

ge²p² global

governance, ethics, evidence, policy, practice

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

Issue 39 :: 19 Mar 2026

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].

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.

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

Proposed Data Collection Submitted for Public Comment and Recommendations [Autism]

A Notice by the Centers for Disease Control and Prevention on 01/27/2026

This document has a **comment period that ends in 52 days. (03/30/2026)**

NEW - Agency Information Collection Request; 30-Day Public Comment Request

A Notice by the Health and Human Services Department on 02/27/2026

This document has a **comment period that ends 03/30/2026/**

Concept paper on the guideline revision on good pharmacogenomic practice

EMA Draft: consultation open Consultation dates: 09/12/2025 to **31/03/2026**

Reference Number: EMA/282050/2025 Summary:

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**

NEW - Call for public consultation – R&D roadmap for arenavirus medical countermeasures

WHO - Call for consultation 12 March 2026 Please **submit your comments by 6 April 2026 –**

E22 General Considerations for Patient Preference Studies; International Council for Harmonisation; Draft Guidance for Industry; [ICH - Availability]

A Notice by the Food and Drug Administration on 02/06/2026

This document has a comment period that **ends in 60 days. (04/07/2026)**

NEW - Proposed Collection; 30-Day Comment Request; NIH Information Collection Web Interface and Forms To Support Genomic Data Sharing and NIH Controlled-Access Data Repository Requirements (OD)

A Notice by the National Institutes of Health on 03/12/2026 **Deadline: April 13, 2026.**

NIH Pause on New Submissions to the NIH Human Embryonic Stem Cell Registry and Request for Information on Reducing Reliance on Human Embryonic Stem Cells in NIH-Supported

NIH Number: NOT-OD-26-031

Release Date: January 23, 2026 **Response Date: April 24, 2026**

NEW - Considerations for the Use of the Plausible Mechanism Framework To Develop Individualized Therapies That Target Specific Genetic Conditions With Known Biological Cause; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 02/25/2026 **Comment period ends 04/27/2026**

NEW - Draft guidance on the conduct of clinical trials during public health emergencies

EMA - Draft: consultation open Consultation dates: 04/03/2026 to **30/04/2026**

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Reference Number: EMA/44884/2026 Summary:

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**

NEW - General Considerations for the Use of New Approach Methodologies in Drug Development; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 03/19/2026 **Comment period that ends 05/18/2026**

FDA Rare Disease Innovation Hub Future Programming; Request for Comments

A Notice by the Food and Drug Administration on 01/30/2026

This document has a **comment period that ends in 328 days. (12/31/2026)**

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

WMA - Declaration of Taipei Revision Launched [Ongoing]

...The Declaration of Taipei tries to achieve a balance between the rights of individuals giving their tissue or data for research and other purposes based on confidentiality and privacy rules while at the same time recognising that health data has become a very powerful tool for increasing knowledge.

In analysing the scenarios that already exist for the use (and misuse) of health data and biobanks, we came to the conclusion that the major risk scenarios may not result from science, but from the commercial, administrative or political use of such data. Limiting our guidelines to research only would have left us blind to the imminent risk of abuse from outside the field of medicine: commercialization, cost-cutting and potential political abuse.

Therefore, in contrast to the Declaration of Helsinki, this policy aims to address any use of health databases and biobanks excluding individual treatment and is not restricted to research. As physicians are the primary custodians of confidential health information, they feel an obligation towards their patients and other persons who entrust them with their data and specimens...

In April 2025, the WMA appointed a workgroup to initiate the revision process of this document. To encourage as much global participation in the revision process as possible, the WMA is collaborating with its members to host a series of regional meetings...

NEW - NIH-Wide Strategic Plan – Public Input

[No due date identified]

NIH seeks community feedback on the next Agency-Wide Strategic Plan. This plan will guide our work over the next five years to fulfill our mission. Input from researchers, other stakeholders, and the general public is essential to ensure transparency in what we do and advance the principles of gold standard science that we all apply to our daily work.

NIH will hold two webinars to gather input from the research community, stakeholders, and the public on the framework that will inform development of the plan:

March 16, 2026, 12:30 to 1:30 PM ET – Registration Link

April 8, 2026, 2:30 to 3:30 PM ET – Registration Link

NEW - Agency Information Collection Request; 30-Day Public Comment Request

A Notice by the Health and Human Services Department on 02/27/2026

This document has a **comment period that ends 03/30/2026/**

Abstract:

HHS, ASPR is seeking approval by OMB on an extension of the existing clearance (OMB Control Number: 0990-0488, Expiration Date: March 31, 2026). HHS is working with the White House and across the federal interagency to launch a multiyear implementation involving the identification and coordination of measurable activities across the United States government, state, local, tribal, and territorial (SLTT) jurisdictions, and private sector partners. Cross-sectoral engagement is the underpinning of many of the interdependent implementation activities. For example, **one such activity involves information collection from SLTT partners on facility, local, and state stockpiling plans to ensure coordinated plans are in place for a future public health emergency.** Potential engagements include, and are not limited

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to, surveys, stakeholder meetings, requests for information (RFI), town hall meetings, and workshops. With each of these different mechanisms of engagement, there is a varied frequency ranging from single engagements to regularly recurring meetings.

Proposed Data Collection Submitted for Public Comment and Recommendations [Autism]

A Notice by the Centers for Disease Control and Prevention on 01/27/2026

This document has a **comment period that ends in 52 days. (03/30/2026)**

SUMMARY:

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comments on a proposed information collection project titled Survey to Promote Resources and Opportunities for aUtistic Teens and young adults (SPROUT). This follow-up survey will allow CDC to collect longitudinal data on prior participants in the Study to Explore Early Development (SEED) and family members in order to better understand the healthcare utilization, service and support needs, and impact of co-occurring conditions on autistic adolescents and young adults and their families, as well as the educational, social, and/or vocational needs and experiences of autistic adolescents and young adults.

Concept paper on the guideline revision on good pharmacogenomic practice

EMA Draft: consultation open Consultation dates: 09/12/2025 to **31/03/2026**

Reference Number: EMA/282050/2025 Summary:

The proposed revised guideline will replace the 'Guideline on good pharmacogenomic practice' (EMA/CHMP/718998/2016). Comments should be provided using this [EUSurvey form](#)

Problem statement

Scientific advancements in the field of pharmacogenomics necessitate a revision of the existing guideline to ensure its continued relevance and applicability. In addition to incorporating new scientific knowledge, this revision aims to provide greater clarity on topics already covered, facilitating more precise and actionable guidance for regulators and stakeholders. The issues requiring major revisions or inclusion of new guidance are:

1. Pharmacogenomic methodology
 - a. Sequencing technologies
 - b. Specific analytical issues
 - i. Polymorphic genes & substrate specificity
 - ii. Deoxyribonucleic acid (DNA) variants in subpopulation
 - iii. Proficiency testing
2. Interpretations and recommendations
 - a. Phenotype and genotype correlations
 - b. General versus specific medicinal product use recommendations
3. Reporting and nomenclature
4. Pharmacogenomic study design
 - a. Interventional studies
 - b. Non-interventional studies

NEW - Call for public consultation – R&D roadmap for arenavirus medical countermeasures

WHO - Call for consultation 12 March 2026 Please **submit your comments by 6 April 2026** –

In 2024 the WHO R&D Blueprint team launched the Collaborative Open Research Consortia (CORCs) to support the Pathogens Prioritization Framework, bringing together a coordinated global research

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community to advance research across various priority pathogen families. The UK Health Security Agency (UKHSA) leads the CORC on arenaviruses and bunyaviruses.

In July 2025 a global meeting of 170 experts was held to discuss the research priorities across the arenavirus family, which informed the development of the *Arenaviridae* research and development roadmap. This roadmap highlights primary challenges, research priorities, and time-phased milestones across the following themes: reservoirs and transmission, surveillance, viral family biology, diagnostics, therapeutics, vaccines, regulatory and clinical development, and social and behavioural science and community engagement.

The CORC has also collectively identified 10 R&D priorities across these themes.

[R&D roadmap for arenavirus medical countermeasures](#)

You are invited to review the roadmap and input any feedback via this feedback form: [Feedback form](#)

E22 General Considerations for Patient Preference Studies; International Council for Harmonisation; Draft Guidance for Industry; [ICH - Availability]

A Notice by the Food and Drug Administration on 02/06/2026

This document has a comment period that **ends in 60 days. (04/07/2026)**

SUMMARY:

The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled “E22 General Considerations for Patient Preference Studies.” The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). When finalized, this guidance will provide general principles for the use, design, conduct, analysis, and submission of patient preference studies (PPS) aimed at informing drug development, regulatory submission and evaluation, drug approvals, and maintenance of such approvals.

NEW - Proposed Collection; 30-Day Comment Request; NIH Information Collection Web Interface and Forms To Support Genomic Data Sharing and NIH Controlled-Access Data Repository Requirements (OD)

A Notice by the National Institutes of Health on 03/12/2026 **Deadline: April 13, 2026.**

... The NIH GDS Policy expects large-scale human genomic and associated data generated using NIH funds to be submitted to an NIH-designated repository, which is an NIH Controlled-Access Data Repository (<https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/accessing-data/requirements>). As a part of that submission, the submitting institution certifies to NIH that the data are appropriate to share through the completion and submission of a data submission form. The data are then made available for secondary research use to qualified Principal Investigators and their institutions after submission of a Data Access Request (DAR) to the NIH Data Access Committee (DAC) for review and approval.

The database of Genotypes and Phenotypes (dbGaP), administered by the National Library of Medicine (NLM), the National Center for Biotechnology Information (NCBI), provides an online system to support data registration and submission as a NIH-designated repository, as well as for providing an online system for access to these data through the Authorized Access System....

NIH Pause on New Submissions to the NIH Human Embryonic Stem Cell Registry and Request for Information on Reducing Reliance on Human Embryonic Stem Cells in NIH-Supported

NIH Number: NOT-OD-26-031

Release Date: January 23, 2026 **Response Date: April 24, 2026**

Purpose

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NIH is assessing research areas ripe for modernization and is seeking public comment on the robustness of emerging biotechnologies to reduce or potentially replace reliance on human embryonic stem cells (hESCs) for research. During this review, NIH is pausing review and approval of applications for new hESC lines to be added to the NIH Human Embryonic Stem Cell Registry.

Now is an opportune time to assess the utility of hESCs in biomedical research, specifically, areas of research that could not occur, or areas in which newer, validated models could serve as a replacement. Accordingly, NIH is requesting public input on the following research areas:

1. Research areas in which currently approved hESC lines sufficiently meet the needs of the research community as well as research areas for which new hESC lines are needed;
2. Research areas for which hESCs are the gold standard and could not be pursued if hESCs were unavailable;
3. Research areas in which the robustness of emerging biotechnologies such as induced pluripotent stem cells, adult stem cells, etc., can replace the use of hESCs;
4. Research areas in which additional investments should be made to bolster validated models to replace use of hESCs.

NEW - Considerations for the Use of the Plausible Mechanism Framework To Develop Individualized Therapies That Target Specific Genetic Conditions With Known Biological Cause; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 02/25/2026 **Comment period ends 04/27/2026**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Considerations for the use of the Plausible Mechanism Framework to Develop Individualized Therapies that Target Specific Genetic Conditions with Known Biological Cause.” The draft guidance document describes considerations for generating substantial evidence of effectiveness and evidence of safety of individualized therapies based on a plausible mechanism framework. The guidance specifically discusses genome editing and RNA-based therapies; however, the general concepts may apply to other types of individualized therapies. Specifically, the draft guidance applies when clinical evidence from a limited number of patients will be available to support the individualized product's safety or efficacy in the intended patient population.

NEW - Draft guidance on the conduct of clinical trials during public health emergencies

EMA - Draft: consultation open Consultation dates: 04/03/2026 to **30/04/2026**

Reference Number: EMA/44884/2026 Summary:

In case of serious cross-border threats that endanger public health in the European Union (EU), as defined in Article 3(1) of Regulation (EU) 2022/2371 -including pandemic situations-, the European Commission may declare a public health emergency (PHE) at EU level. Serious cross-border threats can be of biological, chemical, environmental or unknown origin, or may correspond to public health emergencies of international concern under the International Health Regulations, as described in Article 2 of Regulation (EU) 2022/2371.

Before declaring a PHE, the European Commission will consider expert opinions from the European Centre for Disease Prevention and Control, and from other relevant bodies, such as Commission expert groups, EU Agencies and the Advisory Committee established under Regulation (EU) 2022/2371. The Commission will also liaise with the World Health Organization to share its analysis and inform it of a planned declaration of a PHE at EU level.

The EU legislation (Regulation (EU) No. 536/2014, referred to hereafter as the CTR), and revised or new international guidance (e.g. ICH E6(R3), ICH E8(R1), ICH E19) that became applicable after the COVID-19 pandemic, support a risk proportionate approach in the design and conduct of clinical trials.

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This guidance is intended for sponsors and all stakeholders involved in the design and conduct of clinical trials. In the absence of available EU legislation related to PHEs, the provisions described in this document apply to the extent permitted by national legislation.

Comments should be provided using this [template](#). The completed comments form should be sent to acteu@ema.europa.eu

NEW - General Considerations for the Use of New Approach Methodologies in Drug Development; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 03/19/2026 **Comment period that ends 05/18/2026**

SUMMARY:

The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled “General Considerations for the Use of New Approach Methodologies in Drug Development.” The purpose of this draft guidance is to provide drug developers with a validation framework and general recommendations for using new approach methodologies (NAMs) in drug development. Although animal toxicity studies have proved to be a critical method to identify potential risks to human health, finding ways to improve human relevance while reducing the use of animals by developing reliable NAMs furthers an important Center for Drug Evaluation and Research (CDER) priority to move away from reliance on animal testing. The recommendations in this draft guidance are intended to highlight scientific principles of study design and reporting that can be applied broadly and flexibly in the validation of NAMs used in drug development. This draft guidance is not intended to address specific NAMs and does not address the use of NAMs in drug discovery; rather, it encourages the use of NAMs in regulatory submissions, especially when they improve the predictivity of nonclinical studies for increased safety in clinical trials.

FDA Rare Disease Innovation Hub Future Programming; Request for Comments

A Notice by the Food and Drug Administration on 01/30/2026

This document has a **comment period that ends in 328 days. (12/31/2026)**

SUMMARY:

The Food and Drug Administration (FDA or the Agency) is announcing the following request for comments for a future public workshop series entitled “Rare disease Innovation, Science, and Exploration (RISE) Workshop.” The purpose of the public workshops is to focus on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. The workshops will primarily focus on cross-cutting or common issues and will not be focused on any specific product under review by the Agency. The Agency further welcomes comments that highlight general rare disease-related issues of potential interest for the FDA Rare Disease Innovation Hub (Hub) to inform its future activities

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

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.

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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

NEW - Call for Inputs – Protection of human rights defenders in the digital age

Office of the High Commissioner for Human Rights **Deadline: 31 March 2026**

Inputs are sought to gather information on the ways in which the work and safety of HRDs are affected by digital technologies. We will look at overarching trends which we have identified as particularly relevant to protection of HRDs: how digital technologies affect the communications, privacy and safety of HRDs; how legislative and regulatory measures impact digital spaces; and how companies have responded to identified risks affecting HRDs on their platforms and services.

NEW - Call for inputs: Implementation of inclusive humanitarian assistance and safeguards for the rights of persons with disabilities in the context of current humanitarian reform processes

Special Procedures **Deadline: 30 April 2026**

Issued by Special Rapporteur on the rights of persons with disabilities

Objectives

Through this report, the Special Rapporteur intends to shed light on the practical challenges to implementing inclusive humanitarian assistance in line with the CRPD; and measures, safeguards, and good practices that can ensure that humanitarian reform processes, including the Humanitarian Reset, strengthen rather than undermine the inclusion and participation of persons with disabilities.

NEW - Call for inputs: International financial architecture, debt and the right to education

UNHCHR = Special Procedures **Deadline: 30 April 2026**

...The report will examine how debt regimes, debt sustainability frameworks, macroeconomic policy approaches and financing arrangements promoted by international financial institutions and other global economic actors, as well as resulting austerity measures, affect States' capacity to mobilize and allocate the maximum of available resources to education.

Grounded in international human rights law and informed by the human rights economy approach, the report will assess how fiscal constraints, policy conditionalities and financing models mandated through the debt architecture interact with States' minimum core obligations, their duty to realize the right to education and the prohibition of unjustified retrogression. Particular attention will be given to implications for equitable access to quality public education and to structural accountability issues within international financial governance such as the applicability of normative agreements to private lenders and Global North dominance in the governance structures of major international financing institutions...

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NEW - Call for inputs - Draft General Comment on the Application of the International Covenant on Economic, Social and Cultural Rights in Situations of Armed Conflicts

call for input | Treaty bodies Issued by CESCR **Deadline: 15 May 2026**

Objectives

The main objective of the General Comment is to provide interpretative clarity and authoritative guidance on the application of the ICESCR in situations of armed conflicts. The General Comment will address the entire conflict cycle: structural risk and prevention, active hostilities, occupation or effective control, stabilisation and post-conflict reconstruction. It will clarify how Covenant obligations continue across all phases, and how ESCR protection contributes to conflict prevention, humanitarian action, transitional justice, peacebuilding and sustainable recovery.

NEW - Call for inputs: The impact of trade agreements on women's economic empowerment

Office of the High Commissioner for Human Rights

12 June 2026 **Input/comments must be received by 12 June 2026 .**

Objectives

In order to inform the preparation of the report, OHCHR seeks written contributions, comprising replies to the guiding questions below, from United Nations Member States, United Nations entities, including the United Nations Entity for Gender Equality and the Empowerment of Women, the International Labour Organization, the World Trade Organization, the United Nations Children's Fund, the United Nations Conference on Trade and Development and other relevant United Nations agencies, funds and programmes, relevant special procedures of the Human Rights Council, regional organizations and human rights bodies and civil society, including women's and children's rights organizations.

NEW - Call for inputs - Draft General Comment on the Application of the International Covenant on Economic, Social and Cultural Rights in Situations of Armed Conflicts

UNHCHR - Issued by CESCR **Deadline: 15 May 2026**

Purpose:

To inform the Committee on Economic, Social and Cultural Rights' draft general comment on the Application of the International Covenant on Economic

Objectives

The main objective of the General Comment is to provide interpretative clarity and authoritative guidance on the application of the ICESCR in situations of armed conflicts. The General Comment will address the entire conflict cycle: structural risk and prevention, active hostilities, occupation or effective control, stabilisation and post-conflict reconstruction. It will clarify how Covenant obligations continue across all phases, and how ESCR protection contributes to conflict prevention, humanitarian action, transitional justice, peacebuilding and sustainable recovery.

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Emerging/Disruptive Technologies

:: Call for Public Consultation

No new calls identified.

:: Resources, Events

No new resources, events identified.

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Biodiversity/Environment/Climate/Disaster Mitigation

:: Call for Public Consultation

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**

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.

:: Resources, Events

No new resources, events identified.

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Science Integrity/Evidence to Policy/ Open Science

:: Call for Public Consultation

No new calls identified.

:: Resources, Events

No new resources, events identified.

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Heritage/Cultural Assets

:: Call for Public Consultation

No new calls identified.

:: Resources, Events

No new resources, events identified.

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Governance, Peace, Trade, Global Finance

:: Call for Public Consultation

No new calls identified.

:: Resources, Events

No new resources, events identified.

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

E2D(R1) Postapproval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports; International Council for Harmonisation

A Notice by the Food and Drug Administration on 03/04/2026 **FINAL GUIDANCE**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a **final guidance** for industry entitled “E2D(R1) Postapproval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports.” The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance updates the 2003 guidance titled “E2D Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting,” by clarifying the use of new or increasingly used data sources (e.g., social media, market research programs, patient support programs). This final

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guidance clarifies the use of new postapproval safety sources and update terminology and standards for postapproval adverse event reporting. The guidance replaces the draft guidance “E2D(R1) Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports” issued on March 14, 2024, and the final guidance issued September 15, 2003.

M14 General Principles on Planning, Designing, Analyzing, and Reporting of Non-interventional Studies That Utilize Real-World Data for Safety Assessment of Medicines; International Council for Harmonisation

A Notice by the Food and Drug Administration on 03/04/2026 **FINAL GUIDANCE**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “General Principles on Planning, Designing, Analyzing, and Reporting of Non-interventional Studies That Utilize Real-World Data for Safety Assessment of Medicines.” The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance outlines general principles on planning, designing, analyzing, and reporting non-interventional studies that utilize real-world data for safety assessment of medicines (*i.e.*, drugs, vaccines, and other biological products). The recommendations in this guidance, while focused on safety, are applicable to non-interventional studies assessing effectiveness and are aligned and complementary with the FDA's other guidances on the generation real world evidence. The guidance includes recommendations and high-level best practices for the conduct of these studies, including articulating the research question, selecting appropriate data sources, defining key variables, addressing potential biases and confounding, conducting analyses, reporting, and submission.

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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 [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

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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

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#

U.S. HHS – Open Requests for Comments

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

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