International <u>Collaboration for Re</u>search methods <u>Development in Oncology</u> 8th CReDO workshop

3rd to 8th March 2025 Lonavala, India

https://credo.ncgindia.org/





About the workshop

The National Cancer Grid of India conducted the eighth International Collaboration for Research methods Development in Oncology (CReDO) workshop at the Larsen and Toubro Leadership Development Academy at Lonavala, near Mumbai between 3rd and 8th March 2025. The objective of this workshop was to train researchers in oncology in various aspects of clinical trial design and to help them to develop a research idea into a structured protocol. Participation was open to researchers with training in surgical, medical or radiation oncology or any branch related to oncology with preference being given to early and middle-level researchers working in an academic setting, who demonstrate commitment to continuing research in oncology.

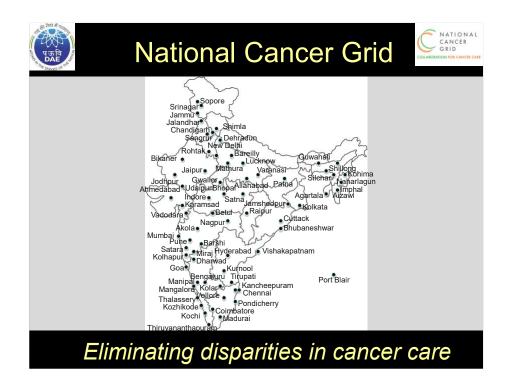
The format of the workshop included protocol development group sessions, didactic talks, small-group breakaway sessions, office-hours (one-toone direct consultation with experts) and "homework". This was supplemented by pre- and post-workshop virtual sessions.



The National Cancer Grid of India

The National Cancer Grid (NCG) of India is a collaboration of more than 375 major cancer centres, research institutes, charitable trusts, patient groups and professional societies, covering the entire length and breadth of the country and is amongst the largest cancer networks in the world. Funded by the Government of India through the Department of Atomic Energy, the NCG has the primary mandate of working towards uniform standards of care across India by adopting evidence-based management guidelines, which are implementable across these centres. It is also intended to facilitate exchange of expertise between centres, cancer workforce capacity building, and to facilitate multidisciplinary collaborative cancer research. The NCG has transformed the overall spectrum of cancer care, education and research in India and had major impact over the past decade. Initiatives of the NCG include adoption of uniform management guidelines for treatment of common cancers in India, institutional peer review, a central "National Cancer Library", refresher courses in surgical pathology, training in clinical research methods, palliative care, standardization of surgical pathology including immunohistochemistry and molecular pathology, quality assurance, establishment of a Centre for Digital Oncology, a Centre for Global Oncology amongst others.

Some of the research proposals developed at past CReDO workshops have been funded by the National Cancer Grid, as multi-centric trials.



Workshop venue

The workshop was held at the Leadership Development Academy of Larsen and Toubro, which is located at Lonavala, 100 kilometres away from Mumbai. Set in the lush green surroundings of the Sahyadri hills, the academy has a fully-equipped training centre with learning halls, library facilities and well-furnished accommodation. It also offers recreational facilities like swimming, a jogging track, gymnasium, indoor and outdoor games.



Workshop Advisory Board

Marc Buyse Mahesh Parmar Arnie Purushotham Ian Tannock International Drug Development Institute, Belgium and California MRC-CTU at University College London King's College, London Princess Margaret Cancer Centre, Toronto

Workshop Organising Committee (Tata Memorial Centre, Mumbai)

Girish Chinnaswamy Durga Gadgil C S Pramesh Priya Ranganathan Manju Sengar Shivakumar Thiagarajan

Workshop faculty

The faculty consisted of international and national experts with extensive experience in oncology research and training in research methodology workshops.

1.	Ajay Aggarwal	London School of Hygiene and Tropical Medicine				
2.	Christopher Booth	Queen's University, Kingston, Canada				
3.	Michael Brada	University of Liverpool				
4.	Marc Buyse	International Drug Development Institute, USA and Belgium				
5.	Girish Chinnaswamy	Tata Memorial Centre, Mumbai				
6.	David Collingridge	Lancet Oncology				
7.	Vishal Deo	Indian Council of Medical Research				
8.	Meenakshi Devidas	St Jude Children's Research Hospital, Memphis, USA				
9.	Caitlin Duffy	St Jude Children's Research Hospital, Memphis, USA				
10.	Chris Frampton	University of Otago, New Zealand				
11.	Paola Friedrich	St Jude Children's Research Hospital, Memphis, USA				
12.	Durga Gadgil	Tata Memorial Centre, Mumbai				
13.	Carlos Galindo-Rodriguez	St Jude Children's Research Hospital, Memphis, USA				
14.	Elizabeth Garrett-Mayer	American Society of Clinical Oncology				
15.	Duncan Gilbert	MRC CTU at University College London				
16.	Dylan Graetz	St Jude Children's Research Hospital, Memphis, USA				
17.	Allan Hackshaw	Cancer Research UK & UCL Cancer Trials Centre				
18.	Sadhana Kannan	ACTREC, Tata Memorial Centre				
19.	Amit Khot	Peter MacCallum Cancer Center, Melbourne				
20.	Mark Krailo	University of Southern California				
21.	Ruth Langley	MRC CTU at University College London				
22.	Patrick Loehrer	Indiana University				
23.	Meritxell Mallafré-Larrosa	City Cancer Challenge Foundation, Geneva				
24.	Indranil Mallick	Tata Medical Center, Kolkata, India				
25.	Aparna Mittal	Patient Advocate, PatientsEngage				

26.	Jammbe Musoro	European Organisation for Research and Treatment in Cancer, Belgium
27.	Mahesh Parmar	MRC CTU at University College London
28.	Shital Patel	Patient advocate, PatientsEngage
29.	C S Pramesh	Tata Memorial Centre, Mumbai
30.	Arnie Purushotham	King's College, London
31.	A S Ramakrishnan	Surgical Oncologist, Chennai
32.	Neil Ranasinghe	Patient advocate, UK
33.	Priya Ranganathan	Tata Memorial Centre, Mumbai
34.	Diana Romero	Nature Reviews Clinical Oncology
35.	Victor Santana	St Jude Children's Research Hospital, Memphis, USA
36.	Balu Krishna Sasidharan	Christian Medical College, Vellore
37.	Manju Sengar	Tata Memorial Centre, Mumbai
38.	Isabelle Soerjomataram	International Agency for Research in Cancer, Lyon
39.	Richard Stephens	Patient Advocate, Cancer Research Advocates Forum, UK
40.	Martin Stockler	University of Sydney
41.	Richard Sullivan	Institute of Cancer Policy, King's College, London
42.	Matthew Sydes	Data Driven Clinical Trials, NHS England
43.	lan Tannock	Princess Margaret Cancer Centre, Toronto, Canada
44.	Shivakumar Thiagarajan	Tata Memorial Centre, Mumbai, India
45.	Vivek Tomar	Patient Advocate, Rise to Survive, New Delhi, India

Special invitees

1.	Bhaveet Radia	Guys' Cancer Academy, UK



CReDO organizing committee



Application for the workshop was through a competitive online application system.

Criteria for participation

Applicants should have fulfilled the following criteria:

- 1. Trained or be in-training in any branch of oncology (surgical, medical or radiation) or any specialty allied to oncology.
- 2. Have an interest in clinical research and show commitment to devote time to clinical research in the years following the workshop.
- 3. Be ready with a research concept (idea) which can be developed into a full-fledged research project.
- 4. Be comfortable with written and spoken English and have basic computer skills.
- 5. Have support from their Supervisor/ Head of Department and Institution to carry out the proposed research project.

Application details:

Participants were selected through a competitive online application process. Each application contained the following details:

- 1. Applicant details
- 2. Brief synopsis of the proposed research
- 3. Applicant's statement of purpose
- 4. Supervisor's statement of support

Selection of participants:

Each application was reviewed by at least two expert reviewers who rated the applications based on:

- 1. Quality of the research concept
- 2. Applicant's statement of purpose
- 3. Supervisor's statement of support
- 4. Value addition to the applicant's institution

Preference was given to early or mid-career researchers from academic institutions who demonstrated commitment to continuing research in oncology. Applicants who were accepted for the workshop had to develop the clinical research concept submitted with their application into a complete clinical trial protocol during the workshop. A total of 76 participants from 21 countries were selected and participated in the workshop.

Workshop participants

National participants

1.	Anuradha Mehta	Tata Memorial Hospital, Mumbai					
2.	Ashwin Phillips	Amala Institute of Medical Sciences, Thrissur					
3.	Bharti Devnani	All India Institute of Medical Sciences, Jodhpur					
4.	Abhilash Konki	Nizams Institute of Medical Sciences, Hyderabad					
5.	S V Saju Meenakshi Mission Hospital & Research Centre, Madurai						
6.	Sasha Pereira	Tata Memorial Hospital, Mumbai					
7.	Nivedita Sharma	All India Institute of Medical Sciences, Jodhpur					
8.	Febin Antony	Amala Institute of Medical Sciences, Thrissur					
9.	Nutan Joshi	Christian Medical College, Vellore					
10.	Tanvi Shah	Tata Memorial Hospital, Mumbai					
11.	Karan Sood	Jawaharlal Nehru Medical College					
12.	Ankita Das	Tata Memorial Hospital, Mumbai					
13.	Tejal Patel	Amrita Institute of Medical Sciences, Kochi					
14.	Lakshmi Menon R	Amrita Institute of Medical Sciences, Kochi					
15.	R Mirunalini	JIPMER, Puducherry					
16.	Anupa John	Tata Memorial Hospital, Mumbai					
17.	Swathi Yennemadi	Tata Memorial Hospital, Mumbai					
18.	Kahkasha	All India Institute of Medical Sciences, Deoghar					
19.	Anusha M	All India Institute of Medical Sciences, Rishikesh					
20.	Joshua John Uzagare	Christian Medical College Vellore					
21.	Ajinkya Kale	Tata Memorial Hospital, Mumbai					
22.	Sujith K	Christian Medical College, Vellore					
23.	Abhijit Talukdar	Dr B Borooah Cancer Institute, Guwahati					
24.	Shreya Rosa Stephen	Christian Medical College, Vellore					
25.	Samreen Jaffar	Tata Memorial Hospital, Mumbai					

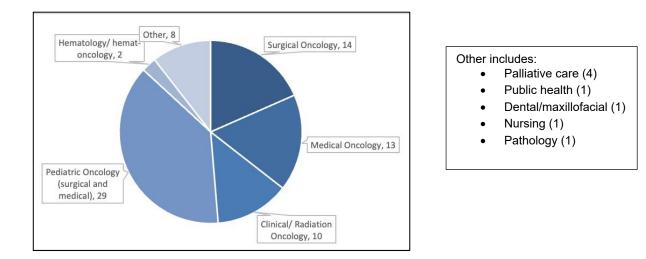
26.	Karthik V	Tata Memorial Hospital, Mumbai					
27.	Kannan P	JIPMER, Puducherry					
28.	Ankita Mallick	Tata Medical Center, Kolkata					
29.	Swaminathan	JIPMER, Puducherry					
30.	Archana MV	Kasturba Medical College, Manipal					
31.	Sidharth Totadri	St John's Medical College and Hospital, Bengaluru					
32.	Anuj Singh	Uttar Pradesh Government					
33.	Guruprasad C S	Regional Cancer Centre Thiruvananthapuram					
34.	Parthasarathi Bhattacharyya	Tata Medical Center, Kolkata					
35.	Jasmeet Sidhu	Tata Medical Center, Kolkata					
36.	Gnanamani Senguttuvan	Christian Medical College Vellore					
37.	Aditi Dwivedi	Tata Memorial Hospital, Mumbai					
38.	Georgeena Elsa Jose	Government Medical College & Cancer Hospital, Aurangabad					
39.	Honey Susan Raju	Meenakshi Mission Hospital & Research Centre, Madurai					
40.	Daniel Raj Joseph Thangasamy	Cancer Institute WIA, Adyar, Chennai					
41.	Hafizul Islam Pathan	Dr B Borooah Cancer Institute, Guwahati					
42.	Meghna Kumar	Homi Bhabha Cancer Hospital & Research Centre, Muzaffarpur					
43.	Hashmath Farhaana.S	Pallium India Trust, Thiruvananthapuram					

International participants

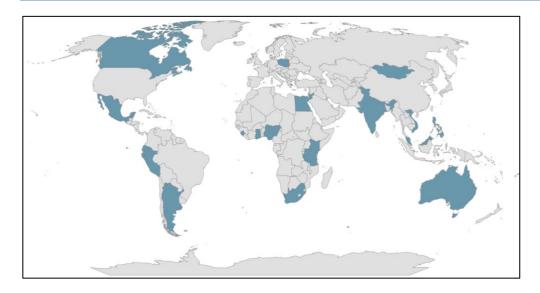
1.	Kristin Wright	Kingston Health Sciences Center, Canada
2.	Dua'a Zandaki	King Hussein Cancer Center, Jordan
3.	Ernestina Nana Boatemaa Schandorf	Korle Bu Teaching Hospital, Ghana
4.	Giselle Mata Cavada	Hospital Infantil Teletón de Oncología (HITO), Mexico
5.	Hannah Grace Segocio	Southern Philippines Medical Center, Philippines
6.	Mohammad Shukri Khoo	UKM Specialist Children's Hospital, Malaysia
7.	Ricardo Martín Solís Velásquez	Ministry of Public Health, Ecuador
8.	Otgonjargal Amraa	The National Cancer Council of Mongolia, Mongolia

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9.	Cesar Alejandro Galvan Diaz	Instituto Nacional De Pediatria, Mexico					
10.	Sergio Miguel Gomez	Ministry of Health, Argentina					
11.	Kamalina Coopasamy	Grey's hospital, South Africa					
12.	Lily Jannete Saldaña Gallo	National Institute of Child Health, Peru					
13.	Sani Sipai	Kanti Children's Hospital, Nepal					
14.	Ashraf Mahmoud	Kilimanjaro Christian Medical Centre (KCMC), Tanzania					
15.	Mitchelle Obat	Aic Kiajbe Hospital, Kenya					
16.	Esraa Maged Mohammad	National Cancer Institute, Egypt					
17.	Nermeen Alhawary	Children's Cancer Hospital, Egypt					
18.	Katarzyna Pawinska-Wasikowska	Institute of Pediatrics Jagiellonian University Medical College, Poland					
19.	Tran Thi Lien Nhi	Bui Ngoc Lan, Vietnam					
20.	Karin Plummer	Griffith University, Australia					
21.	1. Irene Nzamu Kenyatta National Hospital, Kenya						
22.	Nwamaka Lasebikan	National Institute for cancer research and treatment, Nigeria					
23.	Gorky Yupanqui	Hospital Goyoneche, Peru					
24.	Alejandro Olmos Guzman	Instituto Mexicano del Seguro Social, Mexico					
25.	Juan Carlos Pari Salas	Hospital III Goyeneche Arequipa, Peru					
26.	Anita Eseenam Agbeko	Komfo Anokye Teaching Hospital, Ghana, Ghana					
27.	Jasmine Gurung	National Academy of Medical Sciences, Bir Hospital, Nepal					
28.	Adeleye Dorcas Omisore	Obafemi Awolowo University, Nigeria					
29.	Angela Karia	Ocean Road Cancer Institute, Tanzania					
30.	Nashivai Elias Kivuyo	Muhimbili University of Health and Allied Sciences, Tanzania					
31.	Willybroad Augustine Massawe	Muhimbili National Hospital, Tanzania					
32.	Kelfala Marah	Ministry of Health and sanitation, Sierra Leone					
33.	Fatimah Abdulkareem	College of Medicine of the University of Lagos and Lagos Teaching Hospital, Nigeria					

Specialty-wise distribution of participants



Countries represented at CReDO 2025



Other attendees at CReDO 2025

Research personnel

As part of the initiative to build research capacity at a national and global level, we invited research personnel to participate in the CReDO 2025 workshop. These included biostatisticians, imaging data scientists and project managers.

1.	Abhishek Anand	Statistician	International Institute for Population Sciences, India
2.	Sakshi Shimpi	Statistician	Ambuja Foundation, India
3.	Olujide Arije	Statistician	Institute of Public Health, Obafemi Awolowo University, Nigeria
4.	Reena Bhardwaj	Statistician	ICMR - Centre for Cancer Pathology, India
5.	Richa Singhal	Statistician	ICMR - National Institute of Malaria Research, India
6.	Oindrila Roy Chowdhury	Imaging Data Scientist/Statistician	Tata Medical Center, Kolkata, India
7.	Julius Pius Alloyce	Project Manager	Kilimanjaro Clinical Research Institute, Tanzania

Patient advocates

The NCG has partnered with PatientsEngage, a social enterprise, which is a patient/caregiver-focused healthcare platform for supporting the management of chronic diseases to initiate training for individuals who can subsequently serve as patient advocates for research in cancer (PARC) and clinical guideline development. The training included a series of virtual interactive sessions on topics relevant for research and guidelines. Out of 22 participants who went through virtual training, 8 attended the CReDO 2025 workshop to learn the role of patient advocates in protocol development under supervision of patient advocate mentors experienced in participation in clinical research. These participants were embedded in the protocol development groups and contributed actively to the research protocols.

1.	Swati Suramya
2.	Gauri Singh
3.	Amit Shenoy
4.	Neerad Trivedi
5.	Rupak Satpathi
6.	Mahithi Pillay
7.	Gautam Deb
8.	Rachana Vijan

CReDO 2025 faculty with participants and other trainees





Pre-workshop webinars

Starting December 2024, participants attended a series of webinars on the following topics:

- 1. Overview of the workshop
- 2. Research Study designs
 - a. Observational study designs
 - b. Interventional study designs
- 3. Elements of a research protocol
- 4. Searching medical literature
- 5. Research ethics and Informed consent
- 6. Biostatistics

The objective of these webinars was to introduce participants to various concepts of qualitative and quantitative research methodology. The webinars were interactive, and participants were encouraged to submit their questions and problems for discussion during the webinar.

Pre-workshop Protocol Development Group (PDG) interactions

The PDGs form the core activity of the workshop and enable participants to convert their one-page research idea into a full-fledged research protocol ready for IRB / Ethics submission. Workshop participants were divided into groups of 8 each, with each of these groups being mentored by 4 to 5 faculty. Prior to the workshop, feedback was provided by the PDG faculty to the participants:

- a) Initial written feedback on the concept notes was provided through a Google sheet
- b) Virtual meeting: The PDGs met online in separate calls to discuss the research concepts of each participant in the group and provide additional feedback.

Participants were encouraged to work on the feedback before they arrived at the workshop.

During the workshop

The workshop sessions were carefully formulated to meet the objectives while stimulating interactive discussions. Learning sessions were in the following formats:

A. Lectures

These were interactive presentations given by experts on common aspects of the methodology, design and conduct of clinical research proposals. Most of these principles helped participants to complete their research protocols and complement the discussions during the PDGs. These talks were carefully scheduled to aid participants, reflecting the stage of the protocol they were likely to develop on that day.

B. Protocol Development Groups (PDGs)

Participants and faculty met for 2.5-3 hours every day to develop various sections of individual protocols. These sessions built upon the initial suggestions given prior to the workshop. Each of the PDG sessions gave participants constructive feedback of their respective projects by the mentors and other participants, while applying the knowledge gained from the other sessions. Participants learnt as much from observing other

protocols developed in their group, as they did from their own protocols. In effect, this meant that each participant experienced the development of seven other protocols in addition to their own.

C. Meet the expert sessions or "Office hours"

These were direct one-on-one sessions between workshop participants and faculty experts, to clarify specific problems with protocols. Individual assistance with protocols from experts with unique strengths allowed participants to gain from the experience and knowledge of mentors from outside their own PDGs. These sessions were also used for professional career guidance and advice on other aspects of research like grant writing, getting research funding etc.

D. Focused group sessions

Focused sessions were held on specific topics, which were not covered during the common lecture sessions but were important parts of certain research protocols; these also dealt with essential elements to the success of research projects, as well as discussions around challenges and hurdles for different kinds of protocols. These groups were deliberately kept small to facilitate active interactions between the participants and the faculty. The topics for focused group discussions included

- Research in Al
- Incorporating AI in research
- Screening studies
- Implementation research
- Publishing research findings
- Presenting research findings
- All you wanted to ask about statistics
- Value-based research
- Measuring Quality of Life in research
- Pediatric research collaboration
- Quality improvement projects
- Research in resource constrained / conflict areas
- Surgical trials
- Radiation trials
- Research ethics
- Single-centre studies: design and analysis

E. Hands-on sessions

Based on requests from participants, we held hands-on sessions on the use of software including REDCap, R and SPSS.

Special session: Presentation of the best protocols at the workshop (NCG-ASCO joint session)

The faculty mentors for each protocol development group selected the best protocol(s) in their group based on novelty, relevance and feasibility. The selected research ideas (ten in all) were presented to all faculty and participants, during a one-hour session on 7th March 2025.







Workshop agenda

SUN - 2	2nd Mar 2025	PRE-LUNCH	MON	I - 3rd Mar 2025	TU	E - 4th Mar 2025		WED - 5th Mar 2025	т	HUR - 6th Mar 2025		FRI - 7th Mar 2025	S	AT - 8th Mar 2025
		SESSION		Overview and doubts - PRIYA, PRAMESH, MANJU, GIRISH	0830-0900	Phases of trials and Phase I trials: LIZ GARETH MAYER		Association and regression: ALLAN HACKSHAW	0830-0900	Biomarkers in research: HARISANKARAN (virtual)	0830-0900	Handling missing data: SALLY HUNSBERGER (virtual)	0830-0900	Writing a research paper - BALU KRISHNA SASIDHARAN
					0900-0930	Phase II trials: MARK KRAILO	0915-0945	Implementation research - CAITLYN DUFFY	0900-0930	Non-inferiority studies - MAX PARMAR	0900-0930	Systematic reviews: CHRIS FRAMPTON	0900-0930	Quality improvement - PAOLA FRIEDRICH
				Patient and public participation in research			0945-1015	Sample size for observational studies: CHRIS FRAMPTON	0930-1000	Screening Trials - ISABELLE SOERJOMATARAM	0930-1000	Multiple testing: MARC BUYSE	0930-1000	Critical appraisal of published papers: IAN
				RICHARD STEPHENS	0930-1010	Methodological aspects of phase III trials: PRAMESH	1015-1045	Question time: Open forum	1000-1030	Designing trials in smaller populations: MATT SYDES	1000-1030	Brief introduction to the role of Al in oncology: DIANA ROMERO	1000-1030	NCG and research collaboration - PRAMESH
		Ī	1015-1045	Tea break	1010-1040	Tea break	1045-1115	Tea break	1030-1100	Tea break	1030 - 1100	Tea break	1030-1100	Tea break
			1045-1130	Pretest (participants) Briefing (faculty)	1040-1120	Statistics for phase III trials: MARC BUYSE	1115-1145	Qualitative research methods: DYLAN GRAETZ	1100-1130	Question time: Open forum	1100-1130	Predictive and prognostic factors: MARC BUYSE	1100-1145	Feedback session
			1130-1215	Overview of workshop: PRIYA					1130-1215	Survival Analysis: ALLAN HACKSHAW	1130-1210	Novel study designs: MAHESH PARMAR		
				RANGANATHAN	1120-1200	Observational study designs: CHRIS FRAMPTON	1145-1225	Protocol writing: Outcomes and outcome measures: MARC BUYSE			1210-1235	Practical aspects of running a trial - RUTH LANGLEY	1145-1230	Post-test (participants) Feedback (faculty)
		l	1215-1300	Protocol writing:			Aethods: endpoints: ALLAN HACKSHAW	1215-1300 Patient-reported outcomes &	1235-1300	35-1300 Grant writing: DUNCAN GILBERT				
				Introduction/Hypothesis/ Aims/Objectives: MICHAEL BRADA	1200-1300	Protocol writing: Methods: MARTIN STOCKLER		endpoints: ALLAN HACKSHAW		Quality of Life measures:JAMMBE MUSORO				
			1300-1400	Lunch	1300-1400	Lunch	1300-1400	Lunch	1300-1400	Lunch	1300-1400	Lunch	1230-1330	Lunch
		POST-LUNCH SESSION	1400-1630 (tea break in between)	Protocol development session: concept sheets - title/aims/objectives	1400-1700 (tea break in between)	Protocol development session: Study design, Setting, Population, Intervention	1400-1700: (tea break in between)	Protocol development session: Outcomes & measures, Statistical considerations	1400-1630 (tea break in between)	Protocol development session: Overall discussions	1400-1600 (tea break in between)	Protocol development session: Final discussions		DEPARTURE GROUPS STAY BACK
-	KSHOP SESSION cipants only)		1700-1745	Focus small group sessions							1600-1700	Meet-the-expert sessions		FOR WEEKEND BIOSTATISTICS AND
1700-1830	Arrival and settling down				1700-1830	Team-building activity	1715-1800	Focus small group sessions	1645-1730	Focus small group sessions	1800-2100	ASCO joint session Presentation of best 10 protocols		SENIOR RESEARCHER SESSIONS
1830-1930	Registration and pre-workshop session		1900 onwards	Keynote address and Welcome dinner (national costumes)					1730-1830	Meet-the-expert sessions		developed at the workshop - WORKSHOP PARTICIPANTS followed by gala dinner and DJ night		
		Homework (due by 2100) - update concept sheet and protocol each day		Background/rationale, Aim, objectives & hypothesis	Homework (due by 2100) - update concept sheet and protocol each day	Study design, Setting, Population, Intervention, Study procedures	Homework (due by 2100) - update concept sheet and protocol each day	Outcomes & measures, Statistical considerations	Homework (due by 2100) - update concept sheet and protocol each day	Finalising the concept sheet and protocol	Homework	Final concept sheet and protocol to be submitted	3	

Based on feedback from previous participants and in recognition of the need to build research capacity, we had additional sessions over the weekend

Two-day research brain-storming session - 8th and 9th March 2025

Recognizing the need for sustained mentoring and development of nationally important, potentially practice-changing studies developed by midand senior-level researchers (some of whom were past participants of CReDO workshops), we introduced a two-day research brainstorming session at the end of the main workshop. CReDO faculty (including trialists and statisticians) coordinated these sessions and discussed specific problems related to the proposed research projects. The following research ideas were discussed at this session:

	Research idea	Investigator
1.	Is MAP superior to non-MAP regimens and can Carboplatin replace cisplatin in the treatment of Osteosarcoma? - A multicenter randomized controlled study to Optimize Survival (MAC2OS)	Badira C P
2.	A randomized controlled trial to demonstrate "near-equivalence" of alternative dosing of nivolumab and pembrolizumab in advanced cancers: Dose optimization to expand global access	Manju Sengar
3.	A multi-arm multi-stage randomized trial for neoadjuvant treatment of squamous esophageal cancer	C S Pramesh
4.	A Phase III Randomized Study of Low-Dose Chemoimmunotherapy followed by Anti-CD19 CAR-T cell therapy consolidation versus standard of care in de novo Adult B-ALL	Hasmukh Jain & Thomas Eipe



Two-day workshop for biostatisticians - 8th and 9th March 2025

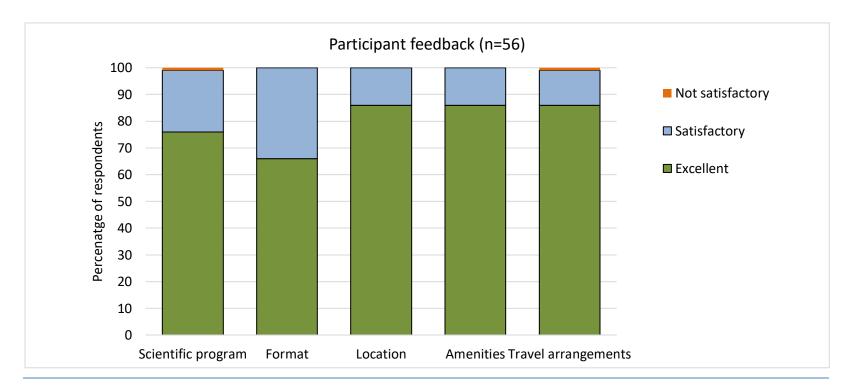
We conducted a two-day workshop for biostatisticians on 8th and 9th March 2025. There were 16 attendees (the six statisticians who had attended the CReDO 2025 workshop as trainees, as well as 10 other statisticians who had attended previous CReDO workshops as trainees). The workshop was mentored by CReDO faculty statisticians. Some of the topics which were discussed included statistical approaches, methods to integrate biostatistics into clinical settings, interaction and communication with researchers, and case-based problem solving.

Workshop Evaluation

An online pre and post-test evaluation of participants was conducted to assess the impact of the workshop. The test questionnaire included a total of 50 items covering various aspects of clinical research methodology and protocol development. These topics were extensively covered during the workshop in the form of didactic lectures and small group discussions. The post-test evaluation showed an improvement in scores.

Feedback from participants

We conducted a post-workshop online survey to obtain feedback from the participants related to various aspects of the workshop – most participants rated the workshop sessions (format, content, duration, academic interactions) and arrangements (venue, amenities, travel, food, and overall arrangements) as excellent. We received some useful suggestions regarding the workshop: protected time for protocol writing, introduction of parallel tracks for some of the lectures



What faculty and participants had to say

I have never seen groups of people being given hour upon hour with world leading experts to structure, I am extremely grateful to have interacted with all restructure and form their protocols. Seeing the the wonderful faculty and for your amazing inputs collaboration and knowledge grow during the week was and mentoring. Looking forward to implement this really inspiring. - Neil Ranasinghe, Faculty, United clinical trial at the earliest – Anusha M Kinadom 9 Excellent and profitable meeting. Honoured to be a part of it. I really appreciate your Thank you for letting us be kindness and care - Sergio Miguel Gomez, part of the workshop. It Participant, Argentina was a memorable experience - Amit Shenoy, patient advocate Attending the CReDO workshop as a trainee was a great experience! Engaging with senior faculty and participants provided valuable insights, especially in oncology research and the design of randomized controlled trials (RCTs). The workshop's theme, 'Shaping Research Ideas,' truly came to life through thought-provoking discussions on methodology, trial implementation, and I've had a wonderful time. I have learned a lot and addressing research challenges. It was inspiring to see been inspired by the CReDO team and the collaborative knowledge-sharing in action, and I look students. Thank you to the organizing team for all of forward to applying these insights in my future research your efforts to make this a great week for all! - Liz and contributing to impactful studies in oncology. - Julius Garrett Mayer, Faculty, ASCO Pius Alloyce, Project coordinator, Tanzania

Thank you for inviting me to be part of such an important initiative in cancer care – Mahithi Pillay, patient advocate

Research ideas developed at the workshop

Clinicopathological outcomes of neoadjuvant chemoradiotherapy vs neoadjuvant chemotherapy in patients with of lower esophageal squamous cell cancer					
Study to quantify smokeless tobacco (SLT) use and objectively assess active SLT consumption among patients of head and neck squamous cell carcinoma: Developing the concept of 'pouch years'					
Leveraging Teleultrasound Technology for Early Breast Cancer Detection and Diagnosis in Nigeria: An Evaluation Study					
Phase II study to evaluate efficacy of MIBG therapy to improve outcomes in children treated for High-risk Neuroblastoma					
Robotic versus laparoscopic total pelvic exenteration for rectal carcinoma- Phase 2 randomized controlled trial					
Holocranial radiotherapy with boost increment in patients with breast cancer					
The Impact of Arm Lymphedema on health-related quality of life in breast cancer survivors treated at Ocean Road Cancer Institute.					
Exploring the feasibility of stepping patients down from tertiary to community hospitals and home care at end-of-life: a mixed method community-based participatory study.					
Comparison of response rates to AI and CDK-4-6 inhibitors versus standard chemotherapy in hormone receptor positive breast cancer necessitating pre-operative systemic therapy- a randomized controlled trial					
Impact of a video based educational program on mitigating anxiety and distress in patients undergoing brachytherapy for cervical cancer:prospective single arm feasibility study.					
Correlation of gut microbiome to infection profile, immune status and outcome of children with cancer related febrile neutropenia					
A phase II study to evaluate the efficacy of lenalidomide in patients with acute lymphoblastic leukemia (ALL) with disease progression or relapse post CART therapy.					
Efficacy of Low dose pembrolizumab with chemotherapy vs chemotherapy in persistent/recurrent or metastatic cervical cancer.					
The efficacy and safety of mirtazapine vs olanzapine in preventing chemotherapy induced nausea and vomiting in combination with the triplet regimen in patients receiving highly emetogenic chemotherapy					
Comparison of Dose Dense High Dose Cytarabine Chemotherapy with Standard High Dose Cytarabine Chemotherapy as Consolidation in Pediatric Acute Myeloid Leukemia					
Title: SCENT- Sustainable Childhood cancer care Excellence in Northern Tanzania Subtitle: Diagnostic Delays and Approach to Improving Abandonment Rates for Childhood Cancers in Northern Tanzania: A mixed-methods study					
A Multicentric Phase 3 Non-Inferiority Trial Comparing FOLFOX/CAPOX Versus Taxol-Carboplatin in Patients with HER2- Negative Metastatic Gastric Cancer.					
QUAD-Shot versus One week palliative radiotherapy with concurrent systemic therapy for locally advanced/metastatic head and neck cancers- A Multi-centric Randomized controlled trial (QUADONE trial)					

Cesar Alejandro Galvan Diaz	Description of the morbidity and mortality associated with oncological treatment through the establishment of an effective and standardized toxicity registry in pediatric patients in hospitals in Mexico.
Daniel Raj Joseph Thangasamy	Comparison of Efficacy of Methadone versus Morphine in Head And Neck cancer(HNC) patients with Neuropathic Pain(NP)– A randomized control trial
Dua'a Zandaki	Oral Vitamin A to Prevent GvHD in Children and Young Adults Undergoing Haplo-identical Hematopoietic Stem Cell Transplantation
Ernestina Nana Boatemaa Schandorf	Evaluating and Enhancing Quality of Life in children with cancer: A Multicentre Study on Physical and psychosocial Well- being
Esraa Maged Mohammad	Weekly Vincristine-Carboplatin versus Monthly Carboplatin in Children and Young Adults with Low-Grade Gliomas: Experience from a Single Pediatric Oncology Center.
Fatimah Abdulkareem	Clinicopathologic, genetic and epigenetic characterization of Early-Onset Colorectal cancer in Nigeria-a comparative prospective study
Febin Antony	Total Neo-adjuvant Therapy with or without Immunotherapy in High-Risk Locally Advanced Rectal Cancer (ToNIC): A Randomized Controlled Trial.
Georgeena Elsa Jose	Clinical validation of Serum Creatinine and Urine pH monitoring with Serum Methotrexate level in predicting the toxicity among children with Acute Lymphoblastic Leukemia receiving High-Dose Methotrexate.
Giselle Mata Cavada	School Inclusion for Pediatric Cancer Survivors
Gnanamani Senguttuvan	Central venous line care bundle and feedback to reduce central line-associated bloodstream infections: A Quality improvement initiative in Pediatric hematology and oncology unit in a low-and-middle-income country
Gorky Yupanqui	Potential Risks Evaluation in the Implementation of new Technologies in Radiotherapy in a Radiotherapy Center of the Southern Macro Region of Peru: An Approach Based on the risk Profile
Guruprasad C S	Phase II window trial of venetoclax based combination therapy of newly diagnosed childhood Acute Meyloid Leukemia
Hafizul Islam Pathan	Development of an indigenous AI Model for Automated Identification and Segmentation of Organs at Risk for Radiation Oncology Treatment Planning
Hannah Grace Segocio	Genetic variants of NUDT15 and Dose Adjustment of 6-Mercaptopurine in Filipino children with Acute Lymphoblastic Leukemia
Hashmath Farhaana.S.	Implementing Advanced Medical Directives in Hospital Settings: Strategies for Effective Integration in Cancer Patients with Serious Health-Related Suffering"
Honey Susan Raju	Urea Cream with Celecoxib vs Urea Cream with Pyridoxine in Drug-Induced Hand-Foot Syndrome (HFS) – A randomised controlled trial
Irene Nzamu	Improving access to oncology specialist care and early referral for timely diagnosis and interventions for children with cancer in Kenyatta national hospital
Jasmeet Sidhu	Precision-based therapeutic strategy to improve survival in patients with poor response to treatment in acute lymphoblastic leukaemia.
Jasmine Gurung	Impact of a structured exercise programme in patients with cancer

Joshua John Uzagare	Open-Label, Prospective, Single Arm phase II trial of 18 weeks Docetaxel+Carboplatin+Pertuzumab+Trastuzumab in Non Metsatatic HER2positive Breast Cancer
Juan Carlos Pari Salas	Use of data science methodology to guide decisions regarding improvement of quality indicators in cervix cancer radiotherapy
Kahkasha	A Comparative study of RAG-based Mobile Assistance versus Traditional Referral Models in patients with Advanced Cancer
Kamalina Coopasamy	Development and Implementation of a National Wilms Tumour Study Protocol in South Africa: Improving Outcomes and Standardizing Care
Kannan P	Single vs. Fractionated HEMOstatic Radiotherapy in GASTric Cancer [HEMOGAST]: A Randomized Trial
Karan Sood	Asthenia Prophylaxis in Cancer Patients
Karin Plummer	DECIDE: a feasibility randomised controlled trial of an e-health pain management decision aid for parents of children undergoing Haematopoietic Stem Cell Transplantation therapy.
Karthik V	A phase III single randomized superiority trial of omental wrapping around the cervical esophagogastric anastomosis after esophagectomy for carcinoma esophagus
Katarzyna Pawinska-Wasikowska	Use of granulocyte transfusions in the management of serious infections among children with cancer and neutropenia
Kelfala Marah	Early breast cancer detection using breast mammography versus incremental clinical breast examination (CBE) in low- income Country.
Kristin Wright	Evaluating patient perspectives about surveillance imaging post-adjuvant treatment for gastrointestinal cancers: a mixed- methods approach
Lakshmi Menon R	Clinical development of EGFR targeted Indocyanine Green-Cetuximab nano-probe for Near- Infrared Image guided surgery of Oral squamous Cell Carcinoma to ensure surgical adequacy
Lily Jannete Saldaña Gallo	"Educational Needs Assessment In Pediatric Surgical Oncology"
Meghna Kumar	Large Scale Implementation of ePROMs (electronic Patient-Reported Outcome Measures) in Patients Receiving Curative Intent Treatment for Oral Cancer in India
Mitchelle Obat	Integration of Early Warning Signs and Training for Community Health Workers in Kenya: Enhancing Outreach Programs
Mohammad Shukri Khoo	A Randomised, Single-Centre Trial of Oral Therapy versus Intravenous Combination Therapy of Empirical Antibiotic Treatment in Children with Low-Risk Febrile Neutropenia
Nashivai Elias Kivuyo	A Randomized Controlled Trial to Compare Preoperative vs Adjuvant Chemotherapy in Triple Negative Breast Cancer Patients with Operable Disease in Tanzania.
Nermeen Alhawary	Toxicity of Acute Myeloid Leukemia
Nivedita Sharma	Impact of Post-Operative Structured Oral Exercise Therapy on swallowing function in oral cavity cancer patients: a phase III Randomized Controlled Trial
Nutan Joshi	Low dose nivolumab in combination with low dose ruxolitinib for the treatment of relapsed / refractory Hodgkin lymphoma

Nwamaka Lasebikan	Implementing a Standardized Quality Assurance Framework for Cancer Care in Abuja: An Evidence-Based Implementation Science Approach
Otgonjargal Amraa	Impact of Childhood Cancer on Family Functioning and Family Quality of Life in Mongolia
Parthasarathi Bhattacharyya	Validation of Early Onco-Critical Phenotype Determining Outcome in Pediatric Onco-Critical Care (POCC) Unit in Resource Limited Setting.
R Mirunalini	Zinc sulphate for chemotherapy-induced dysgeusia in patients with breast cancer
Ricardo Martín Solís Velásquez	Determinants of Diagnostic Time for Childhood Cancer in Ecuador: Analyzing Factors to Improve Early Detection and Outcomes"
Samreen Jaffar	Correlation of oral cavity microbes with neck discharge culture to decide antibiotics in free flaps
Sani Sipai	The clinical profile and outcomes of Non-Hodgkin's Lymphoma in Pediatric patients from a tertiary care center
Sasha Pereira	A Phase II study to evaluate the role of maintenance therapy with 6 mercaptopurine and methotrexate in prolonging the event free survival in patients of relapsed/refractory(R/R)-B ALL, post CAR-T infusion.
Sergio Miguel Gomez	Proposal for an new randomized Acute Myeloid Leukemia protocol in children in Argentina.
Shreya Rosa Stephen	Safety and tolerability of neoadjuvant gemcitabine plus cisplatin(GC) with nivolumab and cisplatin plus methotrexate(CMV) plus vinblastine with nivolumab in frail geriatric patients with node negative muscle invasive bladder cancer
Sidharth Totadri	Challenges faced by children with cancer in going back to school after treatment: a cross-sectional study
Sujith.K	A Phase II open labelled Randomized Controlled Trial Comparing Fludarabine/ Melphalan versus Fludarabine / Treosulfan as Conditioning Regimen in Acute Myeloid Leukaemia in Complete remission
Sv Saju	Pregabalin with or without Duloxetine in the prevention of Paclitaxel-Induced Peripheral Neuropathy – A randomised controlled trial
Swaminathan	A Randomized, Phase II, Multicenter, Open-Label Study of Combining Chemotherapy and Targeted Therapies to Improve Outcomes in Pediatric Langerhans Cell Histiocytosis in Iow-and-middle-income countries
Swathi Rajesh Yennemadi	"A Randomized Phase III Non Inferiority Trial on Effect of Diode Laser Compared To Low Level Laser Therapy on Reduction In Severity Of Oral Mucositis In Head Neck Cancer Patients"
Tanvi Shah	Prospective study of Adjuvant Hepatic Artery Infusion Chemotherapy (HAIC) for resected Colorectal Liver Metastasis (CRLM): Technical modification for resource constraint settings
Tejal Patel	Efficacy of a multi-modal prehabilitation protocol in head and neck cancer patients - a randomised control trial.
Tran Thi Lien Nhi	Evaluation of Asparaginase activity and therapeutic drug monitoring of the Asparaginase used to treat acute lymphoblastic leukemia patients at the Vietnam National Children's Hospital
Willybroad Augustine Massawe	Transforming Nutritional Care for Head and Neck Cancer Patients in Tanzania: Development and Implementation of a Standardized, Culturally Relevant Assessment and Management Protocol (NCT-study)

The objectives of this workshop were:

- a) To train researchers in oncology in various aspects of clinical research methods
- b) To help them to develop a research idea into a structured protocol
- c) To build research capacity by training biostatisticians and other research staff
- d) To facilitate mid- and senior-level researchers with more advanced research designs
- e) To build a cadre of patient advocates for increased involvement in oncology research

Outcomes of the workshop

- a) We used a pre- and post-test survey to assess the impact of the workshop on participants' knowledge. Almost all participants showed an improvement in test scores after the workshop.
- b) All 76 participants who had submitted a one-page research concept sheet at the time of workshop application, converted their ideas into full-fledged protocols.
- c) Seven research personnel (five biostatisticians, one imaging data scientist and one research administrator) attended the main workshop and participated in the training and discussions. In addition, 16 biostatisticians participated in a 2-day special training session for statisticians
- d) Mid- and senior-level researchers participated in a 2-day session to discuss more advanced aspects of their planned and ongoing research projects.
- e) Eight patient advocates attended the workshop and were actively engaged in the development of the research protocols.

Follow-On Efforts / Sustainability of Impact

Feedback to mentor/supervisor: As part of the workshop application process, participants submitted a letter of support from an institutional mentor/supervisor. A copy of the participant's progress at the workshop is mailed to the supervisor with a request to continue encouragement and support to the participant to complete the research study.

Post-workshop webinars: We have a series of monthly post-workshop webinars on various aspects of research methods, which participants are encouraged to attend. These webinars are useful to maintain knowledge, discuss any problems with their research study and seek advice from experienced faculty.

Follow-up surveys: A follow-up survey is mailed to participants every 6 months to assess the status of their research protocol and other research endeavors. Through these periodic surveys, participants are encouraged to initiate their research studies, as well as to undertake other research projects and build collaborations.

Capacity building: Through training of patient advocates and biostatisticians

Workshop fees and scholarships provided

Registration fee for selected participants was 150,000 INR (2000 USD). This covered transport between Mumbai and the workshop venue, accommodation, and all meals at the workshop venue for the duration of the workshop, and access to workshop resources.

We were able to provide complete travel and registration support for 46 participants. In addition, we were able to provide substantial (≈90%) support for registration and/or travel to the remaining participants through NCG grants and from CSR funds. Patient advocate trainees and biostatistics trainees received full support to participate in the workshop

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