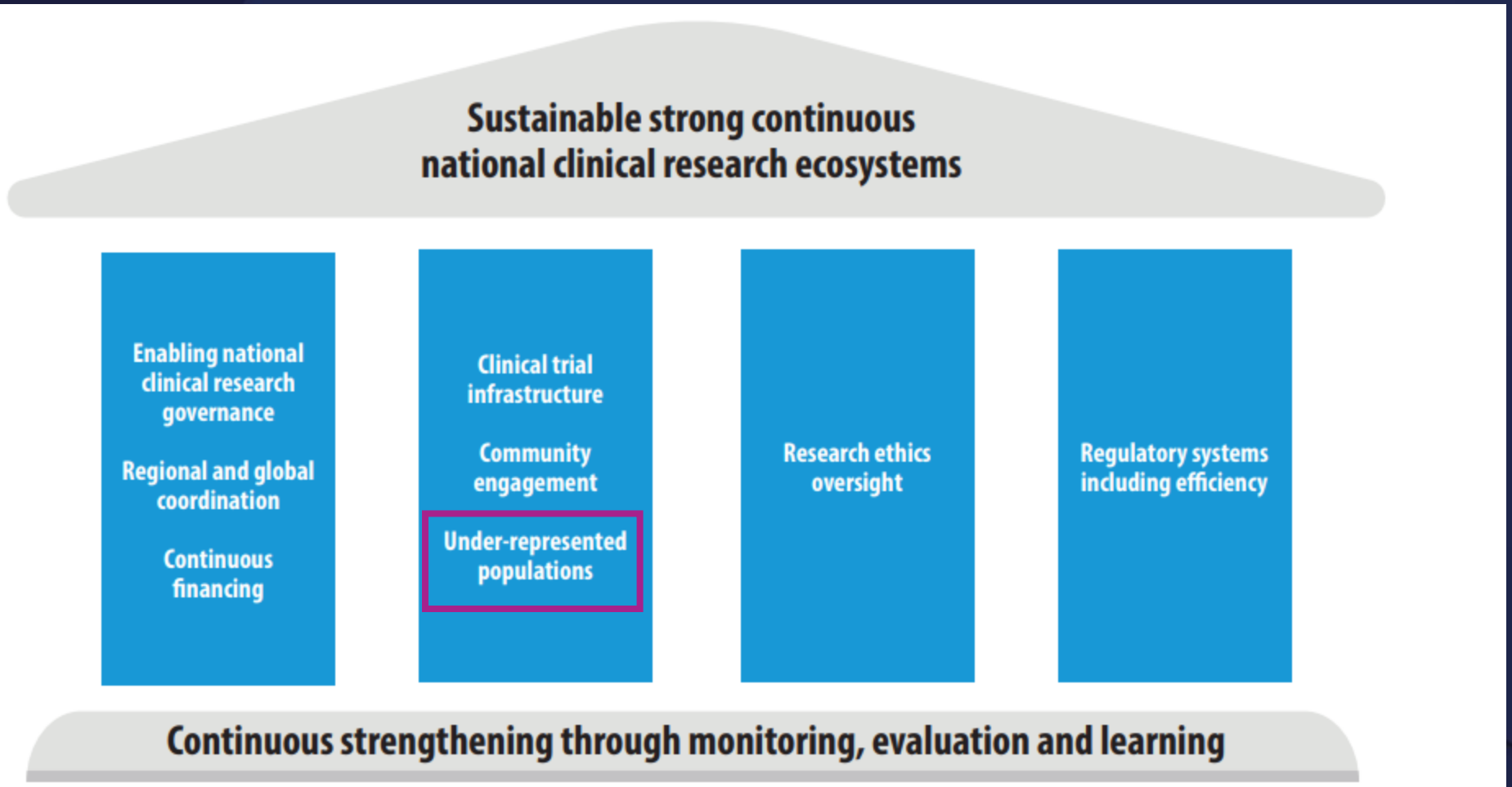
Enabling timely inclusion of pregnant and lactating women in trials

Martina Penazzato MD, MSc, PhD
Science for Health Department
Science Division

March 2025

World Health Organization



Source: Moorthy V, Abubakar I, Qadri F, Ogutu B, Zhang W, Reeder J, et al. The future of the global clinical trial ecosystem: a vision from the first WHO Global Clinical Trials Forum. The Lancet. 2024 Jan 13;403(10422):124–6 (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)02798-8/fulltext).

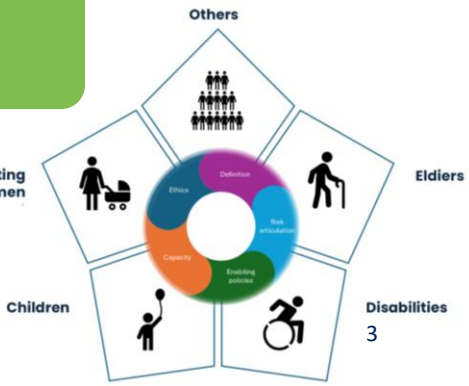
World Health Organization

Policy Guidance for Better Inclusion of Underrepresented Populations in Clinical Trials and Research

Scoping review & Root Cause Analysis to (i) identify underrepresented populations across intervention types (vaccines, therapeutics, diagnostics) and (ii) analyze systemic, structural, and operational barriers, including regulatory, ethical, and logistical constraints.

Policy Mapping & Gap Analysis of existing national and international policies, guidance documents, and toolkits, to identify gaps and inconsistencies and develop principles and criteria for equitable access.

Drafting of policy guidance & implementation tools

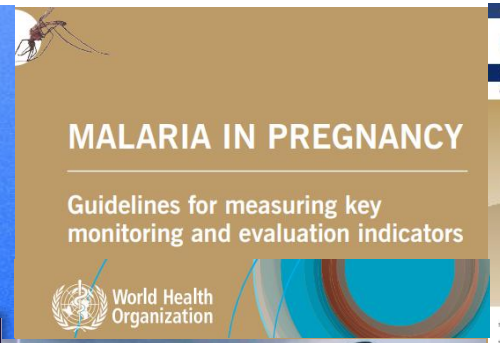


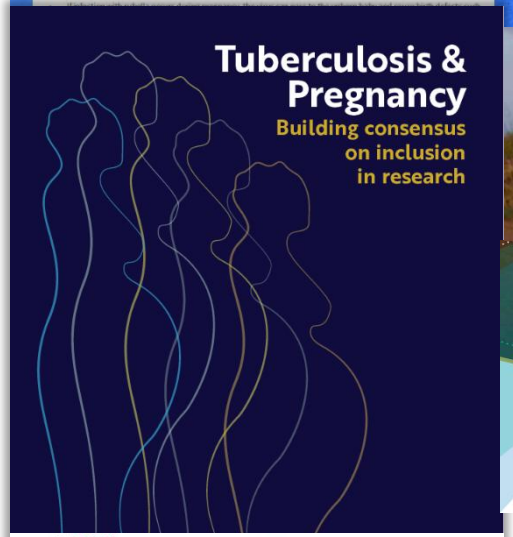
Objective: identify barriers, assess policy frameworks, and deliver actionable tools to promote equity in research participation

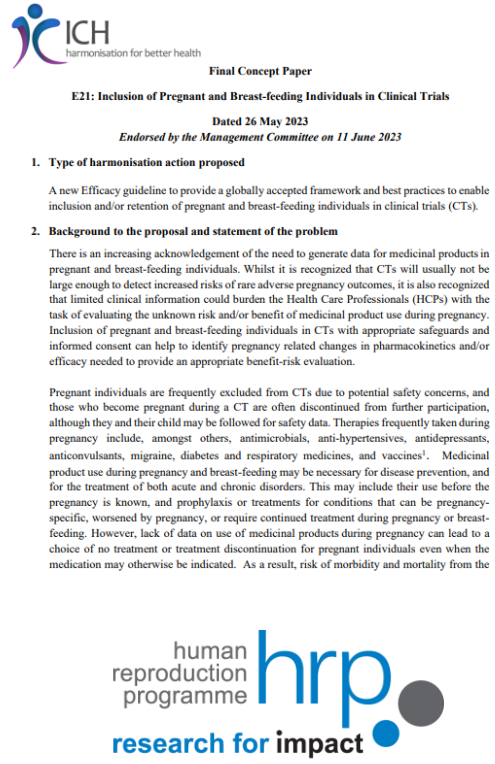
World Health Organization

Driving this global shift demands coordinated action from multiple stakeholders

World Health Organization







human reproduction programme hrp
research for impact
UNDP·UNFPA·UNICEF·WHO·WORLD BANK

Launch of the WHO Task Force for the Timely Inclusion of Pregnant and Lactating Women in Clinical Trials

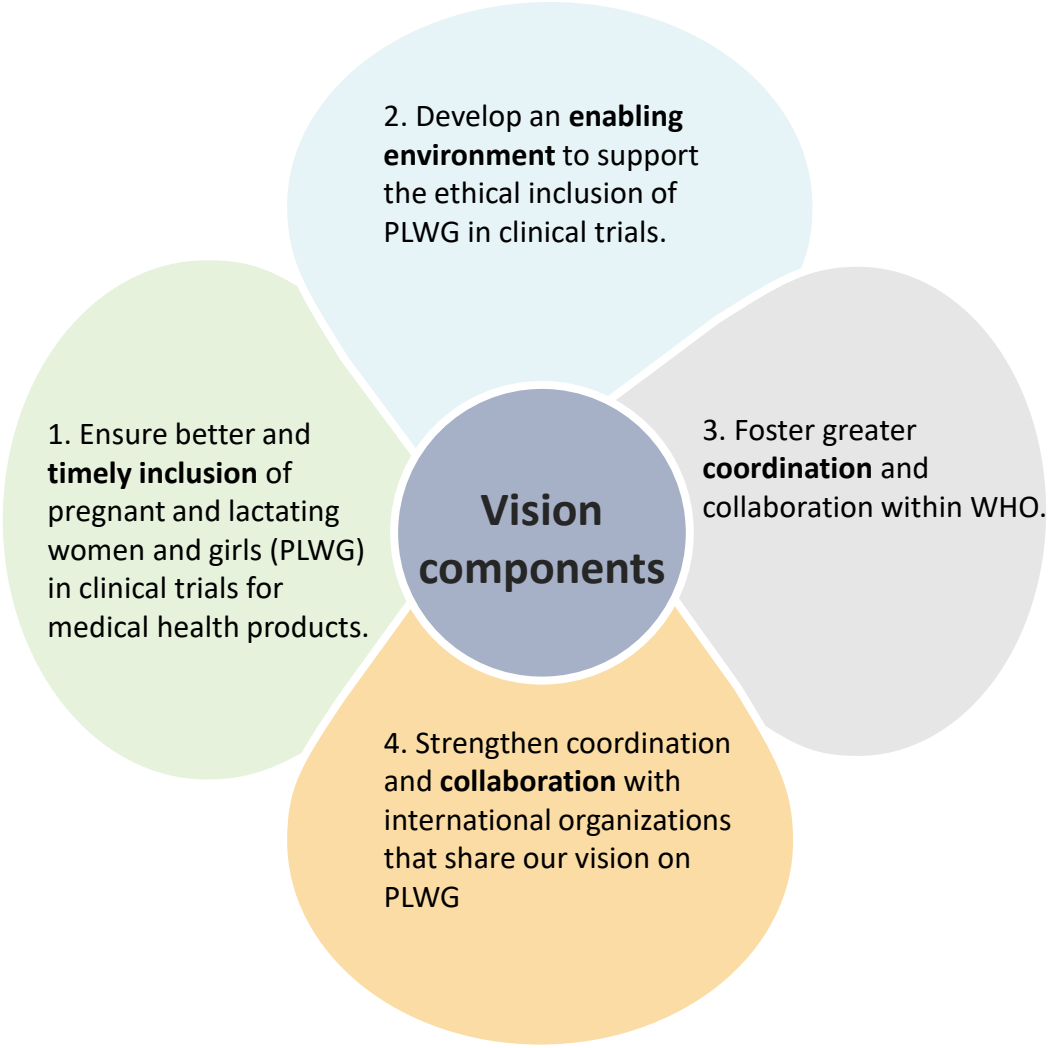
Task Force Facilitators: Martina Penazzato (SCI/RFH) and Mariana Widmer (SCI/HRP)

Task Force Members:

RFH: LITTLER, Katherine; SATHIYAMOORTHY, Vaseeharan
HRP: CHOU, Doris
GTB: MIRZAYEV, Fuad; VERKUIJL, Sabine; RUSEN, Ira David ;
HHS: RENAUD, Francoise; TOWNSEND, Claire;
IVB: MEHRING-LE DOARE, Kirsty Elaine Kay; BENASSI, Virginia;
MCA: DE COSTA, Ayesha; GOGA, Ameena; PORTELA, Anayda Gerarda;
REG: AZATYAN, Samvel; LAUMONIER, Marion; LAMPRIANOU, Smaragda;
AMR: GIGANTE, Valeria;
NTD: SOLOMON, Anthony;
Malaria: OLUMESE, Peter Ehizibue;
Brain Health: CATALDI, Rodrigo;
RO: Saenz, Dr. Carla (PAHO); REINAP, Marge (EURO)

World Health Organization

Our Vision: *To achieve by 2030 timely and ethical inclusion of pregnant and lactating women and girls in clinical trials for medical health products, by creating an enabling environment and fostering collaboration with international partners.*



World Health Organization

Priority activities for 2025

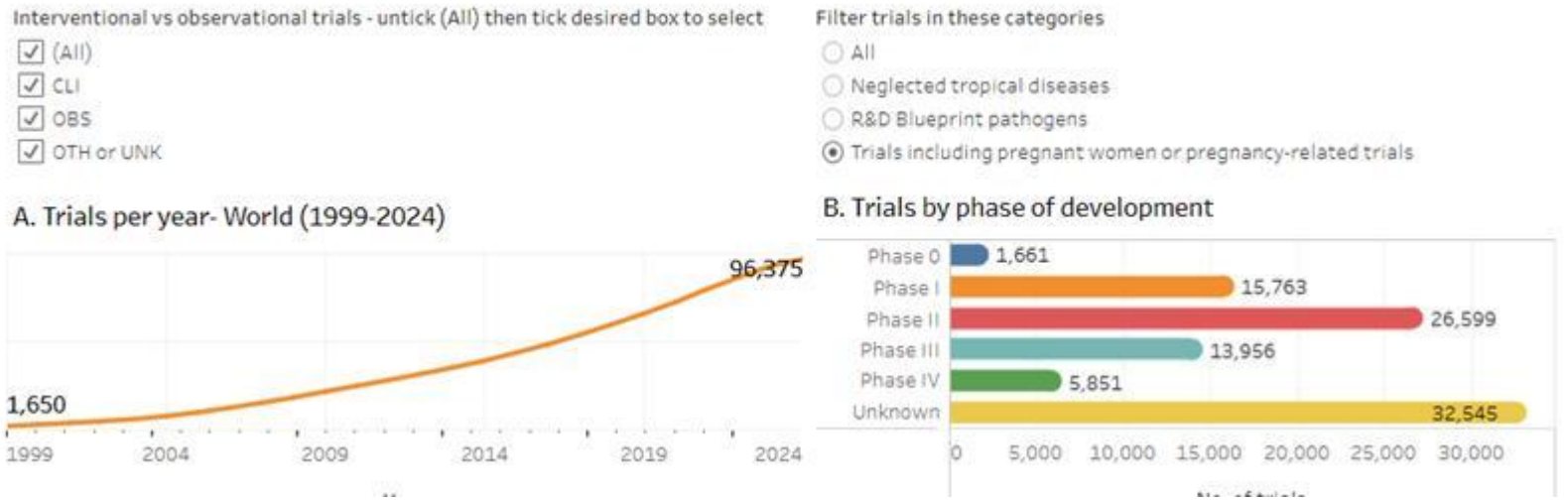
- What is the problem?
- Call to action
- Toolkit
- Language harmonization

World Health Organization

1. What is the problem? Size and implications

- Leveraging ICTRP and R&D Observatory with current filters
- Develop an interface to become a tool for tracking and accountability
- Publication of overall snapshot
- Gather relevant systematic reviews and papers on the topic

Technical advocacy: reflections on the implications of routine exclusion of PLWG in clinical trials



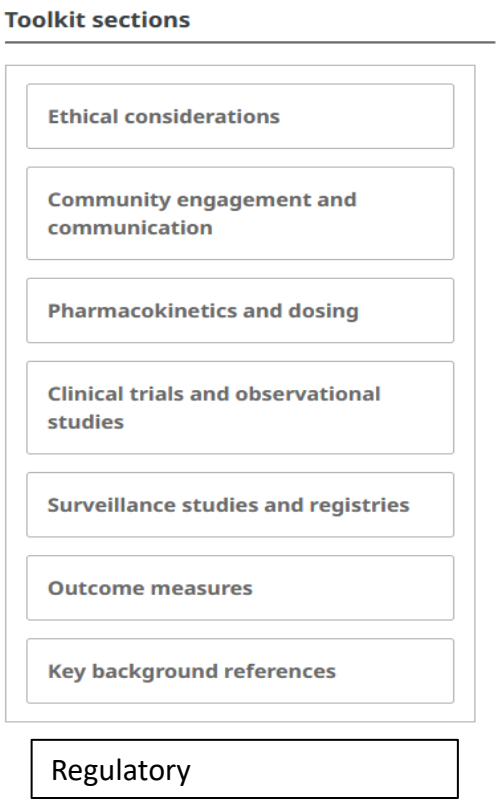
World Health Organization

https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-trial-registrations-by-year-location-disease-and-phase-of-development

3. Generic research toolkit initial draft proposal

Guidance and resources to accelerate the inclusion of pregnant and breastfeeding populations in research.

- Design the structure
- Review HIV toolkit and select what to retain as generic content
- Discuss with Web-developer
- Signpost existing disease specific toolkits (i.e. HIV, TB, IVB)
- Initiate thematic specific modules (i.e. Malaria, antibiotics, maternal products, NTD, NCD, etc.)



HIV & STI

TB

Malaria

Maternal products

Antibiotics

NCD

IVB

NTD

World Health Organization

Research toolkit for use of vaccines in pregnant and lactating women

Kirsty Le Doare

Purpose of the toolkit

•Responds to the global call for equitable inclusion of pregnant & lactating women in vaccine R&D (WHA77, 2024).

•Addresses historical exclusion specifically from vaccine trials → data gaps, delayed access.

•Supports ethical, safe, and timely evaluation of vaccines in pregnancy & lactation.

•Aligns with WHO, PREVENT, CIOMS, and SPEAC frameworks

•Highlights key areas that are distinct from therapeutic research

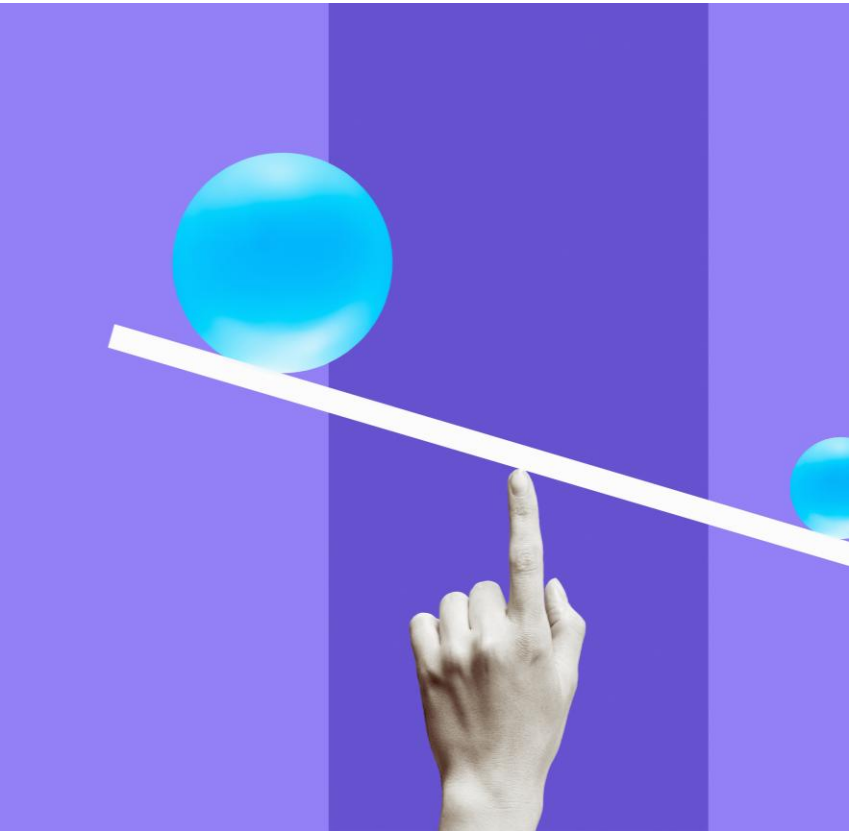
Exclusion → Gaps → Toolkit → Equity

Objectives

Provide rationale & ethics for inclusion in research.

Repository of tools for safe and systematic trial design – including key guidance documents for vaccines in pipeline development

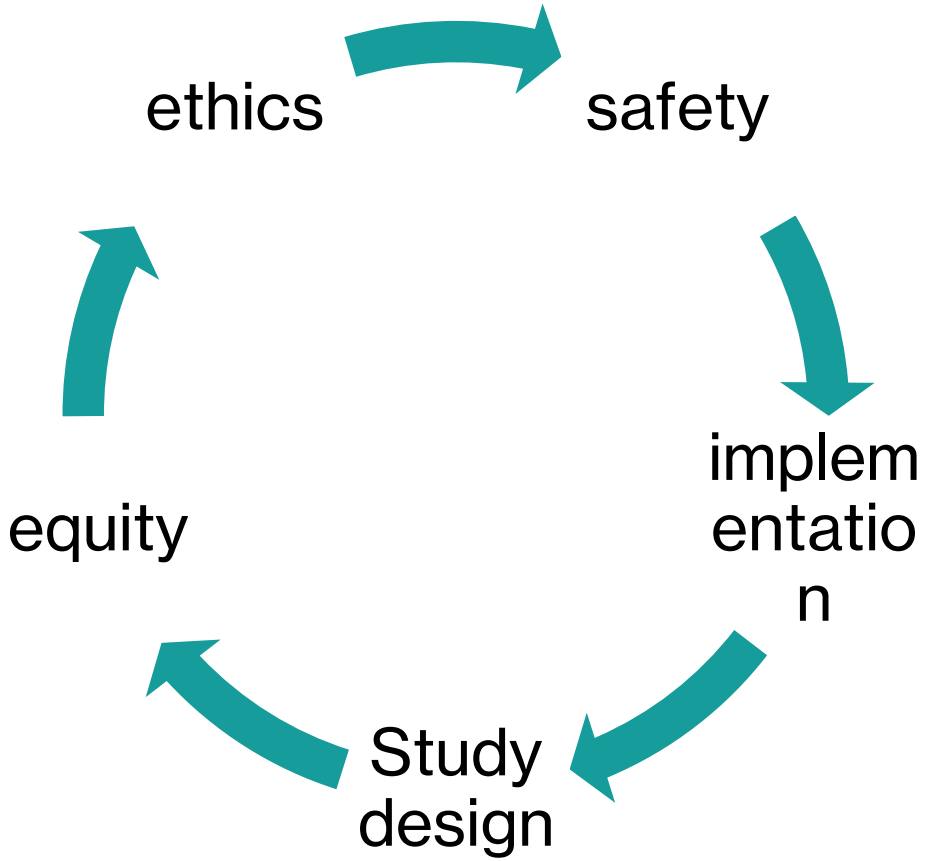
Enable **standardised data collection** on pregnancy & lactation exposures and outcomes.



Key Content

Toolkit covers:

- Ethical considerations → higher risk threshold in pregnancy.
- Pathogen impact (e.g., malaria, TB).
- Vaccine platform safety (protein subunit, mRNA, vectors, etc.).
- Implementation research → integration into antenatal care, pharmacovigilance.
- Study design → adaptive trials, incidental pregnancy management, informed consent.
- Separation of pregnancy and lactation



Impact and Use

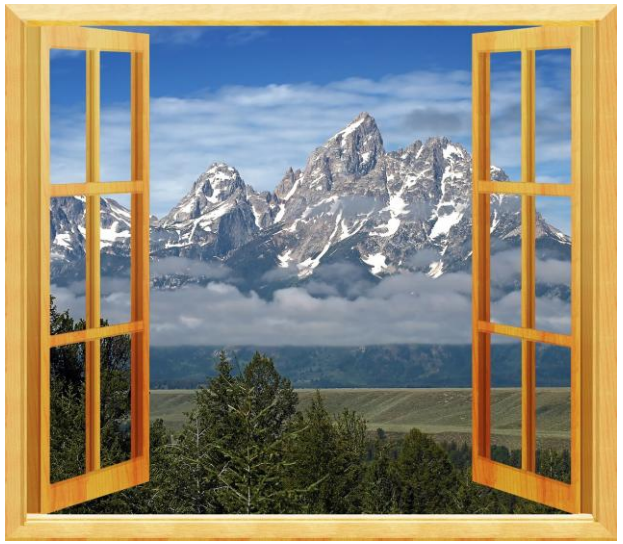
- Helps **sponsors, regulators, clinicians, policymakers** include pregnant & lactating women in vaccine trials.

- Accelerates access to maternal & infant protection, especially in LMICs.

- Living document: updated as new evidence emerges.

In conclusion….

We have a window of opportunity



Many seeds have already been planted

Time to join forces and take concrete steps

……..To move from theory to action

World Health Organization

Thank you

Mariana Widmer
Vasee Moorthy
Katherine Littler
Kirsty Mehring-Le Doare
Francoise Renaud
Lampriamou Smaragda

World Health Organization

Guidance for best practices for clinical trials

Document link:

World Health Organization