Provisional Agenda - v.12.4

4th IABS Controlled Human Infection Model Conference
22nd - 24th May 2023 in Mombasa

Day 1 and Day 2: Disease Specific CHIM and Experience in Africa
Day 3: Utility of CHIM data in Licensure Pathway

This conference builds on the successes and identified challenges from three prior conferences and 1 workshop about human challenge trials also known as human infection studies or controlled human infection models (CHIM). When CHIMs are used to support vaccine development, they can add to what is already known from natural history, epidemiology, and pathogenesis studies to accelerate the vaccine development pathway. However, there are significant safety, ethical, operational, environmental, and scientific issues with intentionally infecting humans with infectious organisms even in the controlled setting of a clinical trial. Nonetheless, these trials have been performed safely and ethically both in non-endemic and endemic regions.

Attend this conference to learn more about these issues and to join in the conversation that will lead to progress and recommendations for enhancing CHIM as tools to develop new and improved vaccines.

Scientific / Organizing Committee

Co-chairs of the organizing committee:

Melissa Kapulu	Centre for Tropical Medicine and Global Health, Nuffield Department of Clinical Medicine, University of Oxford, United Kingdom
Lucinda Manda-Taylor	Kamuzu University of Health Sciences, Malawi
Meta Roestenberg	Leiden University Medical Center, The Netherlands

Members

Pieter Neels	Chair, IABS Human Vaccine Committee
Shobana Balasingam	Wellcome Trust, United Kingdom
Yakubu Nyam Beno	National Agency for Food and Drug Administration and Control, Nigeria
Cecilia Chiu	Wellcome Trust, United Kingdom
Robert Choy	PATH, U.S.A.
Anna Durbin,	Johns Hopkins Bloomberg School of Public Health, U.S.A.
Mainga Hamaluba	KEMRI – Welcome Trust, Kenya
Diadié Maïga	World Health Organization, Congo
Anastazia Older Aguilar	Bill & Melinda Gates Foundation, U.S.A.
Joseph Mfutso-Bengo	Kamuzu University of Health Sciences, Malawi
Kawsar Talaat	Johns Hopkins Bloomberg School of Public Health, U.S.A.

DAY 1 –

	8:30	**Registration**
5 min	**9:00-9:05**	**Welcome - IABS** **Pieter NEELS, Chair of Human Vaccine Committee IABS**
10 min	**9:05-9:15**	**Welcome - KEMRI-Wellcome Trust Research Programme** **Philip Bejon,** KEMRI-Wellcome, Kenya
30 min	**9:15-9:45**	Keynote lecture on history of the pitfalls of CHIM in history **Wolfram METZGER,** University of Tübingen, Germany
30 min	**9:45-10:15**	Keynote lecture CHIM trials anno 2020 **Melissa KAPULU,** KEMRI-Wellcome, Kenya

Chairpersons: **Melissa Kapulu; Meta Roestenberg**

15 min	**10:15-10:30**	CHIM 1: Malaria **Nicholas Day**, Mahidol Oxford Tropical Medicine Research Unit (MORU), Thailand
15 min	**10:30-10:45**	CHIM 2: Shigella **Kawsar Talaat,** Johns Hopkins Bloomberg School of Public Health, U.S.A.
15 min	**10:45-11:00**	CHIM 3: Streptococcus pneumoniae **Kondwani Jambo**, Malawi-Liverpool-Wellcome Trust Clinical Research Programme, Malawi
15 min	**11:00-11:15**	Coffee break
15 min	**11:15-11:30**	CHIM 4: Schistosomiasis **Meta Roestenberg,** Leiden University Medical Center, The Netherlands
25 min	**11:30-11:55**	Plenary discussion
50 min	**12:00-12:50**	Lunch
30 min	**12:50–13:20**	Community and public engagement in Challenge Trials **Noni Mumba**, KEMRI-Wellcome, Kenya
15 min	**13:20-13:35**	CHIM 5: Salmonella **Cherry Gagandeep Kang,** The Wellcome Trust Research Laboratory Division of Gastro-intestinal Sciences Christian Medical College, Vellore, India
15 min	**13:35-13:50**	CHIM 6: COVID-19 **Chris Chiu,** Imperial College London, UK

15 min	**13:50-14:05**	CHIM 7: Zika **Anna Durbin**, Johns Hopkins Bloomberg School of Public Health, U.S.A.

15 min	**14:05-14:20**	CHIM 8: Dengue **Bridget Wills,** Nuffield Department of Medicine, UK
25 min	**14:20-14:45**	Plenary discussion
15 min	**14:45-15:00**	Introduction to group work dividing in groups…
90 min	**15:00-16:30**	First group work on CHIM protocol outline *Preparation of the questions for the workshop*: Moderated by: TBC Malaria Shigella Streptococcus pneumoniae Schistosomiasis
15 min	**16:30-16:45**	Tea break
60 min	**16:45-17:45**	**Chairpersons**: **Cherry Gagandeep Kang and Kawsar Talaat** Plenary discussion: Feed-back from working groups - All
30 min	**17:45-18:15**	Keynote: history of science in Africa, challenges of clinical trials **Ally Olotu**, Ifakara Health Institute, Tanzania
30 min	**18:15-18:45**	Keynote: Ethical aspects of CHIM trials in Africa **Dorcas Kamuya**, KEMRI-Wellcome, Kenya **Primus Chi**, KEMRI-Wellcome, Kenya
30 min	**18:45-19:15**	Plenary discussion
	19:15	Networking reception End of Day 1

DAY 2 –

Chairpersons: **Anna Durbin; Lucinda Manda-Taylor**

10 min	**8:30-8:40**	Welcome back **Pieter Neels,** IABS
90 min	**8:40-10:10**	Second group work on CHIM protocol outline Salmonella COVID-19 Zika Dengue
15 min	**10:10-10:25**	Coffee break

30 min	**10:25-11:05**	Plenary discussion
60 min	**11:05-12:05**	**Chairperson Pieter Neels, Yakubu Nyam Beno** Plenary discussion: Feed-back from working groups
90 min	**12:05-13:35**	Lunch
20 min	**13:35-13:55**	Experience with CHIM from Gabon **Ayola Akim Adegnika**, Centre de Recherches Médicales de Lambaréné (CERMEL), Gabon
20 min	**13:55-14:15**	Regulatory experience on CHIM from Malawi **Martias Joshua,** National Health Sciences and Ethics, Malawi
20 min	**14:15-14:35**	Regulatory experience on CHIM from Kenya **Samuel Kerama**, Pharmacy and Poisons Board, Kenya
20 min	**14:35-14:55**	Regulatory experience from Uganda TBD
30 min	**14:55-15:25**	Tea break
40 min	**15:25-16:00**	Conclusions from a Young African Scientist – **Moses Egesa**, UVRI, Uganda
15 min	**16:00-16:15**	Summary of the meeting by the Chairs
	16:15-16:30	End of Day 2

DAY 3 – Utility of CHIM Data in the Licensure Pathway (Wellcome and CHIMICURRI)

Chairpersons: (US-FDA) (TBC) and (EMA) (TBC)

Topics For Discussion
Agenda still being drafted

Session 1: approval of CHIM trials

- Practicalities of the regulation process
- Ethical aspects from the IRB

Session 2: What is the regulatory value of data from CHIM

- Proof of concept
- Correlate of protection
- Registration purpose

(Examples: malaria, cholera, pertussis etc.)

Session 3 CHIM Models are disease specific, can we learn lessons from one disease for another?

Can we group mucosal, respiratory, gastro-intestinal to feed into harmonization, data/sample sharing etc. Definition of best practice criteria per group of diseases, to get better (easier) access to licensure?

Session 4: CHIM Models are feasible for tropical disease like Schistosomiasis, Leishmaniosis, Hookworm, Dengue, etc. but what challenges/opportunities are there with these being conducted in an endemic setting?

- the CHIM studies in endemic settings are more relevant for the population but also not quite the target, being children
- there is a risk of that pre-existing immunity could result in unfavourable results for the vaccine efficacy studies
- some of these diseases have several serotypes so can CHIM be used to produce data that would enable a multivalent vaccine which shows efficacy for 2 of the 4 serotypes for the licensure package