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

06 October 2023 - Issue 08

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 these 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 consultation opportunities.

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 Final, Published Guidances/Regulations/Laws Employing Calls for Public Consultation

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

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

Request for Information; Potential Changes to the Policies for Oversight of Dual Use Research of Concern (DURC) and the Potential Pandemic Pathogen Care and Oversight (P3CO) Policy Framework
A Notice by the U.S. Science and Technology Policy Office on 09/01/2023
Responses are due on October 16, 2023

Copyright Office Issues Notice of Inquiry on Copyright and Artificial Intelligence
Library of Congress 30 August 2023
Written comments are due Oct. 18, 2023. Reply comments are due by 11:59 p.m. EDT on Wednesday, Nov. 15, 2023..

Call for input: Advocacy of Hatred Based on Religion or Belief - Transformative Responses
UNHCHR - Special Procedures
Issued by Special Rapporteur on freedom of religion or belief
Deadline: 29 October 2023

Call for inputs: Human Rights Council resolution 52/8 on promoting human rights and the Sustainable Development Goals through transparent, accountable and efficient public service delivery
Call for input | Office of the High Commissioner for Human Rights
Deadline: 01 November 2023

Call for input 2023 - Meaningful engagement of Indigenous Peoples and local communities in Article 6.4 mechanism
United Nations Climate Change
5 October to **2 November 2023**

National One Health Framework To Address Zoonotic Diseases and Advance Public Health Preparedness in the United States: A Framework for One Health Coordination and Collaboration Across Federal Agencies
A Notice by the Centers for Disease Control and Prevention on 09/20/2023
Written comments must be received on or before **November 6, 2023.**

NIH Seeking Comment on Draft Scientific Integrity Policy
Posted on September 22, 2023
Comments will be accepted until November 9, 2023

Scientific Challenges and Opportunities To Advance the Development of Individualized Cellular and Gene Therapies; Request for Information
A Notice by the Food and Drug Administration on 09/21/2023
Comment period ends 11/20/2023

Request for Information (RFI): Inviting Comments and Suggestions on Updating the NIH Mission Statement
NIH Posted August 28, 2023
To ensure consideration, **responses must be submitted by: 2023-11-24**

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

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

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/Scope/Background Information – Sorted by Thematic Area

Biomedical Research/Regulation/Governance

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

Status: Step 3

Public consultation dates remaining:

Health Canada, Canada - Deadline for comments by **20 October 2023**

Request for Information; Potential Changes to the Policies for Oversight of Dual Use Research of Concern (DURC) and the Potential Pandemic Pathogen Care and Oversight (P3CO) Policy Framework

A Notice by the U.S. Science and Technology Policy Office on 09/01/2023

Responses are due on October 16, 2023

SUMMARY:

Life sciences research is vital for improving health outcomes and protecting the Nation from infectious disease threats, but a small subset of this research could potentially pose risk of accidents or misuse that could harm human health. It is important to regularly evaluate and update biosafety and biosecurity oversight policies to keep pace with new technological developments and the evolving risk landscape.

The Office of Science and Technology Policy (OSTP) invites comments on potential changes to the Policies for Federal and Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC) and Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO). These policies establish frameworks for review and oversight requirements for certain categories of life sciences research, namely research with certain pathogens and toxins, including at institutions that accept Federal funding for such research... The public input provided through this Request for Information (RFI) will inform policy evaluations and issuance of a revised policy (Revised Policy).

National One Health Framework To Address Zoonotic Diseases and Advance Public Health Preparedness in the United States: A Framework for One Health Coordination and Collaboration Across Federal Agencies

A Notice by the Centers for Disease Control and Prevention on 09/20/2023

Written comments must be received on or before **November 6, 2023.**

PDF: https://www.govinfo.gov/content/pkg/FR-2023-09-20/pdf/2023-20338.pdf

SUMMARY:

The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on the draft National One Health Framework to Address Zoonotic Diseases and Advance Public Health Preparedness in the United States: A Framework for One Health Coordination and Collaboration across Federal Agencies (NOHF-Zoonoses).

…This framework will facilitate One Health collaboration for zoonotic disease prevention and control across the United States Government for the next five years. It describes a common vision, mission, and goals for key federal partners involved in implementing a One Health approach to address zoonotic diseases and advance public health preparedness in the United States.

SUPPLEMENTARY INFORMATION:

CDC and our federal partners invite public comments to inform revisions to the proposed framework and follow-up activities. Commenters are encouraged to answer the following questions:

- Are there any new or proposed objectives that should be prioritized?
- What attributes and characteristics of the proposed framework will most likely lead to success?
- Are there any specific barriers or gaps to achieving success?
- Are there any critical steps or milestones necessary to successfully implement the proposed framework?
- How do state, tribal, local, and territorial partners, non-governmental organizations, academic institutions, private sector partners, and other partners want to engage with federal collaborators to advance implementation of this framework?
- What additional One Health issues should be prioritized in the future?
- What information or recommendations are needed to ensure the guiding principles of health equity, sustainability, stewardship, and a multisectoral approach are adequately addressed in the framework? How can these guiding principles be elevated during follow-up development and drafting of implementation plans?

NIH Seeking Comment on Draft Scientific Integrity Policy

Posted on September 22, 2023

Comments will be accepted until November 9, 2023

Today, NIH is releasing the Draft Scientific Integrity Policy of the National Institutes of Health for public comment. The draft policy articulates the procedures and processes in place at NIH that help maintain rigorous scientific integrity practices. Additionally, the draft policy proposes several new functions to further enhance scientific integrity at NIH and throughout the biomedical research enterprise.

The draft policy incorporates and is responsive to the principles and directives of the Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, Protecting the Integrity of Government Science, and A Framework for Federal Scientific Integrity Policy and Practice.

The full draft policy can be viewed here. . Comments must be submitted through the comment form found at: https://osp.od.nih.gov/comment-form-draft-scientific-integrity-policy-for-the-national-institutes-of-health/.

Additional context on the draft policy can be found in the latest Under the Poliscope blog at: https://osp.od.nih.gov/make-your-voice-heard-on-nihs-draft-scientific-integrity-policy/.

Scientific Challenges and Opportunities To Advance the Development of Individualized Cellular and Gene Therapies; Request for Information

A Notice by the Food and Drug Administration on 09/21/2023

Comment period ends (11/20/2023)

SUMMARY:

The Food and Drug Administration (FDA or Agency), Center for Biologics Evaluation and Research (CBER) is requesting information from stakeholders regarding critical scientific challenges and opportunities to advance the development of individualized cellular and gene therapies (CGTs). FDA intends to gather information and comments submitted in response to this request for information (RFI) to inform potential planning of future town halls, workshops, or discussion papers which could ultimately facilitate the development of additional regulatory science tools, standards, or guidance.

Request for Information (RFI): Inviting Comments and Suggestions on Updating the NIH Mission Statement

NIH Posted August 28, 2023

To ensure consideration, **responses must be submitted by: 2023-11-24**

As the largest public funder of biomedical and behavioral research in the world, NIH works to turn scientific discoveries into better health for all. This RFI will inform NIH's efforts to update its mission statement to ensure that it reflects the NIH mission as accurately as possible. See guide notice NOT-OD-23-163 for more information.

Information Requested

This RFI invites input from interest groups throughout the scientific research, advocacy, and clinical practice communities, those employed by NIH or at institutions receiving NIH support, and the public, on a proposed revised mission statement. The bolded language reflects differences between the current and proposed mission statements.

Current mission statement:

"To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."

Proposed revised mission statement:

"To seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to optimize health and prevent or reduce illness for all people."

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.

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
Committee for Medicinal Products for Human Use (CHMP) 3
Committee for Medicinal Products for Veterinary Use (CVMP)
End of consultation (deadline for comments): 31 December 2023
Comments should be provided using this EUSurvey form).

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.

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

Copyright Office Issues Notice of Inquiry on Copyright and Artificial Intelligence

Library of Congress 30 August 2023

Written comments are due by 11:59 p.m. EDT on Wednesday, Oct. 18, 2023. Reply comments are due by 11:59 p.m. EDT on Wednesday, Nov. 15, 2023..

The Copyright Office will use the record it assembles to advise Congress; inform its regulatory work; and offer information and resources to the public, courts, and other government entities considering these issues.

The notice of inquiry seeks factual information and views on a number of copyright issues raised by recent advances in generative AI. These issues include the use of copyrighted works to train AI models, the appropriate levels of transparency and disclosure with respect to the use of copyrighted works, the legal status of AI-generated outputs, and the appropriate treatment of AI-generated outputs that mimic personal attributes of human artists.

The notice of inquiry is an integral next step for the Copyright Office's AI initiative, which was launched in early 2023. Instructions for submitting comments are available on the Office's website. Commenters may choose which and how many questions to respond to in the notice of inquiry.

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

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Environment/Climate/Disaster Mitigation

Call for input 2023 - Meaningful engagement of Indigenous Peoples and local communities in Article 6.4 mechanism

United Nations Climate Change

5 October to **2 November 2023**

The Supervisory Body encourages Indigenous Peoples, local communities, or groups that work with Indigenous Peoples and local communities to provide inputs on how to meaningfully engage with them on the work of the Supervisory Body and the mechanism. The submission could include input, for instance, on:

- What are the current or anticipated challenges Indigenous Peoples and local communities face in engaging with the Article 6.4 mechanism?
- What mode of communications could facilitate better dialogue between the Supervisory Body and Indigenous communities?
- How would you envision meaningful long-term engagement and active participation from Indigenous Peoples and local communities on the work of the Supervisory Body and the mechanism?

Please submit your input to the Supervisory Body via email at A6.4mechanism-info@unfccc.int.

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Human Rights

Call for input: Advocacy of Hatred Based on Religion or Belief - Transformative Responses

UNHCHR - Special Procedures
Issued by Special Rapporteur on freedom of religion or belief
Deadline: 29 October 2023
Objectives

In this forthcoming report, the Special Rapporteur intends to explore the dimension of hatred and its relationship to intolerance, discrimination, and violence based on religion or belief. She seeks to identify gaps in State and civil society responses to countering advocacy of such hatred, explore their impact, share best practices from the ongoing efforts of different stakeholders, and assess implications for developing transformative responses to counter the advocacy of hatred based on religion or belief.

The Special Rapporteur invites all interested parties (States, UN agencies and international organisations, national human rights institutions, businesses especially media and tech companies, civil society organisations including religious or belief minorities and communities) to provide input for this report in response to the [15] relevant questions noted.

Call for inputs: Human Rights Council resolution 52/8 on promoting human rights and the Sustainable Development Goals through transparent, accountable and efficient public service delivery

Call for input | Office of the High Commissioner for Human Rights
Deadline: 01 November 2023
Purpose:
To inform the report on the role of public service delivery in the promotion and protection of human rights and in the achievement of the Sustainable Development Goals, including in relation to the protection of persons in vulnerable situations, that reflects best practices, challenges and recommendations in assisting national Governments in delivering transparent, accountable and efficient public services.

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

Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies; Guidance for Industry, Investigators, and Institutional Review Boards; Availability – FINAL Guidance

A Notice by the Food and Drug Administration on 09/21/2023
PDF: https://www.regulations.gov/document/FDA-2023-D-3550-0002
SUMMARY:
The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies." This guidance recommends approaches that sponsors of clinical trials of medical products can consider when there is a major disruption to clinical trial conduct and operations due to disasters or public health emergencies, which can include but are not limited to hurricanes, earthquakes, military conflicts, infectious disease outbreaks, or bioterrorist attacks. The appendix to this guidance further explains those approaches by providing answers to questions that the Agency has received about conducting clinical trials during major disruptions.

FDA - Meetings: Mitigating Clinical Study Disruptions during Disasters and Public Health Emergencies

DATES: **The public meeting will be held virtually on October 18 and 19, 2023**, from 10 a.m. to 1:30 p.m. Eastern Time

Meeting only; No public comment opportunity identified

.SUMMARY:

The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled "Mitigating Clinical Study Disruptions During Disasters and Public Health Emergencies." This public meeting will satisfy the mandate of the Food and Drug Omnibus Reform Act of 2022 (FDORA) to convene a public meeting on clinical study flexibilities initiated in response to the COVID–19 pandemic. The public meeting will be convened and supported by a cooperative agreement between FDA and the Clinical Trials Transformation Initiative (CTTI) to bring the clinical research community together to discuss a variety of topics related to mitigating disruptions of clinical studies of medical products during disasters and public health emergencies (PHEs). The meeting format will include presentations and panel discussions.

Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: www.duke.zoom.us/meeting/register/tJAvcO-oqD4vE9Ov1Vv-A3SoItVhL7Rhg66T. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free, and persons interested in attending this public meeting must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products; Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 08/31/2023

August 31, 2023.

PDF: https://www.govinfo.gov/content/pkg/FR-2023-08-31/pdf/2023-18841.pdf

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products." FDA is issuing this guidance as part of its Real-World Evidence (RWE) Program for drugs and to satisfy, in part, the mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance about the use of RWE in regulatory decision making. This guidance discusses the applicability of FDA's investigational new drug application (IND) regulations to various clinical study designs that utilize real-world data (RWD) and clarifies the Agency's expectations regarding clinical studies using RWD submitted to FDA in support of a regulatory decision regarding the effectiveness or safety of a drug that are not subject to the IND regulations. This guidance finalizes the draft guidance of the same title issued on December 9, 2021.

Institutional Review Board Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products; Guidance for Institutional Review Boards and Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY:

The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for institutional review boards (IRBs) and clinical investigators entitled "Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products." FDA is issuing this final guidance to provide recommendations regarding the key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions, including for reviews conducted by a single member of the IRB, to fulfill its obligations under FDA regulations. Although FDA has issued guidance on expanded access requests, including expanded access for individual patients, the Agency is aware that IRBs seek further clarity on this topic.

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