

2nd MEMBERS

ASSEMBLY

THE MEETING WILL START SOON

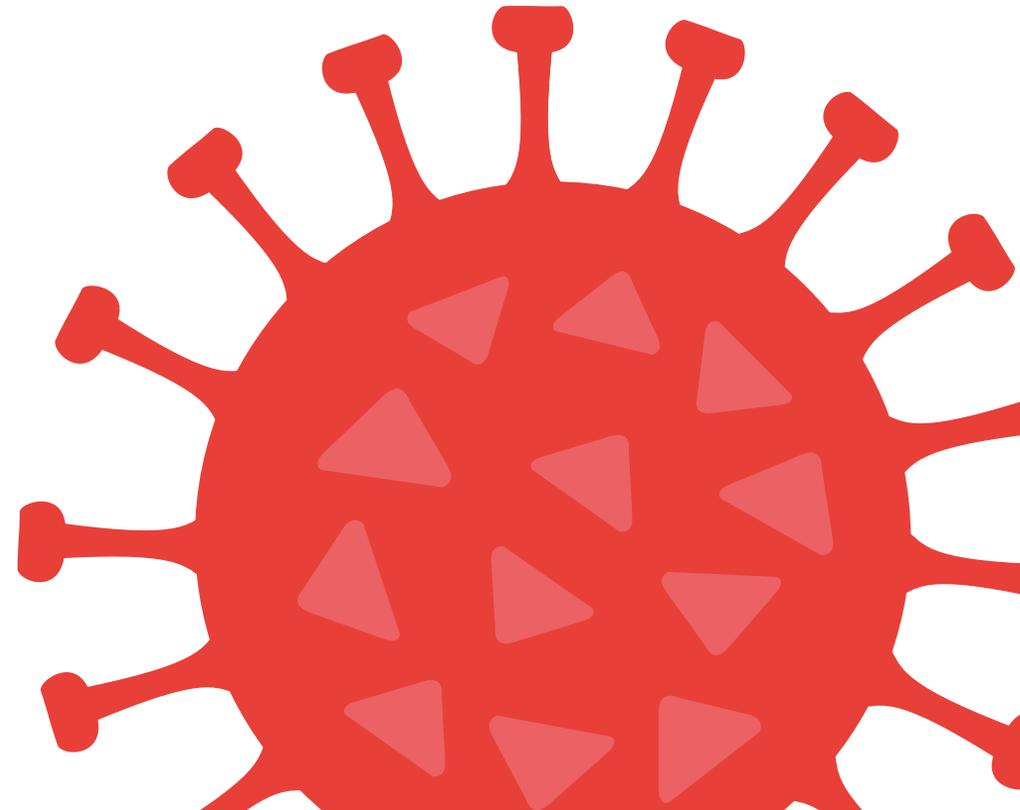


Coalition 2.0 – time for change?



28/02/2023

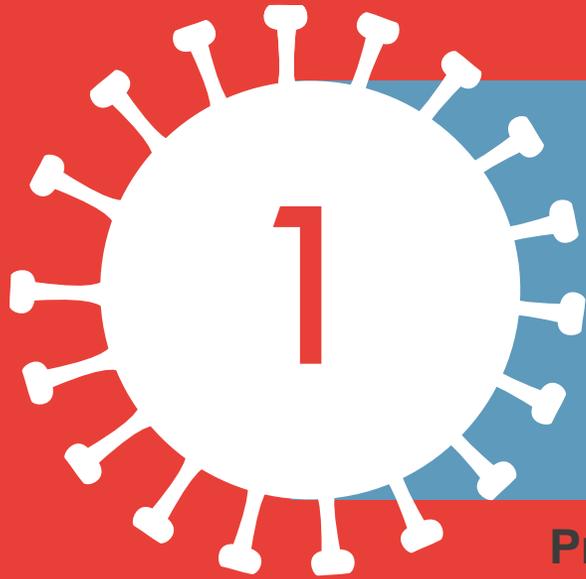
C  **VID-19**
Clinical Research Coalition



AGENDA

TIME (CET)	ITEM
13:00 – 13:05	Welcome & Introduction Prof. Nick White, Steering Committee Chair Thailand & UK
13:05 – 14:05	Working Group Presentations Clinical Epidemiology MNCH Data Sharing VID Social Science Therapeutics
14:05 – 14:15	Presentation of the Coalition's New Host: PANTHER Dr Nathalie Strub-Wourgaft, Steering Committee Member Switzerland
14:15 – 15:15	Presentation on the Coalition Transition & Discussion Prof. Nick White, Steering Committee Chair Thailand & UK

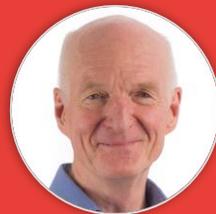




Welcome & Introduction

DURATION: 5 minutes

Presenter:



Prof. Nick White, Steering Committee Chair | Thailand & UK

Housekeeping Announcements (1/2)



Today's meeting is being recorded and a link to the recording will be published soon.



Please ask questions via the Q&A tool at the bottom of your screen. You can also “upvote” people's questions by clicking the thumbs-up icon.



When asking a question please be sure to include the working group or speaker you are addressing it to.



When you leave this event, you will be asked to fill out a short survey. Many thanks in advance for providing feedback!

Housekeeping Announcements (2/2)



During the discussion session, please **raise your hand to indicate that you would like to speak** and unmute yourself (and ideally turn on your camera) if the moderator calls you.



Please send an email to adminIT@covid19crc.org if you have any **technical difficulties** and would like some help.



Please use **#COVID19crc** to tweet about the coalition and this assembly!

Governance: Steering Committee members

NEW



Dr Elvis Temfack

Senior Research Officer, Africa Centers for Disease Control and Prevention, African Union Commission *(Ethiopia)*



Prof. Helen Rees

Founder & Executive Director, Wits Reproductive Health & HIV Institute of the University of the Witwatersrand *(South Africa)*



Prof. Mohammad Abul Faiz

Professor of Medicine *(Bangladesh)*



Prof. Patricia García

Universidad Peruana Cayetano Heredia *(Peru)*



Prof. Philippe Guérin*

Director of the Infectious Diseases Data Observatory *(UK)*



Dr Nathalie Strub-Wourgaft*

NTD and COVID Director & Member of the Executive Team of the Drugs for Neglected Diseases initiative *(Switzerland)*



Prof. Nicholas J. White*

Chairman of the Wellcome Trust's South-East Asian Research Units *(Thailand & UK)*
Chair of the Steering Committee

* Representatives of instigating organizations
COVID19CRC.ORG | 3/ 6

The Coalition Secretariat



Miray Aizouki
Project Associate

✉ maizouki@covid19crc.org

📍 Geneva, Switzerland

🦠 Since January 2023, 100%



Amina Haouala
Secretariat Coordinator

✉ ahaouala@covid19crc.org

📍 Geneva, Switzerland

🦠 Since August 2022, 100%



Dr Brenda Okware
Scientific Coordinator

✉ Bokware@extern.dndi.org

📍 Kampala, Uganda

🦠 Since February 2021, 80%



Maureen Kristin Thiele
Project Manager

✉ Maureen.Thiele@covid19crc.org

📍 Chamonix-Mont-Blanc, France

🦠 Since April 2020, 50%



Nebu
Canine Ambassador

✉ Info@covid19crc.org

📍 Kampala, Uganda

🦠 Since February 2021, 10%



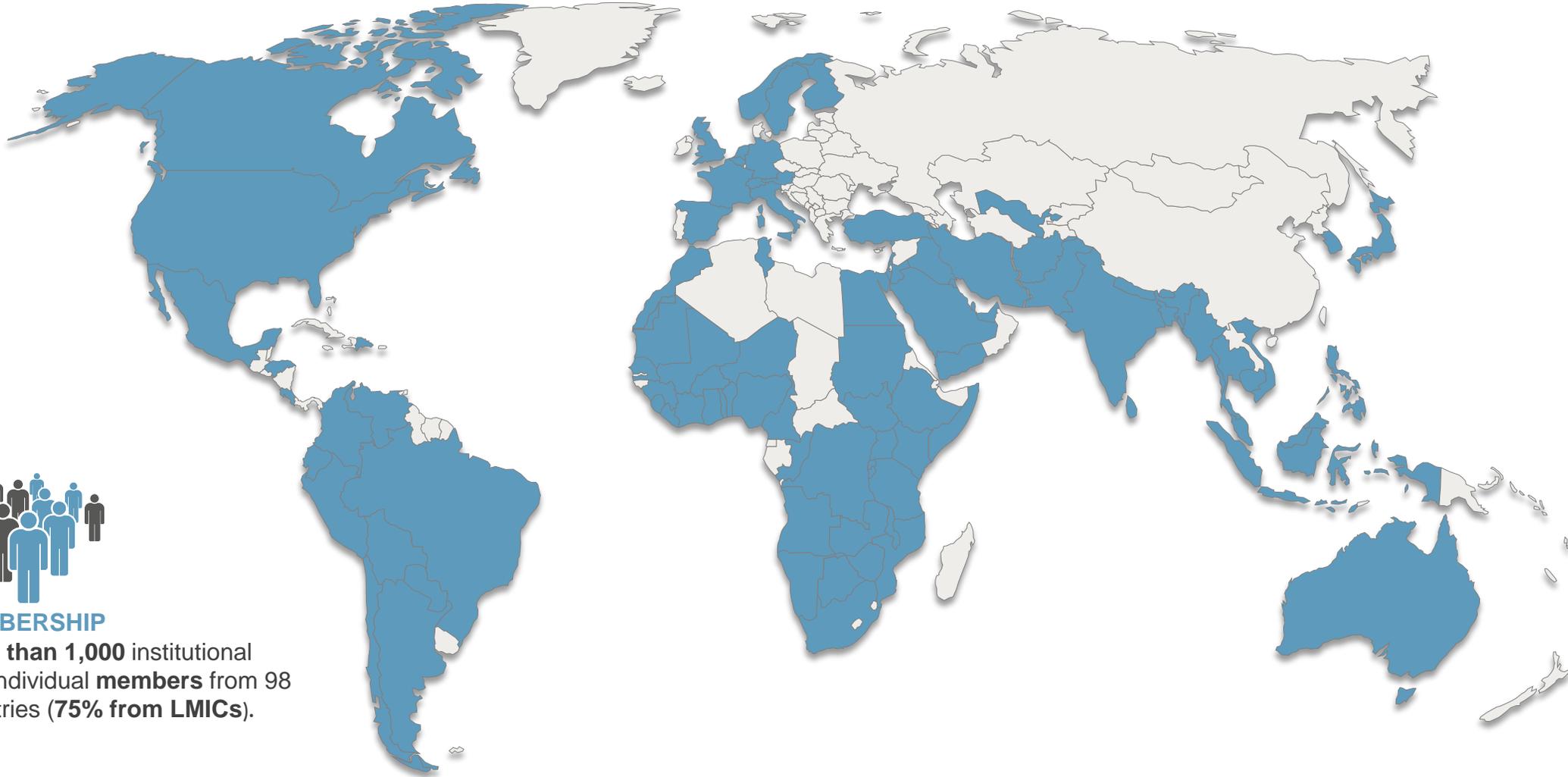
Charlie
Feline Ambassador

✉ Info@covid19crc.org

📍 Geneva, Switzerland

🦠 Since January 2023, 10%

Countries where coalition members are based

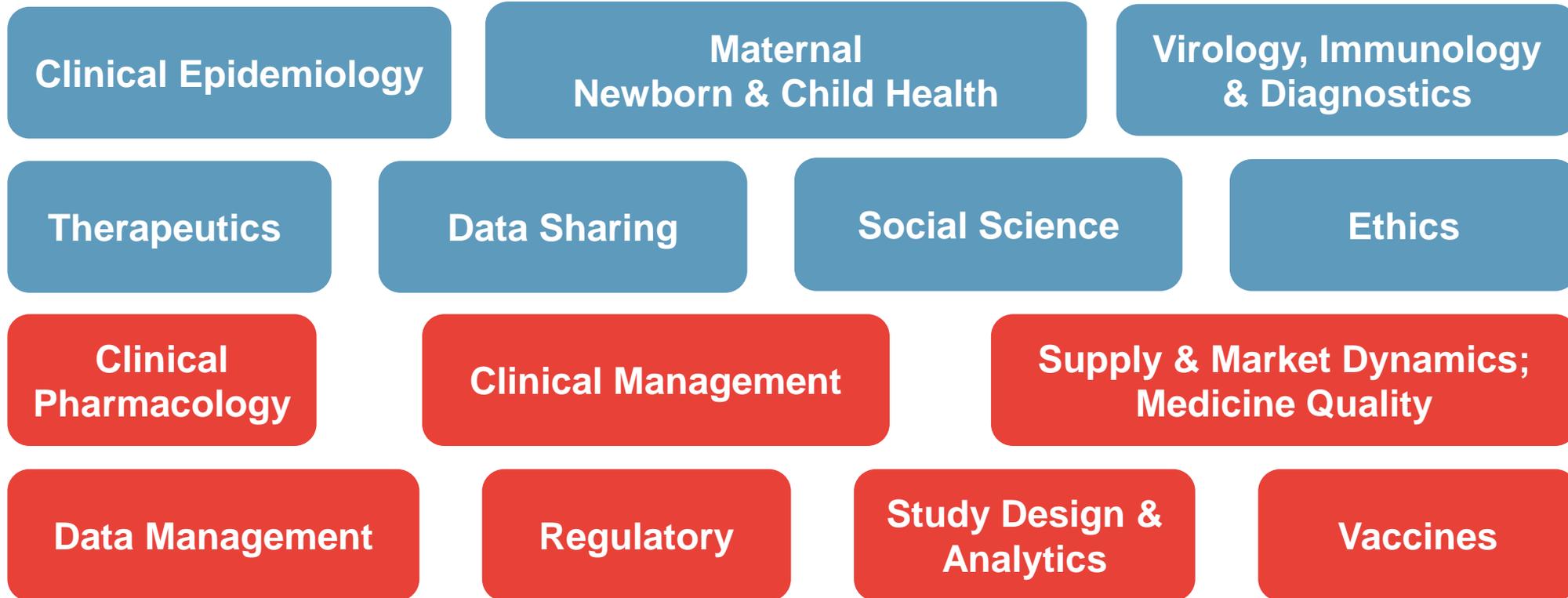


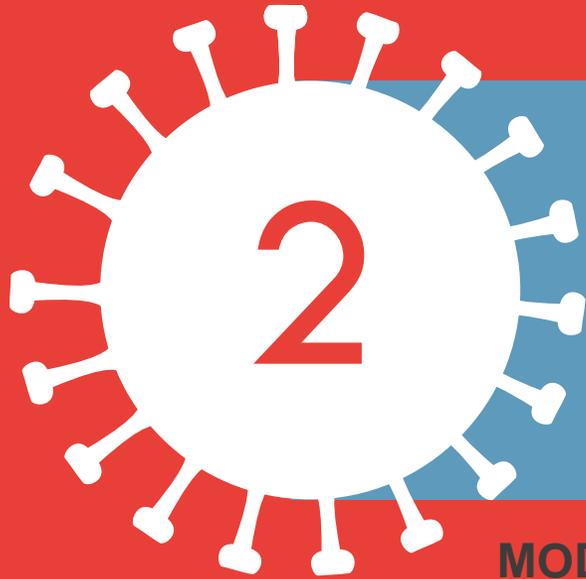
MEMBERSHIP

More than 1,000 institutional and individual members from 98 countries (75% from LMICs).

The Coalition's Working Groups

- **Key engine** for the mission of the coalition
- **Wealth of global expertise** in areas critical for research
- **14** expert working groups; **7 active groups**, **7 expert advisory groups**

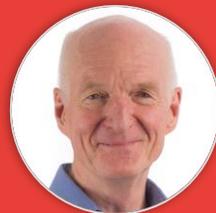




Working Group Presentations

DURATION: 60 minutes

MODERATED BY:



Prof. Nick White, Steering Committee Chair | Thailand & UK

Clinical Epidemiology WG

DURATION: 10 minutes

Presenter:



Prof. Juan Carlos Villar, Working Group Co-Chair | Colombia



Our achievements

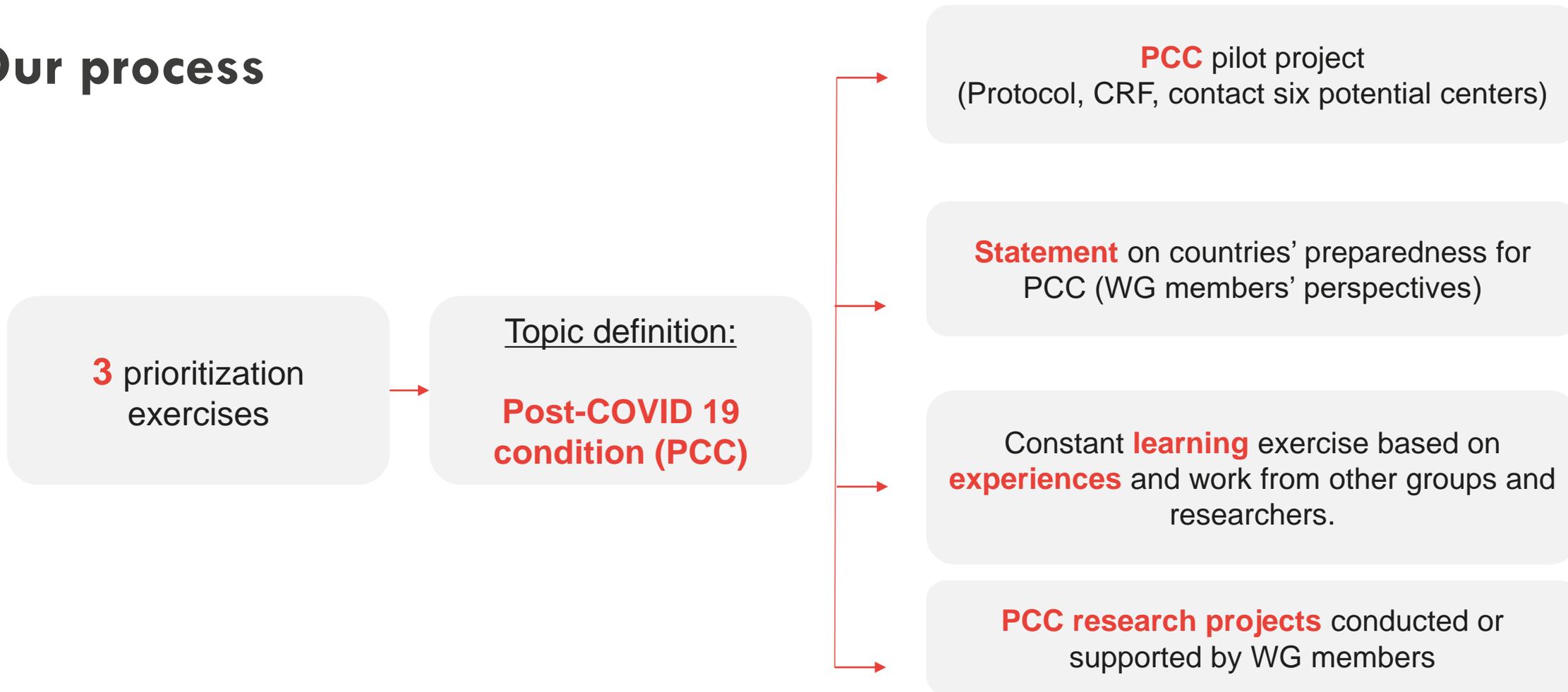
- Bi-weekly meetings from July 2020
- **50** Working group meetings
- **17** members from Latin America (7), USA (1), Africa (4), Europe (3), Asia (2)
- More than **10** sharing sessions (projects, proposal) by WG members and guest speakers

Our achievements

- **Long COVID series:** We held **four** meetings on long COVID **open** to ALL coalition members

Topic	Presenter
Socio-demographic profile, post-recovery physical and mental health consequences amongst patients of COVID-19 in Bangladesh	Dr Tanvir Ahmed and his colleagues from SAJIDA Foundation
Long COVID and its expected burden	Dr Kieran Quinn - Sinai Health System, University of Toronto and the Institute for Clinical Evaluative Sciences (ICES)
Persistence of somatic symptoms after COVID-19 in the Netherlands: an observational cohort study	Aranka Ballering, University Medical Center Groningen (The Netherlands),
Neurological and psychiatric disorders in the 2 years after SARS-CoV-2 infection: incidence, risks, and trajectories	Professor Paul Harrison, Department of Psychiatry, University of Oxford, UK

Our process



Funding opportunities?

Our achievements – Projects from WG members

Long COVID and NCDs (Bogotá, Colombia)

“Impacto de la rehabilitación funcional y cognitiva, en adultos con enfermedades crónicas no transmisibles y Covid-19 prolongado, sobre su capacidad funcional, cognitiva, calidad de vida y la evolución de su condición de base, en Bogotá D.C.”

(Impact of functional and cognitive rehabilitation in adults with non-communicable diseases and post COVID-19, on functional and cognitive capacity, quality of life and progress of the baseline condition, in Bogotá)

Karen Moreno – PI (former Clinical Epidemiology WG Coordinator)

Professor Juan Carlos Villar – WG Co-chair

Our achievements – Projects from WG members

Long COVID and mental health (Thailand)

What is the impact of COVID-19 on mental health in LMICs?

Can we reduce the burden of mental illness with low-cost scalable interventions?

- Pilot study: can we reliably detect mental illness?
- Phase 1: observational study - describe burden of mental illness, identify risk groups and risk factors
- Phase 2: randomised controlled trial - low-cost community-based intervention to reduce the burden of mental illness
- PI: Richard Maude (co-chair)

Challenges and lessons learned

- **Active participation is essential:** all members should be encouraged to engage fully in discussions and contribute their ideas and expertise to the group.
- **Shared ownership and accountability:** all members should feel invested in the group's success and be willing to take responsibility for their individual contributions to the group's goals. This can help to ensure that everyone is working together effectively and towards the same objectives.
- **Funding remains a challenge:** restricted to specific areas or topics, and insufficient support to conduct studies with different centers in LMICs.

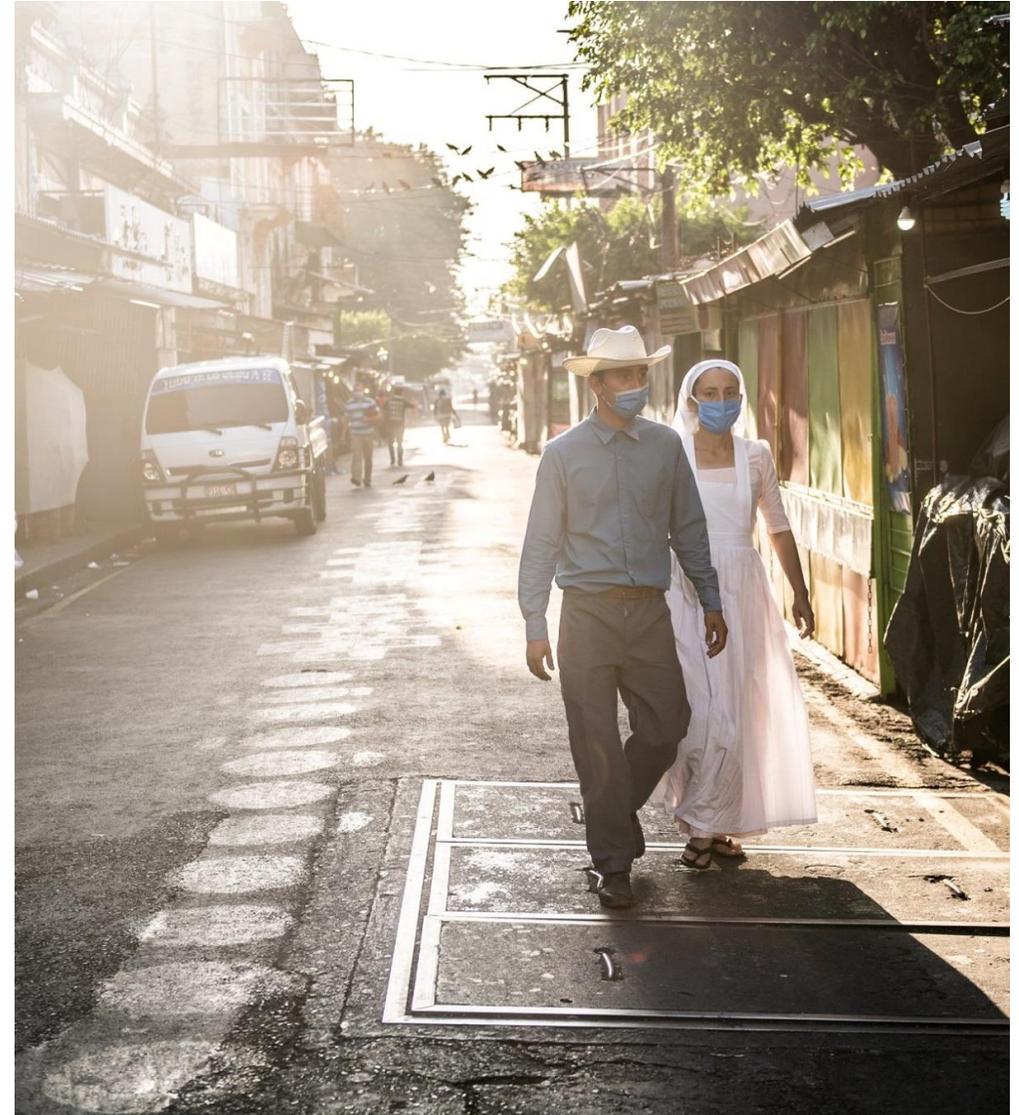
Maternal, Newborn & Child Health WG

DURATION: 10 minutes

Presenter:



Dr Tanusha Ramdin, Working Group Co-Chair
| South Africa





The importance of context specific prevention and control strategies – an assessment of strategies like lockdown on communities; Initial evidence from a global systematic review on impact of lockdown on early pregnancy

Maternal, Neonatal and Child Health (MNCH) working group

Chaired by

Professor Kirsty Le Doare

Professor of Global Health within the Paediatric Infectious Diseases Research Group at St. George's, University of London, based at MRC/UVRI @LSHTM Uganda

and

Dr Tanusha Ramdin

Head of Neonatology and Paediatric Intensive Care Unit at Charlotte Maxeke Johannesburg Academic Hospital

Diverse set of working group members across a variety of LMIC and HIC settings.

PLOS ONE

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

Global research priorities for COVID-19 in maternal, reproductive and child health: Results of an international survey

Melanie Etti, Jackeline Alger, Sofia P. Salas, Robin Siggers, Tanusha Ramdin, Margit Endler, Kristina Gemzell-Danielsson, Tobias Alfvén, Yusuf Ahmed, Allison Callejas, Deborah Eskenazi, Asma Khalil, Kirsty Le Doare,

On behalf of the Maternal, Newborn and Child Health Working Group of the COVID-19 Clinical Research Coalition

Published: September 24, 2021 • <https://doi.org/10.1371/journal.pone.0257516>

Article	Authors	Metrics	Comments	Media Coverage
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- Abstract
- Introduction
- Methods
- Results
- Discussion
- Conclusion
- Supporting information
- Acknowledgments

Abstract

Background

The World Health Organization's "Coordinated Global Research Roadmap: 2019 Novel Coronavirus" outlined the need for research that focuses on the impact of COVID-19 on pregnant women and children. More than one year after the first reported case significant knowledge gaps remain, highlighting the need for a coordinated approach. To address this need, the Maternal, Newborn and Child Health Working Group (MNCH WG) of the COVID-19 Clinical Research Coalition conducted an international survey to identify global research priorities for COVID-19 in maternal, reproductive and child health.

Research question -Have COVID-19 lockdown restrictions caused an increased rate of adolescent pregnancy?

Adolescents and young adults likely to have been affected indirectly by the pandemic.

Lockdown restrictions have caused disruption to education and to sexual and reproductive (SRH) services across the globe. In Sierra Leone, adolescent pregnancy increased by up to 65% in some communities during the Ebola crisis. A similar trend may have occurred in some countries during the COVID-19 pandemic.

MNCH WG members felt that they had seen an increase in adolescent pregnancy rates in their individual local settings.



Why is it important?

- Early childbearing, or pregnancy and delivery during adolescence, can derail girls' otherwise healthy development into adulthood and have negative impacts on their education, livelihoods and health.
- May be forced to drop out of school, with long reaching impacts on their educational and employment opportunities.
- Social consequences – stigma, rejection, violence from family members, peers and partners, early and forced marriage.



Why is it important?

- Health consequences
- Globally, maternal conditions are among the top causes of disability-adjusted life years (DALYs) and death among girls aged 15-19
- Neonatal outcomes may also be affected
- Higher rate of pre-term birth, low birth weight, stillbirth, mortality



Examples

- UNICEF reported 20 per cent spike in the last 15 months in teen pregnancies, or pregnancies of 10-24-year-old girls, who were seeking antenatal care in Eastern Uganda
- In Malawi, 13 000 girls got pregnant and 40 000 married before their 18th birthdays during the emergency school closure, according to the Ministry of Gender, Community Development and Social Welfare

NEWS

How COVID-19 has increased fertility, adolescent pregnancy and maternal deaths in East and Southern African countries

11 July 2021



The epidemiological picture regarding teenage pregnancies is not clear



Early reports of a significant pandemic-related spike in adolescent pregnancies may not be reliable



Good quality data is needed

Methodology

Literature review encompassing both quantitative and qualitative data:

- Country level data, when available, to be analyzed alongside COVID stringency index
- Review of databases included PubMed / MEDLINE / EMBASE / Web of Science/ CINAHL / DHS / WHO database – COVID-19 Global literature on coronavirus disease / Literatura Latinoamericana y deng I Caribe en Ciencias de la Salud (LILACS)
- Team able to include data in English, French and Spanish
- Full protocol available via Prospero (ID number 308354)



NIHR | National Institute for Health Research

PROSPERO
International prospective register of systematic reviews

Print | PDF

A living systematic review of the impact of COVID-19 pandemic on adolescent pregnancy rates ((girls aged 10-19)

Lauren Hookham, Kirsty Le Doare, Tanusha Ramdin, Jackeline Alger, Sofia Salas, Valérie Leroy, Sweta Shanbhag, Tobias Alfvén, Elhadi Miskeen, Kristina Gemzell Danielsson, Mandana Arabi, Yusuf Ahmed

Citation

Lauren Hookham, Kirsty Le Doare, Tanusha Ramdin, Jackeline Alger, Sofia Salas, Valérie Leroy, Sweta Shanbhag, Tobias Alfvén, Elhadi Miskeen, Kristina Gemzell Danielsson, Mandana Arabi, Yusuf Ahmed. A living systematic review of the impact of COVID-19 pandemic on adolescent pregnancy rates ((girls aged 10-19). PROSPERO 2022 CRD42022308354 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022308354

Review question [1 change]

To examine the relationship between lockdown restrictions imposed secondary to the COVID-19 pandemic and the rate of adolescent pregnancy across the globe.

Methods – review of the literature

Literature reviews commenced in April 2022.

Lit review 1: 3977 articles required screening

Included: 6

Data extraction complete

Lit review 2: 5369 articles required screening

Included: 99

Data extraction ongoing

Country level data

Review of World Bank, UNICEF, DHS and WHO datasets

Review of data available from countries themselves (i.e., from MoH reports)

Sub-teams for each WHO region

Commenced in April 2022

Results, quantitative data – 2 papers with original data on adolescent pregnancy

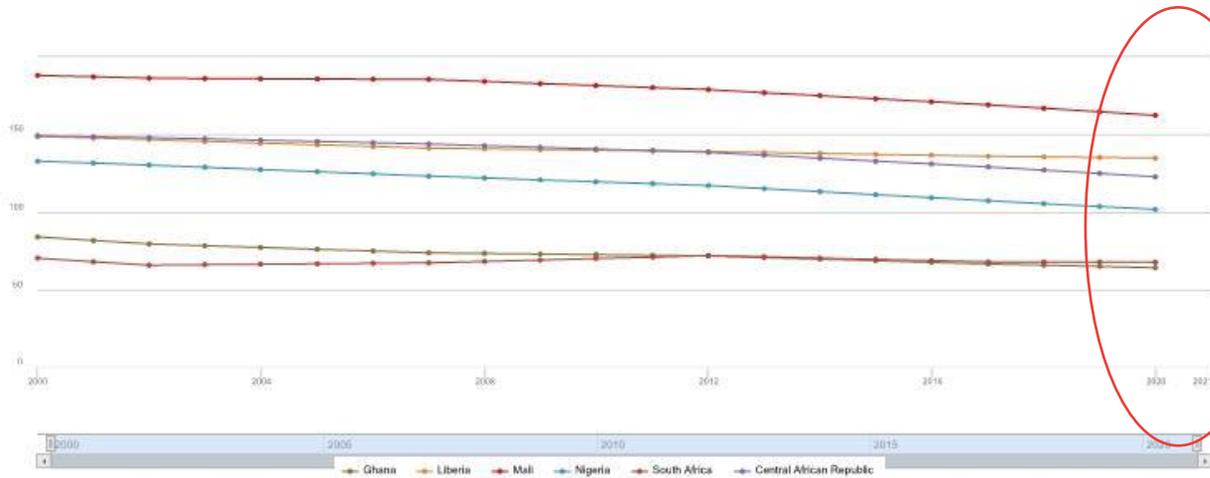
Kenya:

- rural Western Kenya (Zulaika G, Bulbarelli M, Nyothach E, et al, 2022)

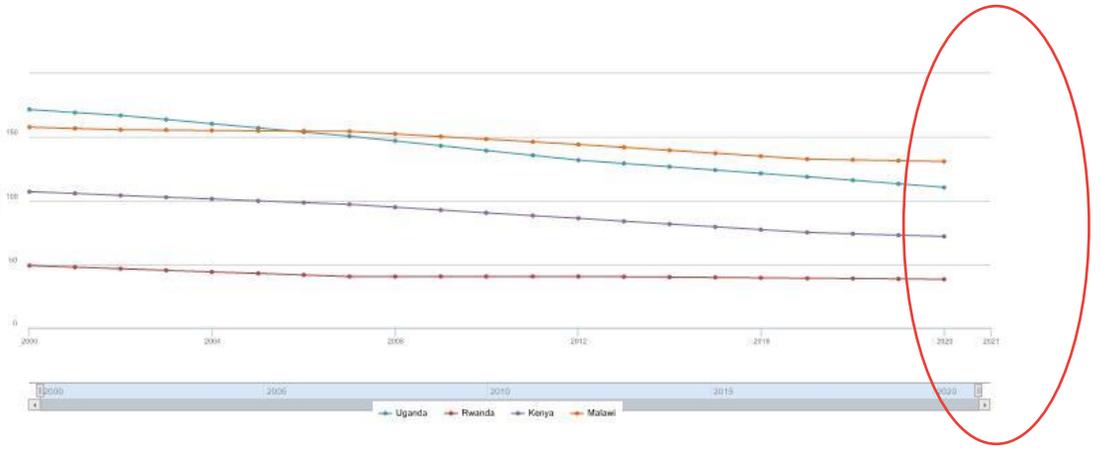
Adolescents who remained out of secondary school for 6 months due to lockdown had twice the risk of pregnancy and 3x the risk of dropping out of school when compared with girls prior to the outbreak.

- National DHS data (Shikuku et al, medRxiv 2020)
- steady rise in numbers of pregnancy in the 15 – 19 years group during the COVID-19 period compared to the pre-COVID period

Analysis – country level data



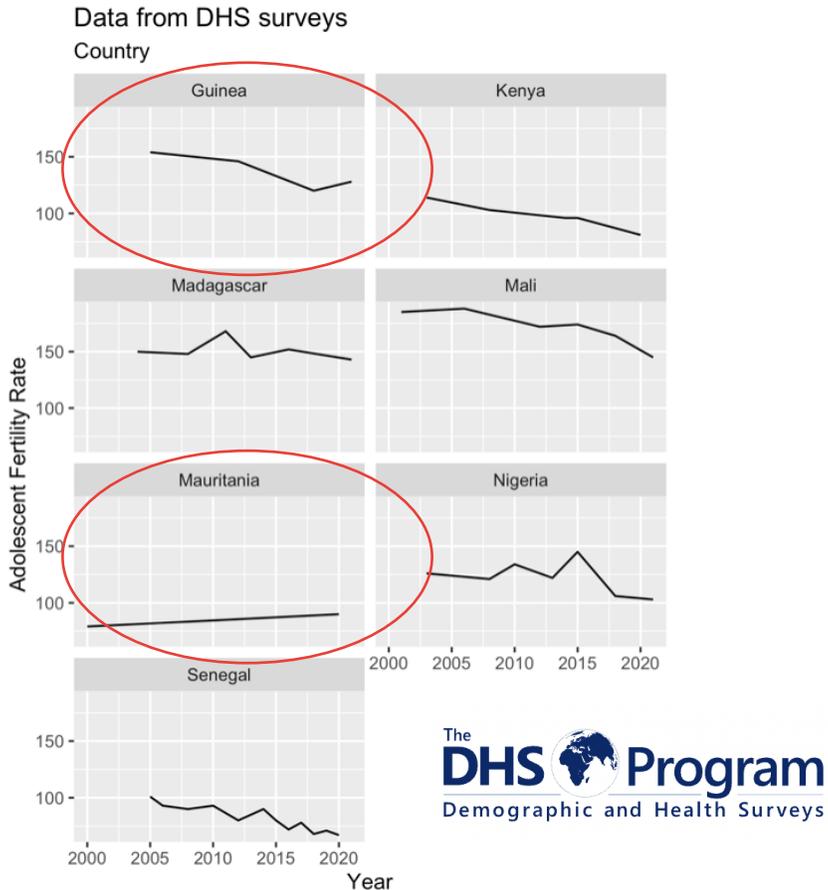
Series : Adolescent fertility rate (births per 1,000 women ages 15-19)
Source: World Development Indicators
Created on: 12/03/2022



Series : Adolescent fertility rate (births per 1,000 women ages 15-19)
Source: World Development Indicators
Created on: 12/03/2022

A reassuring downward trend, but missing key data

DHS data



- Country level data for 2021 not available
 - This will be the critical year for analysis
- No requests for data made directly to relevant Govt departments have so far been successful
- DHIS2 data or equivalent health management systems (HMIS) exist.
- Need open and accessible data

Next steps – survey

- Apparent that country level data is lagging behind, but still an urgent need to understand which countries and communities may have been affected
- Developed a survey as an update to “Pandemic priorities”

Priority setting for the next pandemic: an international survey on maternal, newborn and child health

This survey is being conducted by the Maternal, Newborn and Child Health Working Group of the COVID-19 Clinical Research Coalition. It is a follow-up to a similar survey we conducted two years ago to assess MNCH needs and priorities identified by those working in this field in the first year of the pandemic. This survey includes additional questions on the impact of the pandemic on adolescent reproductive and sexual health, and pregnancy. It should take you roughly 5 - 10 minutes to complete.

If you have any feedback or queries, please contact lhookham@sgul.ac.uk

 lauren.a.f.hookham@gmail.com (not shared) [Switch accounts](#)



What is your role?

- Medical Doctor or medical science
- Nurse
- Epidemiologist
- Midwifery
- Other: _____

Summary

- A lot of literature and reports saying what the impact of the pandemic *might* be
- Little data at present to state **what has actually happened**
- 2021 data eagerly awaited

If you have access to data you would like to share, or you would like to be involved in the project please contact Lauren Hookham (WG Coordinator) at lhookham@sgul.ac.uk.

Thanks to working group members

Kirsty Le Doare, Tanusha Ramdin, Jackeline Alger, Sofia Salas, Helen Rees, Robin Saggars, Lisa Noguchi, Kristina Gemzell-Danielsson, Margit Endler, Tobias Alfven, Yusuf Ahmed, Deborah Eskenazi, Allison Callejas, Ghulam Mustafa, Debra Jackson, Guan Wang, Stembile Mugore, Sawsan Abuhammad, Valeriane Leroy, Elhadi Miskeen, Mandana Arabi, Nkwan Jacob Gobte, Michael Enwere, Melanie Etti, Ana L. Chinchilla, Gisella Vallecillo, Leslie Abimbola, Sweta Shanbhag, Elaine Tan Su Yin, Madelon Finkel, Rozane Elmasri, Stephanie Shih, Shreya Suresh, Edmund Chung, Nurat Wamaya, Amy Ng, Zofia Przypasniak, Yi Lun Khaw, Linnuel Pregil, Matyl Kassouf, Zadok Maingi, Rawnaq Behnam, Jowery Namulondo, Jean Paul Ndayizeye, Christina Ricci, Atalay Goshu, Sasha Baumann, Murundo Simwa, Marian Murunga, Reuben Kughong, Fatimah Odusote, Nirvana Lakha, Sowjenya Ravimani, Natalie Bishop, Carolina Bustillo, Heriberto Rodriguez, Lucas Guimaraes Abreu, Eduardo Núñez, Yasmin Beltrán, Cárcamo, Lola Okunromade, Safa Elhassan, Cerisa Obern, Claudette Hewitt, Wei Yan Lim

Data Sharing WG

DURATION: 10 minutes

Presenter:



Prof. Phaikyeong Cheah, Working Group Chair
| Thailand



WG achievements, challenges, lessons learned

- Created a network of those interested in the ethical and governance aspects of data sharing
- Many webinars, papers
- Webinars are good and can reach many people, but discussions are superficial as time is limited and they are too many people

What role the coalition in general can play to support the WG achieve its objective

- Workshop (f2f if we have the funds) on data sharing with other WG leads, steering committee members, and others interested
- More interactions with data rich groups – sharers and re-users

What the current or next priorities are for the working group or in their area of expertise

RESEARCH

Persistent problem

Lack of sharing, but also lack of re-use

Equitable data sharing in epidemics and pandemics

Bridget Pratt^{1,2*} and Susan Bull³

- Objective is to promote **efficient**, **ethical** and **equitable** sharing – not only efficient
- We have made some progress (e.g., platforms, managed access) but we have not solved some of the old issues – for example:
 - How not to exacerbate existing inequalities – advancing equity
 - Fair attribution, e.g., authorships
 - How to maximise health impact of data sharing – to what extent do academic papers and change in guidelines translate to improvement in health and saving lives
 - Technical issues – FAIR, anonymization

Virology, Immunology and Diagnostics WG

DURATION: 10 minutes

Presenter:



Dr Wilber Sabiiti, Working Group Co-Chair |
UK



Working Group Activities and Outputs

- **Regular working group meetings**
 - Average attendance approx. 50%
- **Biobanking and Sequencing project**
 - Priority research question previously identified, translated to a research proposal
 - Funding still needed
- **COVID-19 testing guidelines review project**
 - Main objective: To create one-stop online resource center for COVID-19 testing guidelines applied in different countries and continents
 - Progress so far: Data base on global testing guidelines created; conference abstract
 - Planned outputs: Main manuscript, online resource

Working Group Activities and Outputs_cont'

- **Conference participation** : 2nd international Conference on Public Health in Africa – Kigali, Rwanda
 - **Coalition side event**: Streamlining disease surveillance across Africa by building biobanking and sequencing capacity: the role of partnerships
 - **Abstract**: An Africa-wide review of national adoption of COVID-19 testing guidelines from WHO or Africa CDC reveals that having testing guidelines increased testing rates
- **Publications**
 - The Global Inequity of COVID-19 Diagnostics: Challenges and Opportunities (DOI: 10.1136/jech-2022-219333)

Challenges and lessons learnt

Challenges

- Lack of funding for the biobanking and sequencing research proposal
- Low WG member attendance of monthly meetings
- Waning motivation in absence of research project

Lessons learnt

- The need for research capacity building is still high in LMICs
- We have interacted with stakeholders in the biobanking and whole genome sequence and learned how we could complement each other
- Synergy is better than duplication and competition
- We are better off doing coordination functions such as spearheading protocol standardization discussions across the board rather than doing wet lab research ourselves

What role the coalition in general can play to support the WG achieve its objectives

- Lobby for funding to support WG activities
- Support grant applications and management
 - Linkage with potential collaborator
 - Secretariat assist in identifying grant calls that WG can apply for
 - Establish a framework for managing grants

VID future prospects

- Application for the EDCTP3 horizon 2023 2nd call on vaccine use and immunity
 - Makerere University Lung Institute (institutional member identified as scientific lead)
 - Reached out members of other WGs to join the application
- Scoping exercise on COVID vaccine uptake and impact on seropositivity
 - Aim to review Johns Hopkins vaccination data with focus on LMICs
 - Review COVID-19 positivity among upper, middle, and lower- income countries in relation to vaccination coverage

Social Science WG

DURATION: 10 minutes

Presenter(s):



Prof. Shelley Lees Working Group
Co-Chair | UK



Social Science Working Group Membership



Priorities during COVID-19

- **Political economy:** how do global and local inequalities shape a range of COVID-19 challenges?
- **Clinical trials:** how do political and social structures, social justice, and community engagement related to clinical trials?
- **Transnationalism:** what are the challenges related to transnational and regional collaboration?
- **Health-seeking behaviour:** how does trust and uncertainty affect health seeking?

Commentary

Key social science priorities for long-term COVID-19 response 

 Shelley Lees¹,  Salla Sariola², Megan Schmidt-Sane³, Luisa Enria¹,  Kit-Aun Tan⁴, Angel Aedo⁵,  Koen Peeters Grietens^{6, 7}, David Kaawa-Mafigiri⁸ On behalf of the COVID-19 Clinical Research Coalition Social Science Working Group
Correspondence to Dr Megan Schmidt-Sane; M.Schmidt-Sane@jds.ac.uk

<http://dx.doi.org/10.1136/bmjgh-2021-006741>



Priorities moving forward

- Widening our focus, with a preference for expanding to infectious diseases with epidemic/pandemic potential (including AMR)
- Study on interdisciplinarity and collaboration in the Coalition
- Focus on associated social and societal issues:
 - Structural inequalities → differential effects of an epidemic on vulnerable populations
 - Political and market arrangements → global vaccine and therapeutics inequity
 - Decolonized and community-centred approach → pandemic preparedness agenda driven by in-country priorities and community-level needs
 - Crisis of mistrust → affects legitimacy of public health preparedness efforts



Photo: UNICEF/8125/Mamadou

Next Steps

- Based on revised focus of the Coalition, we will engage in a priority-setting exercise
- Within working group discussions, wider survey of social scientists
- Publish a piece on 'social science priorities for pandemic preparedness'
- Planning for 2023 and beyond

Therapeutics WG

DURATION: 10 minutes

Presenters:



Prof. Mauro Teixeira Working Group Co-Chair | Brazil



Prof. Joel Tarning Working Group Member | Thailand



Therapeutics Working Group

Established April 2022

- **Membership**
 - 5 members from USA, India, South Africa, Switzerland and Thailand
 - 1 Therapeutics review consultant
 - Co-Chairs: Saye Khoo, Mauro Teixeira
- **Current status**
 - Active WG, recently merged with Clinical Pharmacology WG

3 Main Objectives

Advisory

- For the coalition and extended networks providing **guidance on therapeutics** for COVID-19

Advocacy

- On **approach to therapeutics research** that will generate most relevant evidence
- For **increased research** into therapeutics
- For **equitable access** to therapeutics

Knowledge & evidence generation

- On **therapeutics** for COVID-19 in **low resource settings** including TPP

Key Learnings for repurposing of medicines in COVID-19

- **Developing and evaluating novel compounds** for treatment or prophylaxis of emerging infectious diseases is **costly and time-consuming**
- **Repurposing** of available marketed drugs is an appealing option as they already have an **established safety profile**
 - Substantially reduce cost and time required to make effective treatments available
 - Many drug candidates show efficacy in *in-vitro* experiments, but fail to deliver effect in clinical trials
 - Better approaches to evaluate *in-vitro* data are needed

Key Learnings for repurposing of medicines in COVID-19

- We developed a simple pharmacometric simulation-based approach to evaluate *in-vitro* activity data in combination with expected clinical drug exposure, in order to evaluate the likelihood of achieving effective concentrations in patients
- The **pharmacometric approach bridges *in-vitro* activity data to clinical exposures**, and could be a useful compliment to other methods to prioritize drugs
- We demonstrated that molnupiravir is likely to reach therapeutic levels, and that favipiravir might reach effective concentrations, while ivermectin will not generate clinically relevant concentrations

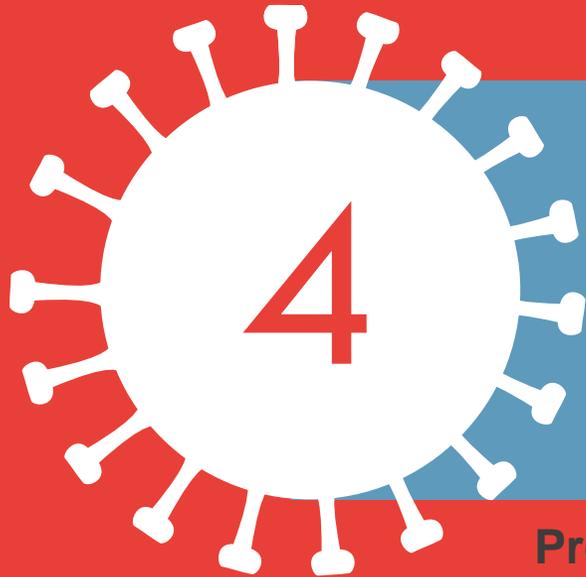
1. Schilling WHK, et al. Pharmacometrics of high dose ivermectin in early COVID-19: an open label, randomized, controlled adaptive platform trial (PLATCOV). *Elife*. 2023
2. Wattanakul T, et al. A pharmacometric approach to evaluate drugs for potential repurposing as COVID-19 therapeutics. *Expert Rev Clin Pharmacol*. 2022.
3. Assmus F, et al. Need for a Standardized Translational Drug Development Platform: Lessons Learned from the Repurposing of Drugs for COVID-19. *Microorganisms*. 2022
4. Driouich JS, et al. Pre-clinical evaluation of antiviral activity of nitazoxanide against SARS-CoV-2. *EBioMedicine*. 2022
5. Abdelnabi R, et al. The oral protease inhibitor (PF-07321332) protects Syrian hamsters against infection with SARS-CoV-2 variants of concern. *Nat Commun*. 2022
6. White NJ, et al. COVID-19 prevention and treatment: A critical analysis of chloroquine and hydroxychloroquine clinical pharmacology. *PLoS Med*. 2020
7. Watson JA, et al. Concentration-dependent mortality of chloroquine in overdose. *Elife*. 2020

Key Considerations for Therapeutics Research in Pandemics

- Pandemics are **challenging** and characterized by panic, media scrutiny, distrust in science, information overload
- COVID therapeutics **research has been hampered** by:
 - lack of accepted pharmacometrics method for drug evaluation
 - reduction in virulence of the virus
 - inequity in access to new therapeutics by communities
 - drug hoarding by richer countries which has hindered independent evaluations
 - Nonrealistic end points

Key Considerations for Therapeutics Research in Pandemics

- **Endpoints** are crucial
 - Should be tailored to primary objective of safety and efficacy
 - Should have definitions that are robust, realistic, feasible and informative for policymaking
 - Relevant populations should be included in end point definitions
 - Large discrepancy between high and low/middle income settings creates a challenge to generalisability of trial findings
 - Existing gap in normal reference ranges for non-Caucasian populations affecting safety and immunogenicity
- **Need for global strategy for evaluation of therapeutics**



The PANdemic preparedness plaTform for Health and Emerging infections Response (PANTHER)

DURATION: 10 minutes

Presenter:



Dr Nathalie Strub-Wourgaft, Steering Committee Member | Switzerland

Preparing a rapid response to emerging infectious diseases

**2nd MEMBERS
ASSEMBLY**

C  **VID-19**
Clinical Research Coalition



PANTHER
Pandemic preparedness platform for
health and emerging infections response

WHY?

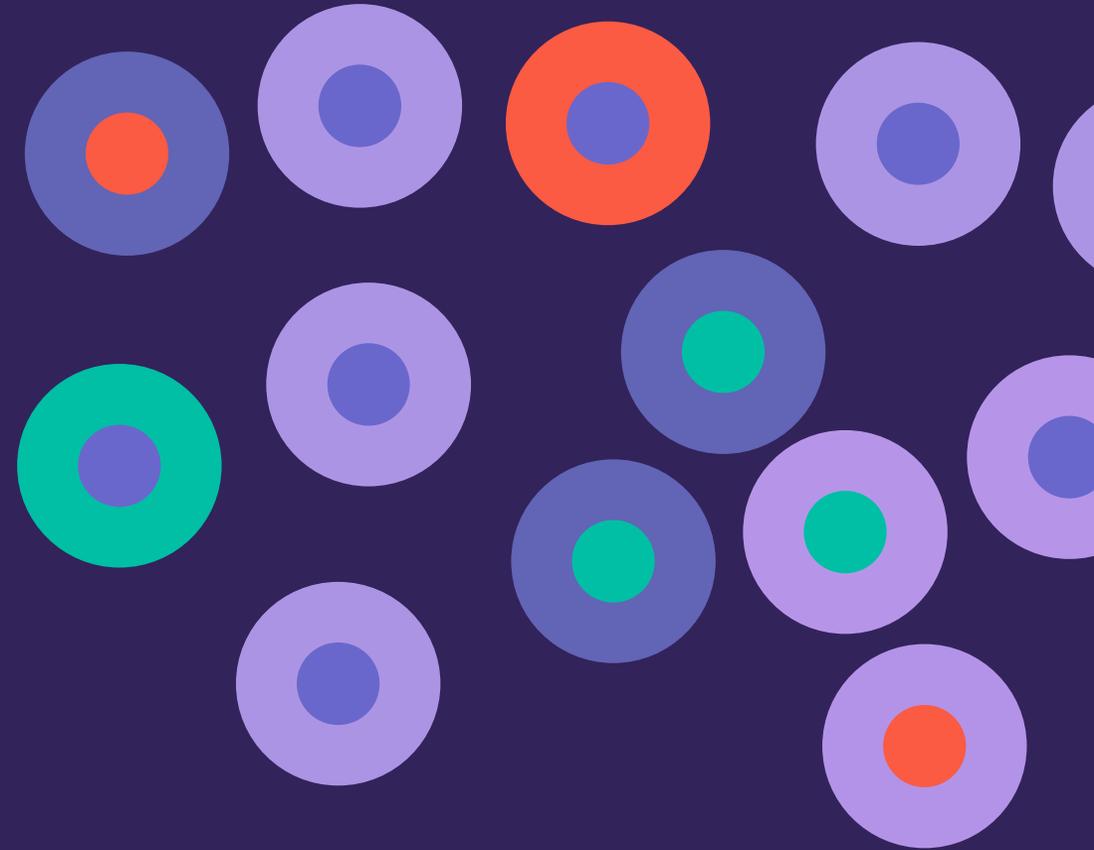




Photo credit: Xavier Vahed-DNDi

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WHY PANTHER?

PANTHER is born from the experiences of addressing patients' research needs during the COVID-19 pandemic in low- and middle-income countries.

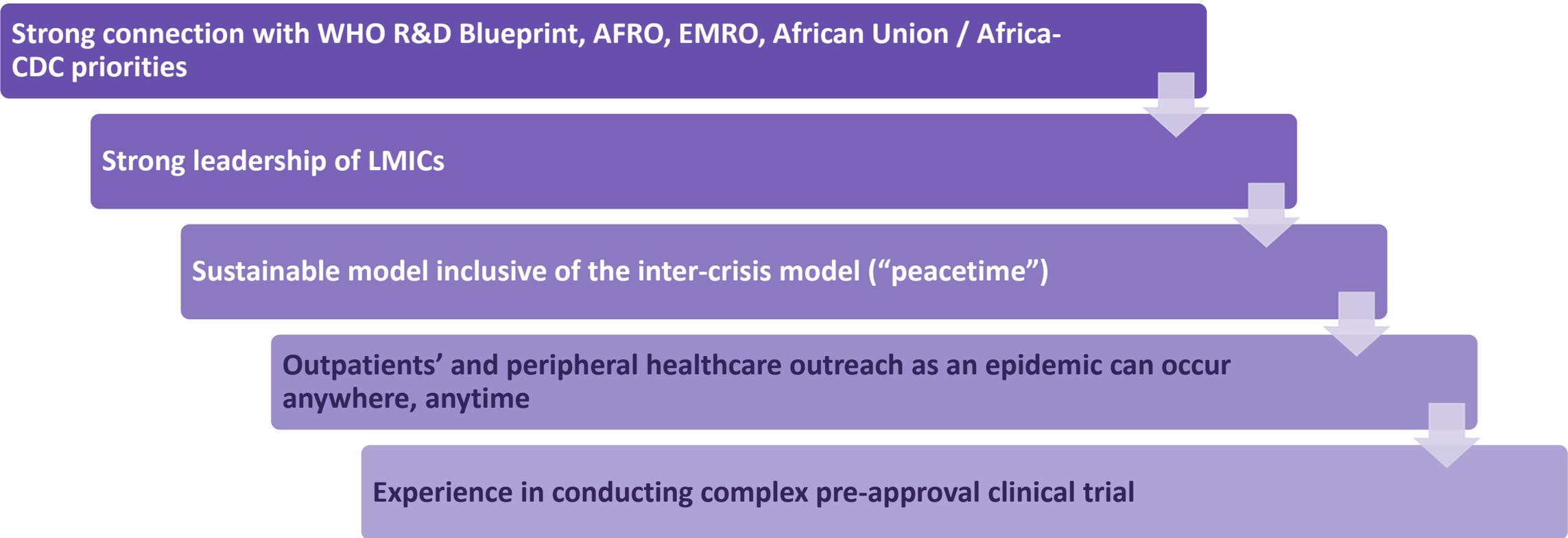
PANTHER was designed to address regional research capacity, administrative, financing, and regulatory hurdles and prompt response to emerging pandemics.

An evolving landscape

- There is a delineated need to **change the approach, including proposing a more collaborative model with LMICS** and rapidly developing a **more concrete and sustainable operational preparedness plan**.
- **WHO agreed to draft and negotiate a WHO convention, agreement, or other international instruments on pandemic prevention, preparedness and response, with a view to adoption under Article 19 of the WHO Constitution.**
- EU sets HERA as a priority, focusing on EU response whilst recognising that international collaboration is required.
- **Africa is discussing an APPRA treaty.**
- **Africa CDC, in its Emergency Preparedness and Response programme, supports developing and testing multi-hazard and multi-sectoral preparedness and response plans for public health emergencies at the national, regional and continental levels.**

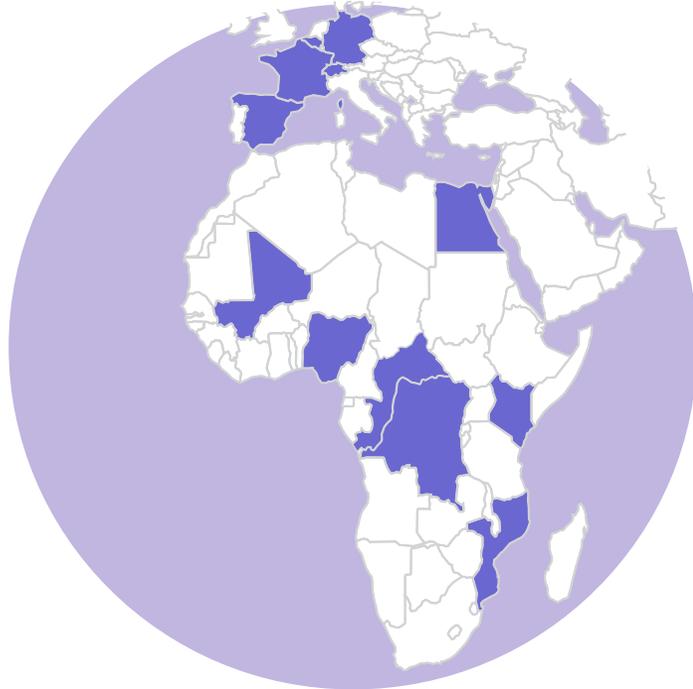
Differentiating factors

Beyond activities identified by the global health communities as a key operational component of the pandemic response, an effective clinical research platform sustained over the years will promote:



GOVERNANCE

An African-led research platform



Samba Sow, President (**CVD-Mali**)
Maha El Rabat, Vice-president (**Cairo University**)
Yazdan Yazdanpanah, Vice-president (**AN-RS-MIE**)
Luis Pizarro, Treasurer (**DNDi**)
Francine Ntoumi, Secretary (**FCRM**)
Mahlet Kifle Habtemariam (**Africa CDC**)
Jürgen May (**BNITM**)
Jean-Jacques Muyembé-Tamfum (**INRB**)
Bernhards Ogutu (**KEMRI**)
Leonardo Simao (**Manhiça Foundation**)
Rafael Vilasanjuan (**ISGlobal**)
Marc-Alain Widdowson (**ITM**)

Elizabeth Lindiwe Makubalo (**AFRO**)
Ahmed Mandil (**EMRO**)
Marie-Pierre Preziosi (**WHO R&D Blueprint**)

Mahlet Kifle Habtemariam (**Africa CDC**)
Margareth Ndomondo-Sigonda (**AUDA-NEPAD-AMRH**)

Marie-Pierre Preziosi (**WHO R&D Blueprint**)
Nathalie Strub-Wourgaft, General Delegate (**PANTHER**)
Nick White (**Oxford Tropical Medicine Research Unit**)
SAB Chair (TBD)
CAB Chair (TBD)

○ Board of Directors

● Institutional partners

○ Observers



OUR VISION

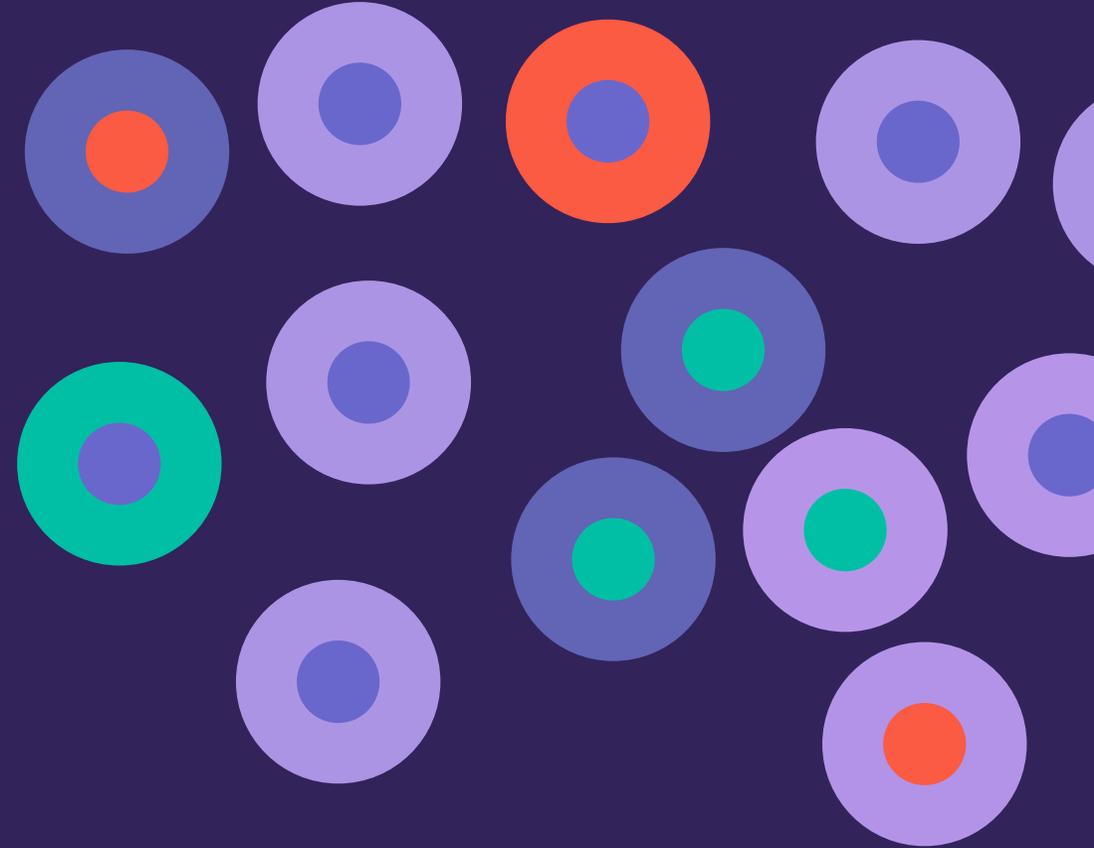
Effectively contribute to the control of future emerging epidemics or pandemics through a flexible clinical research platform response, supporting preparedness and rapid response to emerging infectious diseases via the development of tools (DTV), with a focus on Low- and Middle-Income Countries (LMICs).

OUR MISSION

PANTHER aims to **develop, implement and sustain a “ready to use” living clinical research platform which integrates research capacity in clinical care.**

The platform will provide the human and technical infrastructure to timely address LMIC’s medical research questions through a network of equipped and trained researchers combining experienced African research centres with healthcare sites in key population centres and more remote locations.

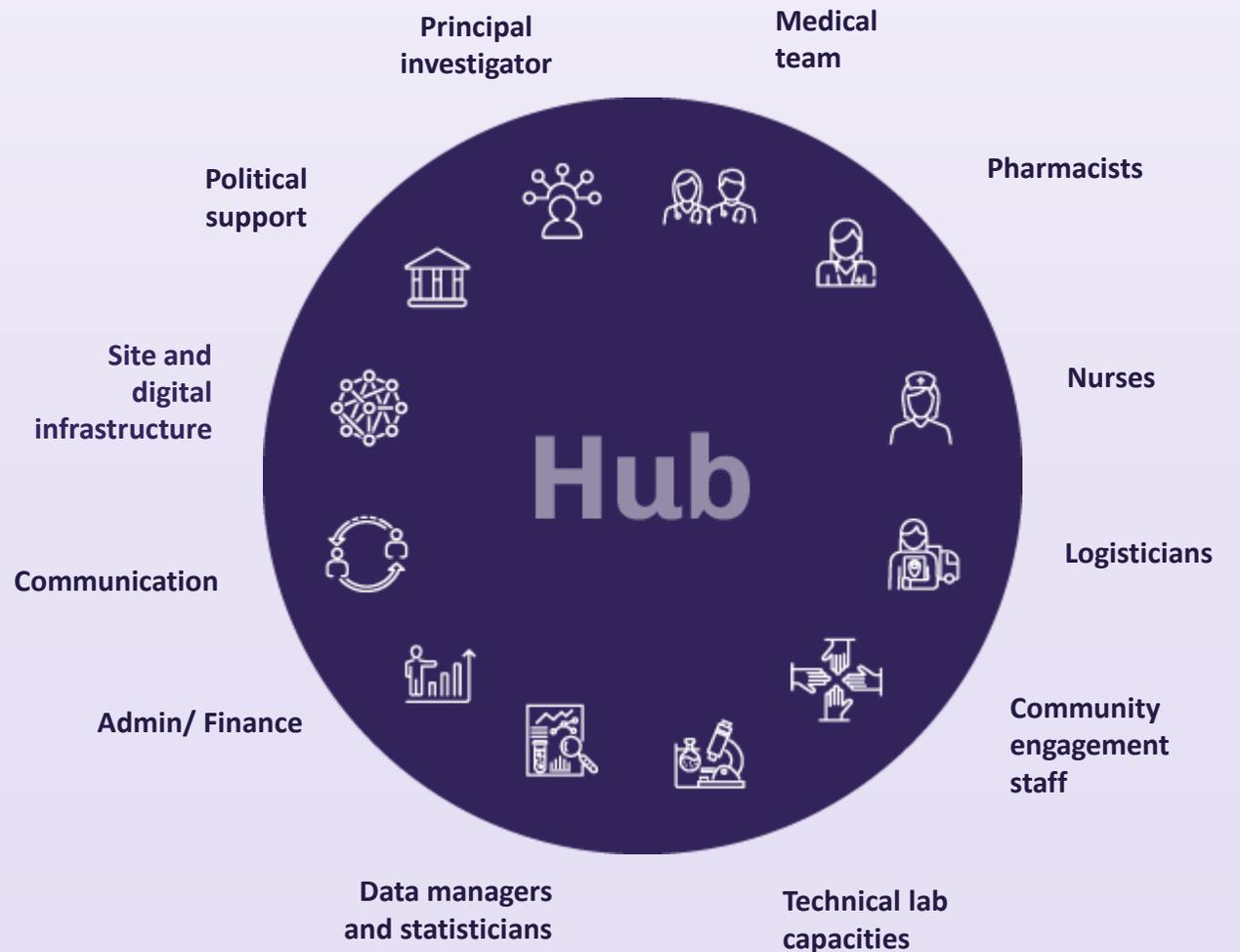
HOW WE WORK



PLATFORM ARCHITECTURE

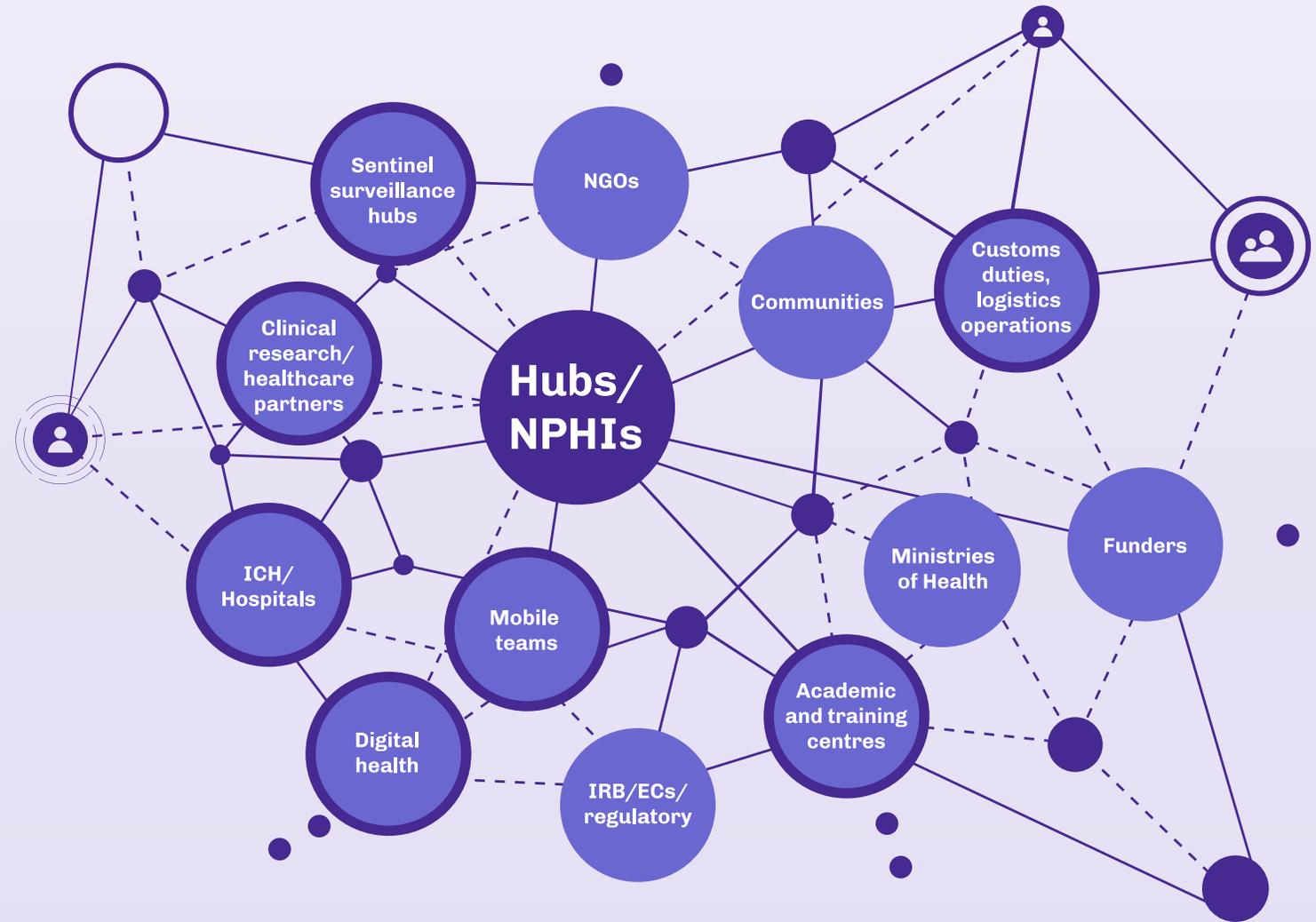
Hubs: core strategic and operational centres for preparedness and response

HUBS will sustain and develop a complete set of competencies and serve as reference platforms with several other qualified operational centres, starting with other active networks and building on their current strengths, complementing their capacities and capabilities where appropriate.



Catalysing a collaborative network for clinical research across the region

- Hubs will be either regional or disease-specific, experienced, and connected with the local or regional stakeholders involved in surveillance, capacity building, policy-making, regulatory, training, and response.
- **Hub leaders** can build new partnerships to conduct training, clinical research and capacity strengthening of partner sites and networks.



KEY ACTIVITIES AND DISTINCT FINANCING INSTRUMENTS

Preparedness and platform management

Sustainable funding

- Strategic priority setting
- Mappings: assessing expertise, potential HR gaps
- Design and management of upskilling and capacity-strengthening selected efforts
- Clinical trial operational preparedness:
- Data-sharing platform and publication principles
- Global network coordination and interaction with external stakeholders
- Mechanism for platform activation
- Financing model design
- Key country site staff/capacity maintenance and animation
- Preparedness activities design and coordination
- Fundraising strategy and sustainable funding
- Administrative management
- Inter-crisis model

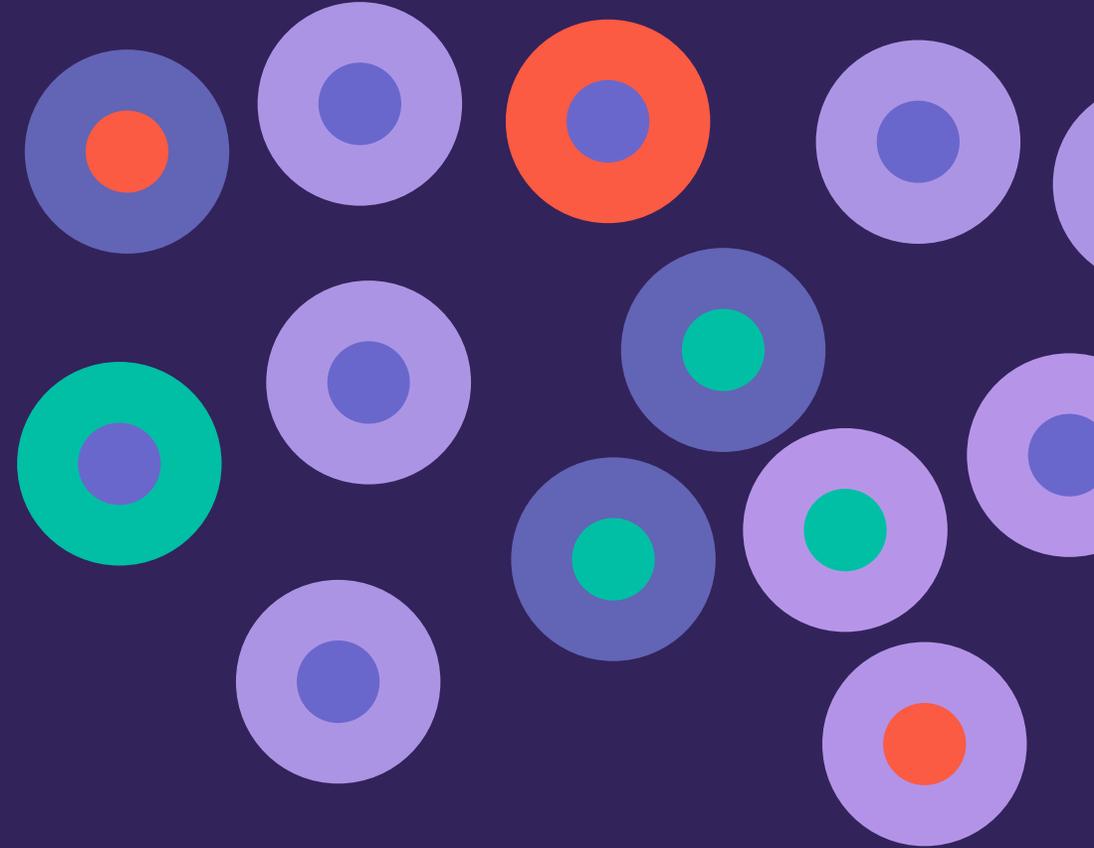
Operational rapid response

Project-specific funding

- Operational priority setting (TPP adjustment to specific health crisis, candidate scientific selection)
- Network architecture for the specific crisis (country selection, partners identification and roles)
- End-to-end operational research
- Network management (including partners and grant management)
- Communication (incl results reporting and publication principles, inter-platform communication mechanisms)

OUR PORTFOLIO

Developing, implementing, and sustaining a ready-to-use living clinical research platform which integrates research capacity in clinical care in Africa



PANTHER PORTFOLIO

Core preparedness

mapping

operational

legal

financial

training

admin

Disease specific preparedness

Response

Lassa fever

INTEGRATE Consortium

Mpox

mosa

mosa

Flu (TBC)

COVID (TBC)

ANTICOV

TO BE CONFIRMED

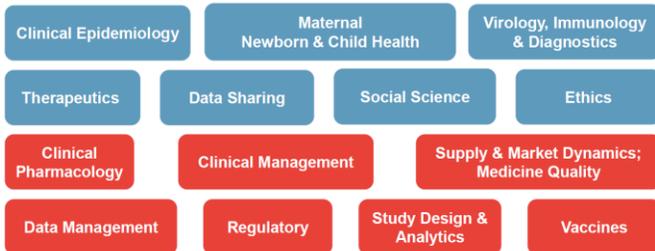
CRC19 and PANTHER: BILATERAL COLLABORATION

Countries where coalition members are based



The Coalition's Working Groups

- Key engine for the mission of the coalition
- Wealth of global expertise in areas critical for research
- 14 expert working groups; 7 active groups, 7 expert advisory groups



1. Scientific, operational know-how exchange

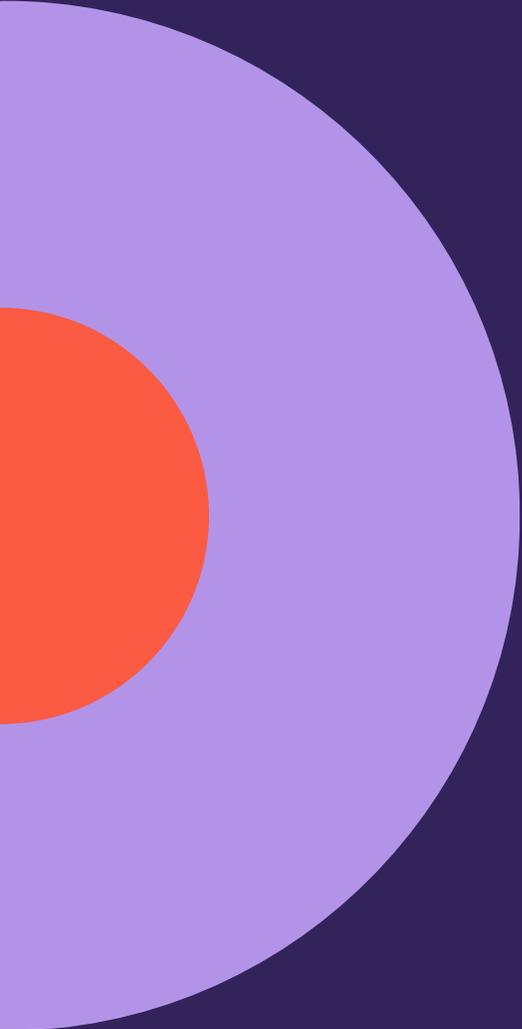


2. Coalition brings:
- working group and partners' expertise
- geographic extension



3. PANTHER brings:
- sustainability to the coalition
- New members

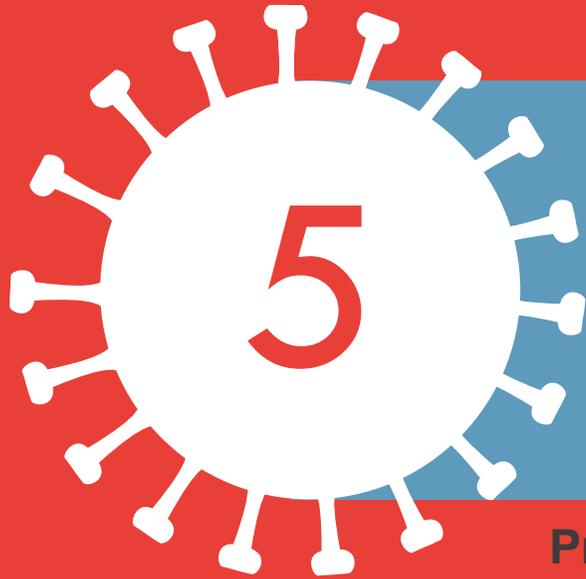




THANK YOU!



PANTHER
PANdemic preparedness plaTform for Health
and Emerging infections Response



The Coalition Transition & Discussion

DURATION: Presentation – 10 minutes | Discussion – 30 minutes

Presenter:



Prof. Nick White, Steering Committee Chair | Thailand & UK

Principles of the Coalition

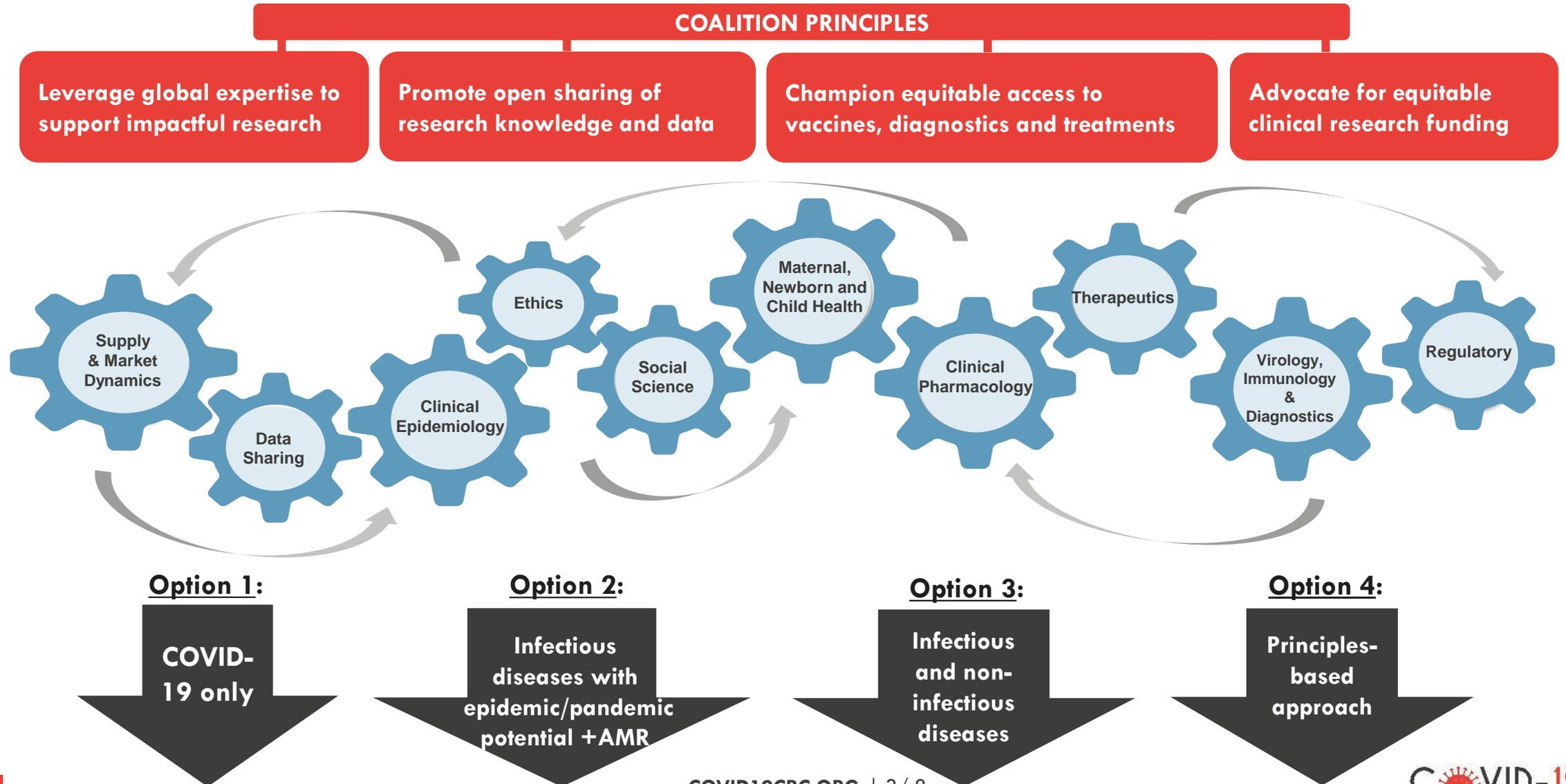
Our *mission* is to advocate and collaborate for the advancement of COVID-19 research that is driven by the needs of people in low-resource settings, and to strive for equitable access to solutions in the global response to the pandemic.

Principles of the Coalition

- **Leverage** global expertise and promote partnerships to support impactful COVID-19 research
- **Promote** open sharing of research knowledge and data, and remove obstacles to timely research
- **Champion** equitable and affordable access to COVID-19 vaccines, diagnostics and treatments
- **Advocate** for equitable clinical research funding*

* *Newly added*

The Coalition's future



Option 1: COVID-19 only

<p>Pros 😊</p>	<ul style="list-style-type: none"> • Current focus, extensive knowledge has been acquired • COVID-19 is still a serious threat • Common thread that attracted membership • Still many COVID-19 unknowns and outstanding questions requiring research • Focus may be seen as a strength
<p>Cons 😞</p>	<ul style="list-style-type: none"> • Expectation of reduced viral pathogenicity • COVID-19 fatigue causing lost momentum • Unclear if coalition can add value • Waning popular interest in COVID-19 • Reduced funding options • Vaccine access is less of an issue, rather a problem of coverage • Risk of COVID-19 exceptionalism that takes resources away from other important topics
<p>Potential short to medium-term (1-3 years) impact</p>	<ul style="list-style-type: none"> • Greater preparedness for new virulent SARS-CoV2 variants • Large datasets to inform prevention and treatment • Improved epidemiological monitoring in LRS • Standard approach for antiviral therapeutics PK/PD model? • Collaboration approach for joint international regulatory reviews (across continents) • Data sharing model for next epidemic

Option 2: Infectious diseases with epidemic/ pandemic potential (including AMR)

<p>Pros 😊</p>	<ul style="list-style-type: none"> • Valuable lessons learned from COVID-19 can allow to prepare better for another epidemic/pandemic • Adaptive flexible clinical research methodologies have been developed during COVID-19 • Greater global interest in pandemic/epidemic preparedness • Established convening power and representativeness • Realistic expectations giving a voice to LMICs • Most epidemics or pandemics begin in LRS • Likely to be the same research community involved • Could cover impact of climate change
<p>Cons 😞</p>	<ul style="list-style-type: none"> • Field is already becoming relatively crowded • Unclear if coalition can add value • Fast-moving landscape with risk of redundancy • Pandemic preparedness is very broad. Where to focus? • Developing effective therapeutics may be difficult for some pathogens
<p>Potential short to medium-term (1-3 years) impact</p>	<ul style="list-style-type: none"> • Facilitation of epidemic preparedness platforms and collaborations • Accelerated reviews and approvals • Community engagement to facilitate acceptance of urgent research • Standard approach for antiviral therapeutics PK/PD model? • Collaboration approach for joint international regulatory reviews (across continents) • Data sharing model for next epidemic

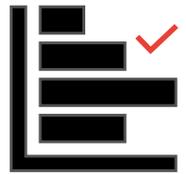
Option 3: Infectious and non-infectious diseases

<p>Pros 😊</p>	<ul style="list-style-type: none"> • Bottom-up approach: expansion building on the working groups' expertise • Problem-based approach with greater focus on equitable access • Addresses changing epidemiology • NCD research is minimal in LRS and NCD is a complication of ID outcomes • Could cover impact of climate change • More diverse and expanded membership • Social science, open science, regulatory, data management, methods and epidemiology approaches similar
<p>Cons 😞</p>	<ul style="list-style-type: none"> • Diffuse messaging • Lack of focus may weaken rather than strengthen • Technical expertise may be insufficient for impact • Direction may become dominated by funding
<p>Potential short to medium-term (1-3 years) impact</p>	<ul style="list-style-type: none"> • Facilitation of broad research platforms and collaborations • Accelerated reviews and approvals • Community engagement to facilitate acceptance of urgent research

Option 4: Principles-based approach

<p>Pros 😊</p>	<ul style="list-style-type: none"> • Focus on leveraging and accelerating research driven by the needs of people in LRS, championing equitable access, promoting data and knowledge sharing, advocating for equitable research funding • Approach based on building capacity, overcoming challenges in LRS and ensuring sustainability in good clinical trial practice in LRS • Promotion of the development of clinical trials of public health importance • More diverse and expanded membership • More interdisciplinarity within the WGs
<p>Cons 😞</p>	<ul style="list-style-type: none"> • Diffuse messaging and lack of focus may weaken rather than strengthen • Technical expertise and resources may be insufficient for impact (too ambitious?) • Direction may become dominated by funding
<p>Potential short to medium-term (1-3 years) impact</p>	<ul style="list-style-type: none"> • Facilitation of broad research platforms and collaborations • Accelerated reviews and approvals • Community engagement to facilitate acceptance of urgent research in LRS • Empowerment, independence and resilience of LRS research

What is your opinion?



Please choose your preferred option via the Zoom poll function

Poll will be available for you to vote anytime throughout the 30-minute discussion.

THANK YOU



2nd MEMBERS

ASSEMBLY

THE MEETING WILL START SOON

 **Coalition 2.0 – time for change?**

 **28/02/2023**

C  **VID-19**
Clinical Research Coalition

