The 2nd WHO Global Clinical Trials Forum

Action for impact

Meeting Chair Ibrahim Abubakar, Pro-Provost (Health) and Dean of the Faculty of Population Health Sciences, University College London

Time (Day 1)	Topic	Moderators/Speakers
Session 1: Set the goals		
9:00 – 9:10	**Welcome and opening remarks.** *Welcome participants, acknowledge stakeholders' support in the past years to the WHO and commitment to the WHA75.8 implementation.*	Jeremy Farrar, Chief Scientist, WHO
9:10 – 9:40	**Update from WHO secretariat on key areas of progress** *Launch of the Guidance, Consultations, CTU-maturity framework, CT training resource hub, Global Action Plan, GCTF Network, Lancet series, National dialogues,* **Update on ethics guidance of relevance to clinical trials**	Vasee Moorthy, Senior Advisor, R&D, Research for Health, WHO. Roli Mathur, ICMR, Katherine Littler, Andreas Reis, Heath Ethics, WHO
9:40 – 10:40	Overview of activities by partners in each of the nine areas of work from the Global Action Plan 1. **Strengthen local leadership and national support.** What are the steps being taken to improve the clinical trial environment and infrastructure in selected countries? Have methods to monitor progress been agreed that could inform monitoring of the Global Action Plan? 2. **Enable implementation of WHO guidance on good clinical trials** What actions can be taken to further implementation of WHO guidance by national authorities, researchers, regulators, funders, ethics authorities? 3. **Enhance engagement with patients, communities and the public.** What are current practices for patient involvement/community and public engagement? What are steps being taken to train patient representatives and clarify engagement competencies for research teams? How do researchers access needed tools? 4. **Address barriers to clinical trials in under-represented populations.** How have working groups advanced inclusion of under-represented populations in key needed trials? What are next steps?	5 minutes each Carren Sui Lin - *Malaysia, Institute for Clinical Research*; Saeed Hamid - *Agha Khan University,* Lola Adeyemi - *Nigeria MoH; Pakistan*, PJ Devereaux - *ACT Canada (940-1000)* Martin Landray – *University of Oxford*, 1000-1010 Nina Gobat, *WHO*, Maria Dutarte, *EUPATI* and Stuart Nicholls, *Ottawa Hospital Research Institute* 1010-1020 Judd Walson, *Johns Hopkins* 1020-1035

	5. **Accelerate access to fit-for-purpose training packages for clinical trials.** What are the gaps in available training materials and what are next steps in developing them?	Denis Xavier - *St John's Research Institute*; Trudie Lang - TGHN 1035-1045
10:40 – 11:10	**Coffee break**. Networking and informal discussions.	
11:10 – 11:50	Overview of activities by partners in each of the nine areas of work from the Global Action Plan 6. **Improve coordination and streamlining regulatory and ethics review.** What are the next steps in improving efficiency/coordination of clinical trial approval processes? 7. **Engage clinical practitioners to integrate clinical trials into health systems and practices.** How to expand models for large scale trials in primary care to improve clinical outcomes? 8. **Step up the use of trial registries to improve research transparency.** What are the key gaps in use of registries, data quality, and how can we improve their utility for the clinical trial ecosystem? 9. **Expand international health research and clinical trial collaboration.** What can the WHO framework do to assist research networks with timely completion of key trials that address evidence gaps?	Indri Rooslamiati - *Indonesia (INA-CRA),* Marco Cavaleri, *EMA,* Kwasi Nyarko - *The African Vaccine Regulatory Forum (AVAREF)* 1110-1120 Andrew Farmer**,** *UK NIHR;* Chris Butler*, Oxford PHC* 1120-1130 An-Wen *University of Toronto, Canada*, Ana Zanoletty, *CTIS site map, EMA* 1130-1140 Jean-Marie Habarugira EDCTP, 1140-1150
11:50 – 13:00	**Stakeholders' feedback and proposals to GCTF activities** *Moderated discussions focusing on aspects:* - *Feedback or suggestions to the active workstreams?* - *Proposals for workstream to be included in workplan 2025-2026?* - *Clarify stakeholders' expectation from the GCTF?* - *How to better engage stakeholders in GCTF activities?*	
13:00 – 14:00	**Lunch break.** *Secretariat discusses with workstream leads to prepare for breakout work*	
14:00 – 14:30 (including transfer to rooms)	**Introduce breakout sessions 1.** *Summarize the key suggestions and proposals from the moderated discussions. Allocate breakout groups. Set expectation for report back.* **Improving national clinical trials ecosystems: Strengthening local leadership across the four pillars of the ecosystem** This session will explore learnings on how to take forward national dialogues on ecosystem strengthening *Guide questions: What have been identified as rate-limiting steps for an efficient and well-capacitated ecosystem in national discussions so far? What is planned to address these? What can be enabled through information sharing between countries? Is there a role for publishing case studies?*	Moderator: Saeed Hamid Rapporteur: Constance Assohou-Luty

	Expanding training initiatives: Making resources accessible to countries Participants will discuss key training initiatives and strategies to ensure resources are accessible to countries, addressing barriers and co-designing solutions. *Guide questions: What are gaps in training material to advance implementation of the WHO guidance? Which are the audiences where material is missing? What is the best way to deliver existing, high quality, free-to-access material?* **Engaging underrepresented populations: Practical steps** This session will focus on identifying practical steps and regulatory strategies to improve engagement with underrepresented populations in clinical trials. *Guide questions: Now that normative guidance is available how do we implement guidance so that regulators, funders, researchers routinely address the needs of under-represented populations?* **Embedding pragmatic trials into health systems: advancing risk-based, proportionate approaches** The session will examine approaches to integrating pragmatic trials into health systems, emphasizing clinician engagement and proportionate risk-based trial designs. **Digitalization and transparency in trials: Streamlining ethics, regulatory and registry data submission systems** Participants will explore how digitalization can enhance efficiency and transparency in clinical trials, focusing on streamlining regulatory and ethics processes and effectively using registry data.	Moderator: Dennis Xavier Rapporteur: Trudie Lang Moderator: Fiona Russell Rapporteur:Martina Penazzato Moderator: Chris Butler Rapporteur: PJ Devereaux Moderator: An-Wen Chan Rapporteur: Manju Rani
14:30 – 16:00	**Breakout discussions** *Moderated group works focusing on:* - *What are the concrete outputs and outcomes?* - *How to progress current activities, with concrete follow-up plans?* - *Any cross-reference to other workstreams and how do you plan to collaborate?* - *Outlook on how to maximize the impact of the outcomes of the workstream?*	
16:00 – 16:20	**Coffee break**. Networking and informal discussions.	
16:20 – 17:30	**Updates from funders and regional initiatives** *5 minutes each on activities related to WHA 75.8, the WHO guidance and in the nine areas of the Global Action Plan*	Alethea Cope, Wellcome Dan Hartmann, BMGF Jean-Marie Habarugira, EDCTP Alice Norton, Joint Statement Val Snewin, UK DHSC Elvis Temfack, Africa CDC Ana Zanoletty, ACT EU
17:30 – 19:30	**Conclude day 1 and networking (Bains des Paquis)**	

Time (Day 2)	Topic	Moderators/Speakers
Session 3: Measure the outcomes		
9:00 – 10:00	**Report back from breakout sessions and other emerging themes.** *Brief report on planned key milestones and outputs, collaboration or support from GCTF secretariat and network*	
10:00 – 10:20	**Coffee break**. Networking and informal discussions.	
10:20 – 12:10	**Breakout sessions 2** *Breakout session to build on Day 1 discussions, focusing on activity outputs contributing to action area outcomes, with* **Patient involvement and community engagement** The session will explore how to take forward the agreed actions, develop a WHO global competency framework for patient involvement and community engagement, and develop a workplan for the next 12-18 months, and identifying key organizations active in this workstream *Guide questions: Now that normative guidance is available, how do we implement guidance so that regulators, funders, researchers routinely embed patient involvement/community engagement in trials, as appropriate?* **Socialization of early draft of Clinical Trial Unit – Maturity Framework** The session will present the draft Clinical Trial Unit – Maturity Framework, inviting stakeholder feedback on its structure, implementation pathways, and alignment with global best practices. *This is a practical working session to allow for input at the beginning of the WHO consultation session on a CTU-MF* **International networks** The session will discuss the role of global and regional clinical trial networks in being able to promptly initiative key policy relevant trials. It will be structured around key rate-limiting steps, and discuss a structured workplan to incrementally address these rate limiting steps over the next 12-18 months *Guide questions: What is progress in addressing the well-known rate-limiting steps in conducting international trials such as clinical trial approval processes, contracting, funding, clinical trial insurance, Material Transfer Agreements, Data Sharing Agreements, import/export permits? What can be enabled through information sharing between networks? Is there a role for publishing case studies?* **Innovative trial designs** Regulatory guidance has been issued for Decentralised trials; adaptive designs may bring additional efficiencies; Platform, Basket and Umbrella designs all have their role. Pragmatic and point-of-care RCTs are specifically supported by the WHO guidance as we seek to enable sustained trials as part of health systems. *What are the current barriers to adoption of efficient, fit for purpose designs rather than traditional designs as the default? Can a workplan be agreed for stakeholders to advance the design, efficiency, and timeline gains and ensure these designs meet other needs for inclusion, and patient centricity?*	Moderator: Stuart Nicholls Rapporteur: Maria Dutarte Moderator: Saeed Hamid Rapporteur: Evelyn Kestelyn Moderator: Tom Nyirenda Rapporteur: Alice Norton Moderator: Martin Landray Rapporteur: Lada Leyens

12:10 – 12:50	**Report back from breakout session 1**	
12:50 – 13:30	**Lunch break**	
Session 4: Measure the outcomes: breakout sessions 3		
13:30 – 15.30	**Taking implementation forward April 2025-April 2026** *Review planned collaborative activities to take forward implementation of WHO guidance, delivery of training, development of practical tools, fill in remaining identified key gaps. Use this time to further develop discussions into workplans for the next 12-18 months in the 9 areas, session 1: patient involvement/community engagement; inclusion of under-represented populations; global training needs; session 2: enable well-designed and innovative trials; taking forward the piloting of the CTU maturity framework; enabling the work of international networks; session 3: digitization of clinical research approvals, with improved registry data and site visualizations.*	3 breakout sessions, for discussions on outcome measures appropriate for action plan
15:30 – 16:00	**Coffee break.** Networking and informal discussions.	
16:00 – 16:30	**Case studies of key international trials** *Sharing successes in timely completion and policy uptake of international trials*	Jean-Marie Habarugira, EDCTP
16:30 – 17:00	**Next steps and closing remark.** *Conclude the forum with next steps, highlighting follow-up of collaborative next steps, including GCTF network and align on priorities for advancing global clinical trial ecosystem.*	