ge²p² global

governance, ethics, evidence, policy, practice
human rights action :: humanitarian response :: health ::
education :: heritage stewardship :: sustainable development

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

21 February 2025 - Issue 28

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, or member states and 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 Adiabu, 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.

Call for Public Consultation: Title/Source/Sorted by Due Date

E6(R3) Good Clinical Practice: Annex 2; International Council for Harmonisation; Draft Guidance for Industry; Availability
A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 02/28/2025**

M15 General Principles for Model-Informed Drug Development; International Council for Harmonisation; Draft Guidance for Industry; Availability
A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 2/28/2025**

Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices; Draft Guidance for Industry; Availability
A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 02/28/2025**

Call for inputs: The role of mercenaries, mercenary-related actors and private military and/or security companies (PMSCs) in the exploitation of natural resources.
UNHCHR - Issued by Working Group on the use of mercenaries **Deadline: 28 February 2025**

Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway; Draft Guidance for Industry; Availability
FDA - Food and Drug Administration on 01/07/2025 **Comment period that ends 03/10/2025.**

Considerations for Including Tissue Biopsies in Clinical Trials
FDA January 7, 2025 - Draft Guidance – **Comment period that ends 03/10/2025**

Call for Input – 2025 Thematic Reports to the UN Human Rights Council and UN General Assembly – Coercive Measures
UNHCHR - Issued by Special Rapporteur on unilateral coercive measures **Deadline: 14 March 2025**

Request for Comments on AISI's Draft Document: Managing Misuse Risk for Dual-Use Foundation Models
National Institute of Standards and Technology, 14 Jan 2025 **Comments before March 15, 2025**

NEW - **New developments in biotechnology applied to animals: an assessment of the adequacy and sufficiency of current EFSA guidance for animal risk assessment**
Public Consultation
EU – European Food Safety Authority :: EFSA Panel on Genetically Modified Organisms
Issue Date: 22 Jan 2025 :: 87 pages **Submissions due 19 March 2025**

The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources, including a global fund ("The Cali Fund"): Submission of views on possible additional modalities of the multilateral mechanism

CBD Convention on Biological Diversity, Notification 2024-114 2024-12-10 **Comments no later than 21 March 2025**

NEW - **Notice of Request for Information (RFI) on Autonomous Experimentation Platforms from Material Genome Initiative**
A Notice by the Energy Department on 01/17/2025 **Responses to the RFI are due by March 21, 2025.**

The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources, including a global fund ("The Cali Fund"): Submission of views on possible new tools and models, such as databases, for making digital sequence information on genetic resources publicly available and accessible
CBD Convention on Biological Diversity, Notification 2024-115 2024-12-10 **Comments no later than 4 April 2025**

Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products Draft Guidance for Industry and Other Interested Parties
FDA, January 2025 **Submit Comments by 04/07/2025**

NEW - **Invitation to submit information for the development of indicators, metrics and progress measurement tools on Biodiversity and Health**
Notification 2025-012
CBD – Public comments due 15 April 2025.

NEW - **GreenData4All – updated rules on geospatial environmental data and access to environmental information**
European Commission - **Public consultation period to 30 April 2025** (midnight Brussels time)

NEW - **Call for Inputs: Care and support for children with disabilities within the family environment and its gendered dimensions**
UNHCHR Special Procedures **Deadline: 30 April 2025**

NEW - **Submission of views and information on biodiversity and climate change**
Notification 2025-005
CBD – Public comment due by 1 May 2025

NEW - **Concept paper on the development of a Guideline on assessment and reporting of mechanistic models used in the context of model informed drug development**
EMA Draft: consultation open **Consultation dates: 14/02/2025 to 31/05/2025**

Interested Parties Meeting: Implementation of the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act
A Notice by the Food and Drug Administration on 01/03/2025. **Comments by June 13, 2025.**

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.

Global consultation on the Copenhagen Framework on Citizen Data

Collaborative on Citizen Data - 2 February 2024

Year-long global consultation spanning over 2024.

The Collaborative will aim to finalize the "Copenhagen Framework on Citizen Data" based on this global consultation and other country piloting studies, and submit to the 56th session of the United Nations Statistical Commission in March 2025.

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

Biomedical Research/Regulation/Governance

E6(R3) Good Clinical Practice: Annex 2; International Council for Harmonisation; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 02/28/2025**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "E6(R3) Good Clinical Practice: Annex 2." The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance is the second annex to "E6(R3) Good Clinical Practice" published June of 2023. This annex provides additional considerations for the application of good clinical practices to a variety of trial designs and data sources. Specifically, this draft guidance discusses trials with decentralized and pragmatic elements and real-world data sources. This draft guidance highlights the importance of quality by design and focusing efforts and resources on critical aspects of the trials that might impact the safety of participants and the reliability of results. The draft guidance is intended to encourage innovation in trial design and provides flexible, modern, and clear good clinical practices for conducting trials, while avoiding unnecessary complexities.

M15 General Principles for Model-Informed Drug Development; International Council for Harmonisation; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 2/28/2025**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "M15 General Principles for Model-Informed Drug Development." The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance discusses the multidisciplinary principles of model-informed drug development (MIDD). This includes recommendations on MIDD planning, model evaluation, and evidence documentation. The draft guidance also includes a harmonized framework for assessing evidence derived from MIDD. The draft guidance is intended to facilitate multidisciplinary understanding, appropriate use, and harmonized assessment of MIDD and its associated evidence.

Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 12/30/2024 **Comment period ends 02/28/2025**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices." This draft guidance provides recommendations to assist sponsors, clinical investigators, and institutional review boards (IRBs) in defining, identifying, and reporting protocol deviations. The

guidance provides definitions for protocol deviations and important protocol deviations. In addition, the guidance provides a recommended classification system for sponsors to report protocol deviations to FDA in clinical study reports for drugs, biological products, and devices; for investigators to report protocol deviations to sponsors and to IRBs; and for IRBs to evaluate protocol deviations.

Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway; Draft Guidance for Industry; Availability

FDA - Food and Drug Administration on 01/07/2025 **Comment period that ends 03/10/2025.**

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway." For drugs granted accelerated approval, sponsors conduct confirmatory studies that must be completed post approval to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. This draft guidance describes FDA's interpretation of the term "underway" and discusses policies for implementing this requirement, including factors FDA intends to consider when determining whether a confirmatory trial is underway prior to accelerated approval.

Considerations for Including Tissue Biopsies in Clinical Trials

FDA January 7, 2025 - Draft Guidance – **Comment period that ends 03/10/2025**

SUPPLEMENTARY INFORMATION:

I. Background

FDA and OHRP are announcing the availability of a draft guidance for industry, clinical investigators, institutions, and IRBs entitled "Considerations for Including Tissue Biopsies in Clinical Trials." This guidance is intended to assist industry, clinical investigators, institutions, and IRBs in understanding considerations for tissue biopsies that may be conducted in adults and in children as part of clinical trials that evaluate investigational medical products and/or that are conducted or supported by HHS. For the purposes of this guidance, a biopsy is a procedure that involves acquisition of tissue from a trial participant as part of a clinical trial protocol.

Although biopsies inherently include varying degrees of risk, in some circumstances, biopsied tissue(s) may be the only way to obtain information that is necessary to answer questions of interest in a clinical trial, such as to determine trial eligibility or to evaluate treatment effects. In general, when biopsies are to be conducted for evaluation of non-key secondary endpoint(s) and/or exploratory endpoints or for unspecified future research uses, they should not be required and instead should be optional…

NEW - New developments in biotechnology applied to animals: an assessment of the adequacy and sufficiency of current EFSA guidance for animal risk assessment

Public Consultation

EU – European Food Safety Authority :: EFSA Panel on Genetically Modified Organisms

Issue Date: 22 Jan 2025 :: 87 pages **Submissions due 19 March 2025**

PDF:

https://connect.efsa.europa.eu/RM/sfc/servlet.shepherd/document/download/069Tk000008lMi3IAE

Abstract

EFSA received a request by the European Commission (in accordance with Article 29 of Regulation (EC) No 178/2002) to provide a scientific opinion on new developments in biotechnology, including synthetic biology (SynBio) and new genomic techniques (NGTs), as applied to current or near-market animals for food, feed and other agricultural uses, with implications for risk assessment methodologies and applicability and sufficiency of the current EFSA risk assessment guidance documents, covering all

aspects of molecular characterisation, food and feed safety, animal health and welfare, and environmental safety.

A horizon scanning exercise identified a variety of animals obtained with new genomic techniques (NGT animals), with the potential to reach the EU market in the short, medium and long term, based on the current stage of market development (commercial, pre-commercial, research and development). Site-directed nucleases (SDN) 1 and 2 modify an endogenous DNA sequence without the intended introduction of any foreign genetic material. No novel hazards have been identified that are linked to either the modification process or the newly introduced trait, when these genomic alterations were compared to established genomic techniques (EGTs) and conventional breeding.

Hazards posed by SDN-3 are of the same nature as those posed by EGTs; the targeted insertion may reduce the potential hazards associated with the disruption of endogenous genes and/or regulatory elements in the recipient genome. Hazards posed by the new trait resulting from the introduced transgenic (SDN3) or intragenic DNA sequence are of the same nature as those posed by EGTs. Hazards posed by the new trait resulting from the introduced cisgenic DNA sequence are of the same nature as those posed by conventional breeding. Off-target mutations from genome editing are similar in nature to those from conventional breeding and do not pose novel hazards.

Consequently, no new potential hazards, and thus, no new risks to humans, animals, or the environment are anticipated. A thorough evaluation of existing EFSA guidance documents for the risk assessment of GM animals revealed that their principles and recommendations provide the basis for assessing the risks of NGT animals for food, feed and other agricultural uses; however, the current text covers only partially the topics in several areas (e.g. animal health and welfare), and might require further updates, adaptations, or enhancements on an ad hoc basis, to address the risk assessment of NGT animals, as outlined in this opinion.

Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products Draft Guidance for Industry and Other Interested Parties

FDA, January 2025 **Submit Comments by 04/07/2025**
Docket Number: FDA-2024-D-4689
PDF: https://www.fda.gov/media/184830/download
Issued by:
Center for Veterinary Medicine
Office of Inspections and Investigations
Oncology Center of Excellence
Center for Biologics Evaluation and Research
Center for Devices and Radiological Health
Center for Drug Evaluation and Research
Office of the Commissioner, Office of the Chief Medical Officer, Office of Combination Products

Purpose

This guidance provides recommendations to sponsors and other interested parties on the use of artificial intelligence (AI) to produce information or data intended to support regulatory decision-making regarding safety, effectiveness, or quality for drugs. Specifically, this guidance provides a risk-based credibility assessment framework that may be used for establishing and evaluating the credibility of an AI model for a particular context of use (COU).

NEW - Concept paper on the development of a Guideline on assessment and reporting of mechanistic models used in the context of model informed drug development

EMA Draft: consultation open **Consultation dates: 14/02/2025 to 31/05/2025**
Reference Number: EMA/5875/2025

Introduction

Mechanistic models, i.e. mathematical or computer models that integrate biopharmaceutical, physico-13 mechanical, (patho)physiological and pharmacological processes, along with population characteristics, 14 are frequently and increasingly used in all phases of the drug research and development life cycle. 15 Mechanistic models covered by this new guideline include, but are not limited to, Physiologically Based 16 Pharmacokinetic (PBPK), Physiologically Based Biopharmaceutics (PBBM) and Quantitative Systems 17 Pharmacology (QSP) models…

Problem statement

Regulators should be able to confidently assess and quantify the potential risks associated with decisions based on mechanistic models, ensuring informed and accurate outcomes. However, due to the nature of these models, this is a non-trivial task and methods for uncertainty quantification are not well established within the current regulatory assessment framework. Moreover, key metrics and components for technical assessment and related acceptance criteria for mechanistic models, given the context of use and regulatory impact are not always clear which leads to their underuse or inappropriate use in drug development or/and poor communication between developers and regulators…

Interested Parties Meeting: Implementation of the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act

A Notice by the Food and Drug Administration on 01/03/2025. **Comments by June 13, 2025.**

SUMMARY:

The Food and Drug Administration's (FDA, Agency, or we) Office of Pediatric Therapeutics, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research are announcing a public meeting entitled “Interested Parties Meeting: Implementation of the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act.” The purpose of the public meeting is to seek input from interested parties, including patient/parent/caregiver groups, consumer groups, regulated industry, academia, and others. This input will enable FDA to obtain any recommendations or information relevant to the report to Congress that FDA is required to submit concerning pediatric drug and biologic development and labeling, as outlined in section 508 of the Food and Drug Administration Safety and Innovation Act (FDASIA).

The public meeting will be held on May 15, 2025, from 9 a.m. to 4:30 p.m. Eastern Time. Regardless of attendance at the public meeting, you can submit electronic or written comments to the public docket.

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.

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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Genetics/Genomics

The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources, including a global fund ("The Cali Fund"): Submission of views on possible additional modalities of the multilateral mechanism

CBD Convention on Biological Diversity, Notification 2024-114 2024-12-10 **Comments no later than 21 March 2025**

As noted in notification 2024-113, at its sixteenth meeting, by decision 16/2, the Conference of the Parties adopted the modalities for operationalizing the multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including the global fund, which are set out in the annex to the decision, and decided that the global fund will be known as the Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources. By the same decision, Parties also set out some intersessional work.

While the Conference of the Parties, in decision 16/2, adopted the modalities of the multilateral mechanism, it also decided (in paragraph 3 of the decision) to explore possible additional modalities, including, in the context of paragraph 7 of decision 15/9 and the annex to decision 16/2, to take products and services into account.

Parties, other Governments, indigenous peoples and local communities, and relevant organizations are invited to submit their views on this issue as soon as possible …

The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources, including a global fund ("The Cali Fund"): Submission of views on possible new tools and models, such as databases, for making digital sequence information on genetic resources publicly available and accessible

CBD Convention on Biological Diversity, Notification 2024-115 2024-12-10 **Comments no later than 4 April 2025**

As noted in notification 2024-113, at its sixteenth meeting, by decision 16/2, the Conference of the Parties adopted the modalities for operationalizing the multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including the global fund, which are set out in the annex to the decision, and decided that the global fund will be known as the Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources. By the same decision, Parties also set out some intersessional work.

In particular, the Conference of the Parties, in decision 16/2, decided to explore possible new tools and models, such as databases, for making digital sequence information on genetic resources publicly available and accessible in a transparent and accountable manner to all Parties.

Parties, other Governments, indigenous peoples and local communities, and relevant organizations are invited to submit their views on this issue as soon as possible…

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Emerging/Disruptive Technologies

NEW - Request for Comments on AISI's Draft Document: Managing Misuse Risk for Dual-Use Foundation Models

National Institute of Standards and Technology, 14 Jan 2025 **Comments before March 15, 2025**
AGENCY: U.S. Artificial Intelligence Safety Institute (AISI), National Institute of Standards and Technology (NIST), U.S. Department of Commerce.
[Docket Number: 250108-0011] XRIN: 0693-XC137
SUMMARY:
The U.S. Artificial Intelligence Safety Institute (AISI), housed within NIST at the Department of Commerce, requests comments on an updated draft document responsive to Section 4.1(a)(ii) and Section 4.1(a)(ii)(A) of Executive Order 14110 on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (AI) issued on October 30, 2023 (E.O. 14110). This draft document, NIST AI 800-1, Managing Misuse Risk for Dual-Use Foundation Models, can be found at https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.800-1.ipd2.pdf. This document is an update to an initial public draft and includes changes based on the previous round of public comment, as well as two new appendices that apply these guidelines to (1) chemical and biological misuse risk and (2) cyber misuse risk.

NEW - Notice of Request for Information (RFI) on Autonomous Experimentation Platforms from Material Genome Initiative

A Notice by the Energy Department on 01/17/2025 **Responses to the RFI are due by March 21, 2025.**
Background
This is an RFI issued by DOE in support of the Material Genome Initiative (MGI) that seeks public input to inform interagency coordination around Autonomous Experimentation (AE) platform research, development, capabilities, and infrastructure. This input will support the efforts of the recently announced MGI Challenges that aim to help unify and promote adoption of the Materials Innovation Infrastructure—through the expansion and integration of capabilities including autonomy, artificial intelligence, and robotics—to realize solutions to challenges of national interest.[1] MGI is a Federal multi-agency initiative for discovering, manufacturing, and deploying advanced materials and supporting U.S. institutions in the adoption of methods for accelerating materials development, with over 15 agency participants…
Purpose
Autonomous experimentation (AE) is defined in the MGI Workshop Report on Autonomous Materials Innovation Infrastructure [2] as "the coupling of automated experimentation and in situ or in line analysis of results, with artificial intelligence (AI) to direct experiments in rapid, closed-loops." The report identifies several technological advances coupled to existing techniques that need to be integrated to realize AE…

NEW - Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

A Notice by the Food and Drug Administration on 01/07/2025 **Comment period ends 04/07/2025**
SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Artificial Intelligence Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations." This draft guidance, when finalized, will provide recommendations regarding the contents of marketing submissions for devices that include artificial intelligence (AI)-enabled device software functions including documentation and information that will support FDA's evaluation of safety and effectiveness. To support the development of appropriate documentation for FDA's assessment of the device, this draft guidance also proposes recommendations for the design, development, and implementation of AI-enabled devices that sponsors may wish to consider using throughout the total product lifecycle (TPLC). This draft guidance is not final nor is it for implementation at this time.

NEW - **Cat II – Intergovernmental meeting, other than international conference of States Intergovernmental Meeting on the draft Recommendation on the Ethics of Neurotechnology**

UNESCO – Event 12 to 16 May 2025

The Intergovernmental Special Committee of technical and legal experts will meet at UNESCOs Headquarters to examine the draft Recommendation on the Ethics of Neurotechnology

Catalogue of Tools & Metrics for Trustworthy AI

OECD AI Policy Observatory

Ongoing

These tools and metrics are designed to help AI actors develop and use trustworthy AI systems and applications that respect human rights and are fair, transparent, explainable, robust, secure and safe…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.

Call for Technological, Legal, and Social Solutions to Counter Disinformation on Social Media

NASEM

No submission deadline date identified.

The National Academies of Sciences, Engineering, and Medicine's *Committee on Evolving Technological, Legal and Social Solutions to Counter Disinformation on Social Media* is seeking creative ideas to detect, measure, and mitigate disinformation on social media and related platforms. If the Committee finds your submission particularly compelling, it will be discussed (or you could be asked to present and discuss it) at an April 10-11, 2024 National Academies' virtual workshop, which will feature two days of interactive brainstorming to foster new research and collaborations and build implementable solutions for a whole-of-society approach to mitigating disinformation and its detrimental effects.

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

No submission deadline date identified.

The International Science Council has invited feedback on its discussion paper, which provides the outline of an initial framework to inform the multiple global and national discussions taking place related to AI.

PDF: https://council.science/wp-content/uploads/2023/10/A-framework-for-evaluating-rapidly-developing-digital-and-related-technologies_ISC_2023.pdf

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Biodiversity/Environment/Climate/Disaster Mitigation

NEW - Invitation to submit information for the development of indicators, metrics and progress measurement tools on Biodiversity and Health

Notification 2025-012
CBD – Public comments due 15 April 2025.

In its decision 16/19, the Conference of the Parties (COP) to the Convention on Biological Diversity requested the Executive Secretary to complete the work conducted pursuant to paragraph 13 (a) of decision 14/4 on the development of integrated science-based indicators, metrics and progress measurement tools on biodiversity and health.

To support this work, I am pleased to invite Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders to submit information that could be useful in the development of the integrated science-based indicators referred above. In preparing the submission, please see below possible elements that may be included :

- Examples of indicators on biodiversity and health (including for human, animal, plant and environmental health), useful to assess progress towards the mainstreaming of biodiversity and health interlinkages, in particular in consideration of the Global Action Plan (decision 16/19, Annex I), section III and paragraph 14.
- Information on data sources and repositories of information that could be used to support the application of the indicators.
- Any efforts that may be related to the development of science-based indicators on biodiversity and health by other organizations or initiatives.

NEW - GreenData4All – updated rules on geospatial environmental data and access to environmental information

European Commission - **Public consultation period to 30 April 2025** (midnight Brussels time)

Summary

The 'GreenData4All' initiative will help deliver on Europe's green and digital transformation by updating EU rules on environmental geospatial data and on public access to environmental information. The aim is to:

enable greater sharing of data between the public & private sectors and with the general public

unlock the full benefits of data sharing for data-driven innovation and evidence-based decisions.

Target audience

The main stakeholders are environmental and geospatial data experts from the Member States responsible for implementing the Directive, public administrations, the open data community, not-for-profit organisations and for-profit organisations in different sectors (environment, geospatial, marine, agriculture, utilities, smart cities, mobility, energy), individuals interested in environmental protection, open source software communities, standardisation bodies, and the scientific community. These are the main beneficiaries in terms of cost savings and the ability of users to access and use data in new and innovative ways.

Why we are consulting

The Commission would like to gather stakeholders' views on the issues identified in the evaluation of the INSPIRE Directive, the challenges of a fast-evolving European data landscape and the possible policy

approaches to address these issues. The consultation will also seek to gather evidence and data to identify and assess policy options and define the scope of the future Directive.

NEW - Submission of views and information on biodiversity and climate change

Notification 2025-005

CBD – Public comment due by 1 May 2025

In its decision 16/22 on biodiversity and climate change, the Conference of the Parties to the Convention on Biological Diversity (CBD) requested Parties, observers and other stakeholders to submit their views on options for enhanced policy coherence, including a potential joint work programme of the Rio Conventions…

Representatives of Parties to the United Nations Framework Convention on Climate Change (UNFCCC) and the United Nations Convention to Combat Desertification (UNCCD), as well as observers and other stakeholders in those processes, are welcome to also submit their views. National focal points to the CBD are encouraged to engage with their UNFCCC and UNCCD counterparts in this regard.

Human Studies Review Board (HSRB) Meetings for 2025

A Notice by the Environmental Protection Agency on 11/29/2024

Public Participation

The HSRB encourages the public's input. You may participate in these meetings via oral comments or written comments.

SUMMARY:

The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of its public meetings of the Human Studies Review Board (HSRB) for 2025. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of third-party human subjects' research that are submitted to the Office of Pesticide Programs (OPP) to be used for regulatory purposes.

Four three-day virtual public meetings will be held on:

1. January 29-31, 2025;
2. April 2-4, 2025;
3. July 22-24, 2025;
4. October 14-16, 2025.

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Science Integrity/Evidence to Policy/ Open Science

NEW - International Research Collaborations: Revisiting Challenges, Progress, and Emerging Opportunities

National Academies of Sciences, Engineering, and Medicine

NASEM Event Jan 28, 2025 12:30PM - 1:30PM ET ***Event Recording***

The Government-University-Industry-Philanthropy Research Roundtable (GUIPRR) reexamined the issues first highlighted in its 2010 workshop, Examining Core Elements of International Research Collaborations. This session revisited challenges such as cultural differences, ethical standards, research integrity, and risk management that shape global partnerships in research.

Panelists from academia and industry discussed how the U.S. is addressing these persistent and emerging challenges, including research security, data protection, and the impact of new technologies

like generative AI. The discussion spotlighted best practices for advancing resilient, cross-sector collaborations across borders.

Expert Panelists:

- James Casey, Esq., CPP, Academic Community Leader & Adjunct Associate Professor, City University of New York; Research Contracts and Data Protection Executive, Casey Privacy Contracting
- Heike Riel, IBM Fellow, Head of Science of Quantum and Information Technology, and Lead of IBM Research Quantum Europe at IBM Research.

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 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.

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Heritage/Cultural Assets

NEW - UNESCO Civil-Military Alliance Forum for the Protection of Cultural Property

Event 16 May 2025 UNESCO headquarters Paris France

In the framework of the UNESCO Civil-Military Alliance for the Protection of Cultural Property and as the culmination of the year-long celebrations marking the 70th anniversary of the 1954 Hague Convention for the Protection of Cultural Property in the Event of Armed Conflict, UNESCO will host the first International Forum of its Alliance at UNESCO Headquarters, Paris, France, on 16 May 2025.

The aim of the Forum is to strengthen international cooperation and dialogue between civilian and military stakeholders to ensure the safeguarding of cultural property in times of peace and in the event of armed conflict…

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Governance

NEW - 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

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.

NEW - 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.

NEW - 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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Human Rights

Call for inputs: The role of mercenaries, mercenary-related actors and private military and/or security companies (PMSCs) in the exploitation of natural resources.

UNHCHR - Issued by Working Group on the use of mercenaries **Deadline: 28 February 2025**
Purpose:

To inform the Working Group's report to be presented to the 60th Session of the Human Rights Council in September 2025.

Background:

…The Working Group intends to dedicate its next thematic report on the role of mercenaries, mercenary-related actors and private military and/or security companies (PMSCs) in the exploitation of natural resources.

Control and/or access over natural resources drive most armed conflicts in the contemporary period. To date, numerous actors including State entities, transnational companies, especially those engaged in the exploitation of natural resources, may encourage the presence of mercenaries, mercenary related actors or PMSCs, either to protect their infrastructures, repress local civil populations or support the armed group that best serves the company's interests.

Mercenaries, mercenary related actors and PMSCs play complex roles in exploitation and/or protection of natural resources. As the scope of actors is diverse, their connections to the resources and the focus of activities vary as well. For instance, mercenaries, mercenary-related actors and PMSCs are mainly involved in exploitation and transfer of the natural resources, as a means of payment for their services. They are hired by companies or governments to protect installations, support armed groups, or suppress local resistance. Their operations often involve other actors, state and non-state, who would help them in transformation of the raw minerals and materials, transportation and distribution…

Call for Input – 2025 Thematic Reports to the UN Human Rights Council and UN General Assembly – Coercive Measures

UNHCHR - Issued by Special Rapporteur on unilateral coercive measures **Deadline: 14 March 2025**

Purpose:

To inform the Special Rapporteur's upcoming thematic reports on "The Impact of Unilateral Coercive Measures on Economic, Labor, and Social Rights", to be presented at the 60th session of the UN Human Rights Council in September 2025 and on "The Impact of Unilateral Coercive Measures on the Right to Education and Other Academic Rights" to be presented at the 80th session of the UN General Assembly in October 2025.

NEW - Call for Inputs: Care and support for children with disabilities within the family environment and its gendered dimensions

UNHCHR Special Procedures **Deadline: 30 April 2025**

Purpose:

To inform the report of the Special Rapporteur on the rights of persons with disabilities to the 80th session of the General Assembly.

Background

Families play a fundamental role in providing care and support to children with disabilities, including protecting and promoting their rights and building capacities for independent living in their communities. This role often extends and evolves throughout the lifecycle, for both those providing and those receiving support, reflecting cultural values as well as insufficient formal systems for support and services.

In the absence of adequate support, reliance on families can significantly impact the realization of the rights of all family members. For children with disabilities (including when they become adults), it can result in overprotection, loss of control over decisions big and small, poverty and economic dependence, isolation, neglect, abuse, violence, and abandonment. Family members bearing the brunt of care and support tasks are more likely to experience poverty linked to reduced opportunities to pursue income-generating activities, limited opportunities for personal growth, isolation, and negative impacts on mental health.

Women, and particularly mothers of children with disabilities, disproportionately assume caregiving and support responsibilities. This is largely done in an invisible, unpaid, and unrecognized manner, and often without adequate support. These women and girls face distinct challenges to enjoy their human rights, an issue that has not received significant attention in studies on support to persons with disabilities and their families, gender equality, and the reduction and redistribution of unpaid care and support work.

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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 Employing Calls for Public Consultation

Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons

Final Rule by the Justice Department on 01/08/2025 Published Document: 2024-31486 (90 FR 1636) (117 pages)
SUMMARY:
The Department of Justice is issuing a final rule to implement Executive Order 14117 of February 28, 2024 (Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern), by prohibiting and restricting certain data transactions with certain countries or persons.

Final Scientific Integrity Policy of the U.S. Department of Health and Human Services

A Notice by the Health and Human Services Department on 12/30/2024
Office of the Assistant Secretary for Planning and Evaluation, Office of the Secretary, HHS.
ACTION: Notice of final policy. The effective date of the Policy is October 16, 2024.
SUMMARY:
The Department of Health and Human Services (HHS) is publishing its Scientific Integrity Policy to increase access to and raise awareness of the Policy.
SUPPLEMENTARY INFORMATION:
Scientific integrity plays a vital role in the mission of HHS. Ensuring integrity in science throughout the Department allows HHS to foster and produce high-quality science, communicate effectively with the public, and base critical policy decisions on trustworthy and rigorous scientific findings. HHS has adopted a Department-wide scientific integrity policy to further strengthen scientific integrity and evidence-based policymaking throughout the Department.
The Scientific Integrity Policy of the U.S. Department of Health and Human Services (Policy) was approved on September 16, 2024. The finalized Policy was announced to the HHS community and

posted on the HHS scientific integrity website, at https://www.hhs.gov/programs/research/scientificintegrity/index.html, on September 30, 2024.

Purpose

The purpose of this policy is to promote a continuing culture of scientific integrity at the U.S. Department of Health and Human Services (HHS). This policy aims to ensure the integrity of all aspects of HHS scientific activities, including proposing, conducting, reviewing, managing, and communicating about science and scientific activities, and using the results of science to inform policy and program decision-making.

Core Values That Support Scientific Integrity at HHS

The success of HHS's mission to enhance the health and well-being of all Americans depends on the development and use of accurate, complete, and timely scientific and technical information. Scientific integrity requires that such information be developed under and subjected to well-established scientific processes, free from inappropriate interference that undermines impartiality, nonpartisanship, or professional judgment. HHS agencies work to maximize the quality, accuracy, objectivity, utility, and timeliness of the scientific and technological information they produce, use, and disseminate. In turn, this information enables HHS to employ innovative approaches to effectively address the many public health and human services challenges that our work targets. These efforts allow accurate, complete, and timely scientific and technical information to improve the design, delivery, and impact of HHS policies and programs, and support equity, justice, and trust. Responsibility for upholding scientific integrity lies with the entire scientific ecosystem, including all HHS employees, its contractors and grantees, and those engaged in science and scientific activities outside HHS.

Final Scientific Integrity Policy of the National Institutes of Health

A Notice by the National Institutes of Health on 10/21/2024

ACTION: Notice of final policy. DATES: This Final Policy is effective on December 30, 2024.

SUMMARY:

The National Institutes of Health (NIH) is issuing this Final NIH Scientific Integrity Policy to promote a continuing culture of scientific integrity at NIH. This Policy codifies NIH's long-standing expectations to preserve scientific integrity throughout all NIH activities, establishes key roles and responsibilities for those who will lead the agency's scientific integrity program, and, as appropriate, establishes relevant reporting and evaluation mechanisms.

SUPPLEMENTARY INFORMATION:

Background

Scientific integrity aims to make sure that science is conducted, managed, communicated, and used in ways that preserve its accuracy and objectivity and protect it from suppression, manipulation, and inappropriate influence (https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting_the_Integrity_of_Government_Science.pdf). In support of our mission, NIH has always sought to incorporate robust scientific integrity principles and practices throughout every level of its scientific enterprise. In fostering scientific integrity, NIH aims to ensure that (1) scientific findings are objective, credible, and readily available to the public, and (2) the development and implementation of policies and programs is transparent, accountable, and evidence-based. NIH has numerous policies and procedures to ensure the Nation's investment in biomedical research is scientifically robust and rigorous and that our workforce maintains the highest standards of integrity. In supporting the NIH mission, all NIH researchers and staff are expected to:

- Foster an organizational culture of scientific integrity,
- Protect the integrity of the research process,
- Communicate science with integrity, and
- Safeguard scientific integrity.

E11A Pediatric Extrapolation; International Council for Harmonisation; Guidance for Industry; Availability

Final Guidance – A Notice by the Food and Drug Administration on 12/30/2024

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "E11A Pediatric Extrapolation." The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance provides a comprehensive and systematic approach to pediatric extrapolation during drug development. Notably, the guidance discusses approaches to safety extrapolation and defining extrapolation as a continuum. The guidance also includes approaches to study designs and statistical methodologies, including modeling and simulation, for developing and implementing pediatric extrapolation. The guidance is intended to provide approaches that can increase the efficiency of pediatric drug development and accelerate the availability of safe and effective drugs approved for use in children. The guidance replaces the draft guidance "E11A Pediatric Exploration" issued on August 29, 2022.

Food and Drug Administration Report and Plan on Best Practices for Guidance; Availability

A Notice by the Food and Drug Administration on 12/03/2024

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Food and Drug Administration Report and Plan on Best Practices for Guidance" (Report and Plan). FDA is publishing this Report and Plan in response to the Consolidated Appropriations Act, 2023, which directs FDA to issue a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents and a plan for implementation of such best practices.

Background

Clear, concise, and timely communication through guidance documents is essential to the public health mission of FDA. FDA guidance documents are prepared for FDA staff, industry, and the public to describe the Agency's interpretation of, or policy on, a regulatory issue. (21 CFR 10.115(b)). Specifically, FDA uses guidance documents to assist regulated industry, FDA staff, and the public in understanding the Agency's current thinking on policy, scientific, medical, and regulatory issues, such as: the design, manufacturing, and testing of regulated products; content and evaluation of applications for product approvals; and inspection and enforcement policies…

LOC Biosecurity laws : Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Mexico, Russian Federation, Saudi Arabia, South Africa, South Korea, Turkey, United Kingdom, United States

Library of Congress, September 2024

LL File No. 2024-023388 LRA-D-PUB-002658 (corrected 10/2024)

Introduction

This report explores various approaches to defining "biosafety" and "biosecurity" in legislation and regulations in the following jurisdictions: Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Mexico, Russia, Saudi Arabia, South Africa, South Korea, Turkey, the United Kingdom, and the United States. These jurisdictions have been chosen because they are members of the Group of Twenty (G20).

Individual country reports are included after the comparative analysis. These reports discuss definitions of "biosafety," "biosecurity," and related terms, when available, as well as information about legislation, regulations, guidelines, and secondary sources discussing subjects related to those topics. Additionally, most G20 nations are signatories to multinational treaties addressing matters of biosecurity and biosafety. The table below at page 5 identifies G20 nations and indicates whether each has signed key multilateral treaties connected to biosafety: the Biological Weapons Convention, the Convention on Biological Diversity, the Cartegena Protocol, and the Nagoya Protocol. As indicated in the table, all G20 nations have either ratified or acceded to the Biological Weapons Convention. All listed nations, apart from the United States, participate in the Convention on Biological Diversity. The Cartagena Protocol and the Nagoya Protocol supplement the Convention on Biological Diversity; most G20 countries have ratified one or both of these treaties…

Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 10/18/2024
ACTION: Notice of availability.
You may submit either electronic or written comments on Agency guidances at any time.
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Guidance for Industry." This guidance is intended to provide a framework for considering whether and what type of long-term neurologic, sensory, and developmental evaluations could be useful in supporting a determination of safety of an FDA-regulated "medical product" (*i.e.,* drug, biological product, or medical device) for use in neonates. Although short-term safety evaluations may be appropriate for adults or other populations, such evaluations may not identify important adverse events in the neonatal population, as medical treatment during the neonatal period coincides with a time of critical growth and physiologic development and latent effects may not be evident until later in life following early-life exposures. Consideration of the potential for long-term neurologic, sensory, and developmental effects in the neonatal population early in a development program is important for establishing safety of a medical product intended for use in neonates. This guidance finalizes the draft guidance of the same title issued on February 13, 2023.

UNESCO - First Draft of the Recommendation on the Ethics of Neurotechnology

UNESCO - SHS/BIO/AHEG-Neuro/2024/2 :: 26 pages
PDF: https://unesdoc.unesco.org/ark:/48223/pf0000391444
Summary
The first draft of the Recommendation on the Ethics of Neurotechnology was prepared by the 24 international experts of the Ad Hoc Expert Group, who convened in Paris in April and August 2024. This text has been submitted to Member States for their comments and observations, opening the intergovernmental phase that will take place until 2025.

Guidance for best practices for clinical trials – WHO

25 September 2024
Overview [excerpted from WHO announcement and guidance executive summary]
The World Health Organization (WHO) today released guidance to improve the design, conduct and oversight of clinical trials in countries of all income levels. This guidance aims to support stronger country-led research and development (R&D) ecosystems to advance health science so that new, safe

and effective health interventions can be made more accessible and affordable globally for people everywhere, faster.

The guidance was developed in response to World Health Assembly resolution WHA 75.8 in an extensive and inclusive process, involving nearly 3000 stakeholders from various sectors across 48 countries. The guidance covers trials for any health intervention, including, but not limited to pharmaceutical medicines; vaccines; diagnostics; nutritional measures; cognitive, behavioural and psychological interventions; preventive care; digital and public health approaches; and traditional or herbal measures.

This document aims to complement other guidance in order to support implementation of universal ethical and scientific standards in the context of clinical trials, with a focus on under-represented populations; it does not represent a legal standard and does not supersede any existing guidance. In particular, this guidance shares many common concepts and principles with guidance produced by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) *(5)*, especially the ICH E8(R1) General Considerations for Clinical Studies guideline *(6)*, *(*the draft ICH E6(R3) Good Clinical Practice guideline *(7)*, and the ICH E9 statistical principles guideline *(8)* and its associated addendum *(9)*. In addition, it shares attributes with two further recent guidance documents that were highlighted through WHO's public consultation process in 2022: those of the Council for International Organizations of Medical Sciences (CIOMS) on clinical research in resource-limited settings *(10)* and the Good Clinical Trials Collaborative (GCTC) *(11)*.

Both the CIOMS and GCTC guidance have served as sources, with adaptations as needed, for this document. Additional sources highlighted through the consultation include the World Medical Association's (WMA) Declaration of Helsinki *(12)* on medical research involving human subjects, the WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks *(13)* and CIOMS' International Ethical Guidelines on Health-related Research involving Humans (2016) *(14)*.

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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

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.europ a.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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