Good data and record management practices in clinical research

Venue: - ICMR Conference Hall, India
Dates: - Nov 29 & 30, 2023

PROGRAM AGENDA

Day 1

10:00 – 10:20	**Opening remarks**	**DG, ICMR** **Dr. Aparna Mukherjee,** ICMR **Dr. Madhur Gupta**, WHO, India **Dr. Sucheta Banerjee Kurundkar,** THSTI, DBT
10:30 – 11:15	**WHO Guidance on good data and record management- the importance of data integrity**	Dr. Madhur Gupta WHO, India
11:15 – 11:30	**Networking break**	
11:30 –12:15	**Principles** (Half an hour lecture + 15 mins interaction or group activity)	Dr. Sucheta Banerjee Kurundkar CDSA-THSTI
12:15 –13:00	**Data handling and record keeping in clinical research** (Half an hour lecture + 15 mins interaction or group activity)	Dr. Seema Pai/Dr. Debjit Biswas Pfizer
13:00 – 14:00	**Group Photograph + Luncheon**	
14:00 – 14:45	**Good documentation practices** (Half an hour lecture + 15 mins interaction or group activity)	Dr. Darshana Dholakia/Richa Sarode J & J
14:45 – 15:30	**TMF, Site files and e-TMF** **Essential documents - before, during and after** (Half an hour lecture + 15 mins interaction or group activity)	Dr. Vineeta Baloni CDSA-THSTI Dr. Sucheta Banerjee Kurundkar CDSA-THSTI
15:30 – 15:45	**Tea/Coffee break**	
15:45 – 16:30	**How to write good documents?** Group activity **Record management** Group activity **Quiz – Semi-finale**	Dr. Sucheta Banerjee Kurundkar Ms. Nidhi Mishra Faculty (Seema and Richa) Ms. Nidhi Mishra Ms. Vandana Chawla
16:30 – 17:00	Concluding Discussion/ Open forum for Q & A	**All resource personnel** **All participants**

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Day 2

10:00 – 10:30	**Recap**	**Participants**
10:30 – 11:15	**Challenges and lessons learned;** **Tips to make the documentation better at clinical trial sites** (Half an hour lecture + 15 mins interaction or group activity)	Dr. Aparna Mukherjee ICMR, Delhi
11:15-11:30	**Networking break**	
11:30 –12:15	**How QRM is used to ensure good data management?** **Management & governance - quality audits** (Half an hour lecture + 15 mins interaction or group activity)	Dr. Anavita Pandiya Novartis
12:15 –13:00	**How do we ensure data quality and reliability?** (Half an hour lecture + 15 mins interaction or group activity)	Prashant Pai/Shyamal Talgaonkar IQVIA
13:00 – 14:00	**Group Photograph + Luncheon**	
14:00 – 14:45	**Data life cycle: Management** **How to address data reliability issues?** (Half an hour lecture + 15 mins interaction or group activity)	Srilakshmi Dhabbala/Dipenjit B Paraxel
14:45 – 15:30	**Presentation by groups** Group activities	Dr. Sucheta Banerjee Kurundkar Ms. Nidhi Mishra
15:30 – 15:45	**Tea/Coffee break**	
15:45 – 16:15	**Quiz**	Ms. Vandana Chawla
16:15– 17:00	**Challenge round**	**Participant groups**
> 17:00	Exit assessment – instructions Concluding Discussion/ Open forum for Q & A	**All resource personnel** **All participants**

Happy Learning