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governance, ethics, evidence, policy, practice

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

28 August 2025 - Issue 34

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

In the context of this mission, GE2P2 Global monitors public consultations/calls for input/RFIs and similar opportunities across its focus areas of global health, human rights, humanitarian action, education/literacy, heritage, climate/environment, peace, and sustainable development.

Monitoring this span of sectors yields a broad variety of public comment opportunities, even though this modality is not employed in any uniform way across the UN system, multilateral agencies, INGOs, member states or their ministerial/regulatory bodies. As we are still exploring this monitoring approach and broadening the range of calls included, we stress that this is an indicative and not an exhaustive digest.

In parallel, GE2P2 Global is striving to respond to public consultation opportunities where the experience and expertise of members of our growing community of practice suggest that a meaningful contribution can be developed. The GE2P2 Global Foundation also functions as the secretariat for the Global Forum for Research Ethics and Integrity – a global group of individuals from over 30 countries who collaborate on analysis and action, including response to selected public consultations.

We welcome information about calls for public consultation – at global or country level – to help enrich this digest. Equally, individuals and organizations/institutions interested in collaborating on joint responses to any of the opportunities listed below are welcome to contact us [David R Curry, GE2P2 Global Foundation, david.r.curry@ge2p2global.org].

Acknowledgements: We appreciate the support of Foundation Senior Fellow Gerald Schatz, JD for his continuing support in helping identify calls included in this digest, and Associate Fellow Sedem Adiabu, MPH, for her critical role in the secretariat function which supports development of submissions to selected calls.

Digest content is organized in three sections:

[1] Title and source of all calls organized by due date [p.2 ff]
[2] All calls, listed with more comprehensive information [i.e., objective, scope] organized by due date under thematic areas: Biomedical Research; Environment/Climate; Human Rights+ [p.5 ff]
[3] Selected Supplementary Content including Final, Published Guidances/Regulations/Laws Employing Calls for Public Consultation [p.15 ff]

We expect to add thematic areas as our digest evolves and becomes more comprehensive.

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

Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Use Authorization of Medical Products
A Notice by the Food and Drug Administration on 07/14/2025 **Comment period ends 09/12/2025.**

Call for written submissions on the draft guidelines on addressing multiple and intersectional forms of discrimination against women and girls with disabilities
UN - Treaty bodies **Deadline: 15 September 2025**

NEW **- Request for Information on Maximizing Research Funds by Limiting Allowable Publishing**
NIH - Notice Number: NOT-OD-25-138
Release Date: July 30, 2025 **Response Date: September 15, 2025**

Proposed Data Collection Submitted for Public Comment and Recommendations – Enhancing Data-Driven Disease Detection in Newborns
A Notice by the Centers for Disease Control and Prevention on 07/18/2025 **Comment period ends 09/16/2025.**

NEW **- Notice of Meeting: Advisory Committee on Research on Women's Health**
A Notice by the National Institutes of Health on 08/25/2025
Date: October 7, 2025. Time: 9:00 a.m. to 4:00 p.m. **Comments due September 16, 2025**

ICH - E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials; International Council for Harmonisation; Draft Guidance for Industry; Availability
A Notice by the Food and Drug Administration on 07/21/2025 **Comment period ends 09/19/2025**

NEW **- Request for Nominations of Members To Serve on the Healthcare Advisory Committee**
A Notice by the Health and Human Services Department on 08/22/2025 **Due: September 22, 2025.**

NEW **- Establishing a Road Map for Accelerated Diagnosis and Treatment of HCV Infection in the United States**
A Notice by the Centers for Disease Control and Prevention on 08/20/2025
Written comments must be received **on or before September 24, 2025.**

Solicitation of Nominations for Appointment to the Advisory Council for the Elimination of Tuberculosis
A Notice by the Centers for Disease Control and Prevention on 07/11/2025. **Nominations must be received no later than September 30, 2025**

NEW - **Call for Public Comment - WHO Classification of Digital Health Interventions v1.0**
WHO 1 September 2022 **Deadline for comments: 30 September 2022, 23:59 (CEST)**

Draft guideline on the quality aspects of mRNA vaccines
Draft: consultation open **Consultation dates: 31/03/2025 to 30/09/2025**
Reference Number: EMA/CHMP/BWP/82416/2025

Request for Public Comment: National Plan for Arctic Research
National Science Foundation on 07/21/2025. **Written responses are due by October 15, 2025.**

NEW - **Call for Input for the report on Peace and International Solidarity**
UNHCHR - Issued by Independent Expert on human rights and international solidarity
Deadline: 17 October 2025

NEW - **Proposed Data Collection Submitted for Public Comment and Recommendations [Data Management Plans]**
A Notice by the Centers for Disease Control and Prevention on 08/26/2025
DATES:CDC must receive written **comments on or before October 27, 2025.**

NEW - **Call for input – Unilateral Coercive Measures and Humanitarian Action**
UNHCHR - Issued by Special Rapporteur on unilateral coercive measures
Deadline: 20 October 2025

NEW - **Onshoring Manufacturing of Drugs and Biological Products; Public Meeting; Request for Comments**
A Notice by the Food and Drug Administration on 08/08/2025 **Comment period ends 10/30/2025**

Concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a veterinary medicinal product
EMA - Draft: consultation open **Consultation dates: 16/04/2025 to 31/10/2025**

Draft concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making
EMA - Draft: consultation open **Consultation dates: 25/07/2025 to 31/10/2025**

Call for input for EMRTD study "Artificial Intelligence, Cultural Rights, and the Right to Development"
Issued by UN Expert Mechanism on the Right to Development **Deadline: 30 November 2025**

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

Contribute a tool - Catalogue of Tools & Metrics for Trustworthy AI

OECD-AI Policy Observatory

Contribute your tools and metrics to our catalogue. No deadline date identified.

This catalogue is a platform where AI practitioners from all over the world can share and compare tools and metrics to help make AI trustworthy, build upon each other's efforts to create global good practices, and speed up the process of implementing the OECD AI Principles. This catalogue can only exist with your contributions and those of AI practitioners from all sectors. You can also share your experience using a tool or metric by submitting a use case.

:: Contribute a tool

:: Share your experience using a tool

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

International Science Council [ISC]

No submission deadline date identified.

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

Biomedical Research/Regulation/Governance

Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Use Authorization of Medical Products

A Notice by the Food and Drug Administration on 07/14/2025 **Comment period ends 09/12/2025.**
OMB Control Number 0910-0595—Extension
SUPPLEMENTARY INFORMATION:

This information collection helps support implementation of Agency policies applicable to the authorization for medical products for use in emergencies under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-3, 360bbb-3a, and 360bbb-3b). For more information regarding emergency use authorization (EUA), visit our website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

The FD&C Act permits the Commissioner of Food and Drugs (the Commissioner) to authorize the use of unapproved medical products for humans and animals, or unapproved uses of approved medical products for humans and animals, during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb-3(c)).

Also, under section 564 of the FD&C Act, the Commissioner may establish conditions on issuing an authorization that may be necessary or appropriate to protect the public health…

NEW - Request for Information on Maximizing Research Funds by Limiting Allowable Publishing

NIH - Notice Number: NOT-OD-25-138
Release Date: July 30, 2025 **Response Date: September 15, 2025**
Purpose
NIH aims to maximize the value of each research grant, and as such, NIH grantees should utilize as much of their grant funds as possible for research activities. While NIH recognizes the value of disseminating and publishing findings, journals with large publishing fees can lead awardees to pay unreasonably high fees from their NI H awards that lessen the funds available for conducting research and which burden American taxpayers.
Proposed Scope
NIH proposes that this Policy apply to all direct publication costs (including APCs and other publishing fees) for grants, contracts, and Other Transactions. Any publication costs would only be allowable for accepted articles, as noted in NIH's Publication Cost Guidance, which outlines other applicable cost considerations. Commensurate guidance will be developed for the NIH Intramural Research Program and NIH employees.
Proposed Effective Date
NIH proposes an Effective Date of this Policy as January 1, 2026.

Context on this issue can be found in a statement previously issued by NIH Director, Dr. Jay Bhattacharya.

NEW - Notice of Meeting: Advisory Committee on Research on Women's Health

A Notice by the National Institutes of Health on 08/25/2025
Date: October 7, 2025. Time: 9:00 a.m. to 4:00 p.m. **Comments due September 16, 2025**
Agenda:
ORWH Director's Report, NIH Inclusion Report, NHLBI's Director's Report, Opening Remarks from NIH Director, Keynote Presentation on ORWH's Role in Transforming Research Gaps into Breakthroughs, and a panel discussion to commemorate 35 years of ORWH's impact on women's health research.
Public Comment
Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 21 days in advance of the meetings. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Proposed Data Collection Submitted for Public Comment and Recommendations – Enhancing Data-Driven Disease Detection in Newborns

A Notice by the Centers for Disease Control and Prevention on 07/18/2025 **Comment period ends 09/16/2025.**
Proposed Project
Enhancing Data-Driven Disease Detection in Newborns (ED3N) (OMB Control No. 0920-1391, Exp. 4/30/2026)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).
Background and Brief Description
The Newborn Screening and Molecular Biology Branch (NSMBB), in the National Center for Environmental Health (NCEH) Division of Laboratory Science (DLS), has the only laboratory in the world devoted to ensuring the accuracy of newborn screening (NBS) tests in every state and more than 78 countries. NSMBB supports NBS programs by conducting research, developing methods, and performing analyses by using complex, state-of-the-art molecular and biochemical techniques for identifying risk factors for diseases of public health importance.
Both NSMBB and state NBS programs are experiencing increased data analytic challenges associated with continued expansion of the number of newborn screening diseases, increased complexity of disease detection, and difficulties in correlating disease markers with disease risk. Further, the addition of late-onset diseases to NBS panels necessitates a better way to routinely capture clinical information and outcomes so that NBS programs can fully appreciate the spectrum of disease they are detecting.
The NSMBB is requesting a three-year Paperwork Reduction Act (PRA) Extension for Enhancing Data-driven Disease Detection in Newborns (ED3N), the NBS data platform, that will address these analytic and post-analytic challenges and promote sharing of molecular, biochemical, and clinical information amongst NBS partners. The information shared will help NSMBB and newborn screening partners be better equipped to assess disease risk and will help harmonize approaches for disease detection in newborns. Given the rarity of newborn screening diseases, it is imperative that data be collected and

analyzed at a national level in order to glean useful insights and to analyze trends. The NSMBB is best suited to oversee this work given its role in providing technical assistance to NBS programs nationally…

ICH - E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials; International Council for Harmonisation; Draft Guidance for Industry; Availability

A Notice by the Food and Drug Administration on 07/21/2025 **Comment period ends 09/19/2025**

SUMMARY:

…The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials." The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance is intended to provide general principles on the conduct of clinical trials that include pregnant and breastfeeding women to inform evidence-based decisions on safe and effective use of medicinal products by these populations.

The draft guidance includes approaches to generating data that support informed decision-making on the safety, dosing, and efficacy of medicinal products during pregnancy and breastfeeding. Additionally, the draft guidance includes recommendations for recruiting and retaining pregnant and breastfeeding women in clinical trials, while reducing burden and harm on these participants.

Background

…The recommendations found in this draft guidance are the product of the Efficacy Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The draft guidance outlines strategies and considerations for developing and implementing clinical studies that include pregnant or breastfeeding women. This draft guidance includes approaches to plan, collect data, evaluate outcomes, and monitor safety of pregnant and breastfeeding women participating in clinical trials safely and ethically. Additionally, the draft guidance includes recommendations for recruiting and retaining pregnant and breastfeeding women in clinical trials. The draft guidance also emphasizes reduction of burden on pregnant and breastfeeding women participating in these trials.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication.

NEW - Request for Nominations of Members To Serve on the Healthcare Advisory Committee

A Notice by the Health and Human Services Department on 08/22/2025 **Due: September 22, 2025.**

SUMMARY:

The Department of Health and Human Services announces its intent to establish the Healthcare Advisory Committee and invites nominations for the Committee. We will consider nominations that are submitted via email to HAC@cms.hhs.gov, by September 22, 2025. The subject line should state "Healthcare Advisory Committee Nomination."

SUPPLEMENTARY INFORMATION:

I. Background

The Healthcare Advisory Committee (hereinafter "the Committee") is authorized under 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The Committee is governed by the Federal Advisory Committee Act (FACA) (Pub. L. 92-463), as amended (5 U.S.C. chapter 10).

The Committee will serve as an advisory body to the Secretary of the Department of Health and Human Services (HHS) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on programs and policies that can help improve the United States (US) healthcare system consistent with the Executive Order Establishing the President's Make America Healthy Again Commission.[1]

II. Advisory Committee

The Committee is tasked with advising the Secretary of HHS and the Administrator of CMS on the following issues as they relate to strategies for improving the operations and outcomes of federally administered healthcare insurance and payment programs:

- Developing a set of actionable policy initiatives that can promote chronic disease prevention and management, as consistent with the Make America Healthy Again policy agenda;
- Identifying opportunities to move towards a regulatory framework of accountability for safety and outcomes that reduce unnecessary red tape and allow providers to focus on improving patient health outcomes not filling out paperwork;
- Sharing actionable levers to advance a real-time data system, enabling a new standard of excellence in care, rapid claims processing, rapid quality measurement and rewards;
- Identifying structural opportunities to improve quality for the most vulnerable in the Medicaid program (outside of more funding for the current system); and
- Securing the sustainability of the Medicare Advantage program, specifically identifying opportunities to modernize risk adjustment and quality measures that assess and improve health outcomes.

NEW - Establishing a Road Map for Accelerated Diagnosis and Treatment of HCV Infection in the United States

A Notice by the Centers for Disease Control and Prevention on 08/20/2025
Written comments must be received **on or before September 24, 2025.**
SUMMARY:
The Centers for Disease Control and Prevention (CDC) announces a two-day convening hosted and facilitated by the Association of Public Health Laboratories (APHL) to discuss hepatitis C diagnostics. Leaders from public health, laboratory, medical, academic, and industry sectors will have the opportunity to provide individual input, without building a consensus, on accelerating the diagnosis of current hepatitis C virus (HCV) infection. Members of the public with interest and expertise in diagnosing HCV infection are also invited to provide individual input. Specifically, the convening will focus on how to leverage the following hepatitis C diagnostic methods: same-day diagnosis and treatment, and viral-first testing.

Solicitation of Nominations for Appointment to the Advisory Council for the Elimination of Tuberculosis

A Notice by the Centers for Disease Control and Prevention on 07/11/2025. **Nominations must be received no later than September 30, 2025**
SUMMARY:
In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is seeking nominations for membership on the Advisory Council for the Elimination of Tuberculosis (ACET). ACET consists of 10 experts including the Chair in fields associated with public health, epidemiology, immunology, infectious disease, pulmonary disease, pediatrics, tuberculosis, microbiology, and preventive health care delivery.
SUPPLEMENTARY INFORMATION:
The Advisory Council for the Elimination of Tuberculosis (ACET) provides advice and recommendations regarding the elimination of tuberculosis (TB) to the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Health, HHS; and the Director, Centers for Disease Control and Prevention (CDC). ACET (a) makes recommendations on policies, strategies, objectives, and priorities; (b) addresses development and application of new technologies; (c) provides guidance and review of CDC's TB prevention research portfolio and program priorities; and (d) reviews the extent to which progress has been made toward eliminating TB.

NEW - Call for Public Comment - WHO Classification of Digital Health Interventions v1.0

WHO 1 September 2022 **Deadline for comments: 30 September 2022, 23:59 (CEST)**

Call for consultation

The World Health Organization (WHO) would like to issue a public call for comments to update v1.0 of the Classification of Digital Health Interventions (CDHI). This will take the form of two public calls: Primary feedback: Call to receive public stakeholders' comments to update the Classification of Digital Health Interventions v1.0.

The WHO CDHI v1.0 was created in 2018 to provide a common digital health vocabulary for diverse stakeholders from numerous backgrounds and areas of expertise. It has since been used by stakeholders of digital health projects with a particular focus on Low and Middle-Income Countries (LMICs). As opposed to previous frameworks that provide highly technical terminology that is mainly intended for computer scientists and software developers in health, the CDHI constitutes a key bridging language between technology-oriented audiences and those in health to facilitate consistent ways of articulating needs and functionalities represented in digital health system implementations.

Since 2018, there have been advances in technology and additional interventions have arisen, prompted by the global pandemic. These, together with calls from expert communities and other stakeholders, have prompted the need to update the CDHI v1.0.

To ensure a broad consultation process, WHO will work with an expert panel and expert groups to review relevant evidence on the application of the CDHI by stakeholders and provide recommendations for update. To enable the process of the update and to ensure the input and consideration of a global group of stakeholders, WHO is issuing this public call, appealing to researchers, government and public health stakeholders, technologists, healthcare providers, donors, implementers and other agencies that utilize (or aim to utilize) the CDHI to provide comments.

Draft guideline on the quality aspects of mRNA vaccines

Draft: consultation open **Consultation dates: 31/03/2025 to 30/09/2025**

Reference Number: EMA/CHMP/BWP/82416/2025

Summary:

This guideline addresses the quality aspects of mRNA vaccines. It addresses specific aspects regarding the manufacturing process, characterisation, specifications and analytical control of mRNA vaccines, as well as the definition of starting materials, active substance and finished product for mRNA vaccines. Additional regulatory considerations are provided for changes in existing mRNA vaccine strains, bivalent and multivalent vaccines, self-amplifying mRNA vaccines, other delivery systems and use of platform technology/prior knowledge. The scope of this guideline is applicable to mRNA vaccines against infectious diseases. Other mRNA-based medicinal products are out of scope of this guideline, although relevant parts of this guideline may be applicable to those. It is not intended to address specific requirements for mRNA vaccines to be used in clinical trials, however the scientific principles described may also be applicable during pharmaceutical development.

NEW - ICH: E20 EWG Adaptive Designs for Clinical Trials

ICH Public consultation dates:

ANMAT, Argentina - Deadline for comments by 8 October 2025
EC, Europe - Deadline for comments by 30 November 2025
Health Canada, Canada - Deadline for comments by 25 September 2025
MHRA, UK - Deadline for comments by 30 November 2025
Swissmedic, Switzerland - Deadline for comments by 30 November 2025
TFDA, Chinese Taipei - Deadline for comments by 13 October 2025

The E20 EWG is working on the development of a new E20 Guideline on "Adaptive Clinical Trials" on the design, conduct, analysis, and interpretation of adaptive clinical trials that provides a transparent and harmonized set of principles for the regulatory review of these studies in a global drug development program. These principles should also provide the flexibility to evaluate / discuss innovative approaches to clinical trial design throughout the development process.
Rapporteur: Dr. Gregory Levin (FDA, United States)
Regulatory Chair: Dr. Christian Roes (EC, Europe)
Date of Step 2b: 25 June 2025 Status: Step 3

NEW - Proposed Data Collection Submitted for Public Comment and Recommendations [Data Management Plans]

A Notice by the Centers for Disease Control and Prevention on 08/26/2025
DATES:CDC must receive written **comments on or before October 27, 2025.**
SUMMARY:
The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Data Management Plan (DMP) Template. The proposed data collection will allow CDC to have a consistent and unified approach for CDC Programs to develop their own Data Management Plans (DMPs).
Background and Brief Description
The Centers for Disease Control and Prevention (CDC), Office of Science (OS) is requesting approval of a New Information Collection Request (ICR) for a period of three years under the project titled, Data Management Plan (DMP) Template. OS operates within CDC, and works to collaborate with the agency's Centers, Institutes, and Offices (CIOs). Multiple CIOs have their own DMPs, and a deep dive into these DMPs showed some common elements. There is a need to have a consistent and unified approach whereby CDC could meet obligations of calls to action…

NEW - Onshoring Manufacturing of Drugs and Biological Products; Public Meeting; Request for Comments

A Notice by the Food and Drug Administration on 08/08/2025 **Comment period ends 10/30/2025**
SUMMARY:
The Food and Drug Administration (FDA, the Agency, or we) is announcing the establishment of a docket to solicit public comments on issues related to accelerating the establishment of new pharmaceutical manufacturing facilities in the United States. FDA is also announcing the following public meeting entitled "Onshoring Manufacturing of Drugs and Biological Products." At this meeting, FDA will present a draft framework that seeks to facilitate onshoring of pharmaceutical manufacturing. Participants will then engage in a guided discussion regarding the proposed framework, its strengths, weaknesses, and opportunities. The group will also discuss additional considerations that may help overcome current challenges faced by industry to onshoring the manufacturing of pharmaceuticals, including active pharmaceutical ingredients (APIs) and finished drug and biological products, and ideas and options within the bounds of FDA's statutory authority that could facilitate such onshoring of manufacturing.
DATES:
The hybrid public meeting will be held on September 30, 2025, from 9:00 a.m. to 4:00 p.m. Eastern Time and will take place in person and virtually.

Concept paper for the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment, resulting from the use of a veterinary medicinal product

EMA Draft: consultation open **Consultation dates: 16/04/2025 to 31/10/2025**
Reference Number: EMA/CVMP/ERA/75412/2023
Summary:

This concept paper provides background to the intended development of a scientific approach for use in the evaluation of the risk for humans exposed to antimicrobial resistance via the environment, originating from use of veterinary medicinal products. It is intended to provide advice on how relevant dossier requirements outlined in Regulation (EU) 2019/6 (e.g., Article 8(2)) may be fulfilled.

Draft concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making

EMA - Draft: consultation open **Consultation dates: 25/07/2025 to 31/10/2025**
Reference Number: EMA/CHMP/225255/2025
Summary:

Randomised controlled trials are the gold standard of evidence to support causal conclusions on the benefits and risks of medicines in regulatory decision making along the lifecycle. However, in some situations, causal conclusions may be derived from a setting where the investigational medicinal product data was collected under a clinical trial protocol while the control arm was not a randomized arm in that same protocol. In these situations, a so-called external control, may be derived from data from other clinical trials, real-world data (RWD) or other data sources.

A reflection paper shall be drafted to describe the main challenges with external controls and further discuss the circumstances and methodological constraints under which the use of external controls could be considered appropriate for generating pivotal or supportive evidence, either for efficacy, safety or other relevant regulatory decision-making objectives.

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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Human Rights

Call for written submissions on the draft guidelines on addressing multiple and intersectional forms of discrimination against women and girls with disabilities

UN - Treaty bodies **Deadline: 15 September 2025**

Purpose:

To further guide states parties and other duty bearers to address the implementation gaps and to collect a repository of good practices in addressing multiple and intersecting forms of discrimination against women and girls with disabilities.

Background

Since it was established, in 2009, the Committee has considered more than 150 reports submitted by States parties to the Convention. The Committee has identified the following gaps in the implementation of article 5 (non-discrimination), article 6 (women with disabilities) and article 16 (protection against violence, exploitation and abuse):

- Limited understanding and awareness about the concept of multiple and intersecting forms of discrimination against women and girls with disabilities.
- Anti-discrimination legislative and policy frameworks do not often recognize multiple and intersecting forms of discrimination against women and girls with disabilities.
- Disaggregated data is not collected regularly and systematically, limiting the possibilities for influencing action-oriented policies and strategies on addressing multiple and intersecting forms of discrimination.
- Limited identification of instances of multiple and intersecting forms of discrimination against women, limited availability of redress mechanisms and broad impunity of perpetrators.
- Limited understanding about gender-based violence and disability-based violence as forms of discrimination.

NEW - Call for input – Unilateral Coercive Measures and Humanitarian Action

UNHCHR - Issued by Special Rapporteur on unilateral coercive measures

Deadline: 20 October 2025

Purpose:

The Special Rapporteur would like to kindly invite relevant stakeholders, including States, international and regional organisations (incl. their agencies and organs), national human rights institutions, civil society organisations, lawyers and academia to submit additional input, comments and suggestions for the finalisation of the document.

Background"

Pursuant to Human Rights Council resolutions 27/21 and 54/15, the Special Rapporteur on the negative impact of unilateral coercive measures on the enjoyment of human rights is requested, in fulfilling her mandate, to inter alia gather all information relevant to the negative impact of unilateral coercive measures on the enjoyment of human rights; to study relevant trends, developments and challenges; and to make guidelines and recommendations on ways and means to prevent, minimize and redress their adverse impact on human rights.

In several of her thematic reports to the UN Human Rights Council and the UN General Assembly and communications to state and non-state actors, and in her latest Guiding Principles on Sanctions, Business and Human Rights and Commentary thereto, the Special Rapporteur has described how unilateral coercive measures in their different forms, including unilateral economic, financial, trade sanctions, both primary and secondary ones, as well as other sanctions-related restrictions, have

adversely impacted the timely and effective delivery of humanitarian assistance to populations in need in sanctioned countries and regions. Complex, overlapping and expanded frameworks of unilateral sanctions, with their multifaceted restrictions and prohibitions, create a serious "chilling effect", exacerbate fear and uncertainty among humanitarian and other actors, thus undermining any meaningful engagement with sanctioned countries and regions, entities, businesses or persons, independently of the type or sector of activity…

Call for input for EMRTD study "Artificial Intelligence, Cultural Rights, and the Right to Development"

Issued by UN Expert Mechanism on the Right to Development **Deadline: 30 November 2025**

Purpose:

To inform the drafting of EMRTD's thematic study on "Artificial Intelligence (AI), Cultural Rights, and the Right to Development." This study is part of the Mechanism's broader mandate to examine emerging global challenges that impact the realization of the right to development.

Background

The Human Rights Council, in its resolution 45/6, welcomed the first report (A/HRC/45/29) of the Expert Mechanism on the Right to Development, and requested it to implement the recommendations contained therein, including the preparation and submission to the Council thematic studies in the discharge of Expert Mechanism's mandate. At its 8th session, the EMRTD outlined the thematic studies that it planned to submit to the Human Rights Council during the 2024-2026 cycle, including a study addressing artificial intelligence, regulation and the right to development.

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Genetics/Genomics

No new calls identified.

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Emerging/Disruptive Technologies

No new calls identified.

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Biodiversity/Environment/Climate/Disaster Mitigation

Request for Public Comment: National Plan for Arctic Research

by the National Science Foundation on 07/21/2025. **Written responses are due by October 15, 2025.**

SUMMARY:

The Interagency Arctic Research Policy Committee (IARPC), chaired by the National Science Foundation, seeks public input from all interested parties on national needs regarding the Arctic and the research necessary to address those needs. The public input provided in response to this RFI will inform the update of the five-year National Arctic Research Plan for 2027-2031.

Seeking Public Input

As called for in the ARPA, IARPC seeks input from any interested individuals and organizations to ensure that the research interests and needs of all are addressed appropriately in the updated Plan. IARPC is committed to an open engagement process throughout the development of the Plan.
In particular, IARPC is interested in feedback in response to the following questions regarding what updates should be made to the Arctic Research Plan 2027-2031:

1. What are the critical issues and needs where federally-funded science, engineering, and technology research should provide knowledge to promote sound decision-making at all levels related to the Arctic?
2. What are examples of research questions that address these issues.

Human Studies Review Board (HSRB) Meetings for 2025

A Notice by the Environmental Protection Agency on 11/29/2024
Public Participation
The HSRB encourages the public's input. You may participate in these meetings via oral comments or written comments.
SUMMARY:
The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of its public meetings of the Human Studies Review Board (HSRB) for 2025. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of third-party human subjects' research that are submitted to the Office of Pesticide Programs (OPP) to be used for regulatory purposes.

Four three-day virtual public meetings will be held on:
1. January 29-31, 2025;
2. April 2-4, 2025;
3. July 22-24, 2025;
4. October 14-16, 2025.

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Science Integrity/Evidence to Policy/ Open Science

:: Call for Public Consultation

The Right to Participate in and Benefit from Science – *Call for Feedback*

ISC / International Science Council
21 November 2024

The ISC's interpretation of 'the right to participate in and benefit from science' provides a clear framework for understanding the right to science, emphasizing its application in research, policy, and global access to scientific knowledge. It clarifies the obligations, opportunities, and responsibilities in ensuring universal access to science, fostering global dialogue to shape a more inclusive and sustainable future.

ISC – The Right to Participate in and Benefit from Science

The International Science Council believes that there is a universal human right to participate in and enjoy the benefits of science, and that it is a responsibility of governments to create and sustain the opportunities of citizens to use this right.

A right to participate in science

This right presumes a right to basic scientific literacy, and a right to scientific education, training and mentoring.

I. A right to participate in generating diverse forms of knowledge through the study of natural and social phenomena using theoretical, observational, experimental, and analytical approaches to introduce and test existing and new models, conjectures, hypotheses and ideas unconstrained by political agendas or belief systems.
II. A right to challenge established knowledge about natural and social phenomena when generating and communicating new models, conjectures, hypotheses and ideas, and the uses to which this knowledge has been or may be put.
III. A right to collaborate and engage in scientific dialogue and research across national, political, regional and other boundaries.
IV. A right to communicate both positive and negative findings.
V. A right to form professional societies and associations.
VI. A right to advocate for the responsible use of science.

A right to enjoy the benefits of science

I. A right not to be excluded from the benefits of science on the basis of unjust discrimination based on race, nationality, ethnic origin, language, sex, gender identity, reproductive ability, sexual orientation, age, disability, political opinion, or religious belief.
II. A right to equitably access information, data, and other resources necessary to enhance scientific knowledge, teaching and research.
III. A right to apply scientific knowledge for technological developments for the good of humanity and the planet.

:: Resources, Events

No new resources identified.

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Heritage/Cultural Assets

:: Call for Public Consultation

No new calls identified.

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Governance, Peace, Trade, Global Finance

:: Call for Public Consultation

NEW - **Call for Input for the report on Peace and International Solidarity**

UNHCHR - Issued by Independent Expert on human rights and international solidarity

Deadline: 17 October 2025

Purpose:

To inform the Independent Expert's report on Peace and international solidarity to be presented to the 62nd session of the UN Human Rights Council in June 2026.

Background

Peace is a *grundnorm* at the foundation of the UN Charter, the Universal Declaration of Human Rights, regional law, and national constitutions. It is one of the conditions for the enjoyment of human rights. Negative peace (the absence of violence or war) receives primary attention from policymakers and researchers. International solidarity movements have been important for the pursuit of peace, calling for the prohibition of nuclear weapons, the pursuit of cease-fire during armed conflict in both

international and national contexts, and demands for truth and reconciliation mechanisms in transitional situations.

Peace is also a process as Article 33 of the UN Charter sets forth an obligatory sequence of pursuit of non-violent dispute resolution. The UN Declaration on the Right to Peace recognizes positive peace through its articulation of equality and non-discrimination as key criteria, hence inclusive programs correcting structural violence are relevant. Moreover, there is renewed focus on creating a culture of peace and solidarity through education in order to improve social cohesion and inclusion.
The report seeks to understand the implementation of peace and how international solidarity supports this aim. The Secretary-General's report A New Agenda for Peace sets forth that peace is grounded in three principles – trust, solidarity, and universality…

:: Resources, Events

Information Report: Oversight Observations To Inform Department of State Realignment of U.S. Agency for International Development Functions

AUD-GEER-25-19 May 2025

Summary of Review

On March 28, 2025, the Department of State (Department) notified Congress of its intent to realign selected U.S. Agency for International Development (USAID) functions within the Department. The information report, which was developed as part of an Office of Inspector General (OIG) evaluation of the Department's initial realignment efforts, is designed to highlight OIG observations from its prior work, and the work of other federal oversight bodies, that could help the Department more efficiently and effectively realign USAID functions.

OIG concluded that the Department is undertaking a significant and multi-faceted integration of select USAID functions concurrent with a reorganization of domestic offices and bureaus in the Department. Individually, these tasks would be daunting. But together, these initiatives could be overwhelming to the organization without a well thought out plan of action. During its work, OIG observed that senior Department leaders involved in the realignment are aware of the challenges that they face. Additionally, OIG recognizes that the Department's Assistance Transition Working Group has established workstreams related to many of the topics discussed in the OIG report.

Although OIG did not make formal recommendations in the report, OIG encourages the Department to consider how issues identified by OIG and other oversight organizations might impact the success of the Department's efforts. Considering previously identified issues will allow the Department to implement best practices.

Although the focus of the information report is the realignment of USAID functions within the Department, the information may also be applicable to the Department's efforts to implement its internal reorganization.

Strategic Foresight Toolkit for Resilient Public Policy

A Comprehensive Foresight Methodology to Support Sustainable and Future-Ready Public Policy

OECD Report 21 January 2025

PDF: https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/01/foresight-toolkit-for-resilient-public-policy_9ad1cd60/bcdd9304-en.pdf

Abstract

By exploring 25 evidence-based potential disruptions across environmental, technological, economic, social, and geopolitical domains, the Strategic Foresight Toolkit for Resilient Public Policy helps anticipate challenges and opportunities that could reshape the policy landscape between 2030 and 2050. These disruptions are not predictions, but hypothetical future developments identified through extensive research, expert consultations, and workshops.

The Strategic Foresight Toolkit features a five-step foresight process, guiding users to challenge assumptions, create scenarios, stress-test strategies, and develop actionable plans. It includes facilitation guides and case studies to support effective implementation. Each disruption is accompanied by insights on emerging trends, potential future impacts, and both immediate and long-term policy options to ensure resilience and preparedness.

Designed for policymakers, public administrators, and foresight practitioners, this publication is designed to promote holistic, strategic and evidence-informed decision-making. It aims to support countries and organisations in using strategic foresight to design and prepare robust and adaptable public policies for a range of possible futures. With its practical methodology and forward-looking approach, the Strategic Foresight Toolkit is a vital resource for building sustainable, resilient, and effective public policies.

Public Integrity Indicators

OECD - Datasetdata-explorer.oecd.org
14 February 2025
Interactive Graphic: OECD Public Integrity Indicators
Overview

Following the adoption of the OECD Council Recommendation on Public Integrity in 2017, the Public Governance Committee (PGC), via its Working Party of Senior Public Integrity Officials (SPIO) subsidiary body, developed the OECD Public Integrity Indicators (PII) to measure the implementation of the OECD Council Recommendation on Public Integrity. The PII are complementary to the OECD Public Integrity Handbook and the OECD Public Integrity Maturity Models.

The OECD Public Integrity Indicators (PII) measure the quality and effectiveness of public integrity systems across six areas:

- Quality of Strategic Framework (data available)
- Accountability of Public Policymaking – covering conflict-of-interest, political finance, lobbying, public information, open government, and public consultation (data available)
- Effectiveness of Internal Control and Risk Management (data available)
- Integrity and Effectiveness of the Justice System (to be launched in 2024)
- Strength of External Oversight and Control (to be launched in 2024)
- Meritocracy of the Public Sector (to be launched in 2025)

The OECD Public Integrity Indicators provide cross-country comparative data to help policy makers and practitioners strengthen the resilience of public integrity systems towards corruption risks and prevent the mismanagement and waste of public funds. The PIIs measure the strength of standard regulatory safeguards (*de jure*) and implementation of these safeguards in practice (*de facto*). The OECD Secretariat collaborates closely with national administrations to obtain primary data collected directly from a wide range of actors across the executive, legislative and judiciary branches.

Regulatory governance

OECD Datasetdata-explorer.oecd.org
14 February 2025
Overview
The OECD Dataset on the Indicators of Regulatory Policy and Governance (iREG) presents up-to-date evidence of regulatory policy and governance practices of the OECD member countries, the European Union as well as the five EU Member States that are not OECD member countries. It focuses on practices as described in the 2012 Recommendation of the Council on Regulatory Policy and Governance (Recommendation), the first international instrument to address regulatory policy as a whole-of-government activity. The data covers in detail three principles of the 2012 Recommendation:

stakeholder engagement, regulatory impact assessment (RIA) and *ex post* evaluation. For each of these areas, the indicators present information in four categories:

1. Systematic adoption records formal requirements and how often these requirements are conducted in practice;
2. Methodology gathers information on the methods used in each area, e.g. the type of impacts assessed or how frequently different forms of consultation are used;
3. Oversight and quality control records the role of oversight bodies and publically available evaluations; and
4. Transparency records information that relates to the principles of open government, e.g. whether government decisions are made publically available.

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

No new calls identified.

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

Supporting Fairness and Originality in NIH Research Applications

NIH Notice Number: NOT-OD-25-132
Final Guidance Release Date: July 17, 2025

Purpose

NIH is providing guidance to researchers on the appropriate usage of artificial intelligence (AI) to maintain the fairness and originality of NIH's research application process. NIH is also instituting a new policy limiting the number of applications that NIH will consider per Principal Investigator per calendar year.

Background

NIH has recently observed instances of Principal Investigators submitting large numbers of applications, some of which may have been generated with AI tools. While AI may be a helpful tool in reducing the burden of preparing applications, the rapid submission of large numbers of research applications from a single Principal Investigator may unfairly strain NIH's application review processes. The percentage of applications from Principal Investigators submitting an average of more than six applications per year is relatively low; however, there is evidence that the use of AI tools has enabled Principal Investigators to submit more than 40 distinct applications in a single application submission round.

NIH will continue to employ the latest technology in detection of AI-generated content to identify AI generated applications, but it is imperative that all NIH research applications are consistent with the NIH Grants Policy Statement (GPS) Section 2.1.2's expectation that institutions and affiliated research teams propose original ideas for funding. AI tools may be appropriate to assist in application preparation for limited aspects or in specific circumstances, but researchers should be aware that using AI comes with its own risks. AI use may result in plagiarism, fabricated citations, or other kinds of research

misconduct. As a reminder, NIH oversees research misconduct investigations and acts on non-compliance (see GPS Section 4.1.27).

Policy

NIH will not consider applications that are either substantially developed by AI, or contain sections substantially developed by AI, to be original ideas of applicants. If the detection of AI is identified post award, NIH may refer the matter to the Office of Research Integrity to determine whether there is research misconduct while simultaneously taking enforcement actions including but not limited to disallowing costs, withholding future awards, wholly or in part suspending the grant, and possible termination.

NIH will only accept six new, renewal, resubmission, or revision applications from an individual Principal Investigator/Program Director or Multiple Principal Investigator for all council rounds in a calendar year. This policy applies to all activity codes except T activity codes and R13 Conference Grant Applications. Based on recent data, this limit will affect a relatively small number of Principal Investigators while enabling the NIH to maintain consistently high-quality grant application review and appropriately steward taxpayer dollars.

2024 NIH Public Access Policy

Notice Number: NOT-OD-25-047

Release Date: December 17, 2024

Issued by Office of The Director, National Institutes of Health (OD)

Purpose

Background

Increasing access to publications resulting from National Institutes of Health (NIH) funding offers many benefits to the scientific community and the public who funded the underlying research. When patients, families, and healthcare providers can access published findings resulting from NIH funding, they are able to better understand and address the most critical health concerns facing their communities. It also allows researchers, students, and members of the public in all communities to have equitable access to such content. This access can accelerate future research, lead to collaboration, and allow interested readers and patients to follow the latest advances more closely. Importantly, these goals reflect NIH's commitment to the responsible stewardship of the Nation's investment in biomedical research by improving transparency and accessibility of taxpayer-funded research, an essential component of fostering trust in research. NIH is issuing this updated Public Access Policy to further advance these goals by accelerating free public access to research results.

NIH has a long history of providing access to research products resulting from its funded research. The NIH Public Access Policy in effect since 2008, requires that NIH-supported researchers submit their final peer-reviewed manuscripts to the National Library of Medicine's PubMed Central® digital archive of full-text biomedical and life sciences journal literature upon acceptance for publication, to be made freely available to the public after an allowable embargo period of not more than 12 months after the official date of publication. The 2008 Policy implements Public Law 110-161, which was made a legislative mandate for FY 2009 and beyond by Public Law 111-8. The Policy has, to date, resulted in more than 1.5 million articles reporting on NIH-supported research being freely available to the public in PubMed Central.

On August 25, 2022, the White House Office of Science and Technology Policy (OSTP) released updated policy guidance (2022 OSTP Memorandum) to all federal agencies with research and development expenditures to further promote equity, advance trust in science, and continue to advance American scientific leadership. Following the 2022 OSTP Memorandum, NIH released its Plan to Enhance Public Access to the Results of NIH-Supported Research in February 2023 (hereafter, the NIH Public Access Plan) and its Draft Public Access Policy in June 2024. The NIH Public Access Plan and Draft Public Access

Policy provided a roadmap for how NIH proposed to accelerate access to scholarly publications, consistent with the government-wide expectation to remove the 12-month embargo period before public availability. This 2024 NIH Public Access Policy is consistent with the expectations of the 2022 OSTP Memorandum regarding scholarly publications and is informed by all public feedback, including comments submitted in response to the NIH Draft Public Access Policy.

Overview of Public Comments

A total of 144 written public comments were received in response to the NIH Draft Public Access Policy. Written comments were received from a variety of constituencies, including those from universities, professional associations, nonprofit organizations, and publishers. In addition, NIH hosted a public listening session on the NIH Public Access Plan in April 2023,and in November 2023, NIH sponsored a workshop held by the National Academies of Sciences, Engineering and Medicine (NASEM) on Enhancing Public Access to the Results of Research Supported by the U.S. Department of Health and Human Services (HHS). Commenters and attendees included academic institutional officials, researchers at various career stages, patient advocates, publishers, and officials from professional associations, many of whom also publish academic journals. NIH reviewed and considered all feedback to inform and develop the 2024 NIH Public Access Policy. Upon the listed effective date, the new Policy replaces the 2008 NIH Public Access Policy…

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Selected Peer-reviewed Journal Literature/Gray Lit Integrating Public Consultation

OECD Guidelines for Citizen Participation Processes

Paris: OECD Publishing. 2022
https://www.oecd-ilibrary.org/governance/oecd-guidelines-for-citizen-participation-processes_f765caf6-en [Accessed 10 Nov 2023]

The *OECD Guidelines for Citizen Participation Processes* are intended for any public official or public institution interested in carrying out a citizen participation process. The guidelines describe ten steps for designing, planning, implementing and evaluating a citizen participation process, and discuss eight different methods for involving citizens: information and data, open meetings, public consultations, open innovation, citizen science, civic monitoring, participatory budgeting and representative deliberative processes. The guidelines are illustrated with examples as well as practical guidance built on evidence gathered by the OECD. Finally, nine guiding principles are presented to help ensure the quality of these processes.

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Selected Resources for Public Consultation Notices, Calls, Processes

UNHCHR UN High Commissioner for Human Rights – Calls for Input

https://www.ohchr.org/en/calls-for-input-listing

UNESCO - Consultations

https://www.unesco.org/en/search?category=UNESCO&text=consultation&category=UNESCO&sort_by=unesco_date#toggle-facets

WHO – Public Consultations
https://www.who.int/home/search?indexCatalogue=genericsearchindex1&searchQuery=public%20consultation&wordsMode=AnyWord

OECD - Consultations and calls for contributions
https://www.oecd.org/about/civil-society/consultations-and-calls-for-contributions.htm

IFAD Public Consultations
https://webapps.ifad.org/members/executive-board-public-consultation

European Medicines Agency's (EMA) open public consultations
https://www.ema.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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