Clinical Trials Summit of Pakistan

17-18 February, 2025

The Core Summit Agenda

Main Auditorium, Aga Khan University, Karachi

Day 1- 17th February 2025

08:00 AM – 09:00 AM	**Registration & Networking**

Opening Ceremony	
Time	**Title**
09:00 AM – 09:10 AM	**Welcome Address & Overview of Summit Objectives** **Tabling the Summit Resolution**
09:10 AM – 09:30 AM	**High level messages:** **Shaping the Future of Clinical Trials in Pakistan**

Session 1- Pakistan Clinical Trials Landscape	
Time	**Title**
09:30 AM– 09:45 AM	**Pakistan Clinical Trials Landscape Report**
09:45 AM– 10:00 AM	**Disease Patterns in Pakistan and Their Impact on Clinical Trials**
10:00 AM - 10:30 AM	**Focus Therapeutic Areas- The Role of Registries** Cardiovascular diseases Diabetes Mellitus Oncology
10:30 AM - 11:00 AM	**Panel Discussion**
11:00 AM- 11:30 AM	**Networking Break**

Session 2: WHO Plenary Session- Best Practices to Strengthen Clinical Trials	
Time	**Title**
11:30 AM- 11:55 AM	**WHO Normative Guidance for Best Practices in Clinical Trials**
11:55 AM – 12:20 PM	**Maturity Frameworks for Clinical Trials Unit**
12:20 PM- 12:45 PM	**Preparing the Region for Large Multinational Clinical Trials**
12:45 PM – 01:00 PM	**Q/A session**

01:00 PM- 02:00 PM	**Lunch & Networking**

Session 3- Regulatory Framework Analysis	
Time	**Title**
02:00 PM – 03:15 PM	**Global Regulatory Insights-Best Practices:** 1. Pakistan 2. UK MHRA 3. Malaysia 4. Egypt 5. UAE 6. Perspectives from FDA
03:15 PM – 03:45 PM	**Panel Discussion** **Way Forward – Insights from Authorities on Pressing Issues** • Key expectations from regulatory authorities. • Addressing pressing challenges in clinical trials: compliance, patient recruitment, and ethical practices. • Strategies for future collaboration and harmonization of regulations.
03:45 PM- 04:15 PM	**Networking Break**

Session 4- Ethical Considerations in Clinical Trials	
Time	**Title**
04:15 PM- 04:30 PM	**Role Of National Bioethics Committee- Advancing Ethical Efficiency** • Too many ethics committees vs single IRB policy • Strategies to explore to avoid repetitive ethics review processes • Rigorous yet efficient ethics review
04:30 PM- 04:45 PM	**Emergency Use Authorizations and Fast-Track Trials: Ethical Dilemmas** • Balancing speed and rigor during public health crises • The role of ethics in fast-tracking vaccines and therapeutics • Lessons from COVID-19 trials
04:45 PM- 05:00 PM	**The Work of AKU Ethics Review Committees in Enhancing Clinical Trials Activity**
05:00 PM- 05:15 PM	**Balancing Risk and Benefit in Trial Design** • Case studies of ethical dilemmas in high-risk trials • Strategies for minimizing harm and maximizing benefit • Adaptive trial designs and their ethical implications
05:15 PM- 05:30 PM	**Equity in Participant Recruitment** • Addressing disparities in clinical trial participation • Recruiting underrepresented populations ethically and effectively • Lessons from global trials on equitable recruitment practices
05:30 PM- 05:45 PM	**Q & A session**

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Session 5- Building Clinical Trials Ecosystems	
Time	**Title**
05:45 PM- 06:30 PM	**Building Clinical Trials Consortia- Case Studies Form Successful Eco Systems.** • Infectious Diseases • Cardio-Metabolic • Oncology • Reproductive Health • Examples from the US
06:30 PM- 07:00 PM	**Panel Discussion** *A Roadmap to Creating a Sustainable Clinical Trial Ecosystem in Pakistan* • Regulatory Framework • Capacity Building • Public Awareness and Engagement • Incentives for Industry • Which strategies should be adopted to strengthen collaborative research? • Which mechanism should be devised to increase opportunities for collaboration between different research stakeholders. • How can we address barriers to cooperation required for networking between countries and within Pakistan?
07:00 PM- 07:15 PM	**Summary Of Discussion and Closing Remarks for Day 1**
07:15 PM	**Dinner**

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Day 2- 18th February 2025

08:30 AM – 09:00 AM	**Tea & Coffee**

Session 6- Stakeholders Collaboration	
Time	**Title**
09:00 AM– 09:30 AM	**Sponsors' Experience with Clinical Trials in Pakistan** • Pakistan Clinical Trial Units • Availability of Patients • Experience with PIs and Site Staff • Potential for Future Studies in Pakistan
09:30 AM– 10:00 AM	**The Evolving Role of CROs in Fostering Multistakeholder Synergy in Clinical Trials**
10:00 AM– 10:30 AM	**Enhancing the Role of Clinical Trial Units in Collaborative Partnerships: Challenges and Opportunities**
10:30 AM- 11:00 AM	**Panel Discussion**
11:00 AM- 11:30 AM	**Networking Break**

Session 7- Engaging Patients and Communities	
Time	**Title**
11:30 AM– 11:50 AM	**Bridging Communities and Research: Facilitating Community-Based Clinical Trials** Challenges and support needed to support community-based studies
11:50 AM– 12:10 PM	**Public and Patient Engagement**
12:10 PM- 12:40 PM	**Plenary Talk:** **Upscaling Human Capacity in Clinical Trials** Capacity building & Modern approach to cope with challenging times

Session 8- Transforming Clinical Trials: Strategies for Innovation, Efficiency, and Global Impact	
Time	**Title**
12:40 PM- 01:00 PM	**Streamlining Clinical Trials-Adopting a Risk-Based Approach and Proportionate Approaches for Effective Trial Management** • Risk-Based Resource Allocation • Proportionate Management Practices • WHO, ICH E6(R3), and E8(R1) alignment to design, manage, and monitor trials to maintain integrity and participant safety
01:00 PM- 01:15 PM	**From Vision to Reality: Enabling High-Impact Clinical Trials in Emerging Markets**

	• Challenges to launch large regional clinical trials. • How can specific hurdles (regulatory, logistical, organizational) be overcome • Establishment of large clinical trials network
01:15 PM– 01:30 PM	**Revolutionizing Clinical Trials: Data Science, Machine Learning, and AI**
01:30 PM- 02:15 PM	**Lunch & Networking**

Session 9- Building Research Excellence	
Time	**Title**
02:15 PM – 02:45 PM	**Developing Research Capacities** • How can we enhance the capacities to conduct robust, high-impact clinical trials? • Different areas of specialization and skills that are needed for each role. • Challenges to talent recruitment and retention • Incentives to support and increase the number of local researchers.
02:45 PM – 03:15 PM	**Becoming a Clinical Trial Site and PI Selection Criteria** Hands-on guidance and actionable strategies.

03:15 PM - 03:30 PM	**Summary of Discussion and Closing Remarks**