

DIRECTOR'S MESSAGE

Solution

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Collaborating center of excellence

It is my privilege to welcome you in our inaugural workshop on "Study Design and Analysis of Clinical Trials". We have embarked on a journey to extend the horizons of knowledge and application in the field of statistics and clinical research. We have an assembly of brilliant minds: I am certain that this endeavor will establish opportunities for collaboration, mentorship, training and scope for developing innovative strategies in healthcare research.

PROGRAM COORDINATORS (From KolGO Trg)



ORGANIZING FACULTY (from SNU)







Aniruddha Choudhuri
Assistant Professor – Statistics
Sister Nivedita University (SNU)



Argha Nath Bhattacharyya Lecturer – Statistics Sister Nivedita University (SNU)



Biswajit Basak Lecturer – Statistics iister Nivedita University (SNU)

ABOUT KolGO Trg (ICMR-CCoE):-

Established in 2018, Kolkata Gynecological Oncology Trials and Translational Research Group (KolGoTrg) is dedicated to improving quality and duration of life for women with gynecological cancers in India, through creation of focused research platforms involving scientists and clinicians across the region.

ABOUT the Programme:-

Kolkata Gynecological Oncology Trials and Translational Research Group (KolGoTrg) is proud to become an ICMR (Indian Council of Medical Research) Collaborating Centre of Excellence and we are happy to announce our first workshop on Clinical Trial designs to be held in December, 2023 in partnership with Sister Nivedita University, Kolkata, India.

We have distinguished guest faculty members from University of Michigan, USA; MRC Biostatistics Unit, Cambridge UK; Newcastle University, UK; London School of Hygiene and Tropical Medicine, UK and University of Sydney, Australia alongside our national faculty members, who will provide insight on Trial designs, methodology and statistical considerations in clinical research.

On behalf of the organizing committee, we wish a great success to this event and look forward to your participation.

Programme Highlights (Format Hybrid):-

- Live Interactive Sessions
- Discussions
- E-Certificate

REGISTRATION FEE: 3000 INR (exclusive of 18% GST)

Contact Us to Register:-

- +91-9330418799 / +91-033-35694187
- research@kolgotrg.org
- www.kolgotrg.org

Registration Link:

 $\underline{\text{https://docs.google.com/forms/d/14ljuYX9sBoAj8HpYlBB-4nWOjD9vR9LlIVNhDK7uZSQ/edit?pli=1}}$

FUNDING SUPPORT:-





ICMR-CCoE
Collaborating Centre of Excellence

KolGO Trg 6th ANNUAL MEETING AND

INTERNATIONAL WORKSHOP ON

" STUDY DESIGN AND ANALYSIS OF CLINICAL TRIALS "

21 Dec 2023 to 23 Dec 2023 KOLKATA, INDIA



KolG0 Irg

ORGANIZING PARTNER:





FACULTY MEMBERS:-



Bhramar Mukherjee Chair Biostatistics, Professor, Epidemiology University Of Michigan, USA

Sofia Villar MRC Investigator University Of Cambridge, UK





Asima Mukhopadhyay Director Kolgotrg, Professor SNU,

Kelley Kidwell

Professor, Biostatistics ociate Chair for Academic Affairs University Of Michigan, USA





Ayon Mukherjee Director and Head-Novel Trial Design Regulatory Affairs and Drug Development Solutions, IQVIA

Luke Vale





Atanu Bhattacharjee Lecturer in Medical Statistics

Joydeep Basu Research Fellow, arwick Medical School, UK





James Wason

rofessor, Population Health Sciences astitute, Newcastle University, UK



Doctoral Researcher, MRC Biostatistics Unit, iversity of Cambridge, Ur





KolGo Trg Website link:-

Val Gebski

Professor and Director of Biostatistics and Research Methodology MRC Clinical Trials Centre, Australia

Arinjita Bhattacharyya ssociate Principal Scientist Merck & Co. Inc.





Partha Pratim Majumder National Science Chair, Science and Engineering Research Board Government of India

Venue: Sister Nivedita University, Kolkata

Address: G Block (Newtown), Action Area I, 1/2, Newtown, New Town, Chakpachuria, West Bengal - 700156

DAY 1: 21st December 2023

| ТОРІС | SPEAKER | | |
|--|--------------------------|--|--|
| SESSION 1: 11:30 AM-2:30 PM | | | |
| Welcome address:GCIG strategic vision for academic | Asima Mukhopadhyay | | |
| Estimation of Quality-of-life adjusted outcomes in Clinical Trials & considerations for innovative trial designs | Val Gebski (Virtual) | | |
| Master Protocols: Basket, platform, and umbrella trials | James Wason (Virtual) | | |
| Economic evaluation as part of Clinical Trials: why when and how | Luke Vale (Virtual) | | |
| Q/A | | | |
| SESSION 2: 3:00 PM-5:00PM | | | |

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Response-adaptive designs for clinical trials from myths to practical considerations

Sofia Villar (Virtual)

Optimal Allocation Proportions and How to Lukas Pin **Target Them** (Virtual)

Q/A

SESSION 3: 5:30 PM-7:30 PM

Sequential, Multiple Assignment. Kelley Kidwell Randomized Trials (SMART) (Virtual) Cluster Randomized Kelley Kidwell

Designs (Virtual)

Q/A

DAY 2: 22nd December 2023

SESSION 1: 10:00 AM-1:00 PM

| Introduction: Capacity building in Clinical Trial design, methodology and implementation | Asima Mukhopadhyay (KolGOTrg) and Dhrubojyoti Chattopadhyay (Sister Nivedita University, Kolkata) |
|--|---|
| Using Real World Data for Clinical Research | Bhramar Mukherjee |
| Life in the Biopharmaceutical Industry through the Eyes of an Early Career Professional. | Arinjita Bhattacharyya |
| Q/A | |

TOPIC

De-escalation trials in academic setting: Barriers and

Joint Longitudinal and survival modelling in clinical trials

Roles and Challenges of Missing Data in

SPEAKER

Atanu

Bhattacharjee(Virtual)

DAY 2 (cont.) : 22nd December 2023

SESSION 2: 2:00 PM - 5:00 PM

| implementation strategies for developing a Master | Asima |
|---|------------------------|
| protocol for IPIROC study | Mukhopadhyay |
| Applying adaptive-designs in challenging settings, practical considerations from implementation to estimation | Sofia Villar (Virtual) |

Q/A

Dinner: Dhamsa Tribal Kitchen, Kolkata

DAY 3: 23rd December 2023

SESSION 1; 8:30 AM - 1:00 PM

| Clinical Trials | Joydeep Basu |
|--|----------------|
| Bayesian Adaptive Designs for Dose Optimization Study in Oncology | Ayon Mukherjee |

CONCLUDING SESSION: GUEST OF HONOUR

Genomics Driven Clinical Trials

Partha Pratim Majumder

Asima

Q/A and Closure of workshop

DAY 3 (cont.): 23rd December 2023

KolGO Trg 6th Annual Meeting: Update on Ongoing and New **Clinical Studies**

SESSION 2: 2:00 PM - 7:00 PM

| GCIG study participation update | Mukhopadhyay & Rahul RoyChowdhury |
|--|---|
| Every Woman study update | Asima Mukhopadhyay, Frances Reid |
| KolGOTrg ongoing studies:- (IPIROC, HIPEC-HR, PRECERCA, NuGenA, PREGNANCY, ROCK) | Asima Mukhopadhyay & Dona Chakraborty |
| KolGOTrg new study ideas:- | |

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|--|--|
| DETEC | Rahul RoyChowdhury/ Damayanti Das Ghosh |
| PROVAT | Susanta RoyChowdhury |
| HRDAIC and PARP RAD | Asima Mukhopadhyay |
| RECERCA | Sharmila Sengupta |
| Neoadjuvant PIPAC | Somasekhar SP |
| INDIGO (Indian Industry Sponsored Gyn Oncology study group) | Asima Mukhopadhyay |

Dinner: The Westin, Kolkata