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governance, ethics, evidence, policy, practice
human rights action :: humanitarian response :: health ::
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Public Consultations Watch :: Global Calls for Input/Public Comment/RFIs

15 June 2023 – Issue 04

GE2P2 Global is a foundation and public benefit corporation affiliate advancing scientific rigor, ethical resilience, and integrity in research and evidence generation informing governance, policy, practice.

In the context of this mission, GE2P2 Global is developing a formal 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, and sustainable development.

This span of sectors yields a broad variety of opportunities, even though public consultation is not employed in any uniform way across the UN system, multilateral agencies, INGOs or UN member states and their ministerial/regulatory bodies. As we are still refining our 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 these opportunities where the experience and expertise of members of its 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 public consultation opportunities primarily focused on global health and biomedical research.

Individuals and organizations/institutions interested in collaborating on responses to any of the opportunities listed below are welcome to contact David R Curry, GE2P2 Global Foundation, at 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.

Opportunities for public consultation are organized by due date of inputs/submissions. The initial list below presents title/ source due date. This is followed by the same information with each call's respective "abstracts" including selected information around purpose, objective, and background. Most opportunities have relatively short time horizons for response, typically 60-90 days from the date of posting.

Public Consultation Calls: Title/Source/Due Date

I4T [Internet for Trust] - Safeguarding freedom of expression and access to information: guidelines for a multistakeholder approach in the context of regulating digital platforms
Corporate author : UNESCO [65720]
Draft 3.0 27 April 2023 **Open for consultation until 27 June 2023**

Stakeholder Listening Session on Amendments to the International Health Regulations (2005)
A Notice by the U.S. Health and Human Services Department on 04/13/2023
Written Comment Re: Stakeholder Listening Session 2 for the IHR " by **Friday, June 30, 2023.**

Call for inputs for the study of the Human Rights Council Advisory Committee on neurotechnology and human rights (HRC resolution 51/3)
Issued by Advisory Committee, UNHCHR **Deadline 02 July 2023**

Methodological Challenges Related to Patient Experience Data; Request for Information and Comments
FDA, posted 05/02/2023 **Comments by July 3, 2023**

NIST Research Data Framework – Request for Comment
U.S. National Institute of Standards and Technology, Department of Commerce
Publication Date: 06/06/2023 Comments by 5 p.m. Eastern time on **July 6, 2023.**

Stakeholder Listening Session for the Intergovernmental Negotiating Body (INB) To Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response
A Notice by the U.S. Health and Human Services Department
"Written Comment Re: Stakeholder Listening Session 2 for the INB " by **Friday, July 7, 2023**

Request for Information; National Priorities for Artificial Intelligence
U.S. Science and Technology Policy Office
Publication Date: 05/26/2023 Comments by 5:00 p.m. ET on **July 7, 2023.**

Real-World Data and Real-World Evidence in Regulatory Decision Making
CIOMS Working Group XIII
Submissions deadline 14th of July 2023

Benefit-risk balance for medicinal products
CIOMS Working Group
Draft report: CIOMS WG XII_For Comment_12June2023
Posted: 03 June 2023 **Comments deadline: 24th of July 2023**

Decentralized Clinical Trials for Drugs, Biological Products, and Devices; Draft Guidance for Industry, Investigators, and Other Stakeholders
FDA Docket No. FDA-2022-D-2870
Deadline: 01 Aug 2023

Call for Inputs: Human Rights Council resolution 49/12 on the rights of persons with disabilities
Office of the High Commissioner for Human Rights
Deadline: 01 August 2023

Call for contributions: Draft General Recommendation n°37 on Racial discrimination in the enjoyment of the right to health
UN - Treaty bodies
Deadline: 04 August 2023

Public Consultation: ICH E6(R3) [GCP] Principles, Annex 1 and Annex 2
ICH - The E6(R3) EWG is working on the revision of the E6(R2) Guideline "Good Clinical Practice" (GCP) .
. E6(R3) Draft Guideline
Public consultation dates:

FDA, USA, Comment period: Aug 6 2023
ANVISA, Brazil - Deadline for comments by 31 August 2023
MHRA, UK - Deadline for comments by 31 August 2023
TFDA, Chinese Taipei - Deadline for comments by 31 August 2023
EC, Europe - Deadline for comments by 26 September 2023

Request for Information on Catalyzing the Development and Use of Novel Alternative Methods to Advance Biomedical Research
Notice Number: NOT-OD-23-140
Office of The Director, National Institutes of Health (OD)
Release Date: June 12, 2023 **Response Date: August 16, 202**

Promoting Environmental Democracy: Procedural elements of the human right to a clean, healthy and sustainable environment
Issued by Special Rapporteur on human rights and the environment, UNHCHR
Deadline: 02 October 2023

ISO/AWI 14155 - Biological and clinical evaluation of medical devices
ISO/TC 194 Stage 20.00
Due: Ongoing at national standards bodies level

Public Consultation Calls: Selected Purpose/Objective/Background Information

I4T [Internet for Trust] - Safeguarding freedom of expression and access to information: guidelines for a multistakeholder approach in the context of regulating digital platforms

Corporate author : UNESCO [65720]
Draft 3.0 27 April 2023 Open for consultation until **27 June 2023**
Document code : CI-FEJ/FOEO/3 Rev.
Collation : 33 pages Language : English
Conference : Internet for Trust - Towards Guidelines for Regulating Digital Platforms for Information as a Public Good, Paris, 2023 [7]

UNESCO is engaged in a series of consultations to develop a set of draft global guidelines for regulating digital platforms, to safeguarding freedom of expression and access to information. These guidelines focus on the structures and processes needed to ensure users have a safer and more critical interaction with online content, to simultaneously support freedom of expression and the availability of accurate and reliable information in the public sphere.

Stakeholder Listening Session on Amendments to the International Health Regulations (2005)

A Notice by the U.S. Health and Human Services Department on 04/13/2023
Written Comment Re: Stakeholder Listening Session 2 for the IHR " by
Friday, June 30, 2023.
Purpose:

The U.S. Department of Health and Human Services (HHS) is charged with leading U.S. participation in the Working Group on the Amendments to the International Health Regulations (2005) and will convene a Stakeholder Listening Session.

The World Health Assembly (WHA) originally adopted the International Health Regulations (IHR) in 1969. The regulations were amended multiple times, resulting in the current IHR (2005). The purpose of IHR (2005) is to prevent, protect against, control, and provide public health response to the international spread of disease. In May 2021, Member States set up a Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) with the intent of strengthening WHO's capacities and ability to support Member States in the prevention and response of public health emergencies. The WGPR produced a report with key findings and recommendations that included amending the IHR. The United States submitted a package of targeted amendments to the IHR for consideration. These amendments seek to improve early warnings and alerts, transparency, and accountability in a manner that does not compromise national security or sovereignty.

Other countries have also submitted proposals [and] the United States seeks feedback from stakeholders on the proposed amendments. The Stakeholder Listening Session is designed to seek input from stakeholders and subject-matter experts on these proposals and to help inform and prepare the U.S. government for engagement with the Working Group on the Amendments to the International Health Regulations (2005).

Call for inputs for the study of the Human Rights Council Advisory Committee on neurotechnology and human rights (HRC resolution 51/3)

Issued by Advisory Committee, UNHCHR

Deadline 02 July 2023

Purpose:

The Human Rights Council Advisory Committee seeks the views and inputs from stakeholders, including Member States, 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, other relevant United Nations agencies, funds and programmes within their respective mandates, national human rights institutions, civil society, the private sector, medical and technical communities, academic institutions and other relevant stakeholders, in order to prepare a study on the impact, opportunities and challenges of neurotechnology with regard to the promotion and protection of all human rights, including recommendations on how human rights opportunities, challenges and gaps arising from neurotechnology could be addressed by the Human Rights Council and its special procedures and subsidiary bodies in a coherent, holistic, inclusive and action-oriented manner, and to present the study to the Council at its fifty-seventh session (September 2024).

Methodological Challenges Related to Patient Experience Data; Request for Information and Comments

FDA 05/02/2023

Comments by July 3, 2023

Background

Under the seventh iteration of the Prescription Drug User Fee Act (PDUFA VII), incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to continue to strengthen capacity to facilitate development and use of patient-focused methods to inform drug development and regulatory decisions, including issuing this Request for Information (RFI) to elicit public input on methodologic challenges encountered by stakeholders, and other areas of greatest interest or concern to public stakeholders. These methodologic challenges may be related to the collection and analysis of patient experience data, generally, or they may be related more specifically to the submission and evaluation of patient experience data in the context of FDA's benefit-risk assessment or product labeling.

NIST Research Data Framework

U.S. National Institute of Standards and Technology, Department of Commerce

Publication Date: 06/06/2023 Comments by 5 p.m. Eastern time on **July 6, 2023.**

SUMMARY:

The National Institute of Standards and Technology (NIST) seeks comments on NIST's Research Data Framework (RDaF or Framework). The RDaF is a tool that aims to help shape the future of open data access and research data management. A broader range of stakeholder views is needed for refining the next version of the RDaF. The current draft of the RDaF is available electronically from the NIST website at: https://doi.org/10.6028/NIST.SP.1500-18r1. All individuals and organizations with influence on and who are influenced by research data management are encouraged to offer their input.

Stakeholder Listening Session for the Intergovernmental Negotiating Body (INB) To Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response

A Notice by the U.S. Health and Human Services Department
"Written Comment Re: Stakeholder Listening Session 2 for the INB " by **Friday, July 7, 2023**
Purpose:

The U.S. Department of Health and Human Services (HHS) and the Department of State are charged with co-leading the U.S. delegation to the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response and will convene an informal Stakeholder Listening Session.

The Stakeholder Listening Session is designed to seek input from stakeholders and subject matter experts to help inform and prepare for U.S. government engagement with the Intergovernmental Negotiating Body.

Matters to be Discussed:

The listening session will discuss potential areas that could be included in a pandemic accord to promote pandemic prevention, preparedness, and response. Topics will include those found in the current draft of the Pandemic Accord. More information can be found at: https://apps.who.int/gb/inb/index.html. Participation is welcome from all stakeholder communities.

Request for Information: National Priorities for Artificial Intelligence

U.S. Science and Technology Policy Office
Publication Date: 05/26/2023 Comments by 5:00 p.m. ET on **July 7, 2023.**
SUMMARY:

The Biden-Harris Administration is developing a National Artificial Intelligence (AI) Strategy that will chart a path for the United States to harness the benefits and mitigate the risks of AI. This strategy will build on the actions that the Federal Government has already taken to responsibly advance the development and use of AI. To inform this strategy, OSTP requests public comments to help update U.S. national priorities and future actions on AI.

Information Requested:

Respondents may provide information for one or more of the questions listed below, as desired. Note that the list below does not cover some AI topics as completely, such as AI research and development, given ongoing or recent RFIs on those topics. [Twenty eight questions are suggested for comment across the following areas]:

- Protecting rights, safety, and national security
- Advancing equity and strengthening civil rights
- Bolstering democracy and civic participation
- Promoting economic growth and good jobs
- Innovating in public services

Real-World Data and Real-World Evidence in Regulatory Decision Making

CIOMS Working Group XIII
Submissions deadline 14th of July 2023
Draft: CIOMS WG XIII_6June2023_Draft report for comment
Background

There is increasing interest in the use of Real-World data (RWD) to support regulatory decision making across the product life cycle. Key sources of RWD are electronic health records, claims data, prescription data, and patient registries. Real-world evidence (RWE) is the clinical evidence about the usage and potential benefits or risks of a medical product derived from an analysis of RWD. For decades, such

evidence has been well accepted for satisfying post-approval safety monitoring requirements but has not been used commonly to demonstrate drug effectiveness, which is a relatively new concept.

As applications are increasing, it is proposed that CIOMS develop a consensus report and recommendations for the use of RWD and RWE in regulatory decision-making related to biopharmaceutical products. This report will cover three key areas:

:: Articulate the different RWD/RWE requirements depending on the intent of use e.g. Regulatory, Payers, and Public Health;

:: Propose harmonized practices and guidance for using RWD and RWE for regulatory purposes (given that there are no existing consensus guidelines);

:: Articulate point of view (POV) on key ethical issues relevant to RWD and RWE and a provisional set of standards to address those issues (the high-level POV may lead to a separate/satellite group of ethicists to deal with it). Full Concept Note (31 March 2020)

Benefit-risk balance for medicinal products

CIOMS Working Group VII report draft, 12 June 2023
Draft report: CIOMS WG XII_For Comment_12June2023
Posted: 03 June 2023 **Comments deadline: 24th of July 2023**

The WG will build on previous considerations established by CIOMS WG IV, incorporating the latest thinking in quantitative and qualitative approaches to the evaluation of benefit-risk (B-R), as well as assimilating visual presentations of benefits and risks to improve transparency and understanding amongst key stakeholders, including patients. The perspective of healthcare professionals and patients will be considered based on other ongoing initiatives as well as new guidelines from regulatory authorities and public-private partnerships.

Decentralized Clinical Trials for Drugs, Biological Products, and Devices; Draft Guidance for Industry, Investigators, and Other Stakeholders; Availability

FDA – U.S. Food and Drug Administration, HHS.
Publication Date: 05/03/2023 Submit comments on the draft guidance by **August 1, 2023**
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry, investigators, and other stakeholders entitled “Decentralized Clinical Trials for Drugs, Biological Products, and Devices.” This draft guidance provides recommendations for sponsors, investigators, and other stakeholders regarding the implementation of decentralized clinical trials (DCTs) for drugs, biological products, and devices. In this draft guidance, a DCT refers to a clinical trial where some or all of the trial-related activities occur at locations other than traditional clinical trial sites.

Call for Inputs: Human Rights Council resolution 49/12 on the rights of persons with disabilities

Office of the High Commissioner for Human Rights
Deadline: 01 August 2023
Purpose:

To inform the Office’s next thematic report on "good practices on support systems to ensure community inclusion of persons with disabilities, including as a means of building forward better after the COVID-19 pandemic" to be presented at the 55th session of the Human Rights Council.

Key questions and types of input/comments sought:

The OHCHR would be grateful to receive any relevant information for the preparation of this study. In particular, we welcome views and information in relation to the questions included in the following questionnaires: Download the questionnaire (PDF): English | Français | Español

Call for contributions: Draft General Recommendation n°37 on Racial discrimination in the enjoyment of the right to health

UN - Treaty bodies

Deadline: 04 August 2023

All stakeholders, including States, United Nations and regional human rights mechanisms, United Nations entities and specialised agencies, national human rights institutions, civil society and grassroot organisations, research institutions, academia and other relevant stakeholders (i.e., health-related entities, practitioners or laboratories) are invited to submit their written comments to ohchr-cerd-gr37@un.org. The current version of the draft General recommendation can be found here in English (original version), French and Spanish (informal translations).

Public Consultation: ICH E6(R3) [GCP] Principles, Annex 1 and Annex 2

The E6(R3) EWG is working on the revision of the E6(R2) Guideline "Good Clinical Practice" (GCP) with a view to addressing the application of GCP principles to the increasingly diverse trial types and data sources being employed to support regulatory and healthcare related decision-making on drugs, and provide flexibility whenever appropriate to facilitate the use of technological innovations in clinical trials. Additional information may also be found in ICH Reflection Paper on "GCP Renovation" on the ICH Reflection Paper page. When complete, E6(R3) will be composed of an overarching principles and objectives document, Annex 1 and Annex 2. E6(R3) Draft Guideline

Public consultation dates:

ANVISA, Brazil - Deadline for comments by 31 August 2023

EC, Europe - Deadline for comments by 26 September 2023

MHRA, UK - Deadline for comments by 31 August 2023

TFDA, Chinese Taipei - Deadline for comments by 31 August 2023

FDA Announces Additional Steps to Modernize Clinical Trials

https://www.fda.gov/news-events/press-announcements/fda-announces-additional-steps-modernize-clinical-trials

ICH HARMONISED GUIDELINE GOOD CLINICAL PRACTICE (GCP) E6(R3)

For Immediate Release: June 06, 2023 **Comment period: Aug 6 2023**

Today, the U.S. Food and Drug Administration is announcing the availability of a draft guidance with updated recommendations for good clinical practices (GCPs) aimed at modernizing the design and conduct of clinical trials, making them more agile without compromising data integrity or participant protections. The updates are intended to help pave the way for more efficient clinical trials to facilitate the development of medical products. The draft guidance is adopted from the International Council for Harmonisation's (ICH) recently updated E6(R3) draft guideline that was developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise.

Request for Information on Catalyzing the Development and Use of Novel Alternative Methods to Advance Biomedical Research

Notice Number: NOT-OD-23-140
Office of The Director, National Institutes of Health (OD)
Release Date: June 12, 2023 **Response Date: August 16, 2023**

Purpose

The National Institutes of Health (NIH) seeks public input on challenges and opportunities for the further development and use of novel alternative methods (NAMs) in biomedical research. NIH investment in these methods have proven beneficial tools across basic and clinical research studies, being developed and applied to interrogate cancer, diabetes, cardiovascular disease, Alzheimer's disease, infectious disease, rare diseases, and more. Each NAM approach has unique strengths and limitations that vary depending on the specific research question being addressed.

To identify areas in which the development and use of NAMs provide the most value to biomedical research, NIH sought the assistance of the Advisory Committee to the Director (ACD), an advisory group that provides advice on matters pertinent to NIH mission responsibilities in the conduct and support of biomedical research, medical science, and biomedical communications. The purpose of this request is to inform the NIH and the development of the ACD's recommendations on high-priority areas for future investment…

Request for Information

To support the activities of the ACD Working Group, NIH is requesting information from the interested individuals and communities on challenges and opportunities for the development and use of NAMs in biomedical research. Input sought includes, but is not limited to, feedback on the following:

:: The use of novel alternative methods to study human biology, circuits, systems, and disease tates. The value of any modeling approach is based on the assertion that known similarities between the model and the subject matter permit conclusions that additional features observed in the model will also be observed in the domain to which the model is applied. An optimal future state is one in which our understanding of human biology is sufficient to design modeling systems that accurately reflect the complexity of that biology. NIH is particularly interested in hearing how NAMs:

- are currently being developed and/or used successfully, including features that maximize scientific utility:
- are advancing progress into understanding specific biological processes or human states, including potential limitations to addressing human variability; and
- could be truly revolutionary for understanding/treating human health, including currently underserved areas of biomedical research.

:: Approaches for catalyzing the development and validation of novel alternative method technologies. Many of the issues with rigor and translatability in animal models must also be addressed for non-animal models, such as considerations of human biological relevance, study design, statistical analysis, data sharing, and reporting. However, there are additional considerations for rigor and translatability that are unique to the development of NAMs, where development of new technologies and methodologies can outpace scientific consensus on standards. NIH is particularly interested in hearing from the public on:

- challenges for building in robustness, replicability, reproducibility and reliability of the technologies and the ensuing datasets;
- strategies for bolstering technology readiness and reliability these technologies; and
- factors potentially limiting the successful integration of these technologies across research approaches and potential solutions.

:: Strategies for maximizing the research value of novel alternative method technologies. Depending on the biological system or disease state, different combinations of methods may be required to provide

the strongest body of evidence. NIH is particularly interested in hearing from the public on how to scale these technologies to more effectively advance scientific inquiry or improve translation, including:

- areas in which coordinated approaches across research disciplines or research sectors would dramatically advance the development and or use of these technologies.
- approaches for sharing technology deployment equitably across labs, including incentives for reliable and reproducible methods integration.
- factors for consideration when maximizing translatability and minimizing bias regarding human variability.

Promoting Environmental Democracy: Procedural elements of the human right to a clean, healthy and sustainable environment

Issued by Special Rapporteur on human rights and the environment, UNHCHR

Deadline: 02 October 2023

Purpose:

To inform the entity's report on the implementation of the human right to a clean, healthy and sustainable environment which will be presented at 55th session of the Human Rights Council.

Background:

The Special Rapporteur has completed a series of six thematic reports on the substantive elements of the human right to a clean, healthy and sustainable environment, including clean air, safe and sufficient water, healthy and sustainably produced food, non-toxic environments, healthy ecosystems and biodiversity and a safe, livable climate. He would like to seek inputs on the procedural or participatory elements of the right to a clean, healthy and sustainable environment, including access to information, public participation and access to justice with effective remedies…

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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