

Gender and Health Research Agenda Setting for COVID-19: Initial Results

Thematic Group 2: Therapeutics & Diagnostics (including vaccines)

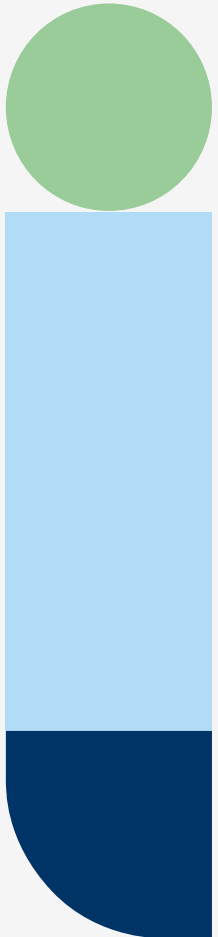
Sex and gender considerations in the research & development of COVID-19 therapeutics, vaccines, diagnostics & digital health interventions

Co-leads: Jeannette Wolfe (USA), Evelynne Bischof (China), Bernadette Ateghang-Awankem (Germany)

Coordinator: Maryam Rumaney (South Africa)

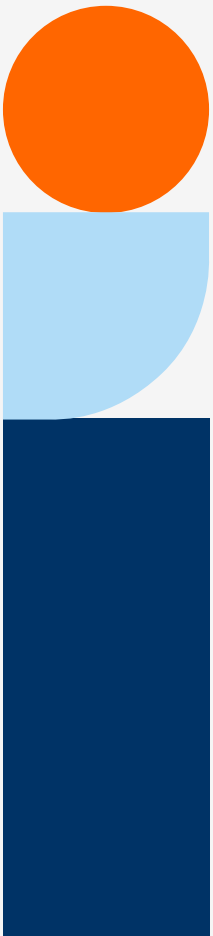
Steering committee focal point: Lavanya Vijayasingham (Malaysia)

Thematic group report process & themes




- 23 contributors across genders, regions, organisations (excluding co-leads, coordinator and steering liaison)
- 4 evolving drafts between February and May 2021
- 42 research questions (long-list distilled through report)
- 4 categories of themes
- 23 Current survey responses

Current thematic top priorities



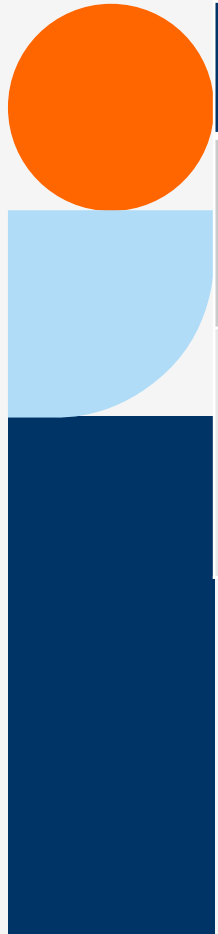
Rank	Research Question	Impact Score	Urgency Score
1	#40: How can pregnant and lactating females be ethically, and safely included in phase 3 and 4 studies for COVID-19 R&D	3.93	2.23
2	#39: What is the extent of the enrollment and participation of women in ongoing and completed COVID-19 clinical trials across various sites and countries	3.79	2.21
3	#8: Does safety, efficacy, optimal dosing regime, and protective duration of the different COVID-19 vaccines differ in pregnant and lactating women, and their foetuses and infants/toddlers?	3.75	2.43
4	#33 In what way are sex and gender related variables integrated into national and global vaccine safety surveillance systems?	3.71	2.31

Current thematic top priorities



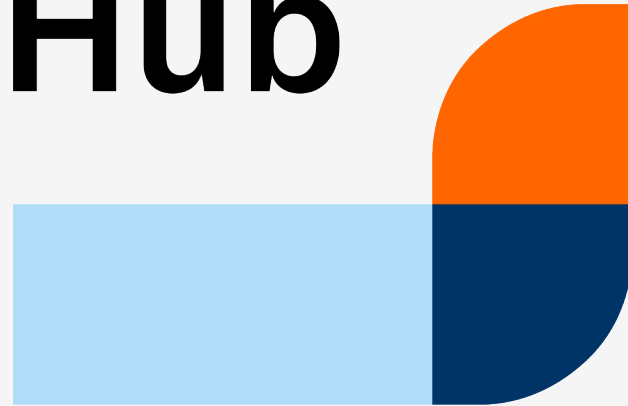
Rank	Research Question	Impact Score	Urgency Score
5	#5: Does safety, efficacy and optimal dosing of different therapeutic interventions for COVID-19, and post-COVID conditions differ by sex, age, race?	3.68	2.36
6	#4: Does safety, efficacy, optimal dosing regime and protective duration of the different COVID-19 vaccines differ by sex, age, race?	3.68	2.64
7	#1: How do the different aspects of human biology (i.e genetics, immunology, biochemistry, physiology, microbiota) contribute to sex-differences in pharmacokinetics, safety and efficacy of COVID-19 therapeutics and vaccines?	3.63	2.20
8	#32: How can international standards and templates for regulatory and evaluation dossiers, including for emergency use vaccine and therapeutic products during pandemics, be adapted to incorporate sex and gender considerations in the evaluation of therapeutic safety and effectiveness, and product registration process?	3.61	1.79

Current thematic top priorities



Rank	Research Question	Impact Score	Urgency Score
9	#25: What clinical trial study design and statistical analysis strategies efficiently and cost-effectively ensure quality sex and gender sensitive analysis and reporting for COVID-19 research?	3.57	2.43
10	#9: Does safety, efficacy and optimal dosing regimens of different therapeutic interventions for COVID-19, and post-COVID conditions differ in pregnant and lactating women, and their foetuses and infants/toddlers?	3.54	2.21

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