



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

Date: February 5, 2025

Venue: Pride Plaza Aerocity, New Delhi, India

**Registration and breakfast (tea/coffee/pastries): 8:15am to 9am**

**Workshop: 9am to 5pm**

Time	Description
<b>8:15-9:00am</b>	<b>Registration and breakfast (coffee, tea, pastries)</b>
9-9:05am	Welcome <i>Speakers: Amit Govil and Shuchi Anand</i>
<b>Didactic Teaching for Morning Session</b>	
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"> <li>Review pragmatic cluster randomized or stepped wedge trials, focusing on strengths and limitations in dialysis populations</li> <li>Discuss the rationale for and introduction to adaptive clinical trial designs</li> <li>Case Study 2: BEAT-Calci: <a href="https://classic.clinicaltrials.gov/ct2/show/NCT05018221">https://classic.clinicaltrials.gov/ct2/show/NCT05018221</a></li> </ul> <i>Speaker: Rathika Krishnasamy</i>
	<u>Clinical Trial Conduct: Tips For Implementing Clinical Trials</u>
10:05-10:35am 30 min incl Q&A	<u>Trial implementation: Part 1</u> <u>Practical issues in design and conduct of clinical studies in the hospital setting</u> <i>Speaker: Ravi Metha</i>
<b>10:35-11am</b>	<b><i>Coffee Break</i></b>
11-11:30am 30 min incl Q&A	<u>Trial implementation: Part 1</u> <u>Trial implementation in context</u> <ul style="list-style-type: none"> <li>Examples of successful implementation of clinical trials and cohort studies within India; ethical dilemmas and cultural nuances that researchers may encounter</li> </ul> <i>Speaker: Manisha Sahay</i>
11:30am-noon 30 min incl Q&A	<u>Trial implementation: Part II</u> <u>Regulatory and Practical Considerations in Trial Implementation</u>

Time	Description
	<ul style="list-style-type: none"> <li>• Best practices for data collection, management, and statistical analysis in the context of clinical trials to ensure data integrity and quality</li> <li>• What is a Site-PI vs a clinical trialist?</li> <li>• Review how to identify, report, and manage adverse events</li> <li>• Budget planning, cost allocation, and financial management</li> </ul> <p><i>Speaker: Srini Beddhu</i></p>
12-12:30pm 30 min	<p><u>Panel: Challenges with clinical trial implementation in India</u></p> <p><i>Panelists: Manisha Sahay, Vijay Kher, Dinesh Khullar, Vivek Jha, Prabir Roy-Chaudhury, Vivek Kumar, Raja Ramachandran</i></p>
<b>12:30-1:30pm</b>	<b>Buffet Lunch</b>
1:30-2pm 30min incl Q&A	<p><u>Generalizability of clinical trial results</u></p> <ul style="list-style-type: none"> <li>• Diversity of representation (male, female, age, SES, ethnicity) in trial populations</li> <li>• Trial design, recruitment strategies, retention strategies</li> <li>• Specific issues in India/South Asia</li> </ul> <p><i>Speaker: Andrea Viecelli</i></p>
<b>Participatory Learning</b>	
2-3:30pm 90 min incl coffee breaks	<p><u>Strengths and Limitations in Different Trial Designs using Case Studies - Breakout group discussions</u></p> <p>Summaries and original versions clinical trials will be provided, 1 case study per two breakout groups. Groups will discuss a modified STROBE checklist and emphasize the following:</p> <ul style="list-style-type: none"> <li>• Trial question of clinical relevance to your patient population</li> <li>• Trial design with a focus on: <ul style="list-style-type: none"> <li>- Strengths (how did they address potential sources of bias; inclusion/exclusion criteria)</li> <li>- Limitations (how might these differ for your patient population and setting)</li> </ul> </li> <li>• Trial results: <ul style="list-style-type: none"> <li>- Internal validity</li> <li>- Can the results be extrapolated to other patient populations?</li> <li>- Barriers to implementation in the real world</li> </ul> </li> </ul> <p><b>Breakout groups and trials/papers for discussion:</b></p> <ul style="list-style-type: none"> <li>• <b>Group 1, facilitated by Amit Govil:</b> CJASN, 2021 - <i>Belatacept for Simultaneous Calcineurin Inhibitor and Chronic Corticosteroid</i></li> </ul>

Time	Description
	<p><i>Immunosuppression Avoidance; Two-Year Results of a Prospective, Randomized Multicenter Trial (BEST)</i></p> <ul style="list-style-type: none"> <li>• <b>Group 2, facilitated by Andrea Viecelli:</b> CJASN, 2021 - <i>Belatacept for Simultaneous Calcineurin Inhibitor and Chronic Corticosteroid Immunosuppression Avoidance; Two-Year Results of a Prospective, Randomized Multicenter Trial (BEST)</i></li> <li>• <b>Group 3, facilitated by Vivek Jha:</b> JAMA, 2022 - <i>Effect of Oral Methylprednisolone on Decline in Kidney Function or Kidney Failure in Patients With IgA Nephropathy; The TESTING Randomized Clinical Trial</i></li> <li>• <b>Group 4, facilitated by Manisha Sahay:</b> JAMA, 2022 - <i>Effect of Oral Methylprednisolone on Decline in Kidney Function or Kidney Failure in Patients With IgA Nephropathy; The TESTING Randomized Clinical Trial</i></li> <li>• <b>Group 5, facilitated by Shuchi Anand:</b> Lancet, 2022 - <i>Personalised cooler dialysate for patients receiving maintenance haemodialysis (MyTEMP): a pragmatic, cluster-randomised trial</i></li> <li>• <b>Group 6, facilitated by Prabir Roy-Chaudhury:</b> Lancet, 2022 - <i>Personalised cooler dialysate for patients receiving maintenance haemodialysis (MyTEMP): a pragmatic, cluster-randomised trial</i></li> <li>• <b>Group 7, facilitated by Ajay K. Singh:</b> NEJM, 2021 - <i>Daprodustat for the Treatment of Anemia in Patients Undergoing Dialysis</i></li> <li>• <b>Group 8, facilitated by Srinivasan Beddhu:</b> NEJM, 2021 - <i>Daprodustat for the Treatment of Anemia in Patients Undergoing Dialysis</i></li> <li>• <b>Group 9, facilitated by Vivek Kumar:</b> NEJM 2023 - <i>Effect of Hemodiafiltration or Hemodialysis on Mortality in Kidney Failure</i></li> <li>• <b>Group 10, facilitated by Rathika Krishnasamy:</b> NEJM 2023 - <i>Effect of Hemodiafiltration or Hemodialysis on Mortality in Kidney Failure</i></li> <li>• <b>Group 11, facilitated by Ravi Mehta:</b> NEJM, 2020 - <i>Timing of Initiation of Renal-Replacement Therapy in Acute Kidney Injury (STARRT-AKI)</i></li> <li>• <b>Group 12, facilitated by Raja Ramachandran:</b> NEJM, 2020 - <i>Timing of Initiation of Renal-Replacement Therapy in Acute Kidney Injury (STARRT-AKI)</i></li> </ul>

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

Note: Attendance certificates will be provided shortly after the workshop via email.