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

24 November 2023 - Issue 10

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

In the context of this mission, GE2P2 Global is refining a monitoring approach to identify public consultations/calls for input/RFIs and similar opportunities across its focus areas of global health, human rights, humanitarian action, education, 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 such 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 into three sections:

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

We expect to add thematic areas as our digest becomes more comprehensive going forward.

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

Submission of information on synthetic biology: Invitation
CBD – Convention on Biological Diversity 26 October 2023 Ref.: SCBD/CPU/DC/WM/MW/91338
N O T I F I C A T I O N
Submissions should be sent by e-mail to secretariat@cbd.int **no later than 24 November 2023.**

Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments; Reopening of the Comment Period
A Notice by the Food and Drug Administration on 09/27/2023
Comment period ends (11/27/2023)

Call for Contributions - OHCHR analytical study on key challenges in ensuring access to medicines, vaccines and other health products (HRC resolution 50/13)
Call for input | Treaty bodies
Deadline: 30 November 2023

Call for inputs for the study of the Human Rights Council Advisory Committee on human rights implications of new and emerging technologies in the military domain (HRC resolution 51/22)
HRC subsidiary body
Deadline: 30 November 2023

Call for inputs - corporate accountability in the context of human rights and climate change
UNHCHR – Issued by Special Rapporteur on climate change
Deadline: 30 November 2023

Call for inputs: Human Rights Council resolution 53/13 on civil society space
Office of the High Commissioner for Human Rights
Deadline: 30 November 2023

Public Health Service Policies on Research Misconduct
U.S. Health and Human Services Department on 10/06/2023
The comment period on the NPRM will be open until December 5, 2023.

Request for Information (RFI): Inviting Comments and Suggestions on Opportunities and Challenges for the Collection, Use, and Sharing of Real-World Data (RWD) Including Electronic Health Records, for National Institutes of Health (NIH) Supported Biomedical and Behavioral Research
U.S. National Institutes of Health on 09/28/2023.
Responses must be received by December 14, 2023

Request for Information (RFI): Environmental Justice Research Gaps, Opportunities and Capacity Building
NIH Notice Number: NOT-ES-23-016 Release Date: October 4, 2023
Response Date: December 15, 2023

EMA – Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle
Draft 13 July 2023
Comm. Medicinal Products - Human Use (CHMP); Comm. Medicinal Products -Veterinary Use (CVMP)
End of consultation (deadline for comments): 31 December 2023

Concept paper on the development of an addendum to the Guideline on clinical development of vaccines on clinical trials for vaccines for immunocompromised individuals (PDF/185.17 KB)
EMA/CHMP Reference number: /453562/2023
First published: 03/11/2023 **Consultation dates: 01/11/2023 to 01/01/2024**

Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers
FDA Docket Number: FDA-2008-D-0053
PDF Guidance Document - https://www.fda.gov/media/173172/download
New deadline for electronic or written comments: January 5, 2024

Solicitation of Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections
A Notice by the U.S. Health and Human Services Department on 11/21/2023
Deadline: 1/20/2024

Concept paper on the revision of the Non-clinical and Clinical Module of the influenza vaccines guideline (PDF/177.49 KB)
EMA
First published: 31/10/2023 **Consultation dates: 01/11/2023 to 30/01/2024**

Concept paper on the revision of the guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches (PDF/208.8 KB)
EMA/CHMP/CVMP
Reference number: 452614/2023
First published: 23/11/2023
Draft: consultation open **Consultation dates: 20/11/2023 to 28/02/2024**
Summary
This guideline aims to encourage stakeholders and authorities to initiate, support and accept development and use of 3Rs testing approaches with the aim to replace, reduce and refine in vivo animal studies for human and veterinary medicinal products.
Comments should be provided using this EUSurvey form.

Call for Papers: Establishing the impact of WHO's normative and standard-setting functions: a call for papers

WHO - Bull World Health Organ. 2023 Oct 1; 101(10): 618–618A. Published online 2023 Oct 1.
The deadline for submissions is 1 March 2024

Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice; Public Workshop: Notice of public workshop; request for comments.

Food and Drug Administration, HHS. PDF
Comments on this public workshop must be submitted by April 5, 2024.

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

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

Biomedical Research/Regulation/Governance

Submission of information on synthetic biology: Invitation

CBD – Convention on Biological Diversity 26 October 2023 Ref.: SCBD/CPU/DC/WM/MW/91338
N O T I F I C A T I O N
Submissions should be sent by e-mail to secretariat@cbd.int **no later than 24 November 2023.**

Summary

At its first meeting in July 2023, the multidisciplinary AHTEG agreed on a process of horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology for the 2023-2024 intersessional period1. The process consists of multidisciplinary expert-driven submissions and a literature review, followed by the assessment and reporting steps, which will occur at the next meeting of the multidisciplinary AHTEG. Following the submissions process, the multidisciplinary AHTEG identified a prioritized list of seventeen (17) trends and issues in synthetic biology, twelve (12) of which were suggested for additional information gathering and further consideration at the next meeting.

Accordingly, to enable an efficacious and non-duplicative process with the Open-ended Online Forum on Synthetic Biology, I am pleased to invite Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit information on these trends and issues in synthetic biology found in Annex I using the template found in Annex II. Submissions from Parties should be made through the national focal points of the Convention on Biological Diversity. In the case of organizations, information should be submitted through the Heads of organizations.

Annex I

1. Additional trends and issues that were identified and prioritized by the multidisciplinary AHTEG for information gathering
2. Engineered bacteria for nitrogen-fixation and fertilizers
3. Transient modification of agricultural plants, pests and pathogens using RNAi or nanomaterials
4. Genome-edited plants
5. Microbiome engineering for non-medical purposes
6. Use of synthetic biology in wild organisms in the context of resilience in threatened species
7. Synthetic biology applications for bioremediation, biodegradation or biomining
8. Technical refinement of novel delivery systems and chemistries to modify organisms in the field or in nature
9. Ability to re-create viruses by chemical DNA synthesis
10. Interaction of synthetic biology organisms in the environment and potential for cumulative effects
11. Dual-use nature and biosecurity implications of synthetic biology.
12. Transboundary movements and relation to detection and identification of synthetic biology organisms, parts and products
13. Increased field testing of synthetic biology applications, including in areas outside the national jurisdiction of the developer or funder

Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments; Reopening of the Comment Period

A Notice by the Food and Drug Administration on 09/27/2023

Comment period ends (11/27/2023)

SUMMARY:

The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice, published in the Federal Register of March 1, 2023, establishing a public docket and requesting information and comments. FDA is reopening the comment period to update comments and to receive any new information.

SUPPLEMENTARY INFORMATION:

In the Federal Register of March 1, 2023 (88 FR 12943), FDA established a public docket to solicit comments on the "Discussion Paper: Artificial Intelligence in Drug Manufacturing." The discussion paper presents areas for consideration and policy development identified by the Center for Drug Evaluation and Research (CDER) scientific and policy experts associated with application of artificial intelligence to pharmaceutical manufacturing. The discussion paper includes a series of questions to stimulate feedback from the public, including CDER and the Center for Biologics Evaluation and Research stakeholders.

Call for Contributions - OHCHR analytical study on key challenges in ensuring access to medicines, vaccines and other health products (HRC resolution 50/13)

Call for input | Treaty bodies

Deadline: 30 November 2023

Purpose:

To inform the OHCHR analytical study on key challenges in ensuring access to medicines, vaccines and other health products (HRC resolution 50/13)

Background:

Vaccine equity and access to medicines is a fundamental component of the full realization of the right to health. Vaccines, medicines and other health products must not only be produced and made available - they must also be accessible to all persons. Yet, access to vaccines, medicines and other health products remains disturbingly uneven in many places.

Council resolution 50/13 requests the Office of the High Commissioner for Human Rights (OHCHR) to prepare an analytical study on key challenges in ensuring access to medicines, vaccines and other health products to be presented to the Human Rights Council at the fifty-sixth session in June 2024.

In order to collect inputs for this forthcoming report, OHCHR has published a short questionnaire available in English, Français and Español.

Public Health Service Policies on Research Misconduct

U.S. Health and Human Services Department on 10/06/2023

The comment period on the NPRM will be **open until December 5, 2023.**

HHS Releases Notice of Proposed Rulemaking to Update 2005 Public Health Service Policies on Research Misconduct

The Office of Research Integrity (ORI) has issued a Notice of Proposed Rulemaking (NPRM) to update the 2005 Public Health Service (PHS) Policies on Research Misconduct. The current regulation establishes the requirements for addressing research misconduct in PHS-funded research. Its purpose is to promote integrity in research, establish the definitions and processes to assess and investigate allegations of research misconduct, ensure the appropriate handling of research misconduct by PHS-funded institutions, and authorize administrative actions, when necessary. Proposed revisions to the

policy build upon previous regulations and make necessary improvements to meet the demands of dynamic changes in biomedical and behavioral research.

ORI policies on research misconduct have not been revised since 2005. Prior to the NPRM release, ORI published a Request for Information (RFI) to solicit views on the 2005 regulations from the public, including key stakeholders and collaborative groups…

This Notice of Proposed Rulemaking (NPRM) expresses ORI's stake and intent in developing and issuing research integrity guidance to support PHS-funded organizations in implementing measures to ensure research integrity.

Request for Information (RFI): Inviting Comments and Suggestions on Opportunities and Challenges for the Collection, Use, and Sharing of Real-World Data (RWD) Including Electronic Health Records, for National Institutes of Health (NIH) Supported Biomedical and Behavioral Research

U.S. National Institutes of Health on 09/28/2023.

Responses must be received by December 14, 2023

Background

Researchers are increasingly using data collected in real-world settings to augment traditional research studies, as well as develop more effective treatments and interventions for patients. These "real-world data (RWD)", defined by the U.S. Food and Drug Administration, are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status. While these data hold tremendous promise for biomedical and behavioral research, they can be collected from a variety of sources through multiple mechanisms, creating challenges for researchers and questions for those whose data are being shared.

Importantly, NIH is committed to ensuring participant privacy and autonomy are protected in all NIH-supported research. As NIH establishes health-related research data platforms that include access to RWD, NIH continues to prioritize maximizing data access while upholding participant preferences regarding the collection and use of their data…

Information Requested

NIH is requesting public comment on the use of RWD for NIH-supported biomedical and behavioral research, including opportunities for leveraging the benefits of RWD and strategies for its responsible use. NIH also seeks to better understand community perspectives on the potential value and constraints—including scientific, administrative, legal, business, and bioethical—for the increased use of RWD in biomedical and behavioral research.

Request for Information (RFI): Environmental Justice Research Gaps, Opportunities and Capacity Building

NIH Notice Number: NOT-ES-23-016

Release Date: October 4, 2023

Response Date: December 15, 2023

Purpose

The National Institutes of Health (NIH) Environmental Justice Working Group invites feedback on the approaches NIH Institutes, Centers, and Offices can take to support research and capacity building efforts to advance environmental justice in the U.S. and globally. All responses should be submitted

electronically at the RFI submission website (https://rfi.grants.nih.gov/?s=6508990aaec4ec015d06fb82 by 11:59:59 pm (ET) on December 15, 2023.

Information Requested

This RFI invites comments from communities with environmental justice concerns, scientific researchers, community-based organizations, consumer advocacy groups, service agencies, health care providers, policymakers and the public. This RFI seeks to identify gaps and opportunities pertaining to environmental justice research and training as well as capacity building needs in areas listed below and highly encourages responses on related topics that are not listed.

Transformative Environmental Justice Research and Action

- Multidisciplinary, transdisciplinary and team science approaches
- Development and testing of multi-level and structural level interventions
- Implementation research to support the uptake, scale-up, spread and sustainment of evidence-based interventions
- Community-led research approaches
- Inclusion of Indigenous Knowledge
- Environmental justice research and action in global settings including low-and-middle income countries
- Cumulative and generational impacts across the life course
- Methods and approaches directed at systems and structural level drivers

Scientific Infrastructure to Support Environmental Justice Research

- Strategies to collect, measure, organize and analyze diverse Big Data streams to improve the quality, linkages between, and harmonization of data
- Data infrastructure (e.g., standards, common data elements, repositories, platforms) needed to facilitate national and international data sharing in support of research
- Leveraging existing datasets, tools, and resources
- Development and testing of environmental exposure assessment methods, tools and sensors
- Adaptation of exposure assessment methods, tools and sensors in environmental justice settings

Community Partnerships to Address Environmental Injustices

- Identification and engagement of key partners in environmental justice research including, but not limited to, community-based organizations, federal, state, and local government agencies/programs and service sectors (e.g., departments of housing, transportation, agriculture, environment), locally owned businesses, and Tribal organizations and communities
- Strategies to engage in trusting and equitable partnerships with populations with health disparities that are at risk from the health impacts of environmental injustices
- Strategies to sustain community partnerships
- Approaches to develop community-based interventions and implementation strategies that address key barriers to the adoption and sustainment of these interventions
- Ethical issues and approaches related to environmental justice research and action with impacted communities

Diverse and Inclusive Workforce to Advance Environmental Justice

- Identification of approaches to reduce t raining gaps and ensure that opportunities to bolster or elevate environmental justice research capacity are accessible for all affected communities
- Strategies (specific activities and approaches) to increase diversity, equity, inclusiveness and accessibility of the scientific workforce conducting environmental justice research, in alignment with NIH's interest in diversity.

Science Communication and Dissemination of Research Findings

- Science communication approaches to disseminate research findings to affected communities, health care providers, educators, and policymakers

- Strategies for culturally and linguistically appropriate, transparent, equitable, and timely reporting back of research findings on environmental injustices
- Methods and opportunities for translating environmental justice research into environmental justice action (e.g., programs, policies)

Science, Research, and Data that would support Federal Environmental Justice Actions

- Data gaps and inadequacies related to environmental justice
- New or expanded data or knowledge sources that should be considered in Federal decision-making, including community generated data
- Ways that cumulative impacts, environmental justice, community-led science, population health, and health disparities research can better inform Federal policy actions

EMA – Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Draft 13 July 2023 1
EMA/CHMP/CVMP/83833/2023 2
End of consultation (deadline for comments): 31 December 2023
Committee for Medicinal Products for Human Use (CHMP) 3
Committee for Medicinal Products for Veterinary Use (CVMP)

This reflection paper provides considerations on the use of AI and ML in the lifecycle of medicinal products, including medicinal products development, authorisation, and post-authorisation. Given the rapid development in this field, the aim of this reflection paper is to reflect on the scientific principles that are relevant for regulatory evaluation when these emerging technologies are applied to support safe and effective development and use of medicines.

Concept paper on the development of an addendum to the Guideline on clinical development of vaccines on clinical trials for vaccines for immunocompromised individuals (PDF/185.17 KB)

EMA/CHMP Reference number: /453562/2023
First published: 03/11/2023 **Consultation dates: 01/11/2023 to 01/01/2024**
Problem statement
The Guideline on clinical evaluation of vaccines EMEA/CHMP/VWP/164653/05 Rev. 1 (3) does not provide detailed guidance on the design of clinical trials to assess the safety, immunogenicity and efficacy of vaccines in immunocompromised individuals. There is a need to provide some guidance on potentially suitable sub-populations of immunocompromised individuals for trials to improve the extrapolation of the findings to other sub-populations. Moreover, to consider designing studies in immunocompromised individuals that not only document whether immune responses are lower than in the immunocompetent population but also give some indication of alternative doses and/or regimens that could provide adequate levels of protection against infectious diseases.

Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers

FDA Docket Number: FDA-2008-D-0053
PDF Guidance Document - https://www.fda.gov/media/173172/download

New deadline for electronic or written comments: January 5, 2024

Overview

This revised draft guidance, when finalized, will provide FDA's current thinking on common questions regarding certain communications by firms to health care providers (HCPs) of scientific information on unapproved use(s) (SIUU) of approved/cleared medical products. Specifically, this guidance relates to firms sharing the following types of communications with HCPs:

:: Published scientific or medical journal articles (reprints)

:: Published clinical reference resources, as follows:

- Clinical practice guidelines (CPGs)
- Scientific or medical reference texts (reference texts)
- Materials from independent clinical practice resources

:: Firm-generated presentations of scientific information from an accompanying published reprint

Solicitation of Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections

A Notice by the U.S. Health and Human Services Department on 11/21/2023

Deadline: 1/20/2024

AGENCY: Office of the Assistant Secretary for Health, Office for Human Research Protections, Office of the Secretary, Department of Health and Human Services.

SUMMARY:

The Office for Human Research Protections (OHRP), a program office in the Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS), is seeking nominations of qualified candidates to be considered for appointment as members of the Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP provides advice and recommendations to the Secretary, HHS (Secretary), through the Assistant Secretary for Health, on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. SACHRP was established by the Secretary on October 1, 2002. OHRP is seeking nominations of qualified candidates to fill three positions on the Committee membership that will be vacated during the 2024 calendar year.

Concept paper on the revision of the Non-clinical and Clinical Module of the influenza vaccines guideline (PDF/177.49 KB)

EMA

First published: 31/10/2023 **Consultation dates: 01/11/2023 to 30/01/2024**

Summary/Problem statement [Excerpt]

The proposed guideline will replace Guideline on influenza vaccines, non-clinical and clinical modules (EMA/CHMP/VWP/457259/2014).

…The current guideline text addresses collection of vaccine effectiveness data for approved vaccines by season. The collection of reliable data, especially brand-specific data, has proven difficult even within countries with high quality influenza disease surveillance. There is a need to rediscuss the feasibility of the current recommendations, while still acknowledging the utility of such data to detect unexpected effectiveness signals.

Overall, there is some degree of urgency to revise the guideline on non-clinical and clinical development of influenza vaccines. In particular, to add sections relevant to the development of

mRNA-based influenza vaccines and to reflect on how lessons learned from the COVID-19 pandemic could be relevant to the development of influenza vaccines, including those intended only for pandemic usage.

Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support

Concept paper on the revision of the guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches (PDF/208.8 KB)

EMA/CHMP/CVMP Reference number: 452614/2023
First published: 23/11/2023
Consultation dates: 20/11/2023 to 28/02/2024
Summary
This guideline aims to encourage stakeholders and authorities to initiate, support and accept development and use of 3Rs testing approaches with the aim to replace, reduce and refine in vivo animal studies for human and veterinary medicinal products.

Comments should be provided using this EUSurvey form.

Call for Papers: Establishing the impact of WHO's normative and standard-setting functions: a call for papers

WHO - Bull World Health Organ. 2023 Oct 1; 101(10): 618–618A. Published online 2023 Oct 1.
The deadline for submissions is 1 March 2024
Editorial
Lisa M Askie[a], Rebekah AL Thomas[a], Rok Ho Kim[a], Mubashar Sheikh[a], Jeremy Farrar[b]
doi: 10.2471/BLT.23.290829 PMCID: PMC10523809

Normative leadership is a core function of the World Health Organization's (WHO) mandate, as outlined in its founding principles.[1] This leadership role is realized by developing evidence-based and ethically sound guidelines as well as other normative products that guide Member States in their public health decisions and actions, and by ensuring their recommendations are implemented.[2] WHO exercises its capacity for normative leadership to influence the development of legal norms and health policy and practice within its Member States…

… In the past five years, WHO has initiated a major change process, driven by its current Thirteenth Global Programme of Work,[6] the transformation agenda, and the need to respond to major global events including the coronavirus disease 2019 (COVID-19) pandemic and other crises. More recently, WHO has developed a comprehensive strategy to enhance its capacities and capabilities at country level, to ensure that its normative work drives measurable impact for all people more effectively.

Despite these initiatives, to date it is unclear whether these changes have improved WHO's credibility and impact as a normative organization. Questions remain as to how successful WHO's normative leadership role has been, how it can be further strengthened and how the impact of WHO's work in countries should be measured and rated in the future. The recent COVID-19 pandemic exposed both the strengths of and the challenges to WHO's normative leadership and global reach. While realizing the crucial role of WHO as a key directing and coordinating authority, the global health community has also witnessed the unprecedented rise of misinformation and mistrust in science.

Considering the spotlight on WHO's global normative leadership role during the pandemic,[7] and looking to prepare for future threats such as the health effects of climate change and ongoing conflict situations, the Bulletin of the World Health Organization calls for papers to help shape and inform WHO's mandate going forward. Topics of interest include: where has WHO succeeded in its normative

leadership role? In what specific areas has it successfully shaped global health, and why were these initiatives successful? Where has WHO normative guidance been less impactful? If so, why was this the case, and what lessons can be learnt to improve impact in the future? What does the future of WHO's normative function look like, particularly in the context of digital technology and artificial intelligence? What aspects of the Organization's mandate, structure, function and administration need to be further strengthened or changed?

The Bulletin welcomes contributions from all stakeholders including public health decision-makers, researchers, and civil society and community representatives. Articles that propose innovative but feasible ways by which WHO can further strengthen its normative leadership and guidance role, are encouraged.

Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice; Public Workshop: Notice of public workshop; request for comments.

Food and Drug Administration, HHS. PDF

Comments on this public workshop must be submitted by April 5, 2024.

SUMMARY

The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled "Advancing the Use of Complex Innovative Designs in Clinical Trials: From Pilot to Practice." The purpose of the public workshop is to discuss aspects of complex adaptive, Bayesian, and other novel clinical trial designs. This workshop is being conducted to meet the performance goal of convening a public workshop on complex innovative design (CID) included in the seventh authorization of the Prescription Drug User Fee Act (PDUFA VII). The workshop may also inform a draft guidance on the use of Bayesian methodology in clinical trials of drugs and biological products. In conjunction with the workshop, FDA is seeking comments on the use of CID to inform regulatory decision making, including high-level case examples of CIDs and approaches that can advance the use of these designs. The public workshop will be held on March 5, 2024, from 9 a.m. to 3:30 p.m. Eastern Time.

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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Emerging/Disruptive Technologies

Call for inputs for the study of the Human Rights Council Advisory Committee on human rights implications of new and emerging technologies in the military domain (HRC resolution 51/22)

HRC subsidiary body
Deadline: 30 November 2023
Purpose:

The Human Rights Council Advisory Committee seek the views of and inputs from stakeholders, including States, United Nations agencies, entities, funds and programmes within their respective mandates, international and regional organizations, the Office of the United Nations High Commissioner for Human Rights, the special procedures of the Human Rights Council, the treaty bodies, national human rights institutions, civil society, the private sector, academic institutions, multi-stakeholder initiatives and other relevant stakeholders, in order to prepare a study examining the human rights implications of new and emerging technologies in the military domain to be presented to the Council at its sixtieth session (September 2025).

Additional information on the mandate can be found on: Human rights implications of new and emerging technologies in the military domain.

Key questions and types of input/comments sought:
English | Français | Español

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.

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Environment/Climate/Disaster Mitigation

Call for inputs - corporate accountability in the context of human rights and climate change

UNHCHR – Issued by Special Rapporteur on climate change
Deadline: 30 November 2023
Purpose:

To inform the Special Rapporteur on the promotion and protection of human rights in the context of climate change's report on corporate accountability in the context of human rights and climate change, to be presented to the 56th Session of the Human Rights Council in 2024.

Background

One of the thematic issues identified by the UN Special Rapporteur relates to corporate accountability in the context of human rights and climate change.

There is a growing call for companies to disclose the risks they are facing with respect to their human rights responsibilities and their actions to address climate change through transitioning to low-carbon economies. The idea is that disclosure will help investors understand such risks so that they can make more informed investment decisions. There is a growing need to ensure that companies assess and report these risks, throughout their supply chain. Initiatives that establish mandatory disclosure and reporting will be explored and evaluated. Gaps in reporting requirements will also be explored.

The Special Rapporteur will also review various initiatives related to environmental, social and governance (ESG) and other corporate disclosure mechanisms to determine whether they provide effective means of reporting on human rights and climate change. Within this context, "greenwashing", "greenhushing" and net zero claims will be reviewed.

The Special Rapporteur will explore the issue of climate change risk for corporations. This will primarily be considered in the context of exposure to climate change litigation risks associated with investments in the fossil fuel industry and greenhouse gas intensive industries…

Key questions and types of input/comments sought

The Special Rapporteur is therefore seeking input from States, business enterprises, civil society organizations and intergovernmental organizations on corporate accountability with respect to human rights and climate change.

Download the questionnaire (WORD): English | Français | Español

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Human Rights

Call for inputs - corporate accountability in the context of human rights and climate change

UNHCHR – Issued by Special Rapporteur on climate change

Deadline: 30 November 2023

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Background

One of the thematic issues identified by the UN Special Rapporteur relates to corporate accountability in the context of human rights and climate change.

There is a growing call for companies to disclose the risks they are facing with respect to their human rights responsibilities and their actions to address climate change through transitioning to low-carbon economies. The idea is that disclosure will help investors understand such risks so that they can make more informed investment decisions. There is a growing need to ensure that companies assess and report these risks, throughout their supply chain. Initiatives that establish mandatory disclosure and reporting will be explored and evaluated. Gaps in reporting requirements will also be explored.

The Special Rapporteur will also review various initiatives related to environmental, social and governance (ESG) and other corporate disclosure mechanisms to determine whether they provide

effective means of reporting on human rights and climate change. Within this context, “greenwashing”, “greenhushing” and net zero claims will be reviewed.

The Special Rapporteur will explore the issue of climate change risk for corporations. This will primarily be considered in the context of exposure to climate change litigation risks associated with investments in the fossil fuel industry and greenhouse gas intensive industries…

Key questions and types of input/comments sought

The Special Rapporteur is therefore seeking input from States, business enterprises, civil society organizations and intergovernmental organizations on corporate accountability with respect to human rights and climate change.

Download the questionnaire (WORD): English | Français | Español

Call for inputs: Human Rights Council resolution 53/13 on civil society space

Office of the High Commissioner for Human Rights

Deadline: 30 November 2023

Background

In its resolution 53/13, the Human Rights Council requested “the High Commissioner to prepare a thematic report that identifies challenges and best practices in regularly assessing civic space trends and contains recommendations with a view to enhancing information-gathering on civic space, and to present the report to the Human Rights Council at its fifty-sixth session.”

Key questions and types of input/comments sought

To prepare the report, the Office of the United Nations High Commissioner for Human Rights welcomes relevant information, including:

[1] With a view to regularly assessing civic space trends, both offline and online, please specify what data or information is available from official sources (government administrative records, statistical agencies, judicial records, or other official sources) at the national and sub-national levels? For instance, in relation to assessing who participates in public affairs at different levels, what type of information is made available in which languages and how often, who accesses information and on which media/channels, on how laws relating to expression, association, peaceful assembly, online and online, are implemented (including by-laws, sub-national regulations, internal instructions, cases before the courts). Do you make use of citizen-generated data? Do you use other non-official sources to collect information, including digital tools or online platforms?

[2] What information or data do your agencies/institutions/organizations collect, record or use on (offline and online) threats and attacks against civil society, including human rights defenders, journalists, trade unionists and from specific population groups (for example: women and girls, children, youth, minorities, indigenous peoples, migrants, older persons, persons with disabilities, LGBTIQ+ etc.)? Do you record threats and attacks against civil society by non-state actors?

[3] Would you like to highlight any best practices in assessing offline and online civic space trends in your country or by your institution? What are the main challenges in doing so systematically or on a regular basis? Have any measures been taken by relevant agencies, institutions, or organizations to improve data collection at national and sub-national levels, including through investing into data collection capacities and structures, as well as in the context of implementation and measurement of progress under the 2030 Agenda for Sustainable Development?

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

Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress - measures to provide for financial security for damage from living modified organisms

CBD Convention on Biological Diversity
N O T I F I C A T I O N Ref.: SCBD/CPU/DC/WM/KG/PD/PS/91317 16 October 2023

In decision CP-10/13, Parties to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress were requested and other Governments were invited to submit information to the Executive Secretary on measures they have in place to provide for financial security for damage from living modified organisms, in particular where they have reported having such measures in place in their fourth national reports.

Against this background, I invite you to submit information on measures in place in your country or jurisdiction to provide for financial security for damage from living modified organisms. The information **should be submitted no later than 30 November 2023** through the BCH using the Submission (SUB) common format accessible at the following link: https://bch.cbd.int/en/register/SUB/new. The submission should include a signed endorsement by the national focal point for the Cartagena Protocol on Biosafety. Full instructions on how to upload submissions are provided at: https://bch.cbd.int/nkl_suppl_protocol/how_to_submit_on_bch-nklsp.docx.

The information received will be compiled and submitted for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting.
In preparing your submission, you may wish to consult the study on financial security mechanisms which was welcomed in decision CP-10/13. The executive summary of the study is available in the six official languages of the United Nations in the annex to document CBD/CP/MOP/10/9, available at https://www.cbd.int/meetings/CP-MOP-10.

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

No new content identified.

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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

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

ICMR [Indian Council for Medical Research] – Public Consultation
https://ethics.ncdirindia.org/CHIS_Public_Consultation.aspx

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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