

Indian Council of Medical Research

Division of Development Research

Meeting for Development of Clinical Trial Monitoring Plans

Date: 4th December 2024

Time: 10:30 AM – 04:10 PM

Venue: Conference Hall ICMR

Time	Topic	Lead discussant/ presenter
10:30-10:35 AM	Welcome and introduction of experts	Dr Taruna Madan Gupta, Scientist G, Head, Division of Development Research ICMR HQ
10:35-10:45 AM	Context of the planned clinical trial and gaps in implementation (QMS, CTM)	Dr Aparna Mukherjee, Scientist F, Head, Clinical Studies and Trials Unit, Division of Development Research, ICMR HQ
10:45-11:15 AM	Clinical Trial Monitoring: an overview and activities before trial initiation	Dr Amit Joshi, Project Lead, Phase II/III, Parexel International
11:15-11:45 AM	Clinical trial monitoring activities during and after the trial	Dr. Monika Bahl, Founder Director, Shodh Clinical Solutions
11:45-12:15 PM	Risk based monitoring in clinical trials	Mr. Sumit Kumar, Clinical Lead and Corporate Trainer, Novotech
12:15-12:50 PM	Quality Management System in clinical trials	Dr Nilanjan Saha, Professor, Center for Translational & Clinical Research, Jamia Hamdard
12:50-1:1:45 PM	Group Photo followed by Lunch	
1:45-3:45 PM	<ul style="list-style-type: none">• Clinical Trial Monitoring Plan and forms<ol style="list-style-type: none">a. Oxfendazole Trialb. HPV Trialc. Anemia Trial• Areas for improvement of the CTM Plan- comments and discussion	Presenter: Dr. Gunjan Kumar, Scientist D, CSTU, ICMR Dr. Aruvi Poomali, Consultant, CSTU, ICMR Dr. Tanu Anand, Scientist E, CSTU, ICMR Experts: <ul style="list-style-type: none">• Dr Nilanjan Saha• Dr. Monika Bahl• Dr. Amit Joshi• Mr. Sumit Kumar
03:45-03:55 PM	Next steps	Dr Aparna Mukherjee
03:55-4:05 PM	Felicitation of the experts	Dr. Taruna Madan, Clinical Studies and Trial Unit team
4:05-4:10 PM	Vote of thanks	Dr. Sudipto Roy, Scientist E, Clinical Studies and Trials Unit, Division of Development Research, ICMR HQ
