World Health Organization (WHO)

CRISPR and Global Health: Towards Ethical Governance and Gene Editing

1. History of the committee

To promote international collaboration in public health, the World Health Organization (WHO), a specialized agency of the UN, was established in 1948. WHO was given a more wide-ranging mandate, determining health as a state of total physical, mental, and social well-being, yet it inherited responsibilities from the International Office of Public Health in Paris and the Health Organization of the League of Nations. On April 7, which is World Health Day, WHO celebrates its beginnings.

WHO is run by the World Health Assembly, which sets policy, and an Executive Board of medical experts who are chosen for three-year terms. The organization has its headquarters in Geneva. Staffed by professionals at headquarters, regional offices, or field sites across the globe, the Secretariat manages daily operations. Through the help of deputies and assistant directors who specialize in fields like family, women's, and children's health or health systems, the agency is overseen by a director general. Additionally, the main sources of funding are contributions from member states and, since 1951, the UN technical assistance program.

The leadership of WHO placed its highest emphasis on supporting nations to achieve universal health coverage, following to international health regulations, broadening access to necessary medical supplies, dealing with environmental, social, and economic health determinants, scheduling responses to noncommunicable diseases, and progressing the Sustainable Development Goals between 2014 and

2019. Furthermore, International sanitary rules are codified by WHO, updates on disease prevention, vaccinations, medications, and chemical risks are shared, and vaccination programs, laboratory support, sanitation, and health education are utilized to aid in epidemic control. Importantly, WHO persisted in fighting diseases like AIDS, TB, and malaria and was pivotal in the 1980 smallpox eradication.

WHO, which acts as an international hub of information and offers guidelines to nations and health agencies, designated COVID-19 a global pandemic in March 2020. There were also political controversies, which included the brief U.S. pullout in 2021 that President Joe Biden later overturned.

Further, WHO helps its member nations by deploying field specialists, advising on national health policies, solidifying public health infrastructure, working to create health clinics, and providing training programs. Amongst the notable Director-Generals are Tedros Adhanom Ghebreyesus (2017–present), Margaret Chan (2007–2017), Lee Jong-Wook (2003–2006), Gro Harlem Brundtland (1998–2003), and Brock Chisholm (1948–1953).

2. *WHO´s transformative journey after 2017*

In July 2017, the World Health Organization (WHO) announced its most ambitious reform strategy, which seeks to improve its influence at the national level and adapt to a world that is changing quickly. Under a single operating model across WHO's three levels—150 country offices, six regional offices, and headquarters—the transition was officially set up in March 2019. With the goal to enhance WHO's capacity to promote global health and well-being, the model was developed in cooperation with staff and Member States and was in line with the Thirteenth General Programme of Work (GPW 13, 2019–2025).

Three strategic goals were the focus of the transition. By integrating output scorecards, new performance metrics, interconnected supply chains, and planning, budgeting, and implementation in harmony, it first focused on optimizing the impact at the national level. Additionally, it bolstered WHO's ability to provide trustworthy scientific guidance by creating the Chief Scientist position, the World Health Data Hub, and improved emergency preparation, antimicrobial resistance, and equity capacities. Furthermore, it utilized international collaborations, creating platforms that brought together stakeholders throughout the globe, particularly the WHO Youth Council, the WHO Civil Society Commission, and the Envoy for Multilateral Affairs.

WHO's procedures were tested during the COVID-19 pandemic, which further showed how important health is to social and economic advancement. The necessity for a strong, adaptable framework has been reaffirmed by issues including dropping vaccination rates, a shortage of workers, climate difficulties, shifting demographics, and geopolitical issues. For the purpose of improving coordination across programs, crises, external relations, and business operations, WHO has set up a new three-level operating model that flattens hierarchies and reduces silos. Building on lessons learned from GPW 13 and COVID-19, country-level enhancements will keep going under GPW 14 (2025–2028), which started in 2023.

Member states' pledge to raise assessed contributions to 50% of the budget by 2028–2029 and workforce reforms which involve career pathways, mentoring, flexible work schedules, and mobility programs are notable turning points. Ultimately, the long-term objective of the transformation is to establish a contemporary, impact-driven, and flexible WHO that has the capacity to address worldwide health problems and provide measurable health gains at the national level.

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1. Introduction

The ability to modify the genomes of humans, animals, and plants presents difficult moral conundrums. Since CRISPR technology enables precise DNA modifications, concerns of safety, equity, and long-term effects are raised. In addition, taking ethical decisions involves evaluating the risks and potential rewards while also taking into account the effects on the person and society as a whole. Culture, religion, individual values, and the current legal system all have an impact on decisions. CRISPR has made it possible for quicker, more focused shifts that can last for generations, as opposed to conventional breeding or medical procedures. Though the technology holds a great deal of potential for disease prevention, agricultural improvement, and ecosystem restoration, it is unrealistic to disregard the potential hazards of misuse or unanticipated consequences. To deal with these issues in a responsible and equitable manner, vigilant surveillance and thorough discussion are necessary.

One of the main concerns with genome editing is safety. While on-target effects can bring about unanticipated alterations at the desired site, off-target consequences happen when CRISPR modifies DNA in undesirable locations. Depending on the organism and the situation, these alterations may have small, major, or unforeseeable effects. Apart from that, larger-scale ecological or societal repercussions, such as effects on food systems, human health, or biodiversity, may be unpredictable. Traditional medicines or selective breeding are slower or less accurate, but they frequently include fewer unknown dangers. Ethical examination needs to weigh short-term and long-term effects, taking into account social responsibility, potential harm, and technological feasibility.

Applications of CRISPR in healthcare are an example of the challenging trade-off between reward and risk. For instance, treatments for inherited illnesses like sickle cell anemia have the potential to improve problems for which there were previously few feasible choices. Whilst the long-term safety of early clinical studies is questionable, the possibility of advantages could change people's lives. When authorizing medicines, regulatory bodies must take into account the disease's severity, the availability of alternatives, and acceptable risk limits. Besides, patient perspectives are especially important because those with serious medical conditions might be inclined to take on more risk. Therefore, the development and application of novel genome-editing treatments are influenced by the interaction of scientific, moral, and individual variables.

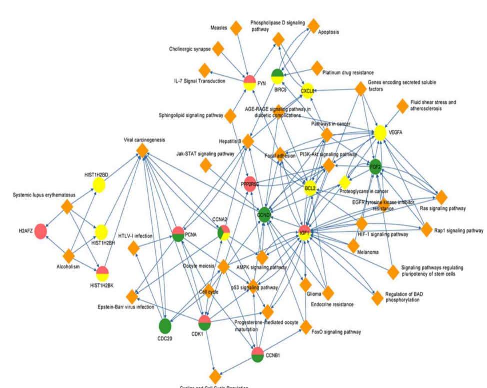
Concerns regarding biodiversity and the environment are of equal importance when it comes to CRISPR ethics. Whereas modifying genetic variety can have unanticipated effects on ecosystems, editing genes in crops or wild species may increase resilience or restore endangered populations. Accordingly, a decrease in gene diversity could make people prone to environmental stresses like disease and climate change. In addition, fairness, access, and global effects are further ethical considerations. Further, it is essential to think about who takes the risks and who gains from the technology? To answer these problems, interdisciplinary cooperation, continuous monitoring, and strict regulation are needed. Genome editing can benefit both society and the environment if innovation and prudence are balanced.

2. Historical context

The discovery of odd repeating DNA sequences in Escherichia coli in 1987 marked the beginning of CRISPR's history. Before Francisco Mojica, a microbiologist at the University of Alicante, investigated comparable patterns in bacteria and archaea in the late 1990s and early 2000s, these sequences—later dubbed CRISPR—were unexplained for years. In 2005, he proposed that CRISPR functioned as an adaptive immune system in prokaryotes after noticing that the spacer regions between repetitions matched virus DNA sequences. Later, CRISPR was established as a bacterial defensive mechanism when Philippe Horvath and Rodolphe Barrangou proved that Streptococcus thermophilus was able to incorporate viral DNA pieces into its CRISPR array, providing genetic memory to identify and destroy future viral infections.

Due to the pioneering work of Emmanuelle Charpentier and Jennifer Doudna, CRISPR was transformed from a bacterial immune system to an instrument for gene editing. In fact, they showed in 2012 that Streptococcus pyogenes' CRISPR-Cas9 system could be engineered to target and cut particular DNA sequences with just one guide RNA. The limitations of previous methods were overcome by this streamlined technique, thereby rendering precise gene editing possible. Shortly thereafter, scientists like Feng Zhang and George Church had the ability to successfully modify CRISPR-Cas9 for use in human and other mammalian cells. Thus, they allowed genome editing in complex creatures while offering opportunities for core biological study, disease models, and therapeutic uses.

Moreover, researchers used CRISPR to explore gene function, create disease models, and look into genetic pathways as its use rapidly spread throughout scientific domains. Its effectiveness and accuracy transformed biological research and sped up basic and applied



scientific discoveries. Accordingly, CRISPR's medicinal promise spurred considerable development efforts, particularly regarding the treatment of genetic diseases. Simultaneously, ethical arguments about heritable modifications and germline editing arose, sparking global conversations about responsible regulation and governance. That said, the revolutionary impact of the technique also sparked patent challenges, emphasizing its scientific and commercial worth yet posing concerns about the fair distribution and accessibility of CRISPR-based treatments around the globe.

As a result of CRISPR's historical significance, Emmanuelle Charpentier and Jennifer Doudna were awarded the 2020 Nobel Prize in Chemistry. Years of groundbreaking research and the profound impact that their work had on science and medicine were recognized with this honor. Since then, CRISPR-Cas9 has come to be used as a crucial genetics tool that allows accurate DNA alteration for study, development of new treatments, and biotech. Furthermore, its efficiency, adaptability, and accessibility have sped up research, while controversies over ethics and regulations continue to influence its application. Overall, the journey of CRISPR from bacterial curiosity to ground-breaking technology serves as a prime illustration of how basic research, creativity, and social variables collaborate to mold modern science.

As CRISPR advanced quickly from lab curiosity to clinical reality, its ethical governance in global health evolved. Scientists were able to look for cures for genetic abnormalities thanks to its accuracy, ease of use, and reduced cost, which sped up clinical studies and right away raised concerns about safety, regulation, and the influence on society. Apart from that, the focus of politicians and bioethicists switched from hypothetical discussions to developing enforceable regulations that could cope with both scientific uncertainty and public expectations as somatic therapies developed and in vivo uses became possible. For instance, clinical trials for beta-thalassemia and sickle cell disease demonstrated both therapeutic advantages and regulatory challenges.

Safety and scientific rigor became early governance goals. Stricter preclinical testing guidelines, the regular use of whole-genome sequencing for safety surveillance, the production of higher-fidelity Cas variants, and enhanced guide RNAs were all prompted by worries about on- and off-target consequences. In addition, any trial procedures included long-term follow-up and open reporting of adverse events, and regulators and research institutions started to demand thorough off-target assessments as requirements for regulatory approval. Further, safer experimental design was further helped by developments in computational prediction tools and delivery methods.

Because heritable modifications impact future generations, germline editing posed a distinct and difficult governance dilemma. For instance, reproductive autonomy, intergenerational responsibility, and the risks of eugenics or enhancement were the main topics of ethical discussions. Indeed, many jurisdictions implemented strict bans or severely restricted regulations on heritable genome editing as a result of these worries, which also led to numerous requests for caution and temporary moratoria on clinical germline applications. Before germline changes are used in therapeutic settings, scientific communities have called for collaborative policymaking, international discussion, and broad social consideration. Thus, scientific groups demanded inclusive policymaking and wide public discussion in order to inform any future clinical decisions.

With the medical promise of CRISPR treatments, equity and harmonization became long-standing governance priorities. The proposals for tiered pricing, public subsidies, capacity building in low-resource settings, and representative clinical trial recruitment were inspired by the high development and delivery costs, specialized infrastructure, and heightened expertise in wealthier regions, which posed a risk of escalating global health disparities. To strike a balance between innovation and prudence, international organizations, regulators, and expert voices promoted standardized guidelines, public involvement, surveillance systems, and adaptive regulation. Ezekiel Emanuel, Alta Charo, and Jennifer Doudna were among the experts who shaped discussions by underlining the importance of infrastructure investment, safety, and equity. Thereby, governance remains iterative on a global scale.

3. *Important Treaties, Agreements, and Conflicts*

a) Meetings/Conventions

Oviedo Convention (1999): A legally binding European instrument that is mentioned as a component of the existing legal framework; Baylis et al. (2020) acknowledged its function in limiting heritable genome alteration across signing states and used it as an indicator of binding constraints.

He Jiankui Affair (2018, announcement in Hong Kong): Substantial governmental responses were prompted by the rogue researcher's announcement of gene-edited newborns at the Second International Summit, which led to global outrage and Chinese criminal proceedings.

Second Gene Editing International Summit (Hong Kong, 27-29 Nov 2018): The important meeting where the He revelation was made, which triggered three significant international reports and an upsurge of governance activity.

International Commission / National Academies Report (IC / NAM 2020): A late but significant chapter on governance principles and proposed national and international processes were incorporated in the first of the three major reports, which focused on a "responsible pathway" for heritable human genome editing.

WHO Framework and Recommendations (WHO Expert Advisory Committee, 2021): A pair of papers that had a governance focus that laid out principles, instruments (hard and soft legislation), and execution scenarios in an attempt to give governments and stakeholders valuable governance resources.

European Group on Ethics Opinion (European Commission, 2021):A Europe-focused ethics opinion that mostly deferred to the WHO complexities of global governance while advocating for democratic discourse, international guidelines, and EU-level mechanisms (such as platforms and observatories).

Third International Summit on Human Genome Editing (2023): A follow-up conference that emphasized fair access—a continuous multistakeholder agreement of norms—and reaffirmed bans on HHGE until safety, legal sanctioning, and rigorous oversight exist.

Regulatory actions on Somatic HGE (2023-24): Somatic (non-heritable) CRISPR therapy specific regulatory advancements (drug approvals and guidelines) show how hard-law regulatory regimes have shifted despite the lack of HGE treaties.

China prosecutions and 2024 ethical-review measures: Legal action taken against a hard-law reaction sparked by the conflict, He (guilty conviction and prison sentence) plus further Chinese regulatory measures (2024) broadening ethical evaluation for life-science and gene-editing research.

b) <u>Treaties</u>

Biological Weapons Convention (opened 10 April 1972 and entered into force 26 March 1975): The Convention calls for approximately 189 States Parties, along with several signatories, establishing a nearly universal legal standard that prohibits the development, production, and stockpiling of biological weapons. It calls for the establishment of national implementation measures, encourages the cultivation of confidence-building initiatives and regularly scheduled conferences, and strengthens diplomatic endeavors aimed at managing dual-use risks arising from advancements like CRISPR. Particularly, in the field of gene editing, it establishes the most prominent international ban on fraudulent exploitation and acts as a foundation for export regulation and criminal law provisions. The merits encompass extensive legitimacy and enduring multilateral involvement. The constraints include inadequate verification measures and enforcement deficiencies that limit the surveillance of clandestine initiatives or their potential abuse.

Budapest Treaty (adopted 28 April 1977 and entered into force 19 August 1980): This WIPO instrument avoids the need to deposit biological material separately in each country where a patent is being sought by requiring the parties to the agreement to recognize microorganism deposits with designated international depositary authority for patent procedures. At present, it encompasses a large number of states and streamlines the prosecution of biotech patents for vectors, cell lines, and microorganisms commonly used in gene editing, thus promoting commercialization and aligning patents across borders. For instance, some benefits for patent applicants include decreased administrative burden and procedural predictability. On the other hand, the drawbacks include the disproportionate geographic distribution of depositary services, operating expenses that could be prohibitive for small testing facilities, and the restricted advantages for non-contracting nations.

Convention on Biological Diversity (opened 5 June 1992 and entered into force 29 December 1993): The CBD is the primary global venue for environmental governance of synthetic biology, gene drives, and discussions of digital sequence information. It has 196 Parties and establishes conservation, sustainable utilization, and equitable benefit sharing for genetic assets. It advises Parties to create risk evaluations, preventive actions, and national permitting procedures that impact intentional ecological uses of gene editing through COP judgments and expert groups. Benefits include capacity building, institutional processes, and worldwide reach. On the other hand, low negotiating cycles, disputed interpretations, especially when it comes to digital sequence information, and uneven national implementation that could end up in gaps in practical oversight constitute some of the disadvantages.

TRIPS Agreement (signed 15 April 1994; entered into force 1 January 1995): WTO countries are bound by TRIPS, which sets minimum international intellectual property standards that have a direct impact on the patentability, duration, and enforceability of biotech innovations, notably methods for editing genes and treatments. In addition to impacting technology transfer discussions and public health flexibilities, it offers stability and monetary rewards that can quicken the development of treatments. Innovation incentives and standardized IP standards are among the benefits. High medical expenses and possible barriers to access in low-income nations, conflicts amongst public health initiatives and patent protection, and complex ties with national laws and benefit-sharing arrangements are other downsides.

Oviedo Convention (opened for signature 4 April 1997 and entered into force 1 December 1999): Article 13 of the Council of Europe instrument, which has been ratified by several European states, forbids deliberate heritable genome modification for ratifying states and restricts genome interventions to therapeutic, diagnostic, or preventive purposes. It also sets legally binding human-rights protections in biomedicine for Parties. The organization's responsibilities include shaping domestic prohibitions, oversight, and review procedures, as well as establishing legally binding ethical and legal boundaries between its regional members. Legal clarity and effective human rights standards in member states are some of the benefits. Regional breadth, non-universal acknowledgment, and unequal internal utilization among European nations are some of its limitations.

UNESCO Universal Declaration on the Human Genome and Human Rights (adopted 11 November 1997): In addition to articulating moral values including human dignity, informed consent, and the preservation of future generations, this unenforceable UNESCO declaration views the human genome as the common heritage of all people. It has an impact upon institutional review boards, national bioethics frameworks, and public policy discussions on restrictions on the therapeutic and research applications of genome editing. Benefits include convincing moral authority and broad normative appeal in numerous nations. That said, lack of legal weight and the difficulties of turning general ideas into precise, enforceable regulatory regulations in domestic law are drawbacks.

Cartagena Protocol on Biosafety (adopted 29 January 2000 and entered into force 11 September 2003): Operating under the CBD, the Protocol, which has around 173 Parties, regulates the transboundary movement, handling, and utilization of live modified organisms that might have an impact on human health and biodiversity. It is essential to the cross-border control of gene-edited organisms and gene drives because it creates prior informed consent processes, case-by-case risk assessment, and a Biosafety Clearing-House for information sharing. Some benefits include information sharing and organized decision-making processes. Disparities in national implementation capabilities, discrepancies in risk interpretation, possible trade obstacles and ongoing debate regarding the coverage of emerging technologies are some drawbacks.

Additional Protocol to the Oviedo Convention on Biomedical Research (done 25 January 2005 and entered into force 1 September 2007): By providing comprehensive rights for study participants, with a focus on voluntary informed consent, ethics committee assessment, and particular protections for vulnerable individuals, this Council of Europe protocol enhances the Oviedo Convention. When ratified, it requires submitting reports, supervision, and procedural protections for clinical research, including somatic genome-editing therapy studies. Advantages include improved procedure clarity and participant protection. The need for domestic legal implementation, a restricted geographic reach, and the possible difficulties associated with multi-jurisdictional therapeutic initiatives are a few limitations.

International Health Regulations 2005 (adopted 23 May 2005 and entered into force 15 June 2007): About 196 States Parties are bound under the IHR to recognize and report public health incidents of global significance as well as to collaborate on surveillance and response. While the IHR does not control research, it becomes relevant when a laboratory incident, inadvertent release, or intentional misuse of modified organisms results in cross-border health problems, necessitating international assistance and notification requirements. Benefits include a coordinated response capability and a clear reporting architecture. Reliance on disparate national competencies, inconsistent compliance, and a lack of preventative measures focused explicitly at dual-use research governance are weaknesses.

UNESCO Universal Declaration on Bioethics and Human Rights (adopted 19 October 2005): This nonbinding proclamation, which is frequently referenced by national ethical authorities and policy makers when crafting regulations on genome-editing research and access, links bioethics with human rights through concepts like informed consent, equity, sharing of benefits, and social accountability. Normative guidance, not legal enforcement, is its primary objective. Benefits include flexibility to various legal systems and global ethical guidelines. The lack of enforceable consequences and inconsistent adoption into national statutory law and regulatory practice are drawbacks.

Nagoya Protocol on Access and Benefit-Sharing (adopted 29 October 2010 and entered into force 12 October 2014): Supported by the ABS Clearing-House, the Protocol, which has approximately 142 Parties, sets out legally enforceable processes for previous informed consent and mutually acceptable terms when obtaining genetic resources. Because sharing benefits and compliance checks may be required, it has a major effect on gene editing for programs that involve biological material or data produced from biodiversity. Benefits include legal clarity for access and equity for resource providers. The intricate nature of compliance, uncertainty of digital sequence information coverage, and probable administrative obstacles that may hinder research cooperation are drawbacks.

International Commission report on Heritable Human Genome Editing (published 8 September 2020): The Commission, which was conceived by popular scientific academies, released a consensus report in September 2020 outlining the scientific, ethical, and governance requirements for any clinical use of heritable genome editing. The report advocates extensive safety evidence, long-term monitoring, and widespread public discussion. The report's thorough interdisciplinary roadmap had an impact on national policies and WHO discussions. Benefits include international credibility and clearly established technical standards. Nonbinding status and the real-world challenge of turning recommendations into enforceable domestic law or generally recognized thresholds are drawbacks.

WHO governance framework and Human Genome Editing registry (published 12 July 2021): To improve the accountability, openness, and monitoring of clinical research, WHO published a global Human Genome Editing Registry along with an organizational framework and recommendations for human genome editing. The guidelines urge solid ethical reviews, governmental supervision structures, and trial registries while distinguishing between somatic and heritable uses. Benefits include uniformed nonbinding regulations and an all-encompassing visibility mechanism. Due to limitations including erratic national compliance, voluntary adoption, and a lack of statutory power, many suggestions depend on domestic adoption to be successful.

WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (adopted 24 May 2024): The convention, which was adopted on May 24, 2024, at the WIPO Diplomatic Conference, aims to encourage traceability and fight biopiracy by requiring patent seekers to make clear whether claimed innovations include genetic resources or related traditional knowledge. Numerous delegations signed it, and it was then made accessible to others for signature; confirmation criteria were necessary for it to become operative. Benefits include increased openness and recognition of resource suppliers. Increased costs associated with registering patents, complicated legal issues during implementation, and an unknown relationship with current national patent systems until signatures are accumulated are some drawbacks.

CBD COP16 in Cali and resumed session concluded 27 February 2025 (COP convened 21 October 2024 to 1 November 2024 and resumed session concluded 27 February 2025): Delegations from 196 Parties participated in the COP, which resulted in decisions and work plans dealing with synthetic biology, engineered gene drives, and the benefit sharing of digital sequence information. These included measures to build capacity, establish funding mechanisms like the Cali Fund, and provide procedural guidance. These results affect how the Parties will control gene-editing programs' environmental discharges, international effects, and equitable benefit sharing. Benefits include new financial management alternatives and coordinated global policies. Among the drawbacks include controversial mandates, tardy national translation, and enduring north and south divisions on finance and access.

Cartagena Protocol CP-MOP11 decisions (key decisions 30 October 2024 with follow-up documents in December 2024 and implementation into 2025): About 173 Parties to the Cartagena Protocol defined capacity building priorities, commissioned expert groups, and accepted agreements on risk assessment and risk management for live modified organisms with engineered gene drives at COP16 and the related CP-MOP11 meeting. These orders coordinate transboundary governance and provide national regulators with guidance on environmental risk assessment, monitoring, and precaution before release. Benefits involve strengthening regional capability and offering helpful technical advice. Unpredictability in science on long-term ecological effects, possible trade disputes, and uneven national implementation resources are drawbacks.

c) Conflicts and Controversies

He Jiankui's Gene Editing Comeback (April 2025)

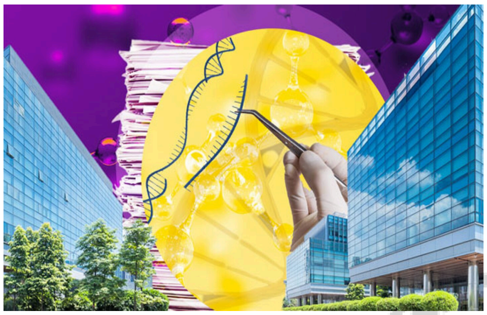
In April 2025, He Jiankui, the Chinese scientist who produced the first gene-edited babies in 2018, returned with claims of developing gene-editing treatments for muscle dystrophy and Alzheimer's disease. He received financial proposals from private organizations, even though he lacked formal affiliations and travel permissions because of previous legal troubles. His reappearance triggered discussions about the governance of heritable genome editing and raised ethical concerns around the world.

Oxitec's GM Mosquito Trials in Djibouti (November 2024)

To fight malaria in Djibouti, Oxitec released genetically engineered mosquitoes in November 2024. These mosquitoes were used for the first time in East Africa during the trial. Environmental organizations and some scientists expressed worries about ecological dangers and the sufficiency of local consultation, despite the government's backing for the program. The dispute brought to light the difficulties of implementing gene-drive technology in various ecosystems.

CRISPR Dual-Use and Biosecurity Alarm (2023–2025)

The availability of CRISPR and genetic engineering methods between 2023 and 2025 prompted worries about possible bioterrorism abuse and unintended release of toxic substances. To mitigate these hazards, experts and decision-makers debated the necessity of stronger biosafety protocols and global laws. Specifically, conversations emphasized the need for strong governance frameworks and the dual-use nature of emerging biotechnologies.



CRISPR Patent Dispute Revival (May 12, 2025)

The patent dispute between the University of California and the Broad Institute around CRISPR-Cas9 gene editing technology was revived by the U.S. Court of Appeals for the Federal Circuit on May 12, 2025. The case was returned for reconsideration after the court determined that the U.S. The Patent Office had misapplied patent law with relation to the invention idea. Consequently, the licensing and commercialization of CRISPR technologies may be greatly impacted by this ruling.

4. Current Issue

As of the second half of 2025, the equitable governance of heritable human genome editing (HHGE) is the primary ethical concern in CRISPR-based gene editing, particularly when it comes to global health. Beyond technological advancements, this issue raises more profound worries regarding safety, accessibility, and misuse, all of which have significant implications for social justice and public health. Modifying the human germline, where alterations may be passed down to subsequent generations, increases the danger of unanticipated or off-target genetic modifications. As a result, these safety issues emphasize the need for prudence when thinking about clinical applications in people and are validated by continuing scientific discussions.

Equity and access are a second major issue. While CRISPR technology has great potential for treating and preventing genetic illnesses, the benefits might not be shared fairly. Global health disparities face the risk of growing as a result of high expenses and underdeveloped health systems in low- and middle-income nations. Advanced treatments are more likely to help wealthier communities, yet they may not reach vulnerable populations. However, the absence of a single international framework for HHGE regulation has led to uneven norms, therefore, increasing the risk of moral failings and making international cooperation on gene editing research and clinical application more difficult.

The possible abuse of CRISPR for non-therapeutic uses, including so-called "designer babies," is another major concern. Indeed, this raises important issues regarding human agency, dignity, and the social effects of genetic alteration. The World Health Organization and other worldwide organizations are working to create global standards that give safety, fair access, and ethical monitoring first priority in response to these worries. Nevertheless, this is a dynamic and complex matter that requires ongoing international discussions and robust governance. Thus, it will be crucial to provide equitable access while avoiding abuse in order to fully realize CRISPR's potential for humanity without worsening inequality or compromising moral principles.

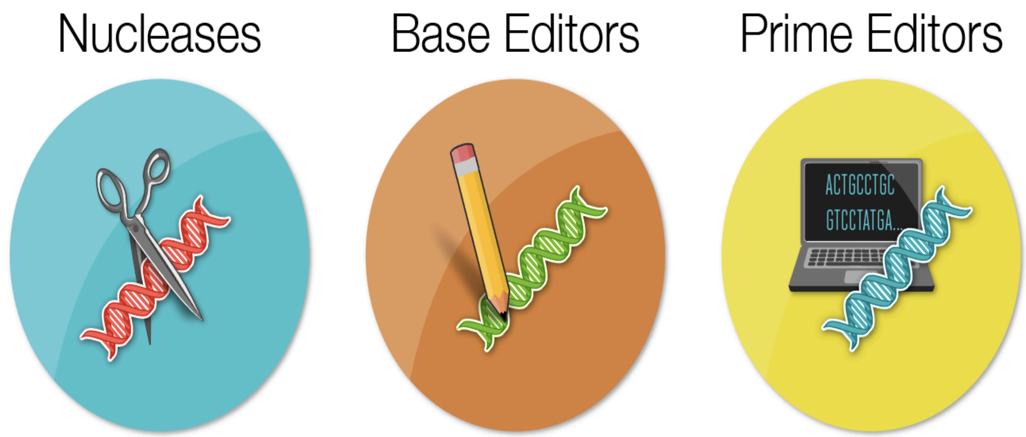
5. *Recent Breakthroughs*

I. Personalized In Vivo CRISPR Treatment for Uncommon Genetic Conditions

Scientists used a patient-specific CRISPR therapy that was administered directly to liver cells in order to treat a baby with carbamoyl phosphate synthetase 1 (CPS1) deficiency. For the first time, an individual-specific gene-editing treatment was given in vivo. By stabilizing the patient's health and reducing the need for lifetime medication, the procedure showed how customized CRISPR techniques can be used to treat rare genetic disorders for which there were no prior treatments.

II. Progress in Prime and Base Editing

Base editing lowers the possibility of undesired mutations through permitting the exact modification of single DNA base pairs without producing double-strand breaks. Prime editing goes a step further by allowing precise placement of DNA sequences for insertion, deletion, or substitution. As a result, these technologies increase precision and security and offer new ways to treat a variety of genetic illnesses, such as blood, neurological, and metabolic defects.



III. **Treatments for Blood Disorders Based on CRISPR**

Editing hematopoietic stem cells was shown in clinical trials for sickle cell disease and beta-thalassemia to assist many individuals get rid of their symptoms. Some individuals were able to cease requiring frequent blood transfusions, showing the revolutionary potential of gene editing in the cure of chronic blood illnesses and the noticeable improvement in quality of life.

IV. **TIGR-Tas Gene Editing System**

By introducing a dual-guide RNA method, the TIGR-Tas system eliminates the requirement for a PAM sequence, enabling more versatile gene targeting. Indeed, it is an appealing option for treating diseases that used to be difficult to edit because of delivery constraints because of its tiny dimensions, which also makes it easier to distribute into cells. Hence, this development may broaden the conditions for which gene-editing treatments can be used.

V. **CRISPR Applications in Neurological Disorders**

CRISPR has been shown in preclinical research to be able to eradicate mutations linked to ALS and Rett syndrome through animal models. These discoveries represent a dramatic change in the way that neurodegenerative diseases may be treated in the future by focusing on the underlying genetic roots of these ailments and opening up the possibility to possible drugs that might delay or even stop disease development.

6. Major stakeholders and their positions

I. World Health Organization (WHO)

With an eye on safety, equality, and ethical monitoring, the World Health Organization (WHO) is driving the charge for establishing international standards for human genome editing. Presenting ideas to direct the responsible use of gene editing technology, the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing published their findings in 2025.

II. The United Nations Educational, Scientific, and Cultural Organization (UNESCO)

It has played a significant role in encouraging the moral application of technology and research, including gene editing. Gabriela Ramos, the assistant director-general of UNESCO, highlighted in 2025 the importance of making sure that technological developments follow moral standards and human rights in order to encourage justice and progress on an international level.

III. The United States

The Food and Drug Administration (FDA) and the National Institutes of Health (NIH) are the primary regulators of gene-editing research and therapies in the United States. Due to safety and ethical issues, the NIH has supported international demands for a moratorium on heritable human genome editing. The Food and Drug Administration continues to monitor the technology for gene editing clinical trials to ensure they comply with stringent safety regulations.

IV. China

Both innovation and controversy have defined China's gene editing strategy. Significant criticism and a corresponding crackdown on unregulated gene-editing activities followed the case of He Jiankui, who carried out illegal gene-editing research on embryos. With continuing biotechnology investments and a focus on developing regulatory frameworks that regulate gene-editing activities, China continues to be an important actor in the sector.

V. **Innovative Genomics Institute (IGI)**

The IGI was established by Nobel winner Jennifer Doudna and has been a leader in the development of CRISPR-based treatments. By developing a customized in vivo CRISPR treatment for a baby with carbamoyl phosphate synthetase 1 (CPS1) deficiency in 2025, the IGI achieved a significant milestone. The result demonstrated how tailored CRISPR strategies are able to treat uncommon genetic illnesses.

VI. **Children's Hospital of Philadelphia (CHOP)**

The development and implementation of the tailored CRISPR treatment for the infant with CPS1 deficiency was greatly helped by CHOP's partnership with the University of Pennsylvania. This successful treatment marked a major breakthrough in personalized healthcare and genetic therapy.

VII. **American Society of Gene & Cell Therapy (ASGCT)**

The ASGCT has been prominent in its opposition to germline gene editing's clinical application, referring to serious safety, ethical, and scientific issues. The association emphasizes the importance of exercising caution and suggests more study and open debate before contemplating any clinical applications.

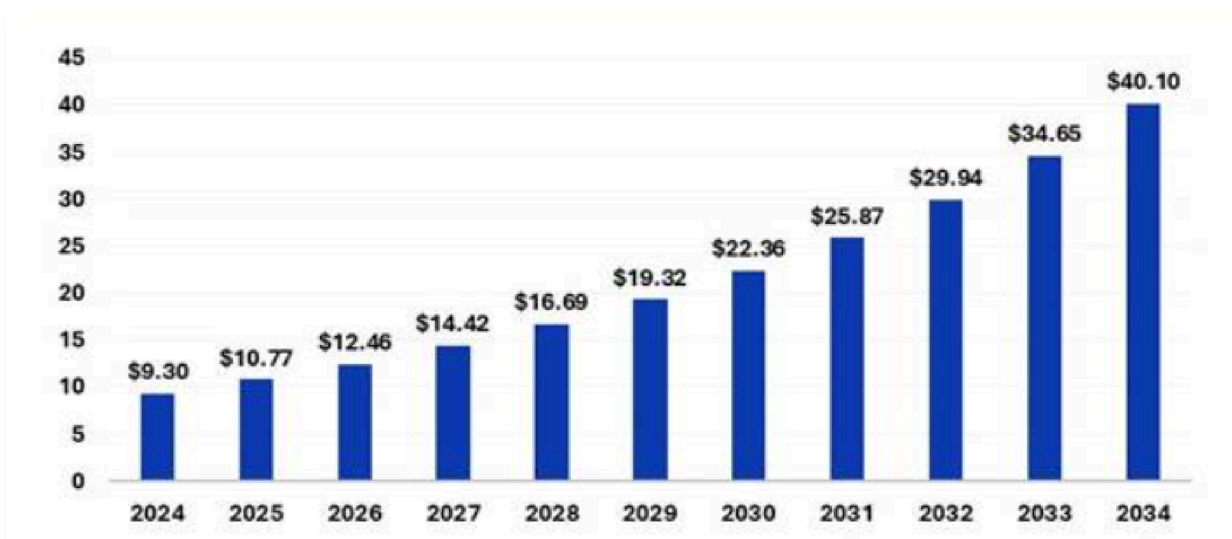
VIII. **Public Health and Bioethics Advocates**

The creation of ethical charters for overseeing the application of CRISPR technology has been advocated by groups like the Global Observatory for Genome Editing. Advocates for human dignity emphasize the need to guard against possible abuses, like eugenics or unequal access to gene-editing treatments.

IX. **He Jiankui**

The Chinese researcher who created genetically altered offspring by doing illegal gene-editing operations on embryos is still a controversial figure. He Jiankui keeps pushing for the use of gene editing in the treatment of genetic illnesses and promotes his studies despite having been condemned to prison for his acts. His acts sparked discussions on the moral limits of gene-editing technology all throughout the world.

7. Current Stats



BioSpace (2025)

The global market for CRISPR-based gene editing is projected to grow at a compound annual growth rate (CAGR) of 14.77% from its mid-2025 valuation of about USD 4.77 billion to USD 16.47 billion by 2034. Additionally, the gene editing market in the US was estimated to be worth USD 3.19 billion in 2024 and is projected to grow at a compound annual growth rate (CAGR) of 15.93% from 2025 to 2034, reaching within USD 13.99 billion.

In vivo base editing therapy VERVE-102, which targets the PCSK9 gene, has shown promising results in clinical applications. A single infusion led to a mean 53% decrease in LDL cholesterol levels in the highest dose cohort (0.6 mg/kg), with the maximum dose group seeing a drop of up to 69%. There were no significant side effects recorded, and the treatment was tolerated effectively.

The gene-editing treatment exagamglogene autotemcel (Casgevy) has shown notable effectiveness in the treatment of sickle cell disease. Based on clinical trials, for at least a year after receiving an infusion, 93.5% of treated individuals did not have any pain crises. Therefore, the therapy's approval by the NHS indicates a major breakthrough in sickle cell disease treatment.

8. Past International actions

The fundamental moral and legal pillars have remained in place for decades. Early, globally focused ethical principles (human dignity, nondiscrimination, respect for consent, and privacy) emerged by UNESCO's Universal Declaration on the Human Genome and Human Rights (1997) and the International Declaration on Human Genetic Data (2003), which acted as a framework for subsequent discussions. The "Oviedo Convention," which was ratified by the Council of Europe in 1997, set legally obligatory requirements for ratifying states regarding biomedical interventions, particularly bans on germline modification. Further, the normative authority of UNESCO's human-genome proclamation became stronger when the UN General Assembly formally approved it. The tone set by those tools is one of caution: preserve human dignity, emphasize informed consent, and limit interventions that could endanger future generations.

For the CRISPR era, governance was redefined by three seminal, tightly scheduled expert papers (2020–2021). In a report for 2020, the International Commission, supported by the Royal Society and the U.S. National Academies, outlined a "responsible pathway" for any country contemplating clinical heritable human genome editing (HHGE). A 2021 Framework for Governance and brief recommendations that focused on institutional, national, regional, and global governance instruments and values were developed by WHO's Expert Advisory Committee. In 2021, the European Group on Ethics (EGE) released an opinion offering advice on ethics and governance to EU decision-makers. Collectively, these three papers identified governance toolkits (hard and soft law), prioritized principles (safety, transparency, public involvement, and equity), and focused on multi-level supervision rather than a single intergovernmental treaty.

Public attention and policy momentum were shaped by international summits and rapidly evolving crises. Indeed, early guidelines for ethical research were established during the 2015 International Summit on Human Gene Editing. Jiankui's publication of live babies from CRISPR-edited embryos during the 2018 Hong Kong summit prompted international outrage, Chinese criminal prosecution, and renewed enthusiasm for governance (including the three main publications mentioned above). A Third International Summit in 2023 reiterated the need for promoting somatic clinical advancements under strict supervision within HHGE's strict confines until there is a clear consensus and legal framework in place. Much of the ensuing soft-law effort was initiated by the "CRISPR babies" case, which highlighted the limitations of current procedures to discourage malicious actors.

Since those reports have been limited and uneven by geography, hard law measures have been implemented. In many jurisdictions, germline uses are already restricted by the Oviedo Convention and other national regulations; systematic surveys (e.g., Baylis et al., 2020) showed that the majority of countries forbid reproductive HHGE. Instead, some regulatory evolution has centered on somatic-therapeutic pathways. For instance, national ethical review systems have been reinforced in certain states, and regulators (FDA, EMA) and drug-approval pathways have undergone changes for gene-editing therapies (accelerated approvals, nonbinding guidance). China extended review criteria for human-involving life-science research in 2024 by combining criminal enforcement in the 2019 He case with additional ethics-review measures. In general, there aren't many legally binding international agreements concerning genome editing; rather, governance has primarily changed as a consequence of modifications to national laws, regulatory guidelines, and agency approvals for somatic therapies.

Moreover, the most active areas have been norm-setting and soft-law. Guidelines for responsible conduct, funding conditions, editorial rules, and institutional review standards have been developed by professional societies, funders, journals, and standards-setting groups (such as ISSCR, ASHG, and other societies) in accordance with WHO/NAM/EGE outcomes. Even in instances in which national law is unaltered, these "soft" tools, guidance manuals, clinical-trial guidelines, funder circumstances, and public engagement toolkits, have had a significant practical effect by establishing what constitutes appropriate research conduct. Even if there are not many clear causative ties to new hard laws, empirical research and interviews indicate that the three main reports (WHO, IC, and EGE) have brought together an identifiable set of moral and scientific principles and modified standards.

The strengths and weaknesses of governance are demonstrated by notable achievements and failures. Successful regulatory pathways for somatic CRISPR therapies which strike a balance between safety and speedy review (demonstrating adaptive regulatory capacity), the creation of a WHO governance framework and recommendations, and rapid standard consolidation following 2018 (strong worldwide condemnation of germline reproductive editing) are examples of successes. The absence of a single binding international agreement, continuing regulatory fragmentation (patchwork national laws), vulnerability to "rogue" actors and medical tourism, a lack of mechanisms to ensure equitable access across nations, and execution gaps for private clinics operating globally are some of the failures and gaps. Without strong national enforcement and international collaboration, the He Jiankui incident remains as a classic example of how norms and soft law alone cannot eradicate any unlawful applications.

Important trends and the consequences for governance in the future. Initially international action has focused on strong soft-law tools (professional standards, funder and journal policies) along with multi-level governance (institutional review, national legislation, regional treaties, and global frameworks). Second, because scientific uncertainty and cultural/ethical diversity make it unattainable to reach a legally binding worldwide agreement, the field has favored flexible, principle-led frameworks over strict, repressive global treaties. Third, HHGE (reproductive use) is still mainly restricted but irregularly policed, while somatic clinical translation (drug approvals, trial oversight) has been most effectively regulated. In the end, converting widely accepted ethical ideals into collaborative, equitable, and enforced mechanisms that prevent abuse, stimulate safe innovation, and assure justice and access for all is the main ongoing problem.

9. Subtopics

a) Subtopic A: Designer Babies: Playing God or Progress?

Designer babies bring the core ethical clash of CRISPR into stark relief: the tension between preventing suffering and making irreversible decisions for future people. Germline edits that eliminate severe genetic disorders could spare families decades of pain, but they also alter the genome of descendants who cannot consent. This raises questions about intergenerational responsibility, long-term risk tolerance, and whether it is morally permissible to accept uncertain harms now for potential benefits to future lineages. Those concerns go beyond lab safety: they probe fundamental values about parental choice, collective duty, and the limits of medical intervention.

These moral concerns get amplified by the societal consequences. Genetic advantages might pass onto geography and wealth if heritable alterations become available unevenly, strengthening disparities over generations. Additionally, efforts to "fix" characteristics that some people consider essential to identity, disabilities, for instance, can dismiss entire communities and eliminate cultural forms of flourishing. Indeed, technical safety simply cannot alleviate concerns that genome editing might be used to advance societal selection rather than public health; historical recollections of eugenics exacerbate skepticism.

Legal restrictions on forceful or commercial misuse, rigorous scientific standards, transparent long-term monitoring, and rigorous equitable measures to avoid socio-genetic stratification are therefore essential for responsible governance. Broad public discussion, true representation of underrepresented perspectives (such as those from indigenous groups and those with disabilities), and a mandatory evaluation of non-editing alternatives are also crucial safeguards in the process. In an effort to prevent clinical innovation from exceeding society's ability to determine the type of future we desire, morally sound policies link advances in technology to democratic decisions.

Furthermore, realistic measures could include enforceable registries, penalties for rogue actors, and temporary moratoriums on the use of clinical germlines until global safety and ethical standards are met. Funding and intellectual property agreements that place the public interest first, along with investments in international capacity building, are equally important in ensuring that wealthy states are not the sole ones making decisions on heritable modification. The debate is limited when designer-baby arguments are presented as exclusively scientific. Thus, a long-term solution must tie technological capability to safety, justice, and shared values among multiple groups of people.

b) Subtopic B: CRISPR Without Borders: Who Decides What's Allowed?

National control alone is inadequate because of the cross-border dynamics of CRISPR. Clinics, researchers, and businesses operate all over the world, and lax regulations in one jurisdiction promote overseas trials, health tourism, and environmental discharges with cross-border impacts. In addition, actors are encouraged to look for favorable venues by this regulatory patchwork, which also leaves enforcement gaps where harm might spread. Consequently, what ought to be a shared global public benefit is rather split into national decisions with global repercussions, weakening biosafety, fair access, and consistent ethical norms.

A combination of focused hard rules and adaptable soft legislation is needed for global governance. Although they lack enforcement, soft instruments such as WHO frameworks, money conditions, and journal standards possess the ability to quickly reflect consensus and shape professional norms. In a field that is changing quickly, enforceable measures offer teeth but move slowly and run the risk of becoming outdated. The practical strategy minimizes jurisdiction shopping yet preserves flexibility by combining basic ethical requirements for clinical and environmental trials, reciprocal acceptance of allowed review systems, and tools for transparency (mandated worldwide registries, codified adverse-event reporting).

The two main points of contention are trademarks and capacity inequalities. Private licenses and patent monopolies have the potential to heighten inequality by limiting access and consolidating control over supporting technology. Furthermore, public-interest licensing, patent pools, and conditional funding are prominent instances of policy tools that may be employed to change incentives in favor of publicly accessible, reasonably priced treatments. At the same time, to make it possible for lower-resource nations to evaluate dangers, keep an eye on releases, and enforce standards instead of relying on outside judgment, they require ongoing technology transfer and regulatory assistance.

Lastly, inclusive, international discussion is essential to legitimacy. To allow for decisions to reflect a spectrum of values rather than just those of technical elites, sustainable norms require forums that bring together scientists, ethicists, patient groups, indigenous leaders, and policymakers. Hence, the best opportunity to make CRISPR governance consistent, accountable, and equitable across borders is given by the hybrid approach, which includes international standards and open infrastructures supported by enforced national law, fair IP and funding arrangements, building capacity, and collaborative discourse.

10. Positions

I. **United States:** Supports moratoria and severe limitations on heritable germline editing; FDA and NIH surveillance provide strong regulatory control for somatic clinical purposes.

II. **China:** Significant biotech funding and ongoing study and development; stricter ethics and laws following the He Jiankui event; bans clinical germline application while encouraging controlled somatic and agricultural uses.

III. **European Union (EGE & many Member States):** precautionary, principle-led strategy that emphasizes safety, human-rights framing, democratic public debate, and limitations on heritable applications; controlled somatic therapies are permitted.

IV. **UK:** In the United Kingdom, editing the germline for reproductive purposes is prohibited, yet strictly regulated embryo research is allowed (under HFEA supervision); somatic therapies follow pre-established regulatory procedures.

V. **Japan:** Forbids the use of reproductive germlines but enables embryo research under certain restrictions; regulations have changed in response to public discussion.

VI. **Brazil:** Reproductive germline editing is forbidden by law and regulation; somatic research is allowed under ANVISA and ethical supervision, although implementation and lucidity differ.

VII. **Australia:** Reproductive germline uses have been limited by regulatory architecture, but regulated somatic research is allowed; government monitoring is called for to be strengthened through reviews.

VIII. **Canada:** Somatic clinical work is still conducted under health and regulatory routes in Canada, however, where it is illegal to alter a person's germline (Assisted Human Reproduction Act).

IX. **South Africa:** Takes a methodical approach to ethics rules; typically forbids clinical germline application, but supports controlled research and regular revisions to the guidelines.

X. **Russia:** Allows regulated research but has divided regulatory details; lacks a clear, unified public law that allows germline editing.

11. Guiding questions

- Before clinical germline editing, what minimal safety and monitoring requirements ought to be fulfilled, and who is responsible for ensuring compliance?
- How may legally binding international regulations preserve national sovereignty while preventing regulatory shopping and unscrupulous actors?
- Which intellectual property and financial tools are required to ensure that everyone has access to CRISPR treatments?
- Should a prohibition on germline editing be imposed by the UN or WHO, and if so, under what conditions would it be lifted?
- Who is responsible for compensating for cross-border damages resulting from gene drives or illegal germline edits?

- Which organization should enforce the necessary dual-use and globally biosafety controls?
- Which protections for participation are necessary for effective decision-making?
- How can international databases and trial monitoring enable accountability, openness, and create action against unethical CRISPR applications?

12.Suggested sources

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