1.1. Conduct a review of the ratification and national implementation of the Oviedo Convention and its Additional Protocols to mark its 30th anniversary and assess their continued impact on biomedical policy. The 30th anniversary in 2027 will mark a key moment to celebrate the Convention's achievements. It will present a timely opportunity – through a dedicated conference and other activities – to reflect on the role of the Convention and its Additional Protocols in guiding biomedical policy, to assess both the extent of their ratification across Member States and the implementation of their principles at national level, as well as to encourage ratification by Member States that have not yet done so. Beyond this, the review represents an opportunity to evaluate how the CDBIO's work can be responsive to national contexts, and how it can be strengthened to meet emerging needs, while promoting awareness of the value of the Convention in Member States that have not yet ratified it. By aligning the Committee's future activities with the practical concerns of Member States, the review will help ensure the continued relevance, legitimacy, and impact of the Convention and the work of the CDBIO.
- 1.2. Increase visibility and dissemination of CDBIO outputs across Member States. The 30th anniversary of the Oviedo Convention offers a strategic opportunity to strengthen awareness of the CDBIO's work and ensure its outputs are effectively utilised at national level. To support implementation, it is essential that the Committee's standards, guidance, and tools are widely accessible, clearly communicated, and tailored to the needs of diverse national stakeholders, including policymakers, professional bodies, patient organisations, and ethics committees. A targeted communication and dissemination strategy, supported also through the CoE Human Rights Education for Legal Professionals (HELP) Programme, will build trust, foster ownership, and help ensure that CDBIO's outputs inform policy and practice across Member States.

Objective 2: Foster a human rights-centred approach to healthcare.

A human rights-centred healthcare culture recognises patients as partners with rights and responsibilities, ensuring human dignity, fairness, equality, and respect for the person across all aspects of care. Rooted in the Oviedo Convention, this approach ensures that patients have a voice in their care and that their rights are actively protected. It means empowering patients through access to information and ensuring that healthcare decisions are justified, proportionate, and informed by patients' rights and wishes. This approach promotes professional accountability, patient safety, and truly person-centred care, strengthening trust and the overall quality of healthcare across Member States.

- 2.1. Develop a Charter of Patient Rights based on the Oviedo Convention. To further uphold and articulate patient rights within a patient-centred and safety-first healthcare paradigm, the CDBIO will develop a comprehensive model Charter of Patient Rights grounded in the principles of the Oviedo Convention and taking into account other international documents on the subject. The Charter will serve as a practical tool to support national implementation, raise public awareness, and promote rights-based, participatory healthcare. It can also serve as a reference for Member States seeking to update or strengthen their own patient rights frameworks in alignment with international human rights standards.
- 2.2 Strengthen health literacy to empower people to be informed, active participants in their healthcare. As health systems become more complex with digitalisation, new technologies, and diverse care settings, individuals must be equipped to critically interrogate information, understand their rights and options, and participate actively in decisions affecting their health. Strengthening health literacy gives individuals the skills, confidence, and understanding to engage meaningfully with health information, distinguish reliable sources from mis- and disinformation, and make informed decisions about their care. It can have important impacts on health and more generally on trust in the healthcare system. Building on the *Council of Europe's Guide to Health Literacy* and the report *Health Literacy Is a Human Rights Concern*, the CDBIO will develop targeted initiatives that respond to the needs of diverse populations and support a patient-centred, rights-based approach to healthcare.

Objective 3: Advance equitable access to healthcare as a core human right.

European health systems face growing pressures from demographic change and post-pandemic strain to rising costs, workforce shortages, and regional disparities, all of which implies a risk of deepening inequities in access to care. Climate-related risks further threaten to widen these gaps. Grounded in Article 3 of the Oviedo Convention and articulated in [CM/Rec\(2023\)1](#), this objective seeks to translate the right to equitable access to healthcare into practice. It aims to identify and address structural and systemic barriers, promote fairness in health resource allocation, and ensure that policies and innovations are assessed through an equity and human rights lens.

- 3.1. Promote inclusive, equitable, and person-centred health and social care for older persons. Older persons continue to face significant barriers to accessing inclusive health and social care that fully respect their rights, values, and wishes. Ageism, fragmented care systems, and limited opportunities to participate in decisions affecting their care can undermine their autonomy, dignity, and overall well-being. Promoting inclusive, equitable, and person-centred health and social care therefore requires recognising older persons as rights-holders, ensuring non-discrimination and equitable access to services, and fostering integrated approaches that support physical, mental, and social well-being while respecting individual preferences and needs.
- 3.2. Identify barriers and good practices to ensure equitable access to health and social care for migrants. Migrants often face significant barriers to accessing healthcare, including legal, administrative, financial, linguistic, and cultural obstacles, resulting in persistent health inequities and poorer health outcomes. These challenges are especially acute for undocumented individuals, who may avoid or delay seeking care due to fear, stigma, or lack of information. As part of the CoE's broader commitment to safeguarding the rights of migrants, the CDBIO can play a key role in promoting equitable access to healthcare for migrants through identifying structural barriers and compile good practices that support inclusive, culturally sensitive, and non-discriminatory healthcare policies across Member States.

ADAPT

STRENGTHENING AND APPLYING HUMAN RIGHTS IN NEW CONTEXTS

Objective 4: Re-examine existing legal instruments and guidance to assess their continued relevance, coherence, and practical application in evolving biomedical

A number of legal instruments and guidance documents issued by the CDBIO require re-examination in light of new developments, including digital transformation, innovative treatments and technologies, the evolution of established practices in the field of biomedicine, and the evolving organisation and delivery of healthcare. The aim of re-examination is to ensure that the instruments remain robust, relevant, and practically useful in addressing contemporary challenges. The re-examination process will be grounded in dialogue with Member States and relevant stakeholders and may include legal, ethical, and policy analysis. It will serve as a foundation for informed decision-making about whether any additional action, such as the development of supplementary guidance or proposals for revision, may be appropriate in the future.

- 4.1. Re-examine the Additional Protocol concerning Biomedical Research to assess its continued relevance and robustness in light of evolving research practices. Since the opening for signature of the [Additional Protocol concerning Biomedical Research](#) in 2005, the landscape of biomedical research has significantly changed. Biomedical research is increasingly shaped by developments such as big data, genomics, AI, and digital platforms. In addition, research models increasingly depend on continuous data repurposing, remote digital participation, and the integration of research into routine healthcare. These developments introduce novel risks and ethical challenges that test the adequacy of existing governance frameworks. Given these shifts, the CDBIO will initiate a re-examination of the Protocol to assess whether its provisions effectively address the ethical and legal implications of evolving research practices and provides sufficient safeguards for participant rights.
- 4.2. Re-examine the Recommendation CM/Rec(2016)6 in light of evolving research practices. Similarly, the landscape of research involving biological materials of human origin has evolved considerably since the adoption of [Recommendation CM/Rec\(2016\)6](#). Key developments include the increasing “datafication” of biological materials, such as the generation and analysis of genomic, proteomic, and metabolomic data, the use of artificial intelligence (AI) to transform biological samples into large datasets for analysis, the integration of biobank infrastructures, and the further expansion of long-term research that serves multiple purposes. These developments raise complex legal, ethical and governance challenges concerning consent for secondary use, data protection, transparency, long-term storage, and appropriate oversight.

- 4.3. Re-examine the Additional Protocol concerning Genetic Testing for Health Purposes to assess its continued relevance, clarity, and applicability in light of developments in genetic science and clinical practice. Since the opening for signature of the [Additional Protocol concerning Genetic Testing for Health Purposes](#), in 2008, the field of genetics and genomics has undergone profound changes. Advances in next-generation sequencing have significantly increased both the volume and variety of genetic information that can be analysed. At the same time, the growing use of polygenic risk scores and AI-driven genomic interpretation tools is reshaping how genetic data are analysed and applied. These developments challenge traditional frameworks of clinical oversight, informed consent, and genetic counselling, and raise complex questions about clinical utility, interpretability, access to data (in particular relating to data from children), and the psychological impact of results. The objective of the re-examination is to evaluate whether the Protocol continues to provide clear, robust, and relevant guidance for current and emerging genetic and genomic testing practices, and to identify any areas where clarification or further guidance may be required.

Objective 5: Explore the evolving scope and interpretation of human rights in biomedicine.

Human rights frameworks remain the cornerstone for protecting dignity, autonomy, and integrity in biomedicine and health. The European Convention on Human Rights is a living instrument, continually reinterpreted through the judgments of the European Court of Human Rights to ensure that fundamental rights remain relevant and effective in changing social and technological contexts. The principles underlined in the CDBIO [Statement on human rights considerations relevant to the COVID-19 pandemic \(2020\)](#), together with those laid down in the Oviedo Convention, reflect and reinforce the fundamental and indissociable link between human rights, responsibility, and solidarity. Building on this foundation, the CDBIO will examine how evolving interpretations of human rights can guide ethical and legal governance in biomedicine, where individual and collective interests increasingly intersect. The Committee will consider how the existing human rights architecture can ensure the protection of human rights remains coherent, inclusive, and responsive to contemporary and future challenges.

- 5.1. Examine how existing human rights frameworks can guide the governance of emerging and converging technologies. Building on the CDBIO's previous work on neurotechnology and artificial intelligence in healthcare, the question as to whether and how existing human rights frameworks can effectively guide the governance of rapidly advancing technologies such as neurotechnology, synthetic biology, human stem cells-based embryo models, artificial intelligence, and gene editing, will be examined. The analysis will focus on how established human rights principles, as articulated in the European Convention on Human Rights, the Oviedo Convention, and related instruments, can be applied to address new ethical and legal challenges arising from these fields.
- 5.2. Explore the relationship between individual rights, collective responsibilities, and solidarity in safeguarding public health. The objective is to examine how human rights frameworks can accommodate collective responsibilities as well as

individual rights in the protection of public health within an increasingly interconnected human, animal, and environmental context. Building on the principles of the Oviedo Convention, it will explore how shared responsibility and solidarity can strengthen equitable, human rights-based responses to global health challenges, including pandemics and the impacts of climate change. The work will also consider how these frameworks can evolve or be implemented to uphold the rights of future generations and promote resilient, sustainable systems of health protection grounded in human dignity and responsibility.

Objective 6: Embed the principles of autonomy, privacy, and integrity within digital health governance and practice.

As healthcare systems increasingly rely on digital platforms – from electronic health records to telemedicine and AI-driven diagnostics – it is essential to examine how the core principles of the Oviedo Convention, including autonomy, privacy and integrity, can be upheld and adapted in a digitally transformed health environment. This objective also extends to the broader digital ecosystem, including the role of social media in shaping health outcomes. Particular attention will be paid to the impact of social media use and AI applications on the health and well-being of young people, exploring how their rights can be better protected in digital contexts. Through this work, the CDBIO will explore how ethical and human rights standards can guide the development of responsible digital environments and inform future governance approaches.

- 6.1. Adapt informed consent models to enable the effective exercise of autonomy in digitally mediated healthcare. In healthcare systems increasingly shaped by digital platforms, continuous data flows, and algorithmic decision-making, the traditional model of informed consent faces new pressures. The widespread collection, reuse, and processing of personal health data, often without the knowledge or explicit consent of patients from whom the data is collected, raises important questions about how to maintain individual autonomy, transparency, and accountability. The CDBIO aims to explore how the principle of informed consent, which is essential for ensuring patients autonomy and protecting their privacy, should be adapted to the digitalisation of medicine in order to fulfil its ethical and legal mission.
- 6.2. Examine the ethical and human rights implications of social media use and of AI applications on young people's health and well-being, and explore standards for responsible digital environments. Digital platforms have become central to how young people connect, learn, and form their identities. At the same time, constant exposure to targeted advertising, misinformation, and harmful content can undermine their mental and physical health. The growing use of AI-driven systems in these environments intensifies these concerns. To address these challenges, the CDBIO will identify standards and governance approaches that support healthier and safer digital environments, placing the protection, well-being, and rights of young people at the heart of digital innovation.

- 6.3. Strengthen the practical implementation of human rights in AI-enabled healthcare. Building on the findings of the CDBIO [Report on the Application of Artificial Intelligence in Healthcare and its Impact on the 'Patient-Doctor' Relationship](#), this action will focus on closing the gap between principle and practice to ensure that human oversight and human rights remain central to AI-enabled healthcare. It will examine how key principles including autonomy, privacy, integrity, non-discrimination, and accountability can be effectively upheld as AI systems are integrated into clinical care and health governance. In this context, tools such as the HUDERIA methodology could offer valuable avenues for assessing human rights, ethical, and social risks, and for supporting Member States in translating principles into practice within AI-driven healthcare systems.

ANTICIPATE

HORIZON SCANNING TO ANTICIPATE FUTURE CHALLENGES

Objective 7: Anticipate and respond to the human rights and ethical implications of rapid technological and societal developments.

This objective seeks to ensure early identification of technological and societal developments that may challenge existing ethical and human rights standards in biomedicine, and to build the capacity to respond to them in an agile and rights-respecting manner. Anticipation involves systematic horizon scanning to detect emerging and converging technologies, evolving research models, and broader societal trends that may have implications for human dignity and individual rights. Response, including ethical review, relies on Research Ethics Committees (RECs) and other governance bodies to engage with these developments in practice. However, by their nature, emerging and converging technologies are characterised by uncertainty and complexity that may challenge the current capacities of many RECs. Strengthening anticipatory and responsive capacity may therefore require the establishment of specialised RECs, the adaptation of existing structures, or the provision of additional resources, expertise, and training to enable committees to discharge their functions effectively and uphold ethical and human rights standards in a rapidly evolving landscape.

- 7.1. Utilise foresight tools to assess potential human rights impacts of new developments in biomedicine and health. Ensuring that biomedical innovations are, from the outset and throughout their entire lifecycle, oriented towards the protection and promotion of human rights requires the adoption of foresight-based approaches and embedding a human-rights-by-design perspective. The CDBIO will utilise foresight tools to identify and assess the ethical, legal, and societal implications of emerging developments in biomedicine and health. This will include commissioning or supporting targeted foresight studies in key areas of innovation. These studies should engage ethical and legal experts, technology developers, and other key actors at the forefront of innovation to foster a well-informed understanding of emerging opportunities and risks. In parallel, the CDBIO will work to build the capacity of national bodies by developing guidance on anticipatory governance, promoting regulatory preparedness, and facilitating knowledge exchange across Member States.
- 7.2. Develop anticipatory governance tools for genomics and population health to protect autonomy and equitable access. The convergence of genomics, biomarkers, wearables, big data, and AI ushers in an era of highly personalised prediction, making it possible to identify population health trajectories and predispositions. This power offers opportunities for stratifying individuals in different risk groups to offer early and targeted interventions. However, this raises ethical concerns about autonomy and the right to an open future. For individuals, knowing detailed future health risks may constrain life choices, educational paths, or

employment opportunities. More broadly, the use of predictive models by institutions could lead to new forms of discrimination or social stratification based on biological data. It potentially creates new duties for clinicians and health services to identify secondary findings and recommend interventions.

- 7.3. Provide guidance and support to strengthen Research Ethics Committees in reviewing emerging biomedical technologies. Emerging biomedical technologies such as AI, gene editing, mirror biology, genomics, stem cells-based models, and neurotechnologies are transforming the landscape of health research, introducing complex ethical questions and technical uncertainties. These developments pose significant challenges for RECs, which are responsible for safeguarding the rights, dignity, and well-being of research participants. To address gaps in expertise, consistency, and resources, the CDBIO will develop targeted guidance and capacity-building support to help RECs effectively evaluate the ethical dimensions of research involving new and evolving technologies.

ENGAGE

BUILDING STRONG, INCLUSIVE ENGAGEMENT

Objective 8: 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, representatives of older persons, the private sector, and professional and ethics bodies, to ensure that the Committee's work is diverse, inclusive, relevant, and visible, and complements the work done by other bodies.

8.1 Review observer status and engagement with non-governmental organisations (NGOs). In light of recent experiences and the changing landscape of stakeholder engagement, it is timely to review current observer status rules and practices within the CDBIO, including identifying and evaluating criteria for participation. This aims to enhance the meaningful engagement of civil society and NGOs by exploring how best to structure and formalise their involvement in the Committee's work.

8.2 Make CDBIO outputs accessible and relevant to diverse audiences. To maximise the impact of its work, it is important that the CDBIO develops dissemination strategies that respond to the specific needs, knowledge levels, and contexts of its diverse audiences. This involves adopting more tailored approaches to content development and communication, including creating materials that are accessible, relevant, and user-friendly.

8.3 Integrate youth and gender perspectives across CDBIO's activities and outputs. CDBIO will actively mainstream the perspectives of young people and apply a gender lens across all its activities and outputs. This will include incorporating youth representatives and gender expertise into relevant working groups, consultation processes, and public engagement initiatives, as well as ensuring that strategic guidance and ethical standards reflect the diverse needs, experiences, and rights of all individuals. This commitment supports the Council of Europe's Gender Equality Strategy and Youth Sector Priorities, reinforcing the principles of inclusion, intersectionality, and participatory governance in the bioethical field.

Objective 9: Strengthen synergies and cooperation on bioethical issues within the CoE and internationally, and foster public debate on developments in biomedicine and health.

Building on the effective mechanisms established under the previous Strategic Action Plan, this objective seeks to reinforce coordination across the CoE and enhance collaboration with other international organisations and bodies concerned with human rights and bioethics, while supporting Member States in promoting inclusive and informed public dialogue on bioethical issues. Given the growing number of international initiatives addressing bioethical matters, it is essential for the CDBIO to focus on its core strength – advancing human rights in

biomedicine and health – while ensuring complementarity and avoiding duplication of efforts. Within this framework, the CDBIO will continue to build strategic partnerships to access external expertise where needed and to contribute its own expertise in relevant international fora. At the same time, and in accordance with Article 28 of the Oviedo Convention, the CDBIO will assist Member States in fostering transparent, participatory, and rights-based public debate on the ethical and human rights implications of developments in biomedicine and health.

9.1 Enhance the representation and participation of the CDBIO within the CoE and other relevant international organisations. To enhance its strategic influence and ensure complementarity with broader efforts in the fields of human rights, biomedicine, and health, the CDBIO will actively strengthen its engagement with relevant bodies both within the CoE and at the international level. This includes establishing regular dialogue with other committees and organisations to identify areas of synergy, share expertise, and avoid duplication of work. By participating in key meetings and contributing to cross-sector initiatives, the CDBIO will ensure that its bioethical perspective is well integrated into wider policy discussions, while promoting the visibility and relevance of its work across institutional settings.

9.2 Support and strengthen the capacity of Member States to facilitate inclusive public debate and consultation on bioethical issues. Building on its [Guide to Public Debate on Human Rights and Biomedicine](#), the CDBIO will support Member States in developing and implementing effective, inclusive, and rights-based public dialogues on bioethical issues. This includes offering capacity-building exercises, sharing good practices, and providing tools to support transparent, participatory engagement with the public, particularly where debate on sensitive or emerging bioethical matters is ongoing or anticipated.

DEVELOPMENT OF THE STRATEGIC PLAN

A drafting group chaired by Siobhán O’Sullivan (Ireland) was established in September 2023 to guide preparation of the new Strategic Plan for CDBIO. The drafting group was composed of Mark Bale (UK), Damaris Carnal (Switzerland), Tomáš Doležal (Czechia), Maria do Céu Patrão Neves (Portugal), Anne Forus (Norway), Signe Mežinska (Latvia), and Marjeta Tercelj (Slovenia). Jessy Jonsdottir (Iceland) from the Advisory Council on Youth was also a member of the drafting group, giving concrete expression to CDBIO’s commitment to integrating the youth voice into the Committee’s work. The Group was supported by Kristof Van Assche (Belgium), Consultant. In April 2024, CDBIO convened a horizon-scanning event in Paris with leading global experts to deliberate on emerging human rights challenges in biomedicine and health. Concurrently, a questionnaire was circulated to Member States, national ethics committees, human rights institutions, and international and intergovernmental bodies.

The [report](#) that followed synthesised expert contributions and questionnaire findings. Experts identified five key shifts necessary for bioethics scholarship moving forward: shifting focus from the individual to the collective-level issues; from local to global (requiring global justice concepts); from human health to human flourishing (addressing systemic barriers); from scholarship to impact; and from being a field to being a hub. Responses to the questionnaire highlighted gaps in existing ethical tools (e.g., in consent, research ethics, and preparedness in crises), pointed to innovative technologies where governance rooted in human rights was necessary (such as AI, genomics, and neurotechnology), and identified domains where CDBIO’s unique contribution could be most impactful. Building on initiatives undertaken during the 2020-2025 Strategic Action Plan, the CDBIO engaged in bilateral exchanges with other Council of Europe bodies to map areas of mutual interest and collaboration. The Strategic Plan is the culmination of this inclusive, evidence-based process, integrating horizon scanning, stakeholder input, expert foresight, and institutional dialogue into a coherent roadmap for action.

IMPLEMENTATION AND MONITORING

This CDBIO Strategic Plan for Human Rights in Biomedicine and Health will form the basis of the Strategic Implementation Plan: Keeping Human Rights at the Core of Biomedicine and Health (2026-2030), and for the outline the CDBIO's priorities for the period 2026–2030. It is intended as a high-level, forward-looking framework to guide the Committee's work, while allowing the flexibility to adapt to new developments, needs, and opportunities in the field of biomedicine and health. The Strategic Plan will be implemented over a five-year period through a dedicated implementation plan, which will set out detailed actions and timelines. Annual planning and review processes will allow for regular reflection and adjustment, ensuring the Plan remains relevant and responsive to the priorities of Member States

Oversight of the implementation of the Strategic Plan will rest with the Bureau of the CDBIO, which will regularly monitor progress and report to the Committee. The Plan builds on the achievements of the previous strategic cycle, while responding to the increasingly complex biomedical, ethical, and societal challenges facing Europe. Its success will depend on the active engagement of delegations, Member States, partners, and stakeholders across the CoE and beyond.

www.coe.int

The Council of Europe is the continent's leading human rights organisation. It comprises 46 member states, including all members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law. The European Court of Human Rights oversees the implementation of the Convention in the member states.