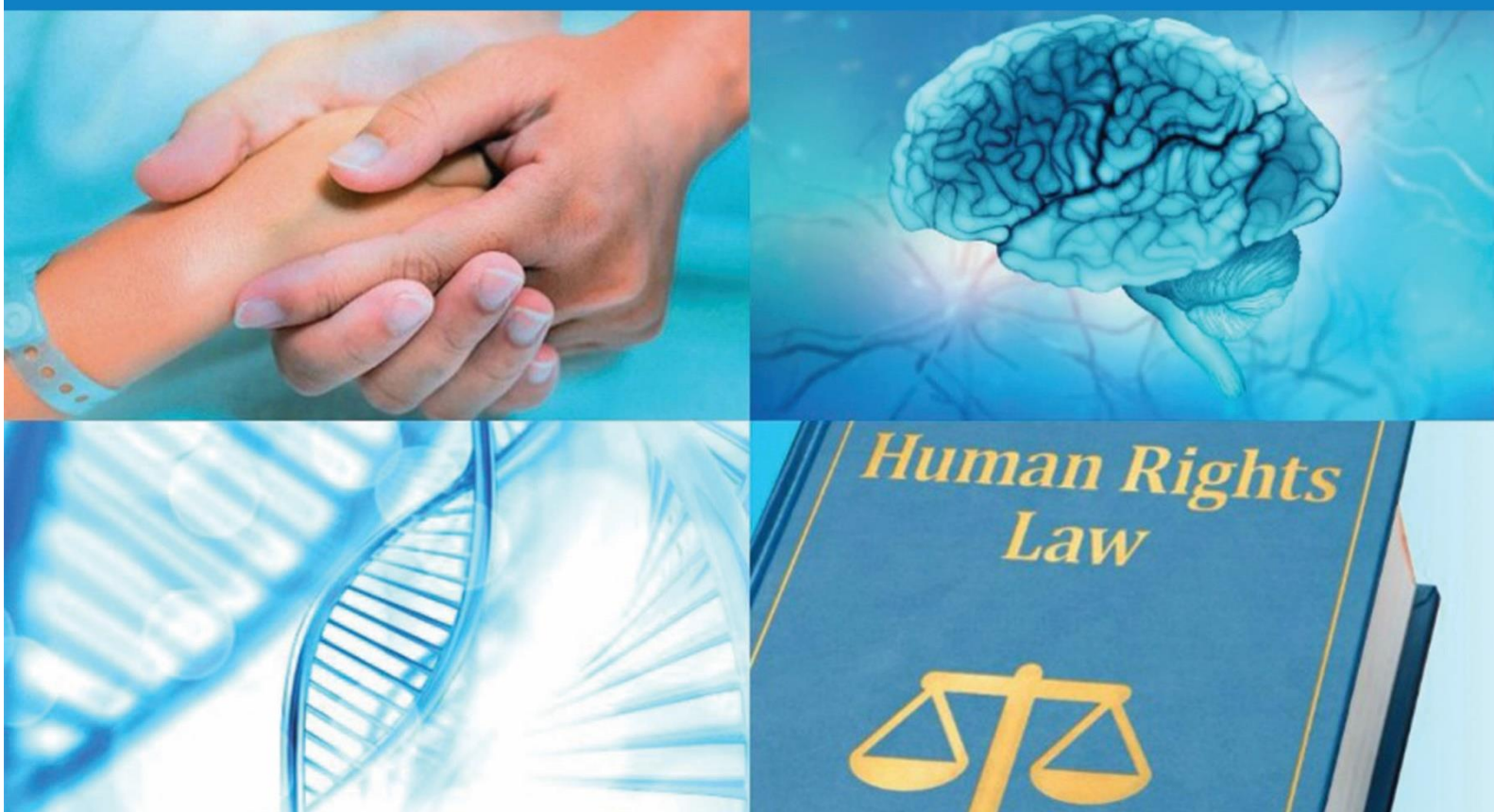


MID-TERM REPORT OF THE STRATEGIC ACTION PLAN ON HUMAN RIGHTS AND TECHNOLOGIES IN BIOMEDICINE (2020-2025)



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

I. RATIONAL AND OBJECTIVES OF THE STRATEGIC ACTION PLAN ON HUMAN RIGHTS AND TECHNOLOGIES IN BIOMEDICINE (2020 – 2025) (SAP)

The human rights challenges arising from the emergence of new technologies, as well as the evolution of established practices were underscored at the International Conference held in Strasbourg on 24 – 25 October 2017, on the occasion of the [20th anniversary of the Convention on human rights and biomedicine](#) (Oviedo Convention).

The Conference also re-emphasised the unique position of the Council of Europe (CoE) to address these challenges, using as a basis, the legal framework of the Convention on human rights and biomedicine. This would allow for solutions to these new challenges to be rooted in human rights and shared European values.

The [SAP](#) was developed utilising insights gathered from the manifold and rich contributions made at the [20th anniversary conference](#), as well as consultation with national and international stakeholders and exchanges with other relevant COE intergovernmental committees and organisations. The Committee also benefited from a number of preparatory studies¹ which informed the development of the SAP. This Plan consists of four main pillars: Governance of Technologies, Equity in Healthcare, Physical and Mental Integrity and Cooperation and Communication, which is a transversal pillar. Under each pillar, specific objectives and related priority actions were identified.

Priority actions were determined on the basis of specific criteria including the demonstrated need, the impact on Council of Europe member States and their populations, the potential to elicit changes in policy or practice over the longer term. The committee considered the opportunities to pool resources and increase impact through co-operation with the other committees of the Council of Europe and/or with other intergovernmental organisations, taking into account the feasibility in light of available resources, expertise, and time. The SAP was adopted by the Committee on Bioethics (DH-BIO)² at its 16th meeting (16-19 November 2019).

The global pandemic served to further highlight the importance of upholding human rights and reinforced the importance of transparent, equitable value-based decisions in addressing this public health emergency. The actions and more specifically the timelines for those actions were adhered to despite the challenges presented by the pandemic, including remote working. Moreover, the Committee successfully re-oriented resources to ensure it could address and advise member states on the human rights and ethical challenges posed by the pandemic in real-time.

II. PROGRESS TO DATE UNDER THE SAP

The progress made in relation to the objectives, and the specific actions identified in the SAP are outlined in the Appendix to this report. In terms of key performance indicators, the Committee has met, and in some cases exceeded the work programme set out in the SAP, and has delivered on the actions, on time and within budget.

¹ [The Rights of Children in Biomedicine](#)
[From law to practice: towards a road map to strengthen the children's rights in the era of biomedicine](#)
[Research report: Bioethics and the Case law of the European Court of Human Rights](#)

² Predecessor of the CDBIO

Of note, the focus on the transversal pillar of Communication and Cooperation has strengthened the interactions with other Council of Europe committees, as well as our partners in other inter-governmental bodies concerned with bioethical and human rights challenges. This has allowed the Committee to rationalise its work programme and deploy its resources as efficiently as possible and to ensure that it can make a unique and valuable contribution to Member States in addressing bioethical issues.

An example of successful cooperation is the joint development of a Guide on children's participation in decision relevant to their health with the Steering Committee for the Rights of the Child (CDENF). Other examples include the cooperation with the Justice and Human Rights Training Division for the launching of the HELP course on key human rights principles in biomedicine, as well as with the Office of the Special Representative of the Secretary General on Migration and Refugees for the development of the Guide to Health Literacy.

In respect of cooperation with other intergovernmental organisations, it is worth highlighting the very successful cooperation with the Organisation for Economic and Cooperation Development (OECD) with which the CDBIO co-organised a round table on human rights and neurotechnologies in November 2021. The Committee has also continued to build successful and constructive working relationship with the World Health Organisation (WHO) and United Nations Education Science and Culture Organisation (UNESCO), with which it has collaborated on questions of common interest, including genome editing, artificial intelligence, and public dialogue regarding scientific and technological developments in the field of biomedicine.

The involvement of international non-governmental organisations (INGO's) in the work of the Committee was welcomed and encouraged. The CoE Conference of INGOs, which is an invited participant to CDBIO meetings, was regularly consulted on topics under consideration by the Committee. In the interests of transparency drafts of CDBIO documents were made publicly available and were subject to public and/or specific stakeholder consultation in the course of the development of legal instruments and guides.

The CDBIO also benefited from specific expertise in the academic sector; namely for the preparation of background information and analysis providing a basis for its work, such as on topics including artificial intelligence, neurotechnologies and genome editing.

Engagement with young people, is an explicit aim of the new working strategy of the CDBIO. To that end, a pilot youth forum on bioethics was held in June 2023, thanks to a voluntary contribution of Ireland. This will inform plans for a Council of Europe wide youth bioethics forum foreseen for 2025 as part of the SAP.

In order to increase the visibility, to raise interest in the Committee's work, and to maximise the uptake and impact of the work, online guides have been developed and translation of adopted documents into non-official languages has been encouraged

To complement this online offering, filmed interviews with Committee members and other experts summarising findings and recommendations have accompanied newly launched including the [rapporteurs report of the round table on human rights and neurotechnologies](#) and the [expert report on the application of AI in healthcare](#).

III. RESPONSE TO COVID-19 PANDEMIC

The SAP was adopted before the Covid 19 pandemic. In the face of this public health crisis, the Committee reacted quickly to reaffirm principles and values that needed to be protected and upheld in responding to the complex challenges confronting member states. On 20 April 2020, the Committee adopted a first [Statement on human rights considerations relevant to the Covid-19 pandemic](#). During the later phase of the pandemic when vaccines became available, a number of member states took the decision to introduce “vaccine passes” which restricted access to public spaces and/or activities based on vaccination status. In response to this policy development, the Committee drafted and adopted the [Statement on human rights consideration relevant to “vaccine pass” and other similar documents](#), in May 2021.

Several resources were made available to member states to support a high rights centred approach to responding to the public health emergency. The Committee collated relevant guidance documentation from CDBIO delegations and other international bodies³, and made them available on a specific web portal. In addition, the Committee organised webinars highlighting the ethical considerations pertaining to [Covid-19 and testing](#) (June 2020), [Covid-19 and health literacy](#) (June 2020) and [Covid-19 and public debate](#) (March 2021).

Furthermore, the re-examination of the priorities defined in the SAP, in the light of the pandemic confirmed the relevance of the specific objectives contained therein namely equity in health care. The Committee agreed to complement the actions already foreseen with attention paid to specific situations encountered during the pandemic. Thus a [Statement on Covid-19 and vaccines – Ensuring equitable access to vaccination during current and future pandemics](#) was published in January 2021 and a new [Recommendation on equitable access to medicinal products and medical equipment in situation of shortage](#) was finalised in November 2022.

With a forward looking focus, under the auspices of the Italian presidency of the Committee of Ministers, the Committee organised, in February 2022, a [conference on Social Resilience and Health Equity: A human right prospective for better resilience and preparedness](#). The [Guide to Health Literacy - Contributing to trust building and equitable access to healthcare](#) was presented on this occasion.

IV. PLANNING FOR THE FUTURE

A. Planned activities under SAP 2023-2025

The activities planned for the second part of the SAP are all under way according to schedule. Furthermore, at the request of the Committee of Ministers to complement the work already achieved in mental healthcare and human rights, the CDBIO is developing a draft recommendation “promoting the use of voluntary measures in mental health care services”⁴.

B. Context and related timeline for priority settings

In response to the recent developments in Europe, including the aggression against Ukraine, and the exceptional challenges raised for democracy, human rights, and rule of law, a fourth Summit of Heads of State and Government of the Council of Europe member States was held

³ <https://www.coe.int/en/web/bioethics/covid-19>

⁴ CM/Del/Dec(2022)1434/4.2

on 16 - 17 May 2023 (Reykjavik, Iceland). A new programme of activities (2024- 2027) will be defined after the Summit.

The priorities identified for the second period of the SAP, i.e. 2024 – 2025, may therefore need to be revised in the light of the outcome of the Summit and new ones will have to be defined for 2026 and 2027.

Besides these new challenges, the pandemic has put pressure on all health care systems of the member states, which may lead to new priorities and planning for challenges to evolving human rights issues ahead.

This midterm report is therefore very timely, as it facilitates reflection on the learnings to date and the opportunity to consider possible avenues for new priority actions. Subject to the agreement of the CDBIO, it is proposed that a new strategic action plan covering the period 2026-2030 will be drafted to guide the work of the Committee. This plan will encompass new priority strategic objectives and actions identified for 2026 and 2027.

To that end, a horizon scanning exercise is being considered in 2024, involving relevant stakeholders and intergovernmental committees and organisations.

C. New topics already identified

The SAP underlined the importance of building on the existing work of the Committee and extending the life and impact of its outputs. Some of the actions undertaken under the current SAP have led to the identification of follow up activities.

The CDBIO supported the proposals for further activities made by:

- the [rapporteurs of the Round Table on human rights and technologies](#), co-organised with the OECD:
 - o Activity(ies) to raise public awareness around neurotechnologies and facilitate inclusive societal deliberation on how such technologies should be deployed and regulated.
 - o Development of an interpretative guide to adapting existing human rights to neurotechnologies. The aim would be to guarantee that the protection of human rights is a guiding consideration throughout the innovation process from research to application of neurotechnologies in biomedicine.

- The rapporteur of the [Workshop on public dialogue on genomic medicine](#):
 - o [Activity(ies) to promote the key elements of a successful dialogue to support policy makers, funders and professionals who are implementing genomics in research or healthcare;
 - o re-examination of the Additional Protocol to the Oviedo Convention concerning genetic testing for health purposes in the light of the outcome of the seminar. and of Rec(2016)6 on research on biological materials of human origin to reinforce “*the importance of earning trust and stressing the role of good and transparent governance*”⁵

⁵ Subject to CDBIO agreement at its 3rd plenary meeting (6-9 June 2023)

Furthermore, building on the transversal pillar of Co-operation and Communication, new areas for possible actions have been identified by other committees to be carried out in cooperation with the CDBIO:

- Following the [Seminar on early intervention on intersex children](#), organised by the CDBIO on 31 May 2022, under the term of reference of the Steering Committee on Anti-discrimination, Diversity and Inclusion (CDADI), cooperation with the CDBIO is planned in respect of the development of a non-binding legal instrument on the equality of rights of intersex persons,
- As part of the new [Strategy for the Rights of the Child \(2023-2027\)](#), under the area “Equal opportunity and social inclusion of children”, access to mental health care for children has been identified as a priority issue, for which possible cooperation with the CDBIO has been suggested.

Finally, some topics identified in the context of the development of the 2020-2025 SAP which fell outside the chosen pillars could be reconsidered for future examination under a new strategic plan.

D. Lessons learned to be taken into account when planning for the future

The SAP 2020-2025 was the first strategic action plan drafted by the Committee. It provided the framework for the Committee to prioritise goals, maximise resources and increase our efficiency and effectiveness. The SAP ensured that the Committee took a more long-term view in relation to its work programme, allowing it to shape agendas in the bioethics sphere rather than simply responding to issues arising. Capacity was also built into the SAP to evolve with challenges and opportunities encountered, as amply demonstrated by the work on COVID-19.

Four key features characterise the implementation of the SAP during this first phase:

- Reactivity
- Adaptability
- Impactful
- Transversality

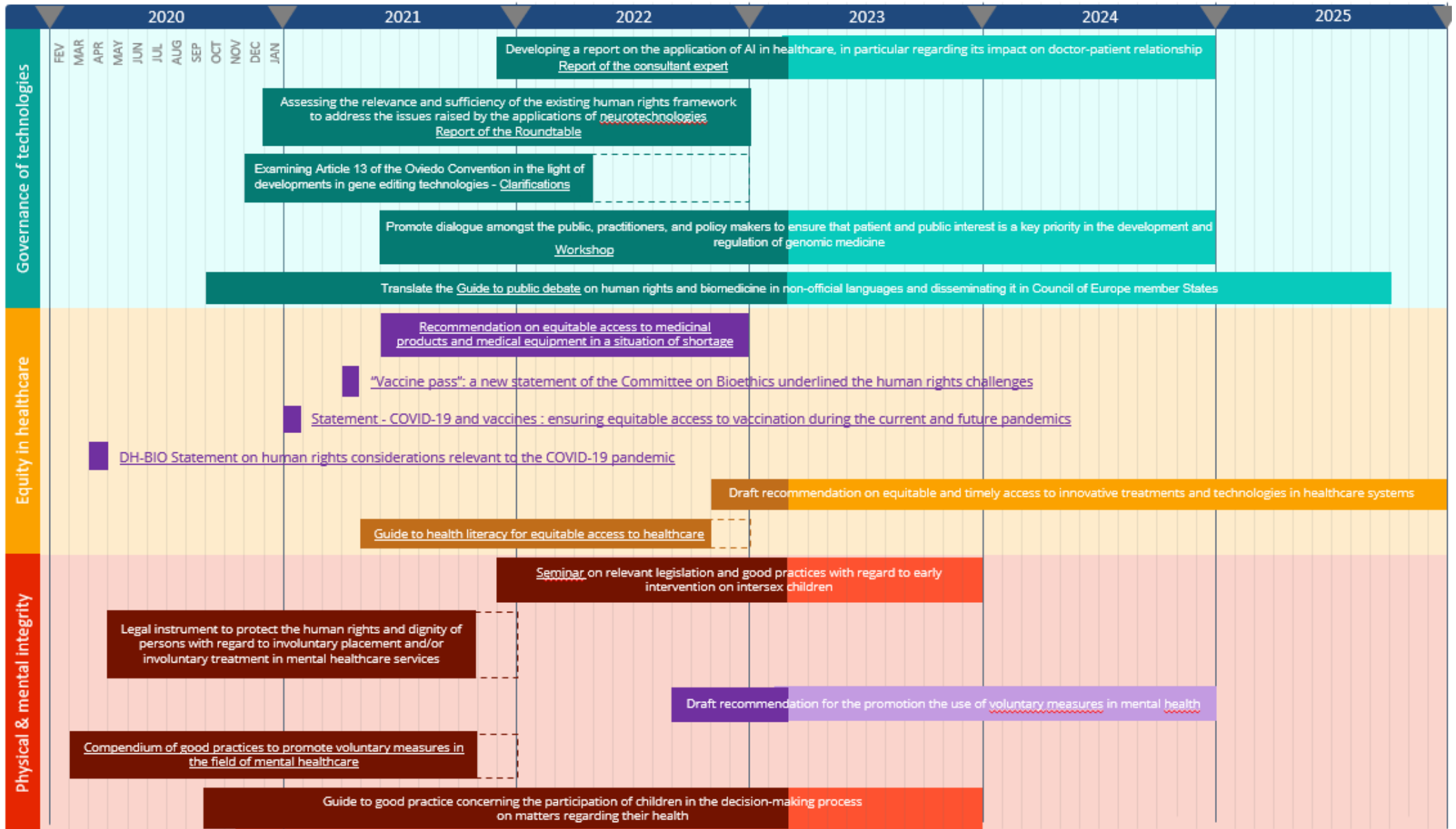
The CDBIO adapted to new ways of working imposed by the pandemic, making it possible to reinforce its actions for the protection of human rights during the public health crisis, while progressing in the implementation of the SAP as planned.

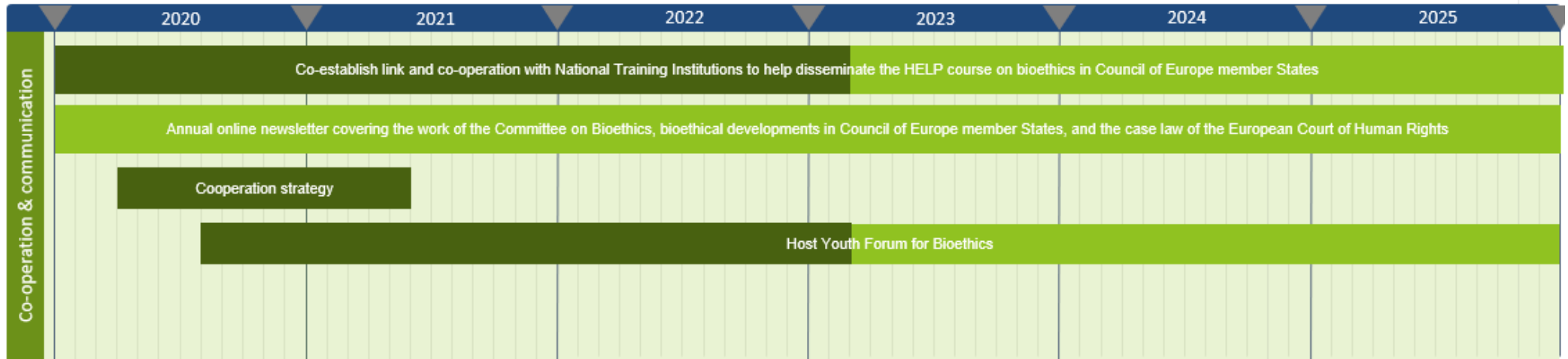
Emphasis was placed on the development of practical tools and the sharing of examples of good practices with a view to facilitate the implementation of legal principles, targeting the relevant stakeholders, including legal and health professionals, as well as patients and their families. Online presentation methods also served that objective, and increased functionality, visibility and impact.

Fruitful cooperation with other CoE committees and intergovernmental organisations were also a hallmark of many of the activities undertaken, ensuring complementarity of competences and increased potential for impact.

Efforts were made to improve communication and dissemination of documents and legal instruments. The intention is to further expand the community of recipients and extend the sphere of influence of the Committee by familiarising policy makers and non-governmental organisations working in the field at the national level with CDBIO guides, recommendations and other useful documents. To achieve this objective a specific and structured strategy may be required, and this could be developed in conjunction with delegations, the CoE Conference of INGO's, as well as other participants and observers in the CDBIO. Similarly, measures to enable the Committee to track progress towards goals and concretely assess the impact of its work could be further developed.

Appendix

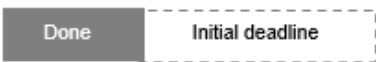





Activity progress



Activity finished before the time limit



 Activity not originally planned