

HIV TREATMENT

MEETING REPORT

# APPROACHES TO ENHANCE AND ACCELERATE STUDY OF NEW DRUGS FOR HIV AND ASSOCIATED INFECTIONS IN PREGNANT WOMEN

DECEMBER 2021





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Approaches to enhance and accelerate study of new drugs for HIV and associated infections in pregnant women: meeting report

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Design and layout by ACW

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The WHO and the IMPAACT Network facilitated a workshop, *Approaches to Enhance and Accelerate Study of New Drugs for HIV and Associated Infections in Pregnant Women*, aimed at gaining consensus on the optimal timing and design of studies of new drugs for treating and preventing HIV and related conditions among pregnant women. This workshop brought together women living with HIV, academic researchers, clinical experts, regulators, industry leaders, funders and other key stakeholders involved in studying HIV-related drugs for pregnant women. The workshop was held virtually on 8-10 December 2020 (part 1) and 6-7 July 2021 (part 2).

## BACKGROUND

With more than 19 million women living with HIV worldwide – most of whom are of childbearing potential – there is a public health imperative to ensure that they can make informed choices about the drugs they take for HIV treatment or prevention. Information to support optimal antiretroviral drug choices in pregnancy has rarely been available for women or their health-care providers, largely because of historically protectionist and conservative approaches to clinical studies conducted among pregnant and breastfeeding women.

Pregnant and breastfeeding women are usually excluded from clinical trials of new agents (pre- and post-licensure). In addition, women of childbearing potential are typically underrepresented in pre-licensure drug trials and are usually required to use dual contraception to participate. Further, those who become pregnant while participating must discontinue the study drug. Therefore, pregnancy safety and pharmacokinetic data for new drugs are routinely delayed by as much as a decade after initial drug approval if studies are performed at all. This results in substantial delays in women accessing new and better drugs. Additionally, despite the lack of data, these new

drugs are prescribed for women of childbearing potential who become pregnant as well as for pregnant women. This results in women having to make decisions about using new agents without adequate information about dosing or safety in pregnancy. This lack of information from trials to guide pregnant women in using antiretroviral drugs shifts the burden of potential risk around drug safety from the clinical trial setting in which safety outcomes are carefully monitored to the real-world clinical care setting in which safety outcomes are not systematically captured.

Multiple agencies and actors have voiced their concerns around the exclusion of pregnant women from clinical trials and the associated harm and risks of these policies. More recently, the importance of allowing pregnant women the opportunity to take part in clinical trials has received renewed attention during the COVID-19 pandemic. Recognizing the urgency of addressing this issue, the IMPAACT Network and WHO held a workshop to refine optimal approaches to studying the safety and efficacy of new HIV-related drugs during pregnancy and to establish the next steps for creating materials and methods that would support the implementation of such studies.

## OBJECTIVES

The overall objectives of the workshop were:

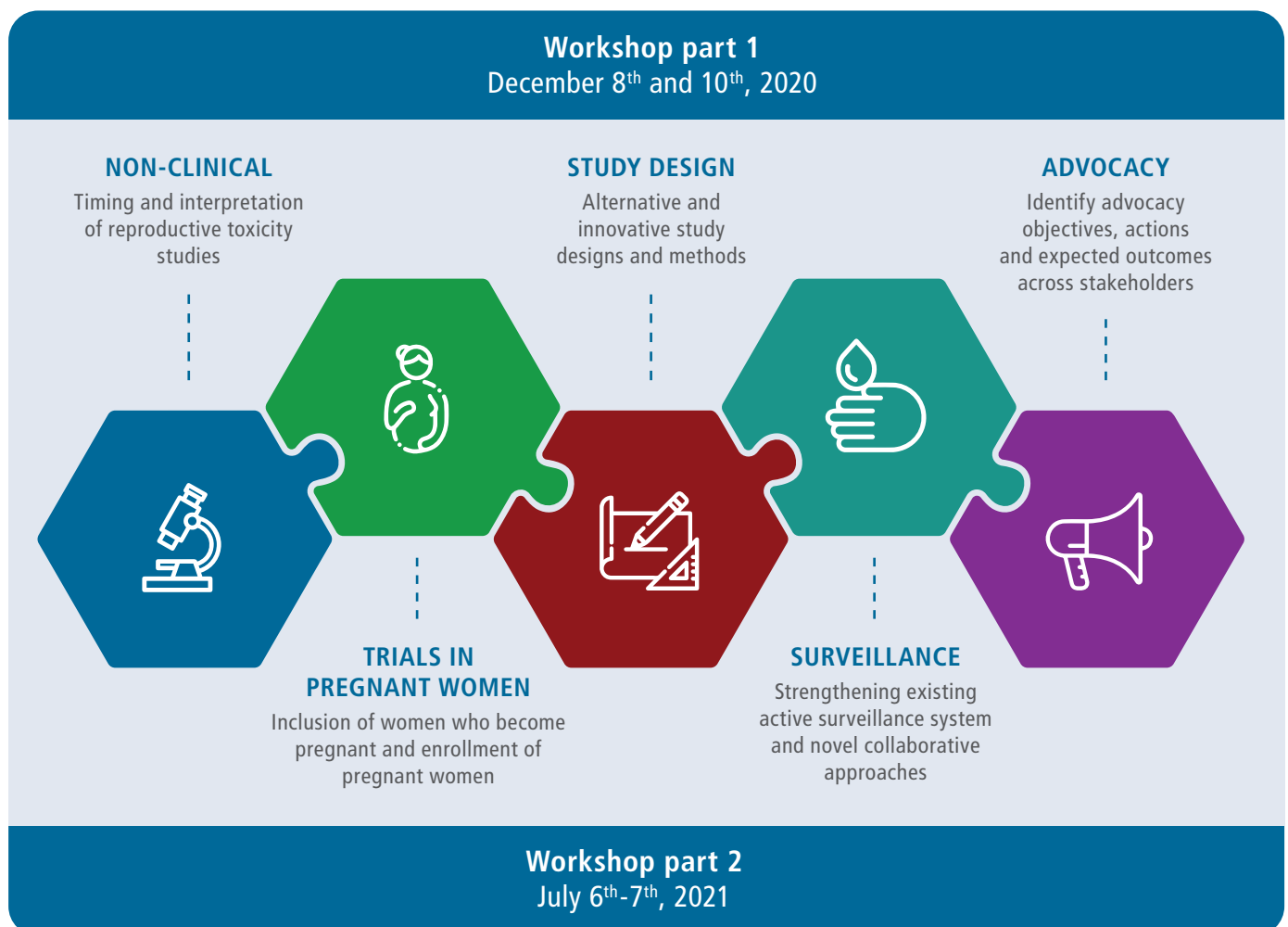
- to refine key principles around optimal approaches to studying new drugs for HIV (treatment or prevention) and associated infections in pregnant women: develop a framework for setting priorities, accelerating and optimizing the type and timing of studies involving pregnant women;
- to review and refine best practices on how to include pregnant women in studies of new drugs that are in Phase 3 studies for non-pregnant individuals; and
- to formulate a strategic action plan for promoting the inclusion of pregnant women in research on new HIV treatment and prevention drugs before drug regulatory authorization.

# METHODS

The workshop co-convened by WHO and the IMPAACT Network brought together more than 100 participants from across the world, including women living with HIV, academic researchers, clinical experts, regulators, industry representatives, funders and other key stakeholders involved in studying drugs for the prevention and treatment of HIV and other infectious diseases among pregnant women. Organizations represented included WHO, IMPAACT, University of Geneva, HIV i-Base, Paediatric Antiretroviral Working Group, PANGEA, International AIDS Society, pharmaceutical companies involved in developing HIV agents, United States Food and Drug Administration, European

Medicines Agency, Special Programme for Research & Training in Tropical Diseases, National Institute of Allergy and Infectious Diseases, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Elizabeth Glaser Pediatric AIDS Foundation, Imperial College London, United States Agency for International Development, AIDS Clinical Trials Group, Microbicide Trials Network, Unitaid, HIV Prevention Trials Network, PHPT, Pregnancy and HIV/AIDS: Seeking Equitable Study, AfroCAB, Treatment Action Campaign, The Lancet, EUROMedCAT, RTI International, Medicines for Malaria Venture and many more including various academic institutions.

**Fig.1 Outline of the workshop**



The virtual workshop was organized in two parts (Fig. 1). Part 1 of the workshop was held virtually over three half-days on 8-10 December 2020 (see Annex 2). Workshop participants then joined virtual working groups to focus on five domains: non-clinical studies, trials involving pregnant women, study design, surveillance and advocacy. Working groups met periodically over the first six months of 2021

before part 2 of the workshop, in which each working group presented overall conclusions and specific strategic actions. Part 2 of the workshop was held virtually over two half-days on 6-7 July 2021 (see Annex 3), enabling the group to review various aspects of the work and develop a shared vision for accelerating studies of new drugs for HIV and associated infections among pregnant women.



# SUMMARY AND KEY OUTCOMES

The workshop brought to light current barriers to investigating new therapeutics for pregnant and breastfeeding women and explored potential solutions with the contribution of all stakeholders involved. Community members emphasized that women should be supported to choose whether or not to take part in a trial. Ethicists highlighted that ethical considerations should be seen as enablers, not inhibitors, of responsible conduct of research in pregnancy, informing how to conduct this research safely and responsibly. Regulators expressed a desire to advance research among pregnant and breastfeeding women with options for acceleration including: retaining women who become pregnant during the study, including robust pharmacokinetic data in pre-market studies and completion of a full non-clinical toxicology package before Phase 3 trials begin. For funders, this was highlighted as a key topic of interest that builds on broader work underway such as the Taskforce on Research Specific to Pregnant and Lactating Women (PRGLAC 15) report submitted to the United States Secretary of Health and Human Services, reporting data in new categories (pregnant women, breastfeeding, maternal health and maternal morbidity and mortality) and improving pregnancy registries. Researchers are striving to generate pregnancy pharmacokinetic and safety data and make that available by (or shortly after) the approval of a new drug that is likely to be used by young women. Industry observers signalled important shifts happening within their multiple companies and highlighted a strong desire to advance this work in conjunction with other stakeholders.

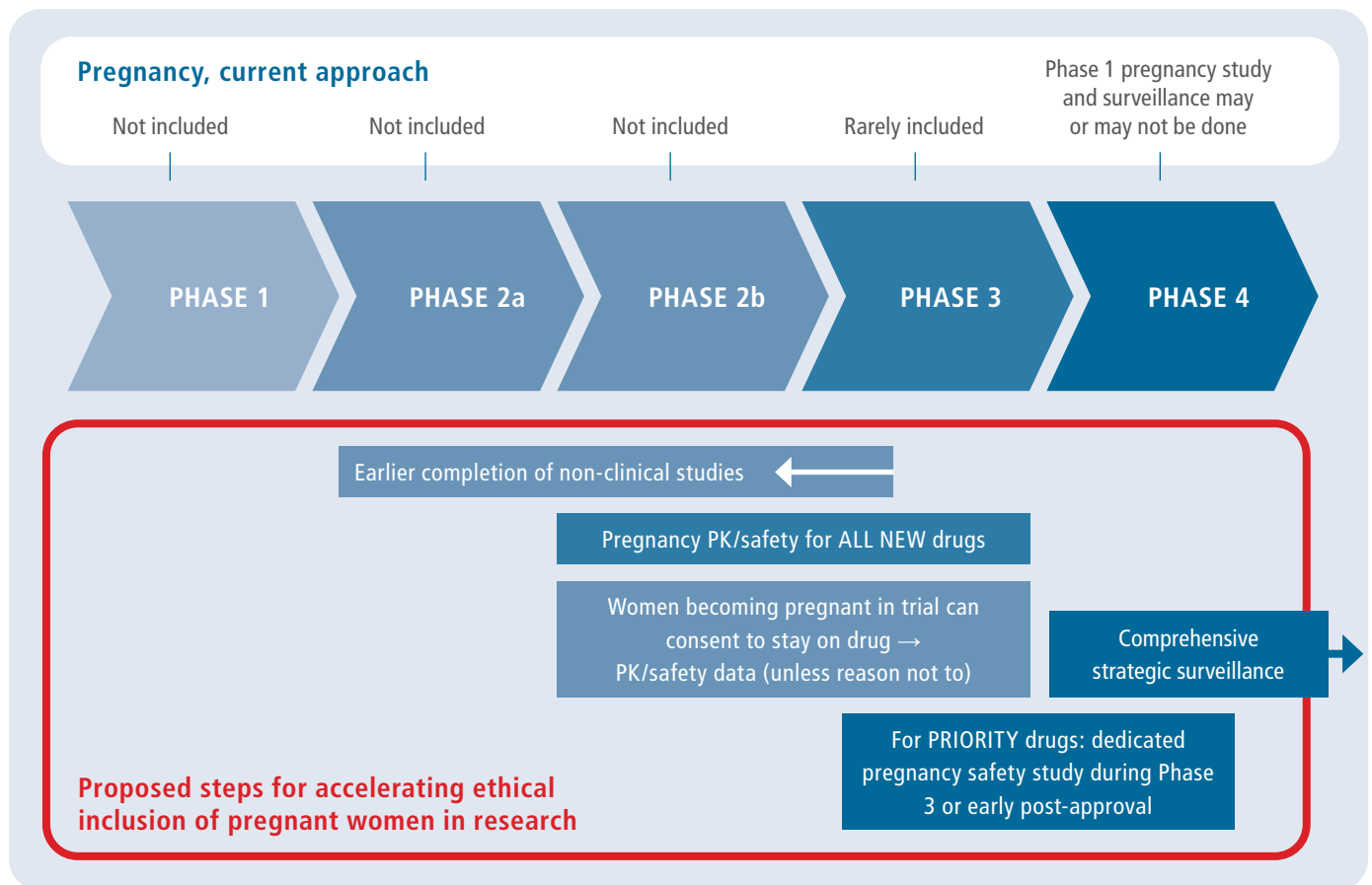


Based on the consultative process, workshop members developed a framework (Fig. 2) for accelerating the inclusion of pregnant and breastfeeding women in pre-licensure clinical trials, with a goal of having pharmacokinetic and preliminary safety data on all new HIV agents in pregnancy available when a drug is approved. The framework includes the following key principles.

- Involve women of childbearing potential affected by HIV from the identification of research questions through the study design, recruitment, conduct and dissemination of results.
- Perform non-clinical developmental and reproductive toxicology studies earlier during drug development for all new HIV agents-
  - Fertility and early embryonic development and embryo-fetal development studies should be completed during or no later than the end of the Phase 2 registrational trials.
  - Pre- and postnatal development studies should be completed during early phase 3 or no later than the end of the Phase 3 registrational trial.
- Women who become pregnant in pre-licensure trials should be given the option to make an informed choice to stay on the study drug once early non-clinical fertility and early embryonic development and embryo-fetal development studies are completed, with no negative signals and dosing being established in non-pregnant women.
- Enrol pregnant women in specific studies to determine pregnancy pharmacokinetic and preliminary safety, as soon as late non-clinical pre- and postnatal development studies are completed with no negative signals, for all new HIV agents.
- Investigate adverse pregnancy and birth outcomes through dedicated pregnancy safety studies for all new priority HIV agents identified through the [Conference on Antiretroviral Drug Optimization](#) as soon as dosing in pregnancy is confirmed.
- Expand the active surveillance of drug safety in pregnancy to enable systematic and rapid detection of adverse maternal, pregnancy and birth outcomes, especially rare events such as birth defects.

Although these principles refer to specific agents for HIV treatment or prevention, the group emphasized how these can also be applied to HIV-associated infections and potentially adapted for other conditions that affect the health of women of reproductive age.

**Fig.2 Framework for accelerated inclusion of pregnant women in pre-licensure clinical trials**



After identifying and agreeing on the core principles and framework described above, workshop participants outlined several strategic actions that were considered critical to concretely realize the vision illustrated by the framework. These actions, summarized in Box 1, are designed to support a concrete shift in practice by developing tools, guidance and resources for those involved

with designing and implementing studies among pregnant and lactating women; by undertaking further early-stage research to inform future modifications and the regulatory framework; by aligning and better coordinating those contributing to surveillance efforts; by sharing knowledge and mobilize key stakeholders through targeted advocacy; and by promoting transparency and accountability.



## Box 1. Strategic actions to implement a new framework for investigating new antiretroviral drugs for pregnant and breastfeeding women



### Non-clinical

The Non-clinical Working Group discussed the optimal timing of the developmental and reproductive toxicology studies for new antiretroviral agents, how best to communicate the significance of the animal findings to clinicians and their patients and the future potential of alternative assays for assessing developmental and reproductive toxicology endpoints. Their strategic action items include:

- sharing information with stakeholders, including industry, regulatory agencies and national authorities, specifically:
  - disseminating the proposed timing of developmental and reproductive toxicology studies for antiretroviral drugs (to initiate parts of the developmental and reproductive toxicology study earlier in the drug development programme to enable pregnant women to be included in the later stages of the pre-approval trials);
- supporting earlier inclusion of pregnant women in clinical trials through several mechanisms:
  - promoting (improving and validating) physiologically based pharmacokinetic modelling to support drug development and inform the dose selected for use among pregnant women;
  - encouraging alternative strategies such as enhanced and combination studies that include both embryo-fetal development and pre- and postnatal development studies to move studies earlier and complete studies more rapidly to enable pregnant women to be included in Phase 3 trials;
  - supporting scientific research to advance alternatives and supplements to current approaches to non-clinical studies;
- exploring approaches to communicate developmental and reproductive toxicology study results into clinical and lay language for use in clinical trial materials (patient information sheets and investigator brochures) to ensure better understanding by clinical trial participants of the developmental and reproductive toxicology study results and how these results informed the clinical trial;
- promoting knowledge sharing with institutional review board and ethics committee members to support full interpretation of developmental and reproductive toxicology study results and/or promote training and consultation with non-clinical experts; and
- developing a toolkit for research in pregnancy that will include the above action items.



### Trials involving pregnant women

The Working Group on Pregnant Women in Clinical Trials focused on defining key principles for optimal approaches to studying new drugs for pregnant women and developing a framework for setting priorities for new agents for study among pregnant women in Phase 2 and Phase 3 clinical trials. Their strategic action items include:

- creating an inventory of all antiretroviral drug trials to track and monitor the inclusion of pregnant women within these trials;
- sharing findings at CADO to inform the process of setting antiretroviral drug priorities specific to pregnancy;
- establishing a mechanism to host ongoing conversations, lead actions and activities for the pregnant women agenda for antiretroviral drugs for prevention and treatment:
  - exploring existing platforms to advance the technical discussion, such as the WHO-convened Paediatric Antiretroviral Working Group and Adult Antiretroviral Working Group;
  - addressing remaining gaps and questions (liability etc.);



- mobilizing stakeholders to adopt the following key principles:
    - a defined set of pharmacokinetic and safety data in pregnancy be required for registering all new antiretroviral drugs;
    - once pharmacokinetics and safety in pregnancy are determined to be adequate, no restrictions on access to the licensed drug during pregnancy;
    - phase 3 registrational trial cannot start unless the pre- and postnatal development study is starting simultaneously or already underway since that study result is critical to conduct the pregnancy pharmacokinetic safety trial; and
    - the pregnancy specific safety trial is underway or planned at the time of registration.
- 



### Study design

The Study Design Working Group focused on articulating situations in which alternatives to existing common study designs should be considered, considering which methods best lend themselves to studying different types of endpoints (pharmacokinetic, safety and efficacy) and summarizing the advantages and disadvantages of alternative approaches. Their strategic action items include:

- establishing basic (minimum) agreed safety endpoints to collect in trials involving pregnant and breastfeeding women to enable harmonization and data sharing across studies:
    - which endpoints and how they will be defined specifically (norms, cut-off points etc.) and measured;
    - minimum recommended criteria for evaluating safety among infants, including the duration of follow-up;
  - creating template protocols for open access and wide distribution, such as for:
    - staged enrolment (women enrolled late in the third trimester → early third trimester → second trimester);
    - integrated pregnancy pharmacokinetic and pregnancy safety trial;
    - adaptive master protocol;
  - creating simplified template case report forms for pregnancy studies that capture the essential exposure and outcome information to facilitate efficiency:
    - sharing case report forms from other studies widely; and
  - establishing a forum for achieving these aims and for facilitating ongoing discussions related to study design across stakeholder groups to continue supporting harmonization.
- 



### Surveillance

The Surveillance Working Group focused on building a new conceptual framework for surveillance of safety of antiretroviral drugs in pregnancy. Their strategic action items include:

- adopting harmonized definitions of adverse pregnancy, birth and maternal outcomes:
  - specifying which outcomes can only be discovered by surveillance, such as neural tube defects and rare events;
  - identifying the approach to getting answers for these outcomes that require surveillance;
- engaging with and identifying existing country programmes and surveillance studies with surveillance data available for central sharing and standardization;

- identifying 3–5 existing or new sites to implement a modular format for active surveillance (with denominators) for the key outcomes described above:
  - identifying ways to improve active surveillance for existing mechanisms;
- advocating for funding mobilization and guidance from regulatory agencies:
  - voluntary public–private partnerships, grants and/or regulatory-driven options; and
- creating targets and monitoring and evaluation goals to monitor the above activities.



### Advocacy

The Advocacy Working Group focused on identifying the main advocacy messages across stakeholder groups and developing the call to action. Their strategic action items include:

- disseminating advocacy messages to the HIV community by convening an International AIDS Society satellite at the 11th International AIDS Society Conference on HIV Science in 2021;
- launching the call to action at a high level and disseminating widely;
- leveraging existing accountability platforms such as the Vatican Platform for High-level Dialogues on children living with HIV; and
- exploring and fully utilizing opportunities to keep women on the research and development agenda of the public and private sector involved with HIV treatment and prevention.

## CONCLUSION AND NEXT STEPS

Workshop participants consolidated an overall shared vision for a transformational shift in the way we conceptualize research of new antiretroviral drugs for treatment and prevention and summarized that in a call to action that outlines how stakeholders involved in studying antiretroviral drugs for HIV treatment and prevention should support greater inclusion of pregnant women and breastfeeding and contribute to a more equitable investigation of new HIV drugs (<https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/call-to-action-to-accelerate-study-of-new-arv-for-pregnant-breastfeeding-women.pdf>).

The groups also agreed to rapidly disseminate the workshop findings via multiple conferences and meetings, especially the International AIDS Society 2021 Pregnant Women Satellite, the CADO4 meeting, the 18<sup>th</sup> European AIDS Conference in 2021 and the 13<sup>th</sup> International workshop on HIV Paediatrics in 2021. The technical discussion of workshop participants will be summarized and disseminated by a journal supplement dedicated to sharing key principles and implementation considerations to support. WHO committed to leverage its convening power to support the continuation of the technical dialogue on this topic to enable the theory to be fully translated into action.



# ANNEX 1. LIST OF PARTICIPANTS

- Olubukola Ayinde, AfroCAB
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- Karen Cohen, University of Cape Town
- Liz Connick, AIDS Clinical Trials Group and Chair, Women's Health Information & Support Centre
- Tim Cressey, PHPT
- Judith Currier, AIDS Clinical Trials Group
- Corinne de Vries, European Medicines Agency
- Sinéad Delany-Moretlwe, HIV Prevention Trials Network
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- Helen Dolk, EUROmedICAT
- Myriam El Gaaloul, Medicines for Malaria Venture
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- Glenda Gray, South African Medical Research Council
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- Amita Gupta, AIDS Clinical Trials Group and IMPAACT Network
- Rohan Hazra, Eunice Kennedy Shriver National Institute of Child Health and Human Development
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- Zeda Rosenberg, International Partnership for Microbicides
- Ted Ruel, IMPAACT Network
- Memory Sachikonye, HIV i-Base UK
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- Moupali Das, Gilead
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### WHO participants

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- Meg, Doherty, HHS
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- Corinne Merle, TDR/SCI
- Andreas Reis, RFH/SCI
- Michelle Rodolph, TPP/HHS

### Organizing committee

- Elaine Abrams, IMPAACT Network
- Alexandra Calmy, University of Geneva
- Polly Clayden, HIV i-Base
- Angela Colbers, Paediatric Antiretroviral Working Group
- Shahin Lockman, IMPAACT Network
- Imelda Mahaka, PANGEA
- Martina Penazzato, WHO
- Françoise Renaud, WHO
- Marissa Vicari, International AIDS Society
- Jennifer Zech, ICAP at Columbia University

# ANNEX 2. WORKSHOP PART 1 – AGENDA

Co-chairs: Alexandra Calmy (University of Geneva) and Shahin Lockman (Harvard University)

## Day 1 – Tuesday, 8 December 2020

Opening remarks: Meg Doherty (WHO) and Sharon Nachman (IMPAACT Network)

Introductions	All
Background and objectives of the meeting	Elaine Abrams (ICAP at Columbia University) Martina Penazzato (WHO)
Setting the stage: key issues and anticipated outcomes	Shahin Lockman (Harvard University) Alexandra Calmy (University of Geneva)
United States National Institutes of Health taskforce: review of recommendations and next steps	Andrew Bremer (Eunice Kennedy Shriver National Institute of Child Health and Human Development)
Current regulatory frameworks and opportunities for change	Prabha Viswanathan (United States Food and Drug Administration) Corrine de Vries (European Medicines Agency)
Industry panel: hurdles and opportunities to accelerate investigation of new antiretroviral drugs in pregnant women	Kathryn Kersey (Gilead) Annemiek de Ruyter (ViiV Healthcare) Kimberley Brown (Janssen) Kathleen Squires (MSD)  Facilitated by Marissa Vicari (International AIDS Society/Cipher)
Discussion	All

## Day 2 – Wednesday, 9 December 2020

Review day 1 and overview day 2	Alexandra Calmy (University of Geneva)
When and how to study antiretroviral drugs in pregnancy: new approaches and good practices	Lynne Mofenson (Elizabeth Glaser Pediatric AIDS Foundation)
Ethically driven framework to investigate new drugs in pregnant women: panel discussion	Maggie Little (Pregnancy and HIV/AIDS: Seeking Equitable Study/University of North Carolina) Jerome Singh (University of KwaZulu-Natal) Samia Hurst (University of Geneva)
Community perspectives: moderated round table	Mary Nyati (Treatment Action Campaign) Lester Baloyi (Treatment Action Campaign) Olubukola Ayinde (AfroCAB) Memory Sachikonye (HIV i-Base) Pamela Jack Fama (study participant, VESTED, Zimbabwe) Angelina Namiba (4M Mentor Mothers Network)  Facilitated by Imelda Mahaka (PANGEA Zimbabwe)
Considerations for and experiences from HIV prevention studies	Sharon Hillier (University of Pittsburgh)
Innovating study design for accelerated investigation in pregnant women	Edward Mills (McMaster University)
Discussion	All

## Day 3 – Thursday, 10 December 2020

Review day 2 and overview day 3	Shahin Lockman (Harvard University)
Review of the antiretroviral drug landscape and available evidence for pregnant and breastfeeding women	Claire Thorne (University College London) Anton Pozniak (Chelsea and Westminster Hospital)
Lessons learned and opportunities lost: case studies from tuberculosis, malaria, hepatitis and COVID-19	Amita Gupta (Johns Hopkins University) Gonzague Jourdain (PHPT) Wiweka Kaszubska (Medicines for Malaria Venture) Loulou Kobeissi (WHO)
Discussion	All
Review goals and expected output for the working groups	Organizing committee
Wrap up and Closing	Elaine Abrams (ICAP at Columbia University) Martina Penazzato (WHO)

# ANNEX 3. WORKSHOP PART 2 – AGENDA

## Day 1 – Tuesday, 6 July, 2021

Welcome back and objectives	Elaine Abrams (ICAP at Columbia University) Martina Penazzato (WHO)
Non-clinical work group report back	Angela Colbers (Radboud University)
Trials in pregnant women work group report back	Elaine Abrams (ICAP at Columbia University)
Study design work group report back	Shahin Lockman (Harvard University)
Surveillance work group report back	Françoise Renaud (WHO)
Wrap up	Shahin Lockman (Harvard University)

## Day 2 – Wednesday, 7 July, 2021

Day 1 summary Introduction to day 2	Shahin Lockman (Harvard University) Alexandra Calmy (University of Geneva)
Community voice	Facilitated by Polly Clayden (HIV i-Base)
Strategic actions	Non-clinical (Yodit Belew – United States Food and Drug Administration) Trials in pregnant women (George Siberry – United States Agency for International Development) Study design (Shahin Lockman – Harvard University) Surveillance (Roger Shapiro – Harvard University)
Advocacy workgroup report back and call to action discussion	Marissa Vicari (International AIDS Society/Cipher)
Closing remarks and next steps	Elaine Abrams (ICAP at Columbia University) Martina Penazzato (WHO)

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