

Antiretrovirals in pregnancy research toolkit: Setting the Stage

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IMPAACT

International Maternal Pediatric Adolescent
AIDS Clinical Trials Network

ANNUAL MEETING

2024

Key Messages

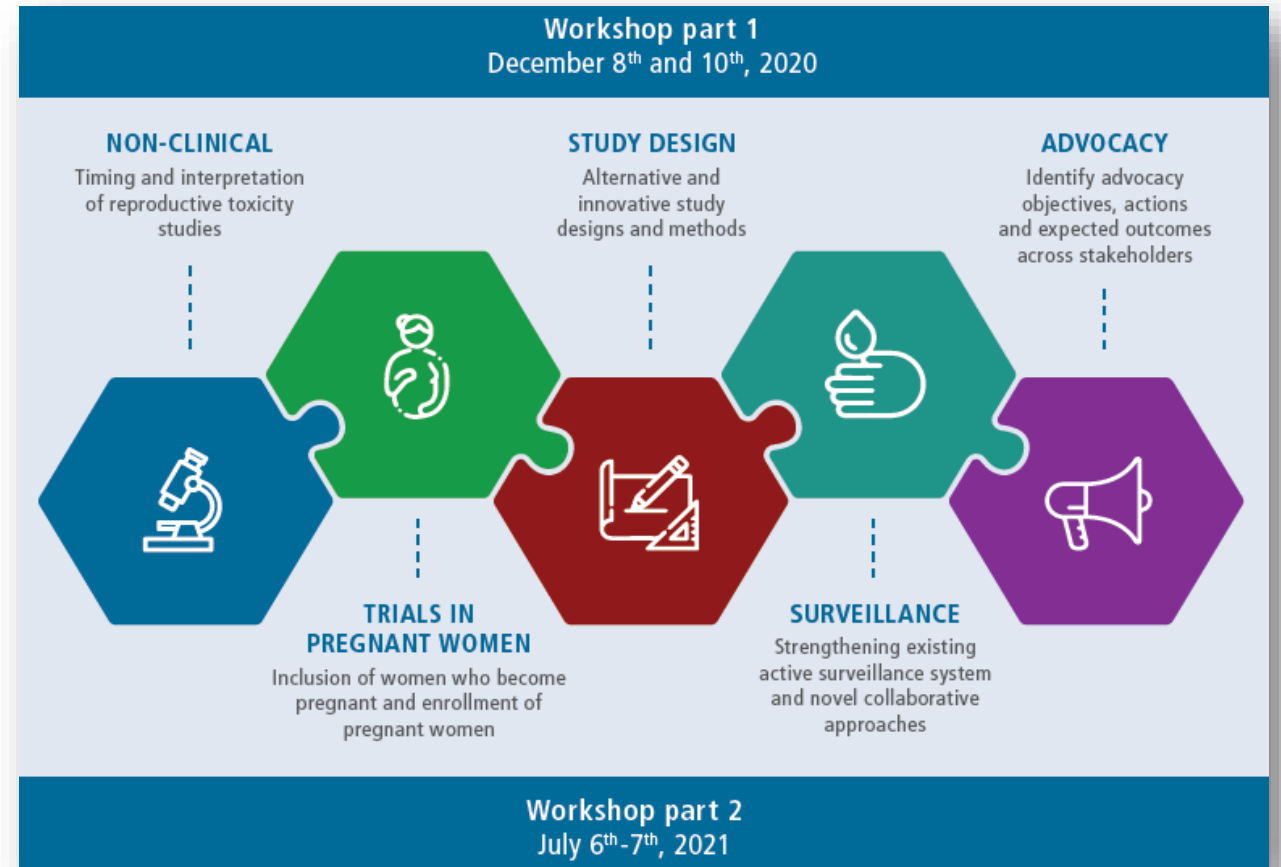
- Historically pregnant and breastfeeding people have been excluded from studies evaluating new medications.
- IMPAACT and WHO convened a workshop with a broad array of collaborators to address these delays and develop new approaches to study new medications in pregnant people.
- WHO convened a new Working Group on Pregnancy and Therapeutics for HIV, Hepatitis and STIs.
- This working group spearheaded the development of the antiretrovirals in pregnancy toolkit to support and accelerate the study of new medications in pregnant people.

WHO & IMPAACT Dec 2020 - July 2021

“Approaches to Enhance and Accelerate Study of New Drugs for HIV and Associated Infections in Pregnant Women”



Academic researchers, regulators, clinical experts, industry leaders, funders, civil society, ethicists, other key stakeholders

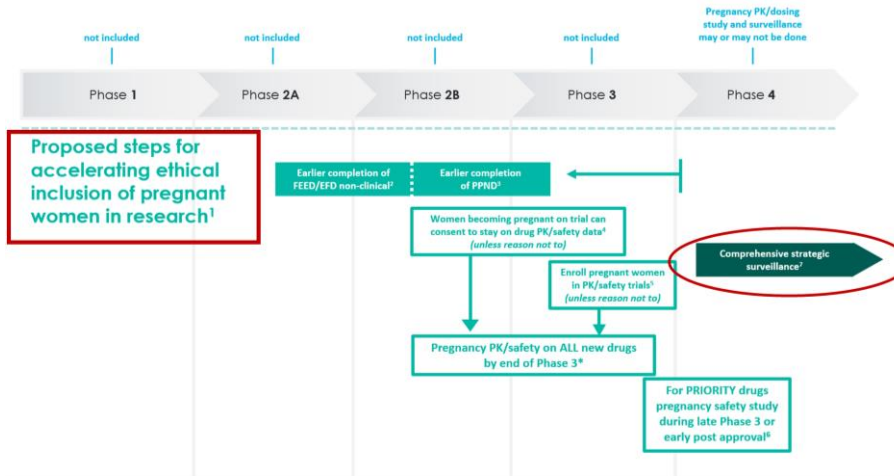


2022 JIAS Supplement: Approaches to enhance and accelerate investigation of new HIV drugs in pregnancy



<https://onlinelibrary.wiley.com/toc/17582652/2022/25/S2>

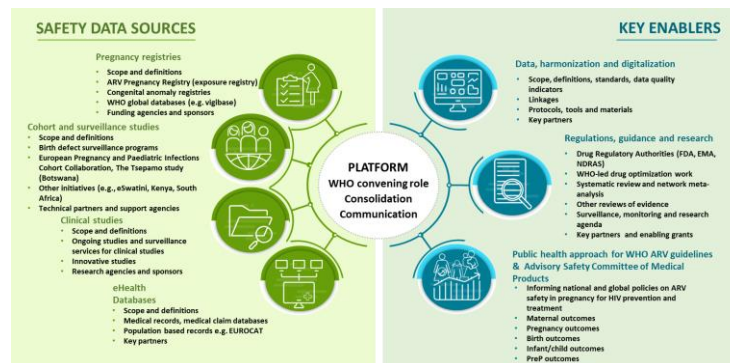
Current approach to inclusion of pregnant women in pre-licensure studies of new antiretroviral agents



Studying new antiretrovirals in pregnancy: Key principles

- ★ If the agent is efficacious in non-pregnant adults (viral load suppression) and adequate drug exposures are achieved in pregnancy, then efficacy can be assumed in pregnancy without additional trials.
- ★ If the agent is efficacious in non-pregnant adults (viral load suppression) and adequate drug exposures are achieved in pregnancy, efficacy for prevention of vertical transmission can be inferred.
- ★ All new agents must be studied in pregnant woman for pharmacokinetics/optimal dosing and short-term safety.
- ★ Dedicated pregnancy safety studies assessing pregnancy, birth and infant outcomes should be conducted for all new ARVs with expected broad use in pregnant women and women who may become pregnant.
- ★ There is no expectation to have meaningful clinical information about teratogenicity risk before registration; Large numbers of observations with exposure at conception/early pregnancy are needed to identify increased risk of rare events and will only come through active surveillance/Phase 4 studies.
- ★ Once pharmacokinetic/dosing and short-term safety in pregnancy are determined to be adequate, there should be no restrictions to access during pregnancy once the ARV is licensed.

New Collaborative Framework for Surveillance of Safety of ARVs in Pregnancy



Call to Action 2021: From theory to practice



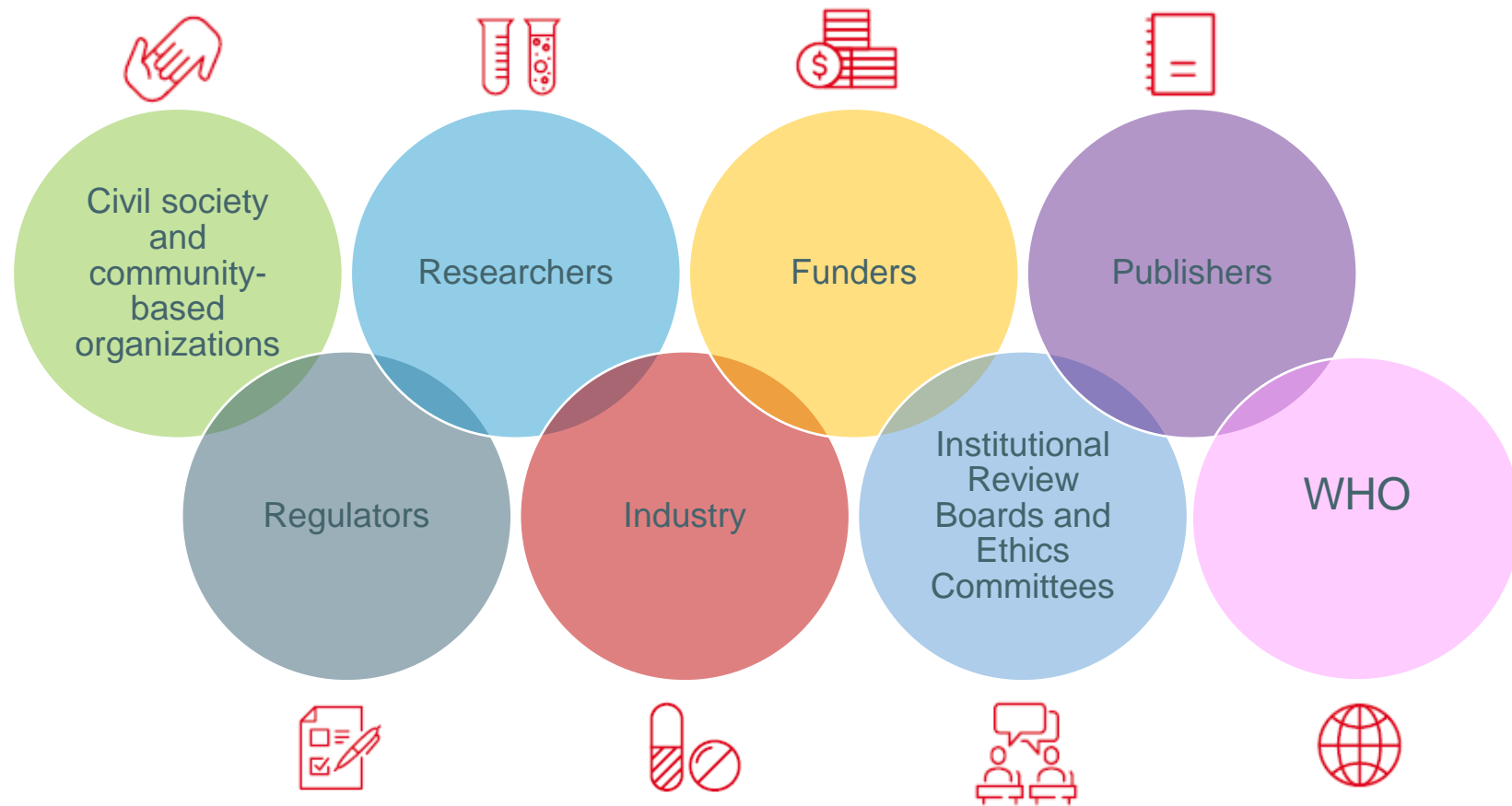
Research for informed choices: Accelerating the study of new drugs for HIV in pregnant and breastfeeding women

A call to action



Photo: ICAP

[call-to-action-to-accelerate-study-of-new-arv-for-pregnant-breastfeeding-women.pdf \(who.int\)](https://www.who.int/call-to-action-to-accelerate-study-of-new-arv-for-pregnant-breastfeeding-women.pdf)



Building on the WHO/IMPAACT workshop, the Pediatric Antiretroviral Working Group (PAWG) and in response to the Call to Action, WHO convened a new **Working Group on Pregnancy and Therapeutics for HIV, Hepatitis and STIs**, to continue the technical dialogue



The WHO-convened working group on Pregnancy and Therapeutics for HIV, Hepatitis, and STIs



Continue the **technical dialogue and implementation of strategic actions** to support implementation and acceleration of R&D and surveillance for new HIV agents in pregnancy



Develop **resources to optimize clinical research** in pregnancy - **toolkit** (endpoints and materials made available)



Technical advice to **WHO guidelines and ARV optimization** processes – **ART and PrEP in pregnancy** (DTG, TAF, CAB LA, LEN, others)



Implement a new **Collaborative framework of surveillance** for the safety of HIV drugs in PLW – **ART and PrEP**



Contribute to **High-Level Dialogues** to galvanize commitment and promote accountability – Roma 6 Global Action Plan



Leverage multiple fora to **disseminate the key principles** and engage with the constituencies – regulatory work ICH, WHA resolution



Facilitate **engagement of community** of women living with HIV, HEP or STIs - from planning to communication

Antiretrovirals in Pregnancy Research Toolkit

- Soft launch at CROI in March 2024
- Piloted among key organizations and PTWG
- Official launch at AIDS 2024



<https://www.who.int/tools/antiretrovirals-in-pregnancy-research-toolkit>

Antiretrovirals in pregnancy research toolkit: Overview