

## *ge<sup>2</sup>p<sup>2</sup> global*

governance, ethics, evidence, policy, practice

### **Public Consultations Watch :: Global Calls for Input/Public Comment/RFIs**

November 2025 - Issue 36

GE2P2 Global is an integrated non-profit foundation and public benefit corporation formed to advance scientific rigor, ethical resilience, and integrity in research and evidence generation – informing responsible governance, policy, and practice.

In the context of this mission, GE2P2 Global monitors public consultations/calls for input/RFIs and similar opportunities across its focus areas of global health, human rights, humanitarian action, education/literacy, heritage, climate/environment, peace, and sustainable development.

Monitoring this span of sectors yields a broad variety of public comment opportunities, even though this modality is not employed in any uniform way across the UN system, multilateral agencies, INGOs, member states or their ministerial/regulatory bodies. As we are still exploring this monitoring approach and broadening the range of calls included, we stress that this is an indicative and not an exhaustive digest.

In parallel, GE2P2 Global is striving to respond to public consultation opportunities where the experience and expertise of members of our growing community of practice suggest that a meaningful contribution can be developed. The GE2P2 Global Foundation also functions as the secretariat for the Global Forum for Research Ethics and Integrity – a global group of individuals from over 30 countries who collaborate on analysis and action, including response to selected public consultations.

**We welcome information about calls for public consultation – at global or country level – to help enrich this digest. Equally, individuals and organizations/institutions interested in collaborating on joint responses to any of the opportunities listed below are welcome to contact us** [David R Curry, GE2P2 Global Foundation, [david.r.curry@ge2p2global.org](mailto:david.r.curry@ge2p2global.org) ].

*Acknowledgements:* We appreciate the support of Foundation Senior Fellow Gerald Schatz, JD for his continuing support in helping identify calls included in this digest, and Associate Fellow Sedem Adiab, MPH, for her critical role in the secretariat function which supports development of submissions to selected calls.

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#### ***Digest content is organized in three sections:***

- [1] Title and source of all calls organized [by due date](#) [p.2 ff]
- [2] [All calls, listed with more comprehensive information](#) [i.e., objective, scope] organized by due date under thematic areas: Biomedical Research; Environment/Climate; Human Rights+ [p.5 ff]
- [3] [Selected Supplementary Content](#) including Final, Published Guidances/Regulations/Laws Employing Calls for Public Consultation [p.15 ff]

*We expect to add thematic areas as our digest evolves and becomes more comprehensive.*

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## Calls for Public Consultation: Title/Source/Sorted by Due Date

### **Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry; Availability**

A Notice by the Food and Drug Administration on 09/25/2025 **Comment period ends 11/24/2025.**  
Docket No. FDA-2017-D-6159 :: 21 pages

### **Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations; Draft Guidance for Industry; Availability**

A Notice by the Food and Drug Administration on 09/25/2025 **Comment period ends (11/24/2025.**

### **Call for input for EMRTD study "Artificial Intelligence, Cultural Rights, and the Right to Development"**

Issued by UN Expert Mechanism on the Right to Development **Deadline: 30 November 2025**

### **ICH: E20 EWG Adaptive Designs for Clinical Trials**

ICH Public consultation dates:

ANMAT, Argentina - Deadline for comments by 8 October 2025

EC, Europe - Deadline for comments by 30 November 2025

Health Canada, Canada - Deadline for comments by 25 September 2025

MHRA, UK - Deadline for comments by 30 November 2025

Swissmedic, Switzerland - Deadline for comments by 30 November 2025

TFDA, Chinese Taipei - Deadline for comments by 13 October 2025

**USA, FDA, Deadline 12/01 2025 Docket No. FDA-2025-D-3023**

### **NEW - Call for inputs - Indigenous Peoples Free, Prior and Informed Consent, Business and Human Rights**

UNHCHR - Special Procedures **Deadline: 01 December 2025**

### **NEW - Public notice and comment on draft WHO Guidance on Evidence Generation for new tuberculosis diagnostics**

WHO - 7 November 2025 **Deadline: 5 December 2025**

### **NEW - Submission of information regarding national legislation, regulations and guidelines on new developments in modern biotechnology that are relevant to the Cartagena Protocol on Biosafety**

CBD Convention on Biological Diversity Notification 2025-138 31.10.2025

Submissions should be received **no later than 8 December 2025.**

### **NEW - Call for input - Draft General Comment No. 38 on Article 22 (Freedom of Association) of the International Covenant on Civil and Political Rights**

Treaty bodies **Deadline: 19 December 2025**

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**Advancing the Development of Pediatric Therapeutics (ADEPT) 10: Addressing Challenges in Neonatal Product Development-Leveraging Rare Disease Frameworks; Public Meeting**

A Notice by the Food and Drug Administration on 09/22/2025 **Public Participation only.**

The public workshop will be held on Wednesday, December 10, 2025, 1:00 p.m.—5:00 p.m. Eastern Time, and Thursday, December 11, 2025, from 8:30 a.m. until 4:00 p.m.

**Malaria: Developing Drugs for Treatment; Draft Guidance for Industry; Availability**

A Notice by the Food and Drug Administration on 09/23/2025. **Comment period ends 12/22/2025.**  
Docket No. FDA-2025-D-0918

**Post approval Methods To Capture Safety and Efficacy Data for Cell and Gene Therapy Products; Draft Guidance for Industry; Availability**

A Notice by the Food and Drug Administration on 09/25/2025 **Comment period ends 12/24/2025.**  
Docket No. FDA-2025-D-3049

**National Center for Complementary & Integrative Health; Notice of Meeting**

A Notice by the National Institutes of Health on 09/26/2025 **Comments no later than January 9th, 2026**

**NEW - Commission launches public consultation on CO2 markets and infrastructure**

EC - 6 October 2025 Directorate-General for Energy **The consultation is open until 9 January 2026.**

**Reflection paper on patient experience data**

EMA **Consultation dates: 29/09/2025 to 31/01/2026**  
Reference Number: EMA/CHMP/PRAC/148869/2025

**NEW - Call for Inputs: Study on “the rights of Indigenous Peoples in conflict and post-conflict situations”**

Issued by Expert Mechanism on the Rights of Indigenous Peoples **Deadline: 31 January 2026**

**NEW - Reflection paper on non-human primates in safety testing of human medicinal products and opportunities for 3Rs implementation**

EMA - Draft: consultation open **Consultation dates: 23/10/2025 to 31/01/2026**

**NEW - Call for input to the report of the Special Rapporteur on violence against women and girls to the 62nd session of the United Nations Human Rights Council on Violence against mothers**

UNHCHR - Special Procedures **Deadline: 06 February 2026**

**NEW - Call for input – Special Rapporteur on summary, extrajudicial or arbitrary executions – The death penalty from the perspective of the prohibition against torture and other forms of ill-treatment and the protection of human dignity**

UNHCHR - Special Procedures **Deadline: 08 February 2026**

**NEW - Public consultation on the COP30 Special Report on “Social Participation” for the implementation of the Belém Health Action Plan**

16 October 2025 14:00 – 15:00 CET **Submit your case by 1 April 2026**

**Invitation to comment on submissions of new descriptions and modifications to existing descriptions of areas meeting the criteria for ecologically or biologically significant marine areas (EBSAs)**

CBD Convention on Biological Diversity *Notification 2025-138 2025-11-01* Comments must be submitted by the CBD National Focal Point (with respect to States) or by the head of the organization **by 1 May 2026**

**ISO/AWI 14155 - Biological and clinical evaluation of medical devices**

ISO/TC 194 Stage 20.00

**Due: Ongoing at national standards bodies level**

**Contribute a tool - Catalogue of Tools & Metrics for Trustworthy AI**

OECD-AI Policy Observatory

***Contribute your tools and metrics to our catalogue. No deadline date identified.***

This catalogue is a platform where AI practitioners from all over the world can share and compare tools and metrics to help make AI trustworthy, build upon each other’s efforts to create global good practices, and speed up the process of implementing the OECD AI Principles. This catalogue can only exist with your contributions and those of AI practitioners from all sectors. You can also share your experience using a tool or metric by submitting a use case.

:: Contribute a tool

:: Share your experience using a tool

**A framework for evaluating rapidly developing digital and related technologies: AI, large language models and beyond - International Science Council Discussion Paper: Invitation to Comment**

International Science Council [ISC]

**No submission deadline date identified.**

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## Public Consultation Calls: Purpose/Objective/Scope/Background Information – Sorted by Thematic Area

### Biomedical Research/Regulation/Governance

#### **ICH: E20 EWG Adaptive Designs for Clinical Trials**

ICH Public consultation dates:

ANMAT, Argentina - Deadline for comments by 8 October 2025

EC, Europe - Deadline for comments by 30 November 2025

Health Canada, Canada - Deadline for comments by 25 September 2025

MHRA, UK - Deadline for comments by 30 November 2025

Swissmedic, Switzerland - Deadline for comments by 30 November 2025

TFDA, Chinese Taipei - Deadline for comments by 13 October 2025

**USA, FDA, Deadline 12/01 2025 Docket No. FDA-2025-D-3023**

The E20 EWG is working on the development of a new E20 Guideline on “Adaptive Clinical Trials” on the design, conduct, analysis, and interpretation of adaptive clinical trials that provides a transparent and harmonized set of principles for the regulatory review of these studies in a global drug development program. These principles should also provide the flexibility to evaluate / discuss innovative approaches to clinical trial design throughout the development process.

Rapporteur: Dr. Gregory Levin (FDA, United States)

Regulatory Chair: Dr. Christian Roes (EC, Europe)

Date of Step 2b: 25 June 2025 Status: Step 3

#### **Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry; Availability**

A Notice by the Food and Drug Administration on 09/25/2025 **Comment period ends 11/24/2025.**

Docket No. FDA-2017-D-6159 :: 21 pages

##### **SUMMARY:**

This guidance provides sponsors engaged in the development of regenerative medicine therapies for serious or life-threatening diseases or conditions with our recommendations on the expedited development and review of these therapies, including as provided under section 506(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by section 3033 of the 21st Century Cures Act (Cures Act). Under section 506(g) of the FD&C Act, a regenerative medicine therapy can be designated as a regenerative advanced therapy if it meets certain criteria. FDA refers to such designation as “regenerative medicine advanced therapy” (RMAT) designation (see section III.C of this document). This guidance describes the expedited programs available to sponsors of regenerative medicine therapies for serious conditions, including those products designated as RMATs. To that end, the guidance provides information about the provisions in the Cures Act regarding the use of the accelerated approval pathway for regenerative medicine therapies that have been granted designation as an RMAT. Finally, the guidance describes considerations in the clinical development of regenerative medicine therapies and opportunities for sponsors of such products to interact with the Center for Biologics Evaluation and Research (CBER) review staff. As a general matter, this guidance addresses regenerative medicine therapies regulated by CBER as biological products under the FD&C Act, section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), and applicable regulations.

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### **Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations; Draft Guidance for Industry; Availability**

A Notice by the Food and Drug Administration on 09/25/2025 **Comment period ends 11/24/2025.**

#### **SUMMARY:**

This guidance provides recommendations to sponsors who are planning clinical trials of cell and gene therapy (CGT) products intended for use in a disease or condition that affects a small population—generally one that meets the definition of a rare disease or condition under section 526(a)(2) of the FD&C Act (21 U.S.C. 360bb(a)(2)). It describes FDA requirements and provides considerations for the use of various clinical trial designs and endpoints to generate clinical evidence to support product licensure. This guidance expands on principles described in FDA’s existing guidance documents related to this topic, , by providing additional recommendations for the planning, design, conduct, and analysis of cell and gene therapy trials to facilitate FDA’s assessment of product effectiveness.

### **Meeting of the Advisory Council for the Elimination of Tuberculosis**

A Notice by the Centers for Disease Control and Prevention on 09/30/2025

The meeting will be held on December 9-10, 2025, from 12 p.m. to 5 p.m., EST. **Written comments by December 2, 2025.**

#### ***Supplementary Information***

#### **Purpose:**

The Advisory Council for the Elimination of Tuberculosis is charged with providing advice and recommendations regarding the elimination of tuberculosis (TB) to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, Centers for Disease Control and Prevention (CDC). Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; provides guidance and review on CDC’s Tuberculosis Prevention Research portfolio and program priorities; and reviews the extent to which progress has been made toward eliminating TB.

#### ***Matters to be Considered:***

The agenda will include discussions on: (1) CDC’s National Center for HIV, Viral Hepatitis, STD, and TB Prevention Update; (2) CDC’s Division of Tuberculosis Elimination Update; (3) Tuberculosis Trials Consortium Update; (4) Reported Tuberculosis in the United States, 2024 (5) Patient Centered Experience and Care; and the (6) Biennial Letter Workgroup Update. Agenda items are subject to change as priorities dictate.

Written Public Comment: Members of the public are welcome to submit written comments in advance of the meeting. Written comments must be submitted by emailing [nchhstppolicy@cdc.gov](mailto:nchhstppolicy@cdc.gov) with subject line “ACET December 2025 Written Public Comment Registration” by December 2, 2025.

Oral Public Comment: Individuals who would like to make an oral comment during the public comment period must register by emailing [nchhstppolicy@cdc.gov](mailto:nchhstppolicy@cdc.gov) with subject line “ACET December 2025 Oral Public Comment Registration” by December 2, 2025. The public comment period is on December 10, 2025, at 2 p.m., EST.

### **NEW - Public notice and comment on draft WHO Guidance on Evidence Generation for new tuberculosis diagnostics**

WHO - 7 November 2025 **Deadline: 5 December 2025**

The World Health Organization (WHO) invites all stakeholders to provide comments by 5 December 2025 on the draft Guidance on Evidence Generation (GEG) for new tuberculosis diagnostics (available [here](#)), by using this [feedback form](#).

The GEG is intended for researchers and other stakeholders involved in generating evidence to inform future WHO policy and operational guidance on tuberculosis (TB) diagnostic testing. Its objectives are to:

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This draft of the GEG has been developed after in-depth consultation with researchers, national TB programmes, technical agencies, regulatory agencies, civil society organisations, and donors. The final version of the GEG is expected to be published in the first half of 2026, after incorporation of feedback during this public comment period and further expert review.

### **Advancing the Development of Pediatric Therapeutics (ADEPT) 10: Addressing Challenges in Neonatal Product Development—Leveraging Rare Disease Frameworks; Public Meeting**

A Notice by the Food and Drug Administration on 09/22/2025 **Public Participation only.**

The public workshop will be held on Wednesday, **December 10, 2025**, 1:00 p.m.—5:00 p.m. Eastern Time, and Thursday, December 11, 2025, from 8:30 a.m. until 4:00 p.m.

#### **SUMMARY:**

The Food and Drug Administration (FDA or we) is announcing the following public workshop entitled “Advancing the Development of Pediatric Therapeutics (ADEPT) 10: Addressing Challenges in Neonatal Product Development—Leveraging Rare Disease Frameworks.” The aim of the public workshop is to discuss common challenges in neonatal and rare disease product development and identify opportunities to leverage rare disease product development frameworks in the neonatal product development space.

#### **DATES:**

The public workshop will be held on Wednesday, December 10, 2025, 1:00 p.m.—5:00 p.m.

#### **I. Background**

Since 2014, FDA has hosted an annual public workshop focused on Advancing the Development of Pediatric Therapeutics (ADEPT). The ADEPT Workshops offer opportunities for stakeholders to meet to discuss challenging scientific issues related to pediatric product development and pediatric regulatory science. The primary aims of ADEPT Workshops are to:

- Discuss advancements in pediatric therapeutics development;
- Identify gaps in current knowledge and explore innovative approaches to address those gaps; and
- Provide a platform for open dialogue between regulators, industry, academia, and patient organizations.

#### **II. Topics for Discussion at the Public Workshop**

The specific topics for discussion at this workshop include, but are not limited to, the following:

- identifying common challenges in neonatal and rare disease product development;
- discussing ethical considerations relevant to neonatal and rare disease product development;
- identifying opportunities to leverage rare disease tools and strategies for neonatal conditions; and
- discussing the regulatory landscape of rare disease programs/resources and their application to neonatal conditions.

### **Malaria: Developing Drugs for Treatment; Draft Guidance for Industry; Availability**

A Notice by the Food and Drug Administration on 09/23/2025. **Comment period ends 12/22/2025.**

Docket No. FDA-2025-D-0918

#### **SUMMARY:**

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Malaria: Developing Drugs for Treatment.” The purpose of this draft guidance is to assist sponsors in the overall development program for drug and biological products for the treatment of malaria, caused by clinically relevant Plasmodium species.



### **Post approval Methods To Capture Safety and Efficacy Data for Cell and Gene Therapy Products; Draft Guidance for Industry; Availability**

A Notice by the Food and Drug Administration on 09/25/2025 **Comment period ends 12/24/2025.**

Docket No. FDA-2025-D-3049

#### ***SUMMARY:***

The purpose of this guidance is to discuss methods and approaches for capturing post approval safety and efficacy data for cell and gene therapy (CGT) products. Given the potential for long-lasting effects of CGT products, and the generally limited number of participants treated in clinical trials conducted to support approval of CGT products, post approval monitoring is important for gathering data on product safety and effectiveness over time. This guidance does not address data collected for the purpose of expanding clinical indications.

### **National Center for Complementary & Integrative Health; Notice of Meeting**

A Notice by the National Institutes of Health on 09/26/2025 **Comments no later than January 9th, 2026**

#### ***Agenda:***

Reports and Updates about Recent and Ongoing NCCIH Led or Involved Activities by NCCIH staff and its Director. Once available, the open session meeting link can be accessed at the Institute's/Center's home page: <https://nccih.nih.gov/about/nacchih>.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should be less than 700 words in length, and should include the name, email address, telephone number and when applicable, the business or professional affiliation of the interested person. Any member of the public may submit written comments no later than January 9th, 2026 (14 days before the council meeting).

### **Reflection paper on patient experience data**

EMA **Consultation dates: 29/09/2025 to 31/01/2026**

Reference Number: EMA/CHMP/PRAC/148869/2025

#### ***Scope***

The purpose of this reflection paper is to encourage systematic consideration of PED in medicine 86 development programmes and regulatory submissions. It also describes general principles on the use of PED across the lifecycle of medicinal products (i.e. during pre-authorisation, benefit-risk evaluation and post-authorisation) and identifies types of PED 8and main sources of PED. The target audiences of this document are medicine developers, regulators, researchers and patient 91 groups who generate, collect and review PED.

Comments should be provided using this [form](#). The completed comments form should be sent to [PED\\_RP@ema.europa.eu](mailto:PED_RP@ema.europa.eu)

### **ISO/AWI 14155 - Biological and clinical evaluation of medical devices**

ISO/TC 194 Stage 20.00

**Due: Ongoing at level of national standards bodies**

#### ***Scope***

Standardization of the approach to biological and clinical evaluation of medical and dental materials and devices together with standardization of biological test methods applicable to those materials and devices as well as good clinical practice principles to clinical investigations in humans of those devices.

#### ***Abstract***

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This document addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical devices.

For post-market clinical investigations, the principles set forth in this document are intended to be followed as far as relevant, considering the nature of the clinical investigation (see Annex I).

This document specifies general requirements intended to

- protect the rights, safety and well-being of human subjects,
- ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results,
- define the responsibilities of the sponsor and principal investigator, and
- assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

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## **Human Rights**

### **Call for input for EMRTD study "Artificial Intelligence, Cultural Rights, and the Right to Development"**

Issued by UN Expert Mechanism on the Right to Development **Deadline: 30 November 2025**

#### *Purpose:*

To inform the drafting of EMRTD's thematic study on "Artificial Intelligence (AI), Cultural Rights, and the Right to Development." This study is part of the Mechanism's broader mandate to examine emerging global challenges that impact the realization of the right to development.

#### *Background*

The Human Rights Council, in its resolution [45/6](#), welcomed the first report ([A/HRC/45/29](#)) of the [Expert Mechanism on the Right to Development](#), and requested it to implement the recommendations contained therein, including the preparation and submission to the Council thematic studies in the discharge of Expert Mechanism's mandate. At its [8th session](#), the EMRTD outlined the thematic studies that it planned to submit to the Human Rights Council during the 2024-2026 cycle, including a study addressing artificial intelligence, regulation and the right to development.

### **Call for inputs - Indigenous Peoples Free, Prior and Informed Consent, Business and Human Rights**

UNHCHR - Special Procedures **Deadline: 01 December 2025**

#### *Purpose:*

To inform the Working Group on BHR on Indigenous Peoples free, prior and informed consent, business and human rights

#### *Background*

The Working Group on Business and Human Rights has systematically stressed that meaningful engagement with Indigenous Peoples and communities includes meeting international standards on the right to free, prior and informed consent (FPIC). However, based on its ongoing engagement with Indigenous Peoples throughout its activities, including country visits, business and human rights Forums and regular consultations, the Working Group has observed a consistent gap in the effective implementation by States and businesses of FPIC requirements in the context of business activities.



The Human Rights Council, in its [resolution 59/25](#) of 8 July 2025 entitled “Human rights and climate change” (para. 24), has requested the Secretary-General to consult Member States and other relevant stakeholders in order to prepare and submit to its sixty-third session a synthesis report on actionable pathways in mobilizing sufficient climate financing and associated challenges and opportunities in the pursuit of the full realization of human rights for all people.

**NEW - Call for Inputs: Study on “the rights of Indigenous Peoples in conflict and post-conflict situations”**

Issued by Expert Mechanism on the Rights of Indigenous Peoples **Deadline: 31 January 2026**

*Purpose:*

In accordance with Human Rights Council resolution 33/25, the purpose of the annual study is to analyse the status of the rights of Indigenous Peoples worldwide in the achievement of the ends of the Declaration, focusing on one or more interrelated articles of the Declaration, at its own choice.

**NEW - Reflection paper on non-human primates in safety testing of human medicinal products and opportunities for 3Rs implementation**

EMA - Draft: consultation open **Consultation dates: 23/10/2025 to 31/01/2026**

Reference Number: EMA/CHMP/55697/2025

*Summary:*

This reflection paper aims to provide an overview of the scientific and regulatory considerations for non-human primate use in safety testing of human medicinal products. It highlights the existing flexibility within published guidelines to incorporate 3Rs approaches and describes novel alternative approaches which may become available in the future. Notwithstanding the detailed conditions outlined herein, some important examples include; use of rodent species (including transgenics) only to evaluate repeat dose toxicity, the waiving of long-term (6 month) studies to evaluate the safety risk associated with monoclonal antibodies, the use of alternative assays to predict malformations or embryo-foetal lethality in developmental and reproductive toxicity.

Comments should be provided using this [EUSurvey form](#)

**NEW - Call for input to the report of the Special Rapporteur on violence against women and girls to the 62nd session of the United Nations Human Rights Council on Violence against mothers**

UNHCHR - Special Procedures **Deadline: 06 February 2026**

*Objectives*

The Special Rapporteur seeks to receive input to examine the forms and manifestations of violence experienced by women and girls because of their status as mothers, including where that status intersects with other grounds. It will be the first report on this subject to the UN Human Rights Council, presented at its 62nd session.

The purpose of the report is to highlight in a comprehensive manner the patterns of discrimination and violence against mothers that are often overlooked; review current policies and practices to end severe discrimination and violence against mothers highlight good practices as well as respond to the needs of mothers that are survivors of violence. The report also intends to offer recommendations for legal, policy, and institutional measures to address them in a manner consistent with international human rights law.

**NEW - Call for input – Special Rapporteur on summary, extrajudicial or arbitrary executions – The death penalty from the perspective of the prohibition against torture and other forms of ill-treatment and the protection of human dignity**

UNHCHR - Special Procedures **Deadline: 08 February 2026**

*Objectives*

The objective of the report is to examine the death penalty from the perspective of the prohibition against torture and other forms of ill-treatment under international law and based on medical and legal evidence.

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**Emerging/Disruptive Technologies**

***:: Call for Public Consultation***

*No new calls identified.*

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**Biodiversity/Environment/Climate/Disaster Mitigation**

**NEW - Submission of information regarding national legislation, regulations and guidelines on new developments in modern biotechnology that are relevant to the Cartagena Protocol on Biosafety**

CBD Convention on Biological Diversity Notification 2025-138 31.10.2025

Submissions should be received **no later than 8 December 2025.**

*Overview*

In its decision CP-11/1 C, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety encouraged Parties to submit information regarding national legislation, regulations and guidelines on new developments in modern biotechnology that are relevant to the Cartagena Protocol on Biosafety and not published in the Biosafety Clearing-House.

**NEW - Commission launches public consultation on CO2 markets and infrastructure**

EC - 6 October 2025 Directorate-General for Energy **The consultation is open until 9 January 2026.**

*Overview*

The European Commission has identified the need to considerably scale-up and invest in clean energy infrastructure and technologies, such as CO<sub>2</sub> infrastructure and storage, as we work to achieve climate neutrality by 2050. For this reason, the Commission has today launched an open public consultation on upcoming legislation and impact assessment on CO<sub>2</sub> markets and infrastructure in the EU. The consultation is open until 9 January 2026. The feedback received will inform the Commission's initiative planned for 2026.

**NEW - Public consultation on the COP30 Special Report on "Social Participation" for the implementation of the Belém Health Action Plan**

16 October 2025 14:00 – 15:00 CET **Submit your case by 1 April 2026**

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In the run up to COP30, WHO in collaboration with the Ministry of Health (MoH) Brazil held a public consultation for a preview of a supporting document for the Belém Health Action Plan – the Special Report on “Social Participation” for Implementation.

This consultation continued to collect ideas and examples after COP30 through to Bonn, showcasing diverse forms of social participation by civil society, NGOs, social movements, and other initiatives that advance climate and health action globally.

This public consultation aimed to:

- Present the outline and framing of the paper on Social Participation and Governance in Health and Climate Change.
- Gather feedback and examples that can strengthen the paper’s evidence base and practical relevance.
- Identify and document case studies of participatory health and climate initiatives, particularly those advancing equity, resilience, and justice.

### **Invitation to comment on submissions of new descriptions and modifications to existing descriptions of areas meeting the criteria for ecologically or biologically significant marine areas (EBSAs)**

CBD Convention on Biological Diversity *Notification 2025-138 2025-11-01* Comments must be submitted by the CBD National Focal Point (with respect to States) or by the head of the organization **by 1 May 2026**

#### *Overview*

The present notification is to inform Parties, other Governments, competent intergovernmental organizations, indigenous peoples and local communities, and other relevant stakeholders that the Secretariat has received submissions containing descriptions of new areas meeting the criteria for ecologically or biologically significant marine areas (EBSAs), as well as modifications to existing EBSA descriptions. These submissions have been uploaded to the webpage for submissions within national jurisdiction for inclusion in the repository, at <https://www.cbd.int/ebsa/ism/submissions/records1>. A list of these submissions is provided in annex I to this notification.

In line with the modalities provided in the annex to decision 16/16, Parties, other Governments, competent intergovernmental organizations, indigenous peoples and local communities, and other relevant stakeholders are hereby invited to submit comments on these submissions. This comment period will be open for six months from the date of the present notification.

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### **Science Integrity/Evidence to Policy/ Open Science**

#### ***:: Call for Public Consultation***

*No new calls identified.*

#### ***:: Resources, Events***

### **The Right to Participate in and Benefit from Science – Call for Feedback**

ISC / International Science Council

21 November 2024

The ISC’s interpretation of ‘the right to participate in and benefit from science’ provides a clear framework for understanding the right to science, emphasizing its application in research, policy, and global access to scientific knowledge. It clarifies the obligations, opportunities, and responsibilities in

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ensuring universal access to science, fostering global dialogue to shape a more inclusive and sustainable future.

### **ISC – The Right to Participate in and Benefit from Science**

The International Science Council believes that there is a universal human right to participate in and enjoy the benefits of science, and that it is a responsibility of governments to create and sustain the opportunities of citizens to use this right.

#### **A right to participate in science**

This right presumes a right to basic scientific literacy, and a right to scientific education, training and mentoring.

- I. A right to participate in generating diverse forms of knowledge through the study of natural and social phenomena using theoretical, observational, experimental, and analytical approaches to introduce and test existing and new models, conjectures, hypotheses and ideas unconstrained by political agendas or belief systems.
- II. A right to challenge established knowledge about natural and social phenomena when generating and communicating new models, conjectures, hypotheses and ideas, and the uses to which this knowledge has been or may be put.
- III. A right to collaborate and engage in scientific dialogue and research across national, political, regional and other boundaries.
- IV. A right to communicate both positive and negative findings.
- V. A right to form professional societies and associations.
- VI. A right to advocate for the responsible use of science.

#### **A right to enjoy the benefits of science**

- I. A right not to be excluded from the benefits of science on the basis of unjust discrimination based on race, nationality, ethnic origin, language, sex, gender identity, reproductive ability, sexual orientation, age, disability, political opinion, or religious belief.
- II. A right to equitably access information, data, and other resources necessary to enhance scientific knowledge, teaching and research.
- III. A right to apply scientific knowledge for technological developments for the good of humanity and the planet.

#### **:: Resources, Events**

*No new resources identified.*

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### **Heritage/Cultural Assets**

#### **:: Call for Public Consultation**

*No new calls identified.*

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### **Governance, Peace, Trade, Global Finance**

#### **:: Call for Public Consultation**

*No new calls identified.*

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## :: Resources, Events

### **Information Report: Oversight Observations To Inform Department of State Realignment of U.S. Agency for International Development Functions**

AUD-GEER-25-19 May 2025

#### *Summary of Review*

On March 28, 2025, the Department of State (Department) notified Congress of its intent to realign selected U.S. Agency for International Development (USAID) functions within the Department. The information report, which was developed as part of an Office of Inspector General (OIG) evaluation of the Department's initial realignment efforts, is designed to highlight OIG observations from its prior work, and the work of other federal oversight bodies, that could help the Department more efficiently and effectively realign USAID functions.

OIG concluded that the Department is undertaking a significant and multi-faceted integration of select USAID functions concurrent with a reorganization of domestic offices and bureaus in the Department. Individually, these tasks would be daunting. But together, these initiatives could be overwhelming to the organization without a well thought out plan of action. During its work, OIG observed that senior Department leaders involved in the realignment are aware of the challenges that they face. Additionally, OIG recognizes that the Department's Assistance Transition Working Group has established workstreams related to many of the topics discussed in the OIG report.

Although OIG did not make formal recommendations in the report, OIG encourages the Department to consider how issues identified by OIG and other oversight organizations might impact the success of the Department's efforts. Considering previously identified issues will allow the Department to implement best practices.

Although the focus of the information report is the realignment of USAID functions within the Department, the information may also be applicable to the Department's efforts to implement its internal reorganization.

### **Strategic Foresight Toolkit for Resilient Public Policy**

*A Comprehensive Foresight Methodology to Support Sustainable and Future-Ready Public Policy*

**OECD Report** 21 January 2025

PDF: [https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/01/foresight-toolkit-for-resilient-public-policy\\_9ad1cd60/bcdd9304-en.pdf](https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/01/foresight-toolkit-for-resilient-public-policy_9ad1cd60/bcdd9304-en.pdf)

#### *Abstract*

By exploring 25 evidence-based potential disruptions across environmental, technological, economic, social, and geopolitical domains, the Strategic Foresight Toolkit for Resilient Public Policy helps anticipate challenges and opportunities that could reshape the policy landscape between 2030 and 2050. These disruptions are not predictions, but hypothetical future developments identified through extensive research, expert consultations, and workshops.

The Strategic Foresight Toolkit features a five-step foresight process, guiding users to challenge assumptions, create scenarios, stress-test strategies, and develop actionable plans. It includes facilitation guides and case studies to support effective implementation. Each disruption is accompanied by insights on emerging trends, potential future impacts, and both immediate and long-term policy options to ensure resilience and preparedness.

Designed for policymakers, public administrators, and foresight practitioners, this publication is designed to promote holistic, strategic and evidence-informed decision-making. It aims to support countries and organisations in using strategic foresight to design and prepare robust and adaptable public policies for a range of possible futures. With its practical methodology and forward-looking approach, the Strategic Foresight Toolkit is a vital resource for building sustainable, resilient, and effective public policies.

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## **Public Integrity Indicators**

OECD - Datasetdata-explorer.oecd.org

14 February 2025

Interactive Graphic: [OECD Public Integrity Indicators](#)

### *Overview*

Following the adoption of the [OECD Council Recommendation on Public Integrity](#) in 2017, the Public Governance Committee (PGC), via its Working Party of Senior Public Integrity Officials (SPIO) subsidiary body, developed the [OECD Public Integrity Indicators](#) (PII) to measure the implementation of the OECD Council Recommendation on Public Integrity. The PII are complementary to the [OECD Public Integrity Handbook](#) and the [OECD Public Integrity Maturity Models](#).

The OECD Public Integrity Indicators (PII) measure the quality and effectiveness of public integrity systems across six areas:

- Quality of Strategic Framework (data available)
- Accountability of Public Policymaking – covering conflict-of-interest, political finance, lobbying, public information, open government, and public consultation (data available)
- Effectiveness of Internal Control and Risk Management (data available)
- Integrity and Effectiveness of the Justice System (to be launched in 2024)
- Strength of External Oversight and Control (to be launched in 2024)
- Meritocracy of the Public Sector (to be launched in 2025)

The OECD Public Integrity Indicators provide cross-country comparative data to help policy makers and practitioners strengthen the resilience of public integrity systems towards corruption risks and prevent the mismanagement and waste of public funds. The PIIs measure the strength of standard regulatory safeguards (*de jure*) and implementation of these safeguards in practice (*de facto*). The OECD Secretariat collaborates closely with national administrations to obtain primary data collected directly from a wide range of actors across the executive, legislative and judiciary branches.

## **Regulatory governance**

OECD Datasetdata-explorer.oecd.org

14 February 2025

### *Overview*

The OECD Dataset on the Indicators of Regulatory Policy and Governance (iREG) presents up-to-date evidence of regulatory policy and governance practices of the OECD member countries, the European Union as well as the five EU Member States that are not OECD member countries. It focuses on practices as described in the 2012 Recommendation of the Council on Regulatory Policy and Governance (Recommendation), the first international instrument to address regulatory policy as a whole-of-government activity. The data covers in detail three principles of the 2012 Recommendation: stakeholder engagement, regulatory impact assessment (RIA) and *ex post* evaluation. For each of these areas, the indicators present information in four categories:

1. Systematic adoption records formal requirements and how often these requirements are conducted in practice;
2. Methodology gathers information on the methods used in each area, e.g. the type of impacts assessed or how frequently different forms of consultation are used;
3. Oversight and quality control records the role of oversight bodies and publically available evaluations; and
4. Transparency records information that relates to the principles of open government, e.g. whether government decisions are made publically available.

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## **Selected Calls for Public Consultation of Global Interest but Limited to State Parties or Other Designated Entities**

*No new calls identified.*

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## **Selected Final, Published Guidances, Frameworks, Regulations, Meetings Employing Calls for Public Consultation**

### **E6(R3) Good Clinical Practice; International Council for Harmonisation; Guidance for Industry; Availability**

A Notice by the Food and Drug Administration on 09/09/2025

#### ***SUMMARY:***

The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “E6(R3) Good Clinical Practice.” The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance includes a principles document and annex 1 and is the precursory guidance to the draft guidance entitled “E6(R3) Good Clinical Practice: Annex 2.” Once complete, the guidance will be composed of a principles document, annex 1, and annex 2. The guidance is intended to outline flexible and modern good clinical practices for conducting clinical trials. Notably, the guidance highlights the importance of quality-by-design, proportionality, and risk-based approaches in conducting clinical trials to ensure safety and reliability of results. The guidance also encourages use of innovative design elements and technology in clinical trials, while avoiding unnecessary complexities. The guidance finalizes the draft guidance of the same title issued on June 7, 2023.

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## **Selected Peer-reviewed Journal Literature/Gray Lit Integrating Public Consultation**

### **OECD Guidelines for Citizen Participation Processes**

Paris: OECD Publishing. 2022

[https://www.oecd-ilibrary.org/governance/oecd-guidelines-for-citizen-participation-processes\\_f765caf6-en](https://www.oecd-ilibrary.org/governance/oecd-guidelines-for-citizen-participation-processes_f765caf6-en) [Accessed 10 Nov 2023]

The *OECD Guidelines for Citizen Participation Processes* are intended for any public official or public institution interested in carrying out a citizen participation process. The guidelines describe ten steps for designing, planning, implementing and evaluating a citizen participation process, and discuss eight different methods for involving citizens: information and data, open meetings, public consultations, open innovation, citizen science, civic monitoring, participatory budgeting and representative deliberative processes. The guidelines are illustrated with examples as well as practical guidance built on evidence gathered by the OECD. Finally, nine guiding principles are presented to help ensure the quality of these processes.

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## Selected Resources for Public Consultation Notices, Calls, Processes

### **UNHCHR UN High Commissioner for Human Rights – Calls for Input**

<https://www.ohchr.org/en/calls-for-input-listing>

### **UNESCO - Consultations**

[https://www.unesco.org/en/search?category=UNESCO&text=consultation&category=UNESCO&sort\\_by=unesco\\_date#toggle-facets](https://www.unesco.org/en/search?category=UNESCO&text=consultation&category=UNESCO&sort_by=unesco_date#toggle-facets)

### **WHO – Public Consultations**

<https://www.who.int/home/search?indexCatalogue=genericsearchindex1&searchQuery=public%20consultation&wordsMode=AnyWord>

### **OECD - Consultations and calls for contributions**

<https://www.oecd.org/about/civil-society/consultations-and-calls-for-contributions.htm>

### **IFAD Public Consultations**

<https://webapps.ifad.org/members/executive-board-public-consultation>

### **European Medicines Agency's (EMA) open public consultations**

<https://www.ema.europa.eu/en/news-events/open-consultations>

### **U.S. Federal Register – “Public Comment” or RFI**

[https://www.federalregister.gov/documents/search?conditions%5Bpublication\\_date%5D%5Bgte%5D=09%2F13%2F2023&conditions%5Bterm%5D=%22public+comment%22+or+RFI#](https://www.federalregister.gov/documents/search?conditions%5Bpublication_date%5D%5Bgte%5D=09%2F13%2F2023&conditions%5Bterm%5D=%22public+comment%22+or+RFI#)

### **U.S. HHS – Open Requests for Comments**

<https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html>

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