



ISN-ANIO Workshop to Promote Global Clinical Trials in Diverse Populations

Date: February 5, 2025

Venue: Pride Plaza Aerocity, New Delhi, India

Time: 9am to 5pm

Time	Description
9-9:05am	Welcome <i>Speakers: Amit Govil and Shuchi Anand</i>
Didactic Teaching for Morning Session	
9:05-9:35am 30 min incl Q&A	<u>Nephrology clinical trials from large to small - what have we learnt and where are we going?</u> <i>Speaker: Ajay K. Singh</i>
9:35-10:05am 30 min incl Q&A	<u>New Clinical Trial Designs in Nephrology</u> <ul style="list-style-type: none"> Review pragmatic cluster randomized or stepped wedge trials, focusing on strengths and limitations in dialysis populations Discuss the rationale for and introduction to adaptive clinical trial designs Case Study 2: BEAT-Calci: https://classic.clinicaltrials.gov/ct2/show/NCT05018221 <i>Speaker: Rathika Krishnasamy</i>
	Clinical Trial Conduct: Tips For Implementing Clinical Trials
10:05-10:35am 30 min incl Q&A	Trial implementation: Part 1 <u>Practical issues in design and conduct of clinical studies in the hospital setting</u> <i>Speaker: Ravi Metha</i>
10:35-11am	Coffee Break
11-11:30am 30 min incl Q&A	Trial implementation: Part 1 <u>Trial implementation in context</u> <ul style="list-style-type: none"> Examples of successful implementation of clinical trials and cohort studies within India; ethical dilemmas and cultural nuances that researchers may encounter <i>Speaker: Manisha Sahay</i>
11:30am-noon 30 min incl Q&A	Trial implementation: Part II <u>Regulatory and Practical Considerations in Trial Implementation</u> <ul style="list-style-type: none"> Best practices for data collection, management, and statistical analysis in the context of clinical trials to ensure data integrity and quality What is a Site-PI vs a clinical trialist?

Time	Description
	<ul style="list-style-type: none"> Review how to identify, report, and manage adverse events Budget planning, cost allocation, and financial management <p><i>Speaker: Srini Beddhu</i></p>
12-12:30pm 30 min	<p>Panel: Challenges with clinical trial implementation in India</p> <p><i>Panelists: Manisha Sahay, Vijay Kher, Dinesh Khullar, Vivek Jha, Prabir Roy-Chaudhury, Vivek Kumar, Raja Ramachandran</i></p>
12:30-1:30pm	Buffet Lunch
1:30-2pm 30min incl Q&A	<p><u>Generalizability of clinical trial results</u></p> <ul style="list-style-type: none"> Diversity of representation (male, female, age, SES, ethnicity) in trial populations Trial design, recruitment strategies, retention strategies Specific issues in India/South Asia <p><i>Speaker: Andrea Vicelli</i></p>
Participatory Learning	
2-3:30pm 90 min incl coffee breaks	<p><u>Strengths and Limitations in Different Trial Designs using Case Studies -</u> Breakout group discussions</p> <p>Summaries and original versions clinical trials will be provided, 1 case study per breakout group. Groups will discuss a modified STROBE checklist and emphasize the following:</p> <ul style="list-style-type: none"> Trial question of clinical relevance to your patient population Trial design with a focus on: <ul style="list-style-type: none"> Strengths (how did they address potential sources of bias; inclusion/exclusion criteria) Limitations (how might these differ for your patient population and setting) Trial results: <ul style="list-style-type: none"> Internal validity Can the results be extrapolated to other patient populations? Barriers to implementation in the real world <p>Breakout groups will present to facilitators (staggered with coffee breaks)</p> <p><i>Facilitators: Shuchi Anand, Amit Govil, Prabir Roy-Chaudhury, Vivek Jha, Srini Beddhu, Ravi Mehta, Ajay Singh, Rathika Krishnasamy, Andrea Viecelli, Vivek Kumar, Raja Ramachandran</i></p>

Time	Description
3:30-4:30pm 60 min	Summary panel discussion: <u>How can we promote the initiation and implementation of clinical trials and use evidence-based medicine in South Asia?</u> <ul style="list-style-type: none"> • What infrastructure exists (local, regional, or other?) • How are young investigators connected? • Are there some upcoming trials that could foster more collaborations? Moderator (YN): <i>Namrata Rao</i> Panelists: <i>Shyam Bansal, Divya Bajpai, Vivek Jha, Ajay Singh, Narayan Prasad, Arpana Mukherjee (ICMR)</i>
4:30-4:55pm 25 min	Closing remarks: learnings and future directions <i>Speaker: Prabir Roy-Chaudhury</i>
4:55- 5:00pm	Thank You <i>Speakers: Amit Govil, Shuchi Anand</i>