Good Clinical Practice (GCP) Workshop on Clinical Research in Traditional Medicine - 2025

Dates: 26th and 27th June 2025

Organized by: Ethics Review Committee, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka

With the collaboration of

International Union of Basic and Clinical Pharmacology (IUPHAR), India

Venue: Mini-auditorium, FIM, UOC.

DAY 1: 26TH June 2025

Timings: 8:00AM to 4:00 PM		
8.00-8.30 AM	Registration	
8.30-8.40 AM	Lightning of Traditional Oil Lamp	
8.40-8.50 AM	Welcome address Dr. M.W.S.J. Kumari, Chairperson, Ethics Review Committee, Faculty of Indigenous Medicine, University of Colombo	
8.50-9.00 AM	Introduction to Good Clinical Practice in Traditional Medicine	**Prof. Kamal Perera** **Dean, FIM, UOC, Sri Lanka**
9.00-10.00 AM	Critically Critical Thinking Overview of GCP & Historical Aspects of Clinical Trials	**Prof. Bikash Medhi,** **PGIMER, India**
10.00-10.30 AM	Principals of ICH GCP and Indian GCP: Investigator's prospective	**Dr. Vaibhav Salvi** **Sanofi, India**
10.30 -10.45 AM	REFRESHMENT	
10.45-11.15 AM	Ethical considerations in clinical trial	**Prof. Bikash Medhi,** **PGIMER, India**
11.15 AM -12.15 PM	Phases of Clinical Trial and Clinical Trial Protocol, Role of Sponsor in clinical Trials	**Dr. Rohit R Desai** **Dr. Reddy's Laboratories Ltd.** **India**
12.15-12.45 PM	Informed consent process in Clinical Research	**Prof. Bikash Medhi,** **PGIMER, India**
12.45-1.30 PM	LUNCH	
1.30–2.00 PM	Pre-clinical toxicity studies in Drug development. How to file IND/NDA application for conventional products including vaccines	**Prof. Bikash Medhi,** **PGIMER, India**

2.00-3.00 PM	Regulations of Clinical Trials	**Dr. Rohit R Desai** **Dr. Reddy's Laboratories Ltd, India**
3.00-3.45 PM	Clinical trial for herbal & AYUSH medicines	**Prof. Kamal Perera** **Dean, FIM, UOC, Sri Lanka**
3.45-4.00 PM	TEA	

DAY 2: 27TH June 2025

Timings: 9:00AM to 4.00 PM		
9.00–9.30 AM	Academic vs Regulatory Trials	**Dr. Pankaj Malhotra** **PGIMER, India**
9.30-10.00 AM	Randomization in Clinical studies	**Dr. Ajay Prakash** **PGIMER, India**
10.00-10.30 AM	How To Conduct BA/BE Study	**Dr. Amey Mane** **Sun Pharma Laboratories Ltd, India**
10.30-10.45 AM	REFRESHMENTS	
10.45-11.15 AM	Clinical Trial Registration	**Dr. Chintan Khandhedia** **Sun Pharma Laboratories Ltd, India**
11.15-11.45 AM	Study Designs in clinical research	**Prof. Usha Dutta,** **PGIMER, India**
11.45 AM-12.15 PM	Basic Statistical tests & Statistical Significance Vs Clinical Significance	**Dr. Ajay Prakash** **PGIMER, India**
12.15-12.45 PM	How to monitor Clinical trials: Sponsor's perspective	**Dr. Rohit R Desai** **Dr. Reddy's Laboratories Ltd, India**
12.45-1.30 PM	LUNCH	
1.30- 2.30 PM	**Practical Session** Randomization, IVRS, eCRF, Sample size calculation	**Dr. Ajay Prakash** **PGIMER, India**
2.30-3.00 PM	Post Marketing Studies and Real-World Evidence	**Dr. Anup Thorat** **Novartis, India**
3.00–3.30 PM	Clinical Trial Design & multisite/multi-regional clinical trial	**Dr. Rohit R Desai** **Dr. Reddy's Laboratories Ltd, India**
3.30 -3.45 PM	Valedictory session and Certificate distribution	
3.45-3.50	Vote of Thanks Prof. K.R. Weerasekara, Secretary, Ethics Review Committee, Faculty of Indigenous Medicine, University of Colombo	
3.50-4.00 PM	**TEA**	

Workshop Coordinators:
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