



**Clinical Research Concept, Design & Conduct**  
**Mahamana Pandit Madan Mohan Malaviya Cancer Centre (MPMMC)**  
**& Homi Bhabha Cancer Hospital (HBCH), Varanasi**  
**April 22-23, 2022**

**Program Agenda**  
**DAY 1 (April 22, 2022)**

Time	Title (Learning objectives)	Presenter
09:00 – 09:30	Registration	<b>Dr. Bhavesh Bandekar</b> Scientific Officer, Clinical Research Secretariat MPMMC & HBCH, Varanasi
	Ice breaker	<b>Mr. Jitender Ahuja</b> Training Coordinator, CDSA, THSTI, DBT <b>Ms. Vandana Chawla</b> Administrator Training, CDSA, THSTI, DBT
09:30 – 09:45	Scope and expectations of the Workshop	<b>Dr. Rohin Hawaldar</b> Consultant, TMC Research Administration Council (TRAC), Tata Memorial Centre, Mumbai
	Introductory remarks Welcome address	<b>Dr. Satyajit Pradhan</b> Director, MPMMC and HBCH, Varanasi <b>CDSA, THSTI</b>
09:45 – 10:30	Clinical research – Why & What (How to formulate the research question)	<b>Dr. R. Badwe (Online)</b> Director, Tata Memorial Centre, Mumbai
10:30 – 11:00	<b>Group photograph followed by networking tea</b>	
11:00 – 11:45	Clinical trial designs	<b>Dr. Angela Meade (Online)</b> Programme Director, MSc Clinical Trials at UCL, Principal Research Scientist, Institute of Clinical Trials & Methodology, UCL, UK
11:45 – 12:30	Essential steps in running clinical trials	<b>Dr. Aleksandra Gentry-Maharaj (Online)</b> Principal Research Fellow, MRC Clinical Trials Unit at UCL, Institute of Clinical Trials & Methodology & Dept. of Women's Cancer, Institute for Women's Health, UK
12:30 – 13:15	Study Protocol Study documents (CRF & ICD)	<b>Dr. Girish Chinnaswamy</b> Mumbai, TMH (Online)
13:15 – 14:00	<b>Lunch break</b>	
14:00 – 14:45	Sample size determination	<b>Dr. S. N. Dwivedi</b> Former Professor, Department of Biostatistics AIIMS, New Delhi; President, Indian Society of Medical Statistics
14:45 – 15:30	Randomization: What, why, and types	<b>Dr. Gayatri Vishwakarma</b> Head-Biostatistics, Indian Spinal Injuries Centre; Former Biostatistician, Rajiv Gandhi Cancer Institute & Research Centre, New Delhi
15:30 -15:45	<b>Tea/Coffee break</b>	
15:45 – 16:30	Data Management – Data types, collection, and analysis	<b>Dr. Mahesh Iyer</b> VP, Global Head-Technical Data Services, GDO Innovation Lead & GDO India Head, Parexel International
16:30 – 17:30	<ul style="list-style-type: none"> <li>Exercises – Group &amp; Individual</li> <li>Closure with Q &amp; A</li> </ul>	



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**Program Agenda**  
**DAY 2 (April 23, 2022)**

Time	Title (Learning Objectives)	Presenter
09:00 – 09:30	Recapitulation	<b>Participants</b>
09:30 – 10:15	Research Outcomes, data analysis (IIT & PPA); Statistical Tests	<b>Dr. Mahesh Iyer</b> VP, Global Head–Technical Data Services, GDO Innovation Lead & GDO India Head, Parexel International
10:15 – 10:30	<b>Tea/Coffee Break</b>	
10:30 – 11:15	Conduct of a study – Responsibility of PI and study team	<b>Dr. Umesh Mahantshetty</b> (Online) Director, TMH, Vizag
11:15 – 12:00	Quality management; Recordkeeping & data handling (includes source documentation)	<b>Dr. Sucheta Banerjee Kurundkar</b> (Online) Director Training, CDSA, THSTI, DBT; NABL and NABH Assessor
12:00 – 12:45	Ethical considerations	<b>Dr. Nandini K. Kumar</b> (Online) Former Deputy Director-General Sr. Grade, ICMR; Vice President, FERCI, Adjunct Faculty, CDSA, THSTI
12:45 – 13:30	Regulatory aspects – one must know	<b>Prof. Y. K. Gupta</b> President, AIIMS Bhopal & AIIMS Jammu; Former Dean & Head of Pharmacology, AIIMS, New Delhi
13:30 – 14:15	<b>Lunch Break</b>	
14:15 – 15:15	Exercises – Group & Individual	
15:15– 15:30	<b>Tea/Coffee Break</b>	
15:30– 16:15	Reporting study results (CONSORT): Importance of Research and Publications for Clinicians or Publishing Research/ How to write a scientific paper	<b>Dr. Sudeep Gupta</b> (Online) Director, ACTREC, Mumbai
16:15 – 17:00	How to run efficient trials? Appraising the evidence. Lessons learned from the trials	<b>Prof. Louise Brown</b> (Online) Prof. of Medical Statistics & Clinical Trials, MRC Clinical Trials Unit, UCL, UK
>17:00	Feedback	All participants
	Exit assessment guidelines	<b>Ms. Vandana Chawla</b> Administrator Training, CDSA, THSTI, DBT
	Concluding remarks Vote of thanks	<b>Dr. Aseem Mishra</b> Associate Professor of Head & Neck Surgical Oncology, Homi Bhabha Cancer Hospital & Tata Memorial Centre, Varanasi <b>CDSA, THSTI</b>