Cross-organizational learning exchange # 2 | A discussion on the scientific approaches to improve and accelerate the research and development of new medicines to be used during pregnancy and lactation

11 November, 2021
16:00-19:00 CET; 10:00-13:00 EST; 7:00-10:00 PST.

Context
After hosting a first consultation on the topic of gender-inclusive research and development (R&D) in 2020, MMV is now convening a second discussion led by the scientific experts. The COVID-19 pandemic has brought attention to the ethical questions raised by the practice of excluding pregnant and lactating people and persons of childbearing potential from biomedical research. Indeed, it has shown that when these populations are excluded from research, they are unlikely to have equitable and timely access to critical interventions. At this consultation, we are placing particular emphasis on strategies to develop new medicines with an aim of making them accessible to pregnant and lactating persons more expeditiously than current practice.

Objective of the discussion
MMV intends to gather feedback on its strategy aimed at accelerating the inclusion of pregnant and lactating women in clinical trials, and to share examples, describe barriers and identify opportunities in gender-inclusive R&D. This discussion will inform follow-up consultations on policy, access, and advocacy where a roadmap for joint action will be considered.

Agenda

I. Introduction
- The context and objectives for this consultation (Wiweka Kaszubska, MMV)
- Regulatory and ethical framework for gender-inclusive research (Anna Thomas, MMV)
- General momentum - HIV, PREVENT, COVID and maternal immunization (Ajoke Sobanjo-ter Meulen, Bill and Melinda Gates Foundation)

II. Specific scientific approaches to include pregnant and lactating women in R&D
- Gathering data early with non-clinical models
  - Presentation: Animal models and DART studies (Melissa Tassinari, Expert Advisory Scientific Committee, MMV)
  - Discussion
- Leveraging translational models
  - Presentation: PBPK modeling (Nada Abla Geiser, MMV)
  - Discussion
- Including pregnant and lactating women in clinical development
  - Presentation: proposal for the earlier inclusion of pregnant and lactating women in clinical pharmacology studies and/or safety and efficacy studies (Myriam El Gaaloul, MMV)
  - Discussion
- Addressing data gaps with post-registration studies
  - Presentation: pregnancy registries & randomized clinical trials (Stephanie Dellicour, Liverpool School of Tropical Medicine)
  - Discussion
III. Summary and next steps
  o Wrap-up (Wiweka Kaszubska, MMV)
  o Comments from participants